

Scientific Working Group for



Forensic Toxicology

**Update for AAFS 2014**

# Today's Agenda

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- ▶ Introduction of the Executive Committee of SWGTOX
  - ▶ Rob Middleberg, Chair
  - ▶ Laurel Farrell, Member-at-Large
  - ▶ Melissa Kennedy, Member-at-Large
  - ▶ Marc LeBeau, Committee Chair
  - ▶ Jeri Roper-Miller, Committee Chair
  - ▶ Madeline Montgomery, Executive Secretary
- ▶ Website, document process, current status of documents
- ▶ Personnel Standards and Breath Alcohol
- ▶ Accreditation and Mass Spectrometry Standards
- ▶ QC Standard
- ▶ Questions

# SWGTOX

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- ▶ Established in October 2009 by the Forensic Toxicology Council
- ▶ The mission of SWGTOX is to develop and disseminate consensus standards for the practice of forensic toxicology in the United States.
  - ▶ Post-mortem toxicology
  - ▶ Human performance toxicology
  - ▶ Non-regulated employment drug testing
  - ▶ Court-ordered toxicology
  - ▶ General forensic toxicology

# SWGTOX

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- ▶ Selected from a diverse group with expertise in areas currently being addressed
    - ▶ Members have voting privileges
    - ▶ Limit of 40 members at one time
      - ▶ Selected by Executive Committee
    - ▶ Member's term length at discretion of Executive Committee
    - ▶ Must remain active within SWGTOX to maintain Member status
  - ▶ Advisors and invited guests add to the expertise, but have no voting privileges
  - ▶ No compensation or honorarium for participation
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# SWG's

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- ▶ Currently there are approximately 22 SWGs
- ▶ Where they've been
  - ▶ DOJ
  - ▶ NIJ
- ▶ Executive vs. Legislative branches of government
- ▶ Where they appear to be going
  - ▶ NIST – Scientific Area Committees
  - ▶ Funding – SOFT and ????
  - ▶ The Federal Register

# Whoa Nellie!

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- ▶ NIST
- ▶ SAC Subcommittees/SACs/OSAC/FPPS
- ▶ SWGTOX EC supportive of the new proposed strategy
  - ▶ Application process – become involved!
- ▶ Process intended to be free-standing within 3-5 years
- ▶ So, where to from here?

Scientific Working Group for



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**Website,**

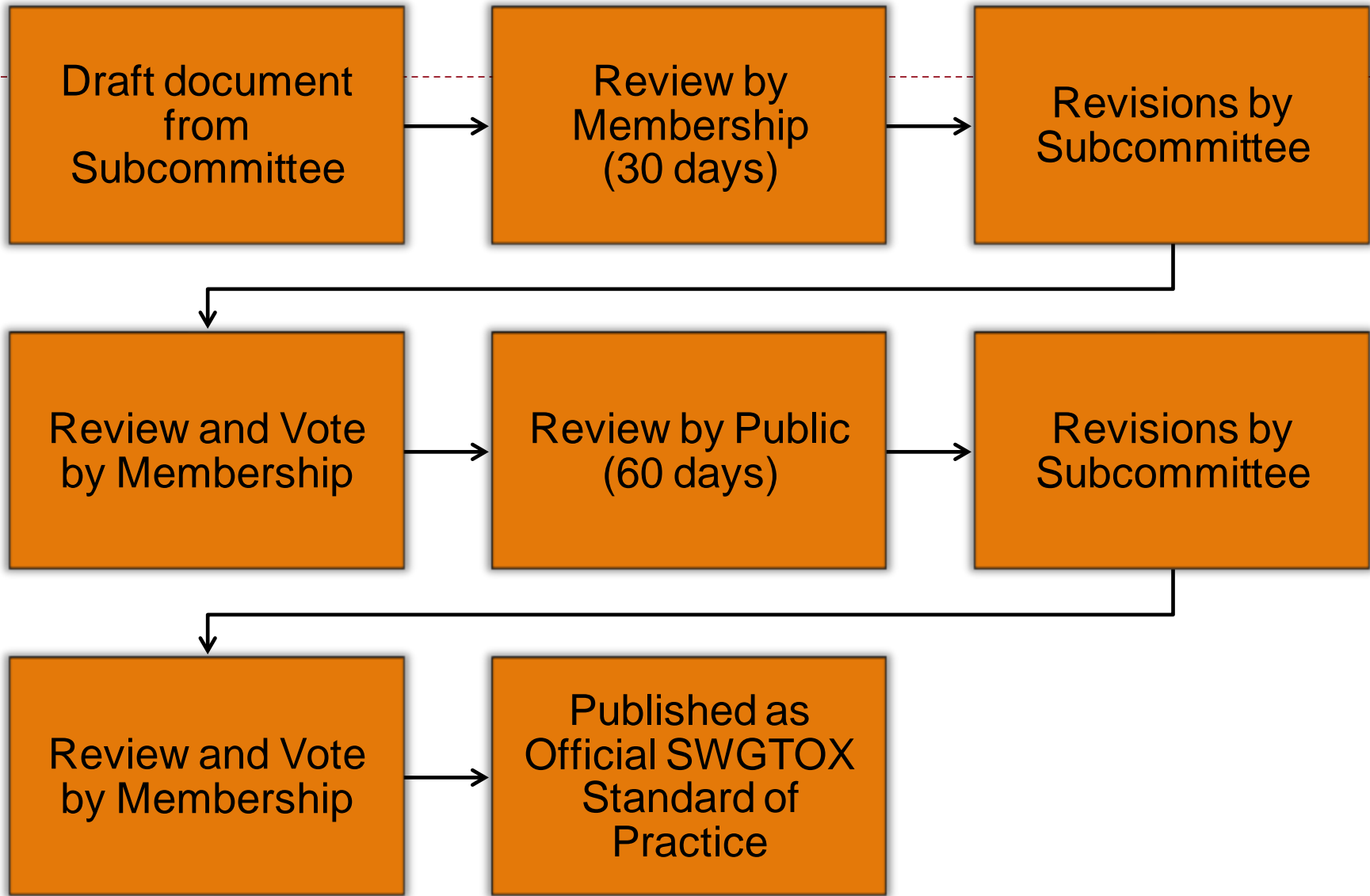
**what we have done, and where we are going**

# www.SWGTOX.org

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- ▶ Mission
- ▶ Scope
- ▶ Objectives
- ▶ Contact Information
  - ▶ [comments@SWGTOX.org](mailto:comments@SWGTOX.org)
- ▶ Standards
- ▶ Documents
- ▶ Meeting Minutes





# SWGTOX Organization

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- ▶ **Three Committees**
  - ▶ Standards, Practice, Protocols and Accreditation
  - ▶ Education, Ethics, Outreach and Certification
  - ▶ Research, Development, Testing and Evaluation
- ▶ **Current Subcommittees**
  - ▶ Accreditation
  - ▶ Breath Alcohol
  - ▶ Education/Certification
  - ▶ Mass Spectrometry
  - ▶ QC

# Current SWGTOX Members

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- ▶ Dan Anderson (CA)
  - ▶ Mike Baylor (NC)
  - ▶ Larry Bowers (CO)
  - ▶ Patrick Callery (WV)
  - ▶ Fiona Couper (WA)
  - ▶ Dennis Crouch (TN)
  - ▶ Kurt Dubowski (OK)
  - ▶ Laurel Farrell (CO)
  - ▶ Mark Fondren (TX)
  - ▶ Bruce Goldberger (FL)
  - ▶ Sue Hackworthy (WI)
  - ▶ Chris Heartsill (TX)
  - ▶ Marilyn Huestis (MD)
  - ▶ Dan Isenschmid (PA)
  - ▶ Amanda Jenkins (MA)
  - ▶ Graham Jones (Canada)
  - ▶ Melissa Kennedy (VA)
  - ▶ Sarah Kerrigan (TX)
  - ▶ Loralie Langman (MN)
  - ▶ Marc LeBeau (VA)
  - ▶ Laura Liddicoat (WI)
  - ▶ Jennifer Limoges (NY)
  - ▶ David Masters-Moore (CA)
  - ▶ Iain McIntyre (CA)
  - ▶ Rob Middleberg (PA)
  - ▶ Madeline Montgomery (VA)
  - David Moody (UT)
  - Michelle Peace (VA)
  - Julia Pearson (FL)
  - Jeri Roper-Miller (NC)
  - Sumnadeep Rana (CA)
  - Tom Rosano (NY)
  - Robert Sears (SC)
  - Matt Slawson (UT)
  - Betsy Spratt (NY)
  - Peter Stout (NC)
  - Jarrad Wagner (OK)
  - Ruth Winecker (NC)
  - Robert Zettl (CO)
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# Published Standards

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- ▶ **SWGTOX Standard for Developing Guide and Code of Professional Conduct in Forensic Toxicology**
    - ▶ Published on-line 12/6/2011
    - ▶ Published in JAT on-line in March, 2013
  - ▶ **SWGTOX Recommendations of the Research, Development, Testing and Evaluation Committee**
    - ▶ Published on-line 1/4/2013
    - ▶ Published in JAT on-line in March, 2013
  - ▶ **SWGTOX Standard Practices for Method Validation in Forensic Toxicology**
    - ▶ Published on-line 05/20/2013
    - ▶ Published in JAT in September of 2013
    - ▶ Checklist being drafted for internal and external audits
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# Next Documents

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- ▶ **Accreditation Standard**
  - ▶ Public comments received and incorporated
  - ▶ SWGTOX vote - passed Feb 17, 2014
- ▶ **Personnel Standards (General and Breath Alcohol specific)**
  - ▶ Public comments received
- ▶ **Mass Spectral Data Acceptance**
  - ▶ SWGTOX comments received

# Document Map ([www.swgtox.org](http://www.swgtox.org))

Title	Status
Standard for Developing a Guide and Code of Professional Conduct in Forensic Toxicology	Published 12/2011
Standard Practices for Method Validation in Forensic Toxicology	Published 05/2013
Recommendations of the Research, Development, Testing, and Evaluation Committee	Published 01/2013
Standard on the Accreditation of Forensic Toxicology Laboratories	Final Vote Passed 02/17/14
Standard for a Quality Management System in Forensic Toxicology	Draft Complete – on hold

# Document Map ([www.swgtox.org](http://www.swgtox.org))

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Title	Status
Breath Alcohol Personnel Standard	In draft
Personnel Standard	In draft
Standard for Mass Spectrometry Data Evaluation in Forensic Toxicology	In draft

# Document Map ([www.swgtox.org](http://www.swgtox.org))

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Title	Status
Breath Alcohol Method Validation and Instrumentation Evaluation Standard	In draft
Breath Alcohol QA Standard	In draft
Standard for the Content in a Forensic Toxicology SOP	In draft
Standard for Quality Control in Forensic Toxicology Analytical Procedures	In draft



# Document Map ([www.swgtox.org](http://www.swgtox.org))

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Standards for	Status
Identification Criteria	To be drafted
Measurement Traceability	To be drafted
Measurement Uncertainty	To be drafted
Proficiency Testing	To be drafted
Reporting Test Results	To be drafted
Specimen Collection and Storage	To be drafted
Amplification Documents for Audits	Checklists will be prepared for appropriate standards

Scientific Working Group for



Forensic Toxicology

**Update for AAFS 2014**

**Education and Certification**

# Current Subcommittee Members

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## General Laboratory

- ▶ Chair: Jeri Roper-Miller (NC)
- ▶ Dan Anderson (CA)
- ▶ Bruce Goldberger (FL)
- ▶ Marilyn Huestis (MD)
- ▶ Sarah Kerrigan (TX)
- ▶ Michelle Peace (VA)
- ▶ Jarrad Wagner (OK)

## Breath Alcohol

- ▶ Chair: Melissa Kennedy (VA)
- ▶ Fiona Couper (WA)
- ▶ Kurt Dubowski (OK)
- ▶ Mark Fondren (TX)
- ▶ Sue Hackworthy (WI)
- ▶ Robert Sears (SC)
- ▶ Bob Zettl (CO)

# Education & Certification Standards

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- ▶ Scientific Working Group for Forensic Toxicology (SWGTOX) Standard for Laboratory Personnel
- ▶ Scientific Working Group for Forensic Toxicology (SWGTOX) Standard for Breath Alcohol Personnel

# Sections of Standards

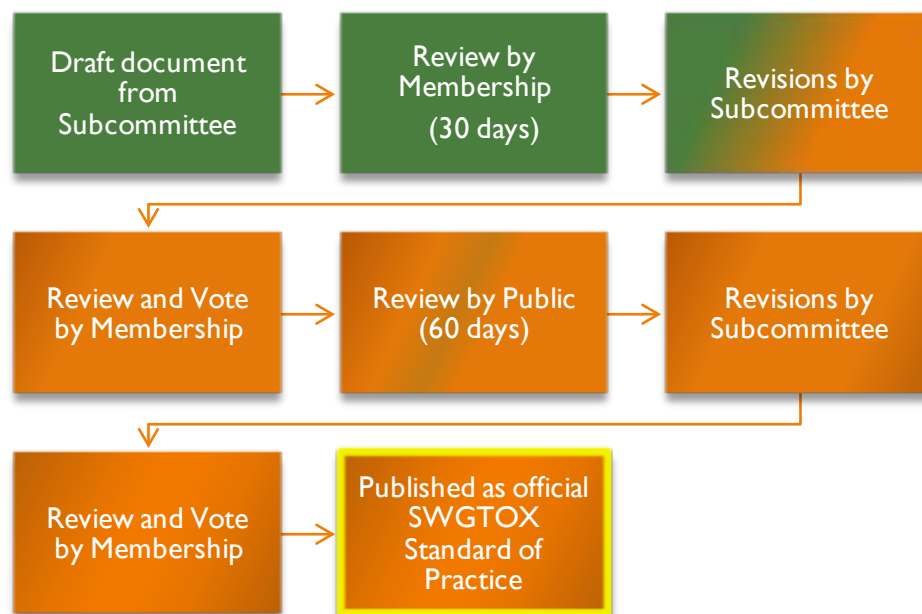
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- ▶ Introduction
- ▶ Definitions
- ▶ Educational Qualifications
- ▶ Training
- ▶ Competency
- ▶ Experience
- ▶ Continuing Education & Professional Development
- ▶ Certification

# Education & Certification Standards

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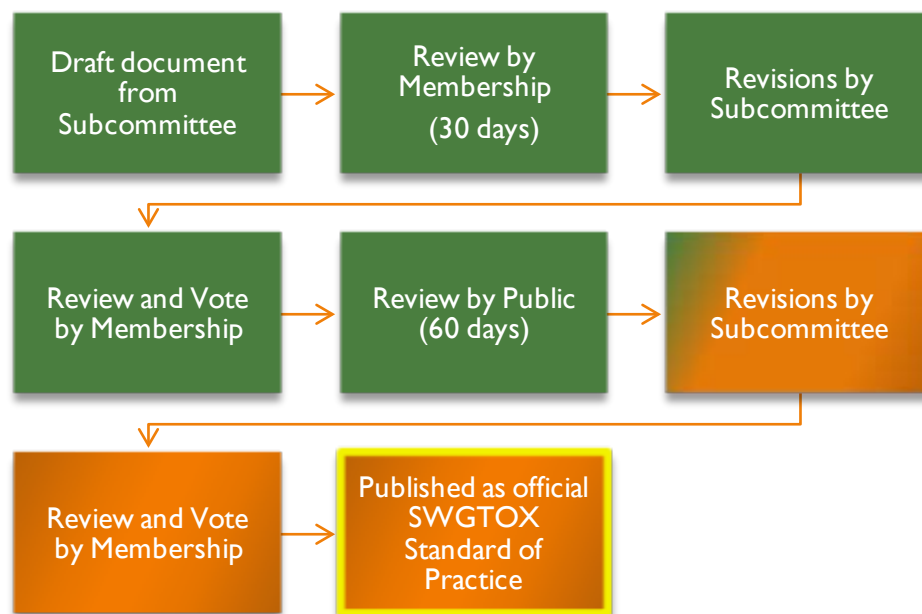
- ▶ Membership Comment period closed October 16, 2013
- ▶ General Personnel Document
  - ▶ 16 Commenters
  - ▶ 77 Comments
- ▶ Alcohol Personnel Document
  - ▶ 13 Commenters
  - ▶ 47 Comments
- ▶ Comments under review
- ▶ Standard will be voted on by the full SWGTOX committee at the next meeting



**OCTOBER 30, 2013 — SOFT**

# Education & Certification Standards

- ▶ Membership Vote: Nov 2013
- ▶ Public Comment: Dec 2013
- ▶ Public Comment Period Closed: February 3, 2014
- ▶ General Personnel Document
  - ▶ 83 Commenters
  - ▶ 321 Comments
- ▶ Alcohol Personnel Document
  - ▶ 49 Commenters
  - ▶ 236 Comments
- ▶ Comments under review
- ▶ Standard will be voted on by the full SWGTOX committee



**FEBRUARY 20, 2014 — AAFS**

Scientific Working Group for



Forensic Toxicology

**Update for AAFS 2014  
Standard on the Accreditation of Forensic  
Toxicology Laboratories**



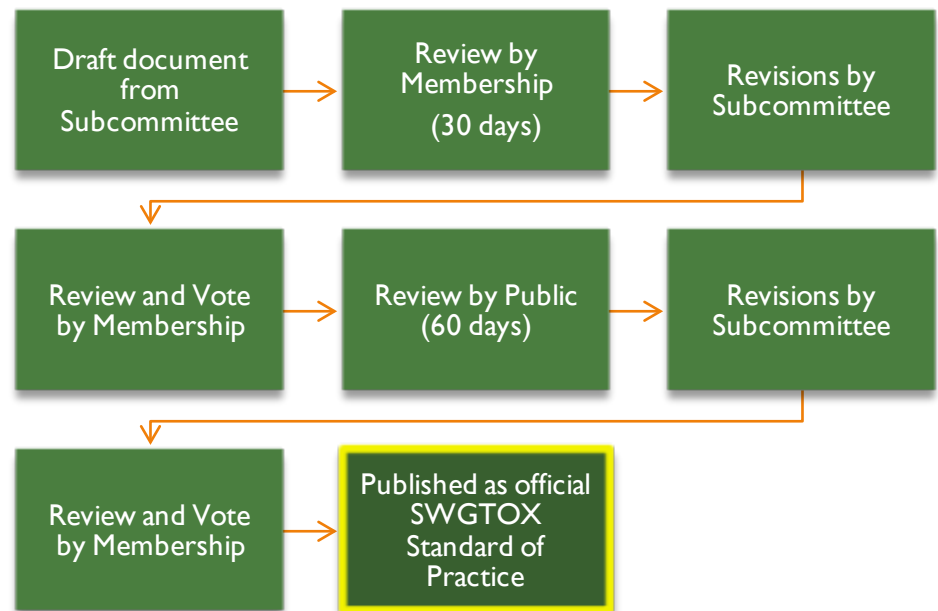
# Current Subcommittee Members

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- ▶ Chair: Graham Jones (Canada)
- ▶ Mike Baylor (NC)
- ▶ Fiona Couper (WA)
- ▶ Laurel Farrell (CO)
- ▶ Laura Liddicoat (WI)

# Standard on the Accreditation of Forensic Toxicology Laboratories

- ▶ Public Comment period closed Nov 12, 2012
- ▶ 68 Commenters
- ▶ 357 Comments
- ▶ Comments were reviewed
- ▶ Revised Standard voted on by the full SWGTOX committee – passed 02/17/14



# Standard on the Accreditation of Forensic Toxicology Laboratories

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- ▶ Sections of the Standard
  - ▶ Introduction

# Standard on the Accreditation of Forensic Toxicology Laboratories

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## ▶ Introduction

- ▶ Provides specific requirements applicable to the accreditation of forensic toxicology laboratories.
- ▶ Provides direction to all accrediting bodies working in this field.
- ▶ Focused on the unique requirements of assessing forensic toxicology laboratories.

# Standard on the Accreditation of Forensic Toxicology Laboratories

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- ▶ Sections of the Standard
  - ▶ Introduction
  - ▶ Definitions
  - ▶ Mandatory Accreditation

# Standard on the Accreditation of Forensic Toxicology Laboratories

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## ▶ Mandatory Accreditation

- ▶ Forensic toxicology laboratories must be accredited.
- ▶ All sub-disciplines for which services are provided must be accredited
- ▶ Provides guidance on sub-disciplines of forensic toxicology
  - ▶ Lists the sub-disciplines from the SWGTOX Bylaws
    - Does specifically include the calibration of instruments used in evidential breath alcohol testing
    - Does specifically include the manufacturing of certified reference material used in the calibration or verification of calibration of breath alcohol instruments.

# Standard on the Accreditation of Forensic Toxicology Laboratories

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- ▶ Sections of the Standard
  - ▶ Introduction
  - ▶ Definitions
  - ▶ Mandatory Accreditation
  - ▶ Basis for Accreditation
  - ▶ Length of Accreditation Cycle
  - ▶ Internal Audits
  - ▶ Scope of Accreditation

# Standard on the Accreditation of Forensic Toxicology Laboratories

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## ▶ Basis for Accreditation

- ▶ Recognized accrediting body
- ▶ Use of a relevant ISO standard as the basis for the accreditation program
- ▶ Inclusion of applicable SWGTOX standards

## ▶ Length of Accreditation Cycle

- ▶ Not to exceed 2 years regardless of the cycle allowed by the accrediting body

## ▶ Internal Audits

- ▶ At least annually



# Standard on the Accreditation of Forensic Toxicology Laboratories

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## ▶ Scope of Accreditation

- ▶ Specify the services provided by the laboratory and evaluated by the accrediting body
  - ▶ Sub-discipline
  - ▶ Matrix
  - ▶ Technology of breath alcohol measuring instrument calibrated

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**Update for AAFS 2014  
Standard for Mass Spectral Acceptance**

# Current Subcommittee Members

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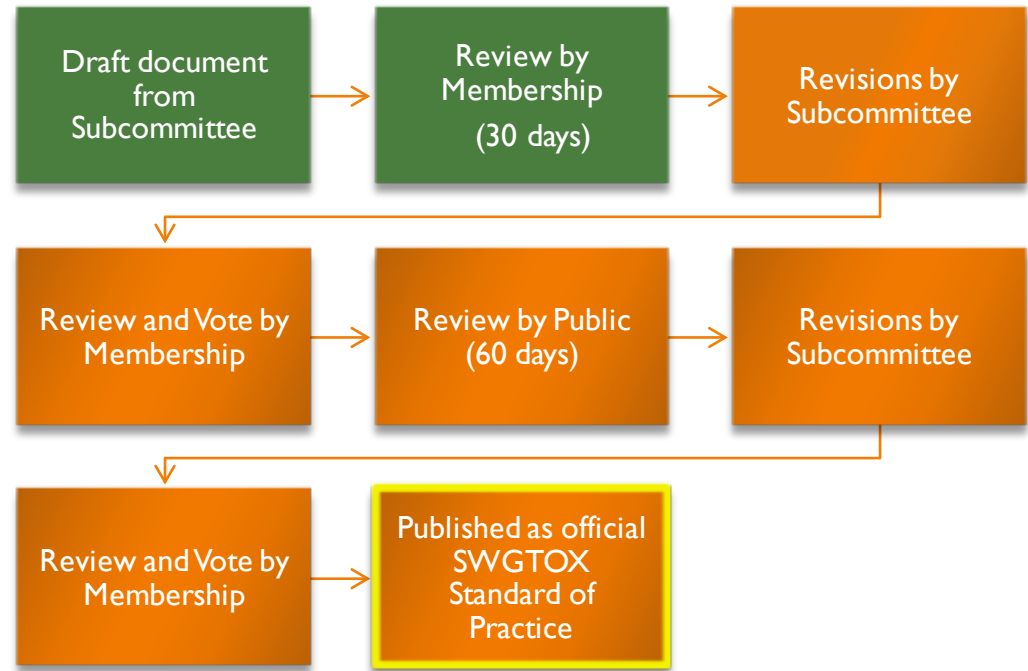
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- ▶ Matt Slawson (UT)
- ▶ David Masters-Moore (CA)
- ▶ Tom Rosano (NY)

# Standard for Mass Spectral Data Acceptance

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## ► Status

- Review by SWGTOX Membership completed Sept 21, 2013
- Subcommittee reviewing comments



# Standard for Mass Spectral Data Acceptance

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## ▶ Focus

- ▶ Criteria for the definitive identification of compounds of interest using mass spectrometry analysis.
  - ▶ Small molecules defined as less than 800 Da
  - ▶ MS analyses following chromatographic (GC or LC) separation of target analyte(s)
  - ▶ Analyte ionization processes such as electron ionization (EI) or chemical ionization (CI)
  - ▶ Not including application of MALDI, ICP and ion mobility mass spectrometry

# Standard for Mass Spectral Data Acceptance

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- ▶ Focus continued
  - ▶ Criteria for the definitive identification of compounds of interest using mass spectrometry analysis.
    - ▶ Various mass analysis techniques and instruments
      - Single quadrupole
      - MS-MS
      - MS<sub>n</sub>
      - Nominal mass resolution
      - Higher mass resolution
  - ▶ This standard isolates mass spectrometry from other topics

# Standard for Mass Spectral Data Acceptance

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- ▶ Sections of the Standard
  - ▶ Introduction
  - ▶ Definitions
  - ▶ MS Analysis Criteria
  - ▶ Data Acquisition and Method Handling

Scientific Working Group for



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**Update for AAFS 2014**

**Standard for Quality Control Program in  
Forensic Toxicology**

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# Current Subcommittee Members

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Chair: Chris Heartsill (TX)

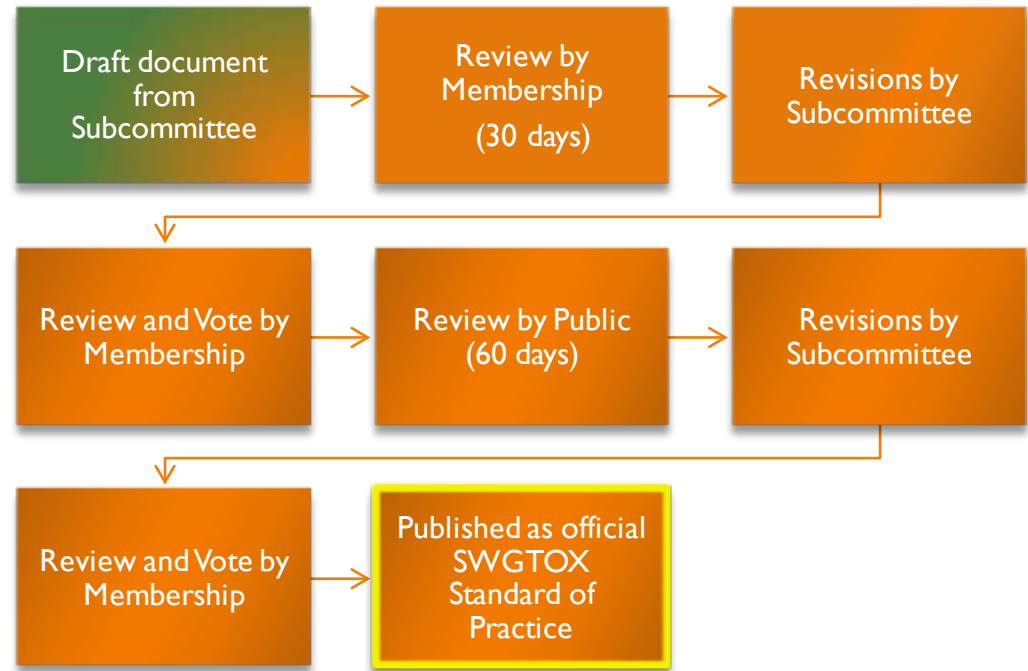
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- ▶ Bob Osiewicz (NY)
- ▶ Julia Pearson (FL)
- ▶ Sumandeeep Rana (CA)
- ▶ Betsy Spratt (NY)

# Standard for Quality Control Program

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## ▶ Status

### ▶ Subcommittee drafting document



# Sections of Standard

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- ▶ Introduction

# Introduction

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- ▶ Minimum standards of practice for quality control in forensic toxicology
- ▶ Part of a comprehensive quality assurance program
- ▶ Quality control intended to verify method is operating within a predetermined set of criteria for a single analysis
- ▶ Also provides evaluation of analytical performance over time.
- ▶ After method is properly validated, QC ensures validity of test result and demonstrates the method's continued fitness for intended use

# Sections of Standard

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- ▶ Introduction
- ▶ Definitions
- ▶ Scope
- ▶ Quality Control Materials
- ▶ Instrument Calibration and Quality Control
- ▶ Chromatography Review in Quality Control
- ▶ Quality Control Review
- ▶ Monitoring Quality Control Data
- ▶ References

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*Thank You!*

