



Controlled Substances Registrants Audit Guidelines

A. Registration

1. Registered researcher has a current registration which is not expired.

Recommendations: The use of a controlled substance requires the user to obtain a DEA registration. Only the Principal Investigator (PI) in the laboratory may apply for and hold a DEA license. University of Colorado affiliated researchers are fee exempt. Environmental Health and Safety must obtain updated DEA registrations.

Reference: 21 CFR 1301.13 and 21 CFR 1301.21

2. DEA registration is applicable to schedules used and storage location.

Recommendations: Users of DEA controlled substance can only obtain, store and use schedules that they are licensed/registered for in the location of registration. Registration must be amended as needed for any changes through the U.S. Office of Diversion Control. A PI that is an MD or Pharm D and holds a registration for their clinical practice, may not use that registration for research purposes.

Reference: 21 CFR 1301.13, 21 CFR 1301.21 and the university Administrative Policy "Management of Controlled and Prescription Drugs in Laboratories on Campus"

B. Ordering

1. Personnel aware that only persons holding a current registration may order controlled substances.

Recommendations: Acquiring controlled substances without a DEA registration or maintaining controlled substance inventory on an expired registration is not permitted. Controlled substance purchases should have a process wherein one individual is responsible for placing the order, a second individual is responsible for receiving the order, and a third individual is responsible for paying for the order. Controlled substances cannot be ordered using a personal procurement card (e.g., A-card or P-card). Any controlled substances which are housed under no registration or an expired registration must be surrendered to the Environmental Health and Safety Hazardous Materials Section immediately for disposal. It is recommended that registration holders always review orders for controlled substances under their registration.

Reference: 21 CFR 1317.05 and the university Administrative Policy "Management of Controlled and Prescription Drugs in Laboratories on Campus"

C. Storage/Use Location

1. Controlled substance containers are in good condition, closed securely, labeled properly and not expired.

Recommendations: If there is no legitimate use or need for the controlled substance container or the container does not meet these criteria, then the registered holder must contact Environmental Health and Safety immediately for disposal of the material.

Reference: 21 CFR 1302

2. Registered holder is using the controlled substance at the registered location or transporting according to DEA guidelines.

Recommendations: Controlled substance must be returned, secured and stored in registered location. If the controlled substance is being used at a different location than listed on the registration, the holder can transport the controlled substance within the scope of their employment.

Reference: 21 CFR 1301.12

D. Security

1. Controlled substances are secured against unauthorized access. Access is limited or restricted at the discretion of the Principal Investigator.

Recommendations: Registration holder must have a double securing system in place and this system must be secured at all times. The securing system must include security measures beyond hallway access doors controlled by key cards/touch pads or pin number access. Registration holder must have an individual cabinet which is not transportable and must be substantially constructed. Non-controlled substances cannot be stored with controlled substances unless permission is granted from the DEA.

Reference: 21 CFR 1301.71 and the university Administrative Policy "Management of Controlled and Prescription Drugs in Laboratories on Campus"

2. Personnel are aware that incidents which result in any loss, theft or diversion needs to be reported immediately.

Recommendations: Make personnel aware that loss, theft or diversion must be reported immediately to the local DEA field office and University Police. The local DEA Office must be called at (720) 895-4040 and DEA form 106: Theft or Loss of Controlled Substances must be completed.

Reference: 21 CFR 1304.11(b), 21 CFR 1304,11(c) and 21 CFR 1304.22(c)

3. Users signed and executed DEA form 222 without a power of attorney.

Recommendations: Any person executing a DEA form 222 on behalf of the registered user needs to have a power of attorney and make it readily available for inspection.

Reference: 21 CFR 1305.05

E. Inventory

1. Inventory log is maintained for controlled substance to ensure proper management of the controlled substance. Biennial report is available.

Recommendations: DEA requires that inventory is maintained for every controlled substance in the lab and made readily available for inspection. Inventories must be maintained to ensure that the controlled substance is not lost, stolen or misused. All controlled substance use must be recorded and should be checked monthly. Biennial reports must be conducted by the registration holder and maintained with the inventory.

Reference: 21 CFR 1304.11(b), 21 CFR 1304.11(c), 21 CFR 1304.22(c) and the university Administrative Policy "Management of Controlled and Prescription Drugs in Laboratories on Campus"

F. Recordkeeping

1. Controlled substance inventory is in *EHS Assistant*®: inventory is current and reflective of controlled substances housed in the laboratory.

Recommendations: *EHS Assistant*® chemical inventory is updated upon receipt and removal of controlled substance from the laboratory. If controlled substance is not used within an annual timeline the chemical inventory is verified annually to ensure inventory is accurate.

Reference: University of Colorado Denver/Anschutz Medical Campus Online Chemical Inventory System User's Manual

2. DEA requires that any DEA form 222 and Environmental Health and Safety destruction paperwork must be held by the lab for a retention period of 2 years. Controlled substance disposal records should be readily available during an inspection.

Recommendations: DEA recommends that any DEA form 222 and Environmental Health and Safety destruction paperwork must be held by the lab for a retention period of 2 years. Controlled substance disposal records should be readily available during an inspection.

Reference: 21 CFR 1304.04, 21 CFR 1304.21, 21 CFR 1304.22, 21 CFR 1305.17 and the university Administrative Policy "Management of Controlled and Prescription Drugs in Laboratories on Campus"

G. Disposal

1. Registration holder understands how to properly dispose of controlled substance.

Recommendations: DEA controlled substances must be disposed of through a licensed Reverse Distributor. Contact Environmental Health and Safety Hazardous Materials Reverse Distributor Group (phone 303-724-0345) or email EHS.hazmat@cuanschutz.edu to have controlled substance removed from the laboratory. Laboratories cannot dispose of any controlled substance by dumping the controlled substance down the sink. If the laboratory finds any controlled substances which are in question or considered abandoned contact Environmental Health and Safety immediately.

Reference: 21 CFR 1317.05 and the university Administrative Policy "Management of Controlled and Prescription Drugs in Laboratories on Campus"