

Controlled Substances in Research

DEA Audit Preparation Checklist

Controlled Substance Licensing and Registration

	Yes	No	Comments/Action
Does the faculty member possess a current State of Georgia controlled substance research license or GA practitioner controlled substance license?			
Is the Georgia license present on site or readily retrievable?			
Does the address on the application and license correspond with the laboratory address and room number where the controlled substances are stored?			
Does a faculty member possess a current DEA 225 researcher registration or DEA 224 practitioner registration?			
Is the DEA Certificate of Registration Form 223 present on site or readily retrievable?			
Are research activities within the scope of the license and DEA registration? (e.g., substance schedule, analytical research, etc.)?			

Inventory Records (Initial, Annual, Biennial, Closing)

	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 available and on site?			
Are the inventory records readily retrievable?			
Are schedules I and II inventory records kept separate from schedule III - V inventory records?			
Were exact inventory quantities and amounts reported for schedules I and II controlled substances?			
Was a closing inventory performed (moving, transferring, retiring)?			

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

	Yes	No	Comments/Action
Are the usage records (logs, general inventory) for the last two years retained on site?			
Are the usage records readily retrievable?			
Are the usage records for schedules I and II substances kept separate from the usage records for schedules 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?			
Do multi-dose vials have their own usage log?			
Do diluted solutions of controlled substances have their own usage log?			
Does the usage record document disposal or destruction of expired or unwanted controlled substances through the Chemical Safety Office?			

Invoice and Purchase Records

	Yes	No	Comments
Are supplier invoices for controlled substances readily retrievable?			
Are supplier invoices for schedules I and II controlled substances kept separately from supplier invoices for schedules 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?			

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DEA Form 222 (Schedule I and II Order Forms)

	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 Savannah DEA regional office?			
Do unused DEA Form 222s with mistakes or those returned from supplier have "VOID" marked across the form?			
Are all executed DEA Form 222s signed by the DEA registrant?			
Do all schedules 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

	Yes	No	Comments
Are expired or unwanted controlled substances kept in a substantially constructed cabinet until disposal or destruction by the Chemical Safety Office?			
Are all disposal forms DEA Form 41 and/or DEA Form 222 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)?			

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Security			
	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?			
Does the controlled substance storage location have minimal traffic flow?			
Is the lab or room where the storage cabinet is stored 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?			
Have background checks been performed on authorized agents and authorized personnel?			
If a formal background check was not performed, 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?			

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Loss or Theft			
	Yes	No	Comments
Have all actual or suspected cases of theft or significant loss been reported to the Public Safety Department and the 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 (DEA registrant or authorized agent and witness)?			
General			
Is a current CV available for the licensed/registered faculty member?			
Are approved animal use protocols available that contain instructions for use of controlled substances?			
Are expired substances promptly removed from inventory and disposed through the Chemical Safety Office?			
Have findings and recommendations from previous inspections been addressed?			