DRUG ENFORCEMENT ADMINISTRATION

ST. LOUIS DIVERSION GROUP

DIVERSION MISSION...

- To prevent, detect, & investigate the diversion of controlled substances from legitimate channels
- To ensure there is an adequate & uninterrupted supply of controlled substances that can be used for legitimate medical, commercial, and scientific needs
HOW IS THIS MISSION ACCOMPLISHED?

- Registration of those who handle controlled substances
- Regulatory requirements relating to drug security and record-keeping
- Issuance of permits to monitor the movement of licit controlled substances across US borders

PRIMARY RESPONSIBILITIES

- Conduct controlled substance audits on manufacturers, distributors, practitioners, researchers, exporters & importers
- Inspect security for those who handle or wish to handle controlled substances
- Investigate registrants who answer yes to liability questions on applications for registration

PRIMARY RESPONSIBILITIES (CONT.)

- Investigate leads regarding diversion by pharmacists, doctors, nurses, employees of registrants, and the illicit user
- Monitor compliance with the CSA and Chemical laws
- Register those who wish to handle listed chemicals
ORDER FORMS

- All purchases/transfers of Schedule I and II controlled substances must be completed using a DEA Form 222.
- All purchases/transfers of Schedule III and V controlled substances must be completed using an Invoice.
  - Invoices must contain all information that is on the DEA Form 222.
- Researchers may transfer controlled substances between one another.
  - Verify valid DEA Registration
  - 5% Rule

ORDER FORMS
DEA FORM - 222

RECORDS
TITLE 21, CFR. 1304.11

- Inventory Requirements
  - Registrants are required to take an initial inventory of all controlled substances on hand on the date they become registered, which should be zero
  - Thereafter, the registrant, at a minimum, is required to take an inventory of all controlled substance on hand every two years (biennial)
  - State controlled substance licenses require an annual inventory
# RECORDS

**TITLE 21, CFR, 1304.11 (CONT.)**

- Required Content of Inventories
  - Registered Name
  - DEA Registration Number
  - Date
  - When Taken (COB or BOB)
  - Name of Substance
  - Quantity of Substance
  - Form of Substance
  - Container Size

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**TITLE 21, CFR, 1304.22 (C)**

- Dispensing Records for Researchers
  - Dispensing Log
    - Name of Substance
    - Form of Substance
  - Number of Units/Volume Dispensed
  - Name and Address of Person Dispensed (Animal)
  - Date Dispensed
  - Name or Initials of Person Dispensing

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**TITLE 21, CFR, 1304.04**

- Maintenance of Records and Inventories
  - All records must be maintained for 2 years per the DEA
    - The State of Illinois requires 5 year retention
**DISPOSAL**  
**TITLE 21, CFR. 1317.05(B)**

- Disposal of Controlled Substances
  - On-Site Destruction
    - Complete DEA Form 41 and
    - Submit to local DEA Office for approval
  - Reverse Distributor
    - Receive completed DEA Form 222 from Reverse Distributor
      - You will be acting as the supplier

**SECURITY**  
**TITLE 21, CFR. 1301.72**

- Physical security controls for researchers
  - Where small quantities permit, a safe or steel cabinet is required
    - If less than 750 pounds, it must be bolted to the floor or wall as to not be readily removable

**SECURITY**  
**TITLE 21, CFR. 1301.74**

- Other Security Controls for Non-Practitioners
  - Theft or Loss of Controlled Substances
    - Must notify DEA Office in writing of any theft or significant loss within one business day
    - A DEA Form 106 must accompany the notification
  - Limit amount of individuals with access to controlled substances
SECURITY
TITLE 21, CFR, 1301

- Other Security Controls for Non-Practitioners
  - Employing Screening
    - Shall not employ any person who has been convicted of a felony offense related to controlled substances
  - Reporting Drug Diversion
    - Employee Responsibility to Report Drug Diversion
  - Registrants shall provide effective controls and procedures to guard against theft

QUESTIONS?
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