



# Annual DEA Audit Readiness Guide

*For Pharmacies, Hospitals, and Pharmaceutical Manufacturers*

This guide provides a step-by-step framework to help facilities prepare for a DEA inspection. It includes documentation requirements, retention timelines, storage best practices, and sample audit questions. Updated for 2025 compliance with 21 CFR and DEA policy.



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# DEA Audit Preparation Framework

## Step-by-Step DEA Audit Preparation Framework

### Step 1: Assign a DEA Compliance Officer

- Designate a responsible individual to oversee controlled substance management.
- Ensure they understand DEA regulations and your internal SOPs.

### Step 2: Maintain Accurate and Complete Records

- Inventory logs
- DEA Form 222 (Schedule I–II transfers)
- DEA Form 41 (Destruction of controlled substances)
- Invoices and shipping records
- Chain of custody documentation
- Employee access logs

### Step 3: Conduct a Self or a Mock Audit

- Schedule internal audits every 6–12 months.
- Verify that all records match physical inventory.
- Check that destruction records are properly signed and filed.
- Need help? [Contact us for a Mock Audit!](#)

### Step 4: Secure Storage Review

- Ensure all Schedule II substances are in DEA-compliant safes or vaults.
- Schedule III–V substances should be locked in secure cabinets.
- Access should be restricted and logged.

### Step 5: Confirm Reverse Distributor Compliance

- Verify that your reverse distributor is DEA-registered.
- Ensure CODs (Certificates of Destruction) are collected and retained.
- Maintain a log of all pickups and returns.

### Step 6: Update SOPs and Training

- Review disposal and storage SOPs annually.
- Train staff on DEA procedures, documentation, and inspections.
- Keep training logs signed and dated.

## Documentation Retention Guidelines

Document Type	Retention Period	Format & Storage Requirements
DEA Form 222 (Schedule II Transfers)	2 years	Paper or electronic, accessible to DEA
DEA Form 41 (Destruction)	2 years	Paper or electronic, with signatures
Biennial Inventory Records	2 years	Must be easily retrievable for audit
Employee Training Logs	2 years minimum	Digital or print with staff signatures
Certificates of Destruction (CODs)	2 years	Attach to destruction logs or archive system
SOPs and Policy Documents	Current + 2 years	Update annually and store centrally

## Mock DEA Audit Questions

- 1

Can you provide your most recent DEA registration certificate?
- 2

Show your last biennial inventory report.
- 3

Where are DEA Form 222 and Form 41 records stored?
- 4

What is your process for handling expired Schedule II drugs?
- 5

How do you verify your reverse distributor is DEA compliant?
- 6

Who has access to controlled substance storage areas?
- 7

How do you handle employee training for DEA compliance?
- 8

Provide a copy of your current SOP for controlled substance disposal.
- 9

How often do you conduct internal audits?
- 10

Are you aware of your responsibilities under 21 CFR 1304?

## Inspection Walk-Through Checklist

### Documentation

- DEA certificate displayed or filed
- All DEA forms filed and accessible
- CODs and reverse distributor contracts available
- Training records organized and current

### Physical Security

- Controlled substance storage meets physical security standards
- Access logs available and up to date
- Disposal area clean and compliant

### Inventory Management

- Inventory matches log entries

**Tip:** Keep a physical or digital audit readiness binder with all the documents listed above. Update quarterly and review monthly with your compliance officer.

**Need Help?** Easy Rx Cycle offers DEA audit support, SOP templates, and reverse distribution services.

Contact us at <https://easyrxcycle.com> or 501-904-2929.