6.2 Reagents

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

6.2.1 Receipt

6.2.1.1 Reagents shall be purchased from reliable vendors and should be traceable to a certified source.

6.2.1.2 Reagents and supplies 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.

6.2.1.3 After a reagent is administratively verified, a log sheet shall be filled out and reflect, at a minimum, the identity of the reagent, source, lot number, date received and by whom, and expiration date. These log sheets shall be maintained within the reagent logbook.

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

6.2.1.5 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, date opened and by whom, sequential identification, etc.).

6.2.1.6 Reagents shall be stored, handled, transported, and used following manufacturer recommendations.

6.2.2 Verification

6.2.2.1 All reagents 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 with the analysis of a positive and negative control and be included in each standard packet where applicable.

6.2.2.2 If any reagent does not work as expected, it shall be removed from use, destroyed, and a new reagent shall be opened/prepared. This shall be documented in the reagent log.

6.2.3 Use

6.2.3.1 Any use of a reagent shall be documented as to the purpose, date, and by whom.

6.2.3.2 When a reagent is prepared, it shall be documented in the reagent log and reflect, at a minimum, the identity of the reagent prepared, date of preparation, initials of the preparer, and expiration date.

6.2.3.3 These reagents shall be stored in appropriate containers and labeled, at a minimum, with the identity of the reagent, date filled/prepared, and initials.

6.2.3.4 Water used for reagent preparation shall be distilled, reverse osmosis, deionized, or higher grade.

6.2.3.5 Lot numbers of reagents shall be the same for all samples in an analytical batch.

6.2.4 Expiration

6.2.4.1 Reagents 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.

6.2.4.2 Reagents prepared in the Toxicology Unit shall expire according to the expiration date provided by the manufacturer, the administrative expiration date, or one year after being made, whichever comes first.
Note: Reagents with shorter expiration dates shall be specifically listed in the appropriate procedure (e.g., Benzoylecgonine Elution Solution).

6.2.4.3 In the event that a reagent must be used past the expiration date (e.g., chemicals such as ethyl ether or chloroform that have short manufacturer expiration dates), the analysis of a known standard/control and negative control shall serve to demonstrate the fitness of use for that reagent. This shall be documented and be included in each standard packet where applicable.