

Controlled Substances in Research Oversight Program

Laboratory Preparation Checklist

Building: _____

Room: _____

PI Name: _____

Controlled Substance Licensing and Registration

21 C.F.R. 1301	Yes	No	Comments/Action
Does a faculty member possess a current DEA 225 researcher registration			
Is the DEA Certificate of Registration Form 223 present on site or readily retrievable?			
Does the address on the DEA registration correspond with the laboratory address and room number where the controlled substances are stored?			
Are research activities within the scope of and DEA registration? (E.g., substance schedule, manufacturing, analytical research, etc.)			
Has DEA registration information been entered EHS?			

Inventory Records (Initial, Annual, Biennial, Closing)

21 C.F.R. 1304	Yes	No	Comments/Action
Was an initial inventory performed (new DEA registrations or address change)?			
Are the initial, and DEA biennial inventory records for the last two years on site?			
Are the inventory records readily retrievable?			
Was a DEA biennial inventory performed and retained on site?			
Are schedule I - II inventory records kept separate from schedule III - V inventory records?			
Were exact inventory quantities and amounts reported for schedule I - II controlled substances?			
Was a closing inventory performed (moving, transferring, retiring)?			

Usage Records (Inventory, Multi-dose, Diluted Solution)

21 C.F.R. 1304	Yes	No	Comments/Action
Are the usage records (logs,) for the last two years retained on site?			
Are the usage records readily retrievable?			

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Are the usage records for schedule I - II substances kept separate from the usage records for schedule III -V substances?			
Were the general inventory and usage records recently reconciled for accuracy?			
Are waste amounts signed by both the DEA registrant (or authorized agent) and a witness?			
Are individual containers or packages labeled with a unique identifier to assist in usage record tracking?			
Do diluted solutions of controlled substances have their own usage log?			
Does the general inventory document transfers of expired or unneeded controlled substances to a reverse distributor for disposal or destruction?			

Invoice and Purchase Records

21 C.F.R. 1305	Yes	No	Comments
Are supplier invoices for controlled substances readily retrievable?			
Are supplier invoices for schedule I - II controlled substances kept separately from supplier invoices for schedule III - V controlled substances?			
Do all invoices contain the following: Name, address, DEA registration numbers of supplier and purchaser, order date, drug names, strengths, container forms, and quantities received?			
Are all invoices signed and dated upon receipt or delivery?			

DEA Form 222 (Schedule I and II Order Forms)

21 C.F.R. 1305	Yes	No	Comments
Are unused and executed DEA Form 222s stored in a locked and secure location?			
Are unused or executed DEA Form 222s readily retrievable?			
Are there any missing DEA Form 222s? If so, have missing forms been reported to the Portland OR DEA office?			
Do unused DEA Form 222s with mistakes or those returned from supplier have "VOID" marked across the form?			

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Are all executed DEA Form 222s signed by the DEA registrant?			
Do all schedule I or II shipments have a corresponding DEA Form 222?			
Are all copy 3 (Purchaser) sections of executed DEA Form 222s complete and accurate?			

Disposal

21 C.F.R. 1317	Yes	No	Comments
Are expired or unneeded controlled substances kept in a substantially constructed cabinet until EH&S assists in disposal or contracted reverse distributor?			
Are all disposal forms and DEA Form 222s (Schedule I and II associated with a reverse distributor transfer kept on site?			
Were non-recoverable waste amounts properly disposed of?			
Are non-recoverable waste amounts documented in the inventory or usage record with two signatures (DEA registrant or authorized agent and one witness)?			

Loss or Theft

21 C.F.R. 1301.76	Yes	No	Comments
Have all actual or suspected cases of theft or significant loss been reported to the OSU Department of Public Safety, EH&S, and DEA?			
Was a DEA Form 106 submitted for actual or suspected cases of theft or significant loss?			
Have losses incurred during shipment been reported to the supplier?			
Are non-recoverable losses documented in inventory or usage record with two signatures (authorized agent and witness)?			

Security

21 C.F.R. 1301.71 – 1301.93	Yes	No	Comments
Have policies or standard operating procedures been developed by the laboratory with respect to storage, administering, and record keeping of controlled substances?			
Are the controlled substances stored in a securely locked, substantially constructed cabinet or safe that is anchored to a wall or the floor?			
Is the storage cabinet located at the address (building and room) as identified on the DEA registration?			

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Does the controlled substance storage location have minimal traffic flow?			
Is the lab or room with the storage cabinet locked when the registrants or authorized agents are not present?			
Are controlled substances requiring refrigeration securely stored or locked in a refrigerator?			
Is access to controlled substances kept to a minimal number of authorized agents?			
Are keys to the controlled substance storage cabinet locked up or secured when not in use?			
Do the locks on the storage room and cabinet have the capability to be reset or rekeyed if an authorized agent resigns, is terminated, or a loss or theft is suspected?			
Is an authorized personnel log kept on site?			
Is the authorized personnel log updated frequently?			
Have all authorized agents read and signed an "Authorized Agent Screening Statement? Are screening statements kept on file?			
Are all screening statements complete and kept on site?			
Are controlled substances delivered directly to a receiving individual in the laboratory?			