Pharmaceuticals and the Universal Waste Rule

Connecticut DEEP Stakeholders Meeting
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PharmEcology Services
WM Healthcare Solutions

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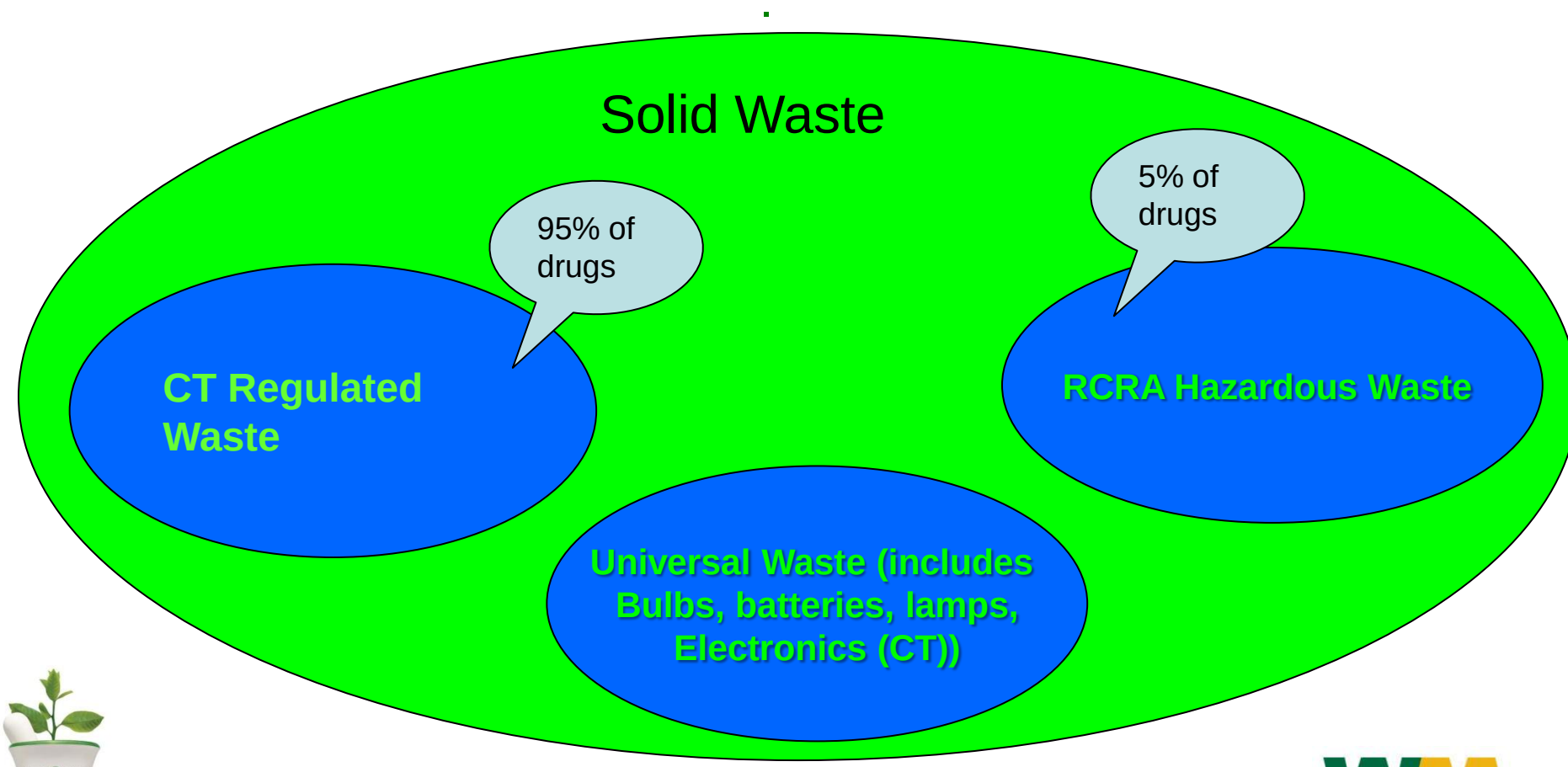
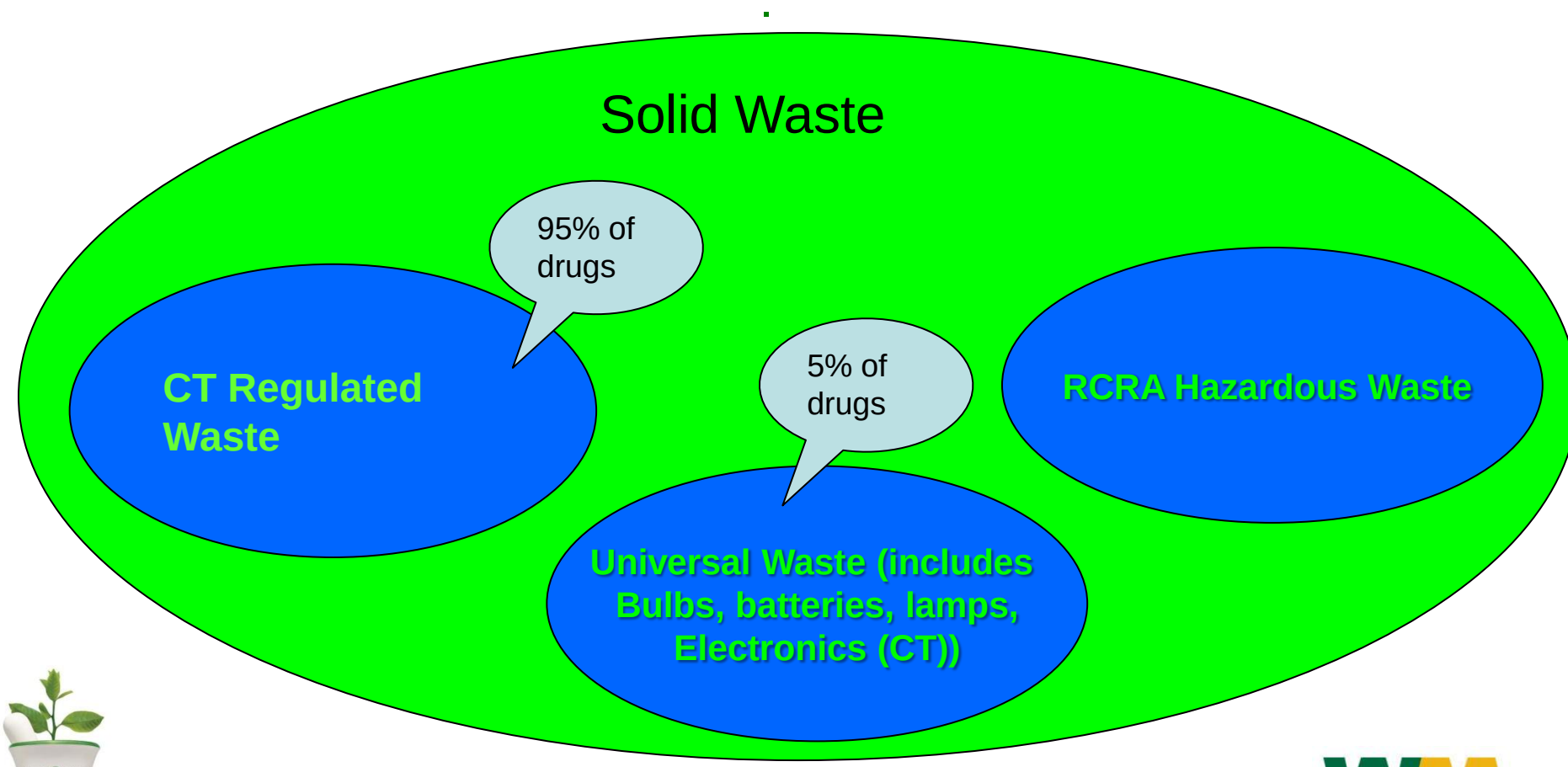
Current Waste Classifications



Proposed Waste Classifications



RCRA:
The Defining Regulation

- Resource Conservation & Recovery Act
  - Enacted in 1976, enforced by the EPA and authorized states
  - Federal regulation of the disposal of solid wastes
  - Encourages the minimization of waste generation
- Defines “hazardous waste”
- “Cradle to Grave” tracking of hazardous waste
- Households are exempt

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RCRA Risk Management & Liability

- Civil and criminal liability
  - Civil: State/USEPA enforcement
  - Criminal: FBI, Attorney General, Grand Jury
- Corporate fines: $25,000/violation/day (CT), $37,500/violation/day (EPA)
- Personal liability: fines and/or imprisonment
- No statute of limitations
- Managers up through CEO liable

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Federally Regulated Hazardous Waste Under RCRA

- P-listed pharmaceuticals (acutely hazardous)
  - Sole active ingredient; unused; empty containers
  - LD50 (oral) 50mg/kg

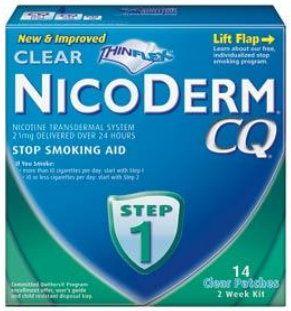
- U-listed pharmaceuticals (toxic)
  - Sole active ingredient; unused

- Pharmaceuticals that exhibit a *characteristic* of hazardous waste (D codes)
  - Ignitability D001
  - Toxicity D004 – D043
  - Corrosivity D002
  - Reactivity D003

Examples of P- and U-listed Drugs

P-listed Drugs

Arsenic Trioxide	P012
Epi & salts (CT)	P042
Nicotine	P075
Nitroglycerin (CT)	P081
Physostigmine Salicylate	P188
Warfarin >0.3%	P001



U-listed Drugs (partial list)

Chloral hydrate (CIV)	U034
Chlorambucil	U035
Cyclophosphamide	U058
Daunomycin	U059
Melphalan	U150
Mitomycin C	U010
Streptozotocin	U206
Lindane	U129
Selenium Sulfide	U205
Warfarin ≤ 0.3%	U248

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Characteristic of Toxicity

- 40 chemicals which must be below specific leaching concentrations
- Fails the Toxicity Characteristic Leaching Procedure (TCLP)
- Must evaluate IVs, such as TPN
  - May come out of regulation due to dilution (chromium, selenium)
- Examples of potentially toxic pharmaceutical ingredients:
  - Chromium D007
  - m-Cresol D024
  - Mercury (Thimerosal) D009
  - Selenium D010
  - Silver D011

Characteristic of Ignitability

- Aqueous Solution containing 24% alcohol or more by volume & flash point<140° F
- Non-aqueous solutions with flash points <140° F
- Oxidizers
- Flammable aerosols
- Hazardous Waste Number: D001
- Rubbing Alcohol
- Topical Preparations
- Some alcohol-based Injections

Examples of Characteristic Hazardous Wastes (D-coded)

Toxicity

- Multi-dose Flu Vaccines (thimerosal preservative)
- Human insulin (m-cresol preservative)
- Silver Sulfadiazine cream (silver)
- Multivitamin/mineral preparations (chromium, selenium)

Ignitability

- Paclitaxel prior to dilution
- Antibiotic topical preparations (Clindamycin Topical Solution)
- Many alcohol-based gels
- Pressurized aerosol inhalers with flammable propellants

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Examples of Pharmaceuticals Exhibiting the Characteristic of Toxicity

Preservatives: thimerosal & m-cresol

Heavy metals: selenium, chromium and silver

Definition of Empty

- To be “RCRA empty”, P-listed containers must be triple rinsed & rinsate discarded as hazardous waste; only used syringes excluded – EPA regulation (in practice, no triple rinsing)
- The EPA requires **P-listed wrappers & packaging to** be managed as RCRA hazardous waste because of the **residue** remaining in them
  - Empty nitroglycerin (CT) and epinephrine (CT) containers, warfarin bottles and wrappers, nicotine envelopes
- U-listed and D codes: empty if **all removed that can be removed by normal means and** no more than 3%, by weight, remaining
  - For vials, can any additional drug be drawn up in a syringe?
  - For bottles, can any additional liquid be poured out?
  - Aerosols – never considered “empty”

Used vs Unused

- If a P- or U-listed drug has been used for its intended purpose, the “used” waste is no longer regulated under RCRA
  - For example, mitomycin (U010) used in a bladder instillation is “used” and if collected in a Foley bag, should be disposed in the yellow trace chemo container
  - A partial IV bag of Cytoxan (U058) is “unused” and should be disposed in a black hazardous waste container
- D code drugs are always regulated, whether “used” or not
  - Unlikely that a “used” D code drug would be available for collection

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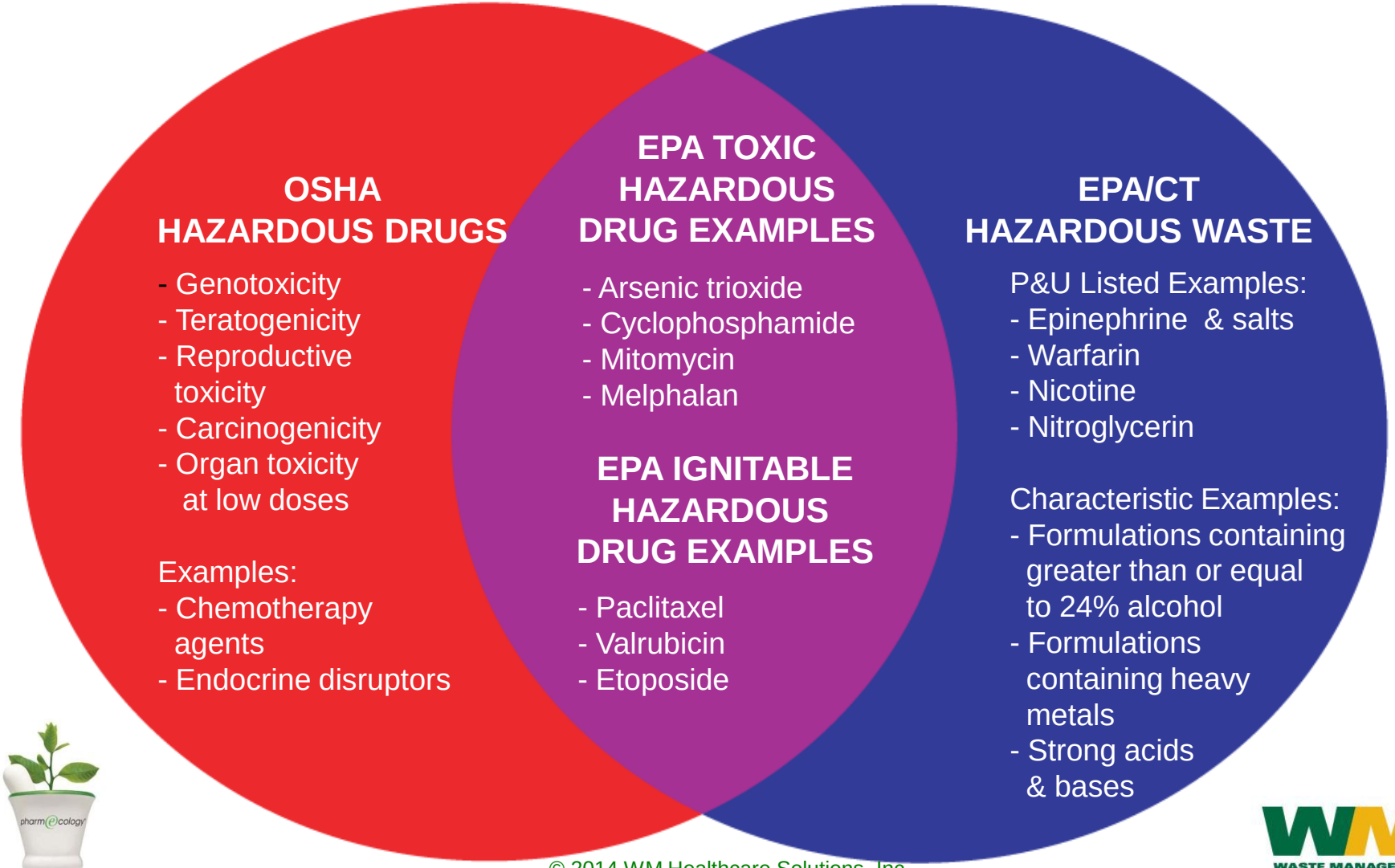
Chemotherapy Agents

- Nine chemotherapy agents are regulated under RCRA (1 P-listed; 8 U-Listed). Examples include:
  - Arsenic trioxide P012
  - Mitomycin C U010
- Over 100 additional chemotherapy agents are not regulated under RCRA (the list was published in 1976), yet should be managed as hazardous waste.
- Examples include:
  - Cisplatin
  - Fluorouracil
  - Methotrexate
  - Taxol® (paclitaxel)

Hazardous Drugs vs. Hazardous Waste
Where OSHA & EPA Meet



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Determining Generator Status under RCRA

- Large Quantity Generator (LQG):
  - generates ≥ 1000 kg/month of hazardous waste, or
  - generates > 1 kg/month P-listed waste, or
  - stores > 1 kg of P-listed waste at any one time.
- Small Quantity Generator (SQG):
  - generates < 1000 kg/month but > 100 kg/month of hazardous waste; and
  - ≤ 1 kg/month P-listed waste, and
  - stores ≤ 1 kg of P-listed waste at any one time.
- Conditionally Exempt Small Quantity Generator (CESQG):
  - Generates ≤ 100 kg hazardous waste/month, and
  - ≤ 1kg P-listed waste/month, and
  - stores ≤ 1 kg of P-listed waste at any one time.

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Generator Requirements Under RCRA

- Perform waste determination for all drug products (update at least annually and have documentation on-site)
- Obtain EPA Identification Number
- Determine generator status
- Segregate drug waste into appropriate containers
- Prepare waste profile: Enables commingling of compatible hazard classes for DOT purposes
- Prepare label: Very specific DOT requirements
- Prepare Uniform Hazardous Waste Manifest: Very specific DOT requirements
- Prepare Land Disposal Restriction Form (Land Ban)

Still More Generator Requirements Under RCRA

- Contract with a state and/or federally permitted RCRA incineration facility - Treatment, Storage & Disposal Facility (TSDF)
- Develop written RCRA training program and conduct training (initial and annual review)
- Develop inspection schedule and inspection log
- Conduct inspections and record in log
- Maintain storage accumulation area requirements (impermeable base, secondary containment, accumulation time, containers closed when not in use, condition, etc.)
- Biennial reporting and contingency planning for LQGs
- Maintain documentation for at least three years

DOT Hazardous Waste Labels and Shipping Descriptions

- DOT shipping description for compatible hazardous waste (flammable/toxic)
  - UN3248, Waste Medicine, Liquid, Flammable, Toxic, n.o.s., 3 (6.1), PG II
- The DOT hazardous waste label is provided and completed by the hazardous waste vendor at the time of pick up based on the waste profiles
- The generator is ultimately responsible for the appropriate shipping preparations and labeling

Hazardous Waste Label Example

- Facility Name
- Facility Address (Street, City, State, Zip)
- Phone Number
- EPA Identification Number
- Waste Codes
- Accumulation Start Date
- Description of Contents (chemical name)

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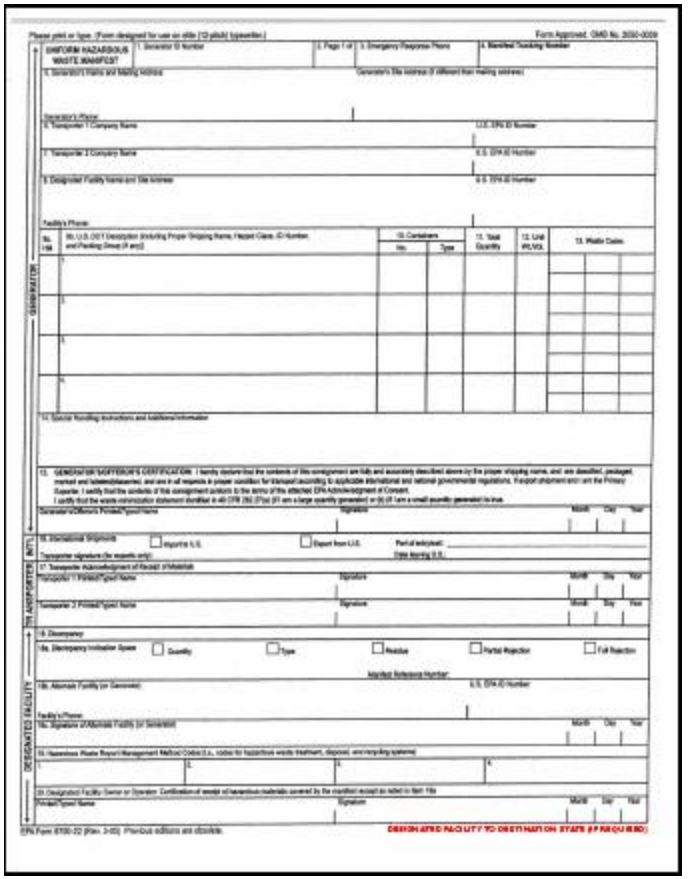
Uniform Hazardous Waste Manifest

- May be completed by the generator or the hazardous waste vendor
- Must be signed by employee who has received DOT hazardous material training
- Make a copy and send to WEED (Waste Engineering & Enforcement Division) within 7 days
- Top copy must be returned by vendor within 35 days; match to generator copy and save for 3 years
- If not received in 45 days, must notify WEED



A Quick Primer on Incinerators

- Municipal (Resource Recovery Facility)
  - Permitted to burn municipal “garbage”
  - Generates electricity from combustion
  - Usually not permitted to handle infectious waste
  - May be permitted to handle non-hazardous pharmaceuticals, with certain volume restrictions
- Medical Waste
  - Permitted by USEPA and the state to accept pathology waste, red bag and red sharps waste, trace chemo waste
  - May be permitted to accept non-hazardous pharmaceutical waste
- Hazardous Waste
  - Permitted by USEPA, known as a Treatment, Storage and Disposal Facility (TSDF)
  - High temperature, molecular bonds broken
  - Authorized to accept the “worst of the worst” hazardous chemicals, shipped on a 6-part Uniform Manifest

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Non-RCRA Hazardous
CT Regulated Waste

- Waste is neither listed nor characteristically hazardous waste
- Defined in Section 22a-448 of Connecticut General Statutes (C.G.S.)
- Must be managed by vendors who are permitted under Section 22a-454 (C.G.S.)
- Wastes include:
  - Materials containing or contaminated with PCBs (CR01)
  - Waste oil and waste soluble oil (CR02 and CR03)
  - Chemical liquids (CR04) and solids (CR05) which include all pharmaceuticals not covered under RCRA

Non-RCRA Hazardous
CT Regulated Waste

- Waste pharmaceuticals may be CR04 (liquids) or CR05 (solids)
- Store wastes in manner similar to hazardous waste
- Picked up by permitted waste hauler (except CR05)
- Shipped using bill of lading or manifest
- For practical purposes, solids and liquids in same container so all must be shipped by permitted waste haulers

Non-RCRA Hazardous CT Regulated Waste

- In CT, transporter and disposal facility must be permitted to take CT Regulated Waste under Section 22a-454 (C.G.S.)
- If shipped out-of-state, facility permitted to accept non-hazardous pharmaceutical waste
- Alternative: Send to Permitted Resource Recovery Facilities with Special Waste Handling Plan for CT Regulated Pharmaceutical Waste
  - Covanta facilities in Preston and Wallingford and Wheelabrator facilities in Bridgeport and Lisbon
  - Typically practical only for consolidated loads

Summary of Current CT Pharmaceutical Waste Streams

Compatible Hazardous Waste*	Aerosols	Trace Chemo (Sharps)	Trace Chemo (Soft)	Non – RCRA Hazardous Drugs	Red Sharps	Municipal Solid Waste	Sewer System
* Dual waste for sharps							

• P-listed (inc. containers)
• U-listed
• D-listed t toxic,
• Ignitable
• Bulk chemo
• Haz/Chemo spill clean up
	• Ignitable aerosols
	• Pressurized aerosols
		• Empty vials and ampules
		• Empty syringes and needles
		• Empty IVs
			• Gowns
			• Gloves
			• Tubing
			• Wipes
			• Packaging
				• All non-RCRA hazardous pharmaceutical waste
				• No biohazardous drugs
				• **No needles**
					• Empty syringes, needles, ampules (except chemo)
					• Potentially infectious drugs
						• Most packaging
						• Most empty bottles and vials
						• Most empty IVs
						• Paper
						• Plastic
						• No drugs
						• No P-waste containers
							• IVs
							  ○ Dextrose
							  ○ Saline
							  ○ Sterile Water
							  ○ Lactated Ringer's
							  ○ K salts
							  ○ Ca salts
							  ○ Mg salts
							• No other drugs

							
Federally Permitted Hazardous Waste Incinerator		**Medical Waste Incinerator**		**Municipal Incinerator Permitted for Special Waste (inc. drugs)**	**Autoclave/ Microwave**		Publicly Owned Treatment Works (**POTW) Need DEEP Discharge Permit**
Ash		**Ash**		**Ash**	**Shredded (Most states)**		
Lined Hazardous Waste Landfill		**Lined Non-Hazardous Waste Landfill**					**Water Supply**

What is Universal Waste?

- Universal Waste Rule finalized May 11, 1995 in Federal Register
- Designed to promote easier collection, recycling, reuse of hazardous wastes that occur throughout the population
- Currently include lamps, batteries, mercury-containing devices, pesticides, and electronics (CT only)

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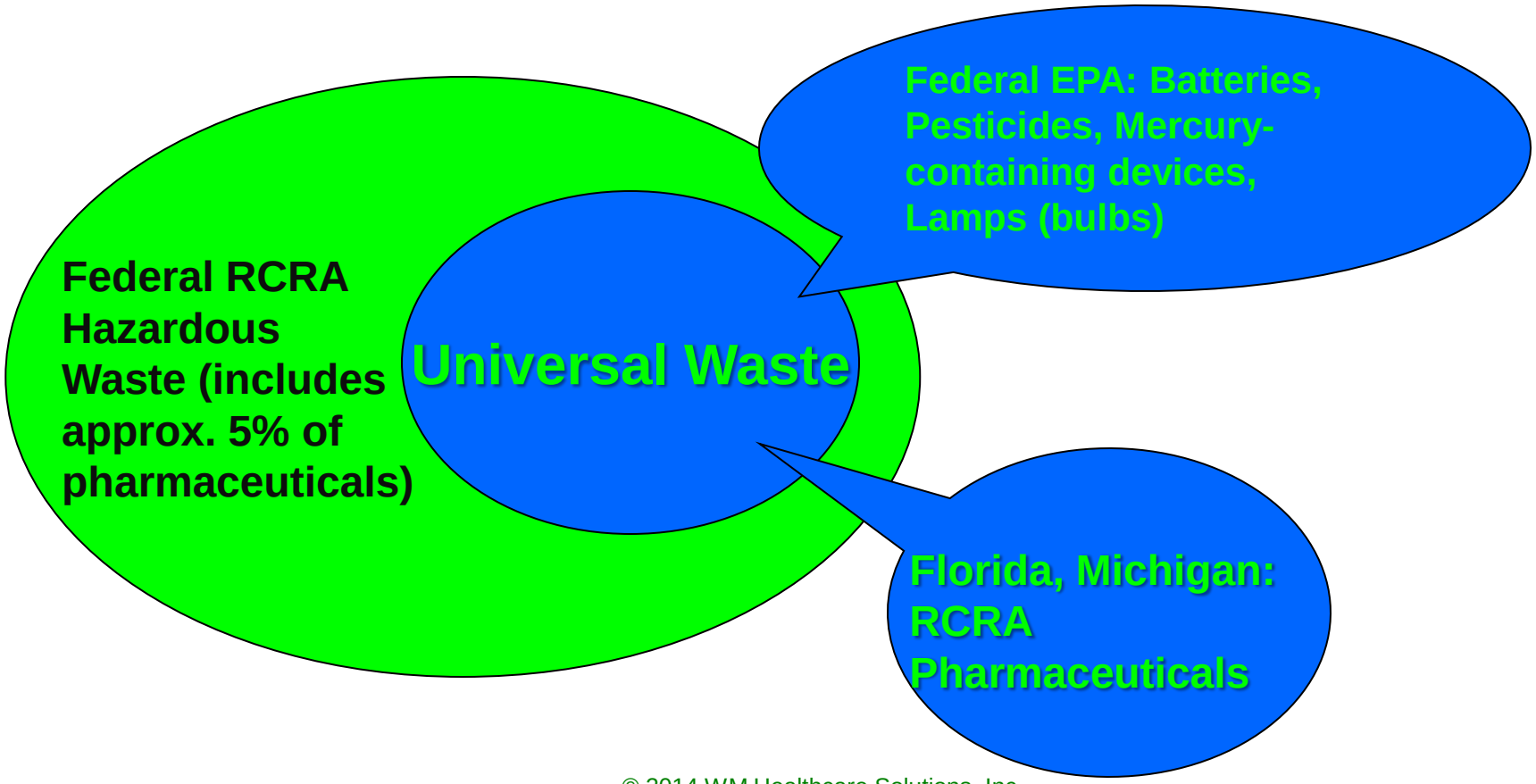
General Goals of UWR

- To encourage resource conservation
- To improve implementation of current RCRA subtitle C hazardous waste regulatory program
- To separate UW from the municipal waste stream

RCRA and Universal Waste

"Universal Waste" is a subset of RCRA hazardous waste.



Benefits of State-Listing Hazardous Pharmaceutical Waste as a Universal Waste

- Increase compliance rates
- Streamline the current regulations/reduce the regulatory burden
- Ensure larger quantities of hazardous pharmaceutical waste are managed properly
- Does not count towards generator status
- Do not need to use Uniform Hazardous Waste Manifest
- Longer accumulation limits (1 year vs. 90 or 180 days)

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What Makes Drug Waste Unique?
Security Issues

- Legend Pharmaceuticals (prescription only) are deliberately restricted in their availability to the consumer AND within the supply chain due to their inherently “dangerous” status regarding human use
- The street value of pharmaceuticals continues to climb due to increased drug costs and shrinking personal resources
- Waste pharmaceuticals continue to have value, including empty vials of IV admixtures that can be used for introducing counterfeit drugs back into the supply chain

What Makes Drug Waste Unique?

- Due to concerns regarding handling, storage, and counterfeiting, FDA and state regulatory authorities have multiple requirements, for example:
  - Licensure (distributors & reverse distributors)
  - Inspections
  - Background checks, drug testing
  - Physical security
  - Criminal penalties
  - “Pedigrees”
- Forward supply chain (manufacturers, distributors) working hard to develop further security measures (e.g. “track and trace” technology)

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EPA Initial Proposal to Add Pharmaceuticals to Universal Waste Rule

- Federal Register publication Dec 2, 2008 –Only applied to drug waste that meets the definition of RCRA hazardous waste
- Only intended for healthcare-type generators, not manufacturers
- Intended to streamline pharmaceutical waste management and encourage consumer take-back programs
- EPA has decided not to move forward with the UWR but is developing a new proposal "to establish appropriate standards for the management and disposal of hazardous waste pharmaceuticals generated by healthcare facilities."
- Notice of Proposed Rule Making now scheduled for August, 2014
- http://www.epa.gov/wastes/hazard/generation/pharmaceuticals.htm

Unresolved Issues

- Can generators ship potentially creditable outdated drugs that become RCRA hazardous to reverse distributors under the new UWR?
- Will UW vendors be required to provide a copy of the Uniform Manifest sent to the TSDF back to the original handler to document proper destruction?
- How will pharmaceutical UW handlers be permitted?
- What is an appropriate DOT Shipping Description?
- Will SQHUW be required to notify/obtain an EPA ID no.?
- What training will be required?
- Will chemotherapy agents be included?

Questions?

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