



## Controlled Substance Compliance: DEA Inspection Guidelines

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The U.S. Department of Justice Drug Enforcement Administration (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](#).

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
- Prison sentence

### Inspection Preparation

Always be prepared! DEA inspections may occur late in the day or near holiday weekends. The registrant **and** all authorized personnel must be knowledgeable about federal and state, regulations, U-M policies, as well as laboratory policies and procedures regarding security, ordering, storage, and administration of controlled substances in research. Have an action plan to immediately retrieve records for a DEA inspection.

U-M *Controlled Substances in Research* policies and procedures are found at: [http://research.umich.edu/research\\_controlled\\_substances/](http://research.umich.edu/research_controlled_substances/).

### Inspection Procedure

Upon arrival of a DEA Diversion Investigator:

1. Review their credentials, photo identification, and obtain their contact information (business card)
2. Inquire about the reason for the inspection
3. **Immediately notify the following of the inspection:**
  - The licensee/registrant
  - The UMOR Controlled Substance Oversight Monitor (see blue box)
4. Reserve a conference room for the investigators to use
5. Sign the **Notice of Inspection** (DEA Form 82), which acts as informed consent (**licensee/registrant only**)
6. Upon request, provide access to the controlled substance storage cabinet or safe (**licensee/registrant or authorized agent only**)

#### UMOR Controlled Substance Monitor

Kelli Christman: 734-764-2003

Email: [CS-monitors@med.umich.edu](mailto:CS-monitors@med.umich.edu)

Pager: Call 734-936-6266, and at the prompt, enter pager **31685**, then your call-back number



### Inspection Procedure (cont'd)

7. Upon request, be prepared to provide any of the following:
  - State of Michigan (SOM) controlled substance license **and** DEA Certificate of Registration
  - Authorized personnel log, with screening statements
  - Laboratory policies and procedures regarding security, ordering, storage, and administration of controlled substances
  - Most recent inventory (e.g., initial, annual)
  - Current usage logs
  - Disposal records
  - Access to controlled substance storage cabinet or safe
  - Purchasing records (i.e., invoices, packing slips, DEA Form 222s), with Schedule I – II records separated from Schedule III – V.
  - Waste or breakage-spillage reports, if applicable (DEA Form 41)
  - Theft/significant loss reports, if applicable (DEA Form 106)

### During the inspection:

- The DEA investigators may audit select controlled substances to track usage from the last annual inventory or purchase invoice. This includes asking the registrant or authorized agents to physically count, weigh, or otherwise inventory the substance.
- Copy any records required by the DEA and obtain a receipt (DEA Form 12) for any original records and/or controlled substances taken off-site.
- Take notes of all recommendations and observations made by the DEA Investigators.
- Ask any questions you might have regarding the DEA findings so corrective actions can be implemented.
- Answer the DEA investigator's questions as concisely as possible. Always be truthful; don't speculate. If you do not 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," or "Please let me find the person with the answer." Ask for clarification if you do not understand a question.
- Be polite and cordial. Do not argue or debate with the DEA investigator.