

Controlled Substance Compliance: DEA Inspection Guidelines

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](#) or, if applicable, bring them back into compliance by verifying:

- Security practices: authorized personnel, controlled substance storage
- Record keeping practices: DEA 222 forms (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
- Prison sentence



Practitioners conducting coincidental research with controlled substances are **strongly advised** to obtain a separate *researcher* license and registration to reduce risk to their medical or dental practice.

The following procedure outlines the steps to prepare for and participate in a DEA inspection.

Inspection Preparation

Always be prepared! DEA inspections may occur late in the day or near holiday weekends. The licensee/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. This includes record keeping requirements and 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/.

Use the [Laboratory Preparation Checklist](#) to assess your inspection readiness.

Inspection Procedure

Upon arrival of a DEA Diversion Investigator:

1. Review their credentials, photo identification, and obtain their contact information
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)

UMOR Controlled Substance Monitors

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- The PI and/or laboratory manager (if different than the registrant or authorized agent)
 - A UMOR Controlled Substance Oversight Monitor (see blue box)
4. Reserve a conference room for the investigators use
 5. Sign the Notice of Inspection (DEA Form 82), which acts as informed consent (**licensee/registrant or authorized agent only**)
 6. Upon request, provide access to the controlled substance storage cabinet or safe (**licensee/registrant or authorized agent only**)
 7. Upon request, be prepared to provide any of the following (**any authorized personnel**)
 - State of Michigan (SOM) controlled substance license **and** DEA Certificate of Registration (Form 223)
 - 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, biennial)
 - Current general and 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.
 - 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 biennial inventory or purchase invoice. This includes asking the licensee/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.