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. All reagents must be labeled with a minimum of:

- Reagent name
- Date made (this can act as the lot number with the prepares initials)
- Expiration date
- Preparer's initials
- Safety Diamond with safety ratings, if required

b. All reagents must be validated and be deemed appropriate for use with the method prior, or contemporaneously to, use in reporting case results. The validation process is generally to:

- When multiple quantities are received and they all have the same lot number, then only one (1) of the standards of the same lot needs to be validated. Once one is validated, then all the standards containing the same lot number will be considered validated and can be used within casework.
- Use the reagent in the method with appropriate control materials (positive and negative).
- Ensure that the reagent provided acceptable performance with both the positive and negative controls.
  - Acceptable performance: assure both the negative and positive controls have no unexplained peaks by GC/MS. Note that 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.

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

- A Reagent Validation Sheet is completed and combined with the analytical data printout (usually the GC/MS TIC).
  1. Validation data is reviewed by another analyst, Lead Examiner or higher prior to acceptance.
  2. When completed this paperwork is filed in the "Reagent Validation" log book maintained in the Unit or stored electronically.
- Accepted reagents are annotated by the addition of a green "validation sticker" to the label. The green sticker will have the method validated for, the date validated and the initials of the person validating the reagent. (example: plant extr. 10/10/10 jmr)
- If appropriate, the stock reagent bottle(s) is appropriately annotated with the new validation information (green validation sticker). When the solution validated is a straight solvent, a validation sticker may be put on all solvent bottles with the same lot number.
- Expired materials will not be used within casework. Expiration dates with just a month and a year will be considered expired on the last day of that month.
- Expiration dates for in-house prepared materials will be one year from the date of material preparation. If a component used to prepare the material has an expiration date earlier than 1 year, that date will be used for the entire material.
- Purchased materials will follow the manufacture expiration dates. If a manufacture expiration date is not provided, the material will assigned an expiration date 5 years from the date of receipt.

2. <u>STANDARDS</u>:

a. Standards for Non-Controlled Substances:

- Standards for non-controlled substances can be maintained in both the controlled substance and the toxicology unit.

b. Standards for Controlled Substances:

- Standards for Controlled Substances used as comparison references generally come in two forms "pure", usually powder, or liquid DEA exempt solutions. In rare occasions

manufactured tablets will be used as comparison standards these are generally obtained from drug control.

- "Pure" Scheduled Standards: these are maintained within the Controlled Substance safe and locked drug refrigerator.(See SOP CS-11)

- DEA exempt standards are maintained in a refrigerator or freezer within the CS or Toxicology sections..

c. **Qualitative Standards**:

1. 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.

2. Once opened the standard will be transferred to a GC/MS or other similar sealable vial and labeled with the name of the compound, date opened, lot number and initials of the person opening the vial.
    1. Expiration dates are based on manufacture guidance.
3. Standards will be run by GC/MS or other instrument as appropriate and evaluated prior to use with casework.

   For GC/MS:

   i. The peak of interest must be present with a good visual spectral match to a published library. The published library match should at least 95%. If match is less than 95% consult a unit lead or higher.

   ii. 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.
       1. 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. An example of this is may be 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 validated through FTIR, the acceptability will be noted on the standard validation sheet.

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

d. **Traceability of Standards**:

1. When working with standards either "pure" or DEA exempt standards the analyst must maintain the traceability of the standard.
2. 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.

E. **REFERENCES**:

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