1. Purpose
   A. This SOP provides guidelines for the oversight and execution of responsibilities by a Central Controlled Substances Custodian (CCSC) with regard to semiannual controlled substance self-inspections by Laboratory Controlled Substances Custodians (LCSC) and annual in-person inspections.

2. General Information
   A. Abbreviations:
      1) Central Controlled Substances Custodian (CCSC)
      2) Controlled Substance (CS)
      3) Controlled Substances Tracking System (CSTS)
      4) Environmental Health and Safety (EHS)
      5) Institute Point of Contact, Chief Research Policy Officer (IPOC)
      6) Laboratory Controlled Substances Custodian (LCSC)
      7) Office of Laboratory Animal Resources (OLAR)
      8) Office of Research Compliance (ORC)

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

3. Coordination of training of LCSCs to perform semiannual self-inspections
   A. In the two weeks prior to the scheduled semi-annual self-inspections (March and September), the CCSC should email all LCSCs reminding them to complete the CS inspection form by the required date:
      o Request a copy of each lab’s list of authorized users.
      o Request that each lab return a copy of the completed CS inspection form to the CCSC.
      o Update inventory in the Controlled Substances Tracking System (CSTS) in access.caltech.edu
      o Email template:
         Hi all LCSCs,
         This is your friendly reminder to complete your semi-annual self-inspection by [insert date in either March or September].
         Please do the following:
         - Send me an electronic copy of your completed inspection form and place the hard copy in your lab’s CS binder. A copy of a blank inspection form can be found on the Caltech ORC website here as Attachment E: https://researchcompliance.caltech.edu/compliance/controlled-substances-and-chemical-precursors
         - Send an updated list of your lab’s authorized users as of the date of your self-inspection.
         - Update your CS inventory in the Controlled Substances Tracking System in access.caltech.edu
Please note that failure to submit the semi-annual inspection certification in a timely manner may result in a temporary suspension of privileges to use controlled substances. Repeated failure may result in permanent suspension of privileges.

Thank you,

B. Following receipt of the CS inspection form and authorized user list, the CCSC ensures that laboratory user list matches the list of approved, trained personnel and will follow-up with the LCSC regarding any discrepancies.

C. After reviewing the forms and correcting any issues, the CCSC will upload both the authorized user list and CS inspection form to the current inventory page in the CST.

D. The CCSC will review the inventory in the CSTS to ensure completeness and accuracy.

4. Annual in-person CCSC Inspection (September, to align with the biennial inventory):

A. Following receipt and review of the CS inspection form, inventory and authorized user list for each lab, the CCSC will arrange an in-person meeting with the LCSC to review the inventory and CS lockboxes. The CCSC will sign-off on the CS inspection form to confirm accuracy.

B. The CCSC will save a copy of the signed CS inspection checklist in the CST current inventory following completion of the inspection.

C. Every two years, the Campus-wide biennial inventory will serve as the annual inspection for that year.
   
   o The ORC coordinates the biennial campus-wide inventories in collaboration with the CCSC and the IPOC (see CS SOP 8 Biennial Inventory).

D. If any possible diversion is discovered during a self-inspection or in-person inspection, the CCSC will report immediately to the IPOC.