



Controlled Substance (CS) Audit Checklist

Administrative	Explanation/Criteria	Yes	No	N/A
Is the DEA registration/license current and a copy available?	Controlled substances can only be attained and stored by those with a Drug Enforcement Administration (DEA) license/registration. Registration must be renewed annually.			
Is the OBN dangerous drugs registration current and a copy available?	The Oklahoma Bureau of Narcotics (OBN) is authorized by Title 63 of the Oklahoma Statutes to enforce the Uniform Controlled Dangerous Substance Act. They require registration by scientific researchers as well as other DEA registrants within the state of Oklahoma.			
Are laboratory specific DEA CS SOPs available?	Standard operating procedures (SOP) must be available regarding the use, recording, disposal, discrepancies, and proper safety equipment required when working with controlled substances.			
Is a copy of DEA CS guidelines available?	Guidelines need to be available for all authorized users.			
If DEA registration is for schedule I research, is a copy of the approved IACUC protocol available?	If a schedule I researcher is conducting animal research, they must have approval from the Institutional Animal Care and Use Committee (IACUC) for animal studies. (21 CFR 1301.18 and 21 CFR 1301.32) Only required for schedule I.			
Physical Security	Explanation/Criteria	Yes	No	N/A
Is access to controlled substances limited by a lock?	Controlled substances must be stored in a locked cabinet or a double locked safe for Schedule II-V drugs or a drug safe with an alarm for Schedule I drugs. This cabinet should be in a secure location with limited access.			
Is the storage safe and cabinet adequately sized?	The storage safe or cabinet must be large enough to maintain stock containers and waste materials.			
Are locks and cabinets in good condition?	Locks and cabinets must be functional and secured.			
Does the area for use of CS have limited access?	Only trained personnel should be in an area where controlled substances are being used.			
Do CS containers have original labels?	Controlled substances must not be transferred from original containers for inventory purposes and labels must not be removed. If the substance is converted or diluted, the new container must be labeled properly.			
Do CS containers have a unique ID # on the label?	Each CS container must have a unique ID # for accurate records.			
Are all CS contained and secured?	Controlled substances should never be left unattended when removed from locked containment.			
Are CS stored separate from non-CS?	Controlled substances must be physically separated from non-controlled substance chemicals. Containers separating CS should be clearly labeled.			

Inventory Control	Explanation/Criteria	Yes	No	N/A
Are the handwritten records for purchase, distribution/dispensing, and disposal of the CS present and up to date?	A copy of the purchase (DEA Form 222) and handwritten records of use and disposal of the controlled substances must be maintained. Records must be up to date and remain in the lab with the controlled substance for at least 2 years from the final use. Inspection date: _____			
Do the forms for records of use have details for an accurate audit?	Records should include: name and source of the substance; date of expiration; date of receipt; unique identification number for the bottle; starting quantity of the CS; date of use; protocol (or project) for which it is being used; animal(s) for which it is being used; person dispensing the medication from storage; person administering the medication; quantity (cc/ml/grams) of agent dispensed administered and wasted; and quantity remaining in the vial/bottle/box.			
Do you have schedule II CS and records?	Schedule II substances must be listed on a separate form or separately from Schedule III-V substances.			
Are initial and biennial inventories on record?	DEA requires an initial inventory and additional inventories every 2 years. Inventories every 6 months are recommended.			
Are SOPs in place for loss, theft, or spills?	The local DEA Diversion Field Office must be notified in writing within one business day of the discovery of a theft or significant loss of any CS. A DEA Form 106 must be completed. A witnessed breakage or spill does not constitute a loss as the registrant can account for the CS.			
Is there a designated route of disposal for any unused CS?	EHS is not authorized to dispose of controlled substances. An inventory of drugs surrendered for disposal must be maintained.			
Are SOPs for destruction of CS available?	DEA requires controlled substances being destroyed by the registrant with a method of destruction sufficient to render all such controlled substances non-retrievable to prevent diversion of any such substance to illicit purposes and to protect public health and safety (21 CFR 1317.90). Incineration is the only current accepted method. DEA Form 41 must be filled out.			
Personnel Security	Explanation/Criteria	Yes	No	N/A
Are records of personnel access present?	Only users authorized by the registered/licensed PI are allowed access.			
Is a screening process/background check done for authorized users?	All authorized users should be screened before given access to controlled substances. OSU does criminal background checks of all employees. The registrant should contact Human Resources for notification of any red flags for any of their authorized personnel. Students who are not employees but are authorized users need to be screened by the employer before being given access. 21 CFR 1301.90 gives guidance on questions to include in screening procedures.			
Are completed questionnaires for authorized users in a secure location?	All employee personal information should be in a secured location. OSU Human Resources should have all results of background checks. All confirmation from Human Resources and questionnaires from students should be stored in a secured location with limited access.			
Is training for CS use in the space documented?	All responsibilities delegated to authorized users must be documented. Authorized personnel should be trained in the use, PPE, recording, disposal, and discrepancy of controlled substances.			

Personnel Exposure & Contamination Control	Explanation/Criteria	Yes	No	N/A
Is general housekeeping maintained?	Proper housekeeping is very important in the safe handling of controlled substances.			
Is PPE available?	PPE must be available to all employees using controlled substances.			

Additional Comments

The registrant/licensee is responsible for managing the controlled substances in accordance with DEA and OBN regulations including inventory, record keeping, and security provisions.

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