Controlled Substances Safety Plan (CSSP)

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REVISION HISTORY

Revision Number	Revision Date	Revised By	Description of Change
00	2020-02-07	Juliette Jones	Initial plan creation and implementation.
01	2021-05-10	Charles Cherrito	Reassignment of CSSO and periodic review.
02	2022-06-14	Charles Cherrito	Periodic review.
03	2022-08-18	Charles Cherrito	More in-depth review.
04	2023-04-12	Charles Cherrito	Review.
05	2023-06-29	Charles Cherrito	Further review.
06	2024-03-11	Charles Cherrito	Link updates, other minor edits.
07	2024-03-19	Charles Cherrito	Additional edits to screening and registration documents.

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INTRODUCTION

The U.S. Department of Justice, Drug Enforcement Administration (DEA), Diversion Control Division, the Florida Department of Business and Professional Regulation (DBPR), and other agencies regulate specific substances that are used for research and instructional purposes at Florida Institute of Technology (Florida Tech). These substances are collectively known as "controlled substances" (CS), and their possession and use are governed by regulations that require established procedures to ensure safety and to prevent abuse.

The key elements of Florida Tech's Controlled Substance Safety Plan (CSSP) that are consistent with the DEA regulations are:

- Proper DEA registration and permitting procedures;
- An internal registration and approval process;
- Administrative and operational controls on the ordering, receipt, disposition, storage, and disposal of these substances;
- Provisions for inventory control, chain of custody, audits, and inspections;
- Provisions for record keeping responsibilities.

Research or instructional use of CS at Florida Tech may only be done under Environmental Health & Safety (EH&S) authorization and a DEA Registration Certificate. Personal Registration Certificates, though available through DEA, may not be used to order, receive, use, or dispose of controlled materials at Florida Tech.

CS may be used only by those registrants (permit holders) who are authorized to use them and only in the laboratory or location that is identified in the protocol (if research) or the place where the instructional activities are to take place. Florida Tech personnel who participate in illicit activities or the misuse of CS are subject to federal and state prosecution, as well as university action such as suspension or termination of employment.

CSSP NOTE #1: CS Abbreviation

Unless otherwise stated, the abbreviation "CS" will be denoted throughout this plan to represent "controlled substances". Additionally, unless specified otherwise, all substances (e.g., Listed Chemicals), will also be represented by the abbreviation "CS".

CSSP NOTE #2: Document Templates

Unless otherwise stated, the Registrant's may utilize their own document templates (in leu of the denoted Appendices) for completion so long as those documents effectively obtain the required information needed to ensure all Florida Tech policies and all Federal/State requirements are upheld. All Appendices (templates) are available by contacting ehs@fit.edu.

PURPOSE

Federal and state regulations require procedures that ensure safe and authorized use of CS at any place of business, research, or manufacturing entity. This CSSP sets forth Florida Tech's guidelines to ensure that the university's research and instructional activities involving CS are carried out in accordance with these federal and state regulations.

This CSSP describes responsibilities and procedures, which shall be adhered to by all individuals and involved departments.

SCOPE

This CSSP will pertain to all Florida Tech properties, except for the below "**EXCEPTION**", and will also address use of CS by Florida Tech employees in relationship with other entities.

EXCEPTION

Florida Tech 's program for management of CS distinguishes between patient-care applications (e.g., Student Health Services) and use by faculty and staff involved in research or instructional activities. The use of CS in patient-care applications is not within the scope of this program. Therefore, Pharmacists and Physicians supporting Employee or Student Health Services will operate under their own Controlled Substance Plan, their own DEA Registration Number, and will maintain their own records of purchase, disposal, and other regulated practices.

RESPONSIBILITIES

Controlled Substance Safety Officer (CSSO)

The Controlled Substance Safety Officer (CSSO) provides guidance and oversight over all aspects of use and management of CS at Florida Tech. The CSSO oversees Florida Tech policies, procedures, and guidelines to ensure that all possession, use, and disposition of CS by personnel at Florida Tech comply with pertinent federal and state regulations and with the specific conditions of permits (registrations) issued to researchers.

Environmental Health and Safety (EH&S)

Florida Tech's Office of EH&S ensures that the CSSO, principal investigators, faculty members, and any other individual employed at Florida Tech, who will have access to CS, are familiar with the provisions of this Plan. Florida Tech EH&S is responsible for:

- Coordinating this Plan;
- Developing, revising, and distributing compliance procedures as needed;
- Assisting registrants as needed with communication between the University and the DEA;
- Issuing purchase and use approvals;
- Auditing (scheduled or unscheduled) of the records and procedures of anyone who has been authorized to utilize CS.

DEA and/or State Registrants

All registrants are responsible for:

- Ensuring the receipt and renewal of DEA Controlled Substance Registration Certificates and Sate of Florida permits as required;
- Compliance with federal and state regulations pertaining to the use of CS;
- Preparation of application packages for obtaining and renewing Registration Certificates and/or Permits;
- Training of auxiliary staff that will receive and use CS from the registrant and/or maintain records concerning the use of CS. Providing the names of auxiliary staff to EH&S and updating their authorization with EH&S;
- Maintaining an accurate inventory of order, receipt, use, storage, loss, and disposal of CS;
- Maintaining strict control over inventory and security for the CS;
- Contacting the DEA/State with questions concerning use of the CS.
- Providing copies of any documents regarding the purchase, use, storage, and disposal of CS.

Shared-Combined Responsibilities

Some responsibilities are shared among parties in order to ensure proper procedures are implemented.

- ✓ **Florida Tech Security Department, the Melbourne Police Department, Brevard County Sheriff's Office, and the DEA** are responsible for assisting in investigations and enforcement actions pertaining to illegal use or possession of CS.

- ✓ **The Registrant, CSSO, and the Registrant's Department Head** are responsible for the implementation of separation procedures, which require the permit holder to obtain clearance from EH&S.

- ✓ **The Facilities Management Department and the Florida Tech Security Department** are responsible for assisting departments, researchers, and faculty members in implementing physical security controls to prevent theft and diversion of CS such as by installing safes, locks, alarm systems, bolting safes to the ground, changing key or card access numbers, etc.

CONTROLLED SUBSTANCE SCHEDULES

Drugs and other substances that are considered CS under the Controlled Substances Act (CSA) are divided into five schedules. An updated and complete list of the schedules is published annually. Substances within each schedule may also be divided into narcotic and non-narcotic categories.

Federal regulations divide CS into five classifications or "Schedules" based on:

- ✓ Whether they have a currently accepted medical use in treatment in the United States;
- ✓ Their relative abuse potential;
- ✓ The likelihood of causing dependence when abused.

Each CS has been assigned an Administrative Controlled Substances Code Number (ACSCN)—also known as a DEA Number. This number identifies the CS for administrative and other purposes, and should be referenced on requisitions, purchase orders, and correspondences with DEA officials.

Schedule I Controlled Substances

Substances in this schedule have no currently accepted medical use in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse.

Examples:
heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), peyote, methaqualone, and 3,4-methylenedioxymethamphetamine ("Ecstasy").

Schedule II/IIN Controlled Substances (2/2N)

Substances in this schedule have a high potential for abuse which may lead to severe psychological or physical dependence.

Examples (II):
hydromorphone (Dilaudid®), methadone (Dolophine®), meperidine (Demerol®), oxycodone (OxyContin®, Percocet®), and fentanyl (Sublimaze®, Duragesic®), amobarbital, glutethimide, and pentobarbital. Other Schedule II narcotics include morphine, opium, codeine, and hydrocodone.

Examples (IIN Stimulants):
amphetamine (Dexedrine®, Adderall®), methamphetamine (Desoxyn®), and methylphenidate (Ritalin®).

Schedule III/IIIN Controlled Substances (3/3N)

Substances in this schedule have a 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.

Examples (III Narcotics):
products containing not more than 90 milligrams of codeine per dosage unit (Tylenol with Codeine®), and buprenorphine (Suboxone®).

Examples (IIIN Non-narcotics):
benzphetamine (Didrex®), phendimetrazine, ketamine, and anabolic steroids such as Depo®-Testosterone.

Schedule IV/IVN Controlled Substances

Substances in this schedule have a low potential for abuse relative to substances in Schedule III.

Examples (IV):
alprazolam (Xanax®), carisoprodol (Soma®), clonazepam (Klonopin®), clorazepate (Tranxene®), diazepam (Valium®), lorazepam (Ativan®), midazolam (Versed®), temazepam (Restoril®), and triazolam (Halcion®).

Schedule V Controlled Substances

Substances in this schedule have a low potential for abuse relative to substances listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotics.

Examples:
cough preparations containing not more than 200 milligrams of codeine per 100 milliliters or per 100 grams (Robitussin AC®, Phenergan with Codeine®), and ezogabine.

LISTED CHEMICALS

Under the Chemical Diversion and Trafficking Act (CDTA) of 1988, List I and List II Regulated Chemical Compounds (Listed Chemicals) require a permit beforehand for ordering from vendors.

Vendors will require this information before issuance of the listed chemical. Each Listed chemical has a unique DEA number. Below are links to the listed chemicals.

https://www.deadiversion.usdoj.gov/chem_prog/34chems.html
https://www.deadiversion.usdoj.gov/schedules/orangebook/f_chemlist_alpha.pdf
Administrator 1310.02(a) & 1310.02(b)

Threshold quantities of precursor and essential chemicals must not be exceeded. Purchasing Department shall make pertinent data available for analysis by CSSO.

List I Chemicals

A chemical specifically designated by the Administrator in §1310.02(a) of that chapter, in addition to legitimate uses, is used in manufacturing a controlled substance in violation of the Act and is important to the manufacture of a controlled substance.

List II Chemicals

A chemical, other than a List I chemical, specifically designated by the Administrator in §1310.02(b) of that chapter, in addition to legitimate uses, is used in manufacturing a controlled substance in violation of the Act.

REGISTRATION (CONTROLLED SUBSTANCES)

Under the Controlled Substance Act (CSA) of 1970, prior to procuring any controlled substance, individuals who order, handle, store, and distribute controlled substances must be registered with the DEA and/or state agencies to perform these functions.

STEP 1: Employee Screening

Submission of the below completed documents to the CSSO (ehs@fit.edu):

- Appendix A: Controlled Substance Request for Registration
- Appendix B: Controlled Substance Employee Screening Certification
  NOTE: all individuals who are expected to have access to controlled substances SHALL complete this document (including the registrant).
- Appendix C: Controlled Substance Use Fact Sheet

The CSSO shall evaluate this information (in coordination with Florida Tech's Human Resource and Security Departments) and determine whether continued application to the DEA is permitted. If the documents are satisfactory, the registrant will continue the application process by completing Forms DEA-225 or DEA-224, as applicable, for submission to the DEA (instructions denoted in the next section of this plan).

SPECIAL NOTE:
Employees with active DEA registrations obtained outside Florida Tech (i.e., from other academic or research institutions) that intend to transfer CS into Florida Tech must contact the CSSO before bringing any CS on Florida Tech property.

STEP 2: Document Submission to DBPR

Florida law recognizes that there are limited instances where the possession of prescription drugs or medical gases, without a valid prescription is warranted. The department is authorized to issue letters of exemption to facilitate the lawful possession of prescription drugs and medical gases by certain qualified persons for lawful research, teaching, or testing, and not for resale.

An Application for Exemption Registration Form No.: DBPR – DDC – 227 must be obtained from the Florida Department of Business and Professional Regulation.

STEP 3: Document Submission to DEA

The registrant may apply for a CS Registration Certificate by completing the pertinent DEA Registration Forms. The registration certificate provides authorization to use controlled substances within specified categories for certain types of research or instruction. Table 1 (located on the next page) can be used as a helpful reference for completing the DEA Forms.

The DEA Forms required for initial CS Registration are as follows:

- Form DEA-225
  Form DEA-225 shall be completed registrants who will be using CS of any Schedule I to V for Research and for Instructional Activities.

- Form DEA-224
  Form DEA-224 shall be completed registrants who will be using CS of Schedule II to V for Teaching (no research).

STEP 4: Document Submissions to EH&S

After completing the appropriate DEA Form(s), completed and/or signed copies of each below documents must be submitted to the CSSO (ehs@fit.edu):

- A copy of the DEA Form submitted and the DEA License
- A copy of the DBPR Exemption Registration
- Appendix D: Controlled Substance Authorized Users List Letter

TABLE 1

The CS Schedule information displayed in the below table applies to substances regulated under federal law.

Registration Class	Schedule	DEA Form	Comment
Analytical Lab	I to V (1 to 5)	New 225 Renewal 225a	1. Section 2: Check "Analytical Lab". 2. Section 3: Check all boxes (Schedule I, Schedule II Narcotic, Schedule III Narcotic, Schedule III Non-Narcotic, Schedule IV and Schedule V). 3. Section 3: Check box for official order forms for Schedule II CS, if applicable. 4. There is no need to list drug codes.
Researcher	I (1)	New 225 Renewal 225a	1. Section 2: Check "Researcher w/Sched I". 2. Section 3: Check "Schedule I". 3. For Schedule II-V CS, a separate registration is required from Schedule I. 4. Check the applicable drug codes in Schedule I. 5. Researcher must attach 3 copies of protocol, including curriculum vitae.
Researcher	II to V (2 to 5)	New 225 Renewal 225a	1. Section 2: Check "Researcher w/Sched II-V". 2. Section 3: Check all applicable boxes (Schedule II Narcotic, Schedule II Non-Narcotic, Schedule II Narcotic, Schedule III Non-Narcotic, Schedule IV and Schedule V). 3. Section 3: Check box for official order forms for Schedule II CS. 4. Check the applicable drug codes in different schedules.
Teaching Institution	I (1)	New 225 Renewal 225a	1. There is no Schedule I registration for Teaching Institution. 2. For institutes like Forensic Sciences, check the box Analytical Lab in Section 2. 3. See Analytical Lab registration.
Teaching Institution	II to V (2 to 5)	New 224 Renewal 224a	1. Section 2: Check "Teaching Institution". 2. Section 3: Check all applicable boxes (Schedule II Narcotic, Schedule II Non-Narcotic Schedule III Narcotic, Schedule III Non-Narcotic, Schedule IV and Schedule V). 3. Section 3: Check box for official order forms for Schedule II CS. 4. Check the applicable drug codes in different schedules.

REGISTRATION (PERMITTING): DIETHYL ETHER

Florida Tech does purchase and use ether compounds (e.g. Diethyl Ether) which require a permit from the State of Florida. Ether licenses and permits are obtained through the Department of Business & Professional Regulation (DBPR). Individuals who need to obtain a permit should be prepared to provide specific requirements per the application (e.g. a complete set of fingerprints).

Regarding Applicants & Applications

Pursuant to 559.79 Applications for License or Renewal, each application for a license or renewal of a license issued by the DBPR shall be signed under oath or affirmation by the applicant, or owner, or chief executive of the applicant without the need for witnesses unless otherwise required by law.

Pursuant to 559.791 False Swearing on Application; Penalties, any license issued by the DBPR which is issued or renewed in response to an application upon which the person signing under oath or affirmation has falsely sworn to a material statement, including, but not limited to, the names and addresses of the owners or managers of the licensee or applicant, shall be subject to denial of the application or suspension or revocation of the license, and the person falsely swearing shall be subject to any other penalties provided by law.

Application Process

Applicants must complete the form DBPR-DDC-233 titled, "*Application for Permit as a Diethyl Ether Manufacturer, Distributor, Dealer, or Purchaser Form No.: DBPR-DDC-233*". This can be done either online or hard copy (instructions for completion and submission are located on the form). A copy of the application and granted permit must be submitted to ehs@fit.edu.

RENEWAL OF REGISTRATIONS

DEA Renewals

DEA grants registration for specified Schedules of CS for a specific period. Approximately 60-days prior to expiration, registrants receive notice from the DEA informing them to renew their registration at the address registered with the DEA. In case of relocation, the registrants must notify the DEA regarding change of address with a copy sent to the CSSO of the institution of relocation as well as the initial location's CSSO.

The forms are required to be submitted to the DEA, and the CCO must be notified of all renewals.

- DEA Form 224 is a three-year registration and is renewed by submission of Form 224a.
- DEA Form 225 is a one-year registration and is renewed by submission of Form 225a.

State of Florida Permit Renewals

Permits for Ether require a new submission for the form DBPR-DDC-233 prior to the expire date. Instructions for completion and submission are located on the form. A copy of the application renewal and granted permit must be submitted to ehs@fit.edu.

ACQUISITION OF CONTROLLED SUBSTANCES

These procedures describe how CS are to be ordered, received, and handled by individuals who are engaged in instructional or research activities at or through Florida Tech. Copies of all documents must be provided to the CSSO.

Adding Controlled Substances: Researcher Permit

The registrant will complete the applicable DEA registration form.

Adding Controlled Substances: Analytical Permit

Analytical lab permit holders are not required to amend their permit to add a CS, provided their current DEA registration already allows for controlled substances of that schedule. Since the analytical may be analyzing and researching with several CS, it may not be practical to list them all, thus Analytical Lab permit holders are not required to list the codes for all CS.

Ordering Procedures

The registrant is the only one who can purchase CS and all requests for purchases must be approved by the CSSO before ordering. It is violation of the Florida Tech's procedures to procure CS without approval from CSSO. When ordering any CS, use the below procedure:

1. Purchase Requisition

   The purchase acquisition is approved and generated through Workday by the registrant. The original will be sent to the Purchasing Department, along with copies of purchase, and the DEA Registration Certificate under which the CS will be purchased and used.

2. Place Order

   Registrants may place orders using the DEA's Controlled Substance Ordering System (CSOS)

3. Invoice

   The invoice should give complete details (name, schedule, code, price, and quantity) of the controlled substance, delivery location, address, phone, and fax number of the vendor. The delivery address of the registrant must match with that given on the registration certificate.

SPECIAL NOTE:

The Purchasing Department is not to process a Purchase Order if the Purchase Order Request was generated by anyone other than the registrant. The Purchase Order must not be processed unless accompanied by the appropriate DEA form (if applicable) and Registration Certificate.

Procurement: General

Procurement of CS must be coordinated with the CSSO. An Appendix E: Controlled Substance Chain of Custody (COC) or similar must be filled out by the registrant that documents the transfer from the vendor to the registrant's custody. The COC form must also be filled out whenever a CS in a registrant's possession is moved to another registered storage location, when a lab is closed out, or when a CS is return distributed for destruction. The CSSO must be provided copies.

Receiving Procedures for Controlled Substances

The Shipping and Receiving Department at Florida Tech will not accept any Controlled Substances directly. CS are to be delivered immediately by the carrier only to the registrants. Shipments must be addressed directly to the registrant's address, and the registrant's signature will be required for pick-up. When the registrant orders a controlled substance, they shall request the vendor to deliver the substance to the attention of the registrant at the registrants registered address.

It is the sole responsibility of registrants to coordinate the shipment and be available during the expected delivery window. Under no circumstances will the CS package be left in the Shipping and Receiving Department.

When a controlled substance is received, it is to be immediately stored in the registrants safe along with a completed Chain of Custody to prevent theft and be available for inspection by an EH&S, state, and/or DEA inspectors.

Storage and Security Procedures

1. CS are to be stored according to requirements for stability and sterility printed on the label (e.g., packaging integrity and refrigeration).
2. The CS must be kept ONLY in a fixed and stationary, secure, and substantially constructed locked cabinet, safe or other containment furniture. Access to the CS cabinet is allowed only to individuals whose names are listed on the Appendix D: Controlled Substance Authorized Users List Letter.
3. A permanently locked room accessible only to the authorized users may serve as a vault if the locked safe is placed in this room.
4. These containment structures should be in a room or office that is not accessible to the general public or students who are not involved in approved laboratory and research activities.
5. Key locks or safe combinations should be changed whenever personnel changes or a theft occurs.
6. Flip-off tops and other types of seals affixed to controlled substance containers are not to be removed prior to use, to assure the integrity of the container.
   ANY unaccountable loss of controlled substance, or loss apparently due to theft or misuse is to be reported to the Florida Tech Security and CSSO immediately upon discovery and to the DEA within 24 hours by filing either a DEA Form 106 or DEA Form 107.
7. CSSO may conduct an inspection of proposed controlled substance storage locations or containment furniture prior to full approval. The storage site is also subject to periodic inspection by CSSO.
8. Section 1301.72 of 21 CFR describes physical security controls for non-practitioners; narcotic treatment programs, and compounders for narcotic treatment programs; storage areas, as under:

Only the registrant shall have keys to the safe or lock box containing the CS. The responsibility for inventory, use, and security of the CS lies solely with the registrant.

Storage and Security: Schedule I and II Controlled Substances

Schedules I and II: Raw materials, bulk materials awaiting further processing, and finished products, which are CS, listed in Schedule I or II, shall be stored in one of the following secure storage areas:

1. Where small quantities permit, a safe or steel cabinet:
    a. Shall have the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques;
    b. If it weighs less than 750 pounds, is bolted or cemented to the floor or wall in such a way that it cannot be readily removed; and
    c. If necessary, depending upon the quantities and type of CS stored, is equipped with an alarm system which, upon attempted unauthorized entry, shall transmit a signal directly to a central protection company or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection the Administrator may approve.
2. Vaults constructed before, or under construction on, September 1, 1971, which is of substantial construction with a steel door, combination or key lock, and an alarm system; or
3. Vaults constructed after September 1, 1971:
    a. The walls, floors, and ceilings of which vault are constructed of at least 8 inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with 1/2-inch steel rods tied 6 inches on center, or the structural equivalent to such reinforced walls, floors, and ceilings;
    b. The door and frame unit of which vault shall conform to the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques;
    c. Which vault, if operations require it to remain open for frequent access, is equipped with a "day-gate" which is self-closing and self-locking, or the equivalent, for use during the hours of operation in which the vault door is open;
    d. The walls or perimeter of which vault are equipped with an alarm, which upon unauthorized entry shall transmit a signal directly to a central station protection company, or a Local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Administrator may approve, and, if necessary, holdup buttons at strategic points of entry to the perimeter area of the vault;
    e. The door of which vault is equipped with contact switches; and
    f. Which vault has one of the following: Complete electrical lacing of the walls, floor and ceilings; sensitive ultrasonic equipment within the vault; a sensitive sound accumulator system; or such other device designed to detect illegal entry as may be approved by the Administration.

Storage and Security: Schedule III-V Controlled Substances

Schedules III, IV and V raw materials, bulk materials awaiting further processing, and finished products which are controlled substances listed in Schedules III, IV and V shall be stored in the following secure storage areas:

1. Safe or steel cabinet as described for Schedule I and II CS;
2. A vault and alarm system as described for Schedule I and II CS;
3. Building used for storage of Schedules III through V controlled substances with perimeter security which limits access during working hours and provides security after working hours and meets the following specifications:
4. Has an electronic alarm system as described in section for Schedule I and II CS;
5. Is equipped with self-closing, self-locking doors constructed of substantial material commensurate with the type of building construction, provided, however, a door which is kept closed and locked at all times when not in use and when in use is kept under direct observation of a responsible employee or agent of the registrant is permitted in lieu of a self-closing, self-locking door. Doors may be sliding or hinged. Regarding hinged doors, where hinges are mounted on the outside, such hinges shall be sealed, welded or otherwise constructed to inhibit removal. Locking devices for such doors shall be either of the multiple-position combination or key-lock type; and
    a. In the case of key locks, key control shall be required to limit access to a limited number of employees; or
    b. In the case of combination locks, the combination shall be limited to a minimum number of employees and can be changed upon termination of employment of an employee having knowledge of the combination.
6. Cage, located within a building on the premises, meeting the following specifications:
    a. Having walls constructed of not less than No. 10 gauge steel fabric mounted on steel posts, which posts are:
        i. At least one inch in diameter;
        ii. Set in concrete or installed with lag bolts that are pinned or brazed; and
        iii. Which are placed no more than ten feet apart with horizontal one and one-half inch reinforcements every sixty inches.
    b. Having a mesh construction with openings of not more than two and one- half inches across the square,
    c. Having a ceiling constructed of the same material, or in the alternative, a cage shall be erected which reaches and is securely attached to the structural ceiling of the building. A lighter gauge mesh may be used for the ceilings of large enclosed areas if walls are at least 14 feet in height;
    d. Is equipped with a door constructed of No. 10 gauge steel fabric on a metal door frame in a metal door flange, and in all other respects conforms to all the requirements of 21 CFR 1301.72(b)(3)(ii), and
    e. Is equipped with an alarm system which upon unauthorized entry shall transmit a signal directly to a central station protection agency or a local or state police agency,

each having a legal duty to respond, or to a 24-hour control station operated by the registrant, or to such other source of protection as the Administrator may approve.

7. An enclosure of masonry or other material approved in writing by the Administrator as providing security comparable to a cage;
8. A building or enclosure within a building which has been inspected and approved by DEA, and continues to provide adequate security against the diversion of Schedule III through V controlled substances, of which fact written acknowledgment has been made by the Special Agent in Charge of DEA for the area in which such building or enclosure is situated;
9. Such other secure storage areas as may be approved by the Administrator after considering the factors listed in Sec. 1301.71(b), (1) through (14);
10. Schedule III through V CS may be stored with Schedules I and II CS under security measures provided by 21 CFR 1301.72(a).

Storage and Security: Non-Controlled Substances, Multiple Storage Sites, and Accessibility

Non-CS, and other materials may be stored with Schedule III through V CS in any of the secure storage areas required by 21 CFR 1301.72(b), provided that permission for such storage of non-controlled items is obtained in advance, in writing, from the Special Agent in Charge of DEA for the area in which such storage area is situated. Any such permission tendered must be upon the Special Agent in Charge's written determination that such non-segregated storage does not diminish security effectiveness for Schedules III through V CS.

Where several types or classes of CS are handled separately by the registrant or applicant for different purposes (e.g., returned goods, or goods in process), the CS may be stored separately, provided that each storage area complies with the requirements set forth in this section.

The controlled substance storage areas shall be accessible only to an absolute minimum number of specifically authorized employees. When it is necessary for employee maintenance personnel, non-employee maintenance personnel, business guests, or visitors to be present in or pass through controlled substance storage areas, the registrant shall provide for adequate observation of the area by an employee specifically authorized in writing. Given below are Access Control Procedures:

1. CS will be stored in safes inside a storage area.
2. The safe will have a key, which can be accessed only by the registrant who shall be accountable for the inventory of the CS.
3. The safe shall be bolted or screwed so that anybody entering the controlled area shall not be able to remove the safe.

DISPOSITION OF CONTROLLED SUBSTANCES

CS are not to be loaned or shared with any other researcher or laboratory. They are only to be used by authorized individuals. Upon final disposition, an Appendix E: Controlled Substance Chain of Custody (COC) or similar, shall be completed for recordkeeping purposes.

Disposition: Loss of Theft of CS

Any loss of CS or discrepancy in record keeping is to be reported to the CSSO immediately upon discovery. If theft or misuse is suspected, Florida Tech Security must also be notified immediately (321) 674-8111. Based on the details and amount involved in reported losses, per the DEA (Theft/Loss Reporting), the registrant may need to file a DEA Form 106 or DEA Form 107. Florida Tech (through Security and EH&S) also reserves the right to impound CS and records pertinent to an investigation into inventory or record keeping discrepancies, or potential misuse.

Disposition: Expired or Unused CS

All expired substances or those left over at the end of the research or instructional activity for which they were required, are to be accounted for.

Disposition: Disposal/Destruction of CS

Individuals disposing of CS may request assistance from the Special Agent in Charge of the area in which the person is located for authority and instructions to dispose of such substance. Alternatively, they could utilize a reputable third party for disposal.

Destruction

If the person is a registrant, they shall utilize a DEA Form 41: Registrant Record of Controlled Substances Destroyed, submitting copies to the CSSO.

Disposition: Loss of CS Due to Spill

A CS Spill Record must be completed for controlled substance wastes due to spill (see example: Appendix G: Controlled Substance Spill Record).

Disposition: Separation Procedures

Employees who have any CS under their control must notify the CSSO, their Department Head, and the Human Resources immediately if they are separating from employment with Florida Tech.

RECORD KEEPING PROCEDURES

The registrants, with oversight of the CSSO, must adequately document all controlled substance purchases, shipment, usage, waste, disposition, and damaged material from a "Cradle-to-Grave". The record of receipt (including original invoices from suppliers or the source of acquisition) must be maintained. Records should include the date of receipt, the supplier, the quantity and dose of the controlled substance received, the expiration date, and the date when the controlled substance was exhausted or discarded as expired.

Each time a quantity of a controlled substance is taken from stock, an entry is to be made in the registrants CS Usage Log (see example: Appendix F: Controlled Substance Usage Log), which also documents the Working Inventory. This form notes the date, quantity used, quantity remaining, and the signature of the individual authorized to handle the controlled substance. An accurate perpetual balance for each controlled substance container is always to be maintained on the usage log.

If there is not enough space on the original usage log to account for all dispensing of a given substance, additional copies are to be properly completed and attached to the original usage log. Copies of the usage log may be requested by the CSSO.

All records must be retained for a period of two (2) years following final disposition of the controlled substance.

INVENTORY AUDITS

Federal regulations require an inventory of all CS be performed at least **initially** (upon receipt or creation) and **once every two years (biennially)**. Inventory audits will be recorded utilizing Appendix H: Controlled Substances Inventory Audit Record.

Initial Inventory Audit

An initial inventory will be conducted and recorded by the Registrant upon receipt of any CS.

Biennial Inventory Audit

Only individuals have on file an Appendix B: Controlled Substance Request for Authorization Record along with the CSSO may conduct the biennial inventory. No other individual has the authority to conduct this inventory.

The total amount of each substance shown as the working perpetual balance is to be audited against the actual inventoried amount. If there are any discrepancies, these must be documented and investigated.

Final Inventory Audit

A final inventory audit may be conducted upon the separation of an authorized Registrant, whether a planned or unexpected separation.

INSPECTIONS

Records and inventories of CS are subject to **unannounced inspections by the CSSO and/or Director of EH&S.** All records and CS must be immediately available for review. Representatives of State and Federal agencies may also wish to inspect the storage, maintenance, safeguarding, use, disposal procedures.

At the time of inspection, the following items are subject to evaluation:

- Proper storage and security arrangements (including proper storage of CS along with Chain of Custody forms).
- Accuracy and completeness of your Controlled Substance Usage Logs and all other relevant records.
- Ensuring that only authorized individuals are handling CS.
- Deficiencies found during previous inspections have been corrected and addressed.
- Procedures for use and disposal of the CS are compliant with State and Federal regulations.

The CSSO will inspect each laboratory or research facility using CS periodically and may be in conjunction with inventory audits. In addition, department or individual researchers are encouraged to perform periodic self-evaluation surveys.

TRAINING

The registrant shall ensure that they, themselves, as well as any authorized user under their Registration is appropriately trained. The training may involve in-person or online curriculum regarding CS usage; however, this Controlled Substance Safety Plan **MUST** also be included in the training.

Registrant's can utilize the Appendix I: Controlled Substance Training Record, for recording such trainings.

APPENDICES

All appendices are available by contacting ehs@fit.edu.

Appendix A--Controlled Substance Request for Registration
Appendix B--Controlled Substance Employee Screening Certification
Appendix C--Controlled Substance Use Fact Sheet
Appendix D--Controlled Substance Authorized Users List Letter
Appendix E--Controlled Substance Chain of Custody (COC)
Appendix F--Controlled Substance Usage Log
Appendix G--Controlled Substances Spill Record
Appendix H--Controlled Substances Inventory Audit Record
Appendix I--Controlled Substance Training Record

REFERENCES

1. Official Versions: Title 21
2. U.S. Department of Justice, Drug Enforcement Administration, Diversion Control Division
3. State of Florida Department of Business and Professional Regulation Division of Drugs, Devices, and Cosmetics
4. Ether Applications and http://flrules.elaws.us/fac/64f-12.022
5. DEA Forms & Applications

CONTACTS

Florida Tech EH&S Contacts

Questions concerning CS may be directed to the Controlled Substance Safety Officer (CSSO) at Florida Tech's EH&S office (321.674-8881) or by emailing ehs@fit.edu.

DEA Contacts

Headquarters
Drug Enforcement Administration
Attn: Registration Section/ODR
PO Box 2639
Springfield, VA 22152-2639
Phone: (800) 882-9539
Email: DEA.Registration.Help@usdoj.gov

Orlando District Office
300 International Pkwy
Heathrow Business Center
Suite 424
Heathrow, Fl 32746

Registration Assistance
571-362 3367

Investigative Matters or Tactical Diversion Squads (TDS)
407-333 7046

Department of Business and Professional Regulation's (DBPR)

Customer Contact Center
2601 Blair Stone Road
Tallahassee, FL 32399
Phone: (850) 487-1395
Account Login