Controlled Substances in Research and Development

BRIEF

Policy Summary

Controlled-substance use in research at Berkeley Lab must comply with all federal regulations, laws, and Department of Energy (DOE) directives. Use of these substances requires implementation of best practices in procurement, accountability, security, and disposal.

No controlled substance or controlled-substance analogue may be created unless prior approval is obtained from the Program Administrator in the Environment/Health/Safety (EHS) Division. No controlled substance may be transferred to or from Berkeley Lab without approval from the Program Administrator in EHS.

Who Should Read This Policy

Employees who work with, handle, procure, or facilitate disposal of controlled substances at Berkeley Lab

To Read the Full Policy, Go To:

The POLICY tab on this wiki page

To Read the ES&H Program Details, Go To:

The Controlled Substances Program Plan

Contact Information

Controlled Substances Program Administrator
Industrial Hygiene Group
EHS
DGBest@lbl.gov

POLICY

A. Purpose

Controlled-substance use in research at Lawrence Berkeley National Laboratory (Berkeley Lab) must comply with all federal regulations, laws, and Department of Energy (DOE) directives. Use of these substances requires implementation of best practices in procurement, accountability, security, and disposal.

B. Persons Affected

Employees who work with, handle, procure, or facilitate disposal of controlled substances at Berkeley Lab.
C. Exceptions

Not applicable

D. Policy Statement

D.1 General (Work Processes A–D)

1. Controlled substances include those defined in Schedules I, II, III, IV, and V of the Controlled Substances Act (Title 21 USC Section 812). The Drug Enforcement Administration (DEA) is the regulatory agency for controlled substances (21 CFR 1300-1308).
2. Berkeley Lab will maintain DEA registrations (Work Process B) for each off-site location and for the Laboratory main site where controlled substances are used.
3. All personnel who have direct access to controlled substances must register with the Program Administrator (Work Process C) and pass an employee screening (Work Process D; required by DEA).
4. Each authorized controlled substances custodian (authorized custodian) must provide secure storage and maintain inventory records that comply with the DEA regulations.
5. Authorized custodians are encouraged to review the Exempt Chemical Preparations List for substances that are not regulated. See http://www.deadiversion.usdoj.gov/schedules/exempt/exempt_chemlist.pdf.
6. Absolutely no controlled substance may be transported between another institution and Berkeley Lab or from Berkeley Lab to another institution (which includes transportation between Berkeley Lab locations) without prior approval from the Program Administrator. No controlled substance or controlled-substance analogue may be created at any Laboratory location unless prior approval is obtained from the Program Administrator.
7. All personnel are required to report any suspicion of illegal use or diversion of controlled substances to the Program Administrator.

D.2 Acquisition Process (Work Process E)

Controlled substances may only be purchased through eBuy vendors or a one-time purchase order. Blanket purchase orders may not be used.

D.3 Custodianship Process (Work Processes F–G)

1. Per DEA regulation, the substances must be delivered to the address on the registration. For Berkeley Lab, the delivery address is One Cyclotron Road, Building 69, Facilities Receiving. Substances will be tracked by the use of a Chain of Custody document for all transfers between authorized custodians, authorized controlled substances workers (authorized workers), and Berkeley Lab locations (Work Process F)
2. The authorized custodian or worker must notify the Program Administrator of any significant loss of material within one business day of discovery.
3. The authorized custodian must update the Berkeley Lab registration information for:
   a. Changes in the storage location or configuration (Work Process G)
   b. Changes in the quantity or specific substance to be used
   c. Changes to the list of persons having direct access to the controlled substances

D.4 Disposal Process (Work Process H)

1. The authorized custodian notifies the Program Administrator of the need to dispose of excess controlled substance.
2. The authorized custodian follows instructions for Schedule I or II substances here: http://www.lbl.gov/ehs/ih/programs/csp/assets/CSdisposalInstrux1_2.pdf.
3. The authorized custodian follows instructions for Schedule III, IV, or V substances here: http://www.lbl.gov/ehs/ih/programs/csp/assets/CSdisposalInstrux3_5.pdf

E. Roles and Responsibilities

Managers, supervisors, and employees must adhere to the provisions of this policy.

<table>
<thead>
<tr>
<th>Role</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>EHS Division Director</td>
<td>Obtains and maintains appropriate DEA research registrations</td>
</tr>
</tbody>
</table>
Authorized controlled-substances custodian

(Authorized custodian)

- Initiates controlled-substance acquisition process for research use
- Reports any suspicions of illegal use or diversion of a controlled substance
- Obtains prior approval from the Program Administrator for transfers of controlled substances from another institution to Berkeley Lab
- Obtains prior approval from the receiving institution and the Berkeley Lab Program Administrator for transfers of controlled substances to another institution
- Obtains specific authorization from the Program Administrator prior to synthesizing a controlled substance or controlled-substance analogue
- Maintains an up-to-date Berkeley Lab registration form for the project and passes an employee screening
- Maintains proper security controls
- Completes Controlled Substances training
- Reviews the Exempt Chemical Preparations List for substances not subject to DEA regulation
- Reports any loss of a controlled substance to the Program Administrator within 24 hours of discovery
- Maintains accountability for all assigned controlled substances, including purchasing and disposal records and inventory use logs
- Understands and maintains awareness of all activities with controlled substances for which he/she is accountable
- Enters chemicals into the Chemical Management System
- Participates in the initial, annual, and terminal Property Management inventory
- Supports the disposal of controlled substances
- Authorizes the synthesis of a controlled substance for research purposes
- Authorizes the transfer of controlled substances to or from Berkeley Lab
- Provides Controlled Substances training
- Approves/disapproves purchase of controlled substances
- Maintains records

Authorized controlled substances worker

(Authorized worker)

- Initiates controlled-substance acquisition process for research use
- Reports any suspicions of illegal use or diversion of a controlled substance
- Passes the employee screening process
- Never transfers a controlled substance from another institution or location to Berkeley Lab without prior approval from the Program Administrator
- Never transfers controlled substances from Berkeley Lab to another institution without prior approval from the receiving institution
- Never synthesizes a controlled substance or controlled-substance analogue without specific authorization from the Program Administrator
- Maintains proper security controls
- Makes accurate entries on the inventory/use log for any controlled substance used
- Completes Controlled Substances training

Subcontract Administrator

- Maintains Procurement records
- Processes one-time purchase requisitions

Accounts Payable

- Maintains invoice and payment records to vendors of controlled substances

Receiving

- Receives and secures controlled substances for all locations
- Initiates Chain of Custody and maintains a copy
- Completes Controlled Substances training

Transportation

- Receives controlled substances for delivery to the research location
- Signs chain of custody as receiver and relinquisher
- Completes Controlled Substances training

Program Administrator or designee

- Administers and directs the Controlled Substances program
- Receives, reviews, and maintains a file of all Berkeley Lab controlled-substances registration forms
- Notifies the Berkeley Lab Security Manager of a theft or loss of a controlled substance
- Supports the disposal of controlled substances
- Authorizes the synthesis of a controlled substance for research purposes
- Authorizes the transfer of controlled substances to or from Berkeley Lab
- Provides Controlled Substances training
- Approves/disapproves purchase of controlled substances
- Maintains records

Human Resources

- Performs employee screenings for those noted above
- Communicates with the Program Administrator about the results of employee screenings

Property Management

- Performs initial and annual physical inventory and conducts inventories for transfers and disposal
- Submits inventory reports to DOE per DOE Order 580.1A
- Maintains appropriate inventory records per DOE Order 580.1A

F. Definitions/Acronyms

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Authorized custodian</td>
<td>A Berkeley Lab employee responsible for overall possession of the controlled substance for a research project</td>
</tr>
<tr>
<td>Authorized worker</td>
<td>A Berkeley Lab employee authorized to receive, handle, access, or manipulate controlled substances for research purposes</td>
</tr>
</tbody>
</table>
G. Recordkeeping Requirements

All records will be kept in accordance with 21 CFR 1304.

H. Implementing Documents

<table>
<thead>
<tr>
<th>Document Number</th>
<th>Title</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td>Inventory/Use Logs</td>
<td>Form</td>
</tr>
<tr>
<td>N/A</td>
<td>Controlled Substances Program Registration</td>
<td>Form</td>
</tr>
<tr>
<td>N/A</td>
<td>Controlled Substances Program Employee Screening</td>
<td>Form</td>
</tr>
<tr>
<td>N/A</td>
<td>Chain of Custody</td>
<td>Form</td>
</tr>
<tr>
<td>03.06.001.001</td>
<td>Controlled Substances Program Plan</td>
<td>Program</td>
</tr>
<tr>
<td>03.06.001.002</td>
<td>Work Process A, General Requirements</td>
<td>Process</td>
</tr>
<tr>
<td>03.06.001.003</td>
<td>Work Process B, DEA Registration</td>
<td>Process</td>
</tr>
<tr>
<td>03.06.001.004</td>
<td>Work Process C, Berkeley Lab Registration</td>
<td>Process</td>
</tr>
<tr>
<td>03.06.001.005</td>
<td>Work Process D, Employee Screening</td>
<td>Process</td>
</tr>
<tr>
<td>03.06.001.006</td>
<td>Work Process E, Purchasing Controlled Substances</td>
<td>Process</td>
</tr>
<tr>
<td>03.06.001.007</td>
<td>Work Process F, Receiving and Transferring Controlled Substances</td>
<td>Process</td>
</tr>
<tr>
<td>03.06.001.008</td>
<td>Work Process G, Storage of Controlled Substances</td>
<td>Process</td>
</tr>
<tr>
<td>03.06.001.009</td>
<td>Work Process H, Disposal of Controlled Substances</td>
<td>Process</td>
</tr>
</tbody>
</table>

I. Contact Information
Controlled Substances Program Administrator
Industrial Hygiene Group
EHS
dGBest@lbl.gov

J. Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Revision</th>
<th>By whom</th>
<th>Revision Description</th>
<th>Section(s) affected</th>
<th>Change Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/2/2012</td>
<td>1</td>
<td>Lunford</td>
<td>Rewrite for wiki</td>
<td>All</td>
<td>Minor</td>
</tr>
<tr>
<td>8/30/2013</td>
<td>2</td>
<td>Rothermich</td>
<td>Update to align with 21 CFR 1300-1321</td>
<td>All</td>
<td>Major</td>
</tr>
</tbody>
</table>

Document Information

DOCUMENT INFORMATION

Title: Controlled Substances in Research and Development

Document number: 03.06.001.000

Revision number: 2

Publication date: 8/30/2013

Effective date: 8/30/2013

Next review date: 8/30/2016

Policy Area: Controlled Substances

RPM Section (home): Conduct of Research & Development

RPM Section (cross-reference): 

Functional Division: EHS

Prior reference information (optional): RPM Sections 2.23, 11.39, 1.06

Source Requirements Documents

- DOE Order 580.1A, Department of Energy Personal Property Management Program Contractor Requirements Document
- 21 CFR 1300-1321, Regulations for Controlled Substances
- Title 21 USC 802(6), Controlled Substances Act

Other Driving Requirements


Implementing Documents

<table>
<thead>
<tr>
<th>Document Number</th>
<th>Title</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td>Inventory/Use Logs</td>
<td>Form</td>
</tr>
<tr>
<td>N/A</td>
<td>Controlled Substances Program Registration</td>
<td>Form</td>
</tr>
<tr>
<td>N/A</td>
<td>Controlled Substances Program Employee Screening</td>
<td>Form</td>
</tr>
<tr>
<td>N/A</td>
<td>Chain of Custody</td>
<td>Form</td>
</tr>
<tr>
<td>03.06.001.001</td>
<td>Controlled Substances Program Plan</td>
<td>Program</td>
</tr>
<tr>
<td>03.06.001.002</td>
<td>Work Process A, General Requirements</td>
<td>Process</td>
</tr>
<tr>
<td>03.06.001.003</td>
<td>Work Process B, DEA Registration</td>
<td>Process</td>
</tr>
<tr>
<td>03.06.001.004</td>
<td>Work Process C, Berkeley Lab Registration</td>
<td>Process</td>
</tr>
<tr>
<td>03.06.001.005</td>
<td>Work Process D, Employee Screening</td>
<td>Process</td>
</tr>
<tr>
<td>03.06.001.006</td>
<td>Work Process E, Purchasing Controlled Substances</td>
<td>Process</td>
</tr>
</tbody>
</table>

Lawrence Berkeley National Laboratory. The official or current version is located in the online LBNL Requirements and Policies Manual. Printed or exported versions are not official. Users are responsible for working with the latest approved revision.
<table>
<thead>
<tr>
<th>Work Process ID</th>
<th>Work Process Description</th>
<th>Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>03.06.001.007</td>
<td>Work Process F, Receiving and Transferring Controlled Substances</td>
<td>Process</td>
</tr>
<tr>
<td>03.06.001.008</td>
<td>Work Process G, Storage of Controlled Substances</td>
<td>Process</td>
</tr>
<tr>
<td>03.06.001.009</td>
<td>Work Process H, Disposal of Controlled Substances</td>
<td>Process</td>
</tr>
</tbody>
</table>