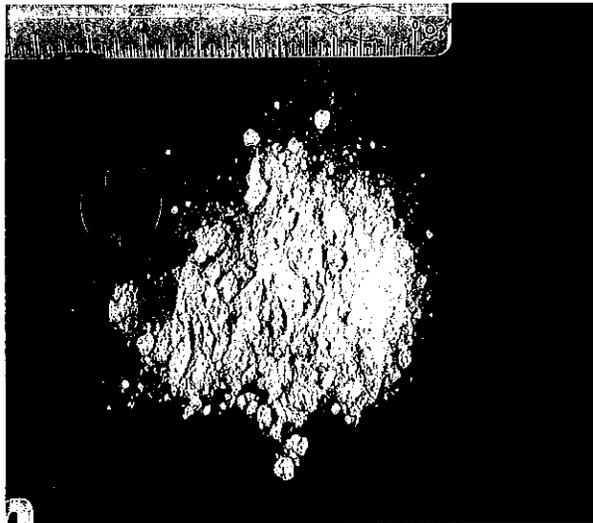


Controlled Substance

Security Procedure

(Schedules I, II, III, IV and V Controlled Substances)

Guidelines for Acquiring & Accounting for Controlled Substances for Scientific Use



Lawrence Berkeley National Laboratory
University of California
Berkeley, California

September 30, 2010

Controlled Substance Security Procedure for the Ernest Orlando Lawrence Berkeley National Laboratory

September 2010

Version 3



Dan S. Lunsford
Environmental, Health & Safety Division
Security & Emergency Operations

9-30-10

(Date)

Future revisions to the CSSP will be summarized in the "Revision Section" and reflected within the primary document. All revisions are reviewed by the CSSP team members and the respective BSO representative. The updated document is posted on the EH&S website with updated copies provided to team members and the BSO. The CSSP signature page is only updated when there is a change in membership.

Table of Contents

Table of Contents	3
Foreword	6
Revisions	7
1 Executive Summary	9
Goals.....	9
Objective.....	9
Summary	9
2 Controlled Substances Used at LBNL	10
Authorities.....	10
3 Roles and Responsibilities	11
Principal Investigator (PI).....	11
Controlled Substance SME	11
Procurement.....	13
Receiving	13
Security	14
EH&S Waste Management	14
Property Management	15
4 Acquisition Guidelines	16
Initiation of Process	16
Procurement.....	17
Receiving	18
Security	19
Transportation	19
5 Custodianship Guidelines	20

Principal Investigator (PI)	20
Property Management	21
EH&S Waste Management	21
6 Disposal Guidelines	22
Principal Investigator (PI).....	22
EH&S Waste Management	22
Property Management	22
Procurement/CSLO.....	23
Shipping	23
7 Controlled Substance Advisory Committee	24
Program Overview	24
Appendix A: Schedules of Controlled Substances	25
Appendix B: Controlled Substance Advisory Committee.....	38
Points of Contact.....	38
Appendix C: Designated Alternate Signer (Sample Memo).....	39
Appendix D: Chain of Custody Form	40
Appendix E: Glossary	42

Foreword

The Controlled Substance Security Procedure was created to comply with Section 802(6) of Title 21, 21 CFR Part 1300 of the United States Code & California Health & Safety Code Section 11100. The Lab is not a distributor of controlled substances as defined in Section 802. As such, a procedure needed to be created for Schedules I, II, III, IV, and V Controlled Substances use in science and research. Thus, in October 2006 the process of planning and developing the procedure began.

The Controlled Substance Security Procedure serves as a guide for Lab stakeholders who either use controlled substances in science and research projects or are involved in its procurement, receiving, delivering, handling, securing, inventorying, and disposal. The goal was to develop guidelines and best practices to ensure safety, accountability, security, and compliance when receiving, distributing, using and disposing of controlled substances.

This is a living document subject to updates as deemed by scientific research. When updates are needed, the Controlled Substances Advisory Committee (Appendix B) will convene to integrate newly introduced best practices.

Dan Lunsford
SEO Group Lead
Environment, Health & Safety Division

Revisions

Revision III (September 2010)

<u>Section</u>	<u>Revision</u>	<u>Page</u>
----------------	-----------------	-------------

The title of this document has been changed to **Controlled Substance Security Procedure**.

<u>Section</u>	<u>Revision</u>	<u>Page</u>
----------------	-----------------	-------------

3	Roles & Responsibilities	
	<ul style="list-style-type: none"> Principal Investigator (PI)/Researcher changed to Principle Investigator (PI) Addition of "Controlled Substance SME" section Addition of bullet 3 to "Procurement" section 	11/12 12 13
4	Acquisition Guidelines	
	<ul style="list-style-type: none"> Added bullets 5, 6, and 7 to "Initiation Process" section 	16
5	Custodianship Guidelines	
	<ul style="list-style-type: none"> Principal Investigator (PI)/Researcher changed to Principle Investigator (PI) 	20
6	Disposal Guidelines	
	<ul style="list-style-type: none"> Principal Investigator (PI)/Researcher changed to Principle Investigator (PI) 	22

Revision II (August 2008)

<u>Section</u>	<u>Revision</u>	<u>Page</u>
----------------	-----------------	-------------

All references to transporting controlled substances between UC Berkeley and LBNL are removed.

Appendix A	Expanded to include Schedule III, IV & V substances	24
Appendix E	Removed	
Appendix D & F	Changed to Appendix C & Appendix D	39 & 42

Revision I (May 2007)

<u>Section</u>	<u>Revision</u>	<u>Page</u>
----------------	-----------------	-------------

3	Roles & Responsibilities	
	<ul style="list-style-type: none"> Principal Investigator (PI) Procurement Security 	11 13 14

<u>Section</u>	<u>Revision</u>	<u>Page</u>
4	Acquisition Guidelines	
	• Initiation of Process	16
	• Procurement	17
	• Receiving	18
	• Security	19
Appendix D	"Designed Alternative Signer" Sample Memo	38
Appendix E	Chain of Custody Flow Chart for Transportation of Substance to UC Berkeley	39
Appendix F	Chain of Custody Form	41

1 Executive Summary

Goals

- To ensure and maintain accountability of controlled substances
- To successfully facilitate obtaining controlled substances for research
- To ensure compliance with appropriate federal, state, and local codes, regulations and laws
- To make the procedure easily accessible and timely to all stakeholders and users to ensure continuity and consistency in the handling and use of controlled substances
- To develop and implement best practices in procurement, accountability, security, and disposal of controlled substances

Objective

To develop a procedure to achieve the above stated goals in a safe and secure manner in support of science.

Summary

Controlled substances are regulated by Section 802(6) of Title 21, 21 CFR Part 1300, United States Code & California Health & Safety Code Section 11100. Scientists can use controlled substances in their research. It is LBNL's goal to develop guidelines and best practices to ensure safety, accountability, security, and compliance when receiving, distributing, using and disposing of controlled substances.

This procedure is developed to ensure consistency, accountability and make available a process in which all Lab stakeholders can use when working with controlled substances.

2 Controlled Substances Used at LBNL

The Controlled Substance Liaison Officer (CSLO) assists Principal Investigators (PIs) in procuring controlled substances on Schedules I, II, III, IV and V for scientific use. Examples of substances used in research by LBNL PIs are listed below:

- Cocaine
- Demerol
- Ethanol
- Hydromorphone
- Morphine
- Nembutal
- Piperdine
- Phenylacetone
- Sodium Pentobarbital

Controlled substances listed on Schedules I, II, III, IV and V (Appendix A) are subject to the procedure contained in this document.

LBNL has a license to purchase only on Schedules I, II, III, IV and V substances. For any questions regarding these materials, please contact the Controlled Substance Liaison Officer (CSLO).

**Absolutely no controlled substances shall be transported
between UC Berkeley and DOE facilities.**

Authorities

DOE Order 580.1 4. Requirements, h. Controlled Substances, Hypodermic Needles, Syringes and Potable Alcohol

Section 802(6) of Title 21, 21 CFR Part 1300, United States Code & California Health & Safety Code Section 11100

3 Roles and Responsibilities

Principal Investigator (PI)

1. Contacts Procurement (Controlled Substance Liaison Officer) to initiate controlled substance acquisition process for research usage
2. Maintains purchase, use and disposal records, documentation and usage log book
 - a. Schedules I, II, III, IV and V
 - b. If substance is brought to LBNL by a scientist from another lab, Lab Security must be notified¹
3. Completes proper paperwork for ordering
 - a. For each order, PI designates a back-up or assistant to receive delivery
 - b. The back-up or assistant must be a full-time, career LBNL employee (see Appendix C for sample "Designated Alternative Signer" memo)
4. Keeps controlled substances in a locked repository (reference DOE Order 580.1 4. Requirements, h. Controlled Substances, Hypodermic Needles, Syringes and Potable Alcohol)
5. Chemical Management System
 - a. Upon receipt of chemical, PI or researcher enters data into Lab's Chemical Management System (CMS)
6. Reports theft, loss and movement on- and/or off-site to EH&S Security and Property Management immediately

**Absolutely no controlled substances shall be transported
between UC Berkeley and DOE facilities.**

¹ Note:

Any controlled substance not processed by the Controlled Substance Liaison Officer (CSLO) must be reported to the Lab Security Manager prior to its arrival at LBNL, e.g. a scientist from another lab brings a controlled substance to LBNL for use.

Once the controlled substance arrives at the Lab, the appropriate elements of this procedure apply.

Roles and Responsibilities (continued)

Principal Investigator (PI)

7. Prior to disposal
 - a. Contact EH&S Waste Management for disposal
 - i. Waste Management provides Project ID for disposal services
 - b. Contact Property Management for disposal inventory
 - i. Custody terminates upon completion of transfer or disposal process
 - ii. Request inventory of assigned substance upon first knowledge (and prior to completion) of termination of employment
 - iii. Informs supervisor of results of inventory
 - c. Transfer assigned substance to a new custodian prior to termination
 - i. Inform supervisor, Lab Security and Property Management of transfer

Controlled Substance Subject Matter Expert (SME)

1. The Controlled Substance SME will check for more than just guest status, but will review the substance and person making the purchase to include the user's need for the substances, if necessary.
2. The back-up Controlled Substance SME will approve the requisition in the absence of the primary when the primary Controlled Substance SME is unavailable.

Roles and Responsibilities (continued)

Procurement

1. Registers with Drug Enforcement Agency and maintains license
2. Receives or requests from PI a "Designated Alternative Signer" memo and sends copy to Receiving for each purchase order
3. The Procurement Controlled Substance Liaison Officer (CSLO) will formally approve the requisition directly following the Drug Approver's approval to ensure continuity and accountability as the single Point of Contact for Controlled Substances for the Lab and vendor.
4. Maintains restricted item list
5. Designates primary and back-up buyer as the Controlled Substance Liaison Officer (CSLO)
6. Maintains Procurement Policy and Procedure
7. Approves and processes purchase requisitions
8. Sends copy of approved Purchase Order for any Controlled Substance to Property Management and Receiving
9. Maintains purchase and registration records
10. Notifies Lab Security for new user lab security check
11. Receives annual controlled substances inventory report
12. Participates on the Controlled Substance Advisory Committee (CSAC)

Receiving

1. Receives and secures controlled substance
2. Maintains receiving records
3. Notifies Lab Security of shipment arrival within 1 business day
 - a. Begins chain of custody process (See Appendix D: Chain of Custody Form)
 - b. Copies Property Management on notification to Lab Security of shipment arrival
4. Participates on the Controlled Substance Advisory Committee (CSAC)

Roles and Responsibilities (continued)

Security

1. Assists with the transportation of the controlled substance, as required
2. Ensures controlled/locked repository (reference DOE Order 580.1 4. Requirements, h. Controlled Substances, Hypodermic Needles, Syringes and Potable Alcohol)
3. Facilitates chain of custody process (see Appendix D: Chain of Custody Form)
4. Communicates with principal investigator to resolve any Security concerns
5. Establishes points of contact, as necessary, such as principal investigators
6. Reviews annual controlled substances inventory report
7. Participates on Controlled Substances Advisory Committee (CSAC)
8. Facilitates transfer of custody when Principal Investigator (PI) is terminated
 - a. Upon notification of PI termination, validates transfer of custody with Property Management and new custodian of substance
9. Facilitates police report upon notification of controlled substance theft or loss

EH&S Waste Management

1. Maintains contract with an appropriate vendor for proper disposal
2. Assists PI in packaging material for disposal
3. Provides and maintains Controlled Substances Disposal Instructions for both Schedule I-II and Schedule III-V controlled substances
4. Processes contractor invoices for disposal
5. Interact with appropriate PIs/Users and agencies, as needed
6. Participates on the Controlled Substances Advisory Committee (CSAC)

Roles and Responsibilities (continued)

Property Management

1. Performs annual physical inventory and conducts inventories for transfers and disposal
 - a. Forwards results to Lab Security and Procurement/CSLO
2. Maintains appropriate records
3. Participates on the Controlled Substance Advisory Committee

4 Acquisition Guidelines

Initiation of Process

1. Researcher initiates purchase request
2. PI approves researcher's request
3. Approved requisition is entered into PeopleSoft by appropriate division office
4. PI provides to Procurement a "Designated Alternative Signer" memo indicating the name and signature of the full-time, LBNL employee who can sign for receipt of the substance in the absence of the PI
5. CSLO (buyer) forwards requisition to Controlled Substance SME.
6. Controlled Substance SME reviews requisition and forwards approval/denial to CLSO (buyer)
7. The CSLO will formally approve the requisition directly following the Controlled Substance SME's approval to ensure continuity and accountability as the single Point of Contact for Controlled Substances for the Lab and vendor. The back-up Procurement CSLO will approve those requisitions when the primary CSLO is unavailable. The CSLO will also notify Property and Receiving of the subsequent PO number associated with the requisition.

If substance is brought to LBNL by a scientist from another lab, the Lab Security Manager must be notified prior to procurement initiation to ensure compliance with this procedure.

Acquisition Guidelines (continued)

Procurement

1. Receives Principal Investigator's/Researcher's
 - a. Request for obtaining controlled substance through respective Division via ePro approval process
 - b. "Designated Alternative Signer" memo
2. Contacts respective vendor for
 - a. Pricing
 - b. Availability of item
3. Creates Purchase Order (PO) and forwards to Vendor
 - a. Forwards copy to Vendor and requires acknowledgement
 - b. Forwards copy of PO to PI
 - c. Forwards copy of PO to Property Management
 - d. Maintains original PO
 - e. Forwards Vendor acknowledgement to PI
4. Contacts Shipping & Receiving to make them aware of upcoming shipment
 - a. Sends email to receiving@lbl.gov and follows up with phone call with arrival date (within 24 hours before arrival of shipment) and tracking number
 - b. Forwards PO# to Shipping & Receiving
 - c. Sends copy of PI's "Designated Alternative Signer" to Receiving
5. Receives notification from Shipping & Receiving that substance has arrived
 - a. Contacts PI to indicate substance has arrived and ready for pick-up or transport by Lab Security

Acquisition Guidelines (continued)

Receiving

1. Receives substance
 - a. Staff reviews work instruction for distribution of substance
 - b. Carrier arrives at Building 69 Receiving Dock
 - c. Package is received
 - d. Scanned into Receiving Tracking System (starts paper trail)
 - e. Informs Receiving staff and sends confirmation email to CSLO (buyer)
 - f. Secures in cage
2. Notifies PI or Authorized Signer for Transfer
 - a. PI travels to Building 69 to take possession of package or
 - b. Package may be delivered via Lab Security or Lab Transportation and PI signature required upon delivery.
3. Initiates Delivery
 - a. Initiates chain of custody process (see Appendix D: Chain of Custody Form)
 - b. After delivery by Transportation is complete (Receiving Lead)
 - c. Notifies Property Management of completed delivery via email
 - d. Forwards a copy of Chain of Custody signed record to Property Specialist
4. Releases controlled substance to
 - a. PI with a copy of the Controlled Substance Procedure
 - b. Or Lab Security

Acquisition Guidelines (continued)

Security

1. Assist with transportation, as required
2. Ensures controlled/locked repository, as required (reference: DOE Order 580.1 4. Requirements, h. Controlled Substances, Hypodermic Needles, Syringes and Potable Alcohol)
3. Continues chain of custody process
4. Communicates with PI to resolve any security concerns
5. Provides a copy of the Controlled Substance Procedure to PI or Designated Alternative Signer
6. Establishes points of contact, as necessary

Transportation

1. Delivers package via the Lab Transportation Department
2. Uses IBox tracking system to record the next custodian in the chain of custody process (e.g. PI or Lab Security) of the controlled substance package
3. Releases or delivers package to the name listed on the package
 - a. Signature is required with proof of identification via Lab badge
 - b. Provides a copy of the Controlled Substance Procedure document to PI or Designated Alternative Signer
4. Ensures controlled/ locked repository, as required (reference: DOE Order 580.1 4. Requirements, h. Controlled Substances, Hypodermic Needles, Syringes and Potable Alcohol)
5. Notifies Receiving upon completion of delivery

5 Custodianship Guidelines

Principal Investigator (PI)

1. Picks-up substance from Shipping & Receiving or receives from Lab Security
 - a. Signs and maintains chain of custody form
 - b. Receives copy of Controlled Substance Procedure
2. Keeps controlled substances in locked repository (ref: DOE Order 580.1 4. Requirements, h. Controlled Substances, Hypodermic Needles, Syringes and Potable Alcohol)
3. Reports theft, loss, or movement on- and/or off-site to Lab Security and Property Management² immediately
4. Contacts Procurement and EH&S Waste Management when ready to dispose of substance
5. Notifies Security upon termination of PI employment
6. Submits Requisition to Procurement/CSLO if additional substance is needed when original substance is depleted

Absolutely no controlled substances shall be transported between UC Berkeley and DOE facilities.

² **Note:**

Any controlled substance not processed by the Controlled Substance Liaison Officer (CSLO) must be reported to the Lab Security Manager prior to its arrival at LBNL, e.g. a scientist from another lab brings a controlled substance to LBNL for use.

Once the controlled substance arrives at the Lab, the appropriate elements of this procedure apply.

Custodianship Guidelines (continued)

Property Management

1. Performs annual physical inventory and conducts inventories for transfer and disposal
 - a. Schedules inventory
 - b. Conducts inventory
 - c. Prepares inventory report
2. Maintains appropriate records
 - a. Updates controlled substance records upon notification of custody status changes (e.g. termination of PI, relocation of substance, transfer of custody)
3. Provides controlled substance disposal container (zip lock bags) to PI

EH&S Waste Management

1. Interacts with regulatory agencies as needed

6 Disposal Guidelines

Principal Investigator (PI)

1. Contacts Procurement/CSLO, Property Management and EH&S Waste Management to begin disposal process
2. Ensures controlled substance is inventoried for disposal
3. Completes vendor Return Request form, following Controlled Substances Disposal Instructions
4. Completes US Postal Service Return Receipt Request and Receipt for Certified/Registered Mail forms
5. Hand-carry delivery of controlled substance package (and USPS forms) to Shipping or via Lab Security Services
 - a. Provides Project ID for shipment costs
 - b. Must deliver package to Shipping same day disposal inventory is conducted
6. Chain of Custody Form is signed and shows transfer of substance from PI or researcher to Shipping or Lab Security Services

EH&S Waste Management

1. Assist the PI in preparing the controlled substance for disposal according to Waste Management process and protocols
2. Provides "Controlled Substance Disposal Instructions" to PI
3. Process the disposal vendor invoice

Property Management

1. Performs controlled substance disposal inventory
 - a. Must be performed same day controlled substance is delivered to Shipping by PI

Disposal Guidelines (continued)

Procurement/CSLO

1. Assists PI in completing vendor Return Request forms for controlled substances on Schedule I-II and Schedule III-V
2. For controlled substances under Schedule I-II, CSLO receives Return Request form, submitted by PI, for processing with disposal vendor
 - a. Distributes DEA form and pre-addressed mailing label from vendor to PI

Shipping

1. Ships controlled substance disposal package to vendor according to Controlled Substance Disposal Instructions

7 Controlled Substance Advisory Committee

Program Overview

A Controlled Substance Advisory Committee (CSAC) has been established and shall meet when necessary to discuss controlled substance issues that impact this procedure. The members of the advisory committee are:

Chair Security & Emergency Operations (SEO) Group Leader, EH&S

Committee Members Control Substance Liaison Officer, OCFO – Procurement

Security Program Manager, EH&S – SEO

Security Operations Manager, EH&S – SEO

Transportation Manager, Facilities

Representative, Berkeley Site Office

Waste Management Group Leader or designee, EH&S

Adjunct Members Property Manager, OCFO – Property Management

Principal Investigator, TBD

The CSAC will conduct an annual assessment of the established protocol and activities during the fourth quarter of the fiscal year and will be scheduled by Procurement. Based on best practices and research needs, the procedure will be updated. The completed revised procedure will be forwarded to the CSAC chair for approval.

Appendix A: Schedules of Controlled Substances

CITE- 21 USC Sec. 812 01/22/02

Website URL: <http://www.usdoj.gov/dea/pubs/csa/8121.htm>

TITLE 21 – FOOD AND DRUGS CHAPTER 13 – DRUG ABUSE PREVENTION AND CONTROL
SUBCHAPTER I – CONTROL AND ENFORCEMENT Part B – Authority To Control; Standards and Schedules

Sec. 812. Schedules of controlled substances

-STATUTE-

(a) Establishment There are established five schedules of controlled substances, to be known as schedules I, II, III, IV, and V. Such schedules shall initially consist of the substances listed in this section. The schedules established by this section shall be updated and republished on a semiannual basis during the two-year period beginning one year after October 27, 1970, and shall be updated and republished on an annual basis thereafter.

(b) Placement on schedules; findings required Except where control is required by United States obligations under an international treaty, convention, or protocol, in effect on October 27, 1970, and except in the case of an immediate precursor, a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance. The findings required for each of the schedules are as follows:

(1) Schedule I. –

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has no currently accepted medical use in treatment in the United States.

I There is a lack of accepted safety for use of the drug or other substance under medical supervision.

(2) Schedule II. –

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.

I Abuse of the drug or other substances may lead to severe psychological or physical dependence.

(3) Schedule III. –

(A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

I Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

(4) Schedule IV. –

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

I Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

(5) Schedule V. –

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

I Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

I Initial schedules of controlled substances Schedules I, II, III, IV, and V shall, unless and until amended (FOOTNOTE 1) pursuant to section 811 of this title, consist of the following drugs or other substances, by whatever official name, common or usual name, chemical name, or brand name designated:

(FOOTNOTE 1) Revised schedules are published in the Code of Federal Regulations, Part 1308 of Title 21, Food and Drugs.

SCHEDULE I

(a) Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Acetylmethadol.

(2) Allyprodine.

(3) Alphacetylmethadol. (FOOTNOTE 2)

(FOOTNOTE 2) So in original. Probably should be "Alphacetylmethadol."

(4) Alphameprodine.

(5) Alphamethadol.

(6) Benzethidine.

(7) Betacetylmethadol.

(8) Betameprodine.

(9) Betamethadol.

(10) Betaprodine.

(11) Clonitazene.

(12) Dextromoramide.

(13) Dextrophan.

(14) Diampromide.

(15) Diethylthiambutene.

(16) Dimenoxadol.

(17) Dimepheptanol.

(18) Dimethylthiambutene.

(19) Dioxaphetyl butyrate.

(20) Dipipanone.

- (21) Ethylmethylthiambutene.
- (22) Etonitazene.
- (23) Etoxadine.
- (24) Furethidine.
- (25) Hydroxypethidine.
- (26) Ketobemidone.
- (27) Levomoramide.
- (28) Levophenacymorphan.
- (29) Morpheridine.
- (30) Noracymethadol.
- (31) Norlevorphanol.
- (32) Normethadone.
- (33) Norpiperone.
- (34) Phenadoxone.
- (35) Phenampromide.
- (36) Phenomorphan.
- (37) Phenoperidine.
- (38) Piritramide.
- (39) Propheptazine.
- (40) Properidine.
- (41) Racemoramide.
- (42) Trimeperidine.

(b) Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

- (1) Acetorphine.
- (2) Acetyldihydrocodeine.
- (3) Benzylmorphine.
- (4) Codeine methylbromide.
- (5) Codeine-N-Oxide.
- (6) Cyprenorphine.
- (7) Desomorphine.
- (8) Dihydromorphine.
- (9) Etorphine.
- (10) Heroin.
- (11) Hydromorphenol.
- (12) Methyldesorphine.
- (13) Methylhydromorphine.
- (14) Morphine methylbromide.
- (15) Morphine methylsulfonate.
- (16) Morphine-N-Oxide.
- (17) Myorphine.
- (18) Nicocodeine.
- (19) Nicomorphine.
- (20) Normorphine.
- (21) Pholcodine.
- (22) Thebacon.

I Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

- (1) 3,4-methylenedioxy amphetamine.
- (2) 5-methoxy-3,4-methylenedioxy amphetamine.
- (3) 3,4,5-trimethoxy amphetamine.
- (4) Bufotenine.
- (5) Diethyltryptamine.
- (6) Dimethyltryptamine.
- (7) 4-methyl-2,5-diamethoxyamphetamine.
- (8) Ibogaine.
- (9) Lysergic acid diethylamide.
- (10) Marihuana.
- (11) Mescaline.
- (12) Peyote.
- (13) N-ethyl-3-piperidyl benzilate.
- (14) N-methyl-3-piperidyl benzilate.
- (15) Psilocybin.
- (16) Psilocyn.
- (17) Tetrahydrocannabinols.

SCHEDULE II

(a) Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

- (1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate.
- (2) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (1), except that these substances shall not include the isoquinoline alkaloids of opium.
- (3) Opium poppy and poppy straw.
- (4) coca (FOOTNOTE 3) leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed; cocaine, its salts, optical and geometric isomers, and salts of isomers; ecgonine, its derivatives, their salts, isomers, and salts of isomers; or any compound, mixture, or preparation which contains any quantity of any of the substances referred to in this paragraph.

(FOOTNOTE 3) So in original. Probably should be capitalized.

(b) Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

- (1) Alphaprodine.
- (2) Anileridine.
- (3) Bezitramide.
- (4) Dihydrocodeine.
- (5) Diphenoxylate.
- (6) Fentanyl.
- (7) Isomethadone.
- (8) Levomethorphan.
- (9) Levorphanol.
- (10) Metazocine.
- (11) Methadone.
- (12) Methadone-Intermediate, 4-cyano-2-dimethylamino-4,4-diphenyl butane.
- (13) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid.
- (14) Pethidine.
- (15) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine.
- (16) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate.

- (17) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid.
- (18) Phenazocine.
- (19) Piminodine.
- (20) Racemethorphan.
- (21) Racemorphan.

I Unless specifically excepted or unless listed in another schedule, any injectable liquid which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers.

SCHEDULE III

(a) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

- (1) Amphetamine, its salts, optical isomers, and salts of its optical isomers.
- (2) Phenmetrazine and its salts.
- (3) Any substance (except an injectable liquid) which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers.
- (4) Methylphenidate.

(b) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

- (1) Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid.
- (2) Chorexadol.
- (3) Glutethimide.
- (4) Lysergic acid.
- (5) Lysergic acid amide.
- (6) Methyprylon.
- (7) Phencyclidine.
- (8) Sulfondiethylmethane.
- (9) Sulfonethylmethane.

(10) Sulphonmethane.

I Nalorphine.

(d) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof:

(1) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium.

(2) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, non-narcotic ingredients in recognized therapeutic amounts.

(3) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.

(4) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(5) Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(6) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(7) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(8) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(e) Anabolic steroids.

SCHEDULE IV

(1) Barbital.

(2) Chloral betaine.

(3) Chloral hydrate.

(4) Ethchlorvynol.

(5) Ethinamate.

(6) Methohexital.

(7) Meprobamate.

(8) Methylphenobarbital.

(9) Paraldehyde.

(10) Petrichloral.

(11) Phenobarbital.

SCHEDULE V

Any compound, mixture, or preparation containing any of the following limited quantities of narcotic drugs, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:

(1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams.

(2) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.

(3) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.

(4) Not more than 2.5 milligrams of 34iphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.

(5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.

-SOURCE-

(Pub. L. 91-513, title II, Sec. 202, Oct. 27, 1970, 84 Stat. 1247; Pub. L. 95-633, title I, Sec. 103, Nov. 10, 1978, 92 Stat. 3772; Pub. L. 98-473, title II, Sec. 507I, 509(b), Oct. 12, 1984, 98 Stat. 2071, 2072; Pub. L. 99-570, title I, Sec. 1867, Oct. 27, 1986, 100 Stat. 3207-55; Pub. L. 99-646, Sec. 84, Nov. 10, 1986, 100 Stat. 3619; Pub. L. 101-647, title XIX, Sec. 1902(a), Nov. 29, 1990, 104 Stat. 4851.)

-MISC1-

AMENDMENTS

1990 – Subsec. I. Pub. L. 101-647 added item (e) at end of schedule III.

1986 – Subsec. I. Pub. L. 99-646 amended schedule II(a)(4) generally. Prior to amendment, schedule II(a)(4) read as follows: "Coca leaves (except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed); cocaine, its salts, optical and geometric isomers, and salts of isomers; and ecgonine, its derivatives, their salts, isomers, and salts of isomers."

Pub. L. 99-570 amended schedule II(a)(4) generally. Prior to amendment, schedule II(a)(4) read as follows: "Coca leaves and any salt, compound, derivative, or preparation of coca leaves (including cocaine and ecgonine and their salts, isomers, derivatives, and salts of isomers and derivatives), and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extraction of

coca leaves, which extractions do not contain cocaine or ecgonine." 1984 – Subsec. (c). Pub. L. 98-473, Sec. 507(c), in schedule II(a)(4) added applicability to cocaine and ecgonine and their salts, isomers, etc.

Subsec. (d). Pub. L. 98-473, Sec. 509(b), struck out subsec. (d) which related to authority of Attorney General to except stimulants or depressants containing active medicinal ingredients. 1978 – Subsec. (d)(3). Pub. L. 95-633 added cl. (3).

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101-647 effective 90 days after Nov. 29, 1990, see section 1902(d) of Pub. L. 101-647, set out as a note under section [802](#) of this title.

EFFECTIVE DATE OF 1978 AMENDMENT

Amendment by Pub. L. 95-633 effective on date the Convention on Psychotropic Substances enters into force in the United States (July 15, 1980), see section 112 of Pub. L. 95-633, set out as an Effective Date note under section [801a](#) of this title.

CONGRESSIONAL FINDING; EMERGENCY SCHEDULING OF GHB IN CONTROLLED SUBSTANCES ACT

Pub. L. 106-172, Sec. 2, 3(a), Feb. 18, 2000, 114 Stat. 7, 8, provided that:

"SEC. 2. FINDINGS.

"Congress finds as follows:

"(1) Gamma hydroxybutyric acid (also called G, Liquid X, Liquid Ecstasy, Grievous Bodily Harm, Georgia Home Boy, Scoop) has become a significant and growing problem in law enforcement. At least 20 States have scheduled such drug in their drug laws and law enforcement officials have been experiencing an increased presence of the drug in driving under the influence, sexual assault, and overdose cases especially at night clubs and parties.

"(2) A behavioral depressant and a hypnotic, gamma hydroxybutyric acid ('GHB') is being used in conjunction with alcohol and other drugs with detrimental effects in an increasing number of cases. It is difficult to isolate the impact of such drug's ingestion since it is so typically taken with an ever-changing array of other drugs and especially alcohol which potentiates its impact.

"(3) GHB takes the same path as alcohol, processes via alcohol dehydrogenase, and its symptoms at high levels of intake and as impact builds are comparable to alcohol ingestion/intoxication. Thus, aggression and violence can be expected in some individuals who use such drug.

"(4) If taken for human consumption, common industrial chemicals such as gamma butyrolactone and 1,4-butanediol are swiftly converted by the body into GHB. Illicit use of these and other GHB analogues and precursor chemicals is a significant and growing law enforcement problem.

"(5) A human pharmaceutical formulation of gamma hydroxybutyric acid is being developed as a treatment for cataplexy, a serious and debilitating disease. Cataplexy, which causes sudden and total loss of muscle control, affects about 65 percent of the estimated 180,000 Americans with narcolepsy, a sleep disorder. People with cataplexy often are unable to work, drive a car, hold their children or live a normal life.

'(6) Abuse of illicit GHB is an imminent hazard to public safety that requires immediate regulatory action under the Controlled Substances Act (21 U.S.C. [801](#) et seq.).

"SEC. 3. EMERGENCY SCHEDULING OF GAMMA HYDROXYBUTYRIC ACID AND LISTING OF GAMMA BUTYROLACTONE AS LIST I CHEMICAL.

"(a) Emergency Scheduling of GHB. –

"(1) In general. – The Congress finds that the abuse of illicit gamma hydroxybutyric acid is an imminent hazard to the public safety. Accordingly, the Attorney General, notwithstanding sections 201(a), 201(b), 201(c), and 202 of the Controlled Substances Act (21 U.S.C. [811\(a\)-\(c\)](#), [812](#)), shall issue, not later than 60 days after the date of the enactment of this Act (Feb. 18, 2000), a final order that schedules such drug (together with its salts, isomers, and salts of isomers) in the same schedule under section 202(c) of the Controlled Substances Act as would apply to a scheduling of a substance by the Attorney General under section 201(h)(1) of such Act (relating to imminent hazards to the public safety), except as follows:

"(A) For purposes of any requirements that relate to the physical security of registered manufacturers and registered distributors, the final order shall treat such drug, when the drug is manufactured, distributed, or possessed in accordance with an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) (whether the exemption involved is authorized before, on, or after the date of the enactment of this Act (Feb. 18, 2000)), as being in the same schedule as that recommended by the Secretary of Health and Human Services for the drug when the drug is the subject of an authorized investigational new drug application (relating to such section 505(i)). The recommendation referred to in the preceding sentence is contained in the first paragraph of the letter transmitted on May 19, 1999, by such Secretary (acting through the Assistant Secretary for Health) to the Attorney General (acting through the Deputy Administrator of the Drug Enforcement Administration), which letter was in response to the letter transmitted by the Attorney General (acting through such Deputy Administrator) on September 16, 1997. In publishing the final order in the Federal Register, the Attorney General shall publish a copy of the letter that was transmitted by the Secretary of Health and Human Services.

"(B) In the case of gamma hydroxybutyric acid that is contained in a drug product for which an application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) (whether the application involved is approved before, on, or after the date of the enactment of this Act (Feb. 18, 2000)), the final order shall schedule such drug in the same schedule as that recommended by the Secretary of Health and Human Services for authorized formulations of the drug. The recommendation referred to in the preceding sentence is contained in the last sentence of the fourth paragraph of the letter referred to in subparagraph (A) with respect to May 19, 1999.

"(2) Failure to issue order. – If the final order is not issued within the period specified in paragraph (1), gamma hydroxybutyric acid (together with its salts, isomers, and salts of isomers) is deemed to be scheduled under section 202I of the Controlled Substances Act (21 U.S.C. [812I](#)) in accordance with the policies described in paragraph (1), as if the Attorney General had issued a final order in accordance with such paragraph."

PLACEMENT OF PIPRADROL AND SPA IN SCHEDULE IV TO CARRY OUT OBLIGATION UNDER CONVENTION ON PSYCHOTROPIC SUBSTANCES

Section 102I of Pub. L. 95-633 provided that: "For the purpose of carrying out the minimum United States obligations under paragraph 7 of article 2 of the Convention on Psychotropic Substances, signed at Vienna, Austria, on February 21, 1971, with respect to pipradrol and SPA (also known as (-)-1-dimethylamino-1,2-diphenylethane), the Attorney General shall by order, made without regard to sections

201 and 202 of the Controlled Substances Act (this section and section [811](#) of this title), place such drugs in schedule IV of such Act (see subsec. I of this section)."

Provision of section 102I of Pub. L. 95-633, set out above, effective on the date the Convention on Psychotropic Substances enters into force in the United States (July 15, 1980), see section 112 of Pub. L. 95-633, set out as an Effective Date note under section [801a](#) of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 384, [811](#), 1115, 1523, 1703 of this title; title 10 section 912a; title 19 section 2484; title 20 sections 1415, 7161; title 29 sections 705, 2006; title 41 section 706; title 42 sections 12111, 12210.

Appendix B: Controlled Substance Advisory Committee

Points of Contact

<u>Contact Name</u>	<u>LBNL Phone</u>
PRIMARY CONTACT	
Dan Lunsford (Primary Contact)	486-6016
SECONDARY CONTACTS	
Ed Anderson (Primary Contact)	486-4575
John Speros (Back-up Contact)	486-4569
Controlled Substance Liaison Officer (CSLO) OCFO – Procurement	
William Llewellyn (Primary Contact)	486-7726
Tammy Brown (Back-up Contact)	486-5232
Transportation Manager Facilities	
John Morgan (Primary Contact)	486-5728
Dave McFann (Back-Up Contact)	
Property Manager OCFO – Property Management	
Landmark Protection Security Operations Manager EH&S – Security & Emergency Operations	486-7791
Nancy Rothermich (Primary Contact)	486-4644
Waste Management Group Leader EH&S – Waste Management	
Mary Gross Department of Energy, Berkeley Site Office	486-4373

Appendix C: Designated Alternate Signer (Sample Memo)

To: Edward Anderson, Controlled Substance Liaison Officer
From: (PI's Name)
Subject: Designated Alternate Signer for PO# _____

I authorize _____, who is a full-time career employee with Lawrence Berkeley National Laboratory, to sign in my absence for substances ordered under PO# _____ for [name of substance(s) ordered under this Purchase Order].

Should I not be available for receipt of the above order, _____ is authorized to receive and sign for the order and bring it to its destination where it will be placed in "locked repository" (ref: DOE Order 580.1 4. Requirements, h. Controlled Substances, Hypodermic Needles, Syringes and Potable Alcohol).

Signed:

Principal Investigator (Date)

Designated Alternate Signer:

Signature (Date)

Print Name

Employee #

Appendix D: Chain of Custody Form

(PLEASE SEE NEXT PAGE)



Appendix E: Glossary

Chain of Custody	<p>Chronological documentation showing the custody, control, transfer, analysis, and disposition of the controlled substance.</p> <p>An identifiable person must always have the physical custody of a controlled substance used for research purposes.</p>
Chain of Custody Form	The documentation used at LBNL showing the transfer of the substance from one person to the next throughout the time the controlled substance is used in LBNL scientific research (See Appendix D)
Controlled Substance Liaison Officer (CSLO)	A DEA-licensed LBNL procurement officer.
Controlled Substance SME	<p>The Controlled Substance SME will check for more than just guest status, but will review the substance and person making the purchase to include the user's</p> <p>The back-up Controlled Substance SME will approve the requisition in the absence of the primary Drug Approver when the primary Controlled Substance SME is unavailable.</p>
Designated Alternate Signer	An LBNL full-time, career employee whom the PI has given the responsibility of signing for the receipt of the controlled substance when the PI is not available on-site.
Ibox	A software tracking system which tracks and sorts packages in the LBNL Receiving environment.
Principal Investigator	Most U.S. Federal and State agencies that support scientific and technical research use the interchangeable titles "Principal Investigator" or "project director" for the scientist or researcher responsible for the technical leadership and administrative accountability of a project. A PI is ultimately responsible for the administration, direction, and management of the project and for its results. Often, funding for the project is also the PI's responsibility. The designation is specific to a single contract, and terminates with the closing of that project. The designation is thus of a different character than for such ongoing leadership positions as division director, department head, and group leader. A PI is always part of Line Management, and from a Safety Line Management perspective, the PI is no different from any other Staff. A PI's role may include being a HEERA Supervisor or Matrix Supervisor.
Researcher	At LBNL, an individual engaged in scientific research.