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1.0 Training Overview

1.1 Training Purpose and Description

1.1.1 Purpose and Goals

The purpose of this training program is to provide a uniform training process for analysts in the Toxicology Section at the Vermont Forensic Laboratory (VFL). This program is designed to ensure and document that those individuals who will be working as analysts are knowledgeable and competent to perform their technical, analytical, and legal duties.

1.1.2 Scope

This program will allow the trainee to familiarize themselves with quality assurance policies and procedures, laboratory set-up, security and safety, evidence handling and chain of custody, the laboratory information management system, sample preparation, testing procedures, report writing, and courtroom testimony. Training will concentrate on test methods currently in use at the VFL and will culminate in a competency test(s). This program is designed for new employees or current employees without prior toxicology experience. A trainee with previous experience in forensic or other toxicology analysis may not require all modules or steps; it is the responsibility of the Toxicology Section Supervisor to determine the duration and scope of the training program for a trainee with previous experience. Similarly, the module content may be tailored as applicable to anticipated job responsibilities.

1.1.3 Documentation

The trainee will compile all documentation associated with training work completed. These files may include, but are not limited to, worksheets, reports, and review sheets. The trainer will review these materials and document completion of required training components. Documentation of training will be maintained at the laboratory.

1.2 Trainee Responsibilities

1.2.1 Instructions for Trainee

The length of time needed to complete the training program will vary and is left to the discretion of the trainer and supervisor. The trainee will be provided access to any required or suggested readings and will be exposed to samples and situations expected to be encountered during routine work in the Toxicology Section. The trainee will keep records, where appropriate, of how training tasks were accomplished (e.g. what ethics training was received, who did the trainee observe testify in court, what additional papers not listed in Appendix I did the trainee reference, etc.). At the conclusion of training, the trainee will evaluate the effectiveness of the training program and suggest any improvements to the section supervisor.

1.2.2 Required Training Modules

The trainee, trainer, and section supervisor shall discuss which portions of the training manual are to be completed by the trainee based on the trainee's anticipated job responsibilities and the trainee's prior experience. This section may also be used to outline re-training requirements for current employees if needed. The requirements for the trainee are outlined below:

	Required? Yes	Required? No	Completed? Date	Completed? Trainer
1. Training Overview	☐	☐		
2. Laboratory Introduction				
2.1. General Laboratory Requirements	☐	☐		
2.2. Safety	☐	☐		
2.3. Section-Specific Requirements	☐	☐		
3. Sample and Evidence Control				
3.1. Evidence Handling for Casework	☐	☐		
3.2. Laboratory Information Management System	☐	☐		
4. Fundamental Scientific Knowledge				
4.1. Documentation of Education and Experience	☐	☐		
4.2. General Knowledge of Forensic Science	☐	☐		
4.3. Working Knowledge of Toxicology Fundamentals				
4.3.1.General Knowledge of Drug Physiology and Pharmacology	☐	☐		
4.3.2.General Knowledge of Analytical Techniques	☐	☐		
5. Applied Scientific Knowledge				
5.1. General Forensic Toxicology	☐	☐		
5.2. Drug Screening Analysis	☐	☐		
5.3. Drug Confirmation Analysis				
5.3.1.Sample Preparation and Extraction Theory	☐	☐		
5.3.2.Liquid Chromatography Theory	☐	☐		
5.3.3.Mass Spectrometry Theory	☐	☐		
6. Laboratory Analysis				
6.1. General Instrument and Equipment Quality Control and Maintenance	☐	☐		
6.2. Screening Analysis	☐	☐		
6.3. Confirmation Analysis	☐	☐		
6.4. Training Sample Processing	☐	☐		
7. Reports and Notifications				
7.1. Generation of Reports	☐	☐		
7.2. Review	☐	☐		
7.3. Mock Cases	☐	☐		
8. Legal Issues				
8.1. Legal System Fundamental Knowledge	☐	☐		
8.2. Expert Testimony Training and Practice	☐	☐		
8.3. Document Preparation	☐	☐		
9. Final Evaluation				
9.1. Competency Tests	☐	☐		
9.2. Written or Oral Examination	☐	☐		
9.3. Mock Court	☐	☐		

1.3 Trainer Responsibilities

The trainer is responsible for instructing the trainee in the operations of the laboratory and the processes and procedures that will ultimately comprise the trainee's job duties. The trainer will ensure that the trainee is exposed to all relevant topics within the training program. The trainer will provide sample sets for the trainee to analyze and will meet with the trainee periodically to monitor progress, review work, and provide feedback. The trainer will assist the trainee in preparing for any assessments, which will include a competency test(s) and may include a mock trial. At the conclusion of training, the trainer will evaluate the effectiveness of the training program and suggest any improvements to the section supervisor.

1.4 Acknowledgement of Training Plan

The signatures of the trainee, trainer, and section supervisor below indicate that the expected responsibilities and required training modules have been discussed and agreed upon.

Trainee: _____ Date: _____

Trainer(s): _____ Date: _____

Section Supervisor: _____ Date: _____

2.0 Laboratory Introduction

2.1 General Laboratory Requirements

The trainee will become familiar with and follow the administrative and quality assurance policies and procedures described in the VFL Quality Assurance Manual.

Task	Trainee	Trainer	Date Completed
I have received a tour and have become oriented to the laboratory.			
I have received ethics training and understand that my position carries ethical responsibilities.			
I have read and understand the required readings outlined for this section in Appendix I.			
I have answered the questions outlined for this section in Appendix II and received feedback on my answers.			

2.2 Safety

The trainee will become familiar with and follow the safety policies and procedures described in the VFL Safety Manual.

Task	Trainee	Trainer	Date Completed
I have received a safety tour lead by the safety officer.			
I have read and understand the required readings and training outlined for this section in Appendix I.			
I have answered the questions outlined for this section in Appendix II and received feedback on my answers.			

2.3 Section-Specific Requirements

The trainee will become familiar with and follow requirements and guidelines specific to the Toxicology section.

Task	Trainee	Trainer	Date Completed
I have read and understand the required readings outlined for this section in Appendix I.			

3.0 Sample and Evidence Control

This training module will include, but is not limited to, the collection, packaging, storage, and handling of evidence, chain of custody, the laboratory information management system (LIMS), and requirements for consuming samples and evidence.

3.1 Evidence Handling for Casework

The trainee will become familiar with and follow the policies and procedures described in the VFL Evidence Handling Manual.

Task	Trainee	Trainer	Date Completed
I have read and understand the required readings outlined for this section in Appendix I.			
I have answered the questions outlined for this section in Appendix II and received feedback on my answers.			
I have observed the receipt, handling, storage, and return of evidence in the Evidence section.			
I have observed the receipt, bench handling, storage, and return of evidence in the Toxicology section.			

3.2 Laboratory Information Management System

The trainee will become familiar with the laboratory information management system (LIMS) in use at the VFL.

Task	Trainee	Trainer	Date Completed
I have read and understand the required readings outlined for this section in Appendix I.			
I have answered the questions outlined for this section in Appendix II and received feedback on my answers.			
I have been introduced to training on the use of the LIMS database.			
I have observed the use of LIMS by a qualified analyst.			

4.0 Fundamental Scientific Knowledge

This training module will ensure that the trainee has appropriate formal education and can demonstrate a working knowledge of the fundamental scientific basis of forensic toxicological analysis.

4.1 Documentation of Education and Experience

4.1.1 Education Requirements

Analysts shall meet the educational requirements outlined by the current accreditation requirements.

The trainee shall produce pertinent materials, such as transcripts, syllabi, or correspondence with instructors, to show that educational requirements are met. These documents will be reviewed and approved by the section supervisor.

4.1.2 Experience Requirements

Prior experience in toxicology may be accepted in lieu of completing portions of this training program. The section supervisor is responsible for determining whether a trainee's prior experience is accepted by the laboratory.

4.1.3 Acknowledgement of Education and Experience

The signatures of the trainee and section supervisor below indicate that the trainee's documentation of education and experience, if applicable, has been reviewed and that the trainee meets the educational requirements to work as an analyst.

Trainee: _____ Date: _____

Section Supervisor: _____ Date: _____

4.2 General Knowledge of Forensic Science

The trainee will become familiar with the various services provided by the VFL. The trainee will develop and demonstrate a general understanding of the scope and breadth of the capabilities of each lab section at the VFL.

Task	Trainee	Trainer	Date Completed
I have read and understand the required readings outlined for this section in Appendix I.			
I have answered the questions outlined for this section in Appendix II and received feedback on my answers.			

4.3 Working Knowledge of Toxicology Fundamentals

4.3.1 General Knowledge of Drug Physiology and Pharmacology

The trainee will develop and demonstrate a general knowledge of drug physiology, pharmacology, and impairment. This training may include reading peer reviewed journal articles and textbooks, as needed, or attending a course on drug pharmacology and highway safety.

Task	Trainee	Trainer	Date Completed
I have read and understand the required readings outlined for this section in Appendix I.			
I have answered the questions outlined for this section in Appendix II and received feedback on my answers.			

4.3.2 General Knowledge of Analytical Techniques

The trainee will develop and demonstrate a working knowledge of sample preparation techniques and analytical testing methods as they apply to forensic drug testing. This training will include reading peer reviewed journal articles, textbook chapters, and other literature as needed.

Task	Trainee	Trainer	Date Completed
I have read and understand the required readings outlined for this section in Appendix I.			
I have answered the questions outlined for this section in Appendix II and received feedback on my answers.			

5.0 Applied Scientific Knowledge

This training module will ensure that the trainee has received appropriate education and training to apply principles of immunoassay screening, sample extraction techniques, liquid chromatography, and mass spectrometry to the analysis of forensic toxicology samples. Training will include, but is not limited to, reading peer reviewed journal articles, textbook chapters, laboratory protocols, manufacturer literature, validation studies, and application notes on the technologies in use at the VFL. Topics may include, but

are not limited to, immunoassay analysis for various classes of drugs of abuse, preparation of whole blood samples for analysis, identification and quantitation of various classes of drugs of abuse by liquid chromatography/mass spectrometry, and the operation and maintenance of various instruments used in the laboratory. Case files and/or instrument records will be reviewed to demonstrate how these techniques are used and documented at the VFL.

5.1 General Forensic Toxicology

The trainee will develop and demonstrate a working knowledge of drug pharmacology and physiology as it applies to DUID, including the pharmacokinetics and pharmacodynamics of various classes of drugs.

Task	Trainee	Trainer	Date Completed
I have read and understand the required readings outlined for this section in Appendix I.			
I have answered the questions outlined for this section in Appendix II and received feedback on my answers.			

5.2 Drug Screening Analysis

The trainee will develop and demonstrate a working knowledge of the Randox immunoassay analyzer in use at the VFL. Training will include, but is not limited to, the theory underlying chemiluminescent biochip assays, operation and calibration of the instrument, and knowledge of the sensitivity and specificity of the drug assays.

Task	Trainee	Trainer	Date Completed
I have read and understand the required readings outlined for this section in Appendix I.			
I have answered the questions outlined for this section in Appendix II and received feedback on my answers.			

5.3 Drug Confirmation Analysis

5.3.1 Sample Preparation and Extraction Theory

The trainee will develop and demonstrate a working knowledge of the extraction methods and techniques in use at the VFL. Training will include, but is not limited to, sample pretreatment, knowledge of various types of sample preparation and extraction techniques, SPE sorbents, sorbent selection for specific analytes, theory and use of positive pressure manifolds and evaporators, and sample reconstitution.

Task	Trainee	Trainer	Date Completed
I have read and understand the required readings outlined for this section in Appendix I.			
I have answered the questions outlined for this section in Appendix II and received feedback on my answers.			

5.3.2 Liquid Chromatography Theory

The trainee will develop and demonstrate a working knowledge of techniques in use at the VFL to analyze blood samples for drugs, including the use of liquid chromatography. Training will include, but is not limited to, the theory of liquid chromatography, column selection, mobile phase selection, instrument and method setup, and troubleshooting.

Task	Trainee	Trainer	Date Completed
I have read and understand the required readings outlined for this section in Appendix I.			
I have answered the questions outlined for this section in Appendix II and received feedback on my answers.			

5.3.3 Mass Spectrometry Theory

The trainee will develop and demonstrate a working knowledge of techniques in use at the VFL to analyze blood samples for drugs, including the use of mass spectrometry. Training will include, but is not limited to, the theory of mass spectrometry, source selection, scan types, ion optics and flow, ion detection and quantitation, and interpretation of results.

Task	Trainee	Trainer	Date Completed
I have read and understand the required readings outlined for this section in Appendix I.			
I have answered the questions outlined for this section in Appendix II and received feedback on my answers.			

6.0 Laboratory Analysis

The analyst trainee will demonstrate the ability to apply knowledge of the currently validated methods and technologies to the analysis of training samples representing the range and type of samples routinely encountered in casework analysis. In addition to laboratory work, this training may include, but is not limited to, reading laboratory protocols, validation studies, peer reviewed journal articles, and reviewing casework.

6.1 General Instrument and Equipment Quality Control and Maintenance

The trainee will develop and demonstrate knowledge of the instrumentation, equipment, and associated quality control requirements in use at the VFL. In addition, the trainee will become familiar with maintenance requirements for the lab space that ensure a clean, effective, and safe working environment.

The trainee will become familiar with the equipment by observing a qualified analyst perform each task. Each task will also be completed by the trainee under the direct supervision of a qualified analyst. The trainee and trainer will document this by both initialing the boxes below.

Equipment/Procedure	Initials & Date Observed	Initials & Date Performed
Lab maintenance including: eye washes, cleaning of work areas, taking out glass, trash, and biohazardous waste		
Pipettes		
Thermometers		
Positive pressure manifolds		
Centrifuges		
Thermoshaker		
Other:		
Other:		
Other:		
Other:		
I have answered the questions outlined for this section in Appendix II and received feedback on my answers.		
I have met the outlined requirements in this section and am authorized in the use and basic maintenance of the equipment listed.		

6.2 Screening Analysis

The trainee will develop and demonstrate knowledge of the instrumentation and procedures used for qualitative drug screening, including reagent preparation, sample preparation for biochip analysis, and quality control and maintenance of the screening instrument.

The trainee will become familiar with various aspects of immunoassay screening including observing a qualified analyst perform each task. Each task will also be completed by the trainee under the direct supervision of a qualified analyst. The trainee and trainer will document this by both initialing the boxes below.

Task/Procedure	Initials & Date Observed	Initials & Date Performed
Calibrators and Control Stock Reconstitution		
Wash Buffer Preparation		
Sample Preparation Including Biochip Preparation/Use		
General use of the Randox including: Evidence Investigator software, calibration and QC procedures, and instrument startup/shutdown procedures		
Routine Maintenance and Record Keeping		
I have answered the questions outlined for this section in Appendix II and received feedback on my answers.		

I have met the outlined requirements in this section and am authorized in the use and maintenance of the Randox Evidence Investigator.	

6.3 Confirmation Analysis

The trainee will develop and demonstrate knowledge of the instrumentation and procedures used for quantitative drug confirmation, including reagent preparation, sample preparation and extraction, instrument set up and operation, quality control and maintenance of the LC-MS/MS.

The trainee will become familiar with various aspects of confirmation testing including observing a qualified analyst perform each task. Each task will also be completed by the trainee under the direct supervision of a qualified analyst. The trainee and trainer will document this by both initialing the boxes below.

Task/Procedure	Initials & Date Observed	Initials & Date Performed
Mobile Phase Preparation		
Extraction Reagent Preparation		
Calibrators/QC Stock Preparation		
Sample Preparation and Extraction Procedures		
General use of the LC-MS/MS including: software, calibration and QC procedures, and instrument startup/shutdown procedures		
Routine Maintenance and Record Keeping		
I have answered the questions outlined for this section in Appendix II and received feedback on my answers.		
I have met the outlined requirements in this section and am authorized in the use and maintenance of the LC-MS/MS.		

6.4 Training Sample Processing

The trainee will apply knowledge of the protocols and procedures in use at the VFL to the analysis of training samples before being authorized to analyze casework samples. The trainer will provide a set of relevant, previously analyzed mock evidence and/or blind proficiency test samples for the trainee to process. The trainee will document each analysis performed and provide the trainer with results from the analyses. The trainee will understand the limitations of selectivity and sensitivity for each analytical method and be able to select appropriate testing methods for each sample.

The number and type of samples processed by the trainee will be sufficient to demonstrate the trainee's ability to competently conduct drug screening and confirmation analyses and produce reliable results. If the section supervisor determines that the sample number or type requirements for the trainee differ from those listed below, documentation of this shall be kept with the training materials.

At minimum, the samples processed for training will include the following:

1. Screening Analysis
   1.1. Analyzed under the general supervision of an experienced analyst, 2 batches, 1 of which contains at least 12 samples, from the pool of past proficiency or previously analyzed samples.
   1.2. Analyzed independently, 2 batches, 1of which contains at least 12 samples, from the pool of past proficiency or previously analyzed samples.
2. Confirmation Analysis
   2.1. Analyzed under the general supervision of an experienced analyst, 2 batches containing at least 3 samples each, from the pool of past proficiency or previously analyzed samples.
   2.2. Analyzed independently, 2 batches containing at least 3 samples each, from the pool of past proficiency or previously analyzed samples.
3. Technical Competency
   3.1. The trainee will demonstrate competency by analyzing a sample and preparing a data package for a previous proficiency test, which will undergo technical review and be approved by the Toxicology Section Supervisor. Test results must be consistent with the previously reported results.
      3.1.1. Successful completion will be documented with a written authorization specifying that the trainee can now act as a technician for a qualified analyst.
   3.2. Analyzed 50 casework samples, including confirmation testing on at least 25 samples, while serving as a technician for a qualified analyst signing the case. The trainee and analyst will both initial case documents that are completed under supervision.

Task/Procedure	Initials & Date Observed	Initials & Date Performed Under Supervision	Initials & Date Performed Independently
Screening Samples			
Confirmation Samples			
I have demonstrated technical competency and am authorized to act as a technician.			
As a technician, I have successfully analyzed at least 50 casework samples, including at least 25 confirmed samples.			

7.0 Reports and Notifications

The trainee will observe the creation of casework reports following the requirements of the Toxicology section. The trainee will demonstrate the ability to generate data packages including instrument printouts or chromatograms, quality control and summary worksheets, and sample preparation sheets, prior to compiling a case file and submitting them for technical review. Training will include, but is not limited to, report format, language used, and the use of the LIMS system to generate reports.

7.1 Generation of Reports

Task/Procedure	Initials & Date Observed	Initials & Date Performed Under Supervision	Initials & Date Performed Independently
Generated a Screening Batch File			

Generated a Case File for a Blood Drug Screening Case Including Analyst Review			
Generated a Confirmation Batch File			
Generated a Case File for a Blood Drug Confirmation Case Including Analyst Review			

7.2 Review

The analyst trainee will become familiar with the policies, procedures, and forms for technical, administrative, and director review of case files. The trainee will develop the ability to perform a technical review of analysts' files and reports by pre-reviewing case files of qualified analysts before they have an official technical review performed by a qualified analyst. The trainee's knowledge of the administrative and director review processes should be such that the trainee can prepare files for administrative and director review.

Task	Screening	Confirmation
I have reviewed the documentation for technical review of casework files.		
I have observed the technical review of blood drug casework by an experienced analyst.		
I have performed "pre-review" technical reviews of blood drug casework.		
I have observed the administrative review of blood drug case files.		
I have observed the director review of blood drug case files.		
I am authorized to perform technical reviews of blood drug casework.		

7.3 Mock Cases

The trainer or designee will prepare mock cases using previously analyzed samples for the trainee. The trainee will analyze these samples, document their lab work using the record keeping system approved for casework, create case files, perform appropriate calculations, and write reports. The trainer will perform mock reviews of these cases and the trainee will revise the case files as needed to pass review.

Task	Trainee	Trainer	Date Completed
I have analyzed samples, prepared case files, and had these files reviewed for at least two mock cases. Case Numbers:			

8.0 Legal Issues

The trainee will develop and demonstrate knowledge of the structure and function of the legal system in the state of Vermont as well as the roles and responsibilities of forensic scientists in this system. The training should be sufficient to prepare the trainee to testify as an expert witness once qualified as an analyst.

8.1 Legal System Fundamental Knowledge

The trainee will develop and demonstrate fundamental knowledge of the legal system. This training will include, but is not limited to, court structure, trial format, discovery and admissibility, courtroom presentation skills, exhibit presentation, and ethical responsibilities of expert witnesses.

Task	Trainee	Trainer	Date Completed
I have read and understand the readings outlined for this section in Appendix I.			
I have answered the questions outlined for this section in Appendix II and received feedback on my answers.			

8.2 Expert Testimony Training and Practice

The trainee will develop and demonstrate knowledge of the responsibilities of expert witnesses and strategies for effective expert testimony. Training will include, but is not limited to, preparation of mock questions and answers for direct and cross examination and observation of courtroom testimony given by a qualified analyst. The trainee should practice direct and cross examination with more than one qualified analyst (analysts may or may not be from the Toxicology section) to receive greater experience and a variety of feedback. Training may also include prearranged or impromptu question and answer sessions.

Task	Trainee	Trainer	Date Completed
I have read and understand the readings outlined in Appendix I.			
I have answered the questions outlined for this section in Appendix II and received feedback on my answers.			
I have observed an analyst be qualified in court as an expert witness in the field of blood drug analysis.			
I have observed a qualified analyst testify in court as an expert witness regarding blood drug physiology and pharmacology.			
I have practiced direct and cross examination pertaining to blood drug physiology and pharmacology with more than one qualified analyst and received feedback.			
I have observed an experienced analyst testify in court as an expert witness regarding the screening of blood samples for drugs, including the principles of immunoassay techniques.			

I have practiced direct and cross examination pertaining to blood drug screening with more than one qualified analyst and received feedback.			
I have observed an experienced analyst testify in court as an expert witness regarding blood drug confirmation testing, including the principles of sample preparation and extraction techniques, liquid chromatography, and mass spectrometry.			
I have practiced direct and cross examination pertaining to blood drug confirmation testing with more than one qualified analyst and received feedback.			

8.3 Document Preparation

The trainee will practice preparing documents that would be requested from an analyst preparing to appear in court.

Task	Trainee	Trainer	Date Completed
I have prepared my curriculum vitae and had it reviewed by at least one qualified analyst.			
I have reviewed at least one blood drug case discovery packet prepared by a qualified analyst or designee.			
I have prepared a practice blood drug case discovery packet and had it reviewed by at least one qualified analyst.			

9.0 Final Evaluation

At the completion of this training program, the trainee's ability to accept the responsibilities of an analyst will be assessed. The nature of final assessment and evaluation may differ based on the trainee's experience and anticipated job responsibilities. The section supervisor is responsible for determining what assessment and evaluation is necessary for the trainee and documenting this.

9.1 Competency Tests

The trainee will pass all applicable competency tests and have documentation of authorization prior to beginning work as a qualified analyst or technician. Competency testing includes written and/or oral exam(s) as well as practical exams. Satisfactory completion of a competency test is required for all analysts regardless of previous experience. The number and type of samples required for the competency test should be sufficient to cover the anticipated spectrum of assigned duties and to evaluate the individual's ability to perform proper testing methods. The section supervisor is responsible for determining the components of a competency test and documenting this. For analysts, the competency test will require the preparation of a written report, which will undergo technical, administrative, and director reviews. The laboratory will maintain documentation of the successful completion of competency tests.

Task	Trainee	Trainer	Date Completed
I have successfully completed a competency test pertaining to blood drug analysis.			

9.2 Written or Oral Examination

The trainee will demonstrate an understanding of the different aspects of forensic toxicology analysis covered in this training manual by completing a written and/or oral examination.

Task	Trainee	Trainer	Date Completed
I have successfully completed a written and/or oral examination pertaining to blood drug analysis.			

9.3 Mock Court

The trainee will understand that each case or sample set examined may potentially require them to testify as an expert witness. As such, the trainee will demonstrate their knowledge of drug testing methods and ability to testify as an expert witness by participating in a mock trial, including both direct and cross examination. The trainee will be evaluated for aspects of performance to include testimony content, response to cross examination, demeanor, and attire. The mock trial will take place prior to the trainee completing independent casework as a qualified analyst.

The case the trainee will testify in may be a competency test case, a fabricated case, or a case which has previously been completed by a qualified analyst. The case selected will be agreed upon by the trainee and trainer.

The mock trial will include, but is not limited to, questions on qualifications, chain of custody, evidence handling, drug screening and confirmation analysis, measurement uncertainty, and technical aspects of the case. Questioning by both the prosecutor and defense attorneys should be relevant and realistic. The atmosphere of the trial will be formal and will be conducted in the same manner as a real courtroom, including conduct and protocol. The trainee should present themself accordingly. The outcome of the mock trial evaluation will be satisfactory or unsatisfactory. If it is determined that the trainee's performance was not satisfactory, the section supervisor will determine what corrective action must be taken. The trainee will need to complete a mock trial with satisfactory performance before beginning work as a qualified analyst. Participants in the mock trial shall provide feedback for the trainee regardless of whether performance was satisfactory or unsatisfactory.

If the trainee has previous testimony experience this requirement may be modified at the discretion of the section supervisor. This modification will be documented. If a mock trial is not required, an alternate form of oral examination must be selected by the section supervisor.

Task	Trainee	Trainer	Date Completed
A case has been chosen for mock court. Case Number:			
I have offered testimony in mock court, including both direct and cross examination regarding the analysis of blood samples for drugs, including the principle of immunoassay screening, sample preparation and extraction, liquid chromatography and mass spectrometry.			
I have offered testimony in mock court, including both direct and cross examination regarding drug physiology and pharmacology.			

10.0 Authorization

At the completion of appropriate training the section supervisor shall provide written documentation authorizing the trainee to begin any of the following tasks: reagent preparation, assisting a qualified analyst as a technician, operating analytical equipment that has an impact on case work, performing technical reviews, and conducting independent casework analysis as a qualified analyst. Completion of appropriate training modules to support this determination will be documented in section 1.2.2. Written authorization documents will specify what processes, methods, or technologies the authorization encompasses. Multiple authorization documents may be issued for the trainee if training modules are completed at different times.

Appendix I: Readings

A: Required Readings

1. Training Overview

1.1 VFL Toxicology Training Manual (TOX_P301)

2. Laboratory Introduction

2.1 General Laboratory Requirements

- ☐ VFL Quality Assurance Manual and associated documents (QA_P100)
- ☐ ANAB Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel.
- ☐ Boyd, J., "Defensibility and Ethics in the Laboratory" Qual Assur J 2003; 7, 79-83.
- ☐ Ethics and Data Integrity for Environmental Labs, 2004 Webinar Series.
- ☐ Gallo, A., "How To Speak Up About Ethical Issues at Work" Harvard Business Journal June 4, 2015
- ☐ Northrup, T. P., "Ethics and Forensic Science" presentation
- ☐ Rosner, R., "Foundations of Ethical Practices in Forensic Sciences" J. For Sci Vol. 42, Issue 6 (November 1997), pg. 1190-1194)
- ☐ Trevino, L. K., et al. "Managing to be Ethical: Debunking Five Business Ethics Myths" Academy of Management Execution, 2004 Vol. 18, No. 2 (May), pg 69-81.
- ☐ Supplemental documents are available through the laboratories shared drive under the training folder, but are not required unless designated as such by the section supervisor.

2.2 Safety

- ☐ VFL Safety Manual (SAF_P100)
- ☐ Meyer, S., "Lead, Noise, Infection Control Training" presentation, 2014.
- ☐ Lab Safety video by BioNetwork: https://www.youtube.com/playlist?list=PL4qaj9envIYnBaQSPpcOMUqWiQUAgPoMq
- ☐ How to clean up a blood spill by Cornell University Environmental Health and Safety: https://www.youtube.com/watch?v=Uh0U3giZJx8

2.3 Section-Specific Requirements

- ☐ VFL Toxicology Screening Manual (TOX_P600)
- ☐ VFL Toxicology Confirmation Manual (TOX_P700)
- ☐ Currently Validated Method Specific Confirmation Manuals, as needed
  - ☐ THC and Metabolites (TOX_P701)
  - ☐ Opiates, Opioids, and Stimulants (TOX_P702)
  - ☐ Benzodiazepines (TOX_P703)
  - ☐ _____
  - ☐ _____
  - ☐ _____

3. Sample and Evidence Control

3.1 Evidence Handling for Casework

☐ VFL Evidence Handling Manual (EH_P100)

3.2 Laboratory Information Management System

☐ FA LIMS How-To Guidelines (LIMS_P100)

4. Fundamental Scientific Knowledge

4.2 General Knowledge of Forensic Science

☐ A Simplified Guide to DNA Evidence; National Forensic Science Technology Center (NFSTC)
☐ A Simplified Guide to Fingerprint Analysis; NFSTC
☐ A Simplified Guide to Firearms Examination; NFSTC
☐ A Simplified Guide to Forensic Drug Chemistry; NFSTC
☐ A Simplified Guide to Forensic Toxicology; NFSTC
☐ A Simplified Guide to Trace Evidence; NFSTC
☐ Dror, L., et al. "Context Management Toolbox: A Linear Sequential Unmasking (LSU) Approach for Minimizing Cognitive Bias in Forensic Decision Making". Journal of Forensic Sciences July 2015. Vol. 60, No.4.
☐ Morris, E. "Cognitive Bias and the Evaluation of Forensic Evidence". The Champion, May 2012.

4.3 Working Knowledge of Toxicology Fundamentals. The trainee should be familiar with the following resources, but need not read each in its entirety.

☐ NIH Tox Tutor; https://toxtutor.nlm.nih.gov/index.html
☐ Negrusz, Adam and Cooper, Gail, ed. Clarke's Analytical Forensic Toxicology. London, UK: Pharmaceutical Press.
☐ Klaassen, Curtis D., ed. Casarett and Doull's Toxicology: The Basic Science of Poisons.
☐ Raymon, Lionel P. Clinical Pharmacology. Downers Grove IL: Becker Professional Education.
☐ Maurer, H. "How Can Analytical Diagnostics in Clinical Toxicology Be Successfully Performed Today?" Ther Drug Monit vol. 34 (5), October 2012.
☐ Maurer, H. "Mass spectrometric approaches in impaired driving toxicology". Anal Bioanal Chem 393, 2009..
☐ Logan, B et al. "Recommendations for Toxicological Investigation of Drug-Impaired Driving and Motor Vehicle Fatalities". J Anal Tox.
☐ Principles of Pharmacology: Pharmacokinetics and Pharmacodynamics of Drugs.

5. Applied Scientific Knowledge

5.1 General Forensic Toxicology. The trainee should be familiar with the following resources, but need not read each in its entirety.

☐ Baselt, Randall C. Disposition of Toxic Drugs and Chemicals in Man.
☐ Baselt, Randall C. Drug Effects on Psychomotor Performance.
☐ Drug Recognition Expert 7-day Course manual. NHTSA rev. 10/2015.

- ☐ Brunton, Laurence, Chabner, Bruce, and Knollman, Bjorn. Goodman and Gilman's The Pharmacological Basis of Therapeutics.
- ☐ Levine B., Principles of Forensic Toxicology.

5.2 Drug Screening Analysis

- ☐ Evidence Investigator Operator Manual. Randox Toxicology Ltd. Rev. 2020
- ☐ DOA Ultra WB kit insert. Randox Toxicology Ltd.
- ☐ DOA Ultra WB Evidence Investigator procedure flow chart. Randox Toxicology Ltd.

5.3.1 Sample Preparation and Extraction Theory

- ☐ Beginner's Guide to SPE. Waters Corporation, 2012
- ☐ Sample Preparation techniques, Tox digital library; CHROMacademy.

5.3.2 Liquid Chromatography Theory

- ☐ Fundamentals of HPLC. Waters Corporation, 2014.
- ☐ Beginner's guide to UPLC. Waters Corporation, 2009.
- ☐ Maurer, Hans. What is the Future of (Ultra) High Performance Liquid Chromatography Coupled to Low and High Resolution Mass Spectrometry for Toxicological Drug Screening? J Chrom A, 2012.
- ☐ The theory of HPLC, CHROMacademy
- ☐ Quantitative and Qualitative HPLC, CHROMacademy
- ☐ Acquity H-Class QSM Overview and Maintenance Guide.
- ☐ Acquity H-Class SM/FTN Overview and Maintenance Guide.
- ☐ Webcast on HPLC troubleshooting, CHROMacademy

5.3.3 Mass Spectrometry Theory

- ☐ The Mass Spectrometry Primer. Waters Corporation, 2009.
- ☐ Xevo TQ-S Micro Overview and Maintenance Guide.
- ☐ Electrospray Ionization Theory under Fundamentals LC-MS, CHROMacademy
- ☐ Levine B., Principles of Forensic Toxicology: Mass Spectrometry

8. Legal Issues

8.1. Legal System Fundamental Knowledge

- ☐ Law 101: Legal Guide for the Forensic Expert; National Clearinghouse for Science, Technology and the Law (NCSTL)
- ☐ Sapir, Gil I., "Legal Aspects of Forensic Science" in Forensic Science Handbook, Vol. 1, ed. Richard Saferstein, Prentice Hall, Inc., Englewood, N.J. 1982, pp1-32 (Chapter 1).
- ☐ Vermont DUI Laws: Title 23, Chapter 13, Section 1201

8.2 Expert Testimony Training and Practice

- ☐ Guidelines for Opinions and Testimony in Forensic Toxicology. ANSI/ASB Best Practice Recommendation 037, First Edition 2019.

B: VFL Toxicology Reference Library

Analysts are expected to be familiar with the contents of the VFL Toxicology Reference Library and be alert for articles and/or references that can be added. Updated references should be added to the VFL Toxicology Reference Library during the review period, when they become available, or when new methodologies or technologies are incorporated into the laboratory protocols.

Appendix II: Training Questions

Questions listed below are intended to be answered by analyst trainees. Headings are numbered in accordance with the section numbering in the body of this manual.

2.1. General Laboratory Requirements

1. Where are the following found:
    a. Mission statement
    b. Documentation/record keeping
    c. Scope of the VFL
    d. Policy on proficiency testing
    e. Audits and casework review
    f. Laboratory objectives
    g. Report writing guidelines
    h. Requests for analysis
2. How often are manuals reviewed? By whom?
3. What are the acceptance criteria for casework?
4. If a key is lost, what must an employee do?
5. Who has access to section areas?
6. Who activates the security alarm? What areas are monitored by the alarm system?
7. What must the employee do if they accidentally cause the alarm to go off?
8. Do the lock systems create an audit trail?
9. What is the role of proficiency testing in the laboratory?
10. What purpose do audits serve?
11. Why should a portion of items tested be retained?
12. Name two types of evidence contamination and how they might be avoided.
13. Can email be used for official business?
14. What are corrective action reports? What is their purpose?

2.2. Safety

1. Who is the Safety Officer for the laboratory?
2. What does “GHS’ stand for and what is the purpose of this system?
3. How often are safety inspections conducted?
4. Where are safety records kept for individual laboratory employees?
5. What are “universal precautions” and when should they be applied?
6. What does “PPE” stand for? What PPE is appropriate for use in the toxicology section?
7. What is the evacuation plan for the laboratory in case of fire or other emergency?
8. What does “SDS” stand for? Where are they kept?
9. What should be done in the event of a chemical spill?
10. How is chemical waste disposed of?

3.1. Evidence Handling for Casework

1. What elements are required for all proper evidence seals?
2. How should blood kits be sealed?

3. How is incoming toxicological evidence stored?
4. What steps are taken if the evidence submission document does not match the submitted items?
5. How might evidence come into the laboratory?
6. Who is permitted to submit evidence?
7. Under what circumstances can evidence be consumed?
8. What should be documented regarding the blood evidence received?
9. What are the requirements for the destruction of blood evidence?

3.2. Laboratory Information Management System

1. What two case numbers are assigned to each case? What is the standard format for each?
2. Which number should be used when communicating with investigators?
3. What is a case record number and how is it generated?
4. Why do many cases have multiple case record numbers?
5. Describe the evidence numbering schematic used by the VFL.
6. What evidence item number or numbers would you assign in the following situation?
    a. Three tubes inside a blood evidence kit numbered A1.
    b. A request for confirmatory testing to be completed subsequent to receiving the screening results?
7. What is the process for documenting an affidavit request in FA?

4.2. General Knowledge of Forensic Science

1. What is forensic science?
2. What are some disciplines of forensic science-both offered and not offered by the VFL?
3. Generally what types of examinations and/or analyses are performed by the disciplines offered by the VFL?
4. What is a Forensic Analyst?
5. Define cognitive bias and list some ways by which to reduce it.

4.3.1 General Knowledge of Drug Physiology and Pharmacology

1. What are the most common routes of drug administration?
2. What is bioavailability? Give an example of how bioavailability may change depending on the route of administration.
3. What processes play a role in drug absorption? What factors might affect the rate of absorption?
4. What is the difference between pharmacology, pharmacokinetics, and pharmacodynamics?
5. How are drugs distributed throughout the body? Why are drugs generally more lipid-soluble than water-soluble?
6. Explain the concept of Volume of Distribution (V_d).
7. What is first pass metabolism?
8. What processes contribute to the biotransformation of drug compounds? What is the difference between Phase I and Phase II biotransformation?
9. What is "half-life" ($t_{1/2}$)? How does $t_{1/2}$ affect the rate of biotransformation of drugs?

10. Describe the basic pharmacokinetic models (zero-order, first-order, and Michaelis-Menton).
11. What are the routes of drug elimination? What factors might affect the rate of elimination?
12. What is the relationship between drug dose and response?
13. What is a therapeutic index (TI) and what does it indicate about a particular drug? Give an example of a drug with a low TI and one with a high TI.
14. Discuss the difference between potency, efficacy, and affinity. By what mechanisms might the potency, efficacy, and affinity of a drug be modulated?

4.3.2 General Knowledge of Analytical Techniques

1. What are some common biological matrices for toxicological testing in a human-performance context?
2. What methods can be used to prepare biological samples for analysis? Why might some matrices require additional preparation steps?
3. What are some methods that could be used to screen samples for the presence of drug compounds?
4. Briefly describe the principle of immunoassay and some of the common types of immunoassays utilized in forensic drug testing. What are the limitations of this method?
5. Explain the terms cross-reactivity, sensitivity, specificity, and selectivity with regard to analytical methods.
6. What are some methods that could be used to confirm the presence of drug compounds in a sample?

5.1 General Forensic Toxicology

1. What are the most common classes of impairing drugs found in DUID cases? Give some examples of each.
2. Describe the mechanism(s) by which the following drugs affect the central nervous system as it relates to DUID investigations:
    a. Amphetamines
    b. Opioids
    c. Benzodiazepines
    d. Barbiturates and Z-Drugs
    e. Cannabinoids
    f. Cocaine
    g. Dextromethorphan
    h. Dissociative anesthetics
    i. Hallucinogens
    j. Tricyclic antidepressants
3. What are active metabolites? When might it be beneficial to test for metabolites rather than a parent drug compound? Why might interpretation of these results be challenging?
4. What is tolerance? Why is it impossible to correlate a blood drug concentration to a level of impairment in a given individual?
5. Define enantiomers. When might chirality play a role in testing for drug compounds?

5.2 Drug Screening Analysis

1. How is a chemiluminescent immunoassay different from ELISA or HEIA?
2. What is the difference between homogenous and heterogeneous immunoassays? List some examples of each.
3. Describe the operation of the Randox screening procedure.
4. Which classes of drugs are tested for using the DOA Ultra biochip?
5. Are there any drug classes that we don't test for?
6. What is a cut off value? How is it determined for an assay?
7. Give an example of a cut off value for a specific assay. Where can you find this information?
8. Are the Randox biochip assays specific only to one target analyte? Why might other drugs yield positive results on an immunoassay test?
9. Why is it critical to confirm the results of a screening test?

5.3.1 Sample Preparation and Extraction Theory

1. What is the purpose of performing an extraction on a whole blood sample?
2. What are functional groups? Explain their role in sample extraction.
3. What is pKa?
4. pH should be how many units above or below the pKa of the compound of interest? Why?
5. How is pH adjusted in whole blood samples?
6. What are the most common types of SPE phases? Which one(s) would you use to extract acidic and basic drugs?
7. How rapidly should samples be eluted from a column when using a positive pressure manifold?
8. In what solvent(s) are samples typically reconstituted after elution or evaporation? Why?

5.3.2 Liquid Chromatography Theory

1. Why is confirmation of a presumptively positive sample necessary for forensic drug testing?
2. Describe the principles of liquid chromatography and the general operation of an LC system.
3. How do liquid chromatography, HPLC, and UHPLC/UPLC differ?
4. What is normal phase liquid chromatography? Reverse phase?
5. Discuss the difference between isocratic and gradient liquid chromatography.
6. What factors can affect resolution in a liquid chromatographic system?

5.3.3 Mass Spectrometry Theory

1. Describe the path a target compound molecule takes through the tandem MS instrument.
2. Why is ionization important in mass spectrometry? List some common techniques used.
3. How does a quadrupole affect the flight path of an ionized molecule?
4. What is the function of the collision cell? What gas is used for this purpose?
5. What is MRM? How does it differ from SIM and Full Scan modes?
6. What is fragmentation? What molecules are being observed during analysis?

7. What is “unit mass” resolution? How does it differ from “high” resolution?
8. Describe how one might differentiate configurative isomers, e.g. 4-methoxyamphetamine and ephedrine. What are some other examples of compounds that might be difficult to differentiate?
9. Is MS able to differentiate stereoisomers? Why or why not?

6.1 General Instrument and Equipment Quality Control and Maintenance

1. What QC checks and maintenance do each of the following require?
   a. Eye washes
   b. Pipettes
   c. Thermometers
   d. Centrifuges
   e. pH meter
   f. Positive pressure manifolds

6.2 Screening Analysis

1. What components are included in a Randox biochip kit? What is each used for?
2. How much whole blood is used to prepare samples for analysis on the Randox instrument?
3. Why are whole blood samples centrifuged prior to analysis?
4. What QC checks and maintenance are required by the Randox instrument?

6.3 Confirmation Analysis

1. Describe the preparation, quality control, and documentation procedures as described in the confirmation manuals for each of the following:
   a. Mobile phases
   b. Extraction reagents
   c. Purchased reagents
   d. Calibration and QC stocks
2. Describe which reagents are required in each confirmation panel and their preparation for each of the following processes:
   e. Sample pre-treatment
   f. Solid phase extraction
   g. Liquid chromatography
3. Describe the quality control procedures that are used to ensure the LC-MS/MS system is acceptable for use in casework.
4. Why does the LC-MS/MS system get calibrated for each analyte? Describe the calibration procedure.
5. What is an internal standard? Why are internal standards used in the quantitative analysis of drug compounds?
6. What are the maintenance requirements of the LC-MS/MS system and the frequency with which they must be performed?
7. Describe the procedure for cleaning the ESI source.

8.1 Legal System Fundamental Knowledge

1. What are my responsibilities as an expert witness?
2. What are my responsibilities as a fact witness?
3. Whose "side" am I on – the prosecution? The defense?
4. Describe the Daubert, Frye, and Melendez-Diaz standards. How do they differ? What admissibility standards are used in Vermont?
5. Describe the appeals court structure in the state of Vermont.
6. The state police have submitted evidence in a case. The prosecutor intends to call you as a witness at trial to present your results. The defense attorney calls and asks you a question about your work. What do you do?
7. Describe the difference between a hearing and a trial.
8. What is a deposition? How is it similar to a trial or hearing? How is it different?

8.2 Expert Testimony Training and Practice

1. Define the following using language that would be appropriate for a jury:
    a. Drug
    b. First-pass metabolism
    c. Blood-brain barrier
    d. Glucuronidation
    e. Non-competitive antagonist
    f. Synergism
    g. Therapeutic index
2. Can a correlation be drawn between drug levels in blood and level of impairment? Why or why not?
3. Define the following using language that would be appropriate for a jury:
    a. Antigen-antibody binding
    b. Chemiluminescence
    c. Cross-reactivity
    d. Charge-coupled device
4. If a sample screens positive but not enough sample remains for confirmation testing, can these results be admitted into evidence? Why or why not?
5. Define the following using language that would be appropriate for a jury:
    a. Solid phase extraction
    b. Liquid chromatography
    c. Electrospray Ionization
    d. Tandem quadrupole mass spectrometry
    e. Product ion
    f. Peak area
6. If a sample screens positive but confirms negative for an analyte, what might that indicate about the sample? What about the opposite?

DOCUMENT HISTORY			
DATE	**VERSION**	**APPROVED BY**	**ACTIVITY OR REVISION**
06/03/2020	1	Lab Director	First edition
01/10/2022	2	Lab Director	Reorganized multiple sections to separate screening from confirmation testing; modified tables throughout for simpler documentation; updated section 7 to align with current reporting and document preparation; updated training questions in appendix 2; minor changes throughout