# Technical Procedure for Receipt and Quality Assurance of Supplies, Equipment, Reference Collections, Standards and Reagents

- **1.0 Purpose** To ensure that supplies, equipment, reagents and standards purchased by the State Crime Laboratory Drug Chemistry Section that affect casework are procured and received properly.
- **Scope** This procedure applies to the Drug Chemistry Section at the Raleigh location of the State Crime Laboratory.

#### 3.0 Definitions

- Quality control (QC) check Confirmation of the reliability of equipment, instrumentation, and/or reagents.
- **Commercial reagent -** Solvent or chemical manufactured or obtained from a commercial source.
- **Critical reagent** Those chemicals which critically affect the quality of tests.
- **Prepared reagent** A dilution or mixture of commercial reagents prepared by a State Crime Laboratory Drug Chemistry Section Forensic Scientist.
- **Reference standard** Measurement standard designated for the calibration of other measurement standards (reference standards or equipment.)
- **Reference material** Material sufficiently homogeneous and stable, with reference to specified properties, which has been established to be fit for its intended use in measurement or in examination of nominal properties.
- **Primary reference material** Any reference material obtained from a source other than the State Crime Laboratory and which has documentation issued by the provider authenticating its chemical composition.
- **Secondary reference material** Any reference material used in the course of casework that has its chemical composition verified by reference material.
- **Authenticating documentation** A certificate of analysis or equivalent documentation provided by the manufacturer of a substance certifying chemical composition or any published spectral data from a an informed treatise generally accepted in the field that identifies a chemical substance.

#### 4.0 Equipment, Materials and Reagents - N/A

#### 5.0 Procedure

#### 5.1 Standards and Controls - N/A

## 5.1.1 Receipt of Supplies, Equipment, Standards and Reagents

- **5.1.1.1** Prior to use, received supplies, equipment, standards and reagents shall be inspected for compliance with specifications in the order by the Section Drug Chemistry or Toxicology Supply Coordinator or designee.
- 5.1.1.2 Materials found to meet specifications shall be marked with the initials of the Drug Chemistry or Toxicology Section Supply Coordinator or designee and the date of receipt. Materials that do not meet specifications shall be handled according to the Laboratory Procedure for Procurement and Receipt.
  - Records: A copy of the packing slip shall be marked with the printed name and signature of the Drug Chemistry or Toxicology Section

Supply Coordinator or designee and the date of receipt. This packing slip will be maintained by the Drug Chemistry or Toxicology Section Supply Coordinator with a copy of the order.

**5.1.1.3** Upon receipt of reference materials and critical reagents the Drug Chemistry or Toxicology Section Supply Coordinator shall notify and/or deliver those items to the individual responsible for performing the additional required checks prior to use in casework.

## **5.1.2** Commercial Reagents

- **5.1.2.1** Upon being opened, commercial reagent containers shall be initialed and dated by the employee who opened them.
- **5.1.2.2** Stock or use containers of commercial reagents shall be labeled with the following:
  - Identity of the reagent (and grade if applicable).
  - Initials of the preparer.
  - Date prepared.
  - Expiration date. If there is no expiration date, it shall be marked "not applicable."
- **5.1.2.3** Commercial reagents shall be documented in the Resource Manager section of FA with the following:
  - Manufacturer's lot number.
  - Date received.
  - Manufacturer.
  - Description.
  - Expiration date, if applicable.

## **5.1.3** Prepared Reagents

- **5.1.3.1** Lot numbers for stock solutions and use solutions of prepared reagents shall be assigned using lot number designations listed in Section technical procedures.
- **5.1.3.2** Internal standard solutions, calibration solutions and verification solutions shall expire one year after preparation unless otherwise specified in the Section technical procedure used for preparation. All other prepared reagents shall expire three years after preparation unless otherwise specified in the Section technical procedure used for preparation.
- **5.1.3.3** The containers of a stock solution or use solution of prepared reagents shall be labeled with the following:
  - Identity of the reagent.
  - Lot number (see Section technical procedures for format) or date of preparation.
  - Initials of preparer.

- Expiration date (see Section technical procedures for format for each reagent).
- Quality control check due date.
- **5.1.3.4** Each new stock solution or use container of prepared reagents shall be documented in the Resource Manager Section of FA with the following:
  - **5.1.3.4.1** Lot number.
  - **5.1.3.4.2** Created date.
  - **5.1.3.4.3** Creator.
  - **5.1.3.4.4** Expiration date.
  - **5.1.3.4.5** Description (optional) The corresponding Section technical procedure may be listed here.
  - **5.1.3.4.6** Comments (optional) Stock or use container may be denoted here.
  - **5.1.3.4.7** Components
    - Stock solutions list the names and lot numbers of all commercial reagents used to make the prepared reagent.
    - Use solutions list the stock solution lot number if taking an aliquot for personal use, or list the names and lot numbers of all commercial reagents used to make the prepared reagent.
    - Description.

## **5.1.3.5** Quality Control Checks

- **5.1.3.5.1** Quality control checks of reagents shall be documented in the Resource Manager section of FA with the following:
  - Date performed
  - Employee who performed the check
  - Identifier of the standard used
  - Whether the reagent worked as expected
  - Due date for next quality control check.
- **5.1.3.5.2** Prepared reagents shall be quality control checked according to the Section technical procedures before the first use.
- **5.1.3.5.3** To ensure reagent reliability, quality control checks shall be performed and documented at six month intervals for prepared reagents that have expiration dates longer than six months except for internal standard solutions, calibration solutions and verification solutions. This applies to use containers only, or if stock containers are used directly.

 The quality control check due date shall be listed on the container.

# **5.1.4** Critical Reagents

- **5.1.4.1** Critical reagents shall be quality control checked by the Toxicology Technical Leader or designee prior to use in casework.
- **5.1.4.2** Chemical Derivatizing Agents for each new lot received:
  - 5.1.4.2.1 Quality control check: the derivatization of a primary or secondary reference material followed by GC-MS analysis shall be required. The mass spectrum produced shall be compared and found to be substantially the same as reference material for the derivatized standard. Upon successful completion of the check, the Toxicology Technical Leader or designee shall mark the chemical derivatizing agent container with initials and date.
    - Records: The mass spectrum generated and the reference material used for comparison shall be marked by the Forensic Scientist who generates the data with the chemical name, supplier and lot number of the chemical derivatizing agent. The Toxicology Technical Leader shall maintain the records.
- **5.1.4.3 Negative Blood** for each new lot received.
  - **5.1.4.3.1** Analysis by Enzyme-linked Immunosorbent Assay (ELISA) shall be negative for each assay.
    - Records: The ELISA data and corresponding QC data will be marked by the Forensic Scientist who generates the data with the supplier and lot number. The Toxicology Technical Leader shall maintain the records.
  - 5.1.4.3.2 Analysis by acid/base solid phase extraction followed by GC-MS analysis shall show the absence of reportable substances according to the Section Technical Procedure for Toxicology Analysis. Upon successful completion of this check and 5.1.4.3.1, the Toxicology Technical Leader shall mark the negative blood container with initials and date.
    - Records: The GC-MS data as specified in the Section Technical Procedure for Toxicology GC-MS will be marked by the Forensic Scientist who collects the data with the supplier and lot number. The Toxicology Technical Leader shall maintain the records.
- **5.1.4.4 Negative Urine** for each new lot received (commercially or employee donated, the lot number of employee donated urine shall be eight digit format year/month/day "NegUrine" Initials of donor):

- **5.1.4.4.1** Analysis by ELISA shall be negative for each assay.
  - Records: The ELISA` data and corresponding QC data will be marked by the Forensic Scientist who generates the data with the supplier and lot number. The Toxicology Technical Leader shall maintain the records.
- 5.1.4.4.2 Analysis by acid/base solid phase extraction followed by GC-MS analysis shall show the absence of reportable substances according to the Section Technical Procedure for Toxicology Analysis. Upon successful completion of this check and 5.1.4.4.1, the Toxicology Technical Leader shall mark the negative urine container with initials and date.
  - Records: The GC-MS data as specified in the Section Technical Procedure for Toxicology GC-MS shall be marked with the supplier and lot number. The Toxicology Technical Leader shall maintain the records.

## 5.1.4.5 Immunoassay Microplate and Conjugate – for each new lot received:

- **5.1.4.5.1** Quality control check: Analysis by ELISA following the kit verification procedure outlined in Use of the Immunalysis Tecan Freedom EVO 75 Workstation to Perform ELISA as a Drug Screen.
  - Records: The ELISA data will be marked by the Forensic Scientist who generated the data with the name, supplier and lot number of the microplate. The conjugate is traceable through the microplate lot number. The Toxicology Technical Leader shall maintain the records.

# 5.1.4.6 Immunoassay Blood Verification Standards – for each new lot received:

- Quality control check: Analysis by ELISA shall produce values that are evaluated as positive in accordance with the acceptance criteria in Use of the Immunalysis Tecan Freedom EVO 75 Workstation to Perform ELISA as a Drug Screen. Upon successful completion of the check, the Toxicology Technical Leader shall mark the immunoassay blood verification standard container with initials and date.
  - Records: The ELISA data and the corresponding QC data shall be marked by the Forensic Scientist who generated the data with the name, supplier and lot number of the standard. The Toxicology Technical Leader shall maintain the records.

## 5.1.4.7 Commercial Multi-component Alcohol Certified Standard Solutions

- 5.1.4.7.1 Quality control check: Analysis by Headspace Gas Chromatography shall identify the listed components. The components shall quantify within +/- 5.0 % of the certified concentration. Upon successful completion of the check, the Toxicology Technical Leader shall mark the commercial multicomponent alcohol certified standard container with initials and date.
- **5.1.4.7.2** Records: The chromatograms shall be marked by the Forensic Scientist who generated the data with the name, supplier and lot number of the standard. The Toxicology Technical Leader shall maintain the records.

#### **5.1.5** Reference Material

**5.1.5.1** In rare circumstances where primary and secondary reference materials are not available, reference material may be used in the course of casework to identify substances only with Technical Leader approval. These instances may include, but are not limited to, unusual steroids and new analogs that are not yet controlled.

## **5.1.6** Primary and Secondary Reference Materials

- **5.1.6.1** Authenticating documentation for all primary and secondary reference materials shall be maintained by the Section Drug Standards Coordinator and stored on the Section shared drive.
- **5.1.6.2** Only reference materials with authenticating documentation may be used in the course of casework to identify controlled substances.
- 5.1.6.3 The Section Drug Standards Coordinator shall analyze primary reference materials on selected in-house instrumentation prior to release for casework. The data produced shall be qualitatively evaluated to ensure it is substantially comparable to authenticating documentation, reference material, and/or published spectral libraries.
- 5.1.6.4 The Section Drug Standards Coordinator shall evaluate data generated on in-house instrumentation from secondary reference materials prior to release for casework. The data shall be qualitatively evaluated to ensure it is substantially comparable to reference material or a spectral reference collection maintained by the State Crime Laboratory.
- **5.1.6.4.1** All secondary reference materials removed from casework shall be documented by the Forensic Scientist who has possession of the evidence on the Drug Acquisition form.

#### 5.1.7 In-house Generated Reference Collections

**5.1.7.1** Spectral reference collections generated within the Laboratory will be traceable to primary or secondary reference materials.

- 5.1.7.2 Current and archived in-house generated spectral reference collections and relative retention time indices shall be maintained by the Section Drug Standards Coordinator and stored in the Drug Folder on the State Crime Laboratory Instrument Network.
- **5.1.7.3** Relative retention time indices shall be traceable to primary or secondary reference materials and specific to an analytical method.
- **5.1.7.4** Spectral reference collections and relative retention time indices will be entitled with:
  - Technique identifier (i.e., MS, IR, VolRT, DrugRT).
  - "Cert."
  - Date in the format YYYYMMDD.
  - Example "MSCert20101207"
- **5.1.7.5** Spectral reference collections and relative retention time indices may be utilized from the instrument network by a Forensic Scientist or downloaded from the network to the data station of an instrument or work station of a Forensic Scientist by the Section Drug Standards Coordinator or designee.

## **5.1.8 Drug Chemistry Reference Materials Vault**

- **5.1.8.1** A vault containing reference materials shall be maintained by the Forensic Scientist Manager and his/her designees for the Drug Chemistry Section.
- **5.1.8.2** Access to the vault shall be limited to the Forensic Scientist Manager and designated Forensic Scientists.
- **5.1.8.3** A two lock system shall be utilized so that single entry access is prohibited.
- **5.1.8.4** A record shall be maintained by the Section Drug Standards Coordinator of the vault inventory, the date and time of entries into the vault, the gross weights of reference materials added to and removed from the vault.
- **5.1.8.5** Reference material containers in the vault shall be labeled by the Forensic Scientist who added the standard to the vault with the contents, the initials of the Forensic Scientist who added the standard to the vault (if known), the date received (if known), and a unique vault identifier.
- 5.1.8.6 An audit of the vault shall be conducted annually in the first quarter of each year by the Section Drug Standards Coordinator or Forensic Scientist Manager designee, and documented by the Forensic Scientist Manager in a memorandum to the Director of the State Crime Laboratory.

#### **5.1.9** Forensic Scientist Personal Reference Materials

- **5.1.9.1** Each Forensic Scientist may maintain a personal inventory of primary and secondary reference materials.
- **5.1.9.2** Forensic Scientists shall maintain a list of all controlled primary and secondary reference materials in their possession.

- **5.1.9.3** A Forensic Scientist may possess only the following amounts of a controlled primary or secondary reference material:
  - No more than five dosage units (i.e., tablets, capsules or any other form that is intended as a dosage unit).
  - Five hundred (500) milligrams of a solid material.
  - Three milliliters of liquid.
- 5.1.9.4 An annual inspection of the personal inventory of primary and secondary reference materials maintained by each Forensic Scientist shall be conducted in the first quarter of each year by the Forensic Scientist Manager or designee and signed and dated by the Forensic Scientist Manager or designee to signify that the inventory is correct.

## **5.1.10** Toxicology Reference Materials

- **5.1.10.1** Reference materials used in Toxicology casework shall be stored in a secured area.
  - Access shall be limited to the Forensic Scientist Manager, Forensic Scientist Supervisors, and Forensic Scientists assigned to the Toxicology Unit.
- **5.1.10.2** The Toxicology Technical Leader shall maintain a record of reference materials stored in the Toxicology Laboratory.
- **5.1.10.3** Reference material containers stored in the Toxicology Laboratory shall be labeled by the Forensic Scientist who adds the standard to the Toxicology Reference Materials with the contents, initials of the Forensic Scientist, the date received, and a unique Toxicology Laboratory identifier.

# **5.1.11** Training Reference Materials

- **5.1.11.1** Training reference materials shall be documented by the Drug Chemistry or Toxicology Training Coordinator to demonstrate their content.
- **5.1.11.2** Reference materials used for training purposes shall be stored in a secured locker in the evidence room. All training reference materials stored in the locker shall be labeled with a unique identifier.
- **5.1.11.3** Access to training reference materials shall be limited to the Drug Chemistry and Toxicology Training Coordinators for the Forensic Scientist Training Program.
- **5.1.11.4** The Training Coordinators shall maintain an inventory and log of training reference materials added and removed.
- **5.1.11.5** Only primary/secondary reference materials from the training reference materials or the section drug vault shall be used to prepare the components of competency tests.

- 5.1.11.6 The Training Coordinators for the Section Forensic Scientist Training Program shall appoint designees to conduct an annual inspection of the controlled substance training reference materials. The results of the inventory shall be recorded in a spreadsheet and summarized in a memo to the Forensic Scientist Manager.
- 5.2 Calibrations N/A
- **5.3** Sampling N/A
- **5.4** Calculations N/A
- 5.5 Uncertainty of Measurement N/A
- **6.0** Limitations N/A
- **7.0** Safety See the State Crime Laboratory Safety Manual.
- **8.0** References N/A
- 9.0 Records
  - Receipts/packing slips for purchased supplies, equipment, standards, and reagents
  - Entries in Resource Manager of FA
  - Container labels
  - QC data generated from reference materials
  - Printable Critical Reagent Label page (see FORMS folder on shared drive)
  - Printable Non-critical Reagent Label page (see FORMS folder on shared drive)
  - Printable Drug Acquisition Form (see FORMS folder on shared drive)
- **10.0** Attachments N/A

Revision History		
Effective Date	Version Number	Reason
09/17/2012	1	Original Document