Toxicology 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 Toxicology in the Raleigh, Triad, and Western locations of the State Crime Laboratory.

3.0 Definitions – see Toxicology Definitions list

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 Toxicology Supply Coordinator or designee.

4.2 Materials found to meet specifications shall be marked with the initials of the Supply Coordinator for Critical Consumables 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 Supply Coordinator for Critical Consumables or designee and the date of receipt. This packing slip will be maintained by the Supply Coordinator for Critical Consumables or designee with a copy of the order.

4.3 Upon receipt of reference materials and critical reagents the Supply Coordinator for Critical Consumables 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 N/A (not applicable).

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

5.3.1 Manufacturer's lot number with regional lab designation added

5.3.1.1 Example: 123456 – R

5.3.2 Date received.

5.3.3 Manufacturer.

5.3.4 Description.

5.3.5 Expiration date, if applicable.

6.0 Prepared Reagents – Daily use solutions such as Base SPE Elution and 2% HCl in Methanol are exempt from these requirements.

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

6.2 All prepared reagents with pending quality control checks shall be maintained separately from approved quality control checked prepared reagents.

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 with regional lab designation added (see example in 5.3.1).

6.3.3 Initials of preparer.

6.3.4 Expiration date.

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 with the following:

6.4.1 Lot number.

6.4.2 Created date.

6.4.3 Preparer.

6.4.4 Expiration date

6.4.5 Description (optional) – Identity of reagent.

6.4.6 Components - List the following items used in the preparation as applicable:

- Reagents
- Stock solutions
- Pipettes
- Balance
- pH meter
- Traceable volumetric glassware

6.5 Negative Blood/Urine Preparation

6.5.1 Negative Blood supplied as packed red blood cells will be reconstituted using the following steps prior to conducting the quality control check:

6.5.1.1 Dissolve 4.4 grams of sodium chloride in 500 ml of dH_2O.

6.5.1.2 Pour in the packed red blood cells and swirl to mix thoroughly.

6.5.1.3 Proceed to **6.5.2.1**. Follow through **6.5.2.5** for complete preparation.

6.5.2 Negative Blood supplied as whole blood from blood banks:

6.5.2.1 Measure the volume of blood received and add sodium fluoride (NaF) based on 1% w/v of whole blood.

6.5.2.1.1 Example: 400 ml blood * 0.01 = 4.0 g of NaF added

6.5.2.2 Store in a refrigerator in a glass container.

6.5.2.3 Assigned the lot number as " YYYYMMDD" (date prepared as the 4-digit year, 2-digit month, and 2-digit day).

6.5.2.4 Quality Control Checked every six months to monitor stability.

6.5.2.5 Expiration date: 1 year.

6.5.3 Negative Blood supplied by a commercial manufacturer:

6.5.3.1 Store in the freezer until ready to thaw for use.

6.5.3.2 Store use containers in a refrigerator.

6.5.3.3 Use manufacturer's lot number.

6.5.3.4 Expiration date: follow manufacturer's recommendation.

6.5.4 Negative Synthetic Urine

6.5.4.1 Store in refrigerator.

6.5.4.2 Use manufacturer's lot number.

6.5.4.3 A pH check shall be performed prior to use with casework.

6.5.4.3.1 The acceptance range for the pH shall be 6.0 – 7.0.

6.5.4.4 Expiration: 6 months.

6.6 Quality Control Checks

6.6.1 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
- Results of any QC checks required in Solution Prep Guidelines
- Quality Control Check due date

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

6.6.3 Quality control checks shall be performed and documented in FA Resource Manager 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.

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

6.6.4 Expiration dates may be extended after the review and approval of QC Check results by the Toxicology Technical Leader

7.0 FA Workstations

7.1 A Resource Manager workstation shall be created for procedure related calibrations, quality control checks and sample analysis. The workstation shall be named with the date and the procedure and shall contain the following when used:

7.1.1 Workstation ID

- Example: BSPE20151001

7.1.2 Created date.

7.1.3 Preparer.

7.1.4 Description (optional) – Identity of procedure.

7.1.5 Comments as applicable such as below:

- Thawed expiration date of reagent
- Lot number and expiration date of reagents not listed in the FA resource

7.1.6 Components - List the following items used in the preparation as applicable:

- Reagents
- Stock solutions
- Pipettes
- Balance
- pH meter

- Traceable volumetric glassware

8.0 Critical Reagents

8.1 Critical reagents shall be quality control checked by the Toxicology Technical Leader or designee prior to use in casework. Upon successful completion of the check, the Toxicology Technical Leader or designee shall review and approve the data, and the Technical Leader shall maintain the associated records in FA.

8.2 All critical reagents with pending quality control checks shall be maintained separately from approved quality control checked critical reagents.

8.3 Negative Blood/Urine - for each new lot received.

8.3.1 Quality control check: Analysis by ELISA following the critical reagent QC check outlined in the Enzyme Immunoassay procedure.

8.3.1.1 Records: The ELISA data and corresponding QC data will be marked by the Forensic Scientist who generates the data with his/her name, name of the supplier, and lot number.

8.3.2 Quality control check: Analysis by extraction procedures followed by instrumental analysis shall show the absence of reportable substances referenced in the Drug Toxicology Reporting procedure.

8.3.2.1 Records: The data will be marked by the Forensic Scientist who generates the data with his/her name, name of the supplier, and lot number.

8.4 Immunoassay Microplate and Conjugate – for each new lot received:

8.4.1 Quality control check: Analysis by ELISA following the critical reagent QC check outlined in the Enzyme Immunoassay procedure.

8.4.1.1 Records: The ELISA data will be marked by the Forensic Scientist who generated the data with his/her name, name of the supplier, lot number of the microplate and lot number of the corresponding conjugate.

8.5 Immunoassay Calibration/Verification Standards – for each new lot prepared/received:

8.5.1 Quality control check: Analysis by ELISA following the critical reagent QC check outlined in the Enzyme Immunoassay procedure.

8.5.1.1 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.

8.6 Commercial Multi-component Alcohol Certified Standard Solutions

8.6.1 Quality control check: Analysis in duplicate by Headspace Gas Chromatography shall identify the listed components. Each component shall quantify within +/- 5.0 % of the certified concentration.

8.6.2 Records: The chromatograms shall be marked by the Forensic Scientist who generated the data with his/her name, name of the supplier, and lot number of the standard.

9.0 Primary and Secondary Reference Materials

9.1 Authenticating documentation for all primary and secondary reference materials shall be maintained by the Toxicology Technical Leader in FA.

9.2 The Toxicology Drug Standards Coordinator shall analyze primary and secondary 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.

9.2.1 The data shall be reviewed and approved by the Toxicology Technical Leader or designee prior to use with casework

10.0 In-house Generated Reference Collections

10.1 Spectral reference collections and Relative Retention time indices generated within the Laboratory will be traceable to primary or secondary reference materials.

10.2 Current and archived in-house generated spectral reference collections and relative retention time indices shall be maintained by the Toxicology Technical Leader in FA.

11.0 Toxicology Reference Materials

11.1 Reference materials used in Toxicology casework shall be stored in a secured area.

11.1.1 Access shall be limited to the Forensic Scientist Manager, Forensic Scientist Supervisors, and Forensic Scientists assigned to Toxicology.

12.0 Limitations

12.1 Trainees shall be supervised by individuals with appropriate work authorization when performing actions (e.g., solution preparations, QC work, instrument operation) that have a direct impact on casework.

13.0 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

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	**6.6** - Added Removed **7.2** – Chemical Derivatizing Agents Inserted new **7.2** **7.3** and **7.4** consolidated **7.3.1, 7.4.1, 7.5, and 7.5.1** – Modified to reflect changes in Technical Procedure for ELISA Drug Screen **7.3.2** – Modified to reflect new procedures and instrumentation, removed requirement for the TL marking the containers **7.5.1** - removed requirement for the TL marking the containers **7.6 –** Clarified requirement, removed requirement for the TL marking the containers, inserted requirement of TL to review and approve data **8.1** – Removed requirement to store on the section share drive
03/20/2015	4	**6.4.7** - added reference to Stock solutions **6.4.7.1 and 6.4.7.2** - removed since added to 6.4.7 **6.4.7.3** - removed, not applicable **6.5.3** - added documentation location **7.3, 7.3.1, 7.3.1.1, 7.3.2, and 7.3.2.1** - reworded to simplification **7.3.3** - added instructions for the preparation of Negative Blood from packed cells. **7.2, 7.3.2, 7.4.1.1, and 7.6.2** - reworded for clarification
02/12/2016	5	**2.0, 5.3.1, 6.3.2 -** added regional lab designations **4.2, 4.3, 4.2.1, 8.1, 8.3, 8.4, and 9.4 -** changed name to match with designation in Toxicology Work Authorization 6.4 (and sub-sections) - re-worded. 6.5.1 (and sub-sections) - re-worded. New 7.0 - added "FA Workstations" section 8.3.3.5 (old 7.3.3.5) and new 8.3.3.6 - modified QC check and expiration schedule. 8.3.4 and 8.3.5 - New sections 8.6.1 (old 7.6.1) - modified 9.1 (old 8.1) - changed responsible position 8.2 - removed 9.2 (old 8.3) - modified Old 8.4 - modified and moved to 9.2.1 10.1 (old 9.1) - added RRT indices 10.2 (old 9.2) - modified person responsible and location Old 9.3 and 9.4 - Removed

02/22/2019	6	3.0 – updated definition 6.0 – added exemption for daily use solutions 6.5 – updated QC documentation requirements 6.5.4 - added 7.1.1 – updated example 8.1, 9.1 and 10.2 - Added "in FA" 8.3.1, 8.3.2, 8.4.1, 8.5.1 – moved "procedure" and updated procedure name 8.3.3 through 8.3.6 moved - new 6.5 – restructured and simplified naming convention 9.2.1 Added "or designee" 12.1 – added