



TENNESSEE BUREAU OF INVESTIGATION

Forensic Services Division

Toxicology Quality Assurance and Procedures Manual

6.3 Reference Material

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The following section is used to ensure that reference material used in the Toxicology Unit is documented, fit for use, properly labeled, and traceable.

6.3.1 Receipt

6.3.1.1 Reference material at the highest purity shall be purchased from reliable vendors and should be traceable to a certified source. When reference material is not available from typical vendor sources, the manufacturer should be contacted for direct supply.

6.3.1.2 Reference material used to make multiple reference standard solutions (i.e., calibrators and controls) should be acquired from separate vendors; however, this may not always be possible given limited availability of certain reference materials.

6.3.1.3 Reference materials shall be administratively verified upon receipt by comparing the request for purchase to the packing slip, copy of the purchase order, etc. Verification shall be made by signing/initialing and dating the purchasing documentation. A copy of this documentation shall be maintained within the Toxicology Unit for at least six years.

6.3.1.4 After a reference material is administratively verified, a drug standard log sheet shall be filled out and reflect, at a minimum, the identity of the drug, source, lot number, date received and by whom, and expiration date. If applicable, the initial gross sample weight of the unsealed container, number of ampules/containers, starting sample weight, concentration, or any other pertinent information should be documented as well. These drug standard log sheets shall be maintained within the drug logbook.

6.3.1.5 A certificate of analysis should be obtained from the manufacturer and placed in the drug logbook following the appropriate log sheet.

6.3.1.6 Each container shall then be labeled to ensure that it is unique and can be traced back to the corresponding log sheet (e.g., date received and by whom, sequential identification, etc.).

6.3.1.7 Reference material shall be stored, handled, transported, and used following manufacturer recommendations.

6.3.2 Verification

6.3.2.1 Reference material shall be verified by a certificate of analysis. If a certificate of analysis is not available, the reference material shall be verified by GC/MS or LC/MS/MS. This verification may be done concurrently with sample analysis (unless sample volume is limited). The verification (i.e., mass spectrum with date and initials and appropriate library match) shall be placed in the drug logbook following the appropriate log sheet.



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6.3.2.2 If the verification of the reference material does not work as expected, it shall be removed from use, destroyed, and a new reference material shall be obtained/opened. This shall be documented in the drug logbook.

6.3.3 Use

6.3.3.1 Any use of a reference material shall be documented as to the purpose, date, amount used, and by whom.

6.3.3.2 When reference standard solutions are prepared, it shall be documented in the drug logbook and reflect, at a minimum, the identity of the drug (including concentration), date of preparation, initials of the preparer, and expiration date.

6.3.3.3 These solutions shall be stored in appropriate containers and labeled, at a minimum, with the identity of the drug standard solution, date made, and initials of the preparer.

6.3.3.4 Appropriate solvents should be used to prepare reference standard solutions. Consult the appropriate reference books (e.g., *Clarke's Analysis of Drugs and Poisons*) for guidance on drug solubility.

6.3.3.5 Water used for reference standard solution preparation shall be distilled, reverse osmosis, deionized, or higher grade.

6.3.3.6 Lot numbers of internal standards shall be the same for all samples in an analytical batch.

6.3.4 Expiration

6.3.4.1 Reference material in powder form shall expire according to the expiration date provided by the manufacturer. If an expiration date is not provided, an administrative expiration date shall be set at five years from the date received.

6.3.4.2 Reference material in solution (e.g., ampules, reference standard solutions) shall expire according to the expiration date provided by the manufacturer or one year after being opened/made, whichever comes first.

6.3.4.3 In the event that reference material is used past the expiration date, it shall be verified for fitness of use. This verification may be done concurrently with sample analysis (unless sample volume is limited). The verification shall be documented and be included in each standard packet where applicable.

6.3.4.4 Reference material shall be secured and inventoried once a year.