FORENSIC CHEMISTRY

TOXICOLOGY SECTION
URINE DRUGS
TRAINING MANUAL

Introduction

This procedure details the training requirements that must be completed before any new employee in the Toxicology Section may be allowed to analyze case specimens without close supervision (i.e., independent casework). Prior to completion of the modules within this manual new employee may work with case specimens as a part of their training, but may do so only if assisted and supervised by a more experienced analyst or supervisor who shall retain custody of the evidence, witness all work with the sample/case, and sign the case reports. All work conducted by the trainee shall be noted within the casefile.

Documented completion of each module within this manual, and completion of the safety training, satisfies all training requirements, and will allow the analyst to obtain the required State Certification for the analysis and detection of drugs in urine samples.

Following completion and authorization by the Forensic Lab Director, any new analyst is allowed full access to all case specimens within the laboratory and may contribute to the completion of a case in any way necessary, including case / batch technical review.

During the training period, if a trainee's performance is unacceptable in any specific section, the Training Coordinator shall notify the trainee and Forensic Lab Director / Quality Manger that performance is/was unacceptable. Notification of the unacceptable performance will be retained in the training binder along with all documentation indicating the trainee 'repeated the section'.

The Forensic Lab Director/Quality Manager may require the trainee to repeat the failed section, and/or augment the training material in the specific section, and/or take other appropriate action as management deems necessary (i.e., disciplinary). Appropriate documentation will be retained in the training binder. Subsequent failures, of either the original or additional modules during the training period will be brought to the attention of higher management by the Forensic Lab Director/Quality Manager. It should be noted that some complex tasks may require more than 1 attempt to learn and master (i.e., extraction). Such repetitions are not viewed as failing a module if the trainee is progressing and 'learning'. Rather, multiple attempts to master a task or module where repeated mistakes and the trainee is not progressing or 'learning' as determined by the trainer will be viewed as failing a task or module, as is the inability to complete the required tasks assigned within the module in a reasonable length of time or reasonable number of attempts.

MODULE 1:

Administrative Procedures and Orientation

Objectives:
Completion of this module will provide the trainee with relevant knowledge in the following administrative areas:

- Administrative policies and procedures for the State of Maine, Health and Environmental Testing Laboratory and Forensic Chemistry Section.

Required Tasks:

1. New employees will be processed through the State of Maine / Health and Environmental Testing Labs administrative offices prior to reporting to the Forensic Chemistry Laboratory.

2. The trainee will be given a tour of the HETL building, and specifically the Forensic Chemistry Lab, and introduced to lab personnel.

3. Assigned Training Coordinator will provide the trainee with an explanation of the purpose of the training program, the expected course of events and outcomes, instructions on maintenance of a training notebook / binder, and a copy of the approved training plan. Trainee will also have the opportunity to ask any questions related to training, and what is expected from all parties.

4. Trainee and Training Coordinator will meet with the Forensic Lab Director to discuss items outlined in the completion checklist below, and to answer any questions.

5. Trainees will be required to complete reading or viewing of the following materials:
   - **a.** Laboratory Quality Manual
   - **b.** Laboratory Standard Operating Procedures Manual
   - **c.** Relevant sectional Procedural Manuals
   - **d.** HETL Safety Program Manual, which includes sections on blood borne pathogens (SharePoint)
   - **e.** American Academy of Forensic Sciences Code of Ethics
   - **f.** American Board of Forensic Toxicology Code of Ethics
   - **g.** ANAB Guiding Principles of Professional Responsibility
   - **h.** Current version of ANAB standards under which the laboratory is currently accredited.

6. It should be noted that the Trainee may be working on multiple modules at the same time. Some modules, or requirements within a module may take a short time to complete, but other items may require more extensive practice and time for the trainee to master.

7. It is recognized that portions of this training program are identical to the Blood Alcohol Training program, and very similar to the Solid Dose Drug Training program. If the trainee has already completed the blood alcohol training and/or solid dose drug program, then repeating the same material again is not required. However, appropriate documentation shall be included within this training to reference and provide objective evidence that the material has been completed previously.

Checklist: Orientation and Administration

1. Trainee has completed New Employee Processing

Trainee	Training Coordinator	Date

2. Trainee has completed State of Maine / HETL New Employee Orientation

Trainee	Training Coordinator	Date

3. Trainee has read the HETL Safety Program Manual. Trainee has toured the facility and is familiar with the location of fire extinguishers, emergency routes and exits, and the evacuation meeting locations. Trainee has discussed with the Forensic Lab Director the concept of Universal Precautions and the expectations for the proper use of PPE and safety equipment within the laboratory. Trainee understands the HETL policy for Hepatitis vaccinations.

Trainee	Training Coordinator	Date

4. Trainee has been provided an explanation of the training program, competency testing, instructions on maintenance of a training notebook, and a copy of the approved training plan.

Trainee	Training Coordinator	Date

5. Trainee has met with the Forensic Lab Director and discussed the following issues:

- Laboratory mission, structure, organization, and capabilities
- Types of casework commonly encountered
- ANAB procedures and oversight
- Aspects of the Toxicology Laboratory Quality Assurance Program
- Instrument maintenance and documentation
- Technical and administrative review of batch and case files
- Preparation, use, and documentation of calibrators/controls
- Proficiency Testing Program
- Forms currently in use in the laboratory

- Hours of operation
- Time and attendance, requests for time off
- Annual and sick leave
- Continuing education and travel requests
- Supply ordering and annual budget process
- Policies regarding confidentiality and reporting of results, including documentation of case communications, telephonic results, and inquiries from the press or other media
- Policies regarding testimony
- Request for pre-trial meetings or depositions in a criminal case
- Request to testify in a grand jury proceeding or preliminary hearing
- Providing lab reports to other agencies
- Discussing the results/conclusions of another analyst's work or the work performed in another section
- Discussing details regarding an on-going investigation, and DHHS policy regarding HIPPA
- Disclosure of case details or comments regarding HETL or HETL Toxicology section via current social networking means (such as: forensic websites, forums, Facebook, internet blogs, chat rooms, etc)
- The potential for re-examination of evidence
- Membership dues and attendance at professional meetings

_____	_____	_____
Trainee	Forensic Lab Director	Date

6. Trainee has completed reading of the following materials:

	Completion Date:	Trainee Initial
Quality Manual		
Standard Operating Procedures Manual		
Urine Drugs Procedures Manual		
American Academy of Forensic Sciences Code of Ethics		
American Board of Forensic Toxicology Code of Ethics		
ANAB Guiding Principles of Professional Responsibility		
Current ANAB Standards and Board Interpretations		

_____ _____ _____

Trainee Training Coordinator Date

Administrative Matters and Procedures documented, completed, and reviewed.

_____ _____ _____

Trainee Training Coordinator Date

Module 2:

Handling and Documentation of Physical Evidence

Objectives:

After completion of this module, the trainee will have the requisite knowledge, skills, and abilities involved in:

- Preservation of hard copy chain-of-custody for physical evidence
- Use of the laboratory LIMS system to document service requests and evidence receipt, and return.
- Compliance with Toxicology Laboratory policies regarding security, handling, packaging, labeling, and preservation of evidence to prevent loss, deterioration, or cross-contamination, including:
    - Security systems in place
    - Verification and documentation of evidence received
    - Sealing of evidence
    - Procedures in the event of receiving unsealed evidence
    - Marking of evidence
    - Evidence storage
    - Final disposition of evidence
- Examination documentation to include:
    - Initials or signature of analyst and toxicology laboratory case number
    - Procedures for strikethrough and interlineation
    - Detailed information on condition and description of the evidence
    - Analyses/examinations performed
    - Composition and disposition of case files

Required Tasks:

- The trainer will discuss the topics listed in the objectives as they relate to evidence handling, packaging, labeling, and preservation, chain of custody, and examination documentation.
- The trainee will observe utilization of the laboratory LIMS system to document service requests and evidence transfer.
- The trainee will observe the physical receipt, transfer, storage, and return of evidence, and the corresponding documentation of hard copy chain of custody.
- The trainee will observe the marking or labeling of physical evidence.
- When the trainee is comfortable with and understands the submission process, the training coordinator will pretend to be a customer submitting evidence, and the trainee shall receive said evidence, completing the contract for lab services and chain of custody documents. No labels printed, and this case will not be entered into StarLims.

- The trainee is required to read the relevant sections of the Quality Manual and Evidence Manual dealing with chain of custody, receipt and return of evidence.

Study Questions:

- Explain the chain of custody system used by the Toxicology section
- How is access to the building, the laboratory, and toxicology evidence controlled, secured, and documented?
- Define a proper seal
- Discuss the proper marking/labeling of evidence
- Who has access to the secured refrigerator in the laboratory?
- What information should be included on each page of your case file?
- How are spelling or other errors handled in note-taking?
- What documentation should be included in a case file?
- How are case files stored within the laboratory?
- How is batch and QC data stored within the laboratory?
- What is the final disposition of evidence when individual casework is completed?

Checklist/Evaluation for Handling of Physical Evidence

1. The trainee has met with the training coordinator and discussed the topics listed in the objectives as they relate to evidence handling, packaging, labeling, preservation, chain of custody, evidence disposition, and security.

Date	Trainee	Training Coordinator

2. Trainee has observed/assisted in receiving, transferring, and returning evidence and documenting on chain of custody form.

Date	Trainee	Training Coordinator

3. Trainee has observed/assisted in preserving and storing evidentiary materials.

Date	Trainee	Training Coordinator

4. Trainee has observed/assisted in marking of evidence, and description of evidence materials if warranted.

Date	Trainee	Training Coordinator

5. Trainee has provided satisfactory answers to written study questions.

Date	Trainee	Training Coordinator

6. Trainee has demonstrated proficiency in use of the LIMS system and completed the exercise with the training coordinator and the submission of evidence.

Date	Trainee	Training Coordinator

7. Trainee has completed the required reading of the following:

Manuals to Read:	Completion Date:	Trainee Initial
Evidence Manual		
Quality Manual – Sections dealing with Evidence, chain of custody, receipt / return of evidence		

_____ _____ _____
Date Trainee Training Coordinator

Handling and Documentation of Physical Evidence documented, completed, and reviewed.

_____ _____ _____
Date Trainee Training Coordinator

Module 3:

Urine Drugs: Screening-Extraction-Confirmation-Report Writing

Objectives:
After completion of this module, the trainee will have the requisite knowledge, skills, and abilities involved in:

- Sample check-in to validate accurate information such as names, case #, etc
- Initial screening of urine samples for drugs
- Preparing buffers and reagents used in urine extractions, and completing associated forms
- Preparation of Internal Standards used in urine drug assays
- Sample preparation and extraction
- GC/MS maintenance and preparation for the run
- Developing a sequence list and running samples
- Analyzing the data generated and completing associated forms
- Creating final report for customer
- Submitting all work within the 'batch' for technical and administrative review
- Signing the final report and sending report to customer

Required Reading:

- Urine Drugs procedures manual.
- Med-Tox package inserts which include instructions for using the Med-Tox screening
- Randox Instrument User manual
- Advances in Analytical Toxicology, Vol II. Baselt, Randall C., 1989. Chapters: 1, 6-9.
- Dispostion of Toxic Drugs and Chemicals in Man, 5th Edition, Baselt, Randall C., 2000. (Trainee shall become familiar with this book, researching and reading about drugs as they are encountered in training. Trainee is not required to read book cover to cover).

Required Tasks:

- The trainer will discuss the topics listed in the objectives as they relate to the urine drugs assays, (Med-Tox, Randox Biochip screening, and GC/MS confirmation).
- The trainee will observe the entire process as it is performed by the trainer (Med-tox screening, calibration of Randox, case preparation and analysis using Randox, solid phase extraction and GC/MS confirmation, and completion of all associated forms, entering data into LIMS, and report writing).
- The trainee is required to read and follow the Urine Drugs Procedures and demonstrate the ability to follow that method and generate results.

- The Trainee is required to screen negative and positive samples using Medtox. (Postive samples may be CAP samples from previous PT tests). Photos of Medtox cartridge shall be taken and preserved in training binder as objective evidence of completion.
- After watching the calibration and screening procedure (Randox), the Trainee will prepare and successfully complete a minimum of 3 Calibration Curves with minimal assistance from the trainer. Trainee will complete all paperwork / forms and submit to Trainer for review. (These curves maybe with expired calibration standards and biochips)
- After watching the Trainer complete the screening, extraction and confirmation process, the Trainee will successfully complete the process of sample screening, extraction and confirmation, without observation by the trainer, using old proficiency test samples, or actual urine samples provided by the trainee. Trainee will successfully complete **at least 2** batches (approximately 5-10 samples/batch), with all associated QC samples, complete all paperwork / forms, and submit to Trainer for review. Reports will not be created.
- The Trainee will prepare at least 5 drug standards with the trainer, inject into the GC/MS and confirm the identity. Trainee will compare observed retention time and compare to previous library entry. Trainee will retain the GC/MS data in their training binder. Trainee will also locate and print the COA of the standards used. On the COA, the Trainee will circle the lot number of the standard, and it's expiration date. Trainee will also hand write the lot# and Exp date of the standard on the GC/MS data, if it was not entered when the sample was sequence was setup on the instrument.
- The trainee is required to watch and assist in the creation of Urine Drug reports using StarLims. There is no minimum established as it is recognized that mastering the Starlims software package may be quick, or lengthy depending on the computer literacy of the trainee. It is also noted that the analyst will not be able to create reports under their name until training is completed and they are authorized to work independently. To fulfill the report creation requirements of this training program, the trainee may work with, and in the presence of the trainer entering data from the Trainers cases. The Trainee shall retain 'extra copies' of these reports for their training binder, while the Trainer signs and sends official reports to the customer.

Study Questions:

- How are samples checked to ensure accuracy once they are received within the lab?
- Describe how the Randox Biochip analyzer works.
- Explain the process of calibration and sample screening used with the Randox Biochip analyzer.
- Describe the process of creating a sequence and running samples on the Randox.
- Describe the requirements a calibration curve (Randox) must meet before being used for casework
- Describe the requirements / acceptance criteria for GC/MS confirmation: Specifically detailing the retention time, S/N ratio, and library match requirements

- Explain the process for technical review. What needs to be included within the case folder before submitting it for technical review?

Checklist/Evaluation for Urine Drug Analysis

8. The trainee has met with the training coordinator and discussed the topics listed in the objectives as they relate to Urine Drug assays (Med-Tox, Randox Biochip, and GC/MS Confirmation).

Date	Trainee	Training Coordinator

9. Trainee has read the Urine Drugs Procedures Manual and other required readings and watched the entire process in urine drugs. (Medtox screening, Randox screening, Extraction-GC/MS confirmation, and report writing with Starlims).

Date	Trainee	Training Coordinator

10. Trainee has prepared at least 5 drug standards with the Trainer and confirmed identity with GC/MS. (Instrumental data, and COA added to training binder).

Date	Trainee	Training Coordinator

11. Trainee has successfully completed at least 3 calibration curves using the Randox Biochip analyzer with minimal assistance from the Trainer. (Data is retained).

Date	Trainee	Training Coordinator

12. Trainee has successfully screened, extracted and confirmed at least 2 batches (5-10 samples/batch) with all associated QC samples, completed paperwork /forms and submitted to Trainer

Date	Trainee	Training Coordinator

13. Trainee has provided satisfactory answers to written study questions.

Date	Trainee	Training Coordinator

14. Trainee has demonstrated proficiency in use of the LIMS system, including the creation of reports.

_____	_____	_____
Date	Trainee	Training Coordinator

Urine Drugs: completed and reviewed.

_____	_____	_____
Trainee	Training Coordinator	Date

MODULE 4:

Criminal and Civil Law, Procedures, and Testimony

Objectives:

Completion of this module will provide the trainee with relevant knowledge in the following areas of criminal and civil law and procedures:

- The structure of the court system in the state of Maine
- Current Maine Rules of Evidence concerning relevancy of forensic evidence and expert testimony
- Brady and Giglio material, analyst malfeasance

Completion of this module will also provide the trainee with the requisite knowledge, skills, and abilities to provide effective testimony regarding the analysis of forensic evidence, including courtroom procedures involving:

- Oath and subsequent direct examination, including
  - Qualifications and voir dire
  - Recognition and identification of evidence
  - Chain of Custody
  - Toxicology reports
  - Explanation of examinations and conclusions
- Cross examination and redirect
- Use of visual aids or presentation materials

Required Reading Materials:

The trainee is required to complete reading or viewing of the following materials / websites related to The Criminal Courts within the State of Maine and Brady / Giglio issues.

- Maine Court Systems (by County): http://www.courts.maine.gov/maine_courts/
- Current Rules of Evidence in Maine: http://www.courts.maine.gov/rules_adminorders/rules/text/mr_evid_2015-9-1.pdf
- Maine OUI Laws: http://www.maine.gov/dps/bhs/impaired-driving/laws.html
- Brady Disclosure: https://en.wikipedia.org/wiki/Brady_disclosure
- Practical Guide to Brady Motions: http://www.ncids.org/Defender%20Training/2008%20New%20Felony%20Defender%20Training/BradyHandout.pdf
- Giglio vs. United States: https://en.wikipedia.org/wiki/Giglio_v._United_States
- U.S. Justice Department Policy on Giglio: https://www.justice.gov/archives/ag/policy-regarding-disclosure-prosecutors-potential-impeachment-information-concerning-law

Required Tasks:

1. Observe a minimum of 2 courtroom testimonies. One testimony of a qualified examiner in the area of Urine Drugs, and one from another discipline within the Forensic Chemistry Section. Discuss the testimony with the appropriate examiner/analyst.
2. Trainee will meet with the Forensic Lab Director/Quality Manager after reviewing the required reading to discuss violations of Brady/Giglio, as well as general analyst malfeasance in the Forensic Sciences.

Study Questions:

- Who acts as the "gatekeeper" in determining the relevance and reliability of scientific evidence?
- List the criteria used by the Courts to determine if scientific evidence is reliable
- Briefly describe the structure of the Maine court system
- What is a Brady violation?
- Define the following terms:
  - Voir dire
  - Direct examination
  - Cross examination
  - Redirect
  - Chain of custody
  - Expert witness

Exercises:

- The trainee will prepare an up-to-date curriculum vitae
- The trainee will prepare written answers to the following questions:
  - Could you please introduce yourself to the jury?
  - How are you currently employed?
  - How long have you been employed by the State of Maine as a Chemist in the Tox section?
  - What are your duties/responsibilities as a Chemist in the Toxicology section?
  - Are you certified by the State of Maine, Dept of Health and Human services (DHHS) to examine urine samples for the presence of drugs?
  - What exactly does that mean, and how do you gain such certification?
  - Can anyone gain this certification?
  - Did you have to complete any training before getting this certification?
  - Can you tell us about that training? Who provided it and what did it cover?
  - How were you employed before this position?

- Can you tell us a little about your educational background?
- Are you a member of any professional societies?
- You already described your basic duties/responsibilities a Chemist in the Toxicology section, but can you elaborate on the type of testing that is conducted within the toxicology section? Meaning how does the lab receive samples? From whom? How do they get to the lab and how do they move thru the lab?
- And you, on behalf of the laboratory, issue a report that details your findings?
- Does anyone in the lab review your findings before they are released? Who and how is that accomplished?
- Do all urine samples submitted to the lab contain drugs?
- What happens if you examine a sample that is supposedly from an OUI suspect, but you don't find any drugs?
- Can you tell us what a proficiency test is?
- Are you required to work 'proficiency tests'?
- How often?
- Are results from proficiency tests reviewed? By whom?
- What happens if you 'fail' a proficiency test?
- Have you ever failed a proficiency test?
- Can you explain (in lay-terms) what a GC/MS system is, and how it detects the presence of a drug in a urine sample?
- How do you know the result is really the drug you state it is?

- The trainee will satisfactorily complete a mock trail scenario(s), to include the following sections:
  - Qualifying information
  - Recognition and introduction of physical evidence
  - An explanation of the examinations conducted and their results, using visual aids and presentation materials as applicable
  - Conclusions and interpretations

Checklist: Criminal and Civil Law, Procedures, and Testimony

1. The trainee has observed at least 2 courtroom testimonies of a court qualified examiner within HETL, and at least 1 being in the toxicology discipline. Trainee has discussed the testimony with the analyst who testified after the case is completed.

Date	DA	Witness	Defendant	Court/Charge

Trainee _____ Training Coordinator _____ Date _____

2. The trainee has satisfactorily prepared an up-to-date curriculum vitae.

Trainee _____ Training Coordinator _____ Date _____

3. The trainee has prepared satisfactory written answers to the outlined qualifying questions.

Trainee _____ Training Coordinator _____ Date _____

4. The trainee has provided satisfactory written/oral (circle one) answers to the study questions.

Trainee _____ Training Coordinator _____ Date _____

5. The trainee has met with the Forensic Lab Director / Quality Manager to discuss Brady and Giglio issues, and analyst malfeasance in general.

Trainee _____ Training Coordinator _____ Date _____

6. The trainee has successfully completed mock trial(s) covering the following areas (attach documentation):

	Completion Date	Trainee Initials
Qualifications		
Recognition/ introduction of evidence		
Examination/results/presentation materials		
Conclusions and interpretations		

Trainee _____ Training Coordinator _____ Date _____

7. The trainee has completed required reading/viewing of the following materials:

	Completion Date	Trainee Initials
Maine Court Systems		
Current Rules of Evidence in Maine		
Maine OUI Laws		
Brady Disclosure		
Practical Guide to Brady Motions		
Giglio vs. United States		
U.S. Justice Department Policy on Giglio		

Trainee _____ Training Coordinator _____ Date _____

Criminal and Civil Law, Procedures, and Testimony documented, completed, and reviewed.

Trainee _____ **Training Coordinator** _____ **Date** _____

Urine Drug Training Manual Completed:

Training Coordinator _____ **Forensic Lab Director** _____ **Date** _____