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

2.0 Scope – This procedure applies to the Drug Chemistry Section of the Pitt County Sheriff's Office Forensic Services Unit.

3.0 Definitions

- **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 an informed treatise generally accepted in the field that identifies a chemical substance.
- **Approved Vendor -** Supplier of a product or service that meets ISO/IEC 17025:2017 – Forensic Science Testing and Calibration Laboratories Accreditation Requirements
- **Commercial reagent -** Solvent or chemical manufactured or obtained from a commercial source.
- **Controlled Substance** – A drug, substance, or immediate precursor included in Schedules I through VI of the North Carolina Controlled Substances Act, North Carolina Administrative Code, or included in Schedules I through V of the United States Controlled Substances Act.
- **Prepared reagent -** A dilution or mixture of commercial reagents prepared by a Drug Chemistry Section chemist.
- **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 which has documentation issued by the provider authenticating its chemical composition.
- **Quality control (QC) check -** Confirmation of the reliability of equipment, instrumentation, and/or reagents.
- **Secondary reference material** - Any reference material used in the course of casework that has its chemical composition verified by reference material.
- **Verification** – Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled.

4.0 Receipt of Supplies, Equipment, Reference Materials and Reagents

4.1 Prior to use, received supplies, equipment, reference materials and reagents shall be inspected for compliance with specifications in the order by the Technical Leader or designee.

4.2 Materials found to meet specifications shall be marked with the initials of the Technical Leader or designee and the date of receipt. Materials that do not meet specifications shall be handled according to the Laboratory Procedure for Reference Standards and Materials.

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

4.3 Upon receipt of reference materials the Technical Leader or designee 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 employee who opened the container.

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 Document Management System (DM) 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 can be assigned using lot number designations listed in the discipline technical procedures.

6.2 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 technical procedures for format) or date of preparation.

6.3.3 Initials of preparer.

6.3.4 Quality control check due date, or expiration date as applicable.

6.4 Each new stock solution or use container of prepared reagents shall be documented in the reagent log in DM in accordance with QSP 5-6-1 – Reference Standards and Materials, unless otherwise specified in a specific technical procedure.

6.5 Quality Control Checks

6.5.1 Quality control checks of reagents shall be documented in the reagent log with the following, unless otherwise specified in this document:

6.5.1.1 Date performed.

6.5.1.2 Chemist who performed the check.

6.5.1.3 Identifier of the standard used.

6.5.1.4 Whether the reagent worked as expected (negative and positive checks).

6.5.1.5 Due date for next quality control check.

6.5.2 Prepared reagents shall be quality control checked according to the 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. This applies to use containers only, or if stock containers are used directly.

7.0 Literature References

7.1 In rare circumstances where primary and secondary reference materials are not available, literature references 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.

8.0 Primary and Secondary Reference Materials

8.1 Authenticating documentation for all primary and secondary reference materials shall be maintained in DM by the Technical Leader or designee.

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

8.3 The Technical Leader (or his/her designee) shall analyze primary reference materials on selected in-house instrumentation prior to release for casework. The data produced shall be qualitatively evaluated by the Technical Leader to ensure it is substantially comparable to authenticating documentation, reference material, and/or published spectral libraries.

8.4 The Technical Leader 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 Pitt County Sheriff's Office Forensic Sciences Unit, or the North Carolina State Crime Laboratory Drug Chemistry Section.

8.5 Expiration date, if applicable.

8.5.1 If an expiration date is not supplied by the manufacturer, or if the expiration date passes and the reference material has not been fully consumed, the material shall be reassessed (as outlined above) prior to use in casework to ensure the quality of the reference material. Reassessment information shall be approved by the Technical Leader or his/her designee and stored in DM.

8.5.2 Reference materials that are used to QC check prepared reagents shall be reassessed annually.

8.5.3 This reassessment may be completed prior to or concurrent with casework as appropriate.

9.0 In-house Generated Reference Collections

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

9.2 Current and archived in-house generated spectral reference collections shall be maintained by the Technical Leader or his/her designee.

10.0 Reference Materials Lock Box

10.1 The lock boxes containing the controlled substance reference materials shall be maintained in the Pitt County Sheriff's Department Evidence Control Unit by the Technical Leader or his/her designee for the Drug Chemistry Section.

10.2 Access to the contents of the lock boxes shall be limited to the Technical Leader or his/her designee.

10.3 A two person system shall be used so that single entry access is prohibited.

10.4 A record shall be maintained in the evidence control unit by the Technical Leader or his/her designee of the date and initials of persons assisting in access. The gross weights of reference materials added to and removed from the lock box shall be documented in the Controlled Substance Standards Inventory, and archived in DM.

10.5 Reference material containers in the lock boxes shall be labeled by the Technical Leader or his/her designee with a unique identifier.

10.6 An audit of the lock boxes shall be conducted annually in the last quarter of each year by the Technical Leader and his/her designee, and documented by the Technical Leader in a memorandum to the Quality Manager of the Pitt County Sheriff's Office Forensic Sciences Unit.

11.0 Chemist Personal Reference Materials

11.1 Each chemist in the Drug Chemistry Section may maintain a personal inventory of primary and secondary reference materials.

11.2 Chemists shall maintain a list of all controlled primary and secondary reference materials in their possession.

11.3 A Chemist may possess only the following amounts of a controlled primary or secondary reference material:

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

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

11.3.3 Three milliliters of liquid.

11.4 An annual inspection of the personal inventory of primary and secondary reference materials maintained by each Chemist shall be conducted in the last quarter of each year by the Technical Leader and his/her designee. The inventory shall be signed and dated by the Technical Leader and his/her designee to signify that the inventory is correct.

12.0 Training Reference Materials

12.1 Training reference materials shall be documented by the Technical Leader to demonstrate their content.

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

12.3 Access to training reference materials shall be limited to the Drug Chemistry Section Technical Leader or designee.

12.4 The Technical Leader or designee shall maintain an inventory and log in DM of training reference materials added and removed.

12.5 Material identified by a Chemist that is suitable for use in training or as reference material shall be documented on a Court Order to be placed in the case file. The Court Order shall be forwarded to the Prosecuting Attorney for disposition by the Quality Manager or designee.

12.6 Only primary/secondary reference materials shall be used to prepare the components of competency tests. Unissued commercially acquired proficiency tests may also be used.

12.7 The Technical Leader or designee shall conduct an annual inspection in the last quarter of each year 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 Quality Manager.

13.0 Records

- Receipts/packing slips for purchased supplies, equipment, standards, and reagents
- Inventories/use logs of primary and secondary standards
- Certificates of Analysis for primary reference material
- Reagent logs
- Container labels
- QC data generated from reference materials
- Court Order

REVISION HISTORY		
CURRENT VERSION	**EFFECTIVE DATE**	**SUMMARY OF CHANGES**
1	2017/11/14	Original Document.
2	2018/04/01	**Title** – Added "Drug Chemistry" **Purpose, 4.0, 4.1** – Updated "standards" to "reference materials" **Definitions** -Removed definition of Critical Reagent. Added Controlled Substance and Verification definitions. Alphabetized definitions. **7.1** – Replaced "reference material" with "literature references." **8.5** – Added expiration date requirements for reference materials.
3	2018/10/22	**Entire document –** Updated "Illicit Drugs Discipline" to "Drug Chemistry Section". Corrected typos. Added "or his/her designee" **7.0** – Replaced "Reference Material" with "Literature References"**10.4** – Added "and archived"
4	2020/01/15	**Header – Updated "Instruments" to "Drug Chemistry"** **Definitions** – Added "Approved Vendor" **8.3** - Added "or designee" for analysis and TL for evaluation of data collected on new primary standards. **10.0** and **11.0** – Made lock boxes plural, and added "or his/her" to designee. Changed responsibility for all yearly controlled substance standards inventory to TL, and memo written from TL to QM.