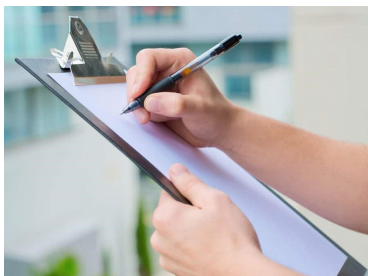


FACT SHEET: Controlled Substance Inspections



NEED TO KNOW:

1. Authorized Users are anyone you have given access to the stock containers of Controlled Substances.
2. By default, the Controlled Substances training module is hidden. Contact OEHS to enroll your lab members.
3. An equivalent live training session is available from OEHS staff. Times and zoom links will be posted in the Announcements section of SciShield.
4. All required forms are available on the OEHS website Controlled Substances page: <https://oehs.tulane.edu/controlled-substances>
5. There are 2 Continuous Usage Log forms available. One is for stock solutions of controlled drugs, the other is for diluted working solutions containing smaller concentrations of controlled drugs.

MORE INFO:



OEHS conducts annual inspections of laboratories participating in the Tulane Controlled Substances program. These inspections help prepare researchers for inspections by the Louisiana Board of Pharmacy and Drug Enforcement Agency as well as ensuring best practices that reduce the likelihood of drug diversion. Participation in the inspection process is required to use the OEHS On-site Drug Destruction Service.

APPLICABILITY:

- Inspections are conducted only in research or teaching labs where the director or responsible faculty member is purchasing and storing controlled substances themselves for use in their lab operations. Inspections are not conducted for veterinary medicine departments, medical practitioner, or researchers who are sourcing controlled substances from a university vivarium or animal program.
- OEHS may conduct inspections for researchers applying for a new DEA license to prepare for a visit by the DEA or LABP.

SECURITY:

- All controlled substances must be stored in a dedicated, substantial cabinet, safe, or drawer. This location requires 2 barriers to access. This generally means 2 locks must be opened to access the storage location.
- The 2 barriers DOES NOT include lab or building doors if people other than the licensee's Authorized Users have access to them. It also does not include lockboxes or containers that can be easily picked up and stolen. OEHS recommends installation of a wall-mounted narcotics safe with 2 locks as the best option to store drugs in the lab.
- Any Schedule 1 or 2 drugs must be stored separately from Schedule 3, 4, and 5 drugs.
- Expired or non-controlled drugs should be stored separately.

DOCUMENTATION:

OEHS will examine all related documentation for completeness. All records must be retained for at least 2 years. Consult the "DEA Checklist of Required Records for Researchers". This includes:

- Current DEA and LABF licenses.
- Initial and Biannual drug inventories.
- Purchasing records. Invoices for all drugs. Also receipts for Schedule 1 and 2 drugs.
- Continuous Usage Logs for all stock and working dilution containers of drugs in use.
- Destruction records (Form 41's) for all destroyed drugs.
- Theft records (Form 106's) for any stolen or missing drugs.
- Authorized User list. Keep the list updated as your Users change.
- Tulane Authorized User Attestation Forms for all Authorized Users. These only need to be completed once for each User.
- OEHS Renewal Form

TRAINING:

The licensee and any one in the lab who will be using Controlled Substances purchased using the that license must complete the "Use of Controlled Substances in Research" training module available on TULearn or via a live training session with OEHS.

This training is required annually. Anyone completing this training should print their completion certificate or grade and keep it with the licensee's other records.

ADDITIONAL RESOURCES:

- DEA Website: <https://www.dea diversion.usdoj.gov/>
- LABP Website: <https://www.pharmacy.la.gov/>