Priority Action Report

Toxicology Subcommittee

Chemistry / Instrumental Analysis Scientific Area Committee

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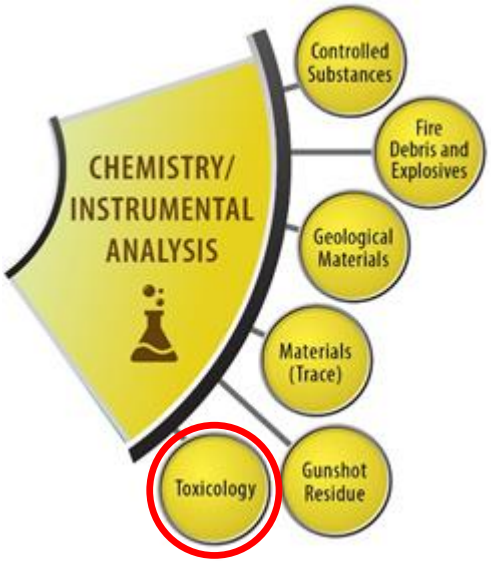
NIST
National Institute of
Standards and Technology
U.S. Department of Commerce

Discipline Description



The OSAC Subcommittee on Toxicology will focus on standards and guidelines related to the analysis of biological samples for alcohol, drugs, or poisons, and the interpretation of these results.

Subcommittee Leadership

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Chair	Marc A LeBeau, PhD	FBI	2	marc.lebeau@ic.fbi.gov
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Executive Secretary	Fiona Couper, PhD	WA State Patrol	2	fiona.couper@wsp.wa.gov

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17	Dustin Tate Yeatman, MS	Palm Beach County Sheriff	4	yeatmand@pbso.org

January 2016 OSAC Toxicology Subcommittee Meeting
Leesburg, Virginia

Summary of Standards/Guidelines Priority Actions

Topic	Working Title of Document
1	Standard Practices for Method Validation in Forensic Toxicology
2	Standard Practices for Measurement Traceability in Forensic Toxicology
3	Standard Practices for Method Validation in Forensic Toxicology – Breath Alcohol Measuring Instrument Calibration
4	Standard Practices for Quality Control in Forensic Toxicology
5	Guidelines for Opinions and Testimony in Forensic Toxicology

OSAC Review/Approval of Standards of Practice

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Topic 1: Method Validation

Document Title: **Standard Practices for Method Validation in Forensic Toxicology Laboratories**

Scope: Minimum standards of practice for validating analytical methods in forensic toxicology.

Objective/rationale: Provide objective evidence that a method is capable of successfully performing at the level of its intended use and identify limitations under normal operating conditions.

Issues/Concerns: Revision of SWGTOX Validation Standard

Task Group Chair Name: Marc LeBeau

Task Group Chair Contact Information:

marc.lebeau@ic.fbi.gov

Date of Last Task Group Meeting: October 2015

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Topic 1: Method Validation

Key Components of Standard:

- Delineates when to validate and revalidate analytical methods
- Requires formation of validation plan
- Defines required validation parameters based on method's scope
- Provides specific requirements for conducting validation experiments
- Explains documentation requirements of validation records
- Appendices provide examples, as well as recommendations on how to streamline method validation experiments

Topic 1: Method Validation

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Topic 2: Measurement Traceability

Document Title: **Standard Practices for Measurement Traceability in Forensic Toxicology**

Scope: Minimum standards of practice for establishing measurement traceability in forensic toxicology testing and calibration methods.

Objective/rationale: Provide objective evidence that measurement traceability has been established in forensic toxicology methods.

Issues/Concerns: New concept for laboratories accredited by bodies that do not follow ISO standards

Task Group Chair Name: Dustin Yeatman
Task Group Chair Contact Information:
yeatmand@pbso.org
Date of Last Task Group Meeting: January 2016

Topic 2: Measurement Traceability

Key Components of Standard:

- Explains what may be considered a measurement
- Provides NIST's essential elements of measurement traceability
- Demonstrates how measurement traceability may be established through the calibration of equipment and use of certified reference materials
- Describes measurement traceability requirements based on method scope
- Defines laboratory equipment that must be calibrated to establish measurement traceability

Topic 2: Measurement Traceability

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Topic 3: Breath Alcohol Calibration

Document Title: **Standard Practices for Method Validation in Forensic Toxicology – Breath Alcohol Measuring Instrument Calibration**

Scope: Minimum standards for validating calibration methods in forensic toxicology laboratories performing evidentiary Breath Alcohol Measuring Instrument calibration.

Objective/rationale: Provide objective evidence that a method is capable of successfully performing at the level of its intended use and identify limitations under normal operating conditions.

Issues/Concerns: None

Task Group Chair Name: Melissa Kennedy
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Date of Last Task Group Meeting: January 2016

Topic 3: Breath Alcohol Calibration

Key Components of Standard:

- Delineates when to validate and revalidate analytical methods
- Requires formation of validation plan
- Defines required validation parameters based on method's scope
- Provides specific requirements for conducting validation experiments
- Explains documentation requirements of validation records
- Appendices provide examples, as well as recommendations on how to streamline method validation experiments

Topic 3: Breath Alcohol Calibration

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Topic 4: Quality Control

Document Title: **Standard Practices for Quality Control in Forensic Toxicology**

Scope: Minimum standards of practice for quality control in forensic toxicology laboratories

Objective/rationale: Provide objective evidence that day-to-day use of a method continues to perform as validated

Issues/Concerns: None

Task Group Chair Name: Ruth Winecker
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ruth.winecker@dhhs.nc.gov
Date of Last Task Group Meeting: January 2016

Topic 4: Quality Control

Key Components of Standard:

- Defines requirements of quality control programs within forensic toxicology laboratories
- Explains use and verification of QC materials
- Provides direction on preparation, storage, expiration, and documentation of calibrators and controls
- Instructs on calibration and control of chromatographic, immunoassay, spectrophotometric, and other assays
- Explains elements of quality control reviews, as well as long-term monitoring of QC data

Topic 4: Quality Control

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Topic 5: Opinions and Testimony

Document Title: **Guidelines for Opinions and Testimony in Forensic Toxicology**

Scope: Delineates guidelines for practices in forensic toxicology opinion reports and testimony.

Objective/rationale: Recommends practices to be used in expert opinions, including those defined as "appropriate" and "inappropriate".

Issues/Concerns: None

Task Group Chair Name: Madeline Montgomery
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Date of Last Task Group Meeting: January 2016

Topic 5: Opinions and Testimony

Key Components of Guideline:

- Explains difference between basic analytical toxicology reports and opinion reports
- Provides direction on elements of expert opinions
- Defines appropriate opinions and testimonies that are scientifically supported
- Describes opinions and testimony that are inappropriate for a toxicologist to address

Topic 5: Opinions and Testimony

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Other Ongoing Topics

Document Evaluation Task Group

- Evaluation of existing standards and guides
- Identification of gaps in the catalog of standards and guides
- Facilitation of document reviews and approvals using canvass or SDO processes

Task Group Chair Name: Fiona Couper
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Date of Last Task Group Meeting: January 2016

Terminology Task Group

- Establish glossary of terms in the field of forensic toxicology to be used within documents developed by the subcommittee

Task Group Chair Name: Kenneth Ferslew
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Date of Last Task Group Meeting: January 2016

Additional Topics of Interest

- Standard for Mass Spectrometry Data Evaluation in Forensic Toxicology*
- Standard for Forensic Toxicology Reports*
- Standard for Identification Criteria for Forensic Toxicology*
- Standard for Content of Forensic Toxicology Standard Operating Procedures
- Standard for Estimating Measurement Uncertainty in Forensic Toxicology
- Guideline for Specimen Collection and Storage in Forensic Toxicology
- Standard for Quality Control Practices for Breath Alcohol Testing
- Standard for Proficiency Testing in Forensic Toxicology
- Standard for Minimum Testing Requirements in Forensic Toxicology

* Indicates new Task Group initiated

Research Gaps Identified

- Emerging Drugs of Abuse and Therapeutic Agents
  - *Develop analytical methods, evaluate existing and novel sample preparation techniques, epidemiological studies, metabolite identification, post-mortem distribution, pharmacodynamics/pharmacokinetic studies*

- Herbal and Dietary Supplements and Plant-based Toxins
  - *Develop analytical methods, improve understanding of toxicity*

Research Gaps Identified

- Human Factors Impact on Forensic Toxicology
  - *Determine whether cognitive and contextual biases impact how cases are analyzed and conclusions made, impacts of motivational issues, fitness for duty (e.g. fatigue, visual acuity), scientific culture, group dynamics and error management*

- Postmortem Distribution and Redistribution
  - *Comprehensive tissue distribution studies to provide data on relationship between tissue and blood drug/metabolite concentrations, further characterization of chemical/biological mechanisms of PMR, specific chemical markers to provide evidence of PMR, development of mathematical relationships to evaluate PMR*

Summary

- Continue to coordinate efforts of SWGTOX with OSAC Toxicology Subcommittee
- Finalize unfinished SWGTOX documents
- Initiate development of key documents related to quality assurance in forensic toxicology

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1	Standard Practices for Method Validation in Forensic Toxicology
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