

Controlled Substances SOP 04: Removal of Controlled Substances from Caltech**1. Purpose**

This procedure describes the transfer of unused or expired controlled substances from Caltech to a third party reverse distributor for the proper destruction of the controlled substances at a DEA authorized facility. Pursuant to 21 CFR § 1317, a non-practitioner in lawful possession of a controlled substance in its inventory that desires to dispose of that substance shall do so ... [by] [p]romptly deliver[ing] that controlled substance to a reverse distributor's registered location by common or contract carrier or by reverse distributor pick-up at the registrant's registered location. At Caltech, a Purchase Order (PO) with Caltech terms and conditions must be issued in order to cover the work. The reverse distributor will come on site to perform a controlled substances inventory and issue all required DEA Form 41, Registrant's Inventory of Drugs Surrendered, and, as applicable, DEA 222 Forms, to transfer Schedule II substances.

Caltech has two separate licenses for Controlled Substances. While the transfer of inventory for destruction for both licenses will occur on the same day, under a single PO, the process described below, will be carried out, in parallel but separately for each license. After transfer, the reverse distributor will then transport the controlled substances for destruction via their own process. After proper destruction, the Vendor will issue a Certificate of Destruction, which will be accompanied by a log that indicates the destruction time and witnesses, as required by the regulations.

2. Regulatory References

- A. 21 CFR § 1317
- B. 40 CFR § 261-264, 267-268
- C. 49 CFR Part 172 et seq.

3. Training Requirements

All Controlled Substances SOP.

4. 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)
 - 8) Uniform Distribution, Transfer, and Disposal Form (UDTD)
- B. Caltech has two DEA licenses, one managed by EHS and one managed by OLAR. Each license has its own CCSC, who is responsible for implementing this SOP, as described.

5. Procedure

- A. Waste Accumulation, Inventory Management and Frequency of Disposal:

- 1) All unused or expired (Waste) CS, will be stored in a secured Disposal Storage Area. The Waste CS Inventory for the EHS and OLAR licenses will be stored and inventoried separately from one another.
- 2) To the extent practical and possible, Caltech will dispose of Waste CS every six months to prevent accumulation on campus.
- 3) Taking into consideration the high cost of disposal, EHS in consultation with the IPOC, may choose to extend the accumulation period in order to make the disposal process cost effective.
- 4) When the quantity of Waste CS in the Disposal Storage Area I is approaching 50% capacity, the CCSCs for the EHS and OLAR licenses will identify a mutually agreeable date (Disposal Date) for the transfer and disposal of the Waste CS to an authorized reverse distributor. **At least three weeks of time must be set aside to organize the disposal.**

B. Engaging Approved Reverse Distributor Vendors:

Qualified Vendors must meet the following criteria:

- 1) Possess a proper RCRA Part B Permitted Hazardous Waste Storage Facility, as defined by Federal law 40 CFR §§261-264, and 267-268; AND
- 2) All employees are permitted Class A Hazmat Drivers under 49 CFR Part 172 et seq.; AND
- 3) Possess a CA Department of Justice AND Federal Department of Justice DEA authorization to ship controlled substances; AND
- 4) Have appropriate liability insurance for this type of transport and service as determined by the Procurement Services at Caltech; AND
- 5) Provide a DEA registered facility where the controlled substances will be taken for destruction, AND
- 6) Provide properly completed inventory DEA Form 41 pursuant to 21 CFR 1317, prior to removal of controlled substances from Caltech, in order for Caltech to review the destruction inventory and ensure alignment of Caltech records with the inventory provided on DEA Form 41.
- 7) Provide a copy of the completed DEA Form 41 including the date, location, and method of destruction as well as witness signatures along with any other relevant documentation to Caltech to certify destruction. The vendor must provide this certification no later than 180 days after the destruction date.

The CCSCs will verify that the list of approved reverse distributors meets all these criteria prior to engaging any vendor for Waste CS for removal and destruction.

C. Initiating the Waste Removal and Destruction Process

- 1) Procurement – Purchase Order (PO) with Caltech Terms and Conditions
 - i. Identify which approved vendor (AV) will be used for a particular Waste CS removal and destruction.
 - ii. Contact Procurement Services to issue a PO that has appropriate Caltech Terms and Conditions. Advise Procurement Services that this is for the removal and destruction of Waste CS. Attach any additional EHS controlled substances waste disposal management terms and conditions, including vendor requirements articulated in 5. B. 1)-7) to the request.
- 2) Vendor Arrangement
 - i. The EHS CCSC will contact the AV to arrange for disposal on the Disposal Date. Upon finalization of the Disposal Date, the EHS CCSC will notify the IPOC and coordinate with the OLAR CCSC for disposal

D. Disposal Date: Inventory

- 1) The EHS CCSC will create a copy of the Disposal Excel Spreadsheet, listing the Waste CS Inventory, for each license and remove all PI information. The CIT Control Numbers, CS Names, Amount Remaining per Container, and the CS Schedule Number should remain on the spreadsheet. If the Waste CS has a National Drug Code (NDC), it should be included. The OLAR spreadsheet will be provided to the OLAR CCSC to review and confirm accuracy, before the next step.
- 2) The EHS CCSC will send the spreadsheets to the AV so the AV can prepare the DEA 41 Inventory Forms, one per license.
- 3) The CCSCs will copy data from each of their respective spreadsheets onto a Caltech Disposal Certification Document for their license.
- 4) On the Disposal Date, both CCSCs will meet the AV representative at the Disposal Storage Area. The AV representative will inventory the items and verify the presence of each bottle on the Caltech Disposal Certification Document. Each CCSC will monitor the CS Waste inventory for their license at the same time as the AV representative is logging in inventory, to verify accuracy. **Any empty CS Waste containers will be placed in a separate bucket for disposal as hazardous waste.** CCSCs should note which containers on their Caltech Disposal Certification are separated out for hazardous waste disposal in this process.
- 5) Upon completion of the inventory, the AV representative will provide a DEA 41 Inventory Form for all Waste CS that have been transferred from Caltech to the AV for reverse distribution and final Waste CS destruction. The AV will issue a DEA222 Form for all Schedule I or II materials transferred. A quotation for the cost will be provided at the same time.
- 6) **The AV Representative and each CCSC will sign their respective Caltech Disposal Certification Forms.** The AV representative will identify all AV forms requiring a signature. Each CCSC will sign all the forms required, including any DEA 222 Forms issued by the AV to the CCSC for CS Schedule II.
- 7) When the inventory is complete, the CS Waste inventory will be secured in the AV container. If transport and disposal of the CS Waste from Caltech will occur on a date other than the Disposal Date, the secured AV Container will be returned to the Secured Disposal Storage Area and housed until the AV scheduled Collection Date.
- 8) Upon the receipt of the DEA 41 Inventory from the AV, each CCSC should reconcile their CS Waste Inventory on the Caltech Disposal Certification Document to their license's DEA 41 Inventory Form provided by the AV. CCSCs should confirm and indicate, on their Caltech Disposal Certification, that any empty containers, which are not included on the DEA 41 Inventory Form, have been moved to hazardous waste disposal. All outstanding forms or documentation will be signed, scanned and sent back to the AV representative for confirmation. The originals will be collected by the AV representative on the Collection Date.

E. Collection Date: Transport and Disposal

- 1) The AV will schedule a Collection Date. On the Collection Date, the AV representative will have some additional forms for the CCSCs to sign prior to finalizing the transport and disposal.
- 2) Once the Waste CS, which have been stored in the AV container, are removed from the Secured Disposal Storage Area, properly labpacked and placed on board the AV vehicle, the Waste CS will be considered transferred into the custody of the AV, and the reverse distribution process is complete from Caltech's perspective.
- 3) If a DEA 222 form has been issued as a part of the disposal, make a copy of the form and send it to the Registration Section of the local Los Angeles field office or email it to DEA.Orderforms@usdoj.com.

- 4) The AV will send a Certificate of Destruction, consisting of at least a copy of the completed DEA Form 41 and any other associated documentation, including, but not limited to, the Department of Transportation shipping documents confirming that the material has been destroyed.

6. Documentation and Recordkeeping

A. Documentation

The CCSC for each license shall create a PDF with the following components:

- 1) Caltech Disposal Certification Document (Waste CS Inventory List): List of and detailed information about all CIT Control Numbers in the Waste CS Inventory and disposition as empty containers disposed of as hazardous materials or disposition as transferred to AV for reverse distribution.
- 2) AV DEA 41 Inventory Forms: This information should have been reconciled to the information in the Caltech Disposal Certification Document. Any outstanding discrepancies shall be investigated and a written explanation provided for each Waste CS inventory divergence.
- 3) AV DEA 222 Forms: 222 Forms corresponding to Schedule I or II Waste CS transferred to the AV.
- 4) Corresponding UDTD: Reconcile and compile all UDTD corresponding to Waste CS on the Caltech Disposal Certification Document, including (but not limited to) the CIT Control Number, the amount of CS remaining, PO number, Caltech DEA 222 Serial numbers for CS Schedule II, and any AV DEA 222 Serial numbers. Investigate any missing UDTD forms and document reasons for discrepancies or failure to find a UDTD form.
- 5) Final and Complete (Signed) Copy of the AV DEA 41 Inventory/Destruction Form: This copy should bear the date of destruction and will be due from AV within 180 days of the actual destruction. Any other certification of destruction or additional associated documentation, bearing all appropriate signatures should be included.

Save the file named: YYYYMMDD Controlled Substances Disposal Package – License # -ORG

B. Recordkeeping

- 1) The CCSCs shall store the Documentation File in the Disposal Folder on Sharepoint.
- 2) The Documentation must be retained for two years following the documented date of destruction.