A. **PURPOSE**:

Many of the standards used in the Unit are controlled under the United Stated Controlled Substance Act. There are requirements for the storage and access of these substances that must be maintained; these requirements are part of maintaining drug licenses under the DEA and CT Consumer Protection - Drug Control. This procedure outlines the storage, accessing and handling of Controlled Substance standards within this laboratory.

B. **RESPONSIBILITY**:

1. Analysts assigned to the Unit are responsible for the proper handling of Controlled standards.
2. The Section Supervisor (however titled) is responsible to assure that Controlled Substances are maintained in a manner consistent with this SOP.
3. The Deputy Director (DD): is responsible to assure that controlled standards are maintained in a manner consistent with this SOP and to assure that the state and federal drug licenses are reviewed. The DD is also responsible to keep updated with changes to drug laws which pertain to the CS section and specifically to the maintenance of the drug standards.

C. **SAFETY**:

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

D. **PROCEDURE**:

General:

1. All controlled standards are maintained in the Unit, either in the safe, or lock drug refrigerator; based on the manufacturers recommendations.
2. Currently only the Deputy Director, Section Supervisor and analysts assigned to controlled substances have access to these areas.
3. If a Toxicology analyst requires a Controlled Standard it will be gained through a CS analyst or section supervisor.
4. Whenever possible only standards which are certified standards will be purchased as reference standards. Certificates of analysis will be maintained on the reference standards.

i. Rarely it will be necessary to obtain reference standards from atypical sources (such as the DEA laboratory for new designer drugs), generally these sources will provide an analysis profile (usually GC/MS and/or IR spectra). This profile will act as the certificate of the drug.

5. Standards are grouped by their schedule:
    i. Schedule I and II: (C1+C2) these standards are maintained separately in trays in the safe and drug refrigerator depending on their storage requirements.
    ii. Schedule III, IV and V (C3, C4 and C5): these standards are maintained together in trays in the safe or drug refrigerator separated from the C1 and C2 standards.

6. Records: the records for the maintenance and use of Controlled Substance standards are maintained in the Controlled Substance section in the "Controlled Substance Activity/Inventory Records" books.
    i. There are two sets of "Controlled Substance Activity/Inventory Records" books; one for the drugs stored in the safe and one for those stored in the refrigerator.
    ii. Within each book there is a "Controlled Substance Activity/Inventory Record" sheet for each bottle of controlled substance within the storage unit.
    iii. 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.
    iv. New standards:
        1. When a new controlled substance standard is purchased (either a new drug or a restock of a drug currently in inventory) a “Controlled Substance Activity/Inventory Record" sheet must be completed for it (CS-11.1). Fill in:
            a. Name of substance
            b. Lot
            c. Manufacturer’s name
            d. Location to be stored, safe or refrigerator (based on the manufacturer’s recommendation)
            e. Schedule
            f. ID of box it will be placed in
            g. Date Received

h. Amount purchased (grams or milligrams)

i. Weight of substance with container

2. Once filled in the form is placed in the appropriate record book
3. If the controlled substance is new to the laboratory (a new drug) it must be given a drug identification number (the next number in sequence), see the analysts in charge of maintaining this list.
4. The first time a new standard is used it will be validated (See SOP CS-3).

7. Accessing the standards:

i. When a standard in the safe is needed, it requires two people to open the safe together. This is generally the analyst that needs the substance and a second analyst in the CS or Toxicology sections.

ii. The "Controlled Substance Activity/Inventory Record" for the drug needed will indicate where the item is located. (Safe or drug refrigerator).

iii. The analyst and the witness either open the safe (which is a combination) or the refrigerator (keyed lock) as needed and retrieve the required item. Since there may be multiple bottles/lots of a single drug, the analyst and witness need to assure that the correct substance and lot number is taken. The storage location is closed immediately after the needed substance(s) is removed.

1. The combination to the safe is known to the Deputy Director, Controlled Substance Supervisor and analysts assigned to the section. All analysts must securely maintain the combinations that are supplied to them.
2. The key to the drug refrigerator is in a lock box in the CS section. The combination to the lock box is known to the Deputy Director, Controlled Substance Supervisor and analysts assigned to the section.
3. If a new analyst is assigned to the section, they will be given the above mentioned combinations by the section Supervisor. Since it is desirable to not have these combinations be known, there will not be a written record of the combinations given to the individual.

iv. The analyst and witness complete the "Safe/Drug Refrigerator Access" log (CS-11.4)

1. This form logs who is opening the storage location, when, what is being taken and the witness initials that they agree to what was taken.

v. Once the above is completed the analyst (without a witness) completes the "Controlled Substance Activity/Inventory Record" for the substance (CS-11.1).
    1. Weigh the bottle with the contents.
    2. Weigh the amount being taken.
    3. Weigh the bottle with contents after removing the needed portion.
    4. Return the substance to the storage area with a witness (this need not be the same witness that witnessed the opening of the storage area).

vi. If the substance is consumed the analyst with a witness will rinse the bottle with methanol or ethanol and discard the rinse with the case drug waste and throw away the bottle. They will write on the "Controlled Substance Activity/Inventory Record" sheet for the drug "Consumed –bottle discarded" the date and both the analyst and witness will initial. This will act as the record of destruction/consumption for the substance.

vii. If the solution prepared is greater than 1 mg/ml a Controlled Substance disposition record form must be maintained. (CS-11:2) These solutions are still considered controlled and must be treated in the same way as the pure drug standard. If the solution is to be made and completely consumed in the same day a disposition record does not need to be maintained.

1. Complete the following:
    a. Substance name with the manufacturers name and lot number
    b. Schedule
    c. Preparers name and date made
    d. Concentration prepared (mg/ml) and type of solvent
    e. Prepared for use as
    f. Solution storage location

2. When a portion is used, complete the date, amount used, amount remaining, purpose, and initials.
3. The Disposition Record is filed in the "Controlled Substance Activity/Inventory Records" book along with the sheet for the pure drug standard.
4. These solutions are considered as part of the drug inventory and are included when an inventory is performed.
5. If the solution is to be disposed of this is to be done with a witness. The disposition record is completed.
    a. Disposal can be through either dilution and disposal with case drug material or by signing over the solution to a drug control agent.

8. Inventory:

i. Every year, no more than 13 months from the last inventory, an inventory will be performed of the substances stored in the safe and drug refrigerator. This will be performed by two employees acting as witnesses of the other. Every item will be weighed (with packaging) and this will be compared to the weight last recorded for the item. Analysts opening the safe or drug refrigerator for the inventory must complete the "Safe/Drug Refrigerator Access" log for each day they access the storage unit however under items removed write in "inventory". Note that Federal guidelines require an inventory be completed every two years, the Division of Scientific Services chooses to perform this annually.

1. The two analysts will proceed by comparing each "Controlled Substance Activity/Inventory Record" sheet against the actual item.
    a. Assure that for every sheet there is a bottle of substance.
    b. Weigh the bottle with substance and compare the value to the last recorded weight.
    c. Any sheets that are marked "Consumed –bottle discarded" will be removed and placed in the archived records.
    d. The individuals performing the inventory will complete the "For Annual Inventory" section of the "Controlled Substance Activity/Inventory Record" sheet for each drug.

i. They will note any weight discrepancies of more than 20%, or unfound items. Any weight changes of >20% will be re-weighed to verify the result.

ii. Weight differences are often seen with:

1. Items stored in the refrigerator
2. Items that are hygroscopic that take on water

iii. At the end of the inventory they will write a report to the Deputy Director itemizing any discrepancies that are not resolved during the inventory.

iv. The 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 hydroscopic nature of a drug) or a QAR for a missing item.

E. **REFERENCES**:

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