

Controlled Substance Laboratory Mobile Inspection Form

The Drug Control Division is utilizing all-inclusive mobile inspection forms that encompass multiple inspection types and business models. Inspection sections and/or inspection fields may intentionally remain blank when such sections and/or fields do not apply to the inspection type and/or business model for which the mobile inspection forms are being utilized. Please contact the Drug Control Agent who conducted your inspection if you feel an inspection section and/or inspection field was inadvertently left blank.

Controlled Substance Laboratory

Controlled Drug "Activity" Conducted by the Laboratory

Analytical	
Clinical	
Canine or Instructional	
Research	
Other	

Controlled Drugs Handled by the Laboratory

Schedule I	
Schedule II	
Schedule III	
Schedule IV	
Schedule V	
Medical marijuana	

Schedule I Stock

		Yes	No	Advised
1	Does the laboratory's Schedule I controlled drug stock include stock that may be unstable, of extremely small quantity, or of such a nature as to require special storage conditions?			
2	Did the laboratory contact the Drug Enforcement Administration to schedule an inspection with respect to the laboratory's Schedule I controlled drug stock?			

Schedule I Stock Storage

		Yes	No	Advised
1	Does the laboratory store Schedule I controlled drug stock in an approved manner? [Section 21a-262-7(a)]			
2	Does the laboratory require other security safeguards for Schedule I controlled drug stock in lieu of those required by Section 21a-262-1 through 21a-262-10 inclusive (i.e. watchman service, full electrical protection of the building, electric alarms, etc.)? [Section 21a-262-7(a)]			

Schedule I Stock Procurement			
	DEA 222 Forms		
	Controlled Substance Ordering System (CSOS)		
	A combination of DEA 222 Forms and CSOS		

Schedule II Stock		Yes	No	Advised
1	Does the laboratory's Schedule II controlled drug stock include stock that may be unstable, of extremely small quantity, or of such a nature as to require special storage conditions?			
2	Does the laboratory's Schedule II controlled drug stock include barbiturates used solely for a sedative or anesthetic effect on animals?			
3	Does the laboratory's Schedule II barbiturate stock used solely for a sedative or anesthetic effect on animals total less than or equal to 10 controlled drug units?			

Schedule II Stock Storage		Yes	No	Advised
1	Does the laboratory store Schedule II controlled drug stock in an approved manner? [Section 21a-262-7(a)]			
2	Does the laboratory require other security safeguards for Schedule II controlled drug stock in lieu of those required by Section 21a-262-1 through 21a-262-10 inclusive (i.e. watchman service, full electrical protection of the building, electric alarms, etc.)? [Section 21a-262-7(a)]			

Schedule II Stock Procurement			
	DEA 222 Forms		
	Controlled Substance Ordering System (CSOS)		
	A combination of DEA 222 Forms and CSOS		

Schedule III Stock Storage		Yes	No	Advised
1	Does the laboratory store Schedule III controlled drug stock in an approved manner? [Section 21a-262-7(b)]			

Schedule IV Stock Storage		Yes	No	Advised
1	Does the laboratory store Schedule IV controlled drug stock in an approved manner? [Section 21a-262-7(b)]			

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Schedule V Stock Storage		Yes	No	Advised
1	Does the laboratory store Schedule V controlled drug stock in an approved manner? [Section 21a-262-7(b)]			

Controlled Drug Safe		Yes	No	Advised
1	Does the laboratory have a safe for the storage of controlled drug stock?			
2	Does the laboratory's safe for the storage of controlled drug stock have a minimum of a "B" burglary rate? [Section 21a-262-1(f)(1)]			
3	Is the laboratory's safe for the storage of controlled drug stock equipped with a re-locking device? [Section 21a-262-1(f)(2)]			
4	Does the laboratory's safe for the storage of controlled drug stock weigh at least 750 pounds or is such safe rendered immobile by being securely anchored to a permanent structure of the building? [Section 21a-262-1(f)(3)]			
5	Does the laboratory's safe for the storage of controlled drug stock have adequate interior space to store all controlled drugs required to be kept within the safe? [Section 21a-262-1(f)(4)]			

Storage and Security		Yes	No	Advised
1	Has the laboratory provided safeguards which can be regarded in toto as an adequate substitute for some element of protection required of such laboratory? (e.g. supervised watchman service, full electrical protection of the building, electric alarms, etc.) [Section 21a-262-2(a)]			
2	Does the laboratory maintain all stocks of controlled drugs in all schedules in a secure area or location accessible only to specifically authorized personnel? [Section 21a-262-2(b)]			
3	Does the laboratory store all controlled drugs in such a manner as to prevent theft or diversion of these preparations? [Section 21a-262-2(b)]			
4	Does the laboratory maintain all equipment used for storage of controlled drugs such as approved vault(s), approved safe(s), caged areas, cabinets, enclosures, etc. securely locked except for the actual time required to remove or replace needed items? [Section 21a-262-2(c)]			
5	Does the laboratory keep locks in good working order with keys removed therefrom? [Section 21a-262-2(c)]			
6	Does the laboratory ensure that keys to locks are not left in a location accessible to other than specifically authorized personnel? [Section 21a-262-2(c)]			
7	Does the laboratory maintain any stock of controlled drugs in excess of the quantity actually required for normal, efficient operation? [Section 21a-262-2(g)]			

8	Are controlled drugs in the process of testing, use, or research by the laboratory immediately returned to the laboratory's required storage location upon completion of each process? [Section 21a-262-7(c)]			
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DEA 222 Order Forms		Yes	No	Advised
1&2	Did the laboratory's DEA registrant grant power of attorney to sign DEA 222 order forms? [CFR 1305.05(a)]			
3	Are the laboratory's power(s) of attorney available for inspection? [CFR 1305.05(a)]			
4	Did any individual sign DEA 222 order forms who was not granted power of attorney by the laboratory's DEA registrant to sign such forms? [CFR 1305.05(a)]			
5	Does the laboratory maintain unexecuted DEA 222 order forms in an organized manner?			
6	Does the laboratory keep unexecuted DEA 222 order forms securely in a limited access area?			
7	Does the laboratory have any "pre-signed" unexecuted DEA 222 order forms?			
8	Are the laboratory's executed DEA 222 order forms readily available for inspection? [Section 21a-261(a)]			
9	Does the laboratory maintain executed DEA 222 order forms separately apart from other drug records? [Section 21a-254(f)]			
10	Does the laboratory maintain executed DEA 222 order forms in an organized manner?			
11	Are the laboratory's DEA 222 order forms properly executed? [CFR 1305.12]			
12	Are the laboratory's DEA 222 order forms properly filled? [CFR 1305.13]			
13	Does the laboratory maintain executed DEA 222 order forms for a period of three years from the date of the transaction recorded? [Section 21a-254(f)]			

Electronic Orders (CSOS)		Yes	No	Advised
1&2	Did the DEA registrant grant power of attorney to sign CSOS orders? [CFR 1311.45]			
3	Does the DEA registrant maintain a record that lists each person granted power of attorney to sign CSOS orders? [CFR 1311.45(b)]			
4	Did any individual sign CSOS orders to whom the DEA registrant did not grant power of attorney to sign such orders? [CFR 1311.45]			

5	Does the laboratory properly secure CSOS private key(s)? [CFR 1311.30]			
6	Do the laboratory's CSOS certificate holders maintain a copy of the subscriber agreement that the Certification Authority provides for the life of the certificate? [CFR 1311.60(c)]			
7	Does the laboratory maintain CSOS records on a central server? [CFR 1305.27(c)]			
8	Are the laboratory's CSOS records readily retrievable at the registered location when maintained on a central server? [CFR 1305.27(c)]			
9	Are the laboratory's electronically-maintained CSOS records readily retrievable from all other records? [CFR 1311.60(a)]			
10	Are the laboratory's electronically-maintained CSOS records easily readable or easily rendered into a format that a person can read? [CFR 1311.60(b)]			
11	Does the laboratory retain for each CSOS order filled the original signed order and all linked records for that order for three years from the date of the transaction recorded? [Section 21a-254(f)]			
12	Does the laboratory retain all copies of each unaccepted or defective CSOS order and each linked statement for three years from the date of the transaction recorded? [Section 21a-254(f)]			
13	Does the laboratory retain an electronic copy of all voided CSOS orders for three years from the date of the transaction recorded? [Section 21a-254(f)]			
14	Does the laboratory complete and verify CSOS orders in CSOS upon receipt from the supplier?			

Receipt Records		Yes	No	Advised
1	Does the laboratory maintain receipt records of controlled drugs that bear the DATE on which controlled drugs were RECEIVED? [Section 21a-254(f)]			
2	Does the laboratory maintain receipt records of controlled drugs that bear the NAME OF PERSON FROM WHOM controlled drugs were RECEIVED? [Section 21a-254(f)]			
3	Does the laboratory maintain receipt records of controlled drugs that bear the ADDRESS of the person FROM WHOM controlled drugs were RECEIVED? [Section 21a-254(f)]			
4	Does the laboratory maintain receipt records of controlled drugs that bear the KIND of controlled drugs RECEIVED? [Section 21a-254(f)]			
5	Does the laboratory maintain receipt records of controlled drugs that bear the QUANTITY of controlled drugs RECEIVED? [Section 21a-254(f)]			

6	Does the laboratory keep receipt records of controlled drugs on the laboratory's premises? [Section 21a-254(h)]			
7	Does the laboratory maintain receipt records of controlled drugs current and separate from other business records in such form as to be readily available for inspection at reasonable times? [Section 21a-254(h) and Section 21a-261]			
8	Does the laboratory maintain receipt records of controlled drugs separately apart from other drug records? [Section 21a-254(f)]			
9	Are the laboratory's receipt records of controlled drugs void of the use of a foreign language, codes, or symbols to designate controlled drugs or persons in the keeping of such records? [Section 21a-254(h)]			
10	Does the laboratory keep records of all controlled drugs received by them separately apart from other drug records for a period of three years from the date of the transaction recorded? [Section 21a-254(e)]			

Disposition Records		Yes	No	Advised
1	Does the laboratory maintain disposition records of controlled drugs that bear the DATE on which controlled drugs were DISPOSED? [Section 21a-254(f)]			
2	Does the laboratory maintain disposition records of controlled drugs that bear the KIND of controlled drugs DISPOSED? [Section 21a-254(f)]			
3	Does the laboratory maintain disposition records of controlled drugs that bear the QUANTITY of controlled drugs DISPOSED? [Section 21a-254(f)]			
4	Does the laboratory maintain disposition records of controlled drugs that bear the NAME OF THE PERSON to whom or for whose use controlled drugs WERE USED? [Section 21a-254(f)]			
5	Does the laboratory keep disposition records of controlled drugs on the wholesaler's premises? [Section 21a-254(h)]			
6	Does the laboratory maintain disposition records of controlled drugs current and separate from other business records in such form as to be readily available for inspection at reasonable times? [Section 21a-254(h) and Section 21a-261]			
7	Does the laboratory maintain disposition records of controlled drugs separately apart from other drug records? [Section 21a-254(f)]			

8	Are the laboratory's disposition records of controlled drugs void of the use of a foreign language, codes, or symbols to designate controlled drugs or persons in the keeping of such records? [Section 21a-254(h)]			
9	Does the laboratory keep records of all controlled drugs disposed of by them separately apart from other drug records for a period of three years from the date of the transaction recorded? [Section 21a-254(e)]			

Inventory Records		Yes	No	Advised
1	Does the laboratory maintain inventory records of controlled drugs that bear the DATE on which the initial or annual inventory was CONDUCTED? [CFR 1304.11(a)]			
2	Does the laboratory maintain inventory records of controlled drugs that bear the TIME OF DAY the initial or annual inventory was COMPLETED (opening of business or close of business)? [CFR 1304.11(a)]			
For each controlled drug in finished form ...		Yes	No	Advised
3	Does the laboratory maintain inventory records of controlled drugs that bear the NAME of each controlled drug inventoried? [CFR 1304.11(e)(6)]			
4	Does the laboratory maintain inventory records of controlled drugs that bear the FINISHED FORM of each controlled drug (e.g. 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) inventoried? [CFR 1304.11(e)(6)]			
5	Does the laboratory maintain inventory records of controlled drugs that bear the NUMBER OF UNITS OR VOLUME of each finished form of each inventoried controlled drug in each commercial container (e.g. 100-tablet bottle or 3-milliliter vial)? [CFR 1304.11(e)(6)]			
6	Does the laboratory maintain inventory records of controlled drugs that bear the NUMBER OF commercial CONTAINERS of each finished form (e.g. four 100-tablet bottles or six 3-milliliter vials) of each inventoried controlled drug? [CFR 1304.11(e)(6)]			
7	Does or did the laboratory have any controlled drugs that are DAMAGED, DEFECTIVE, IMPURE, awaiting disposal, or held for quality control purposes on the inventory date?			
For controlled drugs that are damaged, defective, impure, awaiting disposal, held for quality control purposes, or maintained for extemporaneous compoundings ...		Yes	No	Advised
8	Does the laboratory maintain inventory records of controlled drugs that bear the NAME of the CONTROLLED DRUG inventoried? [CFR 1304.11(e)(6)]			
9	Does the laboratory maintain inventory records of controlled drugs that bear the TOTAL QUANTITY of the CONTROLLED DRUG inventoried to the nearest metric unit weight or the total number of units of finished form? [CFR 1304.11(e)(6)]			

10	Does the laboratory maintain inventory records of controlled drugs that bear the REASON why the registrant is MAINTAINING the inventoried controlled drugs? [CFR 1304.11(e)(6)]			
11	Does the laboratory maintain inventory records of controlled drugs that bear the COMPLETE LISTING of all controlled drugs ON HAND? [CFR 1304.11(a) and Section 21a-254(h)]			
12	Did the laboratory prepare an inventory of all controlled drugs on hand on the date the laboratory first engaged in the research of controlled drugs? [CFR 1304.11(b)]			
13	Does the laboratory prepare annually within four days of the first day of May of the calendar year a complete and accurate record of all controlled drugs on hand on the date the inventory is taken? [Section 21a-254(h)]			
14	Does the laboratory maintain the initial and annually prepared complete and accurate records of all controlled drugs on hand in written, typewritten, or printed form at the laboratory's registered location? [CFR 1304.11(a) and Section 21a-254(h)]			
15	Does the laboratory maintain the initial and annually prepared complete and accurate records of all controlled drugs on hand current and separate from other business records in such form as to be readily available for inspection at reasonable times? [Section 21a-254(h) and Section 21a-261]			
16	Are the laboratory's initial and annually prepared complete and accurate records of all controlled drugs on hand void of the use of a foreign language, codes, or symbols to designate controlled drugs or persons in the keeping of such records? [Section 21a-254(h)]			
17	Does the laboratory keep the initial and annually prepared complete and accurate records of all controlled drugs on hand on file for three years? [Section 21a-254(h)]			

Additional Comments		Yes	No	Advised
1	Does the inspecting agent have any additional comments with respect to this controlled substance laboratory inspection?			

Not

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