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PHARMACEUTICAL WASTE TRAINING

40 CFR § 266.503

ACRONYMS

FIRST, WE ARE GOING TO LEARN SOME REGULATIONS

(definitions on slides to follow)

OSHA-Occupational Safety
and Health Administration

EPA-Environmental
Protection Agency

NFPA-National Fire
Protection Association

OSHA

- With the Occupational Safety and Health Act of 1970, Congress created the Occupational Safety and Health Administration (OSHA) to ensure safe and healthful working conditions for workers by setting and enforcing standards and by providing training, outreach, education and assistance.

EPA

U.S. Government. Environmental Protection Agency: an independent federal agency, created in 1970, that sets and enforces rules and standards that protect the environment and control pollution.



It is a trade association that is based in the United States but has international members as well. This association creates standards and codes that are used by businesses, local governments, and other organizations to help improve fire safety. NFPA was first formed in 1896 by insurance firms who were looking to standardize fire sprinkler systems, which were an emerging technology at the time. Today, the NFPA has over 50,000 members, 9000 volunteers, and 250 technical committees.

NFPA



Code of Federal Regulations Regulatory Overview

If anyone has ever tried to read the *Code of Federal Regulations*, you'll know it's no easy chore. Listed below is where to look for information regarding a specific agency.

- **What is a CFR?**

Code of Federal Regulations

- **What is Title 49 CFR?**

DOT Code of Federal Regulations (Safety in transit)

- **What is Title 29 CFR?**

OSHA Code of Federal Regulations (Safety of workers and people)

- **What is Title 40 CFR?**

EPA Code of Federal Regulations (air, land, water)



REGULATIONS RESOURCE CONSERVATION RECOVERY ACT (RCRA)

- Goal to promote protection of human health and the environment
- Conserve valuable material and energy resources
- Federal Regulations
- RCRA requires the EPA to promulgate and enforce regulations regarding the management of hazardous waste
- Mandatory procedures for compliance with RCRA, must be followed by facilities where hazardous waste is accumulated, transported, treated or disposed

- Cradle to Grave

One of the oft-forgotten imperatives of the Resource Conservation and Recovery Act ([RCRA](#)) is that you're responsible for any hazardous waste you "generate" from "cradle-to-grave." This includes its generation, transportation, treatment, storage, and disposal.

- Compiled into Title 40 CFR

Why are we doing this Training?

- ❑ Water has been tested thru out the united States and found large amounts of Pharmaceutical Waste in our Drinking water
- ❑ Because of this Hospitals are the prime target.
- ❑ Environmental Protection Agency provides Best Management Practices for all hospitals and this includes a Pharmaceutical Waste Program at every facility.

Consequences for Non-Compliance

Non-compliance can result in fines for the network.

The average fine can run anywhere from \$700 to \$250,000.

Example Violation & Associated Penalties

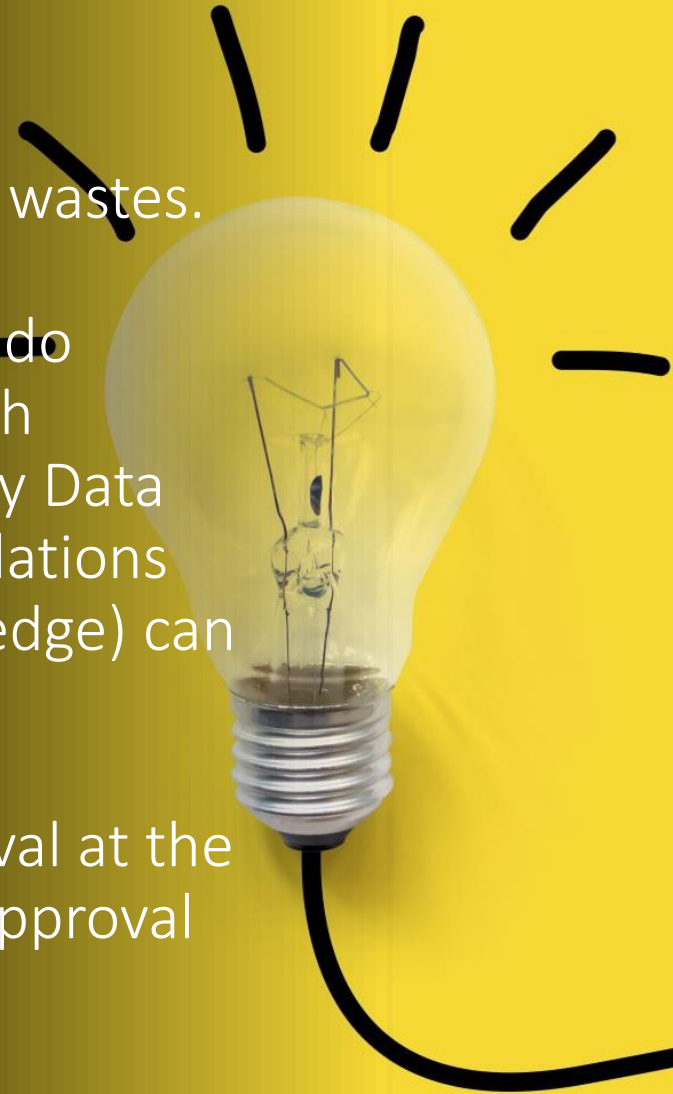
- **Count 1: Undated, Unlabeled containers of hazardous waste stored for greater than 90 days**
 - Moderate/Major = \$12,250
 - Multi Day = 179 days @ \$600 per day
 - Total Penalty = \$119,650
- **Count 2: Open Containers of hazardous Waste**
 - Minor/Minor = \$5000
- **Failure to conduct weekly inspections**
 - Minor/Moderate = \$1,933
 - Multi Day = 156 Weeks @ \$135 per day
 - Total Penalty = \$22,993

Waste Determination

Your pharmaceuticals or products become a waste when you deem them wastes.

Once deemed a hazardous waste must do hazardous waste determination for each particular waste (profile, analysis, Safety Data Sheet (SDS), Hazardous Materials Regulations (HMR) (*see attached pamphlet*), knowledge) can be utilized.

Then submit the information for approval at the designated waste facility to obtain an approval number for shipment and disposal.





Determine: UN HAZARD CODES

- Each UN hazard code number has a hazard identifier, which encodes the general hazard class and subdivision. Each hazard code is divided further into sub-classes. As an example, the six hazard code divisions for Class One hazards are mass explosion, fragment producing non mass explosion, minor blast or fragment producing mass fire, moderate force with no blast or fragment, very insensitive explosive substance (with a mass explosion hazard) and explosive article (extremely insensitive).

Then Determine: Hazard Classes see attached DOT 16 Chart

Nine Classes of Hazardous Materials

Class 1: Explosives
Divisions: 1.1, 1.2, 1.3, 1.4,
1.5, 1.6



**Class 6: Poison (Toxic) and
Poison Inhalation Hazard**

Class 2: Gases
Divisions: 2.1, 2.2, 2.3



Class 7: Radioactive

**Class 3: Flammable
Liquid and
Combustible Liquid**



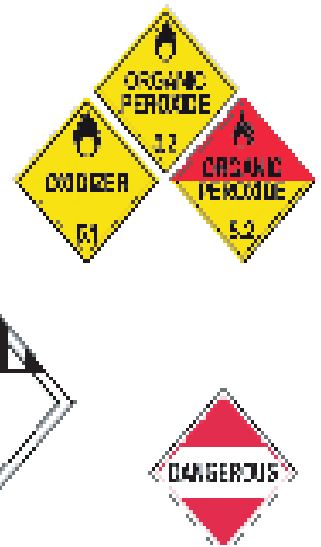
Class 8: Corrosive

**Class 4: Flammable
Solid, Spontaneously
Combustible, and
Dangerous When Wet**
Divisions 4.1, 4.2, 4.3



**Class 9:
Miscellaneous**

**Class 5: Oxidizer and
Organic Peroxide**
Divisions 5.1, 5.2



Dangerous

Revised 04/13





Determine: Packing Groups

PG reflect the degree of danger

- PG 1 indicates great danger
 - PG 2 indicates moderate danger
 - PG 3 indicates minor danger
-

(see attachment)

- PG correlates to the strength of the package
- The higher danger the stronger packaging used
- Assists first responder in determining hazards and risks present

Determine:

In addition to checking the *lists of hazardous wastes in the regulations*, a generator must determine if a waste exhibits one of the following characteristics:

Ignitability D001

Corrosivity D002

Reactivity D003

Toxicity D004 to D043

WASTE - ARSENIC (TCLP >/= 5PPM) (007440-38-2)	D004
WASTE - BARIUM (TCLP >/= 100 PPM) (007440-39-3)	D005
WASTE - CADMIUM (TCLP >/= 1.0 PPM) (007440-43-9)	D006
WASTE - CHROMIUM (TCLP >/= 5.0 PPM) (007440-47-3)	D007
WASTE - LEAD (TCLP >/= 5.0 PPM) (007439-92-1)	D008
WASTE - MERCURY (TCLP >/= 0.2 PPM) (007439-97-6)	D009
WASTE - SELENIUM (TCLP >/= 1.0 PPM) (007782-49-2)	D010
WASTE - SILVER (TCLP >/= 5.0 PPM) (007440-22-4)	D011
WASTE - ENDRIN (TCLP >/= 0.02 PPM) (000072-20-8)	D012
WASTE - LINDANE (TCLP >/= 0.4 PPM) (000058-89-9)	D013
WASTE - METHOXYCHLOR (TCLP >/= 10.0 PPM) (000072-43-5)	D014
WASTE - TOXAPHENE (TCLP >/= 0.5 PPM) (008001-35-2)	D015
WASTE - 2,4-D (TCLP >/= 10.0 PPM) (000094-75-7)	D016
WASTE - 2,4,5-TP (SILVEX) (TCLP >/= 1.0 PPM) (000093-72-1)	D017
WASTE - BENZENE (TCLP >/= 0.5 PPM) (000071-43-2)	D018
WASTE - CARBON TETRACHLORIDE (TCLP >/= 0.5 PPM) (000056-23-5)	D019
WASTE - CHLORDANE (TCLP >/= 0.03 PPM) (000057-74-9)	D020
WASTE - CHLOROBENZENE (TCLP >/= 100.0 PPM) (000108-90-7)	D021
WASTE - CHLOROFORM (TCLP >/= 6.0 PPM) (000067-66-3)	D022
WASTE - O-CRESOL (TCLP >/= 200.0 PPM) (000095-48-7)	D023
WASTE - M-CRESOL (TCLP >/= 200.0 PPM) (000108-39-4)	D024
WASTE - P-CRESOL (TCLP >/= 200.0 PPM) (000106-44-5)	D025
WASTE - CRESOL (TCLP >/= 200.0 PPM)	D026
WASTE - 1,4-DICHLOROBENZENE (TCLP >/= 7.5 PPM) (000106-46-7)	D027
WASTE - 1,2-DICHLOROETHANE (TCLP >/= 0.5 PPM) (000107-06-2)	D028
WASTE - 1,1-DICHLOROETHYLENE (TCLP >/= 0.7 PPM) (000075-35-4)	D029
WASTE - 2,4-DINITROTOLUENE (TCLP >/= 0.13 PPM) (000121-14-2)	D030
WASTE - HEPTACHLOR (AND ITS EPOXIDE) (TCLP >/= 0.008 PPM) (000076-44-8)	D031
WASTE - HEXACHLOROBENZENE (TCLP >/= 0.13 PPM) (000118-74-1)	D032
WASTE - HEXACHLOROBUTADIENE (TCLP >/= 0.5 PPM) (000087-68-3)	D033
WASTE - HEXACHLOROETHANE (TCLP >/= 3.0 PPM) (000067-72-1)	D034
WASTE - METHYL ETHYL KETONE (TCLP >/= 200.0 PPM) (000078-93-3)	D035
WASTE - NITROBENZENE (TCLP >/= 2.0 PPM) (000098-95-3)	D036
WASTE - PENTACHLOROPHENOL (TCLP >/= 100.0 PPM) (000087-86-5)	D037
WASTE - PYRIDINE (TCLP >/= 5.0 PPM) (000110-86-1)	D038
WASTE - TETRACHLOROETHYLENE (TCLP >/= 0.7 PPM) (000127-18-4)	D039
WASTE - TRICHLOROETHYLENE (TCLP >/= 0.5 PPM) (000079-01-6)	D040
WASTE - 2,4,5-TRICHLOROPHENOL (TCLP >/= 400.0 PPM) (000095-95-4)	D041
WASTE - 2,4,6-TRICHLOROPHENOL (TCLP >/= 2.0 PPM) (000088-06-2)	D042
WASTE - VINYL CHLORIDE (TCLP >/= 0.2 PPM) (000075-01-4)	D043

Characteristic of Ignitability D001

Aqueous Solution containing 24% alcohol or more by volume & flash point <140° F.

A Liquid having a flash point <140° F.

An ignitable compressed gas (certain aerosols)

An oxidizer

Hazardous Waste Number: D001

Examples of Ignitable Discarded Pharmaceuticals D Listed

Rubbing Alcohol

Paregoric (CIII)

Cleocin T Topical Solution

Retin A Gel

Listerine Mouthwash

Erythromycin Topical Solution

Silver Nitrate (oxidizer)

Collodion Based Preparations

Corrosivity – D002 code

- Liquids that have a pH less than or equal to 2.0 or greater than or equal to 12.5
- Liquids that corrode steel at a rate greater than 0.25 inches per year at a test temperature



Corrosivity

• 1. Acids

• **Acids** are corrosive substances that;

- Will neutralise alkalis
- Turn blue litmus paper red.
- Dissolve some metals
- Taste sour
- Have a pH level less than 7

• **Some examples of common acids include:**

- Sulfuric Acid (H_2SO_4)
- Hydrochloric Acid (HCl)
- Nitric Acid (HNO_3)
- Citric Acid ($\text{C}_6\text{H}_8\text{O}_7$)

2. Bases

Bases are corrosive substances that:

- Will neutralise Acids
- Turn red litmus paper blue.
- Taste bitter
- Are slippery to touch
- Have a pH level greater than 7

Some examples of common bases include:

- Sodium Hydroxide (NaOH)
- Calcium Hydroxide ($\text{Ca}(\text{OH})_2$)
- Sodium Carbonate (Na_2CO_3)
- Aluminium Hydroxide ($\text{Al}[\text{OH}]_3$)

Reactivity- D003 code

- Contains Cyanides or Sulfides which can generate toxic fumes if exposed to pH conditions between 2.0 and 12.5
- React violently to form potentially explosive mixtures or can generate toxic gases if mixed with water
- Are normally unstable and readily undergo violent change without detonating
- Can detonate or explode if heated or exposed to a strong igniting source
- Can detonate or explode under standard conditions
- Are classified by the Federal Department of Transportation as explosives

Reactive

Hazardous waste that is classified as reactive includes the following:

- Materials that tend to be unstable at normal temperatures and pressures
- Water reactive materials
- Explosives
- Cyanide or sulfide bearing wastes

Examples include:

- Pyrophoric metals such as sodium
- Cyanide wastes
- Ethers
- Peroxides

TCLP Toxicity –D004-D043 codes

- A waste exhibits the characteristics of TCLP Toxicity if its extract [from a precise extraction procedure called the Toxicity Characteristic Leaching Procedure (TCLP)] contains any of 25 listed organic compounds, 8 metals, 4 pesticides and 2 herbicides in concentrations equal to or greater than the specified limits



Examples of Wastes Toxic

influenza virus vaccine	D009 mercury
Selenium Shampoo	D010 selenium
Silver Nitrate Sticks	D011 silver
Lindane	D013 lindane

Insulins:

lantus	D024 cresol
Levemir	
Isophane	
Aspart	
Humulin	
Novalin	

EXAMPLE

Trichloroethylene (T.C.E.) may be needed if:

- F001 solvent, if used in degreasing
- F002 solvent, if used for other solvent applications
- K030 if heavy ends from T.C.E. production
- U228 if discarded commercial chemical product, off-spec material, container or spill residue
- D040 if T.C.E.. concentration in TCLP extract >.5PPM, regardless of origin

Pharmaceutical Waste:

Two main types of pharmaceutical waste: hazardous and non-hazardous.

Hazardous waste as defined by EPA RCRA is waste with properties making it dangerous or potentially harmful to human health or the environment and includes chemicals and drugs.

RCRA Hazardous Examples P-Listed Pharmaceutical Waste

- Arsenic P012
- Epinephrine P042
- Nicotine P075
- Nitroglycerin P081
- Physostigmine P204
- Physostigmine Salicylate P188
- Warfarin >0.3% P001

RCRA Hazardous Warfarin:

- If present in dosage forms over 0.3%, the whole preparation is a “P” listed pharmaceutical waste when decision is made to waste.
- Tablet weighing's demonstrated that all of the common tablet strengths are >0.3% warfarin, and therefore P waste when discarded.
- $5\text{mg}/210\text{mg}$ (tablet weight) = 2.4%

RCRA Hazardous Warfarin:

Acutely hazardous

LD50 < 50mg/kg

Sole active ingredient

No concentration threshold

Cause entire formulation to be hazardous

Weight of container/solvent included

>1 kg/month (2.2 lbs.) = Large Quantity
Generator

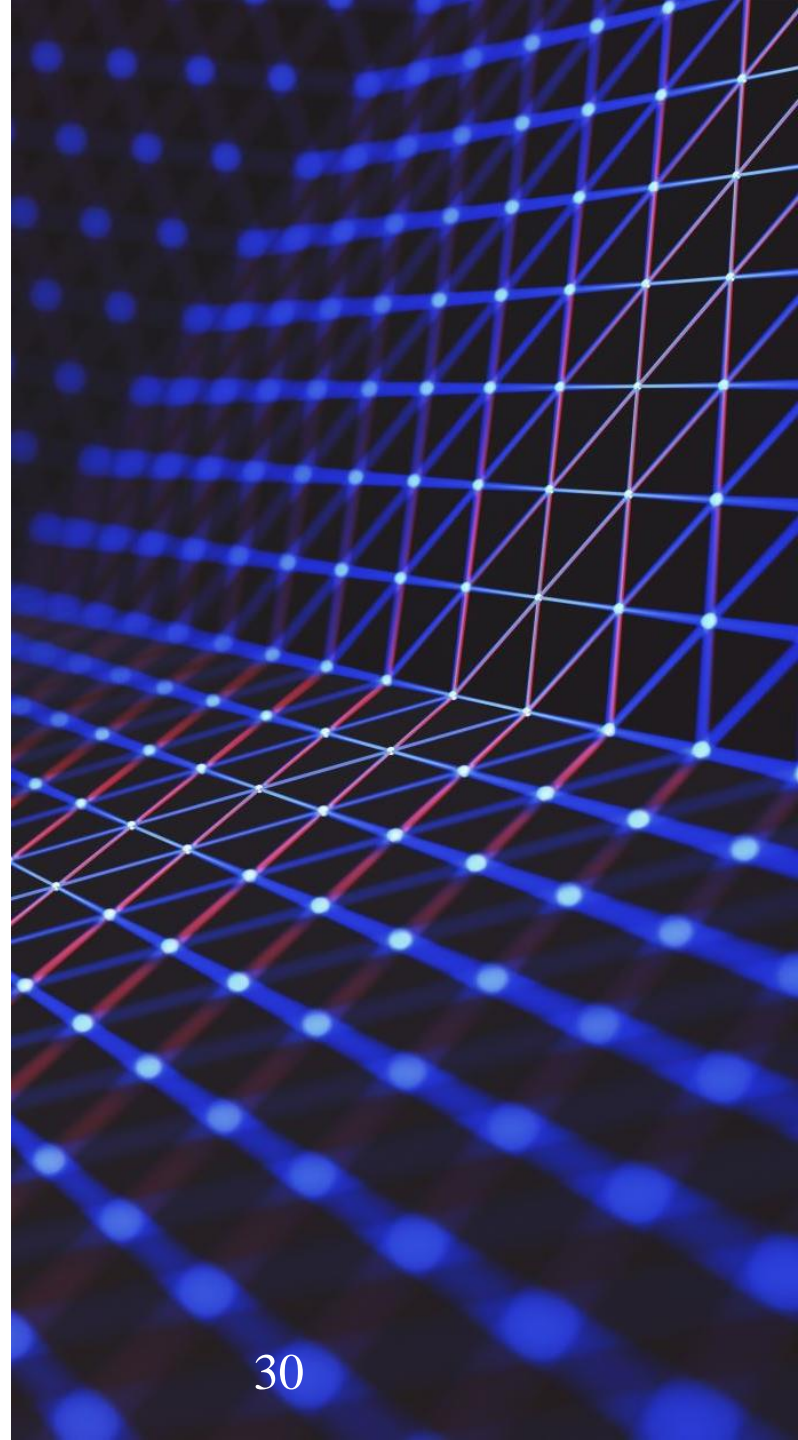
Epinephrine in syringes:

PA Hazardous Waste Program:
epinephrine in a discarded syringe is not
a P listed waste.

Rationale: once the syringe has been
used for patient care, it has been used
for its intended purpose.

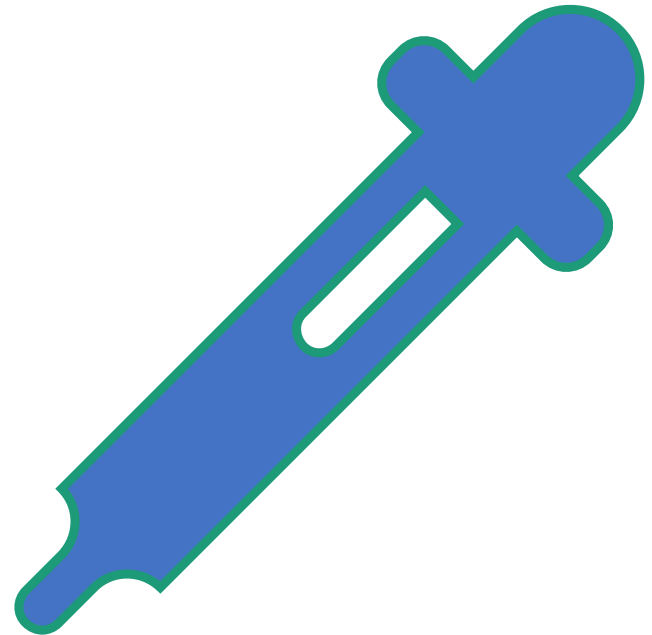
Applies to partially used epinephrine IV
admixtures, also per PA.

RCRA: applies to any P or U listed drug in
a syringe as waste, after patient use.



Epinephrine in syringes:

- Epinephrine syringes after emergency use (e.g. Code Blue): discard in sharps container.
- EXPIRED unused epinephrine STILL considered P listed waste.



Nicotine:

- Patch dosage forms: after patient use, consider “used”? Or “unused”?
- Expired unused may be returned to reverse distributor for credit.
- Patient home disposal not regulated by RCRA.



U-Listed Waste:

- May be U-listed due to toxicity, ignitability, corrosivity, reactivity
- Pharmaceuticals U-listed primarily due to toxicity

Examples of U-listed Pharmaceutical Waste

• Chloral Hydrate(CIV)	U034
• Chlorambucil	U035
• Cyclophosphamide	U058
• Daunomycin	U059
• Melphalan	U150
• Mitomycin C	U010
• Streptozotocin	U206
• Lindane	U129
• Saccharin	U202
• Selenium Sulfide	U205
• Warfarin<0.3%	U248



Basic Description For Waste Shipping Paperwork (utilizing the hazardous materials regulations (HMR) (see attached pamphlet)

- Must be in a set sequence
- 1.UN Identification number
- 2.Proper shipping name
- 3.Primary hazard / division
- 4.Subsidiary hazard / division
- 5.Packing group

- **Example:**
- UN3249, Waste Medicine, solid, toxic, n.o.s.,(Warfarin), 6.1, PG II, **P001**

Category 2: Non RCRA Hazardous Pharmaceuticals



- Non-hazardous or non-RCRA waste is waste that is not governed by RCRA laws. But it still must be disposed of properly in order to protect our communities and comply with other state and federal regulations.
- Non-RCRA pharmaceutical waste accounts for about 85 percent of all hospital pharmacy inventory waste.



Type of container usually
utilized for Non RCRA
Regulated Pharmaceutical
Waste



Label Information Required:

Generator:

Site Address:

Site Telephone:

Generator Status:

Non RCRA Regulated Pharmaceuticals

Approval Number:

Date of Accumulation:

Usual color utilized for non-RCRA Hazardous
Pharmaceuticals is blue lid.

Non RCRA Hazardous Labelling



Type of container usually utilized
for RCRA Regulated
Pharmaceutical Waste



- **Generator:**
- **Site Address:**
- **Site Telephone:**
- **Generator Status:**

- **UN3249 , Waste Medicine,
solid, toxic, n.o.s. P001**

- **Approval Number:**
- **Date of Accumulation:**





HAZARDOUS WASTE

STATE AND FEDERAL LAW PROHIBITS IMPROPER DISPOSAL
IF FOUND, CONTACT THE NEAREST POLICE OR PUBLIC SAFETY
AGENCY OR THE U.S. ENVIRONMENTAL PROTECTION AGENCY OR
THE CALIFORNIA DEPARTMENT ON TOXIC SUBSTANCES CONTROL
FOR FURTHER INFORMATION.

NAME _____ PHONE _____
ADDRESS _____
CITY _____ STATE _____ ZIP _____
EPA IDENTIFICATION NO. / WASTE TRACKING NO. _____
EPA WASTE NO. _____ STATE WASTE NO. _____ REGULATORY UNIT NO. _____
CONTENTS/COMPOSITION _____


PHYSICAL STATE: SOLID LIQUID GASEOUS REACTIVE OTHER _____
HAZARDOUS PROPERTIES: FLAMMABLE TOXIC

[_____]
[_____]
[_____]

EXCEPT WHERE SHOWN OTHERWISE
HANDLE WITH CARE!



RCRA Hazardous Labeling



Basic Description For Waste Shipping Paperwork (see attached manifest example)

- Must be in a set sequence
- 1.UN Identification number
- 2.Proper shipping name
- 3.Primary hazard / division
- 4.Subsidiary hazard / division
- 5.Packing group

- **Example:**
- UN3249, Waste Medicine, solid, toxic, n.o.s.,(Warfarin), 6.1, PG II, **P001**

Shipping Papers Subject to manifest requirements for Hazardous Materials/Wastes (see attached manifest and instructions)

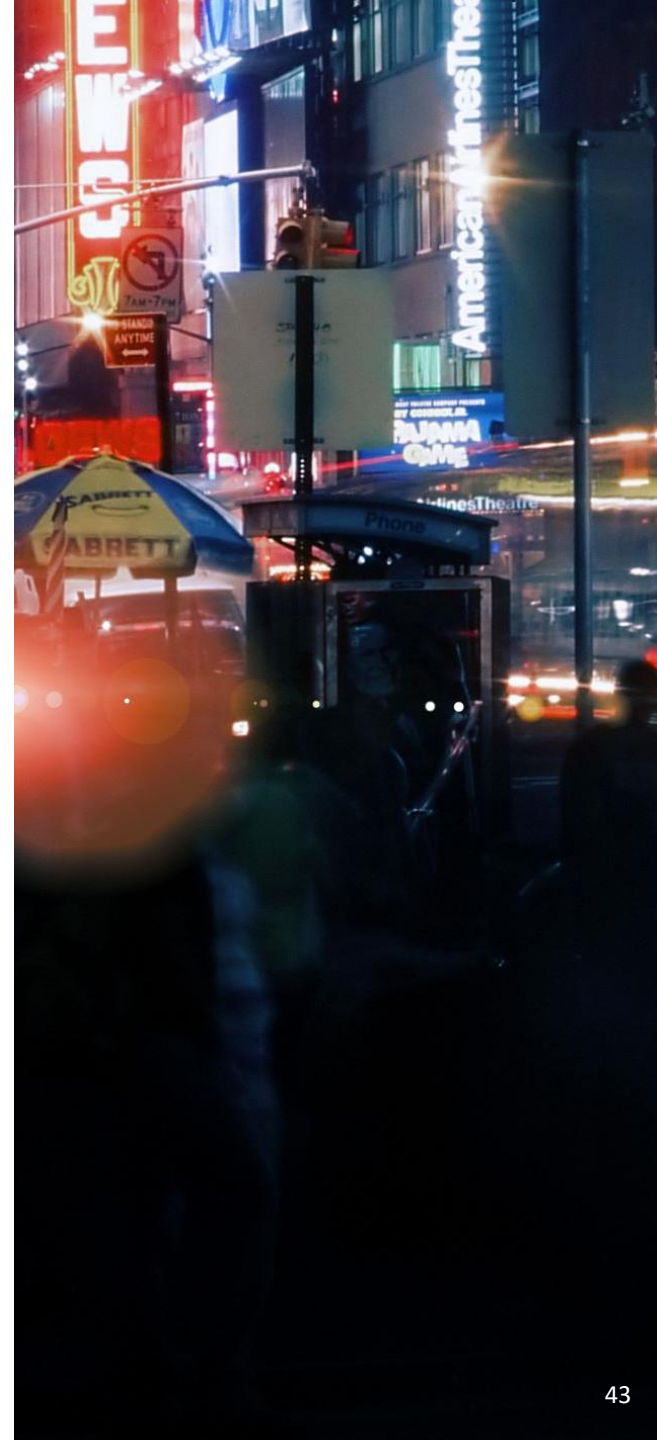
- **Preparation**
- A trained shipper is responsible for properly completing the appropriate shipping documents
- **Types of Shipping Papers**
- Bill of Lading
- Air Bill
- EPA Hazardous Waste Manifest
- **Shipping Paper Requirements**
- Must include the following:
- Basic description
- Total quantity including unit of measure
- Shipper's certification statement
- Shipper's signature
- Emergency information
- Each person who offers a waste material for transport must certify that the material is offered in accordance with the HMR by printing on the shipping paper
- In addition, the emergency response telephone number must be placed on the shipping paperwork.

The image shows a sample of an EPA Hazardous Waste Manifest form, Form 3540-0209. The form is divided into several sections:

- Generator:** Includes fields for generator name, address, phone, and EPA ID number.
- Transporter:** Includes fields for transporter name, address, phone, and EPA ID number.
- Designated Facility:** Includes fields for facility name, address, phone, and EPA ID number.
- Manifest Table:** A table with columns for 'No. of U.S. DOT Description (including Proper Shipping Name, Hazard Class, ID Number, and Packing Group (if any))', 'No. Containers', 'Type', 'Total Quantity', 'EPA ID No. (if any)', and 'Total Units'. A large 'VOID' watermark is overlaid on this section.
- Signatures and Certifications:** Includes sections for generator, transporter, and facility signatures, along with checkboxes for various certifications and emergency response information.

Placard the Vehicle

- Shipper is responsible for determining and providing the necessary placards
- Placement of Placards
- Readily visible from the direction it faces (except where coupled)
- Placement of Placards
- The required placarding of the front of a motor vehicle may be on the front of a tractor instead of or in addition to the front of the cargo body
- Placard Exceptions
- Not required for:
 - Infectious substances
 - Limited Quantities identified on shipping papers
 - Hermetically sealed in containers in accordance with 173.13
 - HM packaged as small quantities under 173.4
 - combustible liquids in non-bulk containers
 - PIH boxes



How Can Hazardous RX Waste Generation Be Minimized? continued

Single dose vials vs. multiple dose vials

Patient specific oral syringes vs. 10 cc. repacks (e.g. chloral hydrate for pediatric use)



Assessing Current Practices

- Performing department reviews
 - Quantative volumes/weights of discarded drugs difficult to obtain
 - Informal but well documented interview process in pharmacy and nursing units can determine current medication disposal practices
 - Schedule units in advance
 - Emphasize “no wrong answer” approach
 - Utilize data from automated dispensing machines
 - Conduct a frequency analysis, especially for drugs which become hazardous waste



How Can Hazardous RX Waste Generation Be Minimized? continued

Single dose vials vs. multiple dose vials

Patient specific oral syringes vs. 10 cc. repacks (e.g. chloral hydrate for pediatric use)

Municipal Trash

With proper sorting methods of non-hazardous and RCRA hazardous pharmaceuticals can save costs.

With proper sorting methods empty medication vials (~70%) can yield approximately 25 -30 % cost savings.

Examples:

- Most packaging
- Most empty bottles and vials
- Most empty IV's
- Paper
- Plastic
- No drugs
- No P-waste containers

Test

Name Student: _____

Date: _____

1. What is a CFR?
2. Which EPA Code number is for the Federal Regulations (air, land, water) _____
3. What is the goal of RCRA?
4. What is one consequence that can result from non-compliance?
5. Your waste becomes waste when you deem it?
True or False

Test (continued)

6. PG correlates to the strength of the package?
True or False
7. There are how many hazard classes?
8. What is the Characteristic Code for Ignitability?
9. What are the two main types of pharmaceutical waste?
10. What is the waste code for Warfarin?
11. What are the 5 parts of the set sequence for a waste shipping name?
12. How Can Hazardous RX Waste Generation Be Minimized?