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2.5 Standards, Controls and Reagents

2.5.1 Standards and Controls

Standards and controls prepared in-house or obtained commercially must be verified prior to use unless accompanied by a Certificate of Analysis traceable to a reference material or reference standard that is either:

- a) a National Metrology Institute that is a signatory to the BIPM - CIPM Mutual Recognition Arrangement with the certified reference material listed in the BIPM key comparison database (KCDB).

OR

- b) an accredited reference material producer that is accredited to ISO Guide 34:2009 or ISO 17034 by an accrediting body that is a signatory to a mutual or multilateral recognition arrangement in an ILAC recognized regional accreditation cooperation or the ILAC Mutual Recognition Arrangement, with a scope of accreditation covering the certified reference material.

It may be worth noting that materials used solely for evaluation of measurement precision need not comply with the requirements for measurement traceability.

2.5.1.1

In-house standards and controls must be tested against currently used and previously verified known standards/controls. Evidence of this testing shall be maintained in the respective unit.

2.5.1.2

The Unit Supervisor shall ensure the documentation for verification of standards and controls is maintained and made available to all employees utilizing those standards and controls.

2.5.1.3

The protocols for use, storage and handling of standards and controls are found in the discipline specific procedures manuals.

2.5.2 Reagents

2.5.2.1

Reagents shall be reliability tested prior and/or concurrent to their use in casework. The routine recorded use of appropriate controls is a suitable method to ensure the continued reliability of reagents. The recorded use of appropriate controls shall be maintained in the case file record or as required in section 2.5.2.2 of this procedure.

2.5.2.2

If not recorded in the case file, a reagent log form (electronic or hard-copy) shall be kept for all internally prepared batch reagents and will include at a minimum, the identity of the reagent and the preparation date or lot number. Records maintained shall identify the preparer of the reagent, the components used

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in preparation and/or testing, who tested it, the components used in preparation and that it worked as expected. The discipline specific procedure manuals shall provide further guidance on the maintenance and storage of records of preparation and verification of reagents.

2.5.2.3

Reagents prepared for a single analysis or daily use and disposal shall be documented in the case record. It is not necessary to record these reagents in the reagent log.

2.5.2.4

If during the course of use, a reagent's reliability is questioned or unsatisfactory, then the reagent shall be removed from circulation to prevent use, and may be destroyed or disposed as appropriate. The removal of the questionable reagent from circulation shall be documented in the reagent log.

2.5.2.5

Specific requirements dealing with the formulation of reagents and quality control of reagents are found within the discipline specific procedure manuals. The protocols for use, storage and handling of reagents are found in the discipline specific procedures manuals.

2.5.2.6

Unmixed and stored chemicals, solvents and cleaning solutions are not considered reagents and as such, are not subject to the requirements of this section.

2.5.2.7

The expiration date for Biology and DNA in-house prepared reagents shall be indefinite for those stored frozen or refrigerated in un-opened aliquots and one year for opened, in-use aliquots. Commercial reagents that do not have an expiration date shall be indefinite, unless they are considered a critical reagent whereby the expiration date shall be two years from the date the aliquot is opened. If the commercial reagent has no expiration date, is in powder form and is pre-measured for future use and stored under similar conditions to the original, the expiration date shall be indefinite. The open date and expiration date shall be clearly noted on the reagent container.