Controlled Substances SOP 06: Central Controlled Substances Custodian Implementation of Semiannual Inspections

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) Environmental Health and Safety (EHS)
      4) Institute Point of Contact, Director of Research Compliance (IPOC)
      5) Laboratory Controlled Substances Custodian (LCSC)
      6) Office of Laboratory Animal Resources (OLAR)
      7) 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 self-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 self-inspection to the CCSC and maintain an electronic copy in the respective CCSC SharePoint folder.
      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 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 semi-annual inspection form can be found on the Caltech EH&S website here as Attachment E: http://www.safety.caltech.edu/services/controlled_substances
         
         Please also send an updated list of your lab’s authorized users as of the date of your self-inspection.
         
         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 self-inspection form, the CCSC should ensure that laboratory user list matches the list of approved, trained personnel and follow-up with the LCSC regarding any discrepancies.
C. The CCSC will save a copy of the self-inspection form in the SharePoint folder for the respective license and lab.

4. Annual in-person CCSC Inspection:
   
   A. Following receipt and review of the self-inspections forms for each lab, the CCSC will arrange an in-person meeting with the LCSC to review the inventory and CS lockboxes. The CCSC will use the biennial inventory checklist to perform the inspection.
   
   B. The CCSC will save a copy of the biennial inventory checklist in the SharePoint folder 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.