



Inspection Report for Laboratories with Controlled Substances

Laboratory Name \_\_\_\_\_ Inspecting Agent \_\_\_\_\_ Inspection Date

Person In Charge \_\_\_\_\_ E-mail \_\_\_\_\_

Secondary Contact \_\_\_\_\_ E-mail \_\_\_\_\_

Primary Location \_\_\_\_\_ Mailing Address \_\_\_\_\_

Phone # \_\_\_\_\_ Fax # \_\_\_\_\_ Registration # \_\_\_\_\_ Drug Enforcement Administration Registration # \_\_\_\_\_

Other Individuals Responsible for Controlled Substances

Type of Activity Using Controlled Substances	Controlled Substances Used	Names of Controlled Substances Used	Name of Wholesaler Providing Controlled Substances
Analytical	Schedule I		
Research	Schedule II		
Instruction	Schedule III		
Clinical	Schedule IV		
Other	Schedule V		

**Controlled Substance Units (Sec. 21a-262-1(e))**

- #100 tablets or capsule = 1 unit
- 1 pint of a liquid = 1 unit
- 1/8 ounce of a powder, crystal, flake, or granule= 1 unit
- 1 multiple use vial = 1 unit
- 10 suppositories = 1 unit
- 10 single dose ampules, tubexes, dosettes, hyporettes or other single dose package forms for injection whether powder or in solution = 1 unit

Partial containers of controlled substances shall be considered as being full when determining the total quantity of controlled substance stock. Larger package sizes shall be counted according to the number of controlled substance units they contain. Packages sizes less than a full controlled substance unit shall be counted as the fraction of controlled substance unit which the package size contains, i.e. #50 tablets = 0.5 units

**A.STORAGE (21a-262-7)**

1. Is the facility storing Schedule I and/or Schedule II controlled substances? (If yes, a safe is required unless the only substance stored is a barbiturate in questions 2) (21a-262-7)	Yes	No	Advised	Comments

2. Is any of the Schedule II stock a barbiturate type of medication solely used for its sedative or anesthetic effect on animals and in a quantity not more than No. 10 Controlled Substance Units? (If yes, the barbiturate may be treated like a Schedule III) (21a-262-7(a))	Yes	No	Advised	Comments
3. Are Schedule III, IV or V Controlled Substances stored separately in an approved safe or separate secure locked location accessible only to the minimum number of specifically authorized personnel essential for efficient operation? (21a-262-7(b))	Yes	No	Advised	Comments
4. Are controlled substances in the process of testing, use or research immediately returned to the required storage location upon completion of each process? (21a-262-7(c))	Yes	No	Advised	Comments

**B. SAFE REQUIREMENT (Sec. 21a-262-1)**

Is a safe required? (21a-262-4a) Yes No Advised

If no, please skip this section.

Manufacturer	Model #	Serial Number	Weight	
1. Does the safe have a minimum of a "B" Burglary rate? (21a-262-1(f)1)	Yes	No	N/A	
2. Is the safe equipped with a re-locking device? (21a-262-1(f)2)	Yes	No	N/A	
3. Does the safe weigh at least 750 pounds or is it rendered immobile by being securely anchored to a permanent structure of the building? (21a-262-1(f)3)	Yes	No	N/A	Comments
4. Does the safe have adequate interior space to store all controlled substances required to be kept within the safe? (21a-262-1(f)4)	Yes	No	N/A	Comments

**C. SECURITY (Sec. 21a-262-2)**

1. Does the registrant have other safeguards (i.e. watchman service, full electrical protection of the building, electric alarms, etc.)? (21a-262-2(a))	Yes	No	Advised	Comments
2. Are all stocks of controlled substances in all schedules in a secure area or location accessible only to specifically authorized personnel? (21a-262-2(b))	Yes	No	Advised	Comments

3. Are all equipment used for the storage of controlled substances securely locked except for the actual time required to remove or replace needed items? (21a-262-2(c))	Yes	No	Advised	Comments
4. Are locks in good working order with keys removed from them? (21a-262-2(c))	Yes	No	Advised	Comments
5. Are keys accessible to personnel that are not authorized to obtain controlled substances? (21a-262-2(c))	Yes	No	Advised	Comments

**D. RECORD KEEPING (21a-254)**

**Receipt**

**Schedule I and II**

1. Are the records readily available? (21a-254(f))	Yes	No	Advised	Comments
2. Are the forms kept separate from all other records? (21a-254(f))	Yes	No	Advised	Comments
3. Are the order forms kept securely? (CFR 1304.04)	Yes	No	Advised	Comments
4. Have the forms been properly executed? (CFR 1305.12)	Yes	No	Advised	Comments

**Schedule III-V**

1. Do the receipt records contain the following? (Must have all) (21a-254(f))	Date of Receipt			Comments
	Name and address of person from whom received			
	Kind and quantity of controlled substances received			
2. Are the receipt records kept separate from all other records? (21a-249(k))	Yes	No	Advised	Comments

**E. DISPOSITION RECORD**

1. Are the disposition records readily available?	Yes	No	Advised	Comments
2. Are the disposition records for Schedule I + II and Schedule III-V separately maintained?	Yes	No	Advised	Comments

3. Do the disposition record contain the following: (21a-254(b))

Date used  
Manner of Use  
Item, Strength, Form Used, Quantity used  
Identification/Experiment Number  
Name of Researcher, Analyst, etc.

Comments

**F. BIENNIAL INVENTORY (21a-254(h))**

1. Was a biennial inventory conducted?

Yes      No      Advised

Comments

2. Is the biennial inventory readily available?

Yes      No      Advised

Comments

3. Was the biennial inventory properly executed?

Date Conducted  
Time of Day Completed  
Schedule I + II Separate from Schedule III-V  
Signature  
Complete Listing

Comments

Other Safeguards/Comments

Drug Control Agent Signature

Date

Representative Signature

Date

Not For Official Use