

Controlled Substances User SOP 04: Discrepancy in Controlled Substances Inventory**1. Purpose**

This procedure describes how to address a discrepancy in the Controlled Substances inventory.

2. Regulatory References**3. General Information****A. Abbreviations:**

- 1) Authorized Person (AP)
- 2) Central Controlled Substances Custodian (CCSC)
- 3) Controlled Substance (CS)
- 4) Controlled Substances Tracking System (CSTS)
- 5) Environmental Health and Safety (EHS)
- 6) Institute Point of Contact, Chief Research Policy Officer (IPOC)
- 7) Laboratory Controlled Substances Custodian (LCSC)
- 8) Office of Laboratory Animal Resources (OLAR)
- 9) Office of Research Compliance (ORC)
- 10) Principal Investigator (PI)
- 11) Uniform Distribution, Transfer, and Disposal Form (UDTD)

B. Caltech has two DEA licenses and each license has its own CCSC, who is responsible for training personnel and managing CS inventory on their respective licenses.

4. Procedure

Discrepancies can be found at various times such as (1) During Self Inspections, (2) During Biennial Inventories, (3) When attempting to use a CS, or (4) When attempting to dispose of an expired or “empty” CS. Explanations for discrepancies can be documentation or disposal errors, mechanical loss during administration, accidental loss during administration, unexplained loss, theft or diversion.

- 1) When a discrepancy is identified in the Controlled Substances inventory, the LCSC or CS user should immediately notify the CCSC and the IPOC. NOTE: A significant discrepancy may need to be reported to the DEA within 24 hours. If the loss is greater than ½ a container or the equivalent of an average human dose of the CS, step 2 must be done immediately upon learning of the diversion.
- 2) The CCSC will meet with the LCSC as soon as possible to gather necessary documentation. The LCSC and CCSC will review the CS notebook entries, identify the current inventory and compare the dates of use versus the dates of entry. A summary, as described, below, including copies/photos of the logbook, vials or any other relevant information should be forwarded to the IPOC, and, If there is a logical explanation for the discrepancy, this should be noted in the communication to the IPOC.

Discrepancy Summary

Date Discrepancy Discovered:

Lab:

CS User:

CS NAME AND NDC:

Amount of Discrepancy (volume and actual CS in mg):

Describe Discrepancy (reference logbook entries):

Describe Possible Explanations for Discrepancy:

- 3) An investigation will be organized including the IPOC, the relevant CCSC, and, as necessary, an representative from Caltech Security. The investigation committee will meet with all responsible individuals in the lab, including the PI, to understand the discrepancy.
 - a. If the discrepancy was caused by user error in documentation or by improperly disposing of the container. If the container was accidentally disposed of, the CCSC will remind the user that all CS containers must be retained and returned to the CCSC. If the documentation is incorrect, the CCSC will re-train the individual on how to properly document the use of CS.
 - b. If the discrepancy was caused by hub loss or through other mechanical loss due to the procedure where the CS is administered, options for minimizing loss will be discussed and, if not mitigable, a process for documenting the mechanical loss will be discussed and implemented.
 - c. If the discrepancy was caused by physical loss during administration (spillage/dropping), this should be documented along with any evidence corroborating the physical loss.
 - d. If the discrepancy is not related to a. b. or c., and an unexplained loss or possible theft or diversion occurred, the IPOC will ensure that Caltech Security and OGC are included in discussions regarding next steps.
 - i. Federal regulations require that registrants notify the Field Division Office of the Administration in their area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals **within one business day of discovery of such loss or theft**. The registrant shall also complete the, and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft ([21 C.F.R. §1301.76\(b\)](#) and [21 U.S.C. §830\(b\)\(1\)\(C\)](#)). The DEA Form 106 can be completed via [Theft/Loss Reporting Online \(TLR\)](#) or download the [fillable PDF](#) version and submit to your [Local Diversion Field Office](#)