ENVIRONMENTAL HEALTH AND SAFETY

RESEARCH SAFETY

CONTROLLED SUBSTANCES (23)

Controlled Substances Compliance in Labs

Inspection Preparation

- The Federal Drug Enforcement Agency (DEA) as well as the Indiana Professional Licensing Agency may make announced or unannounced inspections of any registrant's-controlled substance storage location.
- During an inspection, a diversion investigator will perform an audit to ensure compliance with security and record keeping requirements.
- The registrant and all authorized personnel must be knowledgeable about state regulations, Purdue policies as well as laboratory policies and procedures regarding security, ordering, storage and administration of controlled substances in research.
- The state and federal regulations require that controlled substance records be "readily retrievable."
- All laboratory members involved in the handling of controlled substances should know where the records are stored and be able to produce them for inspection.



Administrative Operations

Biosafety and Environmental Health
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The DEA, part of the U.S. Department of Justice, is a law enforcement agency that can assess civil and criminal penalties. While compliance investigators may work with registrants to bring them into compliance, non-compliance can also result in:

- Letter of admonition
- Fines of \$10,000 for each violation (including negligent record keeping)
- Suspension or revocation of licenses
- Prison sentence

Purdue Controlled Substances in Research policies and procedures are found here: Purdue Controlled Substances. (https://bit.ly/3FwcDR2)

