

## AUGUSTA UNIVERSITY

### DEA INSPECTION GUIDELINES FOR CONTROLLED SUBSTANCE COMPLIANCE

#### **Background**

The U.S. Department of Justice Drug Enforcement Agency (DEA) makes periodic unannounced inspections to audit registered controlled substance storage locations and laboratories. In a typical audit, DEA Diversion Investigators ensure that the controlled substance licensee/registrant is compliant with the [Controlled Substance Act](#) or, if applicable, bring them back into compliance by verifying:

- Security practices: authorized personnel, controlled substance storage.
- Record keeping practices: [DEA Form 222](#) (if applicable), invoices, complete and accurate inventories, use, and waste logs. Particular attention will be paid to documented discrepancies.

The DEA is a law enforcement agency, with the ability to assess civil and criminal penalties. Non-compliance violations can result in increasing levels of penalty including:

- Letter of Admonition
- \$10,000 fine to the licensee/registrant for each violation
- Suspension or revocation of a controlled substance practitioner and/or research registration
- Incarceration

#### **Inspections**

Upon arrival of the DEA inspector to your lab or office:

1. Review their credentials, photo identification and obtain their contact information (business card).
2. Inquire about the reason for the inspection.
3. Notify the following of the inspection:
  - The licensee/registrant (or authorized agent, if the registrant is unavailable)
  - The PI and/or laboratory manager (if different than the registrant or authorized agent)
  - The Chemical Safety Office (706-721-2663).
4. Reserve a conference room for the investigator's use.
5. Sign the Notice of Inspection ([DEA Form 82](#)), which acts as informed consent (licensee/registrant or authorized agent only).

### During the Inspection:

1. Upon request, provide access to the controlled substance storage cabinet or safe (licensee/registrator or authorized agent only). Prepare to show the inspector the location of the keys.
2. Upon request, be prepared to provide any of the following (any authorized personnel):
  - State of Georgia controlled substance license and DEA Certificate of Registration ([DEA Form 223](#));
  - Authorized personnel log;
  - Laboratory policies and procedures regarding security, ordering, storage, and administration of controlled substances;
  - Most recent inventory (e.g., initial, semi-annual, biennial). NOTE: Augusta University inventories are performed semi-annually;
  - Current general and usage logs;
    - Use logbook must document name of drug, lot # or unique identifier, date administered, concentration administered, amount administered, amount remaining, and name or initial of person administering the drug.
  - Disposal Records. [DEA Form 41](#) (Dispose of expired drugs as soon as possible. Expired drugs contribute to the on-hand quantity until disposed.);
  - Access to controlled substance storage cabinet or safe;
  - Purchasing records (i.e., invoices, packing slips, [DEA Form 222s](#)), with Schedules I-II records separated from Schedules III-V;
  - Breakage-spillage reports, if applicable ([DEA Form 41](#));
  - Theft/significant loss reports, if applicable ([DEA Form 106](#));
  - Curriculum Vitae;
  - Approved animal use protocols (indicate controlled substance provisions).
3. The DEA investigators may audit select controlled substances to track usage from the last biennial inventory or purchase invoice. This includes asking the licensee/registrator or authorized agents to physically count, weigh, or otherwise inventory the substance.
4. Copy any records required by the DEA and obtain a receipt for any original records and/or controlled substances taken off-site.
5. Take notes of all recommendations and observations made by the DEA investigators.
6. Ask any clarifying questions you might have regarding the DEA findings.
7. Answer the DEA investigator's questions as concisely as possible. Always be truthful; don't speculate. If you don't know the answer to a question, be thoughtful and helpful in your answer, explaining, "I don't have the answer offhand, but I know where to find it".
8. Be polite and cordial. Do not argue or debate the DEA investigator.

### After the Inspection

1. Implement corrective actions.
2. Notify the Chemical Safety Office (706-721-2663) of any findings and lessons learned for other licensees/registrants.
3. Respond promptly to any DEA communications.

Additional guidance is available in the DEA License section on the [Chemical Safety Office](#) website.