



# Record-Keeping Requirements: Inventories

AKA Paperwork!





# In this presentation

The main objective of this presentation is to discuss the importance of inventories when managing your controlled substances. You do not need to conduct inventories for dangerous drugs.

We will also review when to conduct the inventories and how to document it adequately per GA law and DEA regulations.



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# Inventories

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Researchers with a DEA license are required to conduct

- Initial inventory
- Biennial inventory

An “inventory” is a complete and accurate list of all controlled substances in the possession of the registrant at the time of the inventory, as determined by an **actual physical count** for schedule I-V controlled substances.



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## Inventories

- One of the most common discrepancies in DEA inspections or QA/QI Reviews involves inventories.
- This includes incomplete inventories or maintaining no inventories at all.
- The following information will help you follow federal requirements and keep your DEA registration in good standing.



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## Inventories per Schedule

A separate inventory is required for each registered site.

A separate inventory is required for Schedule I-II and Schedule III-V controlled substances.

[Form 6](#) should be used to conduct an inventory.

- Use Form 6A for initial inventory
- Use Form 6B for Annual/Biennial Inventory.

**Note** the date and Beginning of Business (BOB) or Close of Business (COB) on the form. This is required by law to be on the form.



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## Where to keep my inventories?

Inventory records of schedule I and II controlled substances must be kept separate from all other records of the researcher.

Inventory records of schedules III, IV, and V controlled substances must be maintained either separately from all other records of the researcher or in such form that the information required is readily retrievable from ordinary business records of the researcher.

Inventory records must be maintained at the registered location for at least three years for copying and inspection, per Emory policy.



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## Initial Inventory

- Registrants are responsible for performing and documenting an initial inventory of all Controlled Substances on hand upon receipt of a new DEA license.
- Initial inventory should be “zero”.
- The date and beginning of business (BOB)/close of business (COB) are required by law to be included on the inventory.

# BOB or COB?

## BOB (Beginning of Business)

Before controlled substance use has begun for the day



## COB (Close of Business)

After all controlled substance use has been completed for the day





# Annual/Biennial Inventory

- The Registrant must perform a physical inventory of all Controlled Substances on hand every 24 months following the date of the initial inventory. Remember this is an actual count/weighing/measuring of all drugs on hand.
- The inventory should also include controlled substances that have expired and are awaiting destruction.
- **ORIC recommends conducting an annual inventory.** Many researchers complete an annual inventory when they renew their DEA license.



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## Completion of Form 6A and 6B

- The following slides will walk you through completion of Inventory Forms
- Although the use of ORIC forms isn't required, it's strongly recommended **as all the information on the form is federally required**. If an ORIC form doesn't work for your lab, let us know & we'll see if we can modify.

# All new ORIC Forms come with working instructions

## Working Instructions Form 6A: Controlled Substances Inventory: Initial Inventory

### Definitions:

- a) **Controlled Substance** - The Controlled Substances Act (CSA) places all substances which were in some manner regulated under existing federal law into one of five schedules. This placement is based on the substance's medical use, potential for abuse, and safety or dependence liability. More information can be found in [Title 21 United States Code \(USC\) Controlled Substances Act Alphabetical List of Controlled Substances](#)
- b) **Initial Inventory** – The Initial Inventory is to be completed at the Beginning of Business (BOB) or Close of Business (COB) upon receiving the DEA Registration and prior to ordering controlled substances.
- c) **Registrant** – A person licensed and registered with DEA to distribute, manufacture, administer, dispense, import, or export a Controlled Substance.
- d) **Stock Bottle** – The container/bottle that was received from the supplier. The stock bottle has the original labels from the manufacturer.
- e) **Working Bottle**- A chemical solution made for actual use in the lab, usually made from diluting or combining stock or standard solutions.

### Box 1 Instructions: Registration Information

1. Complete the Registrant's Name, DEA #, and address in this section. The information must appear exactly (in its entirety), as it does on the Registrant's DEA License.
2. Record the date the inventory occurred and the name of the person(s) conducting the inventory (two people are recommended).
3. BOB/COB – Circle if the inventory was completed at the Beginning of Business (BOB) or Close of Business (COB). The inventory must be done prior to the start of any daily activities or after the daily activities have been completed. There may be no movement of drugs during the inventory count.

### Box 2: Complete Physical Inventory for ALL Controlled Substance on hand at the time of inventory

1. This section is pre-filled out as there should not be any controlled substances on hand prior to the Registrant receiving the DEA Registration.

# Form 6A: Controlled Substances Inventory

## Initial Inventory: Schedule III - V

*Instructions: An initial inventory is always zero. You must create and maintain a separate inventory sheet for Schedule I & II Controlled Substances and Schedule III - V Controlled Substances. Dangerous Drugs are not to be inventoried on this sheet.*

Box 1: Registrant Information				
Registrant's Name: <i>Joe Smith</i>	DEA #: <i>RS1234567</i>	Registered Address: <i>123 Main Street, Room #567, Atlanta, GA, 30325</i>		
Date of Inventory: <i>12/20/23</i>	<input checked="" type="radio"/> BOB <input type="radio"/> COB* (circle one)	Name Persons conducting Inventory	Employee #1: <i>Joe Smith</i>	Employee #2: <i>JoAnn Taylor</i>

Box 2: Complete Physical Inventory for ALL Schedule III - V Controlled Substance on hand at the time of inventory							
Line No.	Name of Substance	Concentration/Strength	Initial Volume/Quantity of Container	Number of Containers	Total Quantity/Volume on Hand per Concentration/Strength	Stock/Working	Active or Expired
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							

No Controlled Substances On Hand

If you are approved for Schedule I-V, you must complete a separate form for Schedule I-II and Schedule III-V

**Form 6B: Controlled Substances Inventory**  
**Annual Inventory ~~X~~ Biennial Inventory \_\_\_\_\_ : Schedule III - V**

*Note: A Biennial inventory must be conducted once within every two years of the date of the Initial Inventory. An annual inventory is recommended. A separate inventory sheet for Schedule I & II and Schedule III - V Controlled Substances must be maintained. Stock and Working Bottles, and Expired Containers must all be counted.*

Box 1: Registrant Information				
Registrant's Name: <i>Joe Smith</i>	DEA #: <i>RS1234567</i>	Registered Address: <i>123 Main Street, Room #567, Atlanta, GA 30325</i>		
Date of Inventory: <i>12/19/23</i>	<b>BOB</b> /COB* (circle one)	Name Persons conducting Inventory	Employee #1: <i>Joe Smith</i>	Employee #2: <i>JoAnn Taylor</i>

Box 2: Complete Physical Inventory for ALL Schedule III - V Controlled Substance on hand at the time of inventory							
Line No.	Name of Substance	Concentration/Strength	Initial Volume/Quantity of Container	Number of Containers	Total Quantity/Volume on Hand per Concentration/Strength	Stock/Working	Active or Expired
1	<i>Ketamine</i>	<i>100mg/ml</i>	<i>10ml</i>	<i>3</i>	<i>30ml</i>	<i>stock</i>	<i>active</i>
2	<i>Ketamine</i>	<i>100mg/ml</i>	<i>10ml</i>	<i>1</i>	<i>9ml</i>	<i>stock (open)</i>	<i>active</i>
3	<i>Ketamine</i>	<i>100mg/ml</i>	<i>10ml</i>	<i>1</i>	<i>3ml</i>	<i>stock</i>	<i>expired</i>
4	<i>Ketamine/Xylazine/Saline</i>	<i>20/30/1ml</i>	<i>10ml</i>	<i>1</i>	<i>5ml</i>	<i>working</i>	<i>active</i>
5	<i>Ketamine/Xylazine/Saline</i>	<i>20/30/1ml</i>	<i>10ml</i>	<i>2</i>	<i>12ml</i>	<i>working</i>	<i>expired</i>
6							
7							
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10							
11							
12							
13							
14							
15							



# Knowledge Check

