

# REGISTRANT INSPECTIONS





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**Diversion Investigators**

**Drug Enforcement Administration (DEA)**

**Charleston, W.V. District Office (CDO)**

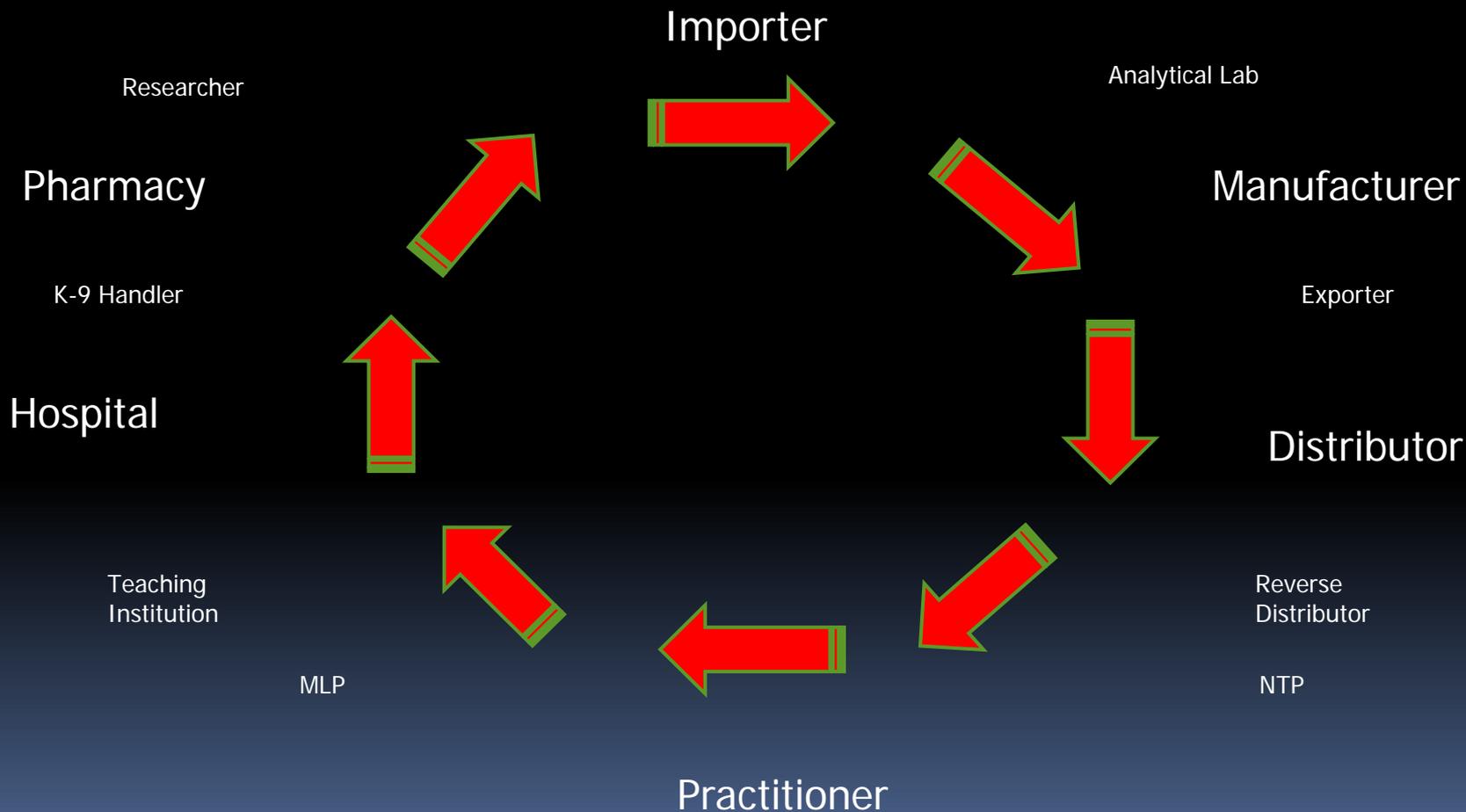
**304-347-5209**



**Disclosure: Bobby Otero**

**I have no relevant  
personal/professional/financial  
relationship(s) to disclose**

# DEA's Closed System of Distribution



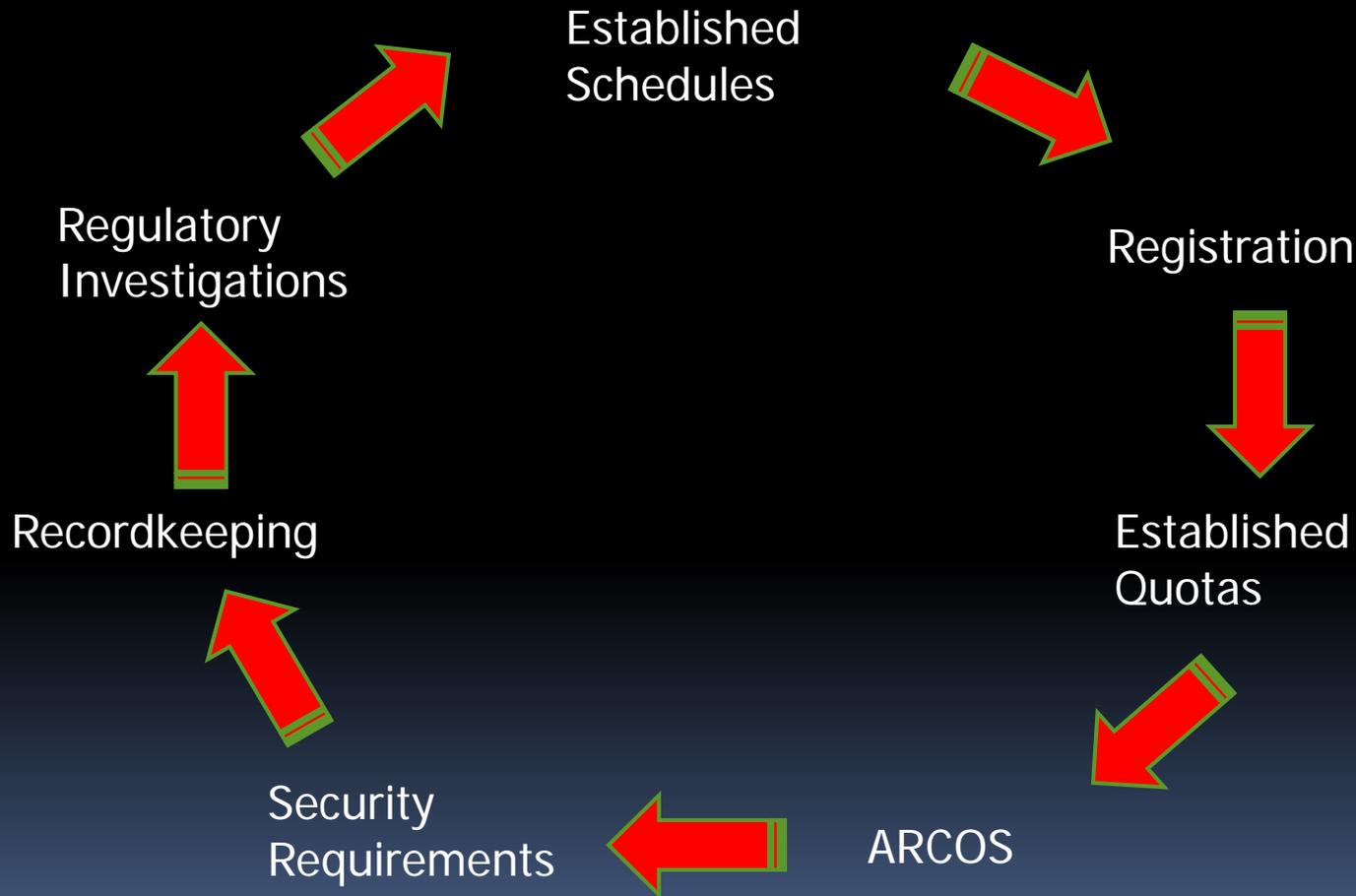
# Closed System of Distribution

The DEA is responsible for:

- the oversight of the system
- the integrity of the system
- the protection of the public health and safety



# Closed System of Distribution



# Registrant Inspections



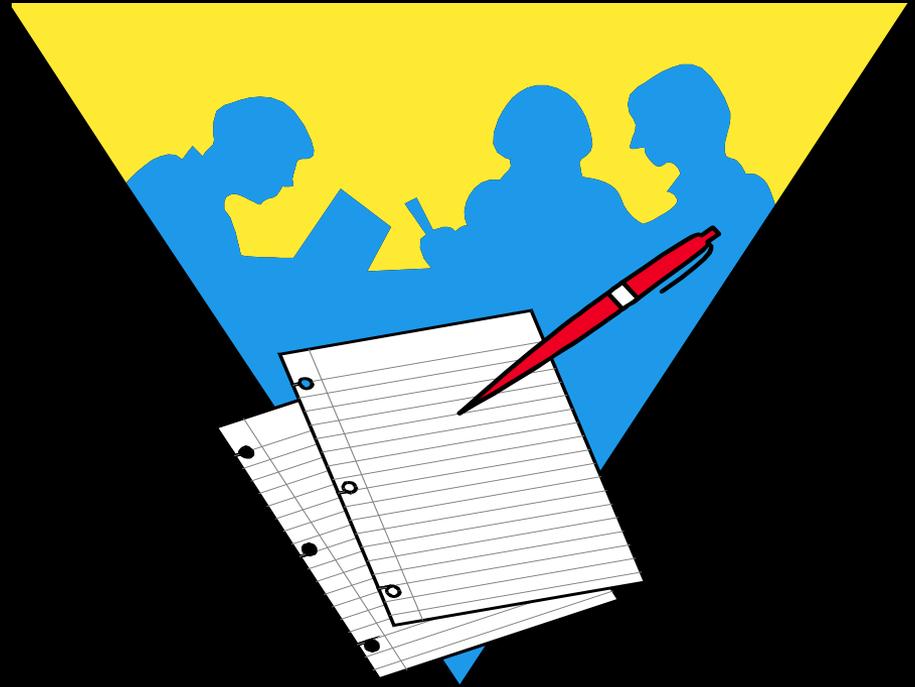
# Registrant Inspections



## Regulatory Inspection defined:

A periodic review of records, security, and business practice to determine if continued registration is in the best interests of the general public.

# Registrant Inspections



## Reasons for visiting and inspecting:

- Ensure compliance and responsible sales
- Identify potential areas of diversion
- Grievance complaint
- Local, state or federal referral

# Registrant Inspections

## Upon Arrival:

- Arrive unannounced
- Appointments afford opportunities to conceal crimes or complicate access
- Identify the decision maker



# Registrant Inspections



## Upon Arrival:

- Display credentials: seek cooperation
- Obtain informed consent (NOI)
- Obtain Administrative Inspection Warrant

# Registrant Inspections

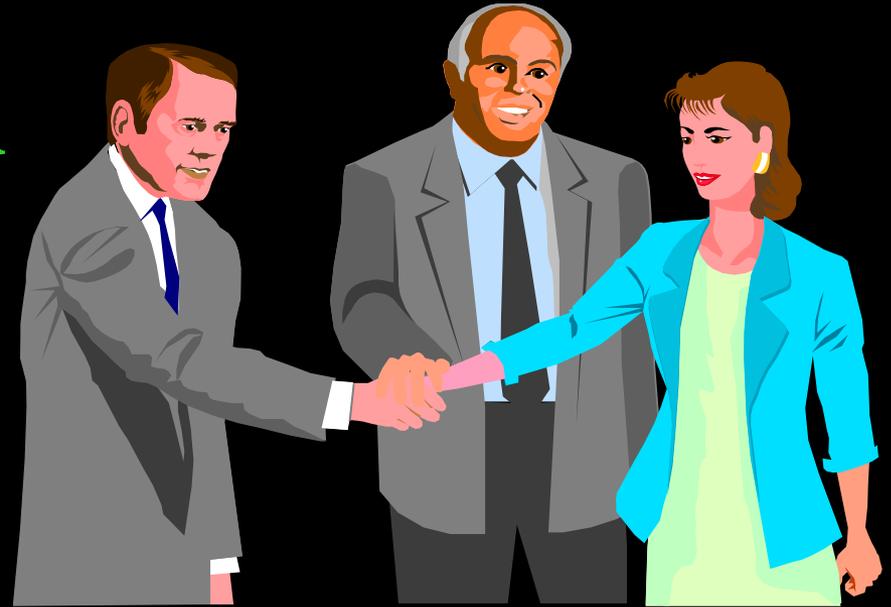
## Investigators confirm:

- **State authority/licensure**
- **List of owners/corporate officers**
- **List of responsible individuals (DOB/SSN)**
- **Physical security for drugs**
- **Recordkeeping compliance**
- **Understanding of federal regulations**

# Registrant Inspections

## Conduct background checks:

- Identify the responsible individuals
- Identify the individuals with access to cage, vault, and cont sub



# Registrant Inspections

## Records review:

- Review records and record keeping system (purchases, sales, disposals, etc)
- Identify primary customers and their activity/volume for selected products

# Registrant Inspections

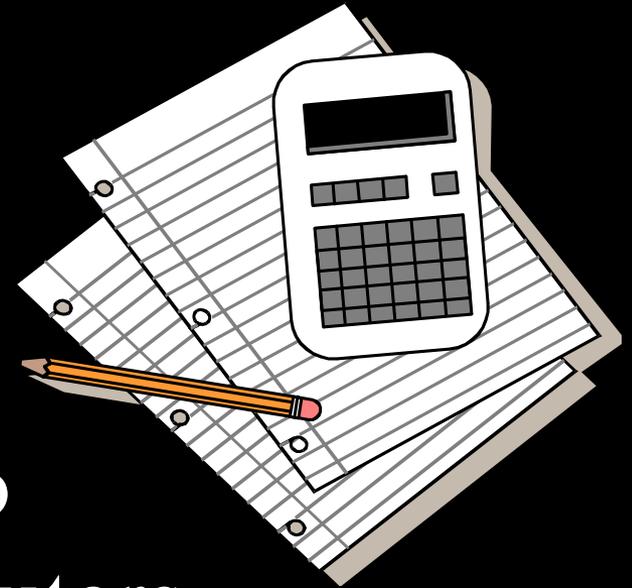
## Records review:

- Review overall purchase to sales consistency
- Identify suspicious transactions or trends (cash sales, excessive purchases, etc)

# Registrant Inspections

## For Audits:

- Immediately secure access to inventory, records, and computers
- Count inventory with management
- Get agreement on inventory count



# Registrant Inspections

Overall  
safety  
review:



# Registrant Inspections

Overall  
business  
procedure  
review:

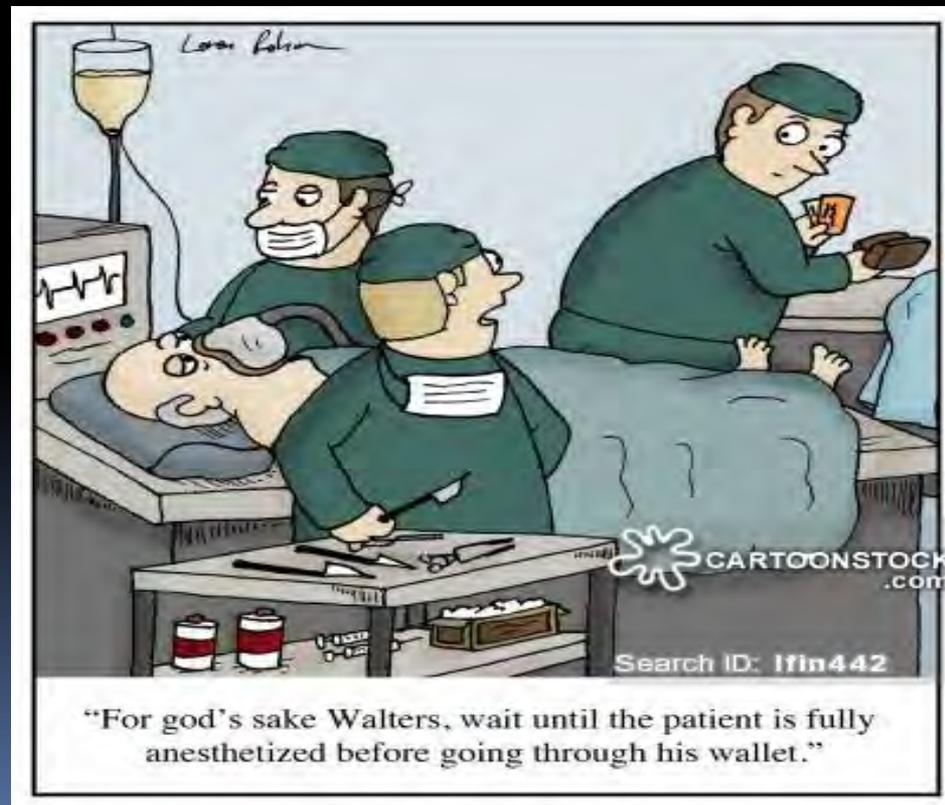


# Registrant Inspections

Overall  
security  
review:



# Responsibility of Registrants



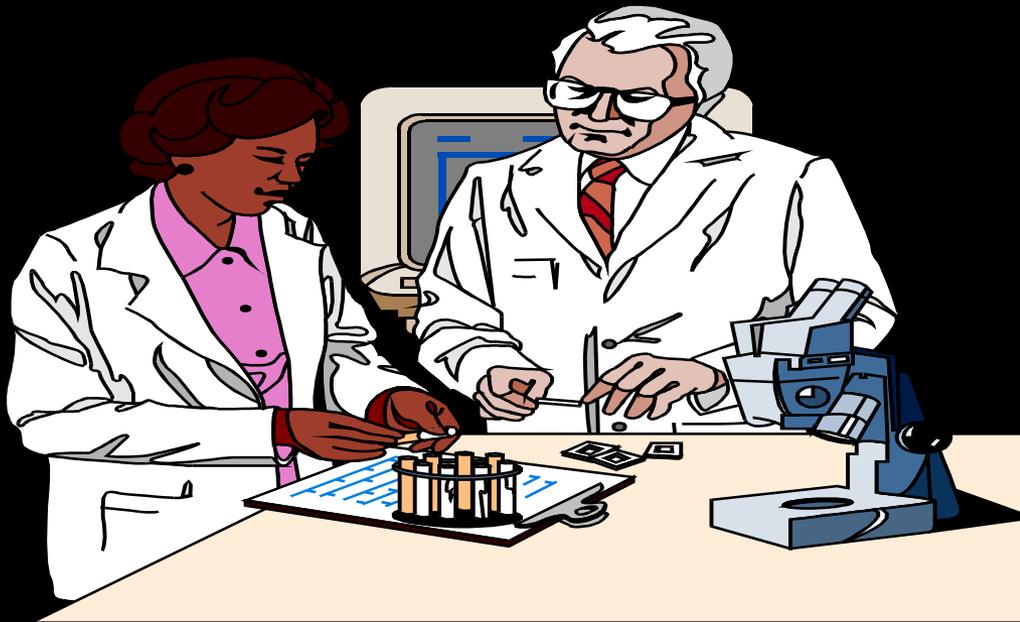
# Registrant Responsibility



**Upon Receiving Controlled Substances:  
Must take a complete physical inventory  
("Initial Inventory")**

**Title 21, CFR 1304.11(b)**

# Registrant Responsibility



**Must take a complete physical inventory  
every 2 years from date of Initial Inventory  
("Biennial Inventory")**

**Title 21, CFR 1304.11(c)**

# Registrant Responsibility

## Inventories:

- Think “Checkbook”!



# Registrant Responsibility

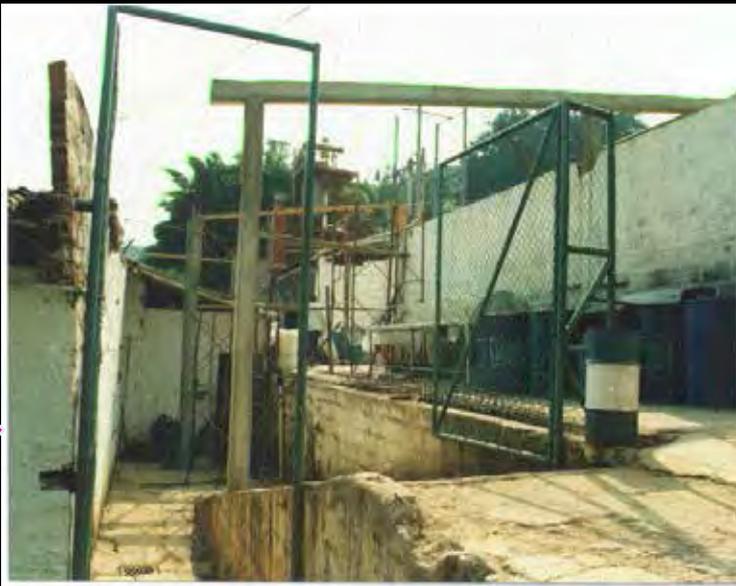
2 + 2 Must Equal 4!



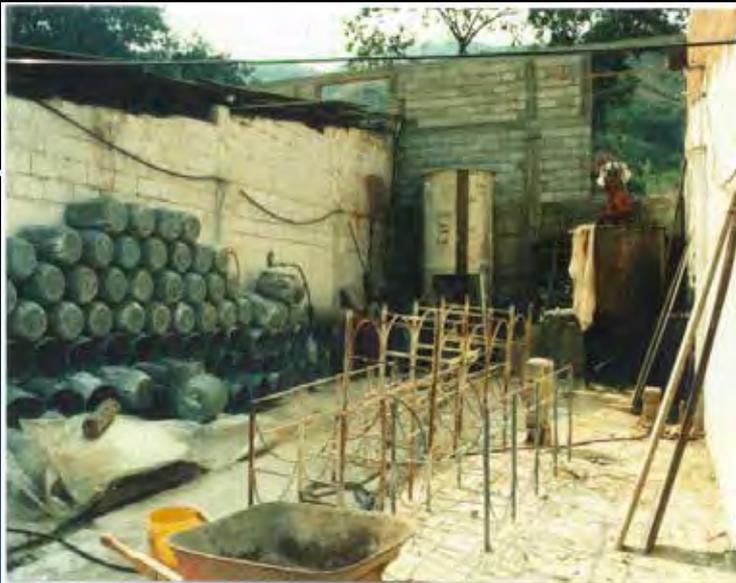


# Quimicos Mil Saldarriaga Medellin, Colombia





**Note lack of infrastructure**



# Registrant Responsibility

## Maintain Complete and Accurate Records (Minimum 2 years)

- **DEA-222 Order Forms**
- **Purchasing Invoices**
- **Inventories**
- **Any DEA-related correspondence**



**Title 21, CFR 1304.04(a)**

# Registrant Responsibility

## Recordkeeping:

- **Maintain records separate from all other records**
- **“Readily retrievable”**



**Title 21, CFR 1304.04 (f) and (g)**

# Registrant Responsibility

## Recordkeeping:

- **Must maintain complete and accurate records of receipt and distribution of controlled substances.**

**Title 21, CFR 1304.21(a)**

# Registrant Responsibility

## Recordkeeping:

- **Must complete DEA-222 order forms with the date and quantity received.**

**Title 21, CFR 1305.13(e)**



# Registrant Responsibility

## Recordkeeping:

- **Must provide effective controls against theft and diversion of controlled substances.**

**Title 21, CFR 1301.71**



# Registrant Responsibility



**Must provide adequate security for controlled substances:**

- **Perpetual inventory** (not required)
- **Report thefts or loss**
- **Destruction/disposal**



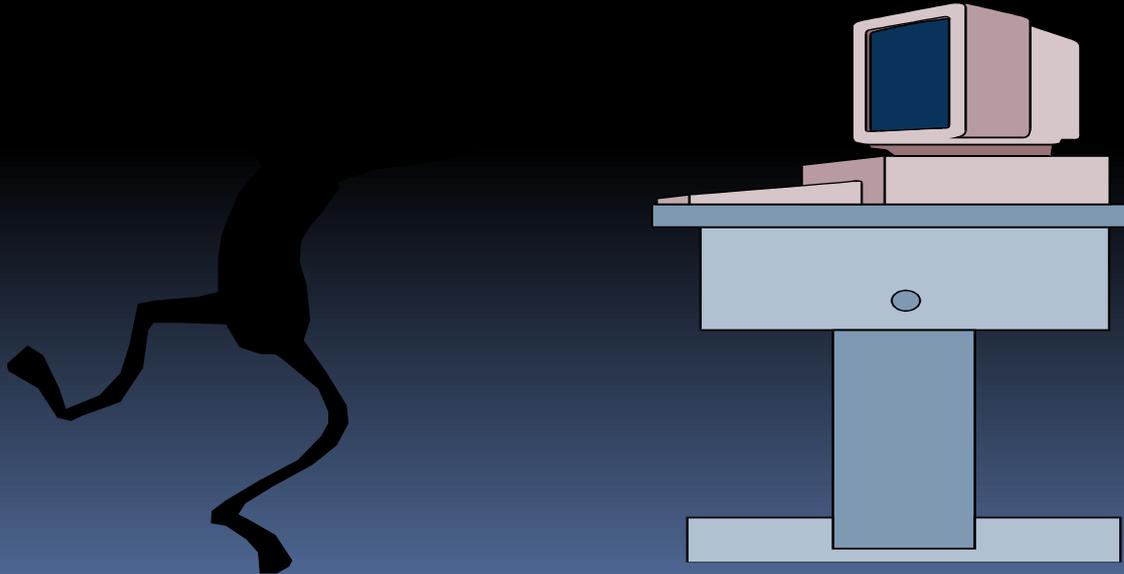
# Registrant Responsibility

**Must provide adequate security for controlled substances:**

- **Vault and/or Cage**
- **Store in a “...securely locked, substantially constructed cabinet”**
- **Disperse among the stock**
- **Limit access**



# Result of Inspection



# Result of Inspection

## Possible Measures:

- **Verbal Warning**
- **Letter of Admonition (LOA)**
- **Memorandum of Agreement (MOA)**
- **Immediate Suspension Order (ISO)**
- **Order To Show Cause (OTSC)**



# Result of Inspection

**Title 21, USC 842(a)(5):**

- **Civil: Provides a remedy of maximum \$10,000 USD per violation.**



# Result of Inspection

## Arrest and/or Criminal Fines

Title 21, United States Code (USC) 841

Title 21, USC 842

Title 21, USC 843



Provides a remedy for criminal violations

# Registrant Inspections



*"All the other women in the office are suing you for sexual harassment. Since you haven't sexually harassed me, I'm suing you for discrimination."*

**COMPLIANCE,  
NOT  
NECESSARILY  
PERFECTION!**

# Things to Consider



# KNOW YOUR CUSTOMER!



# TRUST YOUR GUT INSTINCT – FIRST INSTINCT IS USUALLY THE BEST

**lunchbreak** by cta

The thieves broke into the pharmacy  
and stole all of the viagra!



Sounds like we should be on the  
look-out for hardened criminals...



# Do Not Ignore the Red Flags!







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