

**Controlled Substances SOP 08: Biennial Inventory**

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**1. Purpose**

This procedure describes the inventory process conducted every two years for the Controlled Substances program.

**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. Training Requirements**

## A. Training of LCSC

**5. Procedure**

EHS conducts inventories of its licensed CS holders in March of every odd-numbered year. OLAR conducts inventories of its licensed CS holders in September of every odd-numbered year.

## Timeline:

- 1) Two months prior: CS group (CCSCs, staff from EHS, OLAR, ORC and Audit Services & Institute Compliance) determines date of Biennial Inventory.
- 2) One month prior: Meet with members of CS group (CCSCs, staff from EHS, OLAR, ORC and Audit Services & Institute Compliance) to confirm date and review process and assignment of inspection teams.
- 3) One to two months prior: Schedule date for Waste CS pickup to occur before inventory date (if this does not occur, the Waste CS must be inventoried). Waste removal is performed according to CS SOP 4 (Removal of Controlled Substances from Caltech).

- 4) One month to three weeks prior: Meet with members of CS group to review and confirm process, last day of CS pickup, and team assignments.
- 5) One to three weeks prior: Last day to receive Waste CS from labs.
- 6) Two weeks prior: ORC emails PIs and LCSCs ([Attachment A](#)) to inform of upcoming biennial inspection and give timeframe of visit. ORC emails Division Chairs with a list of labs that are approved for CS.
- 7) End of day before inventory:
  - a. CCSC emails reminder of inspection to labs ([Attachment B](#)). This email includes:
    - Instruction to labs to input changes in inventory in the CSTS and email [orc@caltech.edu](mailto:orc@caltech.edu) on day of inventory
    - A copy of the CS inspection form ([Attachment E](#))
    - A copy of ORC's email with instructions
  - b. Unlock the inventory function in the CSTS for each lab to be inspected.
- 8) Day of Inventory:
  - a. CS group meets at the appointed time and location
  - b. CS group follows Day of Inventory Instructions (below)
- 9) After Inventory:
  - a. Upload the signed CS Inspection Form ([Attachment E](#)) to the current inventory in the CSTS.
  - b. Make any necessary updates
  - c. Generate a hard copy/ electronic file of full inventory to be signed. Save the signed copy in the CSTS. It is a legal requirement to have the signed document on hand and accessible for DEA inspections.

**ATTACHMENT A:****Email Language for PI and LCSC notifications of Biennial Inventory**

1<sup>st</sup> Notice sent to Faculty from IPOC two weeks prior to inventory

Dear Faculty,

Your lab is registered with Caltech as one that utilizes controlled substances (CS) under Caltech's **EHS/OLAR** License. This year, we are required to complete our biennial inventory of all CS. We have set the date for the **EHS/OLAR License** (your license) inventory for **MONTH, DAY, YEAR, at the opening of business**. Please make sure that your lab custodian (or an alternate) is in the lab on the morning of **Month, Day, Year** to complete the inventory in the Controlled Substances Tracking System and perform an inspection. Detailed instructions will be sent to the lab custodians and reminders sent again on the evening prior to the inventory. The completed inspection and inventory forms will need to be provided on the day of the inspection.

Please feel free to call me with any questions.

Best regards,

**IPOC NAME**

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1<sup>st</sup> Notice sent to Lab Custodians from ORC (CS Administrator) two weeks prior to inventory

Dear Lab Custodians,

An email has been sent to your PI to inform them that **MONTH, DAY, YEAR** will be the date for our campus wide biennial controlled substances inventory of controlled substances on the **EHS/OLAR License** (your license). This inventory is essential for maintenance of our license from the DEA even if you do not have any controlled substances in your lockbox(es). **On Month, day, year, first thing in the morning**, you, or an alternate who can perform an inventory, must be in the lab.

On **Month, Day, Year you will be asked to perform and inventory and an inspection**:

**(1) Inventory:** At the start of the workday, BEFORE any controlled substances is taken from the stock, please update the inventory in the Controlled Substances Tracking System (CSTS) with the amount of each controlled substance you have in your lab. This process should include comparing (by eye is acceptable) what is actually in the bottle with the corresponding entries in your logbooks. You should initial and date next to the logbook entry that corresponds to the amount of controlled substance you report on your form. Please also note any apparent discrepancies in your logbooks. A member of the

controlled substances team will come by your lab that morning to confirm your records are properly documented, so please be sure to be readily available in your laboratory.

After completing the inventory, immediately email [ORC@caltech.edu](mailto:ORC@caltech.edu), but no later than 11 AM on **Month, Day**.

**(2) Inspection:** A member of the controlled substances team will meet you at your lab between 9 AM and noon to review your inventory (including comparing the CS inventory and logbooks with the vials), logbooks, documentation, and CS authorized personnel list. They will also confirm the location of your lockbox and key storage as well as look at your CS stocks. This will suffice as your Semi-Annual inspection.

After updating the inventory in the CSTS, immediately email [ORC@caltech.edu](mailto:ORC@caltech.edu), but no later than 11 AM on **Month, Day**. The information from all labs at Caltech will be compiled to generate a complete inventory for the campus **EHS/OLAR** License. This inventory will be kept with the **EHS/OLAR** License Central Custodian and will be provided to the DEA upon request.

**Please respond to this email, confirming receipt and indicate the person who will be performing the inventory for your lab.**

If you have any questions, please feel free to contact your Central Custodian, or me. We appreciate your assistance in this matter and your continued patience. If all goes well with this inventory, our next inventory will not be for another two years.

Best regards,

**IPOC NAME**

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**ATTACHMENT B: Notice sent day prior to Inventory (FROM EHS or OLAR)**

Dear Lab Custodians,

Attached is the controlled substances inspection form for you to use on the inventory day, **Month, Day, Year**. Instructions on completing the inventory are available in the Controlled Substances Tracking System (CSTS). Reminder: you must complete an inventory in the CSTS even if your lockbox(es) are empty.

**Please follow these instructions so that the Inventory can go smoothly:**

The inventory must be updated based on the inventory in your lockbox FIRST THING in the morning on the **Day of Inventory** and submitted NO LATER THAN 11 AM on **Month, Day, Year**.

**Please email [ORC@caltech.edu](mailto:ORC@caltech.edu) once the inventory is completed.**

After you have completed the inventory, please print it out. An inspection team will be coming to your lab to collect a copy of your inventory and inspection forms and to review your CS materials. Once the inventory is complete, you will sign the inspection form and save a copy in your CS binder. You will also email the signed copy to your Central Custodian.

Please refer to the email sent to you earlier from Grace Fisher-Adams, Institute Point of Contact, for more details (copied, below) and feel free to call me if you have any additional questions.

Thank you so much for your assistance. We greatly appreciate it!

Best,

**CENTRAL CUSTODIAN NAME**

**REMINDER OF INSTRUCTIONS**

Dear Lab Custodians,

An email has been sent to your PI to let them know that **MONTH, DAY, YEAR**, will be the date for our campus wide biennial controlled substances inventory of controlled substances on the OLAR License (your license). This inventory is essential for maintenance of our license from the DEA. **On Month, Day, Year, first thing in the morning**, you, or an alternate who can perform an inventory, must be in the lab.

In addition to the biennial inventory, we will be conducting your annual inspection. Individuals from OLAR, EHS or Audit Services and Institutional Compliance (the controlled substances team) will be coming by your lab to facilitate the inspection.

On **Month, Day, Year**:

**(1) Inventory:** At the start of the workday, BEFORE any controlled substances is taken from the stock, please update the inventory in the Controlled Substances Tracking System (CSTS) with the amount of controlled substances you have in your lab. This process should include comparing (by eye is acceptable) what is actually in the bottle with the corresponding entries in your logbooks. You should initial and date next to the logbook entry that corresponds to the amount of controlled substance you report on your form. Please also note any apparent discrepancies in your logbooks. A member of the controlled substances team will come by your lab that morning to confirm your records are properly documented, so please be sure to be readily available in your laboratory.

After completing the inventory, immediately email [ORC@caltech.edu](mailto:ORC@caltech.edu), but no later than 11 AM on **Month, Day**.

**(2) Inspection:** A member of the controlled substances team will arrive at your lab between 9 AM and noon to review your inventory (including comparing the CS inventory and logbooks with the vials), logbooks, documentation, and CS authorized personnel list. They will also confirm the location of your lockbox and key storage as well as look at your CS stocks. This will suffice as your Semi-Annual inspection.

**Please respond to this email, confirming receipt and indicate the person who will be performing the inventory for your lab.**

If you have any questions, please feel free to contact **NAME (the EHS or OLAR Central Custodian)** or me. We appreciate your assistance in this matter and your continued patience. If all goes well with this inventory, our next inventory will not be for another two years.

Best regards,

**CENTRAL CUSTODIAN NAME**

**Controlled Substance Day of Inventory Instructions**

Items Needed	Person/Group Responsible	Completed
Copies of “Controlled Substances Program Annual Inspection Checklist” – enough for each lab + extras	ORC	
Copies of EHS/OLAR CS DEA Schedule	EHS or OLAR	
Copies of map locations to be verified – enough for each inspection group	EHS or OLAR	
List of each labs’ authorized users to cross reference with lab’s list of users	EHS or OLAR	
Phone or other device to access off-campus numbers/PI contact list in case of emergency	Each inspection group	
Clipboards for each inspection team	ORC	
Pens for each inspection team	ORC	
Coffee and snacks for inspection teams	ORC	

Inspection Team Checklist	Completed
1) Introduce yourself and state that you are there for the biennial inventory inspection	
2) The lab should complete the CS Inspection Form. The inspection team will review the form for accuracy and completeness.	
3) Ensure that the LCSC sends the signed CS Inspection Form to the CCSC via email and puts a printed copy in their binder.	
4) Go through each line of the inventory to make sure all CS match logbook and UDTD with the vials (when applicable) and identify any discrepancies. Confirm that all entries are understandable.	
5) The CCSC will generate the inventory and the inspection team will ensure that the LCSC prints a copy for the binder.	
6) The team lead will inform the CCSC to generate the inventory for the lab to print, sign, and store a copy in binder and send back a signed copy to the inspectors. The complete inspection checklist should be signed and sent to the CCSC to be uploaded to the CST. Send a copy of the inventory to the ORC.	
7) Discuss any needed changes to the process and update SOPs and forms as needed.	
8) Thank the laboratory and return to the central meeting location.	

CCSC Items (Post-Biennial Inspection)	Completed
1) Upload inspection forms into CSTS( <a href="#">Attachment E – Controlled Substances Inspection Form</a> )	
2) File inventory forms in DEA binder	