

Controlled Substances SOP 08: Biennial Inventory

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 (CST)
- 5) Environmental Health and Safety (EHS)
- 6) Institute Point of Contact, Director of Research Compliance (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 February 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 Audit Services & Institute Compliance, EHS, OLAR, ORC) to confirm date and review process and assignment of inspection teams.
- 3) One – 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).
- 4) One month prior: Meet with members of CS group to review process and assignments.

- 5) One – three weeks prior: Last day to receive Waste CS from labs.
- 6) Two weeks prior: ORC emails PIs and LCSCs to inform of upcoming biennial inspection and give timeframe of visit.
- 7) End of day prior:
 - a. Teams are assigned to labs for inspection.
 - b. CCSC runs inventory reports for each lab for day of Biennial Inventory on CST.
 - c. CCSC emails reminder of inspection to labs. This email includes:
 - “Biennial Controlled Substances Inventory Form,”
 - Instruct labs to email the completed Excel Inventory Form to orc@caltech.edu on day of inventory.
 - “Self-Inspection Form,”
 - a copy of ORC’s email with instructions.
 - d. CCSC creates Mastercopy of all labs’ “Biennial Controlled Substances Inventory Form” (organized by lab) in SharePoint to use for data entry on day of inspection.
 - OLAR must complete its own Disposal “Biennial Controlled Substances Inventory Form,” independent of the CCSC and send email to ORC the next morning.
 - Both EHS and OLAR CCSC must generate an inventory for the Disposal Inventory, if any.
- 8) Day of Inventory:
 - a. CS group meets at appointed time in appointed location.
 - b. CS group follows Day of Inventory Instructions.
- 9) After Inventory:
 - a. Scan signed “Biennial Controlled Substance Inventory Forms” and add to SharePoint.
 - b. File Biennial Inventory Forms.
 - c. File Self-Inspection Checklists.
 - d. File Annual Checklists.
 - e. Make any necessary updates.

Email Language for PI and LCSC notifications of Biennial Inventory

1st Notice sent to Faculty from ORC 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. In order to facilitate the process, we have separated the biennial inventories of the EHS License from the OLAR License. We have set the date for the **EHS/OLAR** (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 and return inventory forms. Detailed instructions will be sent to the lab custodians and reminders sent again on the evening prior to the inventory. The inventory forms will need to be filled out and returned to ORC@caltech.edu, so that the data can be compiled.

Please feel free to call me with any questions.

Best regards,

IPOC NAME

1st Notice sent to Lab Custodians from ORC two weeks prior to inventory

Dear Lab Custodians,

An email has gone 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 **EHS/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.

At the start of the work day (i.e. before anyone takes any controlled substances from the stock) on **Month, day, year** please record on the form provided by your Central Custodian the amount of controlled substances you have on hand. 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.

After completing the form, immediately email it to 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 indicating who will be performing the inventory for your lab.

If you have any questions, please feel free to contact **EHS or OLAR 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

Notice sent day prior to Inventory (FROM EHS or OLAR)

Dear Lab Custodians,

Attached is the inventory form for you to use on the inventory day, **Month, Day, Year**.

Please follow these instructions so that the Inventory can go smoothly for all of us:

The Excel spreadsheet must be filled in based on the inventory in your lock box **FIRST THING** in the morning on the **Day of Inventory** and the form returned **NO LATER THAN 11 AM** on **Month, Day, Year**.

If you have no inventory in your box, there is no need to adjust the Excel sheet that was emailed to you.

Upon completing the inventory, please email the Excel sheet to ORC@caltech.edu.

After you have emailed the Excel sheet, please print it out and sign it. Please also email the completed Self Inspection Form- to **EHS or OLAR Email contact**. An inspection team will be coming to your lab to collect the documents and to review your CS binder.

Please refer to the email sent to you earlier from Grace Fisher-Adams for more detail (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,

EHS or OLAR Custodian

REMINDER OF INSTRUCTIONS

Dear Lab Custodians,

An email has gone 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 work day, BEFORE anyone takes any controlled substances from the stock, please record on the form provided by the **EHS/OLAR** Central Custodian, 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 form, immediately email it to 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 on request.

(2) Inspection: A member of the controlled substances team will come by your lab between 9 AM and noon to review your inventory, logbooks, documentation, and CS authorized personnel list. S/he 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 indicating 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,

IPOC 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 Items	Completed
1) Introduce yourself and state that you are there for the biennial inventory inspection	
2) Ask if they emailed the Excel file “Biennial Controlled Substances Inventory Form”	
3) Collect original signed “Biennial Controlled Substances Inventory Form”	
4) Go through each line of the “Biennial Controlled Substances Inventory Form” to make sure all drugs match logbook and UDTD and field entries are understandable	
5) Ask LCSC if they have emailed or have a copy of the “CS Self-Inspection Form” to give to EHS/OLAR	
6) Verify map of all lockboxes and/or safe is up to date	
7) Go through “CS Program Annual Inspection Checklist”	
8) Sign off on “CS Program Annual Inspection Checklist” and bring back to EHS/OLAR CCSC	



CONTROLLED SUBSTANCES PROGRAM BIENNIAL INSPECTION CHECKLIST

	YES	NO	N/A
1. LABORATORY AUTHORIZATION(S)			
a. ATTACHMENT A (CONTROLLED SUBSTANCES AUTHORIZATION FORM) AVAILABLE	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. APPENDIX A-1 FORM (DIVISIONAL APPROVAL) AVAILABLE (IF APPLICABLE)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i. UPDATES TO AUTHORIZED CS CONSISTENT WITH CCSC RECORDS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
COMMENTS OR OTHER OBSERVATIONS _____			

2. AUTHORIZED INDIVIDUALS			
a. APPENDIX B FORM AVAILABLE FOR ALL INDIVIDUALS WORKING WITH CS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. UPDATES TO AUTHORIZED INDIVIDUALS CONSISTENT WITH CCSC RECORDS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
COMMENTS OR OTHER OBSERVATIONS _____			

3. CS CONTROL NUMBER, UDTD CERTIFICATES AND LOGBOOKS			
a. UDTD CERTIFICATES AVAILABLE	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. UDTD CERTIFICATES MATCHES CS PHYSICAL INVENTORY	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. CS PHYSICAL INVENTORY AND BIENNIAL INVENTORY FORM MATCH LOGBOOK	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. CS LOGBOOKS ARE COMPLETE AND CLEAR	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. SEMI-ANNUAL SELF INSPECTION REPORTS AVAILABLE (MINIMUM PAST TWO YEARS)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
COMMENTS OR OTHER OBSERVATIONS _____			

4. SECURITY			
a. CS LOCKBOX IS MAINTAINED LOCKED	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. CS LOCKBOX KEYS LOCATED IN A SECURE AREA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. ALL CS LOCKBOXES LISTED AND APPROVED BY CCSC PER MAP	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
COMMENTS OR OTHER OBSERVATIONS _____			

5. ADDITIONAL OBSERVATIONS OR RECOMMENDATIONS (EXPLAIN) -

CCSC REPRESENTATIVE (NAME)

LCSC NAME

DATE

CCSC REPRESENTATIVE SIGNATURE

LCSC SIGNATURE

_____/_____
BUILDING / ROOM NUMBER

