

Controlled Substances Compliance

Department of Environmental Health & Safety

Acknowledgments

The information presented in this training is a collaborative effort of University of Central Florida's (UCF) and Florida International University's (FIU) EH&S Controlled Substances Compliance Officers.

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Objectives

- ✓ What is a controlled substance (CS)?
- ✓ How to stay in compliance with the FIU Controlled Substances Compliance Program

Course Outline

- CS use – research, teaching, analytical, clinical, exemptions
- Registration process and approval
- Acquisition
- Responsibilities
- Security and storage
- Inventory
- Disposal
- Recordkeeping

Introduction

- The use of controlled substances at FIU for research, analytical, teaching, or clinical purposes is regulated by the following entities:
 - United States Drug Enforcement Agency (DEA)
 - FIU Controlled Substances Committee
- All authorized users are required to adhere to regulations and procedures set forth by these entities

Overview

- What is a Controlled Substance?
 - A drug or other substance, or its immediate precursor that may have a narcotic, stimulant, depressant, or hallucinogenic effect on the central nervous system
 - Include materials (listed chemicals and equipment found at the clandestine drug laboratories) that can be used for production of CS (as well as other regulated chemicals)
 - Identified as substances needing extensive licensing (registration), storage, security, use, and disposal requirements
 - Regulated by Title 21 Code of Federal Regulations Part 1300 to end
 - Divided into five schedules (I, II/IIIN, III/IIIN, IV, and V)
 - A list of DEA controlled substances is available on the EH&S Controlled Substances webpage [here](#).

Overview

Schedule	Description	Examples
I	No accepted medical use in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse; Requires Form 222	Heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), peyote, methaqualone, and 3,4-methylenedioxymethamphetamine ("Ecstasy")
II/IIN	High potential for abuse which may lead to severe psychological or physical dependence; Requires Form 222	Schedule II: hydromorphone (Dilaudid®), methadone (Dolophine®), meperidine (Demerol®), oxycodone (OxyContin®, Percocet®), and fentanyl (Sublimaze®, Duragesic®), morphine, opium, codeine, and hydrocodone Schedule IIN: amphetamine (Dexedrine®, Adderall®), methamphetamine (Desoxyn®), and methylphenidate (Ritalin®)
III/IIIN	Potential for abuse less than substances in Schedules I or II and abuse may lead to moderate or low physical dependence or high psychological dependence	Schedule III: products containing not more than 90 milligrams of codeine per dosage unit (Tylenol with Codeine®), and buprenorphine (Suboxone®) Schedule IIIN: benzphetamine (Didrex®), phendimetrazine, ketamine, and anabolic steroids such as Depo®-Testosterone.
IV	Low potential for abuse relative to substances in Schedule III.	alprazolam (Xanax®), carisoprodol (Soma®), clonazepam (Klonopin®), clorazepate (Tranxene®), diazepam (Valium®), lorazepam (Ativan®), midazolam (Versed®), temazepam (Restoril®), and triazolam (Halcion®)
V	low potential for abuse relative to substances listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotics	cough preparations containing not more than 200 milligrams of codeine per 100 milliliters or per 100 grams (Robitussin AC®, Phenergan with Codeine®), and ezogabine.

Overview

- What are Listed Chemicals?
 - **Listed chemicals (List I and II)** are chemicals specifically designated by the Administrator that are used in manufacturing a controlled substance in violation of the Act and are important to the manufacture of a controlled substance
 - Only those who manufacture, distribute, import or export are required to obtain a DEA registration
 - Purchase and use of listed chemicals by researchers does not require registration, **BUT** it does require approval from the EH&S CSCO and may require additional information from the vendor for purchase

For the DEA List I and II Chemicals, click [here](#).

Overview

- What is a Controlled Substance?
 - **Synthetic Drugs**, also referred to as **New Psychoactive Substances**, represent an emerging and ongoing public health threat in the United States.
 - Synthetic Drugs may have cute names like **Green Giant**, **Joker**, **N-bomb**, or **Flakka**. Some may be sold in colorful little baggies at gas stations and convenience stores.
 - Many of these Synthetic Drugs are controlled under federal law which makes manufacturing or distributing them a prosecutable offense, even if it is sold as an over-the-counter

Overview

Exempt Chemical Preparations and Mixtures

- Any chemical preparation or mixture containing one or more controlled substances listed in any schedule which is intended for laboratory, industrial, educational, or special research and not for general administration to a human or animal
- Must meet certain criteria to be exempt from the application on all or any part of the Controlled Substances Act
- For a list of DEA exempt preparations and mixture, click [here](#).

Overview

Exempt Chemical Preparations and Mixtures

- Contains no narcotic controlled substance and packaged in a form or concentration that does not present any significant potential for abuse

OR

- Contains either a narcotic or nonnarcotic controlled substance and one or more denaturing agents in such a manner that the preparation or mixture does not present any potential for abuse

Overview

Exempt Chemical Preparations and Mixtures

- Any individual requesting to have a preparation or mixture containing a controlled substances exempted must send an application for an exemption to the DEA Drug and Chemical Evaluation Section. For more information, click [here](#).
- The DEA has the right to revoke or modify any exemption granted pursuant of the Controlled Substances Act, part 1308.23
- For more information on Part 1308.24 Exempt Chemical Preparations, click [here](#).

Registration

- Any individual interested in using controlled substances at FIU must be approved by the EH&S Controlled Substances Compliance Office (CSCO). This includes exempt chemical preparations and mixtures.
- Approval must be obtained **PRIOR** to submitting a DEA application
- The following items must be submitted to the CSCO for review and approval:
 - ✓ Questionnaire for employees/individuals with access to CS
 - ✓ Security Screening Form for all employees/individuals with access to CS
 - ✓ CS Request for Authorization
 - ✓ Signed CS Fact Sheet for all employees/individuals with access to CS
 - ✓ Details of CS storage and security
 - ✓ Schedule and code for each CS
 - ✓ Protocols for use of each CS - quantity required for each experiment/study and annual quantity required

Registration

Prior to procuring any controlled substance, each user must obtain a DEA registration number AND an exemption letter from the Florida Department of Business & Professional Regulation (DBPR).

DEA Application

- The DEA application form required depends on the type of activity conducted
- Application forms can be submitted online or via mail
- The average time for processing a new DEA registration is 4-6 weeks provided that the application is complete. The DEA recommends checking the following prior to submission:
 - Complete the application in its entirety;
 - Sign and date the application;
 - Enclose the appropriate fee or enter the credit card area information;
 - Mail the application to the address printed on the form (if not submitting online)

Registration

DEA Registration Types and Application Forms

- Additional information pertaining to application fees and approved activities are available on the DEA website [here](#).
- State entities are exempt from registration fees

Business Activity	Controlled Substance	DEA Application Form	Registration Period (years)
Dispensing and Instructing (Hospital/Clinic, Retail Pharmacy, Practitioner, Teaching Institution)	Schedules II-V	New- 224 Renewal – 224a	3
Research	Schedule I	New -225 Renewal – 225a	1
Research	Schedule II-V	New -225 Renewal – 225a	1
Chemical Analysis	Schedule I-V	New -225 Renewal – 225a	1
Manufacturing – Exempt chemicals and preparations	Schedule I-V	New -225 Renewal – 225a	1

Registration

Florida Department of Business & Professional Regulation (DBPR) Exemption

- The DBPR is authorized to issue letters of exemption to facilitate the lawful purchase and possession of prescription drugs and medical gases by certain qualified persons
 - Examples: Universities performing research protocols and Community Colleges for teaching professional programs) for lawful research, teaching, or testing, and not for resale
- Users must complete Application for Exemption Registration Form No: DBR-DDC-227 (available online [here](#))

Registration

Renewal and Reinstatement

- Registration is valid for a certain time period, and must be renewed by the user prior to the expiration date
- The DEA allows one calendar month grace period for reinstatement of an expired registration
 - If the registration is not renewed within this grace period, a new application will be required
- **IMPORTANT!** Federal law prohibits the handling of controlled substances and/or List I chemicals under an expired registration

Registration

DEA Certificate Duplications

- Certificate duplications can be obtained from the DEA upon request at no additional cost
- Requests can be submitted online, by calling the DEA Registration Service Center, or via email at DEA.Registration.Help@usdoj.gov
- You must have access to your DEA Registration number to complete the request

Registration

Adding Controlled Substances

- Complete the applicable DEA registration form (DEA-224 or DEA-225)
- Submit the following information to the EH&S CSCO:
 - Completed DEA registration form
 - A letter to the DEA requesting registration of additional CS required
 - A copy of the current permit
 - A copy of the research protocol describing the quantity of CS required for each experiment and annually
 - Security and access procedures
 - A copy of the registrant's CV

Registration

Registrant Separation

- Individuals with active DEA registrations must notify the EH&S CSCO if they are separating from the University
- Prior to separation, the individual must complete the following:
 - ✓ Inventory and disposition all CS and/or listed chemicals
 - ✓ Return all keys associated with the safe and locked cabinet to the CSCO
 - ✓ Schedule final inspection with CSCO to validate inventory compilation

Registration

Registration Termination

- The registration of any individual will terminate when:
 - A. such person dies,
 - B. ceases legal existence,
 - C. discontinues business or professional practice,
 - D. or surrenders a registration
- For B-D, the registrant must notify the Special Agent in Charge of Administration in the area and seek authority and instructions for disposal
- The Special Agent in Charge will authorize and instruct to dispose in the following manners:
 1. Transfer to a person registered and authorized under the Act to possess the substances
 2. Deliver to an agent of the Administration or the nearest Administration Office
 3. By other means as determined to assure the substance is accessible to unauthorized persons

Registration

Registration Termination

- Revocation of registration may occur in the following instances:
 - Failure to report changes in the use of the controlled substance
 - Failure to address documented violations in the required time frame
 - Unapproved use or distribution of controlled substances to unauthorized personnel

Purchasing, Storage, and Use

Congratulations! Now that you received your DEA registration, you are ready to proceed with obtaining your controlled substances.

Prior to placing your order, you need to ensure the following items are in place:

- ✓ An approved safe is installed and secured inside a locked room with controlled access
- ✓ Personnel planning to have access the CS have completed the required paperwork
- ✓ Order Form 222 is accessible for completion
 - ✓ DEA form 222 may be ordered online: [here](#), by calling the DEA Headquarters Registration Unit, or the nearest DEA Registration Field Office.

Purchasing, Storage, and Use

Purchasing

- Complete the online request form [here](#). The request will be sent directly to the Controlled Substances Compliance Office for review and approval.
- Once approved, the supplier will request a copy of the registration and DEA Form 222 (for Schedule I and II CS) to process the order. **NOTE: DEA Form 222 is not required for Schedule III-V CS.**
- All CS orders will be shipped directly to the address on the DEA registration.

Purchasing, Storage, and Use

Security and Storage

- All CS must be secured against unauthorized access and removal
 - Two independent locking mechanisms are required to secure CS (example: locked cabinet and locked door)
 - Safes or cabinets where CS are stored must be bolted or screwed in non-removable locked cabinet of substantial construction. The combination and/or key will be accessible only by the registrant.
- Schedule I and II CS must be stored separate from other CS and hazardous chemicals

Purchasing, Storage, and Use

Security and Storage

- Upon receipt of the CS, check the package to ensure the contents are intact
 - Any issues should be documented and reported to the supplier and CSCO immediately
- Record the details of the CS, including weight and weight of container with CS, in a designated logbook
 - Each CS should have a dedicated logbook or logbook section for tracking
- Place the CS in the safe along with any associated or blank DEA Form 222 copies and the logbook
 - Only the DEA registrant should have access to the locked safe, cabinet, or other secure containment.
 - Approved individuals requesting CS must receive it from the registrant



Purchasing, Storage, and Use

Use

- Upon opening the CS, check to ensure the contents are intact
 - Any issues should be documented and reported to the supplier and CSCO immediately
- Record the details of the CS, including weight and weight of container with CS, in a designated logbook
 - Each CS should have a dedicated logbook or logbook section for tracking
- Place the CS in the safe along with any associated or blank DEA Form 222 copies and the logbook
 - Only the DEA registrant should have access to the safe
 - Approved individuals requesting CS must receive it from the registrant
- Sharing or loaning CS is **STRICTLY PROHIBITED**

Purchasing, Storage, and Use

Use

- **ALL** CS use and waste, including dilutions, must be recorded in a logbook for each CS. Any discrepancies in weight, including loss, must be reported to the registrant and the CSCCO
- Inventory for CS should be maintained and reconciliated
 - EH&S will check your record keeping to assure compliance during compliance inspections and the biennial inventory
 - Inventory must be kept for three years from the initial start date

Compliance

Inspections

- DEA
 - Conducted upon initial license application request, addition of controlled substances to current license, or as warranted by the DEA Administrator
- EH&S
 - Conducted annually by the EH&S CSCO
- Self-Audits
 - Conducted annually as a section of the EH&S Lab Self-Audit; section contains questions pertaining to controlled substance security

Disposal

- All CS must be disposed by the registrant in accordance with 21 CFR 1317, Subpart A
- The EH&S CSCO must be notified prior to disposal. Notification should include the following:
 - CS Name, DEA schedule, Quantity, # of vials/containers, DEA registration
 - The inventory for disposal must be verified and signed by the CSCO
- **IMPORTANT!** This includes unused, unwanted, or expired CS

Disposal

- CS can be disposed of in the following ways:
 - Deliver to a registered reverse distributor* by carrier OR reverse distributor pick-up at the registrant's registered location
 - Destroy CS in accordance with 21 CFR 1317, subpart C using an on-site method of destruction
 - For return/recall, pick-up from the registrant's location OR delivery from carrier to the registered manufacturer of the CS or another registrant authorized by the manufacturer to accept recalls/returns
- All methods require completion of DEA Form 41 - Registrants Inventory of Drugs Surrendered. Submission to the DEA is not required unless requested to do so.

*Shall be registered with the DEA as a reverse distributor unless exempted by law or otherwise authorized; **must destroy CS no later than 30 calendar days after receipt**

Disposal

Methods of Destruction – Subpart C

- Method shall be sufficient to render all CS non-retrievable*
- Options for destruction include:
 - Transport of CS to a registered location for destruction requires the presence of two employees throughout the loading, transport, and unloading process
 - Transport of CS to a non-registered location for destruction requires the presence of two employees throughout the loading, transport, unloading, handling process AND witness the destruction
 - On-site destruction at the registered location

*Permanently alter any CS physical and/or chemical state through irreversible means to render the CS unavailable and unusable; **examples – incineration or chemical digestion**

Disposal

Methods of Destruction – Subpart C

- If the CS is destroyed on-site at the registered location, the following procedures must be followed:
 - Two employees of the registrant shall handle or observe the handling of the CS until rendered non-retrievable

AND

- Two employees of the registrant must personally witness the destruction until rendered non-retrievable

Reporting

- Federal regulations require notification to the Field Division Office of the Administration in the area (in writing) of the theft/significant loss of any controlled substance or listed chemical
 - Must be reported within one business day of discovery of such loss or theft
- DEA Reporting Forms
 - DEA Form 106 – Report of Theft or Loss of Controlled Substances (available online)
 - DEA Form 107 – Report of Theft or Loss of Listed Chemicals

Recordkeeping

- Each registrant is required to maintain copies of the following:
 - ✓ Florida exemption letter
 - ✓ DEA registration
 - ✓ Employee screening questionnaire
 - ✓ Purchase and order records, including DEA Form 222
 - ✓ Receipt records
 - ✓ Invoices for Schedule I and II CS shall be stored separately from Schedule III-V
 - ✓ Use log
 - ✓ Inventory
 - ✓ Disposal records
 - ✓ Any DEA-related correspondence
- Records must be maintained onsite for a minimum of three years and readily retrievable

Recordkeeping

Biennial Inventory

- Federal regulations require an inventory of all CS be performed at least once every two years
- The Controlled Substances Compliance Office will send out a reminder for this information to all users in January.
- Users should submit the inventory to ehs@fiu.edu .
 - **IMPORTANT!** Inventory must contain the following information for each CS: name, schedule, DEA Drug Code, lot number, date, quantity of unopened containers and container size, quantity of opened containers and container size, remaining amount in opened container(s)*, concentration, and form (solid or liquid), and DEA registrant signature

Summary

- Working with CS requires a valid registration granted by the DEA.
- Any work involving the use of CS must be approved by the EH&S Controlled Substances Compliance Office (CSCO)
- The EH&S CSCO will help to ensure you are compliant with DEA regulations by:
 - Assisting with the registration, purchase, and disposal process
 - Conducting compliance inspections to ensure requirements are maintained
- Failure to maintain compliance with DEA requirements could result in termination of your DEA license

DEA Contact Information

DEA Headquarters

Mail: Drug Enforcement Administration
Attn: Registration Section/ODR, PO Box 2639
Springfield, VA 22152-2639

Phone: Registration - (800)882-9539, 8:30 am-5:50 pm EST

Email: DEA.Registration.Help@usdoj.gov

Website: <http://www.deadiversion.usdoj.gov/index.html>

Miami Division Office

3200 Meridian Parkway, Unit 107

Weston, FL 33331

Phone: (800)667-9752

Questions?

EH&S Lab Safety and Controlled Substances Compliance

Phone: (305) 348-6849/(305) 348-7882

Email: ehs@fiu.edu

Website: <https://ehs.fiu.edu>