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.

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. Inventory (Initial)

a. Acquired standards will have the date received and the analyst will place their initials on the standard's container. This information may be placed on a larger container if the primary container is too small or not conducive to writing.

b. Newly obtained controlled substance standards will be weighed (both container and contents) and information logged with all other controlled substance standards. This information is currently stored through hardcopy but may be stored electronically in the future.

c. The records for the maintenance and use of controlled substance standards are maintained in the Controlled Substance Unit's, 'Controlled Substance Activity/Inventory Records' binders (or electronic alternative).

   i. There are two sets of 'Controlled Substance Activity/Inventory Records' binders – one for the drugs stored within the safe and one for those stored in the refrigerator/freezer.

   ii. Within each binder there is a 'Controlled Substance Activity/Inventory Record' sheet for each unit of controlled substance within the storage unit.

   iii. Standards are grouped by their schedule:

      (a) Schedule I and II: (C1+C2) These standards are maintained separately in trays in the safe and drug refrigerator/freezer depending on their storage requirements.

      (b) Schedule III, IV, and V: (C3, C4 and C5): These standards are maintained together in trays in the safe or drug refrigerator/freezer separated from the C1 and C2 standards.

   iv. The paperwork is separated so that the sheets for the C1 and C2 controlled substances are maintained in one book in a set in the beginning of the book (alphabetically) and the sheets for the C3, C4 and C5 controlled substances are maintained in another book in the set.

   v. When a controlled substance standard is received (either a new drug or a restock of a drug currently in inventory) then a 'Controlled Substance Activity/Inventory Record' sheet must be completed (CS-11.1).
   The following information will be recorded:

      (a) Name of substance (Common Name or IUPAC name)

      (b) Lot Number

      (c) Expiration Date

      (d) Storage Location (e.g., safe, refrigerator, freezer)

      (e) Box number

(f) Schedule (federal)

(g) Date the controlled substance standard was received or inventoried

(h) Amount of controlled substance upon initial receipt

(i) Weight of the standard's container plus the contents

vi. Once information is completed within the form, it is placed in the appropriate record binder (or stored electronically).

2. Initial Opening

a. The date opened will be recorded on the outside of the controlled substance standard's container. This information should also be recorded electronically.

3. Storage/Handling/Accountability

a. All controlled standards are maintained in the Unit within either a safe or a lockable refrigerator/freezer. Standards are stored according to manufacturer recommendation.

b. 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.

c. The 'Controlled Substance Activity/Inventory Record' (or electronic inventory system) for the drug will indicate where the item is located. (e.g., safe, refrigerator, freezer).

d. Standards are retrieved from either the combination safe or from the locked refrigerator/freezer and then the storage location is closed immediately after retrieval. Analysts must ensure that they take the correct drug and lot number that is needed for their work and accurately document any amount taken.

e. The analyst taking the standard will complete the 'Safe/Drug Refrigerator Access' log (CS-11.3). This form logs who is opening the storage location, when and what is being taken.

f. The analyst taking a solid controlled standard will fill-in the 'Controlled Substance Activity Record' (CS-11.1) and record (at a minimum):

i. Date, initials of analyst taking the drug standard, and reason for use.

ii. Starting weight of the bottle with the drug contents.

iii. Weight of the standard being taken.

iv. Ending weight of the bottle with the drug contents.

v. Return the controlled standard to the appropriate storage area.

vi. If the substance is consumed then the analyst (with a witness) will:

(a) Rinse the bottle 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) Document accordingly on the form with a witness.

g. The analyst taking a liquid controlled standard that has a concentration greater than 1 mg/mL then they will fill-in the 'Controlled Substance Disposition Record' (CS-11.2) for each use and record (at a minimum):

i. Date, initials of analyst taking the drug standard, and purpose for use.

ii. Starting volume of the bottle with the drug contents.

iii. Volume of the standard being taken.

iv. Ending volume of the drug contents.

v. Return the controlled standard to the appropriate storage area.

vi. If the substance is consumed then the analyst (with a witness) will:

(a) Rinse the bottle 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) Document accordingly on the form with a witness.

h. File the 'Controlled Substance Disposition Record' (CS-11.2) form with Controlled Substance Activity/Inventory Records' binders (or electronic alternative).

i. These solutions are considered as part of the drug inventory and are included when an inventory is performed.

j. 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.

i. Prior to disposing of powder standards via dilution, a lead examiner or higher should be consulted.

4. Inventory (Annual)

Every year, no less than 11 months or more than 13 months from the last inventory, an inventory will be performed of the controlled substances stored within the safe and drug refrigerator/freezer. This will be performed by two (2) employees acting as witnesses to each other. Every solid controlled substance standard will be weighed (with packaging)

and compared to the weight from the last recorded weighing event for that item. Analysts accessing the safe or drug refrigerator/freezer for the inventory must complete the "Safe/Drug Refrigerator Access" log for each day they access the storage location and will select "inventory" for the reason/purpose.

a. The two (2) employees will proceed by comparing each "Controlled Substance Activity/Inventory Record" sheet against the actual item.

   i. Ensure that for every sheet there is an associated controlled substance standard.

   ii. Weigh the container with substance and compare the value to the last recorded weight.

      (a) Balance used to record weight should have similar reportable range as used in previous year

   iii. 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).

   iv. The individuals performing the inventory will complete the "For Annual Inventory" section of the "Controlled Substance Activity/Inventory Record" sheet for each drug.

   v. They will note 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.

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

   vi. Any standards not found will be recorded as such.

   vii. At the end of the inventory a report will be generated itemizing any discrepancies that are not resolved during the inventory.

   viii. The Assistant Director or Deputy Director 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)).

E. **REFERENCES**:

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