



## Controlled Substance Guidelines

# Lafayette College Controlled Substance Guidelines

Department of Public Safety – Environmental, Health and Safety

Standard Operation Procedure (SOP) #39 – Revised November 2012

## **Guidance for Controlled Substances Used In Research**

### **Introduction**

Because of their potential for misuse and abuse, items listed by the U.S. Department of Justice, Drug Enforcement Administration (DEA) as controlled substances are subject to special procurement, storage, use, and disposal requirements. These include federal and state licensing (prior to procurement), maintaining detailed storage and use records, and special disposal procedures.

Since the College cannot, by law, maintain a blanket registration for controlled substances, it is the responsibility of individual researchers using these materials to obtain appropriate registrations and licenses.

### **Licensing**

All faculty and staff that wish to work with controlled substances must be licensed by the DEA. The College does not have a blanket license to cover purchases of such materials. However, Public Safety's Environmental, Health and Safety Division (EHS) can facilitate controlled substance licensing for individual Lafayette researchers.

- [Information on applying for a license \(DEA Form 225\).](#)
- [Information on various drug schedules.](#)

In addition to the application form, faculty and staff will need to provide the DEA with the following:

- The applicant's social security number.
- The applicant's curriculum vitae.
- A copy of the research protocol summarizing the procedures to be performed using controlled substances, including specific information on monitoring drug usage, inventory control, destruction, security, storage and access to the material.
- Names of all persons who will have access to the controlled substances or records.

Note that the State of Pennsylvania does not issue licenses for the use of controlled substances (a question asked on the application or by the DEA).

### **License Renewal**

License holders will be notified by U.S. Mail prior to the expiration of their DEA license. If continued work with controlled substances is anticipated, licensees are strongly encouraged not to let their license expire.

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### **Storage**

Controlled substances must be stored in a manner that prevents theft or diversion of the material. Schedule 1 materials (those with a high potential for diversion AND a high potential for abuse) must be stored in a safe; Schedule 2-5 materials must be stored in a substantially constructed cabinet that is locked at all times and cannot be easily removed from the lab/office. The location of the safe or cabinet should have limited access during normal working hours and be secured after hours. The licensee should maintain a list of all persons who are authorized to have access to controlled substances.

In addition to the scheduled controlled substances, there are also chemicals that are regulated under the Controlled Substances Act because they are precursors to or reagents used in the manufacture of illicit drugs. Many of these are common laboratory reagents; many have a threshold below which reporting is not required and ordering does not require a DEA license. A table of these chemicals can be found [here on the DEA website](#).

### **Record Keeping**

Licensees must maintain detailed inventory records as specified in [21 CFR 1304.03](#). All records must be maintained for at least two years, and five years is advisable. Records should include purchasing records, which can be an invoice, shipping papers, or a packing slip, and must contain: the name, address and DEA number of the company where the controlled substance was purchased, the name of the controlled substance purchased, the size and strength of the controlled substance purchased, the amount purchased, and the date of receipt (which may be hand-written).

Usage records must include the date that the material is used, the initials of the person dispensing on behalf of the licensee, the name of the controlled substance, the strength and size of the controlled substance, and the amount dispensed.

Records for Schedule I and II drugs must be kept separately from records for Schedule III material.

Complete inventory requirements can be found at [21 CFR 1304.11](#). In addition to these specific requirements, additional general requirements include:

- A separate sheet must be used for each compound. The sheet must list the date, amount of receipt, source of the material, and fate of the material (i.e., destroyed in chemical reaction, neutralized, disposed, etc.).
- Each licensee must be able to account for all of any given compound that they are licensed to work with (i.e., licensees must know the amount they have on hand at any given date).
- The inventory must be updated at least annually, and whenever materials are removed from their original container.

### **Disposal**

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Unwanted or outdated controlled substances should be disposed of through a DEA-licensed reverse distributor for disposal. Contact Lafayette Public Safety's EHS Division for a list of vendors available for disposal. Disposal pricing will vary depending on the quantity of materials that you have. Copies of all disposal documents must be kept on file by the DEA registrant.