Standard Operating Procedures Manual

FORENSIC CHEMISTRY SECTION
Maine Health and Environmental Testing Laboratory

ABOUT THIS DOCUMENT

Electronic Copy is Controlled Copy
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The procedures contained in this document are reviewed at least annually. Any changes are reviewed-approved-and authorized by the Quality Manager/ANAB Director. Obsolete/retired procedures are archived and retained for at least two years. Staff acknowledge the receipt of the updated/revised document.

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1. RELEASE/ACCESSIBILITY OF LABORATORY RESULTS

Purpose

This section sets forth the policy of the Health & Environmental Testing Laboratory's Forensic Chemistry Section regarding the release of laboratory test results and records.

Scope

This section details the proper handling of case results and records accessibility.

Procedure

A) Storage Time Limitations:

1. Case files/folders shall be retained in the laboratory for 2 years.

2. After 2 years, the files/folders are transferred to the State Archive's long-term record storage facility and stored for 18 years.

3. The combined storage time (in the laboratory, and archives) shall be 20 years. The official retention policy can be found here: https://www.maine.gov/sos/arc/records/state/2021policyletter.pdf

B) Accessibility of Records/Results:

It is the policy of the FCS to treat all information in the case files/folders, as **confidential.** Compliance with this policy is mandatory and is considered a condition of continued employment.

Employees will not release test results or the content of case files to any individual or entity that does not have the authority to possess the information. Persons with this authority are appropriate members of the HETL staff, the agency conducting the investigation, the agency submitting the evidence, the defense attorney representing the defendant (via submission of the appropriate release form or a discovery request), the Attorney General's Office, Bureau of Motor Vehicle, and the District Attorney's Office of the jurisdiction involved.

2. DISCOVERY REQUESTS/SENDING PERSONAL IDENTIFIABLE INFORMATION (PII)

Purpose

This section sets forth the policy of the Health & Environmental Testing Laboratory's Forensic Chemistry Section regarding discovery requests or any documents containing PII.

The policy for accessing and controlling the release of results are covered in Sections 4.2.4 and 8.4 of the Quality Manual

Scope

This section details the proper handling of discovery requests for case results and records, or any documents containing PII.

1. **Discovery Requests**

Requests are received from attorneys via mail, fax or email with the appropriate case information and specific information requested.

When a request for discovery is received from the District Attorney's Office, or defense counsel, it is given to a chemist for processing.

The chemist gathers the requested information, makes any needed comments on a copy of the Discovery Request regarding the requested information, and prepares a digital folder on the K drive containing scanned files of all requested information. The folder on the K drive shall be labeled as the date it was completed_Attorney's last name_Subject's last name. Once completed, a scanned copy of the discovery request with any comments made during the preparation of the requested documents shall also be added to the folder on the K drive.

Once all requested documents are located in the folder on the K drive, the entire folder will be compressed, or zipped, to prepare it for distribution. Right click on the folder, select "Send to…" and then select "Compressed (zipped) folder." A compressed folder will then be created in the same location as the original folder and will be identifiable as the icon with the zipper down the middle of a folder. The zipped discovery material will then be shared using OneDrive, or password protected for other means of sharing. To share folders using OneDrive, the following the steps should be followed:

1. Move the zipped file to a OneDrive folder
2. Click the share icon to the right of the file name 

3. Type the email addresses for each individual that should be granted access to the folder.

4. Click the Copy button to get a shareable link.

Once all files have been uploaded, a notification shall be sent that a discovery request was made and has been filled. The notification will include instructions outlining how to access the records and include the shareable link to the files. Please notify the recipient that only those receiving the email will have access to the folder, unless other requests are made. If additional recipients are requested, follow the steps above to share the files with additional individuals.

If the request originated from the District Attorney's Office, only the DA's office shall receive the notification. If the request originated from the Defense Attorney's Office, a notification shall be sent to both the requesting Defense Attorney and the associated District Attorney for that jurisdiction. Breath Testing discovery requests will only be sent to the requestor's office.

The original discovery request containing any comments made during the preparation of the requested documents, dates associated with the completion/transmittal of materials and any other correspondence related to the request will be filed in the specific case folder, if related to a case folder. Any discovery requests filed in the case folder shall include the case number and initials of the analyst.

For billing, copy the appropriate page of the Discovery Request that states the subject name, the attorney requesting the Discovery, and the address of that attorney. If there is no address on the request, hand write the address for that specific attorney on the copied page. Highlight the subject name, attorney's name and attorney's address on the form and apply an appropriate price for each request. Completed forms should be scanned and emailed, with the subject line of the email listing the law firm, to the Division of Program and Fiscal Coordination at HETL.Receivables@maine.gov .

Discovery Request Fees:

1.	Case Folder Only	$50.00
2.	Comprehensive	+$30.00/hour

2. **Sending Documents that Contain PII**

Any document that includes two or more pieces of identifying information is required to be sent securely. The documents are considered secure if they are sent using one of the following ways:

- Emailed to a maine.gov email address
- Faxed
- Shared using OneDrive

- Password protected, with the username and file(s) being sent in separate emails from the password. The email containing the password shall not include the word "password" in the email.

3. FREEDOM OF ACCESS REQUESTS

The Maine Department of Health and Human Services Policy # DHHS-02-12 outlines the policies and procedures related to Freedom of Access Act (FOAA) requests. Full information relating to FOAA can be found on the intranet at:

http://inet.state.me.us/dhhs/foaa/

All FOAA Requests must be acknowledged within 5 days of receipt. **Therefore, copies of all FOAA Requests letters will be forwarded to the HETL's Designated FOAA Coordinator as soon as possible. The FOAA Coordinator is listed within the PDF of the above referenced Document.**

The FOAA Coordinator acknowledges the request, stating HETL will produce the requested records to the extent that such records are "public records" as defined by the Freedom of Access Act.

When a request is received it is given to a chemist for processing, the chemist gathers the requested information, and prepares copies, printouts or digital files of the requested information and provides the information to the FOAA Coordinator to be sent to the requestor.

Copies of the FOAA Request and any comments made in the processing of the request, will be filed in the specific case folder, if related to a case folder.

4. DISTRIBUTION OF REPORTS / CERTIFICATES OF ANALYSIS

Purpose

This section sets forth the policy of the Health & Environmental Testing Laboratory's Forensic Chemistry Section regarding the distribution of completed laboratory reports / Certificates of Analysis

Scope

This section details the proper distribution of case reports/certificates

Procedure

A. CERTIFICATE OF ALCOHOL ANALYSIS

One (1) original/notarized certificate is sent to the Bureau of Motor Vehicles* and one (1) is sent to the appropriate District Attorney's Office. One (1) copy of the consent card(s) is sent along with each original certificate.

One (1) copy of the original/notarized certificate is sent to the arresting officer. One (1) copy of the consent card(s) is sent along with the copy of the original/notarized certificate.

If requested, one (1) copy of the original/notarized certificate will be distributed as per the requesting officer.

One (1) copy of the original/notarized certificate is placed in the case folder, along with any un-notarized certificate(s).

B. CERTIFICATE OF URINE/BLOOD DRUG ANALYSIS

One (1) original/notarized certificate is sent to the Bureau of Motor Vehicles* and one (1) is sent to the appropriate District Attorney's Office. One (1) copy of the consent card(s) is sent along with each original certificate.

One (1) copy of the original/notarized certificate is sent to the arresting officer. One (1) copy of the consent card(s) is sent along with the copy of the original/notarized certificate.

If requested, one (1) copy of the original/notarized certificate will be distributed as per the requesting officer.

One (1) copy of the original/notarized certificate is placed in the case folder, along with any un-notarized certificate(s).

*Warden Service and Marine Patrol certificates are not sent to the Bureau of Motor Vehicles unless the incident occurred on a roadway. Postmortem testing and Drug Facilitated Crime cases are not distributed to Bureau of Motor Vehicles. Bureau of Motor Vehicles mail should be sent to:

Motor Vehicle Division
OUI Section
Station #29
Augusta, ME 04333

See Section 9 for reports being sent to OCME.

C. CERTIFICATE OF CONTROLLED SUBSTANCE ANALYSIS

1. Cases submitted by the Maine Drug Enforcement Agency (MDEA):

The original/notarized certificate is sent to the Supervisory Special Agent for the specified MDEA field office. A 2nd original/notarized certificate (or copy) may be sent to the District Attorney if requested.

One (1) copy of the original/notarized certificate is placed in the case folder, along with any un-notarized certificate(s).

2. Cases submitted by a Local Police Department (any Law Enforcement agency other than MDEA).

The original/notarized certificate is sent to the appropriate District Attorney's Office.

One (1) copy of the original/notarized certificate is sent to the arresting officer.

One (1) copy of the original/notarized certificate is placed in the case folder, along with any un-notarized certificate(s).

5. NOTARIZING CERTIFICATES OF ANALYSIS

Purpose

This section sets forth the policy of the Health & Environmental Testing Laboratory's Forensic Chemistry Section regarding the Notarizing of Certificates of Analysis generated by Certified Chemists within the Forensic Chemistry Section.

Scope

All Certificates of Analysis (when duly signed and sworn to by a person certified as qualified for these purposes by the Maine Department of Health and Human Services under certification standards set by the Department), are admissible as evidence in a court for the State of Maine and for the District of Maine (federal court).

Procedure

- After the analysis has been completed, the Certificate of Analysis will be generated/printed through the laboratory's LIMS system and placed within the case folder.
- The Certificate of Analysis and the data contained in the case folder will undergo both Technical and Administrative Review.
- After the case has been reviewed, the Chemist will assemble the documents and appear in person before the Notary.
- When appearing before the Notary, the Chemist will provide the Notary with a "Notary Record Form" (see FORMS on SharePoint) containing a list of the Certificates of Analysis that are being submitted for notarization.
- The Notary will have the Chemist make an oath as to the results of the Certificate of Analysis for all of the cases listed on the Notary Record.
- Each individual Certificate of Analysis will be signed by the Chemist in the presence of the Notary and the date of the appearance will be recorded by the Notary on the Certificate of Analysis.
- A copy of the completed Notary Record Form for each notary "event" (appearance before a notary) will be retained by the Notary for 10 years.

6. ARCHIVING CASE FILES/FOLDERS

Purpose

This section sets forth the policy of the Health & Environmental Testing Laboratory's Forensic Chemistry Section regarding the archiving of case files/folders.

Scope

The purpose of this procedure is to provide guidance for the archiving of all case files/folders generated by the Forensic Chemistry Section. The archives retention schedule for all case files/folders generated by the Forensic Chemistry Section shall be maintained according to the following schedule:

Total retention period – 20 years
Retain in Laboratory – 2 years
Retain in Archives Center – 18 years

A. PREPARING RECORDS TO BE SENT TO STATE OF MAINE ARCHIVES

Files/folders are placed in a preprinted archives box, which can be obtained from the DHHS mailroom.

The boxes containing the case files/folders are inventoried with the beginning and ending case numbers, the first and last received dates, and first and last log dates, and recorded on the Transmittal of Records Form.

The box is given an "Agency Box Number". (This number is the next sequential number determined from the previous Transmittal of Records Form).

Personnel from the Archives Record Center will complete the location number and retention date.

All required forms referenced in this section, along with a complete description of Archives services, policies and procedures can be found at:

www.maine.gov/sos/arc/records/state/index.html

B. SENDING RECORDS TO STATE OF MAINE ARCHIVES

To send records to archives the Transmittal of Records - Form must be completed and forwarded to the Department of Records Officer (Clerk IV in Financial Services) for signature.

The completed and signed form is then forwarded to the Maine State Archives. Once the completed and signed copy of the Transmittal of Records Form has been received by Maine State Archives, arrangements with the Records center can be made for the transfer of records.

The completed Transmittal of Records Forms are retained in the Forensic Chemistry Section, either in hardcopy or electronic form.

C. REQUESTING CASE FILES/FOLDERS FROM STATE OF MAINE ARCHIVES

To request file/folders from archives, complete the Archives Request Form by an HETL staff member with access to the State Archives Record Center. That person will forward the form to the State Archives Record Center.

A representative from State Archives will contact the requester regarding the manner for delivery of the file/folder to the HETL.

7. OUI ALCOHOL/DRUG KIT EVALUATION

Purpose

This section sets forth the policy of the Health & Environmental Testing Laboratory's Forensic Chemistry Section regarding the OUI Alcohol/Drug kit evaluation and approval.

Scope

MRS 29-A requires the kits/materials used in the collection of blood and urine for the purposes of determining blood alcohol concentration, and blood and urine for the purposes of drug analysis, be approved by the Maine Department of Health and Human Services. This section details the proper evaluation of collection kits/materials prior to distribution and use by Law Enforcement.

Procedure

A. BLOOD KITS

1. Blood collection kits are ordered through an Approved State Vendor (not to be confused with a Forensic Chemistry approved vendor according to ANAB criteria).

2. When a shipment of blood kits arrives, one kit from each lot is chosen by the HETL Shipping and Receiving staff and submitted to the FCS for Quality Control testing. A chemist will test the collection tubes and swab for volatiles and ethanol contamination, and the collection tubes for drug contamination.

3. A copy of the CERTIFICATE OF COMPLIANCE from each specific tube lot will be downloaded from the Becton-Dickinson Company's website. This information is found at www.bd.com/regdocs/searchcoa.do. This site requires the user to enter the BD Catalog Number (367001) and the specific Lot Number found on the blood collection tubes.

4. The analyst will complete the Certified DHHS Blood Collection Kit Reagent sheet listing all the lot numbers and expiration dates associated with the kit(s) and the form is reviewed by the Quality Manager. A packet containing the completed Certified DHHS Blood Collection Kit Reagent sheet, BD Certificate of Compliance, correspondence notifying staff the kits have been approved, and packing slip is created and retained.

5. The results of the evaluation are retained in the designated BLOOD KIT QA folder located in the Chemistry Office.

6. If the QA evaluation shows no evidence of contamination, staff are notified the kits have been approved and can be assembled and stamped “Approved by Maine HETL”. Approved, prepared kits are stored in the stockroom.

B. URINE DRUG KITS

1. Urine collection kits are ordered as necessary through an Approved State Vendor (not to be confused with an approved vendor according to ANAB criteria).

2. Kits have no Expiration Date.

3. When a shipment of urine kits arrives, one kit from each lot is chosen by the HETL Shipping and Receiving staff and submitted to the FCS for Quality Control testing. A chemist will test the collection cup for drug contamination and complete the Urine Collection Kit QC Form.

4. A packet containing the completed Urine Collection Kit QC Form, correspondence notifying staff the kits have been approved, and packing slip is created and retained.

5. Upon approval, the Shipping and Receiving Department will insert the required paperwork, stamp the box “Approved by Maine HETL”, and distribute to Law Enforcement Agencies throughout the State as requested.

6. Forensic Chemistry will continue to perform ongoing evaluations of the urine collection cup, as cups from unused kits are utilized for collection/storage of known blank urine that is ultimately used as the negative control in the screening/confirmation process of urine drug testing. Evidence of contamination within the sterile collection jar is reported to the Forensic Laboratory Director for further investigation.

8. SENDING SAMPLES TO A THIRD-PARTY OR REFERENCE LABORATORY

Purpose

This section sets forth the policy of the Health & Environmental Testing Laboratory's Forensic Chemistry Section regarding the forwarding of samples to a third-party or reference laboratory.

Scope

Occasionally HETL is requested to send a biological specimen or drug sample to another laboratory for an analysis. This may be at the request of a police officer, District Attorney, defense attorney, Judge, subcontract testing, etc.

Procedure

Prior to sending the sample, the analyst shall confirm the test code/analysis type and billing arrangements with the requestor.

If the request is from a defense attorney, HETL must also have the written permission (email is acceptable) of the submitting agency or District Attorney who is involved with the case before the sample is sent.

If the request is related to subcontracting, HETL will receive written or verbal permission from the client or District Attorney prior to sending the sample for testing. This permission will be retained in the casefile.

Upon receiving a request to send a sample to a reference lab and meeting the requirements listed above, the sample will be retrieved and packaged for shipment. HETL will, to the best of the lab's ability, follow the guidelines and packaging requirements of the laboratory the sample is being sent to. This may include packaging the sample in a secondary container, appropriate labeling, and completion of any forms/paperwork, letter requesting analysis, chain of custody, etc required by the laboratory to facilitate the analysis of the sample. If blood or urine samples are sent in the mail the package must be marked "Exempt human specimen"

This procedure is not meant to be exhaustive and shall not substitute for any requirements specified by the receiving laboratory, or packaging requirements of the carrier chosen to transmit the sample from HETL to the receiving laboratory.

9. OUI Samples from Fatalities

Purpose

This section sets forth the policy of the Health & Environmental Testing Laboratory's Forensic Chemistry Section regarding the forwarding of blood samples from fatality cases to the Office of the Chief Medical Examiner (OCME).

Scope

Occasionally HETL receives samples from Law Enforcement Agencies of the decedent in a motor vehicle accident. These kits or specimens should be forwarded to the OCME if that information is known to HETL. The OCME will determine if alcohol and/or drug testing shall be performed by HETL and will submit the sample to HETL if that testing is desired.

Procedure

When the lab becomes aware of a sample having originated from a deceased individual, the Chemist or Evidence Technician will ensure the OCME is notified.

If a sample is submitted in person, and the sample was determined to be from a deceased individual prior to being logged into StarLIMS, HETL will return the sample to the submitting agency with instructions to submit the sample to OCME. If a sample is submitted by mail, and the sample was determined to be from a deceased individual, the sample shall be logged into StarLIMS and stored properly, while the OCME is notified to retrieve the sample.

If the sample was logged in to StarLIMS, a report will be issued to the submitting agency indicating the sample has been given to the OCME.

Samples submitted by the OCME will be tested for alcohol and drugs, when possible. The OCME has requested to have all reports sent unsigned via emailed and one signed copy will be retained in the casefile.

10. STAFF MEETINGS

Purpose

This section sets forth the policy of the Health & Environmental Testing Laboratory's Forensic Chemistry Section regarding staff meetings

Scope

Section meetings are held to promote good communication, which is essential to the effective operation of the Forensic Chemistry Section.

Specific Objectives

Section meetings will be held monthly as time and caseload allow. Weekly meetings will be held as schedules allow with individuals or specific disciplines.

The Section Supervisor will make daily rounds (as time allows) to afford staff the opportunity to address and discuss issues in the section.

11. EMPLOYEE DEVELOPMENT

Purpose

This section discusses the programs available for the continued development of laboratory personnel.

Scope

The HETL attempts to foster an atmosphere wherein employees are encouraged to develop and improve their knowledge and skills, and remain up to date on current issues, and practices within their specific discipline.

Specific Objectives

To accomplish this, HETL subscribes to various professional Journals. Employees are encouraged to read and share journals as a method to maintain current with specific issues, and trends within their field.

Additionally, employees are encouraged to participate in professional development programs such as attending forensic meetings, symposiums, web-based trainings, and technical training courses. HETL provides funding to attend these meetings when said funding is available.

Employees are also encouraged to participate within their field by holding offices in the professional organizations they participate in, and to present posters/papers when possible.

Finally, employees are encouraged to seek Professional Board Certification from an appropriate Certifying body when they become eligible.

12. HAZARDOUS WASTE DISPOSAL

Refer to HETL's Hazardous Waste Disposal Plan located on SharePoint. Specifics for each method may be found in the corresponding analytical procedure.

13. BILLING

Purpose

This section sets forth the policy of the Health & Environmental Testing Laboratory's Forensic Chemistry Section regarding the billing for tests and testimony conducted by the Forensic Chemistry Section,

Billing for Testing Scope

Upon completion of a case, the analyst should review the invoice in STARLIMS to ensure the correct pricing is present, based on the current Maine Rule 10-144 Chapter 257, and the correct number of items/tests is listed. Additionally, the analyst should ensure the correct agency was billed for the case folder. If there are any case notes indicating an agency other than the submitting agency should be billed, the STARLIMS billing should be appropriately updated. Please see the STARLIMS SOP for instructions relating to updating billing.

The Chemistry Section Supervisor is responsible for submitting client billing information related to testing to the Administrative Section of the HETL. Billing will be done on predetermined schedule. Either monthly, bi-weekly, or weekly depending on the number of cases worked, and scheduling with the Administrative section. A billing file is created in STARLIMS, and reviewed, before being forwarded to the billing department for processing.

Billing for Testimony Scope

Upon appearing for testimony, the analyst should determine the fee for the services provided, based on the current Maine Rule 10-144 Chapter 257. The analyst shall send an email to the HETL finance group at HETL.Receivables@maine.gov including the following information:

- Prosecutor or Attorney who requested the testimony
- Name and location of the court
- HETL Case number
- Subject's name
- Duration of time the analyst spent traveling and at court

14. CLANDESTINE LABORATORY RESPONSE POLICY

Purpose

This section sets forth the policy of the Health & Environmental Testing Laboratory's Forensic Chemistry Section regarding the response and liability for chemists responding to a clandestine laboratory operation.

Scope

Occasionally, the MDEA or Federal DEA will request the services of a chemist from the HETL to respond to and assist in the processing of a clandestine drug laboratory for evidential purposes. This policy addresses the protocol for notification and agency liability for the responding chemist.

Procedure

A. When the MDEA or DEA becomes aware of a possible clandestine lab operation, the appropriate agent will contact the Forensic Chemistry Section (FCS) Supervisor . At that time, arrangements will be made for the assignment of a chemist to respond to the operation.

B. If notification of a clandestine drug lab occurs "after hours" (between 5:00 pm and 8:00 am) the MDEA Clandestine Lab Enforcement Team (CLET) Coordinator will directly contact one of the certified chemists.

C. If the chemist is available, he/she will make the appropriate arrangements with the CLET Coordinator regarding travel arrangements and meeting place. In the absence of the FCS Supervisor, approval and responsibility for responding will be through the CLET Coordinator.

D. Once the chemist responds to the request, he/she is considered "activated" for duty. If activated "after hours", the chemist is subject to the contractual rules regarding overtime as stated in Article 10, Section E of the Agreement between the State of Maine and the MSEA.

E. While at the clandestine lab operation, the chemist will be under the direction and supervision of the MDEA CLET Coordinator or his/her designee. The chemist will follow all established MDEA policies and procedures.

15. DESTRUCTION AND RETURN OF EVIDENCE

Purpose

This section defines the protocol for the destruction of evidence not retrieved by a submitting agency after completion of analysis.

Scope

The HETL does not have the facility for the long-term storage of post-analysis evidence. The following measures are followed to dispose of all evidence not retrieved by the submitting agency after analysis is completed. Listed times start with the completion of analysis.

Specific Objectives

- Blood samples for blood alcohol analysis will be retained for at least 6 months before they are destroyed.
- Urine samples for drug analysis will be retained for at least 6 months before they are destroyed.
- Solid dose drug samples will be returned to the submitting agency upon completion of testing.

Blood & Urine Evidence Destruction:

Once analysis has been completed for a blood/urine sample, the evidence shall be destroyed no earlier than six months from the last analysis end date unless claimed by the officer or a responsible official. When destroying blood/urine evidence, the last analysis end date can be determined by viewing the last storage entry on the chain of custody. If that date is greater than six months to the date of destroying, then the evidence may be destroyed.

To destroy the sample and associated kit box/container/clamshell, use the location on the chain of custody to pull the evidence from the correct location. Cross check the HETL case number on all kit boxes, blood tubes/urine container with the HETL case number on the chain of custody. For blood samples ensure the number of tubes for each case matches the number of tubes pulled to destroy. Cross check the subject name on the evidence with the name on the reverse side of the chain of custody (if available). The blood/urine samples are to be placed into a biohazard labeled bin for destruction. The kit boxes/containers and/or interior plastic clamshell containers will be evaluated for any subject or confidential information on the box. If subject or confidential information is listed on the box/bag/clamshell, that section of the container shall either be separated from the remainder of the container and placed into a biohazard bin for destruction or obliterated using an obliteration stamp and put into the regular garbage. The remainder of the container that does not have any subject or confidential information shall be put into the regular garbage for destruction. If any part of the box/clamshell appears to be contaminated with biohazard material, the entire box/clamshell shall be placed into a biohazard bin for destruction.

The incinerator shall not be used to burn anything other than veterinary waste, in compliance with the DEP license for the unit.

Using the "Destroyed" stamp, stamp the final entry (or bottom of the page) with the date the sample is being destroyed and initial on the witness line. The chain of custody form stamped as destroyed with initials shall be filed into the appropriate case file.

Blood and urine samples will be disposed of in accordance with the HETL's Bio-Hazardous Waste Policy. The case file will be updated to indicate the sample has been destroyed.

Solid Dose Drug Evidence Return:

Solid dose drug evidence is returned to the submitting agency. The pink receipt form for each sample that is returned will be completed by the official retrieving the evidence, and a copy of the completed pink form is made and returned with the evidence.

16. REFERENCE STANDARDS AND EQUIPMENT

Purpose

This section discusses the protocol for the Forensic Chemistry Section's conformance with ANAB's /ISO requirements on equipment and reference Standards.

Scope

This policy addresses the calibration of equipment and reference standards. The items used by the Forensic Chemistry Section are:

- Instruments - (GC-MS, Headspace-GC-FID, FTIR, Randox, LC-MS/MS)
- Pipettes/Diluter/Flasks used in quantitative methods
- Class 1, Class 2, and Ultra-Class weights
- Balances used for weight determination
- Centrifuges and pH Meter
- Microscopes

Specific Objectives

Instruments - (GC-MS, Headspace-GC-FID, FTIR, Randox, LC-MS/MS)

Calibration Checks: Calibration checks will be done using standards specified in the Instrument QC Check log and/or the instrument SOP for the specific discipline.

Maintenance: Maintenance requirements will follow vendor recommendations where possible and will be outlined in the instrument maintenance procedure within the specific discipline SOP. When maintenance is conducted, reports and/or invoices indicating the type of service will be stored in the maintenance log for that specific instrument.

Preventative maintenance and/or repairs will be performed by the manufacturer of the instrument if possible, or a qualified service provider that has been approved.

The instrument must pass a QC check prior to returning to service after any major in-house maintenance/repairs, repairs by a vendor, or preventative maintenance performed by a vendor. Examples of major in-house maintenance include, but are not limited to, cleaning the MS Source, changing to a new column with similar properties, and trimming the column.

Balances and Weights
Calibration - Balances will be calibrated annually by a 17025 accredited calibration lab, whose scope includes appropriate balance calibration.

Balances used to report weights will be checked at least monthly with Class 1, Class 2, and/or Ultraclass weights.

Class 1, Class 2, and Ultraclass weights are calibrated annually by an approved vendor employing materials traceable to the national standards at NIST, and shall be an ISO 17025 accredited calibration lab, whose scope of accreditation includes calibration of mass weights. Weights will be noted as being in tolerance or out of tolerance on the calibration report provided by the vendor.

Maintenance: Annually (at least) in conjunction with Calibration.

Pipettors and Dilutor
Calibration - Pipettors will be checked annually by an approved ISO 17025 Calibration lab whose scope meets the needs of HETL. Pipettors and the dilutor will be noted as passing or failing calibration on the calibration report provided by the vendor. Pipettors used in quantitative analysis will be checked quarterly internally, to ensure the pipette falls within the current uncertainty of measurement calculation. If a pipette fails, the quarterly check it will be pulled from service until a vendor calibration can be performed.

Glassware
Calibration – Quantitative glassware will be checked every five years by an approved ISO 17025 Calibration lab whose scope meets the needs of HETL. Glassware will be noted as passing or failing calibration on the calibration report provided by the vendor. If glassware is suspected to be compromised between calibration intervals, it shall be removed from casework and sent for calibration before resuming use.

Centrifuges and pH Meter
Maintenance – Centrifuges and pH Meters will be maintained annual by a service provider listed on the approved vendors list, when possible.

Calibration checks – pH meter will be calibrated in-house with each use and a QC check is performed prior to each use. pH must be within ±0.5 to pass QC check.

Microscopes
Maintenance – Microscopes will be cleaned annually by a service provider listed on the approved vendors list, when possible.

17. REFERENCE MATERIALS/HANDLING OF CONTROLLED SUBSTANCES

Purpose

This section discusses the protocol for the Forensic Chemistry Section's conformance with ANAB/ISO requirement on traceability and federal regulations regarding the handling of controlled substances.

Scope

This policy addresses the use of reference materials. These reference standards employed by the Forensic Chemistry Section are:

Drug Standards
Ethanol Calibration Standards
Ethanol Controls

Specific Objectives

All standards and control materials will be obtained from approved providers based upon historical use and/or vendor evaluation and will have a Certificate of Analysis (COA) when available. When the standard arrives in the lab the purchase packing slip is reviewed to verify that the item matches what was meant to be purchased, and ensure the standard is placed in the proper storage conditions. Standards must be stored at the temperature recommended by the vendor to maintain traceability.

Prior to use, ensure that a valid COA is available and on file within the laboratory. COAs from standards produced in accordance with ISO 17034 will be reviewed and retained. All reference materials will be verified and approved by reviewing the COA, comparison to a previous lot, comparison to a published library, and/or comparison of published literature or COA data, where appropriate. The documentation of this approval and the method of approval will be retained. Any internal reference materials will be checked as far as is technically and economically practicable. Ethanol standards and controls will meet acceptance criteria in the Alcohol Determination Procedures Manual. Drug standards and controls will meet acceptance criteria in the associated testing procedure. Verifications will be traceable to the material's specific lot number and manufacturer. Any indication of degradation of the standard will result in the discontinuation of use of that standard.

HETL is registered as an Analytical Laboratory with the DEA, which allows for the possession of Schedule I-V controlled substances. Registration is renewed annually.

Controlled substance standards, which are compounds listed in the federal Controlled Substances Act (https://www.dea.gov/drug-information/csa), and are marked as non-DEA exempt through the vendor, will require a DEA 222 form for purchasing. Please let the Forensic Lab Director know when one of these standards is to be purchased so a DEA 222 form can be sent to the appropriate vendor. Following completion of the DEA 222 form, it shall be copied and retained with the

Forensic Lab Direction and the original is sent to the vendor. Upon arrival of the standards, the DEA 222 form shall be completed to document the date and quantity that arrived. The standard(s) shall be added to the non-DEA exempt inventory and stored in a secured storage area, following the manufacturer's storage temperature requirements, with restricted access (such as a lockable refrigerator or freezer).

Analytical laboratories are required to keep an inventory if more than1 kilogram of any controlled substance (other than a hallucinogenic controlled substance listed in Schedule I), or more than 20 grams of a hallucinogenic substance listed in Schedule I (other than lysergic acid diethylamide), or more than 0.5 gram of lysergic acid diethylamide, is on hand. All other substances and quantities need not be included on the inventory, as stated in 21 CFR 1304.11(e)(5). Inventory requirements can be found in 21 CFR 1304.11. Inventories must be kept on record for at least two years, as stated in 21 CFR 1304.04.

If the controlled substance standard is exhausted during the course of testing, this shall be noted on the inventory so the standard can be removed from the list. If a controlled substance standard requires destruction due to the item being expired or unacceptable, the item must be rendered non-retrievable on-site, with two witnesses present to observe the destruction. Two employees of the registrant shall handle or observe the handling of any controlled substance until the substance is rendered non-retrievable and shall personally witness the destruction of the controlled substance until it is rendered non-retrievable. The destruction must be documented on a DEA 41 form, as stated in 21 CFR 1304.21, and kept on record for at least two years, as stated in 21 CFR 1304.04. Please see the Quality Manager or Forensic Lab Director for options on rendering items non-retrievable.

Analytical laboratories registered with the DEA are not required to keep records of controlled substances used in chemical analysis or other laboratory work or records relating to known or suspected controlled substances received as evidentiary material for analysis, as stated in 21 CFR 1304.23.

If the name or address on the DEA registration requires updating, the form on the DEA website shall be completed and approved to process the change.

COA's (either paper or digital) may be stored within the HETL laboratory or retrieved from the web as needed by staff. It is the analyst's responsibility to ensure a COA is either on the web or in possession of HETL before a standard is used for casework.

18. REANALYSIS PROGRAM

SOLID DOSE DRUG SECTION

Purpose

The blind reanalysis program is an additional quality control measure to ensure SDD results being reported are accurate, and all analysts are following all policies and performing testing in a standardized and reproducible manner.

Scope

When there are at least three fully trained analysts performing seized drug analysis, at a minimum one case, per certified analyst, per quarter will be randomly selected by the Quality Manager following technical review, but prior to administrative review, to be reanalyzed by a second certified analyst.

Method

When a case is selected by the Quality Manager the initial folder will be held by the Quality Manager until the reanalysis is completed. A new folder will be created for the reanalysis, and assigned with the original folder's case number followed by RA. A note will be placed on the folder indicating the data contained inside is the reanalysis data. The original folder, and casefile review form, will also be marked that the folder was selected for reanalysis. The new folder will be assigned to a second certified analyst, who will take custody of the evidence and perform the testing from start to finish, as processing any other assigned case. The second analyst shall not access the results of the initial testing. Reanalysis results will be submitted to the Quality Manager who will compare the results for consistency.

After reviewing the results, the Quality Manager will complete the Reanalysis Form. A copy of the form will be retained with the Quality Manager and the original will be retained in the reanalysis casefile.

All reanalysis results will be retained in the reanalysis case folder, which will be filed with the initial case folder. If any discrepancies are found a Quality Issue Reporting Form will be filled out to determine the appropriate follow up action. Upon completion of reanalysis, if no discrepancies were found, the initial analyst will be notified to update the original report with a comment stating the following:

"This case was selected for reanalysis as part of the Forensic Quality Assurance Program. Reanalysis data is available upon request."

Revision:

REVISED BY	REV (TABLE) #	DATE	Revisions
EAF/LN	1*	5/3/21	Section 15 Destruction of evidence: Added blood and urine destruction of evidence information. Added Revision table.
LN	2	7/12/21	Section 2 updated to state discovery will be sent to requestor and DA will be notified of discovery request if discovery was requested by the defense. Intoxylizer discovery requests added. Section 15: added kit boxes to destruction of evidence.
LN	3	08/05/2021	Reanalysis section expanded to include Urine Toxicology data analysis.
LN	4	02/09/2022	Discovery process updated to include instructions for a file share site.
LN	5	04/12/2022	Section 2: Discovery requests should have case number and initials when added to file. Section 4 A & B. Updated to state a copy of the consent cards will be included with the certificate when sent Section 7.A. updated to remove swab testing as part of the blood kit check for drug contamination Section 15 updated to discuss the return of SDD evidence instead of destruction Section 16 updated to include Class 2 weights and Glassware
LN	6	08/05/2022	Removed address on first page. Section 1: linked to the official record retention policy and added BMV in section B. Section 7: added urine kits and a reference to blood drug testing in the scope Section 9: updated to include HETL PM testing, and more thorough instructions on handling PM samples upon submission Section 12: updated to reference HETL's Waste Plan and removed guidance from this document Section 13: Added scope for testimony billing Section 17: removed vendor links, added storage requirement section, added handling of controlled substances guidance Section 18: updated scope to require reanalysis only when at least three fully trained analysts are present. Removed urine reanalysis procedure following updated method validation.

LN	7	09/22/22	Section 4. B updated to change Department of MV to Bureau of MV. Clarified PM samples and DFC samples are not sent to BMV. Section 8 updated to include the analyst will confirm the test being requested and billing arrangements prior to sending samples to another lab. Additional requirements for labeling for shipping added. Section 9 updated to indicate HETL will test PM samples submitted by the OCME upon request and who receives reports for PM testing Section 15 blood and urine kit box destruction updated to remove incineration as an option.
LN	8	06/30/23	Section 1 updated release of information to a defense attorney to include "via submission of the appropriate release form or a discovery request". Section 4: Department changed to Bureau for Motor Vehicles and the address was added. A note to see section 9 for reports going to OCME was added. Section 8: added drug sample as option to be sent to another lab Section 9: Updated process for sending reports to OCME. Section 14. E. removed "documented in the "Clandestine Drug Laboratory Response – Policy Number: MDEA 55"." Section 17: Added "Please see the Quality Manager or Forensic Lab Director for options on rendering items non-retrievable."
LN	9	10/18/23	Updated Section 2

* For previous revision history please see version history in SharePoint.