NEW YORK STATE | Commission on Forensic Science

March 12, 2021

Division of Criminal Justice Services
Virtual Meeting[1]

9:05 AM – 12:27 PM

DRAFT MEETING MINUTES

Commission Members in Attendance:
Michael Green, Esq., Chair
Pasquale Buffolino, Ph.D.
Lydia de Castro
Jill Dooley, Ph.D.
Hon. William Fitzpatrick, Esq.
Jessica Goldthwaite, Esq.
Michael Marciano, Ph.D.
Hon. Angela Mazzarelli
Scott O'Neill, Ph.D.
Benjamin Ostrer, Esq.
Anne Walsh, Ph.D., M.D.
Ann Willey, Ph.D., J.D.

DCJS Staff in Attendance:
Michael Flaherty, Esq.
Natasha Harvin-Locklear, Esq.
Shelley Palmer
Jackalynne Vimislik

Chairman Green opened the meeting by thanking former members David Loftis and Scott McNamara for their work on the Commission. The Chair also welcomed new members Jessica Goldthwaite, Esq. and Michael Marciano, Ph.D. to the Commission.

Approximate video times

00:00:00 – 00:08:00

[1] Due to the Coronavirus (COVID-19), and pursuant to Governor Cuomo's Executive Order 202.1, issued on March 12, 2020, suspending the Open Meetings Law and **authorizing the attendance of meetings telephonically or other similar service.**

	Approximate video times
Chair Green then took a roll call to establish a quorum as the members were in attendance from their own locations. A quorum was established with 12 members in attendance (Buffolino, de Castro, Dooley, Fitzpatrick, Green, Goldthwaite, Marciano, Mazzarelli, O'Neill, Ostrer, Walsh, and Willey).	**00:08:00 - 00:09:14**
A motion to approve the March 12, 2021 agenda was requested by the Chair, made by Mr. Fitzpatrick, seconded by Dr. O'Neill, and approved unanimously.	**00:09:14 – 00:10:20**
The Chair then asked Commission members for questions or comments on the minutes from the December 11, 2020 Commission meeting. Mr. Ostrer made a motion to accept the minutes, Judge Mazzarelli seconded the motion, and it was approved with 11 votes for, 0 votes against, and 1 abstention [Marciano].	**00:10:20 - 00:11:30**
Under Accreditation/Laboratory Updates, the Chair requested Dr. Graham Jones from the American Board of Forensic Toxicology (ABFT) to give an update in response to letters received by the laboratories regarding assessments. Then, accreditation items and updates were considered for the Erie County Toxicology Laboratory, Monroe County Office of the Medical Examiner Forensic Toxicology Laboratory, Nassau County Division of Forensic Services, Nassau County Medical Examiner's Office Forensic Toxicology Laboratory, New York City OCME Department of Forensic Toxicology, New York City Police Department Police Laboratory, New York State Police Crime Laboratory, Niagara County Sheriff's Office Forensic Laboratory, Onondaga County Center for Forensic Sciences Forensic Toxicology Laboratory, Suffolk County Office of the Medical Examiner Forensic Toxicology Laboratory, Westchester County Division of Forensic Sciences, and Westchester County Division of Forensic Toxicology. Representatives from the laboratories were available via Web-Ex to respond to members' questions.	**00:11:30 00:18:00** **00:18:00 00:20:15** **00:20:15 00:36:40**
Chairman Green requested a motion to accept the binding recommendation from the DNA Subcommittee and to renew the New York State accreditation of the Westchester County Division of Forensic Sciences for a period concurrent with their ANAB accreditation. Dr. Dooley made the motion, it was seconded by Mr. Ostrer, and approved with 11 votes for, 0 against, and 1 abstention [de Castro].	**00:35:00 00:36:00**
The Chair then moved to Old Business. Dr. Dooley provided Commission members with a verbal update on Familial Searching. Next, Commission members revisited the issue related to the letter submitted by the NYS Biology Technical Working Group (BIOTWG) regarding STRMix. The Commission will await updates from the DNA Subcommittee at their next meeting. A Familial Search Regulation Update was given by Dr. Dooley and Special Counsel Natasha Harvin-Locklear. Last, Dr. Walsh provided Commission members with an update on Investigative Genetic Genealogy.	**00:36:00 – 00:45:25** **00:45:25- 01:23:37**
Next item on the agenda was New Business. The Commission reviewed the 2020 Annual Laboratory Summaries. During this agenda item, Dr. Graham Jones of ABFT submitted an email follow up from his earlier discussion with Commission members and was available via Web-Ex to discuss further. Commission members returned to New Business and heard from the New York State Police Crime Laboratory regarding the	**01:23:37 01:45:10**

binding recommendation received from the DNA Subcommittee approving their Familial Search Expansion Validation. The Chair then requested a motion to accept the binding recommendation of the DNA Subcommittee to accept the validation thresholds as recommended by the New York State Police Crime Laboratory. The motion was made by Dr. Buffolino, seconded by Dr. O'Neill, and approved with 11 votes for, 0 against, and 1 abstention [Goldthwaite]. **01:45:10– 01:54:40**

Also, under New Business, Commission members reviewed a binding recommendation from the DNA Subcommittee regarding the New York City OCME Department of Forensic Sciences' validation on Mitochondrial DNA Massively Parallel Sequencing. Members from the laboratory were available for questions from the Commission Members. After discussion, Chairman Green made a motion to send the binding recommendation back to Subcommittee members to review the validation, considering the updated documents submitted by the laboratory. The motion was seconded by Ms. De Castro and approved unanimously. Last, under New Business, Dr. Dooley discussed accreditation compliance. **01:54:40- 01:23:37** **01:23:37 02:08:00** **02:08:00 02:09:45**

The Commission then reviewed disclosures from the Erie County Central Police Services Forensic Laboratory, New York State Police Crime Laboratory, New York City Police Department Police Laboratory, and the Suffolk County Office of the Medical Examiners Forensic Toxicology Laboratory. Representatives from the laboratories were available via Web-Ex to respond to members' questions. **02:09:45 02:22:44**

The Chair then requested a motion to enter Executive Session to discuss matters relating to a current investigation or matters that may lead to the appointment, promotion, demotion, discipline, or suspension of a person. Dr. O'Neill made the motion, which was seconded by Dr. Dooley, and approved unanimously. **02:22:44 02:24:32**

The Commission adjourned into Executive Session. Present were Commission members Buffolino, de Castro, Dooley, Fitzpatrick, Green, Goldthwaite, Marciano, Mazzarelli, O'Neill, Ostrer, Walsh and Willey. The Commission did not take any reportable action during executive session, which commenced, after a short break, at 11:31 AM and concluded at 12:19 PM. The Commission reconvened the Open Meeting. **02:24:32 02:28:07**

Two new business items resulted from executive session. First, a motion was made by Chairman Green to have DCJS OFS staff reach out to the New York City OCME Department of Forensic Biology flagging the specific communication with Pam Sale from ANAB in reference to conversations with the FBI, as well as the DNA Subcommittee's comments with regard to that same conversation. The Commission also requests that the OCME and ANAB be available at the next meeting for comment regarding the referenced comments. The motion was seconded by Mr. Fitzpatrick, and approved with 11 votes for, 0 against, and 1 abstention [de Castro]. Secondly, Chairman Green made a motion to have **02:28:07 02:29:57**

ANAB present at the next meeting of the Commission on Forensic Science to answer questions regarding their process and protocols referenced in documents previously provided to the Commission. Judge Mazzarelli seconded the motion, and it was approved with 11 votes for, 0 against, and 1 abstention [de Castro].

The next meeting is scheduled for June 4, 2021. A motion to adjourn was made by Mr. Ostrer, seconded by Dr. O'Neill, and approved unanimously.

Note:

Video of the open meeting is available at YouTube.

Received by OFS
04/30/21

Erie County Central Police Services - Forensic Laboratory

2021 - 17025T - Surveillance Document Review

Prepared by Alexandria Bradley

Data collected on 2021-04-01

ANSI National Accreditation Board

United States

This assessment report summarizes the outcome of the recent accreditation activity. A separate document, the assessment plan, provides information on the type of activity (*e.g.,* reassessment, surveillance activity, scope extension), the date(s) of the activity, the assessment team members, the requirement documents and the scope by discipline that was assessed for each location. The assessment plan, together with this report, provides a complete picture of the accreditation activity.

The ANSI National Accreditation Board (ANAB) evaluated the competence of the forensic service provider and conformance with all applicable accreditation requirements for the scope of accreditation listed in the assessment plan. Objective evidence of implementation was assessed. The results of an assessment activity are based on a sample of records, locations, and personnel that were available at the time of the activity. Witnessing is an additional technique used in on-site activities.

REQUIREMENTS:

ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories & ANAB ISO/IEC 17025:2017 Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125) evaluated over the accreditation cycle are summarized in the following broad categories:

General requirements related to the forensic service provider's commitment to impartiality and confidentiality in its activities.

Structural requirements related to the range of activities, management structure, the authority, roles and responsibilities of personnel. Documented procedures which ensure a consistent application of activities and the validity of results.

Resource requirements related to the impartiality of personnel. Requirements for a training program, competency testing, authorizations and ongoing monitoring to ensure the competence of personnel. Facility and security suitability for activities. Records and procedures for equipment to ensure proper functioning and where applicable, establishment of metrological traceability. Requirements for externally provided products and services.

Process requirements related to the handling of test and calibration items in a manner to maintain the integrity of the item. Requirements for chain-of-custody of items to be tested and appropriate methods and procedures. Ensuring the required performance of the methods along with monitoring the validity of the results. Requirements to ensure results are supported by sufficient technical records and are reported accurately, clearly, unambiguously and objectively. Procedures for nonconforming work and a documented process for handling complaints. Requirements related to the laboratory information management system protection and integrity of data and information.

Management system requirements related to policies and objectives appropriate for the scope of activities. Requirements to control internal and external documents and records. Requirements to address risks and opportunities and timely, well-documented corrective actions. Requirements for an internal audit program and management reviews.

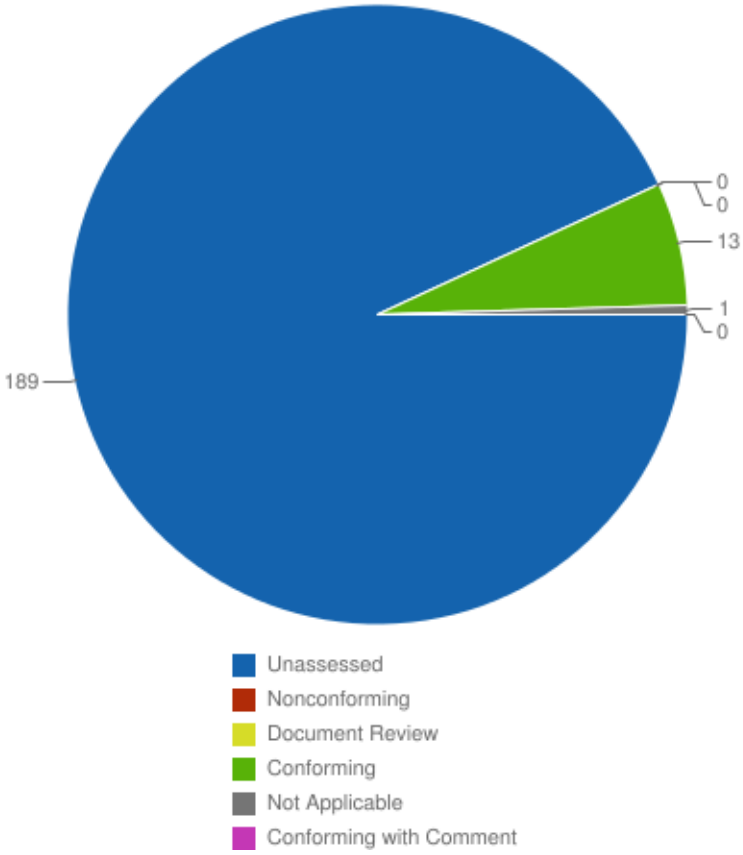
The accreditation activity also evaluates forensic science provider’s conformance with their own management system requirements.

ASSESSMENT RESULT:

Based on the assessment techniques and sampling reviewed during the assessment activity, the assessment team found that the forensic service provider demonstrated competence to operate a management system that fulfills all applicable accreditation requirements, including those specified within their management system.

Any comments (opportunities for improvement) or nonconformities identified during this assessment activity are noted below. All nonconformities will be resolved prior to an accreditation decision by ANAB and a summary provided in a subsequent assessment activity report.

Summary of Comments



Audit Comments

Received by OFS
05/21/21

ANSI National Accreditation Board

May 21, 2021

John R. Clark
Monroe County Crime Laboratory
85 West Broad Street
Rochester, NY 14614

Dear Director Clark,

Congratulations! On April 27, 2021, ANAB approved the continuation of your organization's accreditation based upon the results of your recent surveillance activity. Continuation of accreditation is a formal acknowledgement that your organization continues to operate in conformance with accreditation requirements. The report was provided to you during the assessment activity.

The provided ANAB accreditation symbol may be used to convey your accredited status. An accreditation symbol must not be used in any way which implies accreditation in any area outside of the scope of accreditation. If appropriate, the accreditation symbol may be used on your organization's website, reports, letterhead, business cards, and other official documents. Please refer to PR 1018 Policy on Use of ANAB Accreditation Symbols and Claims of Accreditation Status for all required information. This policy also provides information on your ability to use a combined mark that contains the ANAB accreditation symbol and the International Laboratory Accreditation Cooperation (ILAC) mark.

The next assessment activity is scheduled to be a Reassessment in April 2022.

Thank you for your ongoing commitment to quality and the accreditation process.

Sincerely,

[redacted]

Director of Accreditation
ANSI National Accreditation Board

cc: Marcia Bledsoe, Quality Assurance Coordinator
ANAB Office

Received by OFS
05/21/21

CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

Monroe County Crime Laboratory

85 West Broad Street, Rochester, New York 14614 USA

Fulfills the requirements of

ISO/IEC 17025:2017

ANAB Forensic Testing & Calibration AR 3125:2019

FBI Quality Assurance Standards for Forensic DNA Testing Laboratories:2020

In the field of

Forensic Testing

This certificate is valid only when accompanied by a current scope of accreditation document.
The current scope of accreditation can be verified at www.anab.org.

[redacted]

Expiry Date: 31 August 2022
Certificate Number: FT-0312

Received by OFS
05/21/21

SCOPE OF ACCREDITATION TO:
ISO/IEC 17025:2017
ANAB Forensic Testing & Calibration AR 3125:2019
FBI Quality Assurance Standards for Forensic DNA Testing Laboratories:2020

Monroe County Crime Laboratory

85 West Broad Street
Rochester, New York 14614 USA

FORENSIC TESTING

Expiry Date: 31 August 2022 Certificate Number: FT-0312

Discipline: Biology		
Component/Parameter	**Item**	**Key Equipment/Technology**
DNA Profile Determination	Short Tandem Repeat (STR) Y-Short Tandem Repeat (Y-STR)	Capillary Electrophoresis
Individual Characteristic Database	DNA Profile	National DNA Index System (NDIS)
Physical Comparison	DNA Profile	Software Program
Qualitative Determination	Body Fluid	Chemical General Microscopy Fluorescence Spectroscopy Immunoassay

Discipline: Fire Debris and Explosives		
Component/Parameter	**Item**	**Key Equipment/Technology**
Qualitative Determination	Explosive	Chemical Gas Chromatography General Microscopy Infrared Spectroscopy Mass Spectrometry Microcrystalline X-Ray Fluorescence Spectroscopy
Qualitative Determination	Fire Debris	Gas Chromatography Mass Spectrometry

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Discipline: Firearms and Toolmarks		
Component/Parameter	**Item**	**Key Equipment/Technology**
Distance Determination	Firearm Physical Item	Chemical General Microscopy
Function Evaluation	Firearm	Dead Weight Measuring Equipment Visual
Individual Characteristic Database	Ammunition	National Integrated Ballistic Information Network (NIBIN)
Physical Comparison	Ammunition Fractured Item Tool/Toolmark	General Microscopy Visual
Qualitative Determination	Ammunition Firearm Metal Nitrate Tool	Chemical General Microscopy Measuring Equipment Reference Collection
Serial Number Restoration	Physical Item	Chemical Magnetic Visual

Discipline: Impressions		
Component/Parameter	**Item**	**Key Equipment/Technology**
Enhancement	Footwear Physical Item Tire	Chemical Software Program
Physical Comparison	Footwear Physical Item Tire	Software Program Visual
Qualitative Determination	Footwear Tire	Reference Collection

Discipline: Materials (Trace)		
Component/Parameter	**Item**	**Key Equipment/Technology**
Chemical/Physical Comparison	Coating Fiber/Textile Fractured Item General Unknown Glass Hair Tape	Chemical Gas Chromatography General Microscopy Infrared Spectroscopy Mass Spectrometry Microspectrophotometry Refractometry Thin-Layer Chromatography X-Ray Fluorescence Spectroscopy

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Qualitative Determination	Coating Fiber/Textile General Unknown Glass Hair	Chemical Gas Chromatography General Microscopy Infrared Spectroscopy Mass Spectrometry Microspectrophotometry Refractometry Thin-Layer Chromatography X-Ray Fluorescence Spectroscopy

Discipline: Seized Drugs		
Component/Parameter	**Item**	**Key Equipment/Technology**
Qualitative Determination	Botanical Liquid Solid	Chemical Gas Chromatography General Microscopy Infrared Spectroscopy Mass Spectrometry Microcrystalline Thin-Layer Chromatography
Quantitative Measurement	Solid	Gas Chromatography
Weight Measurement	Botanical Liquid Solid	Balance

When published on a forensic service provider's Scope of Accreditation, ANAB has confirmed the competence required to develop and validate methods and perform on-going quality assurance for accredited activities. For a listed component/parameter, the forensic service provider may add or modify methods for activities without formal notice to ANAB for items and key equipment/technology listed. Contact the forensic service provider for information on the method utilized for accredited work.

Vice President, Forensics

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Received by OFS
04/27/21

Monroe County Crime Laboratory

2021 - 17025T - Surveillance Document Review

Prepared by Meghan Clement

Contract LA

Data collected on 2021-04-01

ANSI National Accreditation Board

United States

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REQUIREMENTS:

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Process requirements related to the handling of test and calibration items in a manner to maintain the integrity of the item. Requirements for chain-of-custody of items to be tested and appropriate methods and procedures. Ensuring the required performance of the methods along with monitoring the validity of the results. Requirements to ensure results are supported by sufficient technical records and are reported accurately, clearly, unambiguously and objectively. Procedures for nonconforming work and a documented process for handling complaints. Requirements related to the laboratory information management system protection and integrity of data and information.

Management system requirements related to policies and objectives appropriate for the scope of activities. Requirements to control internal and external documents and records. Requirements to address risks and opportunities and timely, well-documented corrective actions. Requirements for an internal audit program and management reviews.

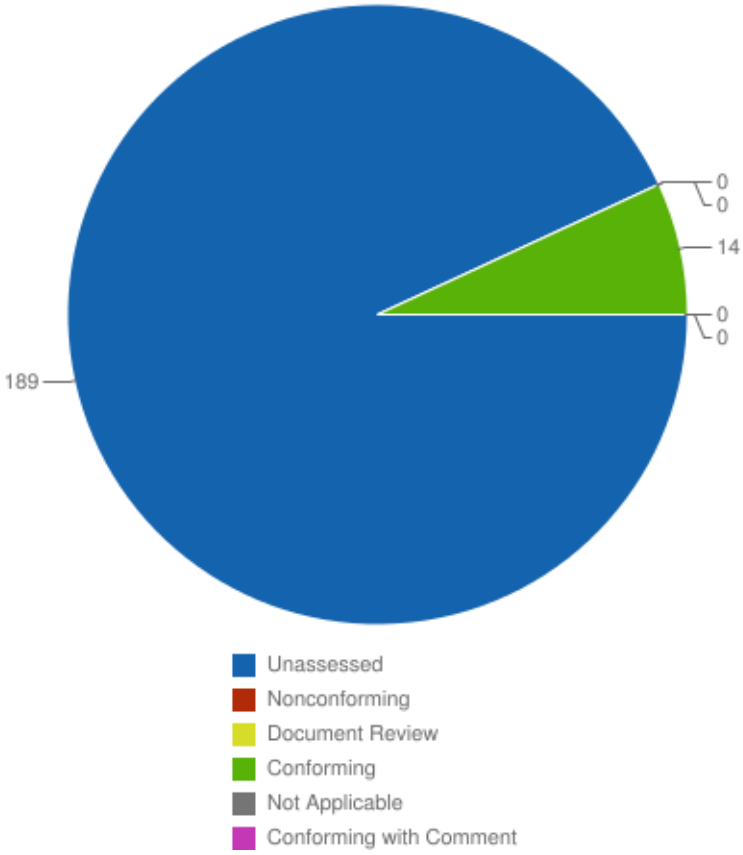
The accreditation activity also evaluates forensic science provider’s conformance with their own management system requirements.

ASSESSMENT RESULT:

Based on the assessment techniques and sampling reviewed during the assessment activity, the assessment team found that the forensic service provider demonstrated competence to operate a management system that fulfills all applicable accreditation requirements, including those specified within their management system.

Any comments (opportunities for improvement) or nonconformities identified during this assessment activity are noted below. All nonconformities will be resolved prior to an accreditation decision by ANAB and a summary provided in a subsequent assessment activity report.

Summary of Comments



Audit Comments

Received by OFS
03/25/21

SCOPE OF ACCREDITATION TO:
ISO/IEC 17025:2017
ANAB Forensic Testing & Calibration AR 3125:2019
FBI Quality Assurance Standards for Forensic DNA Testing Laboratories:2020

Nassau County Office of the Medical Examiner
Division of Forensic Services
1194 Prospect Avenue
Westbury, New York 11590 USA

FORENSIC TESTING

Expiry Date: 28 February 2023 Certificate Number: FT-0243

Discipline: Biology		
Component/Parameter	**Item**	**Key Equipment/Technology**
DNA Profile Determination	Short Tandem Repeat (STR) Y-Short Tandem Repeat (Y-STR)	Capillary Electrophoresis
Individual Characteristic Database	DNA Profile	National DNA Index System (NDIS)
Physical Comparison	DNA Profile	Software Program
Qualitative Determination	Body Fluid Epithelial Cell	Chemical General Microscopy Immunoassay

Discipline: Fire Debris and Explosives		
Component/Parameter	**Item**	**Key Equipment/Technology**
Qualitative Determination	Fire Debris	Gas Chromatography Mass Spectrometry

Discipline: Friction Ridge		
Component/Parameter	**Item**	**Key Equipment/Technology**
Enhancement	Ridge Detail	Chemical Physical Software Program

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Individual Characteristic Database	Ridge Detail	Next Generation Identification System (NGI)
Physical Comparison	Ridge Detail	Software Program Visual

Discipline: Seized Drugs		
Component/Parameter	**Item**	**Key Equipment/Technology**
Qualitative Determination	Botanical Liquid Solid	Chemical Gas Chromatography General Microscopy Infrared Spectroscopy Mass Spectrometry Raman Spectroscopy Thin-Layer Chromatography Visual
Quantitative Measurement	Solid	Gas Chromatography Mass Spectrometry
Weight Measurement	Botanical Liquid Solid	Balance

When published on a forensic service provider's Scope of Accreditation, ANAB has confirmed the competence required to develop and validate methods and perform on-going quality assurance for accredited activities. For a listed component/parameter, the forensic service provider may add or modify methods for activities without formal notice to ANAB for items and key equipment/technology listed. Contact the forensic service provider for information on the method utilized for accredited work.

[redacted]

Pamela L. Sale
Vice President, Forensics

2000 Regency Parkway, Suite 430, Cary, NC 27518
414-501-5494
www.anab.org

The City of New York

POLICE DEPARTMENT

May 7, 2021

To whom it may concern,

This letter is to inform you of a change in the New York City Police Department Police Laboratory's management. On May 6, 2021, Lisa-Marie Bergh was appointed to the position of Controlled Substance Analysis Section Assistant Director. If you have any questions, please feel free to contact me at [redacted]

[redacted]

Dr. Scott O'Neill,
Assistant Commissioner

Received by OFS
04/01/21

ANSI National Accreditation Board

April 1, 2021

Kori Gawrys, Ph.D.
Niagara County Sheriff's Office
Forensic Laboratory
5526 Niagara Street, Ext.
Lockport, New York 14094

Dear Dr. Gawrys,

Congratulations! On March 29, 2021, ANAB approved the continuation of your organization's accreditation based upon the results of your recent surveillance activity. Continuation of accreditation is a formal acknowledgement that your organization continues to operate in conformance with accreditation requirements. The report is included with this letter.

The provided ANAB accreditation symbol may be used to convey your accredited status. An accreditation symbol must not be used in any way which implies accreditation in any area outside of the scope of accreditation. If appropriate, the accreditation symbol may be used on your organization's website, reports, letterhead, business cards, and other official documents. Please refer to PR 1018 Policy on Use of ANAB Accreditation Symbols and Claims of Accreditation Status for all required information. This policy also provides information on your ability to use a combined mark that contains the ANAB accreditation symbol and the International Laboratory Accreditation Cooperation (ILAC) mark.

The next assessment activity is scheduled to be a Reassessment in February 2022.

Thank you for your ongoing commitment to quality and the accreditation process.

Sincerely,

[redacted]

Chris Hamburg
Sr. Manager of Accreditation
ANSI National Accreditation Board

cc: ANAB Office

Received by OFS
04/01/21

CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

Niagara County Sheriff's Office
Forensic Laboratory

5526 Niagara Street, Ext., Lockport, New York 14094 USA

Fulfills the requirements of

ISO/IEC 17025:2017
ANAB Forensic Testing & Calibration AR 3125:2019

In the field of

Forensic Testing

This certificate is valid only when accompanied by a current scope of accreditation document.
The current scope of accreditation can be verified at www.anab.org.

[redacted]
Pamela L. Sale, Vice President, Forensics

Expiry Date: 30 June 2022
Certificate Number: FT-0311

Received by OFS
04/01/21

ANSI National Accreditation Board

SCOPE OF ACCREDITATION TO:
ISO/IEC 17025:2017
ANAB Forensic Testing & Calibration AR 3125:2019

Niagara County Sheriff's Office
Forensic Laboratory
5526 Niagara Street, Ext.
Lockport, New York 14094 USA

FORENSIC TESTING

Expiry Date: 30 June 2022 Certificate Number: FT-0311

Discipline: Biology		
Component/Parameter	**Item**	**Key Equipment/Technology**
Qualitative Determination	Body Fluid	Chemical General Microscopy Immunoassay

Discipline: Fire Debris and Explosives		
Component/Parameter	**Item**	**Key Equipment/Technology**
Qualitative Determination	Fire Debris	Gas Chromatography Mass Spectrometry

Discipline: Firearms and Toolmarks		
Component/Parameter	**Item**	**Key Equipment/Technology**
Function Evaluation	Firearm	Dead Weights Measuring Equipment Visual
Individual Characteristic Database	Ammunition	National Integrated Ballistic Information Network (NIBIN)
Physical Comparison	Ammunition	General Microscopy Software Program Visual

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ANAB ANSI National Accreditation Board ilac-MRA

Qualitative Determination	Ammunition Firearm	Chemical General Microscopy Measuring Equipment Reference Collection
Serial Number Restoration	Physical Item	Chemical Visual

Discipline: Seized Drugs		
Component/Parameter	**Item**	**Key Equipment/Technology**
Qualitative Determination	Botanical Liquid Solid	Chemical Gas Chromatography General Microscopy Infrared Spectroscopy Mass Spectrometry
Quantitative Measurement	Solid	Gas Chromatography Mass Spectrometry
Weight Measurement	Botanical Liquid Solid	Balance

Discipline: Toxicology		
Component/Parameter	**Item**	**Key Equipment/Technology**
Qualitative Determination	Ante-Mortem Biological Item Post-Mortem Biological Item	Gas Chromatography Immunoassay Liquid Chromatography Mass Spectrometry
Qualitative Determination (Volatiles)	Ante-Mortem Biological Item Post-Mortem Biological Item	Gas Chromatography
Quantitative Measurement	Ante-Mortem Biological Item Post-Mortem Biological Item	Gas Chromatography Liquid Chromatography Mass Spectrometry
Quantitative Measurement (Volatiles)	Ante-Mortem Biological Item Post-Mortem Biological Item	Gas Chromatography

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[redacted]

Pamela L. Sale
Vice President, Forensics

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Received by OFS
04/01/21

Niagara County Sheriff's Office - Forensic Laboratory

2021 - 17025T - Surveillance Document Review

Prepared by Tondala Bausano

Data collected on 2021-02-01

ANSI National Accreditation Board

United States

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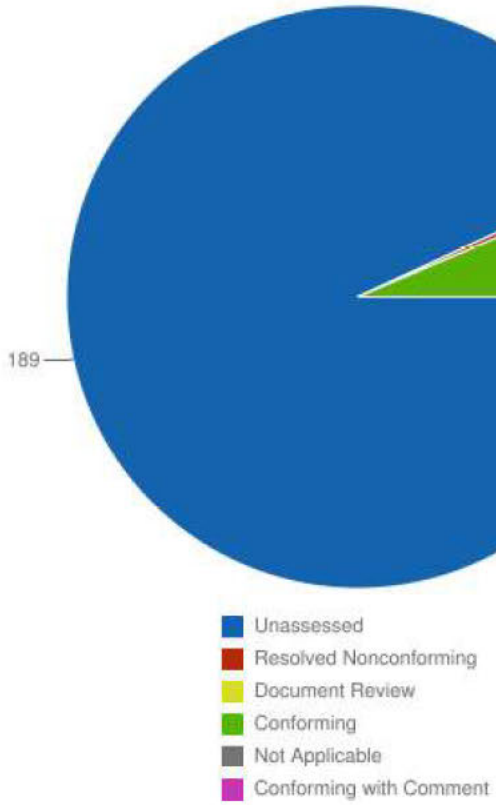
The accreditation activity also evaluates forensic science provider's conformance with their own management system requirements.

ASSESSMENT RESULT:

Based on the assessment techniques and sampling reviewed during the assessment activity, the assessment team found that the forensic service provider demonstrated competence to operate a management system that fulfills all applicable accreditation requirements, including those specified within their management system.

Any comments (opportunities for improvement) or nonconformities identified during this assessment activity are noted below. All nonconformities will be resolved prior to an accreditation decision by ANAB and a summary provided in a subsequent assessment activity report.

Summary of Comments



Audit Comments

8.8 Internal audits (Option A)

8.8.2.b).1 ANAB Accreditation Requirement

Resolved Nonconforming

Requirement

b).1 Do internal audits include direct observation of a sample of accredited services within each discipline?

Add Nonconformity Resolution Workflow

The Laboratory's 2020 internal audits did not include a direct observation of a sample of accredited services within their Fire Debris, Impression Evidence, and Materials (Trace) disciplines.

Completion note: The laboratory performed an evaluation of the cause and extent of the nonconformity, revised their Quality Assurance Manual, and completed a direct observation of a sample of accredited services within their Fire Debris discipline. Cause and extent evaluation records, the revision to the QA Manual and direct observation records were reviewed. The nonconformity is resolved.

From: Dinkel, Constance
To: dcjs.sm.forensiclabs
Cc: QualityMatters (qualitymatters@anab.org)
Subject: FW: DCJS Letter
Date: Thursday, April 22, 2021 7:38:41 AM
Attachments: dcjs - genna-04212021145151930.pdf

Good morning, Effective May 21st, the Chief of the Suffolk County Crime laboratory will be retiring. At that time Donald Doller will assume his responsibilities as the Acting Chief. If you have any questions please let me know. Thank you

Constance Dinkel
Forensic Scientist
Quality Assurance Manager
Suffolk County Crime Laboratory
[redacted]

From: [redacted]
Sent: Wednesday, April 21, 2021 2:56 PM
To: [redacted]
Cc: [redacted]
Subject: DCJS Letter

I have sent this letter to DCJS.

Virginia Falcone
Suffolk County Office of the Medical Examiner
[redacted]

COUNTY OF SUFFOLK

Received by OFS
04/22/21

STEVEN BELLONE
SUFFOLK COUNTY EXECUTIVE

OFFICE OF THE MEDICAL EXAMINER

ODETTE R. HALL, M.D.
Chief Medical Examiner

April 21, 2021

Jackalynne Vimislik
New York State Division of Criminal
Justice Services
80 South Swan Street
Albany, NY 12210

Dear Ms. Vimislik:

This letter is to inform you that Robert Genna, Crime Laboratory Chief at the Suffolk County Medical Examiner's Office, will be retiring effective May 22, 2021.

Sincerely,

[redacted]

Odette R. Hall, M.D.
Chief Medical Examiner

ORH/vsf

xc: Donald Doller
Constance Dinkel

Sidney B. Weinberg Center for Forensic Sciences
William J. Lindsay Complex, Bldg. 487, 725 Veterans Memorial Highway, PO Box 6100, Hauppauge, NY 11788
(631) 853-5555 Fax (631) 853-4673

American Board of
ABFT
Forensic Toxicology ™

Received by OFS
05/20/21

FORENSIC TOXICOLOGY LABORATORY ACCREDITATION CHECKLIST

*****Effective April 1, 2021*****

Laboratory: Monroe Co. Office of the Chief Medical Examiner Toxicology Laboratory

Assessor(s): Robert Osiewicz, Ph.D. (onsite) and Graham Jones, Ph.D. (remote)

Date performed: April 27 & 28, 2021

Table of Contents

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? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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? Yes

A-7 The laboratory must have a procedure for notifying clients and ABFT simultaneously of analytical and other deficiencies that have affected the forensic reliability of reported results.

Occasionally, errors or deficiencies may be uncovered that may have affected the reliability of reported toxicology results.

Conforms? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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? Yes. However, four technical positions are vacant at this time due to resignations. Recruitment is on-hold due to COVID related budget restrictions. Toxicology for a substantial portion of autopsy cases are being directly outsourced to an accredited reference laboratory to compensate for the vacant toxicology positions.

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? Yes

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? Yes

Section B: <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):

Recommend adding the position of Assistant Director to the list of approved analytical data reviewers.

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? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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

Conforms? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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

Conforms? Yes

Section C: 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):

Recommend removing references to policies, methods and/or equipment from the SOP that are not contemporary (e.g., statement in "3i - Data Review and Reporting-1025-5" pertaining to use of chromatographic packed columns).

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? Yes

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

Conforms? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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 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? Yes

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

Conforms? Yes

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? Yes

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? Yes

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

Conforms? Yes

Section D: 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 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? Yes

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? Yes

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.

Unless the assay is validated for alternate matrices, matrix-matched controls can be prepared by fortifying analyte-free matrices such as tissue homogenates, expired blood bank blood or plasma, or another appropriate matrix.

Conforms? Yes

E-4 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? Yes

E-5 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? Yes

E-6 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? Yes

E-7 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? Yes

E-8 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? Yes

E-9 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? Yes

E-10 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? Yes

E-11 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? Yes

E-12 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? Yes

E-13 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? Yes

E-14 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? Yes

E-15 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? Yes

E-16 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? Yes

E-17 If unacceptable results occur in PT programs, the laboratory must take documented corrective action including, as appropriate, a root-cause investigation and the potential impact on past casework.

It is not sufficient to only reanalyze the PT sample and accept the new result if it is within the acceptable range. It is important to investigate the reason for the initial failure and take appropriate documented corrective action. 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).

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.

Conforms? Yes

E-18 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? Yes

E-19 The laboratory must label purchased reagents with at least the date received and date opened.

Conforms? Yes

E-20 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? Yes

E-21 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? Yes

E-22 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? Yes

E-23 Equipment that is uncalibrated, broken, or otherwise out of service must be clearly marked as such.

Conforms? Yes

E-24 The laboratory must regularly monitor and record temperatures on all equipment where temperature control is critical for the application.

Conforms? Yes

E-25 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? Yes

E-26 The laboratory must check the accuracy of balances when critical weighing is performed. Documentation of the checks must be maintained.

Conforms? Yes

E-27 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? Yes

E-28 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? Yes

E-29 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? Yes

E-30 Case data from failed runs must be maintained (paper or electronic), as it forms part of the record of testing performed on any given specimen/case and may be important in the overall context of case review.

Conforms? Yes

E-31 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? Yes

E-32 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? Yes

E-33 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? Yes

E-34 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? Yes

E-35 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? Yes

E-36 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? Yes

E-37 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? Yes

E-38 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? Yes

E-39 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? Yes

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):

Recommend labeling each reagent bottle with a single label listing the content, dates of preparation and expiration, and the preparer. Current practice involves transcribing a new date and initials onto a long piece of tape(s) containing multiple identifiers leading to possible confusion and mistakes.

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? Yes

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.

Conforms? Yes

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? NA

Note: As of January 2021, the College of American Pathologists has expanded the FTC proficiency test to challenge virtually all of the drugs included in the T-series. All FTC challenges are now based on whole blood and at an equivalent number of challenges as the T-series. Consequently, laboratories adhering to the ABFT standards are no longer required to purchase the CAP T-series sets. However, laboratories routinely quantitating drugs in serum or plasma are encouraged to continue to subscribe to the T-series PT sets or another program that challenges a broad range of drugs in serum or plasma.

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? Yes

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

If the concentration of the specimen exceeds the 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? Yes

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

For example, 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? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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**

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? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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

Conforms? Yes

Section G: 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 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? Yes

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? Yes

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? Yes

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? NA

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? Yes

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% relative to a calibrator in the same run.**

Conforms? Yes

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% relative to a calibrator in the same run.**

Conforms? No, but. Transition ratios of no more than ±20% of target are used in practice. However, the SOP is currently written to allow up to ±30% of target.

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? NA

Section H: <u>SUMMARY</u>

General Comments (if any):

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

H-7: Change the ion ratio acceptance criteria in the SOP for LC/MS/MS transition ions from ±30% to ±20% to conform to checklist question H-7. In practice, ±20% is the criteria used for all methods.

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? Yes

List Applicable Techniques: Carboxyhemoglobin by Avoximeter

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? NA

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? NA

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? NA

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? NA

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? Yes

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? Yes

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? Yes

Section K: 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 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 radioactive materials;**
  - **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? Yes

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? Yes

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

Conforms? Yes

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? Yes

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? Yes

Section L: <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):

CONCLUDING SUMMARY COMMENTS

This laboratory is performing forensic toxicology testing to a high standard. The laboratory is fully compliant with the ABFT accreditation standards with one minor exception (H-7) that can be addressed by a small SOP change.

The laboratory does currently have four vacant positions, due to resignations, that the laboratory is unable to fill due to COVID related budget restrictions. Hopefully the laboratory will be able to address the future of those positions in the coming weeks.

Team Lead: [redacted] Date: April 29, 2021

American Board of
ABFT
Forensic Toxicology ™

FORENSIC TOXICOLOGY LABORATORY ACCREDITATION CHECKLIST

*****Effective April 1, 2021*****

Laboratory: Suffolk County Office of the Medical Examiner –Toxicology Laboratory

Assessor(s): William A. Dunn (on site) & Graham Jones (remote)

Date performed: April 29 & 30, 2021.

Table of Contents

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? Yes, Documents reviewed on site.

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? Yes, Documents reviewed on site. It was also observed that the lab maintains basic texts journals and internet access for lab personnel.

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? Yes, Documents reviewed on site.

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? Yes, Documents reviewed on site.

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? Yes, Documents reviewed on site.

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? Yes, Documents reviewed on site.

A-7 The laboratory must have a procedure for notifying clients and ABFT simultaneously of analytical and other deficiencies that have affected the forensic reliability of reported results.

Occasionally, errors or deficiencies may be uncovered that may have affected the reliability of reported toxicology results.

Conforms? Yes, Documents reviewed on site.

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? Yes, Documents (CV's) reviewed on site.

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? Yes, Documents reviewed on site. The laboratory has multiple Forensic Scientists with experience and educational qualifications to interpret toxicological results.

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? Yes, Documents reviewed on site.

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? Yes, Documents reviewed on site.

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? Yes. Michael Katz serves as alternate director and has the educational, authority and professional experience to substitute for the Dr. Lehrer.

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? Yes, Documents reviewed on site.

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? Yes, Documents reviewed on site.

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? Yes, Documents reviewed on site. Personnel – Personnel Training, Proficiency Summaries, Toxicology Training Manual, and Suffolk County Job Descriptions

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? Yes. The laboratory has adequate staff to fulfill its mandate.

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? Yes, Documents reviewed on site.

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? Yes, Documents reviewed on site.

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? Yes, Documents reviewed on site.

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? Yes, Documents reviewed on site.

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? Yes, Documents reviewed on site.

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? Yes, Documents reviewed on site.

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? Yes, Documents reviewed on site.

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? Yes, Documents reviewed on site.

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? Yes, Documents reviewed on site.

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

Conforms? Yes, Documents (hard copy & electronic) were reviewed on site.

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? Yes**.** While witnessing a batch extraction for Alprazolam/α-hydroxy alprazolam "bench notes" were observed and appeared to be current (by approval date).

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).**

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

Conforms? Yes, Documents reviewed on site.

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? Yes, Documentation reviewed on site.

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? Yes, Documents reviewed on site.

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

Conforms? Yes, Documents reviewed on site.

Section C: 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 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? Yes, Documents reviewed on site. Additionally, the inspector observed DWI/DUID kits being made.

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

Conforms? Yes, Documents reviewed on site. Additionally, the inspector observed DUI/DUID, and postmortem specimens being accessioned.

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? Yes, Documents reviewed on site. Additionally, the inspector observed DUI/DUID, and postmortem specimens being accessioned.

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? Yes, Documents reviewed on site. Additionally, the inspector observed DUI/DUID, and postmortem specimens being accessioned. No abnormal samples were received during this inspection.

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? Yes, Documents reviewed on site. The on-site inspector was required to sign in and required a fob to enter the laboratory proper and was escorted to areas for inspection.

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? Yes, Documents reviewed on site.

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? Yes, Documents reviewed on site. Additionally, specimens were observed to be kept properly stored (refrigerated or frozen).

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? Yes, Documents reviewed on site. Postmortem (4) and DUI/DUID (5) case folders were reviewed for completeness.

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? Yes, Documents reviewed on site. Postmortem (4) and DUI/DUID (5) case folders were reviewed for completeness.

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 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? Yes, Documents reviewed on site. The onsite inspector was given a temporary ID and password to access electronic documents (Qualtrex). Access to documents in CME was not granted. Documents in CME were accessed by analysts for the inspectors review when requested.

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

Conforms? Yes, Documents (paper & electronic) were reviewed on site.

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? Yes. Multiple documents reviewed.

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? Yes. Laboratory storage areas for specimens were inspected and found to be compliant.

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

Conforms? Yes, The Laboratory maintains adequate freezer and refrigerator space within the Toxicology laboratory for both the short- and long-term storage of specimens.

Section D: 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 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? Yes, Organizational chart was reviewed on site.

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? Yes, Documents (paper & electronic) were reviewed on site.

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.

Unless the assay is validated for alternate matrices, matrix-matched controls can be prepared by fortifying analyte-free matrices such as tissue homogenates, expired blood bank blood or plasma, or another appropriate matrix.

Conforms? Yes. Yes, Documents (paper & electronic) were reviewed on site.

E-4 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? Yes. Yes, Documents (paper & electronic) were reviewed on site.

E-5 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 re-injected 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? Yes, Documents (paper & electronic) were reviewed on site.

E-6 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? Yes, Documents (paper & electronic) were reviewed on site.

E-7 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? Yes, Documents (paper & electronic) were reviewed on site.

E-8 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? Yes, Documents (paper & electronic) were reviewed on site.

E-9 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? Yes, Documents (paper & electronic) were reviewed on site.

E-10 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? Yes, Documents (paper & electronic) were reviewed on site.

E-11 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? Yes, Documents (paper & electronic) were reviewed on site.

E-12 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? Yes, Documents (paper & electronic) were reviewed on site. The laboratory exclusively uses certified reference materials for all drug quantitations.

E-13 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? Yes, Documents (paper & electronic) were reviewed on site. Additionally, all calibrator and control solutions were observed to be within their expiration dates.

E-14 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? Yes, Documents (paper & electronic) were reviewed on site. The Quality Assurance/Quality Control SOP states that the failure of a negative control generally calls for repeating of entire run and the failure of a positive control may allow for reporting of negative samples.

E-15 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 maybe 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? Yes, Documents (paper & electronic) were reviewed on site and in documents supplies prior to the onsite inspection.

E-16 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? Yes, Documents (paper & electronic) were reviewed on site and in documents supplies prior to the onsite inspection.

E-17 If unacceptable results occur in PT programs, the laboratory must take documented corrective action including, as appropriate, a root-cause investigation and the potential impact on past casework.

It is not sufficient to only reanalyze the PT sample and accept the new result if it is within the acceptable range. It is important to investigate the reason for the initial failure and take appropriate documented corrective action. 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).

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.

Conforms? Yes, Documents (paper & electronic) were reviewed on site and in documents supplies prior to the onsite inspection.

E-18 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? Yes. All reagents, calibrators and controls were observed to have been annotated with the reagent's identity, identity of the preparer, and dated with preparation and expiration dates.

E-19 The laboratory must label purchased reagents with at least the date received and date opened.

Conforms? Yes. Purchased reagents were observed to be dated with received and opened dates.

E-20 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? Yes, Documents (paper & electronic) were reviewed on site.

E-21 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? Yes, Documents (paper & electronic) were reviewed on site.

E-22 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? Yes, Documents (paper & electronic) were reviewed on site. The lab maintains routine maintenance and service logs for all instruments. All instrumentation undergoes preventive maintenance annually as part of service contracts.

E-23 Equipment that is uncalibrated, broken, or otherwise out of service must be clearly marked as such.

Conforms? Yes. Out of service equipment is labeled as such. During the inspection, a biohazard hood was so marked.

E-24 The laboratory must regularly monitor and record temperatures on all equipment where temperature control is critical for the application.

Conforms? Yes. The lab uses a temperature central monitoring system to track all refrigerators and freezers. Heating blocks and evaporators were noted to be monitored and annotated in a log upon use.

E-25 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? Yes, Documents (hard copies and electronic) were reviewed on site.

E-26 The laboratory must check the accuracy of balances when critical weighing is performed. Documentation of the checks must be maintained.

Conforms? Yes, Documents (hard copies and electronic) were reviewed on site.

E-27 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? Yes. Commercial software used. All data is backed up in a secure off site settling with limited access.

E-28 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**
- **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? Yes, Documents reviewed on site. Postmortem (4) and DUI/DUID (5) case folders were reviewed for completeness.

E-29 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? Yes, Documents reviewed on site. Postmortem (4) case folders were reviewed for completeness. It was noted that the laboratory only reports negative immunoassay results on postmortem reports.

E-30 Case data from failed runs must be maintained (paper or electronic), as it forms part of the record of testing performed on any given specimen/case and may be important in the overall context of case review.

Conforms? Yes, Documents (hard copies and electronic) were reviewed on site. The laboratory maintains records of both acceptable and unacceptable runs within each case file.

E-31 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? Yes, Documents reviewed on site. Postmortem (4) and DUI/DUID (5) case folders were reviewed for completeness.

E-32 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? Yes, Documents reviewed on site. Per their Quality Assurance/Quality Control SOP, the laboratory confirms all results by separate analysis of specimens. The laboratory also uses negative controls, blank runs, and specific carry over criteria for all analysis.

E-33 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? Yes, the laboratory does not us pipette tips that are non-disposable.

E-34 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? Yes. Postmortem (4) case folders were reviewed. These case files contain the forensic investigators report and case history. Other information for postmortem cases is available in Qualtrex.

E-35 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? Yes. When the laboratory is unable to test for certain compound that were requested, the laboratory will contact the requesting client and notify them of their scope of analysis.

E-36 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? Yes. Vague terms are not used in laboratory reports.

E-37 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? Yes. Unconfirmed results are clearly indicated if used.

E-38 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? Yes. Outside laboratory results are included in case file and the laboratory performing the test is clearly identified in the released report.

E-39 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? Yes. The lab maintains all case files for 20 years. Homicide case files are maintained indefinitely. QA/QC records are maintained for 15 years.

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), CAP FTC (whole blood drugs), and CAP T-series (serum and urine) 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 and T-series PTs offer a broad range of illicit, prescription, and over-the-counter drugs and metabolites in three matrices. Note: Subscription to the CAP T-series is NOT mandatory after December 31, 2020.

Conforms? Yes. The laboratory subscribes to CAP AL1 (blood alcohol), CAP FTC (whole blood drugs), and CAP DFC-series (urine) proficiency tests.

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), CAP FTC (whole blood drugs), and CAP T-series (serum and urine) 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. Subscription to the CAP T-series is NOT mandatory after December 31, 2020.

Conforms? Yes. The laboratory subscribes to CAP AL1 (blood alcohol), CAP FTC (whole blood drugs), and CAP DFC-series (urine) proficiency tests.

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 FTC and T-series 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 to24 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? Yes. The laboratory subscribes to the CAP DFC-series proficiency tests.

Note: Effective early 2021, the College of American Pathologists is expanding the FTC proficiency test to challenge virtually all of the drugs currently included in the T-series. All challenges will be based on whole blood and at an equivalent number of challenges as the T-series. Consequently, laboratories adhering to the ABFT standards will no longer be required to purchase the CAP T-series sets after 2020. However, laboratories routinely quantitating drugs in serum or plasma are encouraged to continue to subscribe to the T-series PT sets or another program that challenges a broad range of drugs in serum or plasma.

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):

All final reports adequately reflect positive findings, but the scope of testing is not stated. For example, scope of the "qualitative drug results" is not listed. The lab may want to consider adding a list of what compounds are specifically looked for in that panel.

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? Yes. The laboratory uses matrix matched calibrators and controls for all assays.

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

If the concentration of the specimen exceeds the 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? No, Ethanol results were permitted to be reported without dilution for values > 10% above the highest calibrator but less than 20% above the highest calibrator.

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

For example, 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? Yes. Calibrators and controls were observed to be analyzed in the same manner as samples.

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? Yes. Documents reviewed on site.

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

- **For linear regression acceptability using non-labeled internal standards, the coefficient of determination must be ≥0.98.**
- **For linear regression acceptability using matched labeled 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? Yes, Documents reviewed on site.

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? Yes. Documents reviewed on site.

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? Not Applicable. The laboratory does not use historical calibration curves.

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? Yes. All chromatographic assays contain at least one internal standard.

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? Yes. Review of multiple SOP's demonstrates that the laboratory uses appropriate internal standards for all assays.

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? Yes. Review of multiple SOP's show that minimum internal standard areas are defined for all quantitative assays.

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**

Laboratories are strongly encouraged to refer to the OSAC/ASB Standard 036 "*Practices for Method Validation in Forensic Toxicology*" 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? Yes. Method validations for Methadone/EDDP and Bupropion were reviewed and found to follow OSAC/ASB Standard 036

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? Yes. Method validations for Methadone/EDDP and Bupropion were reviewed and found to follow OSAC/ASB Standard 036

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.

Note: 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? Yes. Quality Controls records, both electronic and print were reviewed by the inspector.

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? Yes. Documents (QA/QC SOP and individual assay SOP's) were reviewed on site.

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.

Notwithstanding the above, it is recognized that, in some circumstances, a suitable second test procedure is not available or necessary. For example, the probability that a 75% carboxyhemoglobin result obtained by a properly conducted spectrophotometric assay is incorrect in a well-documented suicide is exceedingly low, whereas the unexpected finding of a 30% carboxyhemoglobin by a similar determination in blood from a motor vehicle accident victim holds a lower degree of certainty. Nonetheless, use of a second confirmatory technique (e.g., visible spectrophotometry, palladium chloride, or GC) is encouraged for all analytes, including carbon monoxide.

Conforms? Yes. Documents (QA/QC SOP and individual assay SOP's) were reviewed on site. All assays (except volatiles and carbon monoxide) are confirmed by a second more specific analysis.

G-16 The presence of a drug or toxicant must be verified in more than one specimen or, if only one specimen is available, by replicate analyses on different occasions and with adequate positive and negative controls in the same matrix.

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 vial or extraction tube used was contaminated.

Conforms? Yes, Documents reviewed on site. Postmortem (4) case folders were reviewed. Laboratory results were confirmed by duplicate analysis, either by separate specimen or separate analysis with appropriate controls.

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

Conforms? Yes. The laboratory employs a dual column GC-FID method for all volatile analysis.

Section G: SUMMARY

General Comments (if any):

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

G-2 The laboratory must report only quantitative results that are within a valid calibration range. The laboratory states "Any sample > 0.48% will be repeated on dilution" (DWI Ethanol Analysis by GC/FID, revision 3).
For ethanol analysis, the allowed reportable value above the high calibrator has been amended to 10 % and the SOP amended accordingly by the close of this inspection, therefore resolving the non-conformity. Additionally, a search of their database indicates that there were no cases where that scenario occurred.
A review of the method validation documents for ethanol demonstrates that this method was found to be linear to at least 1.00%. It was further relayed to the inspector that a linearity control for column validation (Cerilliant Ethanol-500 – an ethanol solution certified to be 0.500%) is run with every change of a chromatographic column.

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? Yes. Documents reviewed on site. The laboratory has a documented procedure for failed MS and MS/MS autotunes.

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? Yes. Documents reviewed on site. The laboratory uses quality match, retention time and the relative complexity of the compound for GC/MS mass spectral identification.

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? Yes. Documents reviewed on site. The laboratory uses quality match, retention time and the relative complexity of the compound for LC/MS mass spectral identification.

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? Yes. Documents reviewed on site. The laboratory uses LC/TOF for screening and confirmatory analysis. A match score is returned based on 4 levels of comparison (accurate mass, retention time, isotope abundance and isotope spacing).

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? Yes. Documents reviewed on site. The laboratory uses commercial software as an aid to identification but not exclusively. Acceptance criteria is clearly defined in each method.

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% relative to a calibrator in the same run.**

Conforms? Yes. Documents reviewed on site.

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 analyte and internal standard. If a second transition cannot be reliably used for confirmation of specific analytes, 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% relative to a calibrator in the same run.**

Conforms? Yes. Documents reviewed on site.

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? Not Applicable. This laboratory does not have an Orbitrap.

Section H: 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 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? Yes. Other analysis in laboratory employs the same standards and protocols used for the previously mentioned procedures.

Applicable Techniques:

Carboxyhemoglobin by UV/VIS:	SOP was reviewed.
Salicylate Confirmation by UV/VIS:	Method in review status and not able for review.

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? Not applicable. This laboratory does perform vitreous chemical analysis**.**

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? Not applicable. This laboratory does perform vitreous chemical analysis.

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? Not applicable. This laboratory does perform vitreous chemical analysis.

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

Note: 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? Not applicable. This laboratory does perform vitreous chemical analysis.

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? Yes, Documents reviewed on site.

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? Yes, Document and representative case folder reviewed on site.

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? Yes, Documents reviewed on site.

Section K: 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 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 radioactive materials.**
  - **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? Yes, Documents (safety manual and training manual) were reviewed on site.

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? Yes, Documents (safety manual and training manual) were reviewed on site.

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

Conforms? Yes. On inspection the laboratory was observed to be cleaned and free of clutter.

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? Yes. On inspection the laboratory was observed to have general ventilation and adequate heating, cooling, lighting, and humidity controls.

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? Yes. The laboratory was observed to have adequate space to perform all technical work and has adequate storage space.

Section L: SUMMARY

General Comments (if any):

At least once an analyst was observed handling biological specimens without using gloves during an accessioning procedure.

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):

In areas where specimens are handled and entries are made into a computer, washable keyboards might be considered.

CONCLUDING SUMMARY COMMENTS

The inspector thoroughly enjoyed inspecting Suffolk County Office of the Medical Examiner Toxicology laboratory. The laboratory is well staffed by very knowledgeable and competent individuals, both technical and administrative. All SOPs are well written and are followed by all staff. The staff was very accommodating and helpful during the inspection and were very open to discussing their operations and incorporating any suggestions. Overall, the Suffolk County Office of the Medical Examiner Toxicology laboratory is a very well-run operation that serves its clients extremely well.

Team Lead:__[redacted]__Date:_____May 8, 2021___

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American Board of
ABFT
Forensic Toxicology ™

Received by OFS
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FORENSIC TOXICOLOGY LABORATORY ACCREDITATION CHECKLIST

*****Effective April 1, 2021*****

Laboratory: Nassau County Medical Examiner's Office

Assessor(s): Daniel Baker, M.S., F-ABFT and Laura Labay, Ph.D., F-ABFT

Date performed: April 09 - 20, 2021 Remote Virtual Inspection

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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? YES

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? YES

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? YES

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? YES

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? YES

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? YES

A-7 The laboratory must have a procedure for notifying clients and ABFT simultaneously of analytical and other deficiencies that have affected the forensic reliability of reported results.

Occasionally, errors or deficiencies may be uncovered that may have affected the reliability of reported toxicology results.

Conforms? YES

Section A: SUMMARY

General Comments (if any):

Non-conformities (list the standard numbers here and explain any non-conformities under each standard):
NONE

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? YES

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? YES

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? YES

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? YES

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? YES

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? YES

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? YES

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? YES

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? YES

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? YES

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? YES

Section B: SUMMARY

General Comments (if any):

Non-conformities (list the standard numbers here and explain any non-conformities under each standard):
NONE

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? YES

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? YES

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? YES

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? YES

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? YES

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? YES

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? YES

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

Conforms? YES

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? N/A

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? YES

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? YES

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? YES

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

Conforms? YES

Section C: SUMMARY

General Comments (if any):

Non-conformities (list the standard numbers here and explain any non-conformities under each standard):
NONE

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? YES

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

Conforms? YES

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? YES

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? YES

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? YES

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? YES

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? YES

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? YES

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? YES

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 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? YES

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

Conforms? YES

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? YES

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? YES

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

Conforms? YES

Section D: SUMMARY

General Comments (if any):

Non-conformities (list the standard numbers here and explain any non-conformities under each standard):
NONE

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

D-14: Recommend to increasing long term retention of postmortem specimens if possible (currently disposal may occur post 30 days of report release). There are sometimes instances where the toxicologist may need to return to the original specimen to verify identity and draw times, or order additional testing based upon new information, requests from pathologists or courts of law.

General: Recommend to cross-reference forms or add links to their locations within SOPs in QualTrax. This makes it efficient for people to locate forms and ensures use of the current version.

Examples:
I.B.3 -> PM Toxicology Evidence Discrepancy Form
I.D.2 -> DWI Chain of Custody Form

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? YES

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? YES

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.

Unless the assay is validated for alternate matrices, matrix-matched controls can be prepared by fortifying analyte-free matrices such as tissue homogenates, expired blood bank blood or plasma, or another appropriate matrix.

Conforms? YES

E-4 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? YES

E-5 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? YES

E-6 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? YES

E-7 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? YES

E-8 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? YES

E-9 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? YES

E-10 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? YES

E-11 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? YES

E-12 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? YES

E-13 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? YES

E-14 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? YES

E-15 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? YES

E-16 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? YES

E-17 If unacceptable results occur in PT programs, the laboratory must take documented corrective action including, as appropriate, a root-cause investigation and the potential impact on past casework.

It is not sufficient to only reanalyze the PT sample and accept the new result if it is within the acceptable range. It is important to investigate the reason for the initial failure and take appropriate documented corrective action. 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).

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.

Conforms? YES

E-18 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? YES

E-19 The laboratory must label purchased reagents with at least the date received and date opened.

Conforms? YES

E-20 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? YES

E-21 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? YES

E-22 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? YES

E-23 Equipment that is uncalibrated, broken, or otherwise out of service must be clearly marked as such.

Conforms? Unable to evaluate remotely.

E-24 The laboratory must regularly monitor and record temperatures on all equipment where temperature control is critical for the application.

Conforms? YES

E-25 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? YES

E-26 The laboratory must check the accuracy of balances when critical weighing is performed. Documentation of the checks must be maintained.

Conforms? YES

E-27 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? N/A

E-28 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? YES

E-29 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? YES

E-30 Case data from failed runs must be maintained (paper or electronic), as it forms part of the record of testing performed on any given specimen/case and may be important in the overall context of case review.

Conforms? YES

E-31 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? YES

E-32 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? YES

E-33 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? YES

E-34 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? YES

E-35 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? YES

E-36 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? YES

E-37 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? YES

E-38 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? YES

E-39 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? YES

Section E: SUMMARY

General Comments (if any):

Non-conformities (list the standard numbers here and explain any non-conformities under each standard):
NONE

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), CAP FTC (whole blood drugs), and CAP T-series (serum and urine) 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 and T-series PTs offer a broad range of illicit, prescription, and over-the-counter drugs and metabolites in three matrices. Note: Subscription to the CAP T-series is NOT mandatory after December 31, 2020.

Conforms? YES

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), CAP FTC (whole blood drugs), and CAP T-series (serum and urine) 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. Subscription to the CAP T-series is NOT mandatory after December 31, 2020.

Conforms? YES

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 FTC and T-series 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? N/A

Note: Effective early 2021, the College of American Pathologists is expanding the FTC proficiency test to challenge virtually all of the drugs currently included in the T-series. All challenges will be based on whole blood and at an equivalent number of challenges as the T-series. Consequently, laboratories adhering to the ABFT standards will no longer be required to purchase the CAP T-series sets after 2020. However, laboratories routinely quantitating drugs in serum or plasma are encouraged to continue to subscribe to the T-series PT sets or another program that challenges a broad range of drugs in serum or plasma.

Section F: <u>SUMMARY</u>

General Comments (if any):

Non-conformities (list the standard numbers here and explain any non-conformities under each standard):
NONE

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.

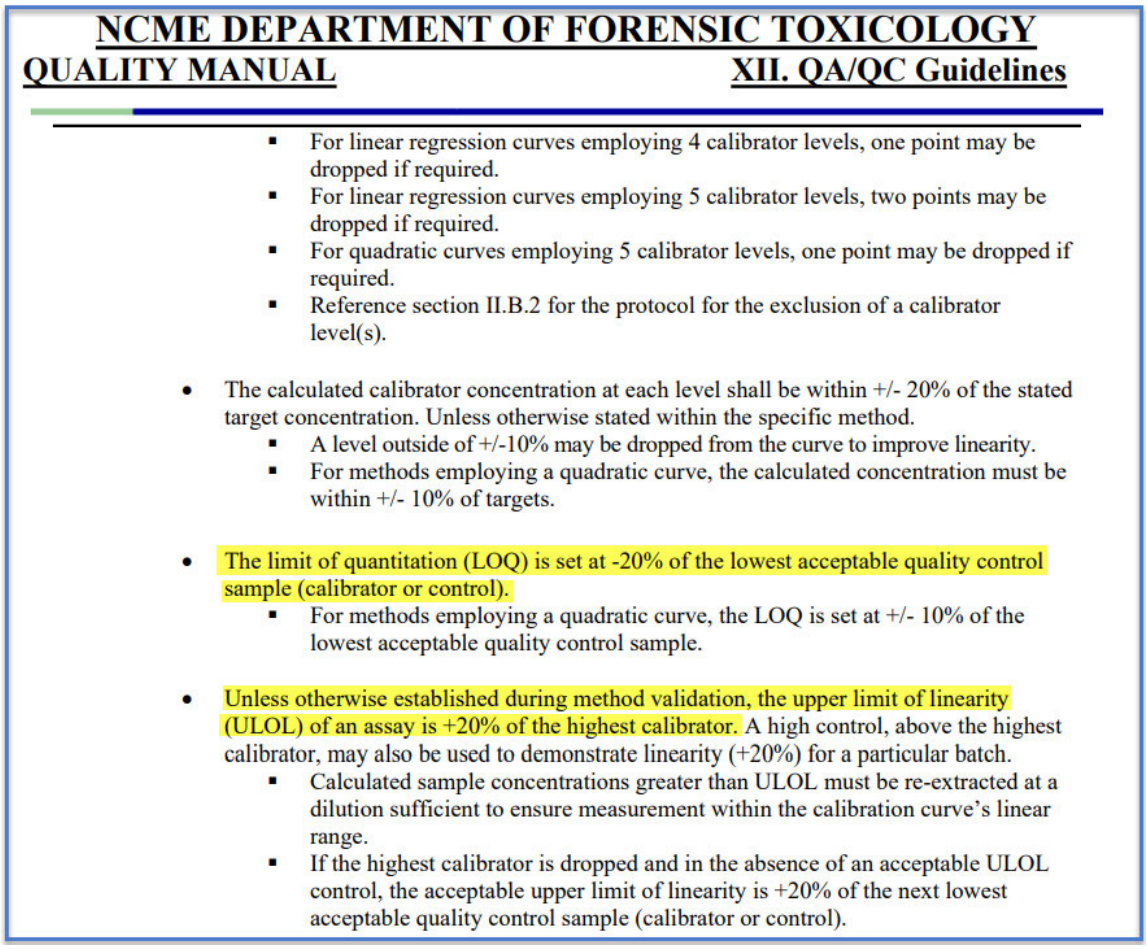
Conforms? YES

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

If the concentration of the specimen exceeds the 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? NO

The laboratory's Quality Manual SOP XII, QA/QC Guidelines permit an expanded calibration range beyond the concentrations of the highest and lowest calibrators:



NCME DEPARTMENT OF FORENSIC TOXICOLOGY
QUALITY MANUAL **XII. QA/QC Guidelines**

- For linear regression curves employing 4 calibrator levels, one point may be dropped if required.
- For linear regression curves employing 5 calibrator levels, two points may be dropped if required.
- For quadratic curves employing 5 calibrator levels, one point may be dropped if required.
- Reference section II.B.2 for the protocol for the exclusion of a calibrator level(s).

- The calculated calibrator concentration at each level shall be within +/- 20% of the stated target concentration. Unless otherwise stated within the specific method.
  - A level outside of +/-10% may be dropped from the curve to improve linearity.
  - For methods employing a quadratic curve, the calculated concentration must be within +/- 10% of targets.

- The limit of quantitation (LOQ) is set at -20% of the lowest acceptable quality control sample (calibrator or control).
  - For methods employing a quadratic curve, the LOQ is set at +/- 10% of the lowest acceptable quality control sample.

- Unless otherwise established during method validation, the upper limit of linearity (ULOL) of an assay is +20% of the highest calibrator. A high control, above the highest calibrator, may also be used to demonstrate linearity (+20%) for a particular batch.
  - Calculated sample concentrations greater than ULOL must be re-extracted at a dilution sufficient to ensure measurement within the calibration curve's linear range.
  - If the highest calibrator is dropped and in the absence of an acceptable ULOL control, the acceptable upper limit of linearity is +20% of the next lowest acceptable quality control sample (calibrator or control).

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

For example, 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? YES

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? YES

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? YES

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? YES

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? N/A

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? YES

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? YES

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? YES

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**

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? YES

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? YES

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? YES

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? YES

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? YES

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? YES

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

Conforms? YES

Section G: SUMMARY

General Comments (if any):

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

G-2

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

G-11: Recommend reviewing and updating Quality Manual SOP X, Validation of Methods, to include interferences and dilution integrity. Update references, SOP cites SOFT/AAFS 2006 Guidance Document. Validation data was reviewed and it demonstrated the laboratory had performed these validation experiments on most recent validations.

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? YES

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? YES

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? N/A

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? N/A

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.

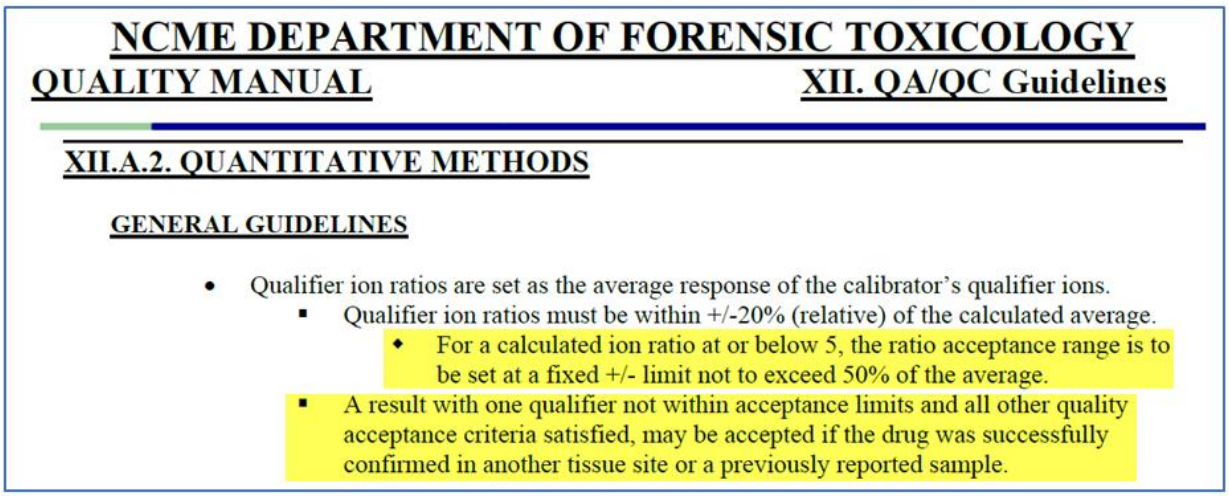
Conforms? N/A

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% relative to a calibrator in the same run.**

Conforms? NO

The laboratory's analyte confirmation/quantification acceptance criteria as documented in Quality Manual XII with regards to the minimum acceptable qualifying ion ratios deviates from ABFT Guidelines:



NCME DEPARTMENT OF FORENSIC TOXICOLOGY

QUALITY MANUAL **XII. QA/QC Guidelines**

XII.A.2. QUANTITATIVE METHODS

GENERAL GUIDELINES

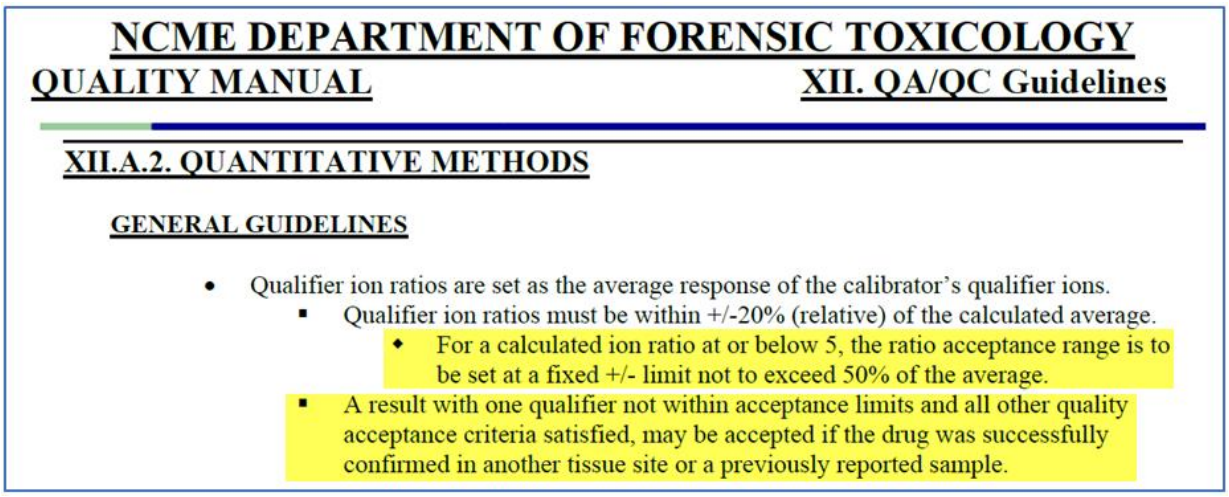
- Qualifier ion ratios are set as the average response of the calibrator's qualifier ions.
  - Qualifier ion ratios must be within +/-20% (relative) of the calculated average.
    - For a calculated ion ratio at or below 5, the ratio acceptance range is to be set at a fixed +/- limit not to exceed 50% of the average.
  - A result with one qualifier not within acceptance limits and all other quality acceptance criteria satisfied, may be accepted if the drug was successfully confirmed in another tissue site or a previously reported sample.

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% relative to a calibrator in the same run.**

Conforms? NO

The laboratory's analyte confirmation/quantification acceptance criteria as documented in Quality Manual XII with regards to the minimum acceptable qualifying ion ratios deviates from ABFT Guidelines:



NCME DEPARTMENT OF FORENSIC TOXICOLOGY

QUALITY MANUAL **XII. QA/QC Guidelines**

XII.A.2. QUANTITATIVE METHODS

GENERAL GUIDELINES

- Qualifier ion ratios are set as the average response of the calibrator's qualifier ions.
  - Qualifier ion ratios must be within +/-20% (relative) of the calculated average.
    - For a calculated ion ratio at or below 5, the ratio acceptance range is to be set at a fixed +/- limit not to exceed 50% of the average.
  - A result with one qualifier not within acceptance limits and all other quality acceptance criteria satisfied, may be accepted if the drug was successfully confirmed in another tissue site or a previously reported sample.

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? N/A

Section H: SUMMARY

General Comments (if any):

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

H-6
H-7

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? YES

List Applicable Techniques:

Cyanide Screening by Colorimetry

Carboxyhemoglobin by UV/VIS

Section I: SUMMARY

General Comments (if any):

Non-conformities (list the standard numbers here and explain any non-conformities under each standard):
NONE

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? YES

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? YES

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? YES

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? YES

Section J: SUMMARY

General Comments (if any):

Non-conformities (list the standard numbers here and explain any non-conformities under each standard):
NONE

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? YES

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? YES

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? YES

Section K: SUMMARY

General Comments (if any):

Non-conformities (list the standard numbers here and explain any non-conformities under each standard):
NONE

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

K-1: Update Methods Manual SOP IX.A to include language addressing practices that should be routinely taken to avoid any cross-contamination or carryover to biological specimens.

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 radioactive materials;**
  - **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? YES

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? YES

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

Conforms? Unable to evaluate remotely.

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? Unable to evaluate remotely.

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? Unable to evaluate remotely.

Section L: SUMMARY

General Comments (if any):

Non-conformities (list the standard numbers here and explain any non-conformities under each standard):
NONE

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

CONCLUDING SUMMARY COMMENTS

I would like to sincerely thank the Nassau County MEO, Forensic Toxicologists for their efforts, preparation and participation in this ABFT virtual re-inspection. Documents uploaded in advance were complete and organized. Their extensive use of a web based quality management software program and the ability to permit us remote access to documents was very helpful to complete this assessment. The staff was quick and forthcoming with case report and analytical data requests. Pride in their work was immediately apparent when answering questions regarding case results. It is evident the Nassau County MEO Toxicology Staff value the peer assessment process and are committed to producing high quality forensic results.

Team Lead/Lab Director: Daniel D Baker IV Date: 04/20/2021

Received by OFS
05/20/21

American Board of
ABFT
Forensic Toxicology ™

FORENSIC TOXICOLOGY LABORATORY ACCREDITATION CHECKLIST

*****Effective April 1, 2021*****

Laboratory: Onondaga County Center for Forensic Sciences

Assessor(s): Matt Slawson, Laureen Marinetti

Date performed: April 3rd- May 3rd

Table of Contents

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? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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? Yes

A-7 The laboratory must have a procedure for notifying clients and ABFT simultaneously of analytical and other deficiencies that have affected the forensic reliability of reported results.

Occasionally, errors or deficiencies may be uncovered that may have affected the reliability of reported toxicology results.

Conforms? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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

Conforms? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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

Conforms? Yes

Section C: 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 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? Yes

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

Conforms? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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 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? Yes

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

Conforms? Yes

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? Yes

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? Yes

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

Conforms? Yes

Section D: 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 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? Yes

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? Yes

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.

Unless the assay is validated for alternate matrices, matrix-matched controls can be prepared by fortifying analyte-free matrices such as tissue homogenates, expired blood bank blood or plasma, or another appropriate matrix.

Conforms? Yes

E-4 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? Yes

E-5 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? Yes

E-6 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? Yes

E-7 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? Yes

E-8 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? Yes

E-9 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? Yes

E-10 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? Yes

E-11 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? Yes

E-12 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? Yes

E-13 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? Yes

E-14 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? Yes

E-15 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? Yes

E-16 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? Yes

E-17 If unacceptable results occur in PT programs, the laboratory must take documented corrective action including, as appropriate, a root-cause investigation and the potential impact on past casework.

It is not sufficient to only reanalyze the PT sample and accept the new result if it is within the acceptable range. It is important to investigate the reason for the initial failure and take appropriate documented corrective action. 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).

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.

Conforms? Yes

E-18 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? Yes

E-19 The laboratory must label purchased reagents with at least the date received and date opened.

Conforms? Yes

E-20 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? Yes

E-21 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? Yes

E-22 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? Yes

E-23 Equipment that is uncalibrated, broken, or otherwise out of service must be clearly marked as such.

Conforms? Yes

E-24 The laboratory must regularly monitor and record temperatures on all equipment where temperature control is critical for the application.

Conforms? Yes

E-25 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? Yes

E-26 The laboratory must check the accuracy of balances when critical weighing is performed. Documentation of the checks must be maintained.

Conforms? Yes

E-27 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? Yes

E-28 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? Yes

E-29 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? Yes

E-30 Case data from failed runs must be maintained (paper or electronic), as it forms part of the record of testing performed on any given specimen/case and may be important in the overall context of case review.

Conforms? Yes

E-31 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? Yes

E-32 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? Yes

E-33 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? Yes

E-34 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? Yes

E-35 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? Yes

E-36 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? Yes

E-37 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? Yes

E-38 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? Yes

E-39 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? Yes

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? Yes

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.

Conforms? Yes

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? NA

Note: As of January 2021, the College of American Pathologists has expanded the FTC proficiency test to challenge virtually all of the drugs included in the T-series. All FTC challenges are now based on whole blood and at an equivalent number of challenges as the T-series. Consequently, laboratories adhering to the ABFT standards are no longer required to purchase the CAP T-series sets. However, laboratories routinely quantitating drugs in serum or plasma are encouraged to continue to subscribe to the T-series PT sets or another program that challenges a broad range of drugs in serum or plasma.

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? Yes

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

If the concentration of the specimen exceeds the 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? Yes

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

For example, 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? Yes

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? Yes

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? Yes

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? Yes

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? NA

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? Yes

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? Yes

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? Yes

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**

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? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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? Yes

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

Conforms? Yes

Section G: 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 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? Yes

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? Yes

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? NA

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? NA

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? Yes

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% relative to a calibrator in the same run.**

Conforms? Yes

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% relative to a calibrator in the same run.**

Conforms? Yes

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? NA

Section H: 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 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? NA

List Applicable Techniques:

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_____

_____

_____

_____

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? Yes

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? Yes

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? Yes

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? Yes

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? NA

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? NA

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? NA

Section K: 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 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 radioactive materials;**
  - **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? Yes

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? Yes

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

Conforms? Yes

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? Yes

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? Yes

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

General Comments (if any):

The virtual assessment did not identify any action items for the lab. This was determined via review of data and PT uploads provided by the lab and review of SOP manuals via online access to their QualTrax system

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

None identified

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

If the state/county entity responsible would release their hiring freeze on the lab, they could rehire a vacant position, which in turn should improve their reporting times.

Team Lead/Lab Director [redacted] Date: May 7, 2021

Received by OFS
05/03/21

American Board of
ABFT
Forensic Toxicology ™

FORENSIC TOXICOLOGY LABORATORY ACCREDITATION CHECKLIST

*****Effective April 1, 2021*****

Laboratory: Westchester County Dept. of Laboratories and Research: Division of Forensic Toxicology

Assessor(s): Anthony Costantino and Ruth Winecker

Date performed: April 2021

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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? Yes

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? Yes.

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? Yes

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? Yes

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? Yes

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? Yes

A-7 The laboratory must have a procedure for notifying clients and ABFT simultaneously of analytical and other deficiencies that have affected the forensic reliability of reported results.

Occasionally, errors or deficiencies may be uncovered that may have affected the reliability of reported toxicology results.

Conforms? Yes

Section A: SUMMARY

General Comments (if any): All areas appear to be covered with SOPs and processes in place.

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? Yes. CV of the director was supplied.

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? Yes

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? Yes CV was supplied

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? Yes. Was able to reasonably discuss all areas.

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? Yes. The QA manager and Senior toxicologist designated in that order.

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? Yes. All training is documented.

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? Yes. Competency assessment program is in place both prior to handling case work and annually thereafter

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? Yes. Transcripts are kept in the administrative file. Training and any continuing education are maintained in the lab-based personnel file.

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? Yes. In addition to the Director the lab currently has 2 Senior Toxicologists, 3 Toxicology Specialists, 1 Assistant Toxicologist, and 1 Laboratory Technician.

The lab has 2 Toxicologist positions that were vacated in 2021 and is in the process of replacing them.

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? Yes But there is a Union rule that prohibits the job from requiring continuing education. The lab offers CE opportunities and encourages outside opportunities. It appears that the staff is active in CE. Records kept in the lab personnel file.

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? Yes and it is documented.
All the employees of the forensic toxicology must annually read *Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel*.

Section B: SUMMARY

General Comments (if any): Yes. The lab is diligent about training, competency, CE and ethical standards. The inspection team conducted interviews of 5 staff members which supported the above comment.

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? Yes

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? Yes. QA Manual

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? Yes. Listed in methods SOPs

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? Yes. New analytes are added as they become recognized or the need is realized. Appears to be more of a real time process than an annual review. As new drugs become available they are added to the in-house data base.

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? Yes. Testing protocols for Medical Examiner, DUI/DUID and DFSA are described.

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? Yes. Procedures have all been approved in the past 2 years. Could not find a policy for frequency of review.

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? Yes

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

Conforms? Yes. Printed and electronic versions.

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? NA The lab does not use abbreviated procedures of any kind.

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).**

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

Conforms? Yes

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? Yes

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? Yes per interview and policy

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

Conforms? Yes. Most if not all deviations are referred to the supervisor or director in each SOP.

Section C: SUMMARY

General Comments (if any): Appears compliant in all areas except with respect to the recommendation of specific SOP for testing vitreous as noted below.

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): With respect to the vitreous testing SOP (also discussed in Section J).

1. Clarify that the samples are to be diluted 1:1 with DI water. The SOP states that the sample requirement is 250 uL vitreous and 250 uL DI water.

2. A better explanation of the setup of the vitreous analytical run with respect to the ordering of all QC and patient specimens. It is broken up in a couple of places and would be more understandable if the order to the run was delineated in one place.

3. Instructions for diluting the Biorad control 1:2 are not included, and the diluent is not specifically identified.

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? Yes. Some information is in the QA manual and others in specific discipline SOPs. The disciplines are Medical Examiner, DUI/DUID, DFSA.

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

Conforms? Yes. Both policy and verified through interview of the specimen processor.

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? Yes, but lab numbers for medical examiner cases is the case number which is generated in the autopsy suite, The lab retains that number through the process. Therefore, there may be gaps in the numbers. The lab and medical examiners are on the same LIS. Accession number for DUI/DFSA are generated at the laboratory.

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? Yes. Condition is recorded if atypical. "decomp" was the most common example.

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? Yes. Policy, procedure and layout secures and segregates access.

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? Yes

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? Yes. Storage areas within the lab as well as the lab itself are locked outside of normal working hours.

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? Yes. All case records are stored in a secured area with limited access via card controlled magnetic locks. Case records are kept on-site for a minimum of two years. After that time records are transferred for long term storage off-site by the Westchester County Records Center.

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? Yes. Same security as the laboratory area.

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 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? Yes. Toxicology results on individual instruments are available to lab personnel only. Results within the LIMS system are password protected. The LIMS has differential access to the results. Results that are placed on the Discovery Portal for District Attorneys are password protected and in PDF format where possible. The discovery portal only has access to the documents scanned into it.

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

Conforms? Yes

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? Yes. Combination of electronic and handwritten.

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? Yes. Refrigerated both upon arrival and when not in use at the bench

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

Conforms? Yes. Observed laboratory and relevant office spaces did not appear to be overcrowded or cluttered.

Section D: SUMMARY

General Comments (if any): This area appears to be covered thoroughly. The facility is secure. Records (electronic and paper) and specimens are secure.

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? Yes. A Senior Toxicologist (Eliza Scuderi) works with the Lab Director and Supervisor to oversee the daily operation of the QA system.

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? Yes. Performed quarterly. Gathered by QA supervisor and signed off by the director.

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.

Unless the assay is validated for alternate matrices, matrix-matched controls can be prepared by fortifying analyte-free matrices such as tissue homogenates, expired blood bank blood or plasma, or another appropriate matrix.

Conforms? Yes

E-4 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? Yes

E-5 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? Yes

E-6 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? Yes

E-7 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? Yes. All quantitative controls are plotted in Excel charts. Mean, standard deviation, %CV and % bias are calculated for all analytes. Frequently run analyses are plotted. All QC is peer reviewed after every analysis. If an analyst spots a trend it is brought to the attention of a supervisor. All QC charts and graphs are reviewed on a quarterly basis by the QA manager and the Director. Failed QC is not plotted in the Excel charts. Rather a note is made on the appropriate excel sheet with the results of the failed QC.

E-8 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? Yes

E-9 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? Yes. Verified by interview.

E-10 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? Yes

E-11 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? Yes

E-12 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? Yes

E-13 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? Yes per QA manual

E-14 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? Yes per QA manual

E-15 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? Yes. PT samples are integrated with patient/donor samples.

E-16 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? Yes. Documentation of review was evident on PT results.

E-17 If unacceptable results occur in PT programs, the laboratory must take documented corrective action including, as appropriate, a root-cause investigation and the potential impact on past casework.

It is not sufficient to only reanalyze the PT sample and accept the new result if it is within the acceptable range. It is important to investigate the reason for the initial failure and take appropriate documented corrective action. 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).

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.

Conforms? No. CAP Series T-C Specimen T-11 the mean for Methamphetamine was 767.25 ng/mL. SD 69.4 ng/mL. Lab result: 579 ng/mL which is -2.7 SD from the mean. Because the result was < 30% from the mean the lab did not investigate. Their internal rule is +/- 30% NOT 20% +/- 2SD

E-18 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? Yes

E-19 The laboratory must label purchased reagents with at least the date received and date opened.

Conforms? Yes. If the label is too small date received for a lot and shipment is recorded in a log which was made available to the inspectors.

E-20 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? Yes. Sometimes tested live because of a possible contamination of a reagent. QC and calibrator responses are relied upon in this case.

E-21 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? Yes. Pipettes are calibrated by an external vendor. Documentation was provided to inspectors. The pipettor dilutor for alcohol is reviewed for consistency in each analytical batch.

E-22 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? Yes. Records made available to inspectors

E-23 Equipment that is uncalibrated, broken, or otherwise out of service must be clearly marked as such.

Conforms? Yes. Saw examples in video tour. Fume hood was out of order.

E-24 The laboratory must regularly monitor and record temperatures on all equipment where temperature control is critical for the application.

Conforms? Yes. The laboratory monitors refrigerator and freezer temperatures as well as documenting heating block and oven temperatures when hydrolyzing or derivatizing samples.

E-25 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? Yes

E-26 The laboratory must check the accuracy of balances when critical weighing is performed. Documentation of the checks must be maintained.

Conforms? Yes

E-27 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? YES Excel charts used for tracking QC data are routinely checked and backed up daily. They can be changed however. New copies are compared to old copies periodically and formulas are checked quarterly.

E-28 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**
- **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? Yes. There is a documented administrative and technical review for accuracy of each final report for completeness and correctness before it is issued. The reviews are documented with the initials of the reviewer next to an attestation of the review.

E-29 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? Yes. Cut-off information for immunoassays is found within the individual SOP. Cross-reactivity information is available from the manufacturer.

E-30 Case data from failed runs must be maintained (paper or electronic), as it forms part of the record of testing performed on any given specimen/case and may be important in the overall context of case review.

Conforms? Yes per SOP and interview.

E-31 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? Yes

E-32 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? Yes

E-33 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? Yes

E-34 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? Yes

E-35 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? Yes

E-36 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? Yes

E-37 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? Medical Examiners reports have two reporting sections. The first is listed as Qualitative where all results are listed (screening and confirmed) and a second section listed as Confirmed where results that are confirmed and quantitated are listed. I think that it is confusing. Below is an example of a report. The lab claims that if they say Qualitative that means screened once. In order for a second test to have been performed then the analyte(s) would be listed under Quantitative. They say that this is understood throughout the system. It's not defined clearly in an SOP. To be reviewed. It may be misleading.
See example report below:

WESTCHESTER COUNTY
DEPARTMENT OF
LABS AND RESEARCH
Division of Forensic Toxicology
10 Dana Road Valhalla, NY 10595

Westchester gov.com

TOXICOLOGY REPORT

[redacted]
Deceased: [redacted]
Age: [redacted]
[redacted]

Samples Submitted for Analysis

_X_Blood (Site: Heart) _X_Urine _X_Vitreous Humor _X_Liver _X_Bile _X_Brain _X_Gastric Contents
_X_Blood-Femoral
Received Date: 06/29/2020

Drug Screen: Qualitative

Specimen	Result	Technique
Blood	Lorazepam, gabapentin, benzoylecgonine, diphenhydramine, and acetaminophen present.	IA or TOF
Urine	Cocaine and benzodizepines present.	IA or GCMS

All documentation pertaining to this report is available in the laboratory.
Explanation of terms:www.criminaljustice.ny.gov/forensic/standardization/toxicology.html

Confirmed Results: Quantitative
(All drug results ± 20% : Ethanol results ± 10%)

Specimen	Component	Result	Technique
Blood (Heart)	Ethanol	0.24 g/100 mL	GCFID
Urine	Ethanol	0.32 g/100 mL	GCFID
Vitreous Humor	Ethanol	0.29 g/100 mL	GCFID
Blood (Heart)	Lorazepam	101 ng/mL	LCMSMS
Blood (Heart)	Benzoylecgonine	0.04 ug/mL	GCMS
Urine	Benzoylecgonine	1.58 ug/mL	GCMS
Blood (Heart)	Cocaine	Not detected at a concentration of 0.02ug/mL	GCMS
Urine	Cocaine	0.06 ug/mL	GCMS
Blood (Heart)	Gabapentin	39 ug/mL	LCMSMS
Gastric Contents	Gabapentin	116 ug/mL	LCMSMS
Gastric Contents	Gabapentin	9 mg/75 mL	LCMSMS

E-38 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? Yes

E-39 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? Yes

Section E: SUMMARY

General Comments (if any): Generally speaking this laboratory has a thorough and vigilant QA program.

Non-conformities (list the standard numbers here and explain any non-conformities under each standard):
E-17: Laboratory uses less strict criteria than +/- 20% or 2SD when evaluating PT results. They use 30% of the participant mean as evaluation criteria.
E-37: Reporting language for presumptive/unconfirmed results in medical examiner cases can appear to be definitive results on the report

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), CAP FTC (whole blood drugs), and CAP T-series (serum and urine) 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 and T-series PTs offer a broad range of illicit, prescription, and over-the-counter drugs and metabolites in three matrices. Note: Subscription to the CAP T-series is NOT mandatory after December 31, 2020.

Conforms? Yes

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), CAP FTC (whole blood drugs), and CAP T-series (serum and urine) 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. Subscription to the CAP T-series is NOT mandatory after December 31, 2020.

Conforms? Yes

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 FTC and T-series 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? Yes

Note: Effective early 2021, the College of American Pathologists is expanding the FTC proficiency test to challenge virtually all of the drugs currently included in the T-series. All challenges will be based on whole blood and at an equivalent number of challenges as the T-series. Consequently, laboratories adhering to the ABFT standards will no longer be required to purchase the CAP T-series sets after 2020. However, laboratories routinely quantitating drugs in serum or plasma are encouraged to continue to subscribe to the T-series PT sets or another program that challenges a broad range of drugs in serum or plasma.

Section F: SUMMARY

General Comments (if any): They subscribe to all of the required PT's listed. In order to be more complete for their test offering would need to include a PT for Carbon Monoxide. The Carbon Monoxide assay is discussed in Section I.

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): Subscribe to a survey for blood carboxyhemoglobin

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? Yes

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

If the concentration of the specimen exceeds the 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? Yes

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

For example, 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? Yes

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? Yes. Each analytical method contains instructions on how many calibrators are required (usually 6) and how to report values depending on whether points are dropped. They don't allow reporting outside of the lowest and highest acceptable calibrators.

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? No. Each assay with labelled internal standard has 0.98 as its acceptability. They conform for non-labeled internal standards but not for labelled internal standards.

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? Yes

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? Yes. Per SOP if a historical calibration is used the curve can be no more than 2 weeks old. Did not observe a standard curve.

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? Yes

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? Yes

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? Yes

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**

Laboratories are strongly encouraged to refer to the OSAC/ASB Standard 036 "*Practices for Method Validation in Forensic Toxicology*" 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? Yes. While the methods are validated the summary of the methods validation is not in a concise document "telling the story". Review of the OSAC document referenced above would make the process and documentation more standardized with the industry.

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? Yes

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.

Note: 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? Yes

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? Yes

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.

Notwithstanding the above, it is recognized that, in some circumstances, a suitable second test procedure is not available or necessary. For example, the probability that a 75% carboxyhemoglobin result obtained by a properly conducted spectrophotometric assay is incorrect in a well-documented suicide is exceedingly low, whereas the unexpected finding of a 30% carboxyhemoglobin by a similar determination in blood from a motor vehicle accident victim holds a lower degree of certainty. Nonetheless, use of a second confirmatory technique (e.g., visible spectrophotometry, palladium chloride, or GC) is encouraged for all analytes, including carbon monoxide.

Conforms? Yes All quantitative assays have two tests which are different when available. BUT In some case only the screening result may be reported for some analytes. They are listed as qualitative. See question E-37. CO uses spectrophotometer method on two different aliquots. A recommendation is to add an additional test such as microdiffusion.

G-16 The presence of a drug or toxicant must be verified in more than one specimen or, if only one specimen is available, by replicate analyses on different occasions and with adequate positive and negative controls in the same matrix.

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 vial or extraction tube used was contaminated.

Conforms? Yes

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

Conforms? Yes

Section G: SUMMARY

General Comments (if any): All quantitative assays have a multipoint curve over an acceptable range, appropriate QC and adequate checks for carryover and interference.

Non-conformities (list the standard numbers here and explain any non-conformities under each standard):
G-5: Quantitative assays with labeled analogue internal standard requires for acceptability of the standard curve a coefficient of determination of greater than 0.98 rather than the required 0.99.

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

1) We reviewed in which a sample of brain was tested for alcohol. The analysis was performed by headspace/GC. They do not homogenize tissue for headspace analysis. It is recommended that they homogenize tissues for headspace analysis.
2) While the Validation protocols appear to be minimally acceptable the process and documentation could be enhanced and more standardized if the OSAC document referenced is followed more closely.

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? Yes.

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? Yes

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? NA. The laboratory does not use full scan on LCMS

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? Yes

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? Yes

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% relative to a calibrator in the same run.**

Conforms? No. The lab uses +/- 25% for ion ratios for Medical Examiner cases. No studies are available that show +/- 20% is not routinely achievable.

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 analyte and internal standard. If a second transition cannot be reliably used for confirmation of specific analytes, 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% relative to a calibrator in the same run.**

Conforms? No. In Medical Examiner cases the blanket acceptance criteria for transition ratios is 25% there are not studies that support criteria of > 20%

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? NA. The lab does not use Orbitrap

Section H: SUMMARY

General Comments (if any):

Non-conformities (list the standard numbers here and explain any non-conformities under each standard):
H-6 and H-7: The laboratory has a blanket acceptability criterion with respect to analysis of Medical Examiner cases for ion ratios and transition ratios of +/- 25% but there are no studies to support that +/- 20% is not feasible.

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? No. External proficiency test for Carbon monoxide can be added

List Applicable Techniques:
_____Spectrophotometry_____

_____

_____

_____

_____

Section I: SUMMARY

General Comments (if any): I-1 No PT for Carbon Monoxide

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):
A section on specimen suitability in the SOP would be advised. The UV-VIS CO results could be affected by absorption from non-target compounds within the low to middle range that might occur with decomposed samples. The SOP should state that decomposed samples are unsuitable. Further, there are second methods for CO and a second method for CO should be adopted by the laboratory, a simple Conway diffusion test would satisfy this requirement. Other options could be to use a second derivative method for the UV-VIS that also uses a different range of the spectrum. This method is good at showing unsuitable specimens as the result for the 4-point absorbance method and the derivative method will not agree. Finally, there are providers for CO proficiency and the lab should consider participating since the dye based QC samples are not equivalent to biologicals.

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? Yes

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? Yes

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? Yes

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

Note: 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? Yes. The laboratory runs a matrix matched glucose control.

Section J: SUMMARY

General Comments (if any): The vitreous assay tests for glucose, creatinine, BUN, sodium, potassium and chloride.

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? Yes. Per SOP and interview: Non-biological samples are either run separately from biological samples or they are sequenced so as not to create a potential for carryover.

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? Yes. These assays are performed rarely. None were performed since mid cycle review. Most common per interview is analysis of liquids for alcohol. Where possible the lab acquires a blank matrix that is similar to the sample being tested as well as obtaining a standard of the drug or toxicant in question for comparison purposes.

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? Yes Non-biological samples are tested by the appropriate SOP. Any additional dilutions or required calculations will be kept with the case file. For example if a case is suspected of containing difluorethane (DFE) it is processed using the ethanol method along with a DFE standard. The DFE standard would be followed by a blank to all for evaluation of carryover.

Section K: SUMMARY

General Comments (if any): If non-biological items are tested they are not tested along with biological samples. Each one is considered on its own with respect to the approach. The lab is aware of potential contamination issues and has processes to prevent and identify any carryover or contamination. There has not been a request in at least 2 years.

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 radioactive materials;**
  - **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? Yes. The laboratory has a safety program that includes procedures for blood-borne pathogens, solvent disposal, spill response and emergency procedures.

All safety manuals are on-line and are accessible by all lab personnel. They contain policies concerning blood-borne pathogens, chemical safety as well as protocols for emergencies of either man-made or natural circumstances. All personnel are required to attend annual safety training and/or review safety sessions on-line

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? Yes All staff members undergo safety training annually.

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

Conforms? Yes. The lab appeared to be a clean and clutter free environment.

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? Yes

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? Yes.
The lab appeared to be adequate for its needs. The lab director agreed with that statement.

Section L: SUMMARY

General Comments (if any): Interviewed staff is aware of safety requirements and acknowledges the SOPs and training program that is in place.
A live tour of the lab via Zoom was conducted.

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

The laboratory provides toxicology services to support postmortem investigation, drugs/alcohol and driving and drug facilitated sexual assault.

The menu is adequate to service each of these service lines. Requests for testing that are outside of the laboratory's in-house offering are referred to NMS Labs.
The average turnaround time for medical examiner and police cases is a little over 40 days.
The laboratory has a comprehensive QA program that addresses each of the areas of this checklist. Staff interviews included 5 staff members whose specific responsibility was one of the following: processing and receiving of samples, bench toxicology, toxicology review and reporting, quality assurance supervision and laboratory direction. All interviews showed a good depth of training and knowledge in the specific job function and answers were compliant with the SOPs and program guidance.
A video tour of the lab showed a secure functioning layout that appeared to be organized and free from clutter.
The non-conformances noted are readily addressable. The recommendations and non-conformances were discussed with the staff.

This inspection was virtual. We relied on the cooperation of the laboratory to upload records that would normally be reviewed onsite. We reviewed records of 30 cases distributed among the various relevant service lines. The laboratory staff was responsive and cooperative with all requests. I estimate that this inspection was more time consuming on some of the lab leadership due to uploading requested case files and other QA related documents than if the inspection was onsite. We also had several Zoom calls to discuss findings and to ask for clarification on certain items. Because of the flexibility of the staff and the availability of the records we were able to conduct the inspection.

Team Lead/Lab Director: Anthony Costantino Date: April 26, 2021

The City of New York

POLICE DEPARTMENT

Received by OFS
04/02/21

April2, 2021

Michael Green, Esq., Chair
Division of Criminal Justice Services
NYS Commission on Forensic Science
80 South Swan Street
Albany, New York 12210

Dear Mr. Green:

During the March 12, 2021 New York State Commission on Forensic Science Meeting statements were made that partially misrepresented the NYPD's intentions relating to Investigative Genetic Genealogy (IGG). The purpose of this letter is to clarify what the NYPD is endeavoring to accomplish relating to IGG and address any misconceptions that may have derived from the meeting.

IGG can be viewed as a three-part process: (1) laboratory analysis to generate a Single Nucleotide Polymorphism (SNP) profile, (2) bioinformatics, and (3) genealogy investigations. The NYPD is exclusively considering performing the genealogical investigative component of the IGG process. The genealogical investigative component is the search of a SNP profile (i.e., putative perpetrator or unidentified human remains) against publicly accessible DNA databases; this will occur subsequent to the completed bioinformatics step of the process. Information learned from the search will be exploited to establish investigative leads to solve the case. The NYPD is not planning to develop the capability to perform SNP analysis, nor is the NYPD planning to perform bioinformatics. Furthermore, the NYPD is not planning to perform SNP profile "interpretation," "mixture analysis," "mixture interpretation," "mixture de-convolution," "statistical calculations", or any other scientific responsibility associated with the IGG process as speculated during the meeting.

I hope this provides a clear understanding of the NYPD's position and intentions as it relates to IGG.

Sincerely,

[redacted]

Deputy Chief

NEW YORK STATE | DNA Subcommittee

Received by OFS
05/11/21

May 11, 2021

Michael C. Green, Esq.
Chair, Commission on Forensic Science
Division of Criminal Justice Services
80 South Swan Street
Albany, New York 12210

Dear Commissioner Green:

At the May 7, 2021 DNA Subcommittee meeting, and as requested by the Commission on Forensic Science, the Subcommittee reviewed the updated materials from the New York City Office of the Chief Medical Examiner (OCME), Department of Forensic Biology regarding the validation of massively parallel sequencing of mitochondrial DNA using Promega PowerSeq and Illumina MiSeq.

The Subcommittee has determined that the changes are indeed typographical in nature and voted to reissue the binding recommendation to accept this validation.

Very truly yours,

[redacted]

Bruce Weir, Ph.D.
Chair, DNA Subcommittee

From: Dinkel, Constance
To: dcjs.sm.forensiclabs; QualityMatters (qualitymatters@anab.org)
Cc: Doller, Donald
Subject: Top management changes
Date: Tuesday, May 25, 2021 11:00:16 AM

Good morning,
With Bob Genna's official last day on Friday, as of yesterday 5/24/21, Donald Doller will be taking on the Acting Chief position, and I will be taking on the Acting Assistant Chief position. I will continue to function as the Quality Manager in this new role until further notice. Once the positions have been formalized I will update you again. Please let me know if you have any questions. Thank you.

Constance Dinkel
Forensic Scientist
Quality Assurance Manager
Suffolk County Crime Laboratory
[redacted]

Vaccination = Freedom from COVID-19
Help Suffolk County get back to normal
COVID vaccines are safe, effective and free

NEW YORK STATE | State Police | Forensic Investigation Center

ANDREW M. CUOMO
Governor

KEVIN P. BRUEN
Acting Superintendent

DR. RAY A. WICKENHEISER
Director

Received by OFS
05/28/21

May 28, 2021

Jill Dooley
Director, Office of Forensic Services
New York State Division of Criminal Justice Services
80 South Swan Street
Albany, New York 12210

RE: Change in Top Management

Ms. Dooley:

Please be advised that on May 27, 2021, Acting Major Brian T. Colwell replaced Major Nicholas A. Banbury as Assistant Laboratory Director following Major Banbury's promotion and reassignment.

Sincerely,

[redacted]

Dr. Ray A. Wickenheiser DPS MBA FAAFS

RAW/eac
cc: File

Received by OFS
05/24/21

American Board of
ABFT
Forensic Toxicology ™

FORENSIC TOXICOLOGY LABORATORY ACCREDITATION CHECKLIST

*****Effective April 1, 2021*****

Laboratory: Erie County Medical Examiner's Forensic Toxicology Laboratory

Assessor(s): Daniel Isenschmid, Ph.D., F-ABFT, Graham Jones, Ph.D., F-ABFT (remote)

Date performed: May 17-18, 2021

Table of Contents

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? YES

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? YES

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? YES

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? YES

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? YES

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? YES

A-7 The laboratory must have a procedure for notifying clients and ABFT simultaneously of analytical and other deficiencies that have affected the forensic reliability of reported results.

Occasionally, errors or deficiencies may be uncovered that may have affected the reliability of reported toxicology results.

Conforms? YES

Section A: SUMMARY

General Comments (if any): Meets the standards

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? YES

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? YES

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? YES

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? YES

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? YES

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? YES

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? YES

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? YES

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? YES

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? YES

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? YES

Section B: SUMMARY

General Comments (if any): Meets the standards.

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? YES

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? YES

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? YES

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? N/A; the laboratory dose not rely solely on targeted screening methods.

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? YES

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? YES

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? YES

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

Conforms? YES

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? NA; abbreviated procedure are not used at the bench.

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? YES

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? YES

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? YES

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

Conforms? YES

Section C: SUMMARY

General Comments (if any): Meets all applicable standards.

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? YES

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

Conforms? YES

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? YES

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? YES

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? YES

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? YES

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? YES

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? YES

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? YES

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 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? YES

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

Conforms? YES

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? YES

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? YES

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

Conforms? YES

Section D: SUMMARY

General Comments (if any): Meets the standards.

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? YES

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? YES

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.

Unless the assay is validated for alternate matrices, matrix-matched controls can be prepared by fortifying analyte-free matrices such as tissue homogenates, expired blood bank blood or plasma, or another appropriate matrix.

Conforms? YES

E-4 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? YES

E-5 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? YES

E-6 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? YES

E-7 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? YES

E-8 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? YES

E-9 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? YES

E-10 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? YES

E-11 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? YES

E-12 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? N/A; all standards purchased are supplied with it certificate of analysis.

E-13 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? YES

E-14 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? YES

E-15 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? YES

E-16 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? YES

E-17 If unacceptable results occur in PT programs, the laboratory must take documented corrective action including, as appropriate, a root-cause investigation and the potential impact on past casework.

It is not sufficient to only reanalyze the PT sample and accept the new result if it is within the acceptable range. It is important to investigate the reason for the initial failure and take appropriate documented corrective action. 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).

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.

Conforms? NO

E-18 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? YES

E-19 The laboratory must label purchased reagents with at least the date received and date opened.

Conforms? YES

E-20 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? YES

E-21 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? YES

E-22 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? YES

E-23 Equipment that is uncalibrated, broken, or otherwise out of service must be clearly marked as such.

Conforms? YES

E-24 The laboratory must regularly monitor and record temperatures on all equipment where temperature control is critical for the application.

Conforms? YES

E-25 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? YES

E-26 The laboratory must check the accuracy of balances when critical weighing is performed. Documentation of the checks must be maintained.

Conforms? YES

E-27 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? YES

E-28 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? YES

E-29 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? YES

E-30 Case data from failed runs must be maintained (paper or electronic), as it forms part of the record of testing performed on any given specimen/case and may be important in the overall context of case review.

Conforms? YES

E-31 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? YES

E-32 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? YES

E-33 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? YES

E-34 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? YES

E-35 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? YES

E-36 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? N/A; the laboratory used "Detected, Unconfirmed."

E-37 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? YES

E-38 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? YES

E-39 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? YES

Section E: SUMMARY

General Comments (if any):

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

E-17 was considered a non-conformity because a PT result that was unacceptable to the standard was not investigated. The following is the basis for the non-conformance:

On the CAP 2020 T-B Series, Sample T-06, the laboratory reported Diphenhydramine at a concentration of 300 ng/mL. The group mean was 408 ng/mL and the target mean was 400 ng/mL. The reported value had a standard deviation of -2.5.

The reported value for Diphenhydramine exceed that requirements of the standard that results be within +/- 20% of the group mean and +/- 2 SD.

This error was not investigated since it was acceptable to CAP, however it did not meet the ABFT standard.

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

The laboratory uses units of mg/L for many compounds which are normally detected at very low concentrations. It is a recommendation that the laboratory consider using units of ng/mL or mcg/L as appropriate (e.g. basic drugs) and reserve units of mg/L for drugs detected at higher concentrations (e.g. acidic drugs).

For the CAP 2020 T-C series, Sample T-13 an unacceptable result was reported for Meprobamate and Carisoprodol. On investigation, it was determined that the error occurred because the analyst had multiplied the result x2 when in practice the case was not analyzed on dilution. While the laboratory indicates on the instrument data what dilution was used, it does not incorporate this in the LIMS system or on run sheets pulled to aliquot the samples. It is recommended that cases prepared on dilution have this noted prior to beginning the confirmation process.

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), CAP FTC (whole blood drugs), and CAP T-series (serum and urine) 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 and T-series PTs offer a broad range of illicit, prescription, and over-the-counter drugs and metabolites in three matrices. Note: Subscription to the CAP T-series is NOT mandatory after December 31, 2020.

Conforms? YES

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), CAP FTC (whole blood drugs), and CAP T-series (serum and urine) 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. Subscription to the CAP T-series is NOT mandatory after December 31, 2020.

Conforms? YES

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 FTC and T-series 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? YES

Note: Effective early 2021, the College of American Pathologists is expanding the FTC proficiency test to challenge virtually all of the drugs currently included in the T-series. All challenges will be based on whole blood and at an equivalent number of challenges as the T-series. Consequently, laboratories adhering to the ABFT standards will no longer be required to purchase the CAP T-series sets after 2020. However, laboratories routinely quantitating drugs in serum or plasma are encouraged to continue to subscribe to the T-series PT sets or another program that challenges a broad range of drugs in serum or plasma.

Section F: SUMMARY

General Comments (if any): Meets the standards.

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? YES

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

If the concentration of the specimen exceeds the 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? YES

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

For example, 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? YES

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? YES

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? YES

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? YES

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? YES

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? YES

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? YES

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? YES

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**

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? YES

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? YES

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? YES

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? YES

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? YES

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? YES

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

Conforms? YES

Section G: SUMMARY

General Comments (if any): Meets the standards

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? YES

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? YES

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? YES

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? YES

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? YES

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% relative to a calibrator in the same run.**

Conforms? YES

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% relative to a calibrator in the same run.**

Conforms? YES

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? N/A; the laboratory does not use Orbitrap technology.

Section H: SUMMARY

General Comments (if any): Meets the standards.

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):

Deconvolution reports (GC/MS) are not used effectively because library matches are not entered; the laboratory primarily uses traditional library search approaches. While not a requirement, adding compounds to the deconvolution library would improve the functionality of this useful tool.

The volatile amines (GC/MS-SIM) procedure, while acceptable, could be improved by moving it to LC-MS/MS.

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? YES

List Applicable Techniques:

_____

Spectrophotometry (COHb by AVOXimeter)

_____

_____

_____

_____

Section I: SUMMARY

General Comments (if any): Meets the standards

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? YES

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? YES

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? YES

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? YES

Section J: SUMMARY

General Comments (if any): Meets the standards

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? YES

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? YES

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? YES

Section K: SUMMARY

General Comments (if any): Meets the standards

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 radioactive materials;**
  - **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? YES

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? YES

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

Conforms? YES

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? YES

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? YES

Section L: SUMMARY

General Comments (if any): Meets the standards

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

Other than a single non-conformance (E-17) the laboratory was well-organized with experienced staff. The renovated laboratory space was well thought out and allowed for adequate space for staff, sample prep and instrumentation. Review of analytical data demonstrated consistent, quality data.

Team Lead/Lab Director [redacted]

Daniel Isenschmid, Ph.D., F-ABFT Date: May 24, 2021

American Board of
ABFT
Forensic Toxicology™

723 N. Weber Street, Suite 103
Colorado Springs, CO 80903
Phone: (719) 362-0452 • Website: www.abft.org

Received by OFS
06/01/21

June 1, 2021

Christine Giffin, M.S.
Erie County Medical Examiner's Office
County of Erie Department of Health
501 Kensington Ave.
Buffalo, New York 14214

Dear Ms. Giffin:

I am pleased to advise you that the Erie County Medical Examiner's Office Toxicology Laboratory has fulfilled the American Board of Forensic Toxicology laboratory accreditation requirements and is granted a Certificate of Laboratory Accreditation in Forensic Toxicology for the period July 1, 2021 to June 30, 2022.

During the course of accreditation, you will be asked to provide evidence of satisfactory participation in recognized alcohol and drug-based proficiency test programs. In addition, prior to the second year anniversary date, the laboratory will receive instructions for application for re-accreditation including re-inspection.

Congratulations to you and your staff! Thank you for your support of laboratory accreditation in Forensic Toxicology. A certificate attesting to your accreditation will be provided in the near future.

Sincerely,

[redacted]

Bruce A. Goldberger, Ph.D., F-ABFT
President

[redacted]

Graham R. Jones, Ph.D., F-ABFT
Chair, ABFT Accreditation

cc: Robert Sears, M.S., F-ABFT
ABFT & ANAB

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June 1, 2021

Rebecca L. Hartman, Ph.D.
Monroe County Office of the Medical Examiner
740 E. Henrietta Road
Rochester, NY 14623

Dear Dr. Hartman:

I am pleased to advise you that the Monroe County Office of the Medical Examiner Toxicology Laboratory has fulfilled the American Board of Forensic Toxicology laboratory accreditation requirements and is granted a Certificate of Laboratory Accreditation in Forensic Toxicology for the period July 1, 2021 to June 30, 2022.

During the course of accreditation, you will be asked to provide evidence of satisfactory participation in recognized alcohol and drug-based proficiency test programs. In addition, prior to the second year anniversary date, the laboratory will receive instructions for application for re-accreditation including re-inspection.

Congratulations to you and your staff! Thank you for your support of laboratory accreditation in Forensic Toxicology. A certificate attesting to your accreditation will be provided in the near future.

Sincerely,

[redacted]

Bruce A. Goldberger, Ph.D., F-ABFT
President

[redacted]BFT
Chair, ABFT Accreditation

cc: Robert Sears, M.S., F-ABFT
ABFT & ANAB

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06/01/21

June 1, 2021

Michael Lehrer, Ph.D.
Suffolk County Office of the Medical Examiner
Suffolk County Office Building, #487
725 Veteran's Memorial Highway
Hauppauge, NY 11787

Dear Dr. Lehrer:

I am pleased to advise you that the Suffolk County Office of the Medical Examiner Toxicology Laboratory has fulfilled the American Board of Forensic Toxicology laboratory accreditation requirements and is granted a Certificate of Laboratory Accreditation in Forensic Toxicology for the period July 1, 2021 to June 30, 2022.

During the course of accreditation, you will be asked to provide evidence of satisfactory participation in recognized alcohol and drug-based proficiency test programs. In addition, prior to the second year anniversary date, the laboratory will receive instructions for application for re-accreditation including re-inspection.

Congratulations to you and your staff! Thank you for your support of laboratory accreditation in Forensic Toxicology. A certificate attesting to your accreditation will be provided in the near future.

Sincerely,

[redacted]

Bruce A. Goldberger, Ph.D., F-ABFT
President

[redacted]

Graham R. Jones, Ph.D., F-ABFT
Chair, ABFT Accreditation

cc: Robert Sears, M.S., F-ABFT
ABFT & ANAB

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Received by OFS
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June 1, 2021

Gail Cooper, Ph.D.
Office of Chief Medical Examiner
City of New York
520 First Avenue
New York, NY 10016

Dear Dr. Cooper:

On behalf of the American Board of Forensic Toxicology, I am advising you that the accreditation of the City of New York Office of Chief Medical Examiner Toxicology Laboratory has been extended to August 30, 2021.

Sincerely,

[redacted]

Bruce A. Goldberger, Ph.D., F-ABFT
President

[redacted]

Graham R. Jones, Ph.D., F-ABFT
Chair, ABFT Accreditation

cc: Robert Sears, M.S., F-ABFT
ABFT & ANAB

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Received by OFS
06/01/21

June 1, 2021

Joseph Avella, Ph.D., D-ABFT-FT
Nassau County Medical Examiner's Office
Forensic Toxicology Laboratory
2251 Hempstead Turnpike Building R
East Meadow, NY 11554

Dear Dr. Avella:

I am pleased to advise you that the Nassau County Medical Examiner's Office Forensic Toxicology Laboratory has fulfilled the American Board of Forensic Toxicology laboratory accreditation requirements and is granted a Certificate of Laboratory Accreditation in Forensic Toxicology for the period July 1, 2021 to June 30, 2023.

During the course of accreditation, you will be asked to provide evidence of satisfactory participation in recognized alcohol and drug-based proficiency test programs.

Congratulations to you and your staff! Thank you for your support of laboratory accreditation in Forensic Toxicology. A certificate attesting to your accreditation will be provided in the near future.

Sincerely,

[redacted]

Bruce A. Goldberger, Ph.D., F-ABFT
President

[redacted]

Graham R. Jones, Ph.D., F-ABFT
Chair, ABFT Accreditation

cc: Robert Sears, M.S., F-ABFT
ABFT & ANAB

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Received by OFS
06/01/21

June 1, 2021

Kristie Barba, M.S., D-ABFT-FT
Onondaga County Center for Forensic Sciences
Forensic Toxicology Laboratory
100 Elizabeth Blackwell Street
Syracuse, NY 13210

Dear Ms. Barba:

I am pleased to advise you that the Onondaga County Center for Forensic Sciences Forensic Toxicology Laboratory has fulfilled the American Board of Forensic Toxicology laboratory accreditation requirements and is granted a Certificate of Laboratory Accreditation in Forensic Toxicology for the period July 1, 2021 to June 30, 2023.

During the course of accreditation, you will be asked to provide evidence of satisfactory participation in recognized alcohol and drug-based proficiency test programs.

Congratulations to you and your staff! Thank you for your support of laboratory accreditation in Forensic Toxicology. A certificate attesting to your accreditation will be provided in the near future.

Sincerely,

[redacted]

Bruce A. Goldberger, Ph.D., F-ABFT
President

[redacted]

Graham R. Jones, Ph.D., F-ABFT
Chair, ABFT Accreditation

cc: Robert Sears, M.S., F-ABFT
ABFT & ANAB

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Received by OFS
06/01/21

June 1, 2021

Christopher Cording, M.S., D-ABFT-FT
Westchester County Department of Laboratories and Research
Forensic Toxicology Laboratory
2 Dana Road
Valhalla, NY 10595

Dear Mr. Cording:

I am pleased to advise you that the Westchester County Department of Laboratories and Research Forensic Toxicology Laboratory has fulfilled the American Board of Forensic Toxicology laboratory accreditation requirements and is granted a Certificate of Laboratory Accreditation in Forensic Toxicology for the period July 1, 2021 to June 30, 2023.

During the course of accreditation, you will be asked to provide evidence of satisfactory participation in recognized alcohol and drug-based proficiency test programs.

Congratulations to you and your staff! Thank you for your support of laboratory accreditation in Forensic Toxicology. A certificate attesting to your accreditation will be provided in the near future.

Sincerely,

[redacted]

Bruce A. Goldberger, Ph.D., F-ABFT
President

[redacted]

Graham R. Jones, Ph.D., F-ABFT
Chair, ABFT Accreditation

cc: Robert Sears, M.S., F-ABFT
ABFT & ANAB