A. PURPOSE:

The quality of the reagents and standards used in the Unit must meet the requirements of the procedures they are used for. Reagents and standards must be maintained in a manner as to protect them from contamination and to assure that they work as expected.

B. RESPONSIBILITY:

Analysts assigned to the Unit.

C. SAFETY:

Appropriate PPE must be used at all times when working with reagents and standards.

1. Chemical hazards: when handling chemicals analysts must observe the safety hazard ratings of the substance
2. Drugs: many of the drug standards can be absorbed through the skin; these include but are not limited to Fentanyl, PCP, LSD and DMT analysts must take caution (e.g., safety glasses, gloves, lab coat) when working with drug standards.

D. PROCEDURE:

1. REAGENTS:

a. Labeling

i. All reagents must be labeled with a minimum of:

a) Reagent name

b) Date made (this can act as the lot number with the prepares initials)

c) Expiration date

d) Preparer's initials

e) Safety Diamond with safety ratings, if required

b. Validation

i. All reagents must be verified and be deemed appropriate for use with the method prior to use in reporting case results.

ii. When multiple quantities are received and they all have the same lot number, then only one of the reagents of the same lot needs to be verified. Once one is verified, then all the reagents containing the same lot number will be considered verifed and can be used within casework.

iii. Ensure that the reagent provided acceptable performance with both the positive and negative controls.

a) Both the negative and positive controls should have no unexplained peaks by GC/MS.

b) It is rare that a reagent is used for any other procedure than an extraction where the final product will be analyzed by GC/MS. If this does occur the analyst must demonstrate that the reagent is appropriate in that analytical method.

iv. When possible, a newly prepared lot of reagent will be run contemporaneously with a previously verified lot. The newly prepared lot and old lot must demonstrate similar performance.

v. A Reagent Validation Sheet is completed and combined with the analytical data printout (usually the GC/MS TIC).

a) Validation data is reviewed by another analyst, Lead Examiner or higher prior to acceptance.

b) When completed, this paperwork is filed in the "Reagent Validation" log book maintained in the Unit or stored electronically.

vi. Accepted reagents are annotated by the addition of a green “sticker” to the label or stock bottle.

a) The green sticker will have the method verified for, the date verified and the initials of the person validating the reagent. (example: plant extr. 10/10/10 jmr)

b) When the solution verified is a straight solvent, a sticker may be put on all solvent bottles with the same lot number.

c. Expiration Dates

i. Expired materials will not be used within casework.

ii. In-house preparations

a) Expiration dates for in-house prepared materials will be one year from the date of material preparation.

b) If a component used to prepare the material has an expiration date earlier than one year, that date will be used for the entire material.

iii. Purchased Materials

a) Follow the manufacture expiration dates.

b) Expiration dates with just a month and a year will be considered expired on the last day of that month.

c) If a manufacture expiration date is not provided, the material will be assigned an expiration date five years from the date of receipt.

d. Traceability

i. Purchased reagents come with a certificate of analysis for each lot; this is to be filed in the appropriate log book or electronically within the section.

2. <u>STANDARDS</u>:

a. Labeling

i. All standards must be labeled with a minimum of:

a) Compound Name

b) Date received and the initials of the person receiving the vial

c) Lot Number (for in-house prepared standard solutions, this is also the "Date Made")

d) Date opened and initials of the person opening the vial.

b. Validation

i. Standards must be verified and be deemed appropriate for use with the method prior to, or contemporaneously to, use in reporting case results

ii. The peak of interest must be present with a good visual spectral match to a published library. The published library match should at least 90%. If match is less than 90% consult a unit lead or higher.
   a) These include but are not limited to the WILEY, SWGDRUG, and PMW libraries and references published in journals such are Micrograms or Journal of Analytical Toxicology, or other reference books such as Clarks or the IDDA.
   b) For "new" compounds where published references are not available the certificate of analysis data sheet can be used to compare the spectra obtained by the Unit to that of the provider of the compound.

iii. Other peaks if present, must be explainable. (Example: 6-MAM in a heroin standard.)

iv. Analysts noting a significant amount of extraneous peaks in the TIC will evaluate the fitness of the standard. In general if extraneous peaks are present at approximately half the peak height of the target compound the standard will be discarded.

v. A Standard Validation Sheet is completed and combined with the analytical data printout (usually the GC/MS TIC)

vi. Validation data is reviewed by another analyst, lead examiner or higher prior to acceptance.

vii. When completed, this paperwork is filed in the "Reagent Validation" logbook maintained in the unit or electronically.

viii. If the standard is verified through FTIR, the acceptability will be noted on the standard validation sheet.

ix. Standards shown to be acceptable as qualitative standards by GC/MS may be used in different methods without verification on that instrument (example: caffeine is used as an internal standard for GC/MS, it need not be verified by FTIR first if it is verified by GC/MS).

c. Expiration Dates

i. Follow the same procedures as for Reagents

d. Traceability

i. Standards come with a certificate of analysis for each lot; this is to be filed in the Standard validation book or electronically within the section.

ii. When working with standards (either DEA non-exempt or DEA exempt) the analyst must maintain the traceability of the standard.

iii. The lot number for in-house prepared or purchased standards will be recorded on the GC/MS paperwork, which is stored in the case file, so that the standard can be traceable to its source.

B. **REFERENCES**:

- Clark's Isolation and Identification of Drugs in Pharmaceuticals, Body Fluids, and Post-Mortem Materials, The Pharmaceutical Society of Great Britain