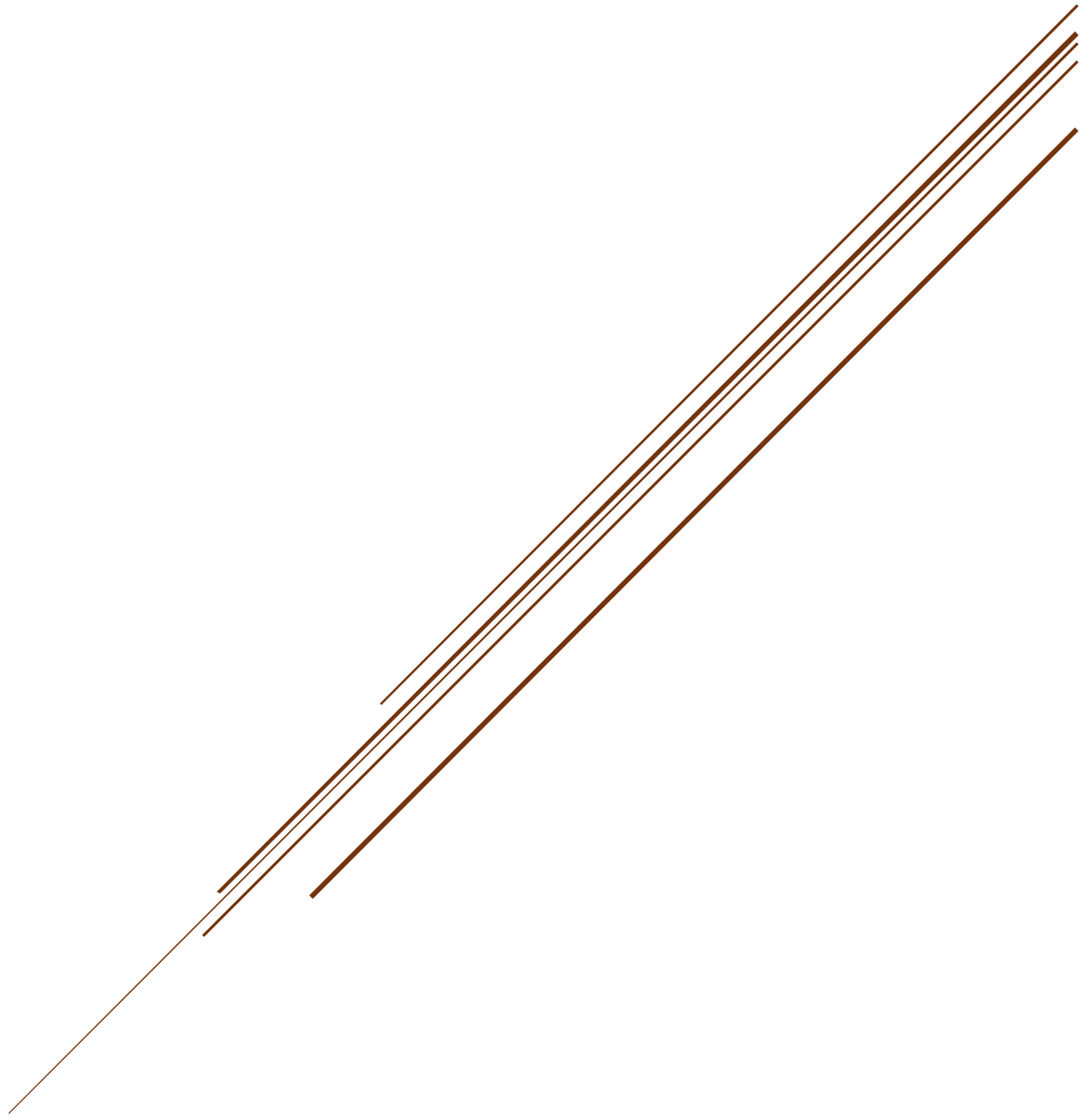


CONTROLLED SUBSTANCES PROGRAM

Including Precursor Chemicals



Blank Page

Table of Contents

I. Program Intent	1
II. Authority	1
III. Scope	1
IV. Definitions	1
Authorized Person	1
Biennial Inventory	1
Controlled Substance	1
Controlled Substance Program Administrator	2
Controlled Substance Use Authorization	2
Department Head	2
Drug Enforcement Agency Registration	2
Listed Chemicals:	2
Precursor Chemicals	2
Research Advisory Panel of California	3
Responsible Individual (RI)	3
Schedules of Controlled Substances	3
Schedule I	3
Schedule II	3
Schedule III	3
Schedule IV	3
Schedule V	3
V. Accountability	4
A. Controlled Substances Administrator	4
B. Environment, Health & Safety Department	4
C. Responsible Individual/CSUA Holder	4
D. Research/Lab Personnel	4

VI. Obtaining a Controlled Substance Use Authorization (CSUA)	5
VII. Acquisition and Delivery of Controlled Substances	5
Acquiring Controlled Substances and Precursor Chemicals	5
Purchasing	5
Acquisition via Any Other Company or Institution	5
Transfer of Controlled Substances to other SFSU Authorized Personnel	5
VIII. Precursor Chemical Acquisition, Use, and Disposal	6
Use, Storage and Disposal	6
IX. Security of Controlled Substances and Usage Logs	7
Acceptable storage of Controlled Substances	7
Unacceptable storage:	7
Recordkeeping	7
Usage Logs	7
Inventory Log	8
Inspections	8
X. Disposal of Controlled Substances	9
Empty Controlled Substance Containers	9
Authorized Personnel Leaving the University or CSUA-Covered Project	9
Prohibited Actions under the Controlled Substance Act	9
Theft, Loss, or Breakage	10
Reporting a Significant Loss to the DEA	10
Non-Significant Loss	10
XI. Process Flow Chart No. 1	11
Authorization to Use Controlled Substances and Managing Waste	11
XII. Process Flow Chart No. 2	12
Controlled Substances Procurement and Receipt Procedure	12

Controlled Substances Program

I. Program Intent

The purpose of the Controlled Substances Program is to provide researchers with information needed regarding the proper and safe use of controlled substances and precursor chemicals in their research. It will provide information on acquisition, storage, approved use, recordkeeping, and disposal.

II. Authority

The Drug Enforcement Administration (DEA) is the agency mandated to regulate the lawful use of controlled substances and List I chemicals under federal law Title 21 Chapter 13 Code of Federal Regulations (CFR) Part 1300 to end. The California Bureau of Narcotic Enforcement and the California State Board of Pharmacy are authorized to ensure compliance with California laws regulating controlled substances and prescription drugs, respectively.

III. Scope

The Controlled Substances program applies to all San Francisco State University (SFSU) faculty, staff, students, contract employees and other personnel working at the main campus and satellite locations where SFSU has management control of controlled substances. This program does not apply to Student Health Services, which must comply with their medical license.

IV. Definitions

Authorized Person

Principle Investigators, Staff Managers, and staff who have successfully completed the authorization process for controlled substance (CS) use and/or pick up. Each person must be listed on the CSUA for the project. Authorized Persons must comply with all laws, regulations, and university policies and procedures regarding controlled substances.

Biennial Inventory

A detailed inventory for all controlled substances present at SFSU or SFSU controlled property on a specified date and time. Must be done every two years at the direction of the Controlled Substance Program Administrator.

Controlled Substance

A controlled substance (CS) is a narcotic or non-narcotic drug under the jurisdiction of the federal Controlled Substances Act and the California Uniform Controlled Substances Act, including but not limited to those substances listed in 21 CFR § 1308.11-1308.15. A current general reference list of controlled substances in alphabetical order can be found at: the [List of Controlled Substances](#). Federal regulations regarding schedules can be found in [Section 1308 of CFR Title 21 \(21 CFR §1308\)](#).

Controlled Substance Program Administrator

The person designated on the DEA Controlled Substance Registration Certificate that manages the acquisition, use and storage of controlled substances.

Controlled Substance Use Authorization

The formal written authorization (aka CSUA) granted to a Responsible Individual to purchase, pick-up and/or use controlled substances approved by the Controlled Substance Program Administrator (CS Administrator). Individuals use this process rather than applying directly to the DEA for registration.

Department Head

The academic department chair or director with oversight of faculty and staff within his/her department. The department head is responsible for determining the need for and authorizing the Responsible Individual (RI) to approve Purchase Requisitions for controlled substances by department members and for assuring that the storage, use, inventories, transfers, and disposal of controlled substances by department members comply with applicable laws, regulations, and campus policies.

Drug Enforcement Agency Registration

Under the Federal Department of Justice (DOJ), the Drug Enforcement Agency (DEA) registration number identifies and validates individuals and institutions that have been authorized by the DEA to purchase, possess, distribute or prescribe controlled substances.

Controlled substances intended for research purposes acquired through drug companies or any other outside institutions must be obtained under the University's registration. An individual researcher may not apply for an individual DEA registration to acquire controlled substances intended for research, instruction, and chemical analysis purposes at SFSU. The SFSU Student Health Center possesses a separate DEA registration number for distribution of controlled substances as a medical provider. [The registration applies to the address location of the registrant.](#)

Listed Chemicals: Chemicals that can be used to manufacture a controlled substance (precursor chemicals). The List I and List II chemicals can be found on the US DOJ web site.

https://www.deadiversion.usdoj.gov/chem_prog/34chems.htm.

Precursor Chemicals

DEA's strategy in curtailing illicit drug manufacturing is to control raw chemicals necessary to produce legal and illegal drugs called 'precursor chemicals' listed in CFR 21 §1310.02(a) [**List I**] and §1310.02(b) [**List II**]. These chemicals have the potential to be used in the manufacture of controlled substances. State and federal laws require that vendors follow stringent regulations regarding distribution of these chemicals. Agencies require purchasers of precursor chemicals to provide their DEA license registration and a brief description of the use/research involving the chemical. In addition, the state of California also maintains a list of [precursor chemicals](#) that includes DEA List I chemicals.

Research Advisory Panel of California

A function of the California Attorney General's office which, pursuant to the California HSC §11480 and 11481, must review and authorize proposed research projects involving certain opioid, stimulant, and hallucinogenic drugs classified as Schedule I or Schedule II Controlled Substances. Researchers must submit applications to the panel for research projects involving:

- Any Schedule I controlled substance (not allowed at SFSU);
- Human research using any Schedule I or Schedule II controlled substance; or
- Research for the treatment of drug abuse using any drug, scheduled or not.

Responsible Individual (RI)

An individual, usually a tenured or tenure-track Principal Investigator or Senior Staff, directly responsible for the function of a particular laboratory, research or service center. In addition to responsibilities as an Authorized Person, this person is the Holder of the Controlled Substance Use Authorization (CSUA). He/she is the only person on the CSUA who may place an **order** request with the CS Administrator.

Schedules of Controlled Substances

Controlled substances are organized into Schedules as listed below.

Schedule I

No currently accepted medical use. Has the highest potential for abuse. (e.g., GHB, heroin). The SFSU Controlled Substance Registration Certificate does not allow Schedule I substances.

Schedule II

Currently accepted medical use with restrictions. [Schedule II](#) has high potential for abuse with severe psychological or physical dependence. (e.g., amphetamine, methamphetamine, cocaine, codeine, morphine, meperidine, methylphenidate, pentobarbital (Nembutal)).

Schedule III

Currently accepted medical use. Abuse of drug may lead to moderate to low physical dependence or high psychological dependence. (e.g., Ketamine, Telazol, testosterone, pentothal. Euthasol is a [Schedule III](#) due to pentobarbital/phenytoin mix).

Schedule IV

Currently accepted medical use. Low potential for abuse relative to Schedule III. (e.g., barbitol, butorphanol, chloral hydrate, diazepam). [Schedule IV List](#)

Schedule V

Currently accepted medical use. Low potential for abuse relative to Schedule IV (e.g., buprenorphine and Zolpidem). [Schedule V List](#)

V. Accountability

A. Controlled Substances Administrator

1. Manage the Controlled Substance Program
2. Maintain DEA Campus registration.
3. Authorize and maintain list of Authorized Persons
4. Provide consultation and approve purchases and transfers of controlled substances and List I chemicals
5. Audit biennial inventory of controlled substances.
6. Conduct random inspections of storage and recordkeeping
7. Prepare expired and unneeded controlled substances for disposal.

B. Environment, Health & Safety Department

1. Oversee the management of the Controlled Substance Program
2. Dispose of expired controlled substances

C. Responsible Individual/CSUA Holder

1. Obtain "Authorized Person" status including all staff and students with access to controlled substances. (CS Form A-1) and (CS Form B)
2. Comply with all procedures to acquire and use controlled substances or Precursor Chemicals (DEA List I or California Precursor List). (Process Flow Chart No. 2)
3. Complete Application for Controlled Substance Use Authorization. (CS Form A), (CS Form A-1), (CS Form B) and (CS Form D)
4. Provide appropriate secured storage of drugs.
5. Maintain Controlled Substance Usage Logs with invoice for 3 years (CS Form C)
6. Submit (biennial) inventory to CS Program Administrator every 2 years. (CS Form E)
7. Request disposal of any expired or no longer needed controlled substances
8. Notify CS Administrator of suspected missing drugs. Comply with investigation by EHS, University Police, and the DEA.

D. Research/Lab Personnel

1. Obtain "Authorized Person" status (CS Form B)
2. Maintain usage log according to proper procedures (CS Form C)
3. Maintain security of drugs at all times

VI. Obtaining a Controlled Substance Use Authorization (CSUA)

Researchers must obtain authorization prior to the use, purchase, or transport of controlled substances and precursor chemicals. Requirements for the Responsible Individual of a CSUA are as follows:

1. The Responsible Individual must complete the application for a **Controlled Substances Use Authorization (CSUA)** ([CS Form A](#)) and complete the **Authorized CSUA Holder – Controlled Substances Screening** form ([CS Form A-1](#))
2. Give all proposed authorized persons the **Authorized Personnel – Controlled Substances Screening** form ([CS Form B](#)). Ensure all staff and students using the controlled substances are listed on your CSUA application.
3. Submit the CSUA application and Controlled Substances Personnel Screening forms with original signatures to the CS Administrator:

Karl Murphy Hensill Hall 822 email: kmurph@sfsu.edu

4. Research involving the use of controlled substances with animals must have an approved IACUC protocol with the substances listed
5. Research involving human subjects and controlled substances must have an approved IRB protocol with the substances listed.

California law requires proposed research projects involving humans using certain opioid, stimulant, and hallucinogenic drugs classified as Schedule I and Schedule II to be reviewed and authorized by the [Research Advisory Panel of California](#) in the Attorney General's Office. Most CS uses at SFSU don't require this step.

VII. Acquisition and Delivery of Controlled Substances

Acquiring Controlled Substances and Precursor Chemicals

Purchasing

- a. The Responsible Individual must submit the purchase requisition for Controlled Substances and precursor chemicals to the CS Administrator for approval. Order requisitions must be placed under the name of the Responsible Individual.
- b. The CS Administrator will send the requisition back to appropriate Procurement Office for processing.

Acquisition via Any Other Company or Institution

A controlled substance provided by a private company or another university for research purposes must go through the procurement process as described above before arriving on University property.

Transfer of Controlled Substances to other SFSU Authorized Personnel

Transfers of controlled substances between SFSU Responsible Individuals (RI) is permitted when approved by the CS Administrator. The receiving RI must submit an updated CSUA application for the transferred substance.

VIII. Precursor Chemical Acquisition, Use, and Disposal

The mission of the Federal DEA's Listed and the State of California's Precursor Chemicals Control Programs are to disrupt the illicit production of controlled substances by preventing diversion of chemicals used to make drugs. Precursor chemicals regulated by the federal DEA may be found in List I and List II under Title 21 CFR §1310.02.

California Health and Safety Code Uniform Controlled Substances Act governs the use of precursor chemicals in the state. ([HSC Div. 10 \[11000-11651\]](#)) A California Department of Justice Controlled Substance Permit is required to purchase precursor chemicals from vendors outside of California. If precursor chemicals are bought from a vendor within California, this special State permit is not required.

For this reason, purchase chemicals on California's precursor chemicals list from an in-state vendor that does have the required permit.

Suggested vendor: Spectrum Chemical Manufacturing Corporation
14422 S. San Pedro Street Gardena, CA 90248-2027
310-516-8000 sales@spectrumchemical.com

California Precursor Chemicals, while not Controlled Substances, are regulated chemicals. SFSU may fall under the exemption in HSC §11000 (e)(4) as an "analytical research facility that is registered with the federal DEA", but interpretations of the law can change. SFSU (as the end user) must provide the vendor with acceptable identification (HSC §11107.1 (a)(1)(B)) and a letter of intent describing how the chemical will be used. See additional requirements below:

1. There is at least a 21-day waiting period after placing an order with the in-state vendor before the chemical may be shipped out.
2. All purchases of precursor chemicals on the DEA's List I and on the California Precursor Chemicals list must go through the SFSU Controlled Substances Program Administrator.

Use, Storage and Disposal

Once approved for purchase, Listed/Precursor chemicals may be acquired and managed in the same manner as all other hazardous materials used by the researcher. The specific procurement, use, recordkeeping, storage, and disposal requirements for controlled substances do not apply to Listed/Precursor chemicals. For example, these chemicals are not included in the controlled substance inventory; disposal of precursor chemicals shall be done through the EH&S hazardous waste disposal program unless otherwise indicated.

IX. Security of Controlled Substances and Usage Logs

Controlled substances and usage logs must be secured to provide for effective prevention of theft. Code of Federal Regulations Title 21 requires registrants to store controlled substances in a locked, securely constructed cabinet. Proper security of controlled substances and usage logs is the responsibility of the Responsible Individual. To prevent theft, controlled substances should never be left unattended, the inventory should be kept at minimum, and access provided to as few researchers as possible. CS storage units should only be used for CS and their use logs.

Acceptable storage of Controlled Substances

1. Schedule I: Safe or steel cabinet equivalent cemented or bolted to the floor or wall or that weighs more than 750 lbs. (*Note SFSU is not permitted to have Schedule I substances*)
2. Schedule II-V: Locking storage drawers which are inaccessible from the upper or lower drawers in the stack
 - Padlocks and hinges must have mounting screws or bolts of the hasp inaccessible when the door is closed and the lock fastened.
 - Storage units must be secure enough to show forced entry
 - Room must be kept locked so only those with a key or under supervision may enter

Unacceptable storage:

1. Portable, locked safety cabinets
2. Corridors
3. Locked drawer that can be accessed from other drawers or cabinets.

Recordkeeping

Usage Logs

Authorized Personnel are required by federal and state law to document the use of controlled substances by logging all details from delivery to disposal. Records must be secured in a locked location and include the order invoice sheet, all Usage Logs, and disposal records. Blank Usage Logs (CS Form C/C1) are provided by the Controlled Substance Program Administrator (CS Administrator). Other formats of the usage logs are not acceptable.

Usage Logs must include:

- Name of the drug
- Strength/Concentration
- Amount received
- Name of principal investigator
- Date received from CS Administrator

Usage Logs must indicate:

- Amount of each use
- Date of use
- Name & signature of the Authorized Person. Initials can be used after the first time a name and signature is entered
- Daily balance

When the Usage Log is completed, send a copy to the CS Program Administrator who maintains a master document file and inventory.

Inventory Log

The CS Administrator audits the campus CS inventory every two years as required by federal law. Researchers will be notified by email two weeks before the completed and signed Inventory Log is due to be returned to CS Administrator. Researchers who fail to complete and return the Inventory Log by the date requested will have their Responsible Individual status suspended until submission of the Inventory Log

Inspections

EHS will conduct random inspections of research labs that use controlled substances including proper storage and recordkeeping procedures.

The DEA may conduct random audits and inspections of SFSU's Controlled Substance Program.

The CS Administrator will audit areas under approved CSUAs every two years when the biennial inventories are due and will include security practices pertaining to controlled substances.

The Institutional Animal Care and use Committee (IACUC) conducts semi-annual inspections of all laboratories approved for animal research. This inspection includes a check of proper storage of controlled substances.

X. Disposal of Controlled Substances

1. Notify the CS Administrator of your intention to dispose of expired controlled substances or precursor chemicals.
2. CS Administrator will schedule a time to receive the drugs from the Authorized Person and will coordinate disposal with a DEA registered reverse distributor.
3. The CS Administrator must maintain a copy of the disposal records along with the usage log(s) and order invoice sheet for 3 years after disposal or terminal use.
 - a. The reverse distributor must be registered with the DEA and licensed to perform disposal or destruction services in the State of California. Current [list of vendors](#).
 - b. The reverse distributor must provide documentation of the final disposition of the destroyed/disposed/returned drugs to the CS Administrator.
 - A Certificate of Destruction and corresponding Form 222 for each Schedule I & II controlled substance covered by that certificate or a DEA Form 41;
 - A completed copy of the waste manifest from the Treatment Storage and Disposal Facility (TSDF);
 - A certificate of return to manufacturer.

Empty Controlled Substance Containers

Authorized Personnel may dispose of empty controlled substance containers by defacing the label, rinsing it out, and discarding in the trash. (*This is not hazardous waste.*)

Authorized Personnel Leaving the University or CSUA-Covered Project

1. When an Authorized Person leaves the University or lab under a CSUA, the Responsible Individual must notify the CS Administrator in writing via email or updated Authorized Personnel list.
2. When a Responsible Individual leaves the University, all controlled substances must be disposed of in accordance with University policies and procedures. Controlled substances may not be transferred to another User or institution. All records of usage and disposal must be forwarded to CS Administrator.
3. The Department Head/Chair/Director becomes responsible if controlled substances are abandoned when the Responsible Individual leaves the University. Department Chairs must contact the CS Administrator to arrange for the appropriate disposal. Failure to comply with the authorization, storage, security, inventory, and recordkeeping process may jeopardize the University's DEA registration and adversely impact other Authorized Persons.

Prohibited Actions under the Controlled Substance Act

Any Authorized Person that violates handling, security, and record-keeping requirements or abandons controlled substances may be subject to the civil penalties outlined in the [United States Code \(USC\): 21 USC Sec. 842](#). Please note that abandoning substances is equivalent to distributing a controlled substance to an unauthorized person. See 21USC §841 (a) (1)

Theft, Loss, or Breakage

Authorized personnel are expected to report missing controlled substances to their supervisor, the CS Administrator, and the SFSU Police Department as soon as the theft or loss is discovered. The CS Administrator and law enforcement will investigate the diversion, loss, or theft of Controlled Substances. Reports will be kept confidential to the extent permitted by law and other University policies.

Reporting a Significant Loss to the DEA

Upon discovery of a theft or significant loss of a Controlled Substance, the CS Administrator must immediately (within 24 hours) submit an initial report in writing to the local DEA office.

DEA Form 106* must be submitted once the circumstances surrounding the theft or significant loss are clear. (May use this for the initial report if desired.) The CS Administrator must send an update to DEA if the investigation takes more than two months.

*DEA Form 106 "Report of Theft or Loss of Controlled Substances". (21 C.F.R. § 1301.76(b)).

Link to DEA Form 106: <https://apps.deadiversion.usdoj.gov/webforms/dtlLogin.jsp>

DEA guidance:

"Breakage of controlled substances does not constitute a "loss" of controlled substances. When there is breakage, damage, spillage or some other form of destruction, any recoverable controlled substances must be disposed of according to DEA requirements. Damaged goods may be disposed of through shipment to a "reverse distributor" or by a DEA approved process.

*If the breakage or spillage is **not recoverable**, the registrant must document the circumstances of the breakage in their inventory records. Two individuals who witnessed the breakage must sign the inventory records indicating what they witnessed. The submission of a DEA Form 41, Registrants Inventory of Drugs Surrendered is **not required for non-recoverable controlled substances**."*

Non-Significant Loss

The Controlled Substance Act does not define the term "significant loss", however, DEA has clarified what the term a significant loss means in their [**Final Rule 2005: Reports by Registrants of Theft or Significant Loss of controlled Substances**](#). Essentially, any unexplained loss or discrepancy should be reviewed within the context of a registrant's business activity and environment.

Example: Repeated loss of small quantities of controlled substances over a period of time may indicate a significant aggregate problem that must be reported to DEA, even though the individual quantity of each occurrence is not significant.

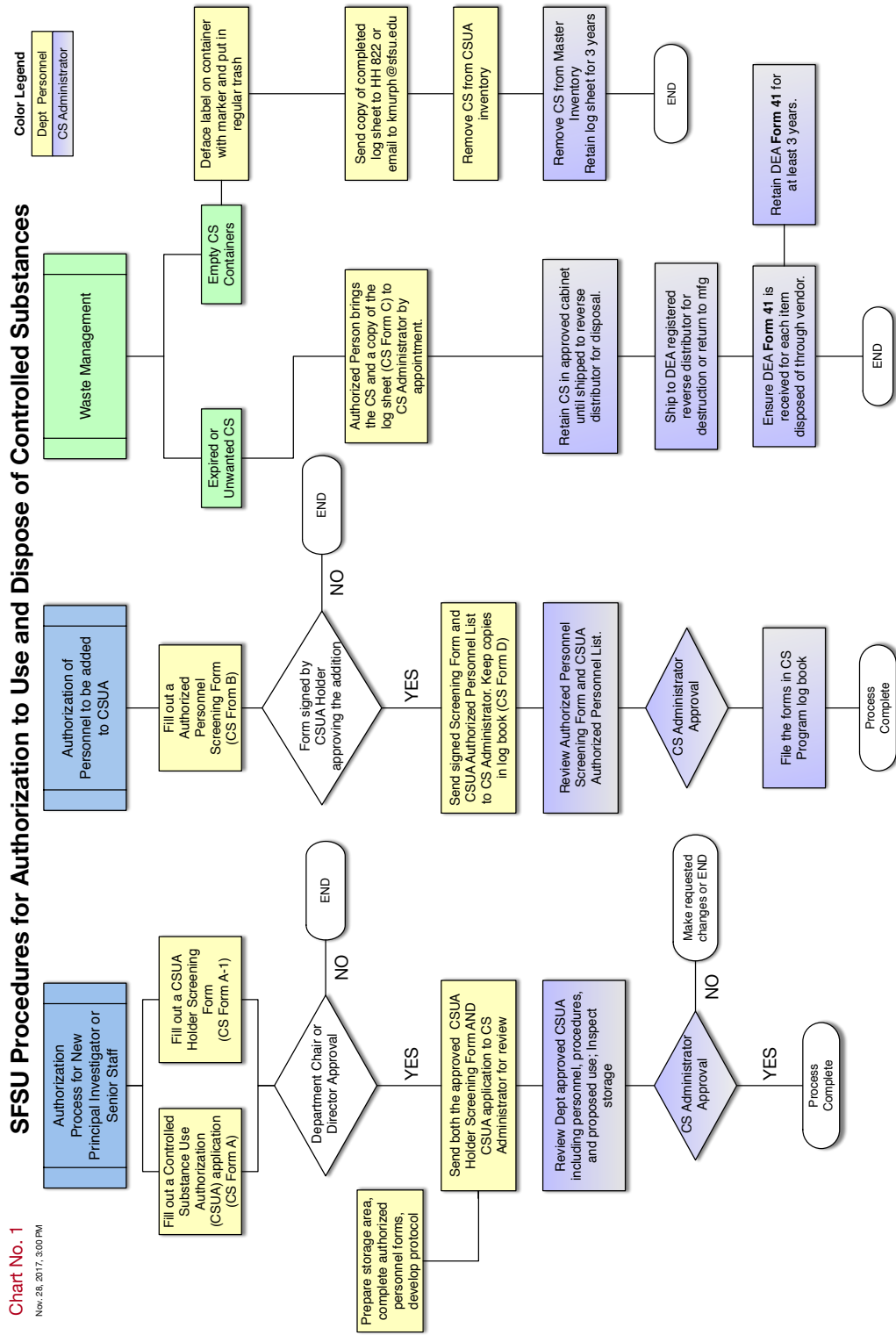
Non-significant losses include evaporation, miscounts or clerical errors and must be documented in the inventory or usage log.

EH&S will perform a review of security and record keeping policies if multiple or chronic record discrepancies occur.

When documenting a non-significant loss, DEA form 106 is not used and DEA is not notified.

XI. Process Flow Chart No. 1

Authorization to Use Controlled Substances and Managing Waste



XII. Process Flow Chart No. 2

Controlled Substances Procurement and Receipt Procedure

