Drug Chemistry Quality Assurance

1.0 Purpose - To ensure that supplies, equipment, reagents and standards that affect casework are procured and received properly.

2.0 Scope - This administrative procedure applies to the Drug Chemistry Sections 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 Receipt of Supplies, Equipment, Standards and Reagents

4.1 Prior to use, received supplies, equipment, standards and reagents shall be inspected for compliance with specifications in the order by the Section Drug Chemistry Supply Coordinator or designee.

4.2 Materials found to meet specifications shall be marked with the initials of the Drug Chemistry 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.

4.2.1 Records: A copy of the packing slip shall be marked with the printed name and signature of the Drug Chemistry Supply Coordinator or designee and the date of receipt. This packing slip will be maintained by the Drug Chemistry Supply Coordinator or designee with a copy of the order.

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

5.0 Commercial Reagents

5.1 Upon being opened, commercial reagent containers shall be initialed and dated by the employee who opened them.

5.2 Stock or use containers of commercial reagents shall be labeled with the following:

5.2.1 Identity of the reagent (and grade if applicable).

5.2.2 Initials of the preparer.

5.2.3 Date prepared.

5.2.4 Expiration date. If there is no expiration date, it shall be marked "not applicable."

5.3 Before use commercial reagents shall be documented in the Resource Manager section of FA with the following:

5.3.1 Manufacturer's lot number.

5.3.2 Date received.

5.3.3 Manufacturer.

5.3.4 Description.

5.3.5 Expiration date, if applicable.

6.0 Prepared Reagents

6.1 Lot numbers for stock solutions and use solutions of prepared reagents shall be assigned using lot number designations listed in Section technical procedures.

6.2 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.

6.3 The containers of a stock solution or use solution of prepared reagents shall be labeled with the following:

6.3.1 Identity of the reagent.

6.3.2 Lot number (see Section technical procedures for format) or date of preparation.

6.3.3 Initials of preparer.

6.3.4 Expiration date (see Section technical procedures for format for each reagent).

6.3.5 Quality control check due date.

6.4 Each new stock solution or use container of prepared reagents shall be documented in the Resource Manager Section of FA, unless otherwise specified in a specific Drug Chemistry section technical procedure, with the following:

6.4.1 Lot number.

6.4.2 Created date.

6.4.3 Creator.

6.4.4 Expiration date.

6.4.5 Description (optional) – The corresponding Section technical procedure may be listed here.

6.4.6 Comments (optional) - Stock or use container may be denoted here.

6.4.7 Components

6.4.7.1 Stock solutions – list the names and lot numbers of all commercial reagents used to make the prepared reagent.

6.4.7.2 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.

6.4.7.3 Description.

6.5 Quality Control Checks

6.5.1 Quality control checks of reagents shall be documented in the Resource Manager section of FA with the following, unless otherwise specified in this document:

6.5.1.1 Date performed.

6.5.1.2 Employee who performed the check.

6.5.1.3 Identifier of the standard used.

6.5.1.4 Whether the reagent worked as expected.

6.5.1.5 Due date for next quality control check.

6.5.2 Prepared reagents shall be quality control checked according to the Section technical procedures before the first use.

6.5.3 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.

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

7.0 Critical Reagents

7.1 Critical reagents shall be quality control checked by the HPLC Coordinator or designee prior to use in casework.

7.2 HPLC buffer:

7.2.1 Quality control check: The HPLC buffer shall have the pH checked before each use to ensure that the pH of the solution is between 2.2 and 2.3. Upon successful completion of the check, the HPLC buffer may be used in analysis.

7.2.1.1 Records: The quality control check shall be documented in the instrument log book with the date of the quality control check, the initials of the analyst that performed the check, and the results of that check.

8.0 Reference Material

8.1 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.

9.0 Primary and Secondary Reference Materials

9.1 Authenticating documentation for all primary and secondary reference materials shall be maintained by the Section Drug Standards Coordinator.

9.2 Only reference materials with authenticating documentation may be used in the course of casework to identify controlled substances.

9.3 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.

9.4 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.

10.0 In-house Generated Reference Collections

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

10.2 Current and archived in-house generated spectral reference collections shall be maintained by the Section Drug Standards Coordinator.

10.3 Spectral reference collections 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.

11.0 Drug Chemistry Reference Materials Vault

11.1 A vault containing reference materials shall be maintained by the Forensic Scientist Manager and his/her designees for the Drug Chemistry Section.

11.2 Access to the vault shall be limited to the Forensic Scientist Manager and designated Forensic Scientists.

11.3 A two lock system shall be used so that single entry access is prohibited.

11.4 A record shall be maintained by the Section Drug Standards Coordinator of the vault inventory, the initials of persons entering, date of entries into the vault, the gross weights of reference materials added to and removed from the vault.

11.5 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.

11.6 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.

12.0 Forensic Scientist Personal Reference Materials

12.1 Each Forensic Scientist may maintain a personal inventory of primary and secondary reference materials.

12.2 Forensic Scientists shall maintain a list of all controlled primary and secondary reference materials in their possession.

12.3 A Forensic Scientist may possess only the following amounts of a controlled primary or secondary reference material:

12.3.1 No more than five dosage units (i.e., tablets, capsules or any other form that is intended as a dosage unit).

12.3.2 Five hundred (500) milligrams of a solid material.

12.3.3 Three milliliters of liquid.

12.4 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.

13.0 Training Reference Materials

13.1 Training reference materials shall be documented by the Drug Chemistry Training Coordinator(s) to demonstrate their content.

13.2 Reference materials used for training purposes shall be stored in a secured area. All training reference materials shall be labeled with a unique identifier.

13.3 Access to training reference materials shall be limited to the Drug Chemistry Training Coordinator(s) for the Forensic Scientist Training Program.

13.4 The Training Coordinator(s) shall maintain an inventory and log of training reference materials added and removed.

13.5 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. Unissued commercially acquired proficiency tests may also be used.

13.6 The Training Coordinator(s) 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.

14.0 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
- Drug Acquisition Forms

Revision History		
Effective Date	Version Number	Reason
02/15/2013	1	Original document created from the Drug Chemistry Technical Procedure for Receipt and Quality Assurance of Supplies, Equipment, Reference Collections, Standards and Reagents.
11/15/2013	2	Added issuing authority to header
08/29/2014	3	**9.5 –** removed secondary standards obtained from casework **10.2, 10.3, 10.4** – removed all references to relative retention time indices **13.2** – changed wording for secure area **13.5** – added commercial proficiency tests