

LIST OF POSSIBLE CONTROLLED SUBSTANCE INSPECTION FINDINGS (printed 2021)

Title	Finding Type	Inspection Question	Corrective Actions	Regulatory Citation
CDS is used or shared inappropriately.	Controlled Substances	Are CDS used only by the registrants and/or that registrant's authorized users?	CDS is used or shared inappropriately: IACUC approval is not the same as DEA/OCSA approval to use controlled substances. Only individuals registered by the DEA and OCSA and their authorized users, defined by HRS as being subordinate to the original registrants and approved by HRS, may use or handle CDS registered to that lab. Collaborators or neighboring labs may not use or share CDS unless expressly authorized to do so through the DEA or OCSA. IACUC protocol approval and/or EHS registration does not constitute permission to share CDS.	21 CFR 1301(e)(v) and (vi); COMAR 10.19.03.03
EHS CDS registration missing or incomplete.	Controlled Substances	Is the lab properly registered for CDS use with EHS?	EHS CDS registration missing or incomplete: All UMB investigators using CDS for research use must register their use with UMB EHS, and keep information up to date on federal and state registration status, authorized users, locations of use, and substances used.	UMB Policy VI-99.00(A) Policy on Research Use of Controlled Substances
Incorrect CDS registration for research use.	Controlled Substances	Is the lab registered for research use of CDS?	Incorrect CDS registration for research use: Registrants may not conduct research using controlled substances using a medical/dental/practitioner registration. A medical or dental registration is intended for prescription, administration, or direct dispensation at the listed place of business and does not allow for authorization of subordinate personnel to handle materials obtained under the license at the registrant's research laboratory. If a clinician prescribes CDS during medical practice and conducts research using CDS, then they must have a research registration with the DEA and with the OCSA as well as a medical registration with the DEA and OCSA, with each registration reflecting the accurate location of use.	21 CFR 1301(e); COMAR 10.19.03.03
DEA or OCSA registration not on file or expired.	Controlled Substances	Does the lab have current research registrations with the DEA and OCSA?	DEA or OCSA registration not on file or expired: Purchase, storage, or use of CDS is not permitted without current and unexpired registrations both with the DEA and the MD OCSA.	21 CFR 1301; COMAR 10.19.03.03
DEA form 223 (Certificate of Registration) not available for inspection	Controlled Substances	Is DEA form 223 maintained at the registered location and available for inspection?	DEA form 223 (Certificate of Registration) not available for inspection: DEA form 223 must be maintained at the registered location in a readily retrievable manner and shall permit inspection of the certificate by any official, agent or employee of the Administration or of any Federal, State, or local agency engaged in enforcement of laws relating to CDS.	21 CFR 1301.35(c)
Authorized personnel list requires an update.	Controlled Substances	Have all authorized users been reported to the DEA, OCSA, and UMB?	Authorized personnel list requires an update: Any UMB faculty member, staff, or student subordinate to a Registrant and authorized by HRS to have access to or use for research Controlled Substances held in a Registered Location under the responsibility of that Registrant must be listed as a Authorized User and are subject to HRS review.	UMB Policy VI-99.00(A) Policy on Research Use of Controlled Substances; 21 CFR 1301.90
CDS not properly secured and stored.	Controlled Substances	Are all CDS secured and/or stored?	Controlled substances not properly secured and stored: CDS must always be stored and secured as approved on DEA and OCSA registrations, double locked in a safe or cabinet of substantial construction. If CDS are being actively used, they must be under the direct control of the registrant or an authorized user.	21 CFR 1301 subpart 71, 72, and 76
Empty CDS containers being stored.	Controlled Substances	Are only full or working volume containers of CDS present?	Empty CDS containers being stored: Some labs keep their empty containers just in case they are needed for disposal. If the container is empty, or as empty as can be reasonably expected, through necessary practices, the registrant or authorized user must deface the original label (so the content is no longer identifiable), triple rinse the container if possible, then throw away the container. Pouring unwanted CDS down the drain or into general hazardous waste containers is not a necessary practice, so this is NOT an accepted means of disposal. This should only be used for containers that are actually empty.	
Non-CDS stored with CDS.	Controlled Substances	Are only CDS kept in securely locked, DEA-approved storage cabinets?	Non-CDS stored with CDS: CDS must be kept stored separately from non-CDS. There is an item in the regulations where Schedule III, IV, and, V substances may be stored with non-CDS, but only with prior written permission from a DEA Special Agent in Charge. Without that written permission, the expectation is that non-CDS are kept separately.	21 CFR 1301.72 (b)(8)(ii)
CDS storage facilities are inadequate	Controlled Substances	Is a securely locked, substantially constructed cabinet or safe anchored to a wall or floor available for storage of CDS?	CDS storage facilities are inadequate: CDS must be stored in a securely locked, substantially constructed cabinet or safe anchored to a wall or floor, as approved by the DEA.	21 CFR 1301 subparts 71, 72, and 76
Inadequate CDS recordkeeping (physical method).	Controlled Substances	Are inventories and logs kept in secure, bound notebooks that cannot be easily modified?	Inadequate CDS recordkeeping (physical method): EHS strongly recommends use of dedicated, bound notebooks, as loose-leaf, spiral-bound, perforated, or solely digital records can lead to lost records, retroactive recordkeeping, and replaced records. All written documentation must be written in indelible ink. When moving records to a bound notebook, there is no need to recreate records that were once on loose-leaf. Transfer over the last relevant data (if you are mid-bottle, move that information over, but you don't need to move over bottles that were used previously) and continue in the bound notebook for the future. Keep all old records in case of inspection for at least 2 years from the date of last entry.	21 CFR 1304.22
Inadequate CDS inventory or log (incorrect, incomplete, illegible).	Controlled Substances	Are CDS records easily read, understandable, and complete?	Inadequate CDS inventory or log (incorrect, incomplete, illegible): All CDS records should be complete and readily understandable. Ideally, the log should follow the CDS from purchase to use and/or disposal.	21 CFR 1304.11 and 21 CFR 1304.21
Schedule I and II records kept with Schedule III-V records	Controlled Substances	Are Schedule I and II records kept separate from Schedule III-V records?	Schedule I and II records kept with Schedule III-V records: Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant; and inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant.	21 CFR 1304.04 (f) and (h)
No biennial CDS inventory.	Controlled Substances	Is a current biennial CDS inventory available for review?	No biennial CDS inventory: A running log notes what is used when; it is used in day to day operations. An inventory is a biennial (every two year) list of every controlled substance, in every formulation, whether stock or working, expired, unexpired, or scheduled for disposal, under a registrant's control on a given date. Registrants are expected to keep both a running log AND a biennial inventory of controlled substances.	21 CFR 1304.11(c)
EHS CDS training records incomplete.	Controlled Substances	Are current training records available for the registrant and all authorized users?	EHS CDS training records incomplete: All registrants and their subordinate authorized users must be trained. This training includes security, recordkeeping, storage, use, disposal, and reporting thefts or losses.	UMB Policy VI-99.00(A) Policy on Research Use of Controlled Substances
Initial inventory incomplete.	Controlled Substances	Was an initial CDS inventory completed?	Initial inventory incomplete: Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with paragraph (e) of this section as applicable. In the event a person commences business with no controlled substances on hand, he/she shall record this fact as the initial inventory.	21 CFR 1304.11(b)

17	Records not retained.	Controlled Substances	Are records (purchase, use, inventory, disposal) kept on site for the last 2 years?	Records not retained: All inventory, use, transfer, disposal, or other CDS records must be kept by the registrant for at least 2 years from the date of such inventory or records for inspection.	21 CFR 1304.04(a)
18	Completed DEA 222 forms are unavailable for inspection.	Controlled Substances	Are completed DEA 222 forms available for all schedule I and II substances?	Completed DEA 222 forms are unavailable: DEA Forms 222, executed or unexecuted, must be maintained separately from all other records of the registrant. DEA Forms 222 are required to be kept available for inspection for a period of two years.	21 CFR 1305.17
19	Unused or unexecuted DEA 222 forms are not secured.	Controlled Substances	Are unused DEA 222 forms kept secured and accounted for?	Unused or unexecuted DEA 222 forms are not secured: DEA Forms 222, executed or unexecuted, must be maintained separately from all other records of the registrant. DEA Forms 222 are required to be kept available for inspection for a period of two years.	21 CFR 1305
20	Closing inventory was not completed.	Controlled Substances	Was a closing inventory completed (moving, transferring, retiring)?	Closing inventory was not completed: A final inventory confirming that no controlled substances remain in a location must be completed.	21 CFR 1304
21	CDS containers do not have unique identifiers.	Controlled Substances	Are multidose or multipack containers labeled with unique identifiers?	CDS containers do not have unique identifiers: Each container, especially multi-dose containers, should have a unique identifier, which is also used in the log. If a package contains 5 bottles of 1 ml each, they should be identified, for example, as 12-1, 12-2, 12-3, 12-4, and 12-5. Each 1ml container in this example must be tracked, rather than treating the whole package as 5ml.	21 CFR 1304
22	Thefts or losses not reported promptly.	Controlled Substances	If the lab has experienced any thefts or losses, have they been reported promptly?	Thefts or losses not reported promptly: Any thefts or losses must be reported promptly to the DEA, OCSA, UMB campus Police and UMB EHS. If you are unsure if the theft or loss has been reported or if you have any information of these activities, reach out to EHS at 410-706-7055.	21 CFR 1301.76
23	DEA form 106 for theft or loss not reported.	Controlled Substances	In the event of a theft or loss, was a DEA form 106 submitted?	DEA form 106 for theft or loss not reported: Any theft or significant loss of any controlled substance must be reported to UMB Campus Police, UMB EHS, MD OCSA, and the DEA within one business day of discovery. In addition, a DEA form 106 must be completed and submitted to the DEA.	21 CFR 1301.76
24	CDS key control needs improvement.	Controlled Substances	Are keys or codes to CDS storage adequately secured?	CDS key control needs improvement: Access to CDS must be strictly managed, which includes key and code control. This may include: separating keys to a double lock box so they are not stored in the same location, ensuring that keys are not conspicuously labeled for CDS, ensuring that keys are returned to the registrant when an authorized user is no longer with the lab, changing access codes or key locations when personnel changes.	
25	Expired or unwanted CDS must be submitted for disposal.	Controlled Substances	Are all CDS present current and unexpired?	Expired or unwanted CDS must be submitted for disposal: Expired CDS should be submitted to EHS to begin the reverse distribution process. Expired CDS should never be administered to live animals.	21 CFR 1304 Subpart A
26	Disposal records incomplete.	Controlled Substances	Has disposal of CDS been recorded appropriately?	Disposal records incomplete: Records of disposal must be maintained in order to account of CDS from purchase to use or disposal. These records should include name of the CDS, quantity, date, manner of distribution or disposal, and the name and registration number of the person to whom it was distributed.	21 CFR 1304.22