



**Scientific Working Group for Forensic Toxicology (SWGTOX)
Standard on the Accreditation of Forensic Toxicology Laboratories**

Document Revisions

Version	Date	Author	Change Description

This standard has been adopted by the Scientific Working Group for Forensic Toxicology (SWGTOX) and is intended to reflect a minimum standard of practice. Laboratories choosing to meet this practice must decide on an implementation plan that is conducive to the operation, resources and means of the laboratory.

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1. Introduction

This standard provides specific requirements applicable to the accreditation of forensic toxicology laboratories and provides direction to all accrediting bodies working in this field. This standard is focused on the unique requirements of assessing forensic toxicology laboratories.

2. Definitions

- 2.1. *Accreditation* – A third party evaluation of a laboratory based on a particular standard(s), other relevant documents and attestation of a laboratory's competence to carry out specific tasks.
- 2.2. *Analyte* – A chemical substance to be identified and/or measured.
- 2.3. *Assessment* – Process undertaken by an accrediting body to evaluate the conformity, competence and effectiveness of a laboratory based on particular standard(s) and/or other normative documents and for a defined scope of accreditation.
- 2.4. *Forensic Toxicology Laboratory* - A facility employing one or more employees (however named) who perform analytical functions in one or more sub-disciplines of forensic toxicology.
- 2.5. *Internal Audit* - An audit conducted by the laboratory itself, or on its behalf, to confirm ongoing compliance with all accreditation requirements.

3. Mandatory Accreditation

- 3.1. Forensic toxicology laboratories must be accredited.
 - 3.1.1. All sub-disciplines of forensic toxicology provided by the laboratory that are within the scope of SWGTOX must be included in the accreditation.
 - 3.1.2. An accrediting body shall recognize the sub-disciplines listed below. Each sub-discipline has unique characteristics that must be assessed. The list excludes programs where mandated, codified rules and regulations currently exist and are outside the scope of this standard (e.g., the National Laboratory Certification Program or the United States Anti-Doping Agency).

- 3.1.2.1. Human performance toxicology (e.g., drug facilitated crimes, driving under the influence of alcohol or drugs), including:
 - 3.1.2.1.1. Calibration of instruments for use in evidential breath alcohol testing.
 - 3.1.2.1.2. Preparation and assignment of concentration value to reference materials when the reference material is used to calibrate an evidential breath alcohol instrument or to check the calibration of an evidential breath alcohol instrument.
- 3.1.2.2. Postmortem toxicology.
- 3.1.2.3. Non-regulated employment drug testing.
- 3.1.2.4. Court ordered toxicology (e.g., probation and parole, drug courts, child services).
- 3.1.2.5. General forensic toxicology - other toxicology performed for a legal purpose in a variety of biological specimens (e.g., non-lethal poisonings or intoxications).

4. Basis of Accreditation

- 4.1. An accrediting body must be recognized to ISO/IEC 17011¹.
- 4.2. Accreditation programs offered by an accrediting body must be based on a relevant ISO standard.
- 4.3. Due to the general nature of ISO/IEC 17025 and similar accreditation standards, accreditation programs must include use of the applicable SWGTOX standards to appropriately assess forensic toxicology laboratories.

5. Length of Accreditation Cycle

- 5.1. The on-site assessment interval for forensic toxicology laboratories shall not exceed 2 years regardless of the maximum accreditation cycle allowed

¹ Recognition to ISO/IEC 17011 evaluates the competence of an accrediting body to perform assessments.

by the accrediting body. The assessment interval is based on a number of factors that include but are not limited to: frequency of changes in technology, method, analyte or matrix.

6. Internal Audits

6.1. An accrediting body shall require forensic toxicology laboratories to conduct an internal audit, at least annually, to ensure continued compliance with accreditation requirements and the laboratory's quality management system.

6.1.1. Audit records must be maintained for a minimum of 5 years.

7. Scope of Accreditation

7.1. Documentation of the awarded accreditation must specify the scope of services provided by the laboratory and evaluated by the accrediting body.

7.1.1. The scope of accreditation must state the sub-discipline(s) of forensic toxicology and the matrix or matrices in which testing is performed and has been assessed by the accrediting body. Additionally, the scope of accreditation may also refer to an analytical technique or a specific test method.

7.1.1.1. The following matrices are to be considered separately for the purposes of accreditation:

- Urine
- Blood and other fluid specimens (e.g., vitreous humor, serum, plasma, cerebrospinal fluid)
- Oral fluid
- Tissues (e.g., liver, lung, kidney, brain)
- Hair
- Gastric content
- Meconium
- Additional matrices will need to be discussed between the accrediting body and the laboratory being assessed.

7.1.1.2. A laboratory can add capability after method validation. The laboratory cannot imply that this

added capability or the reported test result is within the scope of accreditation until an extension of scope has occurred.

- 7.1.2. The scope of accreditation must state the technology used in the breath alcohol measuring instrument being calibrated and/or the type of reference material being certified.
- 7.1.3. An accrediting body shall ensure that a forensic toxicology laboratory does not claim accredited status for any sub-discipline or analytical service that is outside the laboratory's scope of accreditation as defined by the accrediting body.