A. **PURPOSE**:

Many of the standards used within the Controlled Substances Unit are controlled under federal or state regulations, such as the Controlled Substance Act. There are requirements for the storage and access of these substances that must be maintained. These requirements involve maintaining drug licenses from both the Drug Enforcement Agency (DEA) and the State of Connecticut's Department of Consumer Protection – Drug Control Division. This procedure outlines activities such as the procurement, storage, accessioning, and inventory of controlled substance reference standards within the CS Unit.

Controlled Substances Standard pertains to those which are scheduled under the Controlled Substances act or regulated by State of Connecticut Department of Consumer Protection. Standards associated with drugs available by prescription only are exempt from this procedure. Any standard obtained using the laboratory's DEA license is considered to have non-exempt status, and should be treated accordingly. If at any point after the purchase of a standard using a DEA license, the standard becomes DEA Exempt per the manufacture, the standard may be treated like a DEA Exempt standard from that date forward.

B. **RESPONSIBILITY**:

1. Analysts (e.g.. FSE1): Ensures that they properly handle, store, and keep inventory of controlled substance standards according to this procedure.
2. Supervisor and FSE2: Ensures that controlled substance standards are maintained in a manner consistent with this procedure as well as with both state and federal regulations. They also are responsible for ensuring that all quality documents associated with controlled substance standards (e.g., certificates of analysis (CoA), inventory logs) are properly maintained.
3. Management: Ensures that controlled substances are properly maintained by appropriate staff and are knowledgeable about changes to drug laws which pertain to the storage and accountability of controlled substances. They also are responsible for ensuring both state and federal drug licenses are kept current.

C. **SAFETY**:

1. Appropriate PPE will be worn when handling controlled standards. These substances are in their pure form and many can absorb directly through the skin.

D. **PROCEDURE**:

1. Intake / Receiving of New Standard
    a. Mark the date received with the analyst's initials and the expiration date on the standard's container.
        i. This information may be placed on a larger container if the primary container is too small or not conducive to writing.

b. Record the standard electronically (i.e. in LIMS) or using appropriate form.
c. Ensure that the current Certificate of Analysis is stored electronically.
d. DEA Non-Exempt Standards
    i. Record the gross weight (container and contents) of the standard electronically (i.e. in LIMS) or using appropriate form.
    ii. Store in either a safe or a lockable refrigerator/freezer. Standards are stored according to manufacturer recommendation.
e. DEA Exempt Standards
    i. No additional procedures upon intake

2. Initial Opening
    a. Record the date opened and the analyst's initials on the outside of the standard's container. This information should also be recorded electronically (i.e. in LIMS) or using appropriate form.
    b. DEA Non-Exempt Standards
        i. No additional procedures upon opening the standard
    c. DEA Exempt Standards
        i. No additional procedures upon opening the standard

3. Handling/Accountability
    a. DEA Non-Exempt Standards
        i. Only staff associated with the Controlled Substances Unit have access to controlled substance standard storage areas. If a standard is needed within another Unit it will be obtained through staff associated with the CS Unit and appropriately documented as to the reason for the transfer.
        ii. Standards are retrieved from either the combination safe or from the locked refrigerator/freezer and the storage location is closed immediately after retrieval.
        iii. Analysts must transfer the standard into their custody via LIMS.
            a) This transfer will serve as documentation of access to the storage area.
            b) Ensure that the correct standard and lot number is transferred.

            Note: If the safe or locked refrigerator/freezer is accessed for a reason outside of retrieving a standard, this action will also be documented via LIMS.

    b. DEA Exempt Standards

i. These standards are kept in a refrigerator/freezer within the CS Unit that does not have a combination safe or lock.
ii. Access to these standards does not need to be documented

4. Dispensing / Disposal
   a. DEA Non-Exempt Standards
      i. The following must be documented (electronically or using appropriate form) when dispensing the standard:
         a) Date of the analyst taking the drug standard and reason for use.
         b) Starting weight of the container (and contents).
         c) Weight/Volume of the standard being taken.
         d) Ending weight/remaining volume of the container (and contents).
      ii. Return the standard to the appropriate storage area.
      iii. If the substance is consumed, then the analyst (with a witness) will:
         a) Rinse the container with a bleach solution and discard the rinse within an appropriate waste container.
         b) Properly dispose of the container (i.e., glass container in glass disposal box).
         c) Fill out the 'Controlled Substance Disposition Record' (CS-11.2) form and file in the appropriate binder (or electronic alternative).
      iv. Disposals can be performed through either dilutions [to under 1 mg/mL and placed into an organic waste container] or through transfer to a Dept. of Consumer Protection drug control agent.
         a) Prior to disposing of powder standards via dilution, a lead examiner or higher should be consulted.
   b. DEA Exempt Standards
      i. Standards may be disposed of with sample solution waste.
5. Inventory (Annual)
   a. DEA Non-Exempt Standards
      i. Inventory must include any DEA Non-Exempt powders and liquids.
      ii. Every year, no less than 11 months or more than 13 months from the last inventory, an inventory will be performed of the non-DEA exempt standards stored within the safe and drug refrigerator/freezer. This will be performed by two (2) employees acting as witnesses to each other.
      iii. The two (2) employees will proceed by: .
         a) Ensuring that standards are accounted for.
            i.) Any standards not found will be recorded as such.

b) Weighing the container (and contents) and compare the value to the last recorded weight. Weight will be recorded electronically (i.e. in LIMS) or using appropriate form

i.) The balance used to record the weight should have similar reportable range as used in previous year

c) Noting any weight discrepancies of more than 20%. Any drug standards with weight changes of >20% will be re-weighed in order to verify the discrepant result.

i.) Weight differences are often seen with items that are stored refrigerated/frozen or items that are hygroscopic (absorb water).

d) Generating a report/memo itemizing any discrepancies that are not resolved during the inventory.

iv. Any sheets that are marked "Consumed –bottle discarded" (or similar verbiage) will be removed and placed in the archived records (or flagged accordingly within electronic records).

v. A Unit Manager will review the report and address any issues. The method of addressing the issues may be as simple as a notation (such as a weight gain due to the hygroscopic nature of a drug) or a finding within the DSS Quality Section (e.g., Quality Action Request (QAR)).

b. DEA Exempt Standards
   i. The inventory does not include DEA Exempt Standards.

E. **REFERENCES**:

1. US Controlled Substance ACT (http://www.deadiversion.usdoj.gov/21cfr/21usc/index.html section 827)