Pharmaceuticals are just another hazardous waste!
Pharmaceutical Waste

When Pharmaceuticals Become Waste

• A pharmaceutical is considered waste at the time and place the decision is made to discard it.

• A waste determination must be conducted on a discarded pharmaceutical to determine if it is hazardous waste.
  – Spilled, damaged or broken product no longer useable for the intended purpose.
  – An item used in cleaning spills (dry absorbent, paper towels, etc.) must be determined and managed as either hazardous or non-hazardous waste.
Pharmaceutical Waste

When Pharmaceuticals are not a Waste

• Returned for documented credit through the pharmaceutical reverse distribution system to a manufacturer, wholesaler or reverse distributor due to an:
  • Oversupply
  • Expiration of the recommended shelf life
  • Manufacturer recall
  • Product received as a result of a shipping error, or
  • Product is damaged.
• Donated to a charitable organization as described in the Internal Revenue Code
• No decision to discard
Pharmaceutical Waste

How pharmaceutical wastes may be generated:

- Expiration date reached before use (about 3% of all drugs)
- Spill cleanup debris
- Partially used vials from IV prep
- Partially used vials from filling syringes
- Compounding
- Excess medication eliminated from overfilled syringes
- Used syringes and IVs (biohazards if empty, considered to be containers)
- Discontinued or unused preparations
- Unused doses
- Unused medication after treatment is completed
- P-listed pharmaceutical packages
Pharmaceutical Waste

Where Pharmaceutical Waste is Generated

- Surgery
- Pharmacy
- Patient Room
- Emergency Room
- Intensive Care
- Oncology
- Hematology
- Radiology
- Out-patient clinic
### P-listed and U-listed Pharmaceuticals

<table>
<thead>
<tr>
<th>Name</th>
<th>Waste Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arsenic trioxide</td>
<td>P012</td>
</tr>
<tr>
<td>Epinephrine</td>
<td>P042</td>
</tr>
<tr>
<td>Nicotine</td>
<td>P075</td>
</tr>
<tr>
<td>Nitroglycerin(^1)</td>
<td>P081</td>
</tr>
<tr>
<td>Physostigmine</td>
<td>P204</td>
</tr>
<tr>
<td>Physostigmine salicylate</td>
<td>P188</td>
</tr>
<tr>
<td>Warfarin &gt;0.3%</td>
<td>P001</td>
</tr>
<tr>
<td>Chloral Hydrate (CIV)(^2)</td>
<td>U034</td>
</tr>
<tr>
<td>Chlorambucil (chemo)</td>
<td>U035</td>
</tr>
<tr>
<td>Chloroform</td>
<td>U044</td>
</tr>
<tr>
<td>Cyclophosphamide (chemo)</td>
<td>U058</td>
</tr>
<tr>
<td>Daunomycin (chemo)</td>
<td>U059</td>
</tr>
<tr>
<td>Dichlorodifluromethane</td>
<td>U075</td>
</tr>
<tr>
<td>Diethylstilbestrol</td>
<td>U089</td>
</tr>
<tr>
<td>Formaldehyde</td>
<td>U122</td>
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</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Waste Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hexachlorophene</td>
<td>U132</td>
</tr>
<tr>
<td>Lindane</td>
<td>U129</td>
</tr>
<tr>
<td>Melphalan (chemo)</td>
<td>U150</td>
</tr>
<tr>
<td>Mercury</td>
<td>U151</td>
</tr>
<tr>
<td>Mitomycin C (chemo)</td>
<td>U010</td>
</tr>
<tr>
<td>Paraldehyde (CIV)</td>
<td>U182</td>
</tr>
<tr>
<td>Phenacetin</td>
<td>U187</td>
</tr>
<tr>
<td>Phenol</td>
<td>U188</td>
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<tr>
<td>Reserpine</td>
<td>U200</td>
</tr>
<tr>
<td>Resorcinol</td>
<td>U201</td>
</tr>
<tr>
<td>Saccharin</td>
<td>U202</td>
</tr>
<tr>
<td>Selenium sulfide</td>
<td>U205</td>
</tr>
<tr>
<td>Streptozotocin (chemo)</td>
<td>U206</td>
</tr>
<tr>
<td>Trichloromonofluoromethane</td>
<td>U121</td>
</tr>
<tr>
<td>Uracil mustard (chemo)</td>
<td>U237</td>
</tr>
<tr>
<td>Warfarin &lt;0.3%</td>
<td>U248</td>
</tr>
</tbody>
</table>
Common P-listed

- **Warfarin >0.3% (P001)**
  
  Brand names: Coumadin, Jantoven, Marfarin  
  
  - Container residues.  
  - Contaminated wipes.  
  - Discarded Products.

- **Nicotine (P075)**
  
  Brand names: Nicoderm CQ, Nicorette, Nicotrol, Habitrol  
  
  - Unused discarded products. (RO# 14817)
Nitroglycerine (P081)

If medicinal nitroglycerine does not exhibit the characteristic of reactivity (for which it was listed), then it is not considered a listed hazardous waste. RO# 14654

Phentermine (P046) Base chemical only. Appetite suppressant.

Physostigmine (P204)

Ophthalmic solution, trans dermal patches, ointment.
Other P-listed

- Arsenic trioxide (P012)
  Trisenox Injection – Chemotherapy for acute promyelocytic leukemia.

- Epinephrine base (P042)
  EPA has clarified that epinephrine salts are not included in the P042 listing.
  (RO# 14778)

- Physostigmine salicylate (P188) - Injection, intravenous.
## D-List Chemicals in Pharmaceuticals

<table>
<thead>
<tr>
<th>Name</th>
<th>Hazardous Waste No.</th>
<th>Regulatory Level (mg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arsenic</td>
<td>D004</td>
<td>5.0</td>
</tr>
<tr>
<td>Barium</td>
<td>D005</td>
<td>100.0</td>
</tr>
<tr>
<td>Cadmium</td>
<td>D006</td>
<td>1.0</td>
</tr>
<tr>
<td>Chloroform</td>
<td>D022</td>
<td>6.0</td>
</tr>
<tr>
<td>Chromium</td>
<td>D007</td>
<td>5.0</td>
</tr>
<tr>
<td>M-Cresol</td>
<td>D024</td>
<td>200.0</td>
</tr>
<tr>
<td>Lindane</td>
<td>D013</td>
<td>0.4</td>
</tr>
<tr>
<td>Mercury</td>
<td>D009</td>
<td>0.2</td>
</tr>
<tr>
<td>Selenium</td>
<td>D010</td>
<td>1.0</td>
</tr>
<tr>
<td>Silver</td>
<td>D011</td>
<td>5.0</td>
</tr>
</tbody>
</table>
Ignitable pharmaceutical wastes - Erythromycin gel 2%, Texacort solution 1%, flexible collodion, Amyl nitrite inhalers, Silver nitrate applicators, Primatene aerosol, discarded products containing alcohol $\geq 24\%$.

Corrosive - pH $\leq 2$ or $\geq 12.5$ Could occur if the pharmacy compounds medications on-site.

Reactive - Nitroglycerine? Dosage forms are exempted.
D-List Chemicals in Pharmaceuticals

- **Mercury**
  - Elemental mercury in thermometers and sphygmomanometers.

- **Mercury compounds** - Thimerosal and phenylmercuric acetate.
  - preservative in vaccines, eye drops, nasal sprays.

- **Arsenic compounds** - Carbasone (STD treatment), there are others but they are not common.

- **Barium compounds** - Barium sulfate (Used in radiology)
- A container that held a **P-listed** CCP must be managed as a HW, unless the container is rendered “RCRA empty” (see 40 CFR 261.7(b)(3)). RCRA empty for a P-listing = the container has been triple-rinsed. Rinsate must be managed as HW.

- **Count only the weight of the residue toward generator status.**
  - Estimated that residue in a 100-count container is ≤ 1 mg.
  - It would take the combined residues from > 1 million dispensed bottles to reach LQG quantities of > 1 kg/month.
  (RO# 14827)
Management of Empty Containers

- Hazardous Waste Manifests usually list the entire weight of the packaging, empty bottle, and residue. Box 14 - Special Handling Instruction and Additional Information may note that the manifest lists the total weight of containers but is not used to determine generator status.

- Don’t require registration as a Large Quantity Generator if the P-listed line item exceeds 2.2 pounds.
A container that held a U-listed CCP or a characteristic HW is RCRA empty and is not a HW when (40 CFR 261.7(b)(1)): All of the pharmaceutical has been removed that can be removed by normal means; AND no more than 3% by weight of the total capacity of the container remains.

When it is empty, throw it away.
Aerosol Cans

They consist of three different types of materials:

• Liquid product in the can.
• Gaseous propellant in the can.
• The can itself.
Scrap Metal Exemption

• If you plan to *recycle* punctured cans as scrap metal:
  – Setup a satellite accumulation container with a puncture station to safely drain can residues.
  – Label container “Hazardous Waste” or other words to describe contents.
  – Recycle punctured aerosol cans as scrap metal.
Aerosol Cans

Disposal of aerosol cans after puncturing

– *You must receive approval for on-site treatment!*
– Setup a satellite accumulation container with a puncture station to safely drain can residues.
– Label container “Hazardous Waste” or other words to describe contents.
– Dispose of cans as solid waste.
Aerosol Cans

Disposal of aerosol cans without puncturing

– Setup satellite accumulation container.

– Ship as hazardous waste.
• Kentucky has not adopted the new solvent wipes rule!

• You may apply for a variance. A request for variance from a requirement of the waste management administrative regulations shall be submitted in a report in sufficient detail to satisfy a request from the cabinet to provide the analyses, procedures, controls, and other pertinent data necessary to support the request for variance (401 KAR 30:020 Section 2)
Solvent Wipes Rule

The final rule provides a definition for “wipe” and “solvent-contaminated wipe” in 40 C.F.R. 260.10.

- **Wipe** means a woven or non-woven shop towel, rag, pad, or swab made of wood pulp, fabric, cotton, polyester blends, or other material.

- **Solvent-contaminated wipe** means a wipe that, after use or after cleaning up a spill, either:
  
  • Contains one or more of the F001 through F005 solvents;
  
  • Exhibits a hazardous characteristic when that characteristic results from a listed solvent; or
  
  • Exhibits only the hazardous waste characteristic of ignitability due to the presence of solvents that are not listed.
Solvent Wipes Rule

- Solvent-contaminated wipes that contain listed hazardous waste other than solvents, or exhibit the characteristic of toxicity, corrosively, or reactivity due to contaminants other than solvents, **are not eligible for the exclusions.**

- Specifically, the rule includes:
  - A conditional exclusion from the **definition of solid waste** for solvent-contaminated wipes sent for cleaning ("**reusable wipes**") – 40 C.F.R. 261.4(a)(26).
  - A conditional exclusion from the **definition of hazardous waste** for solvent-contaminated wipes sent for disposal ("**disposable wipes**") – 40 C.F.R. 261.4(b)(18)
Solvent Wipes Rule

Storage

– Solvent-contaminated wipes must be accumulated, stored, and transported in non-leaking, closed containers.
– The containers must be able to contain free liquids, if they occur (for example, from compression of the wipes).
– Containers must be closed except when adding or removing wipes.
– A container must be sealed when the container is full, when the wipes are no longer being accumulated, and during transportation.
Solvent Wipes Rule

• Wipes accumulated in an open-head drum or container would be considered closed when the cover makes complete contact between the fitted lid and the rim.

• After accumulation and during transport, this same container must be sealed to meet this standard; thus, the rings must be clamped or bolted to the container.

Note, these examples are consistent with EPA’s closed container guidance (RCRA online 14826, 12/3/2009, and 11/2/2011).
Other examples that may meet the closed container standard:

- Containers with covers opened by a foot pedal (e.g. flip top or spring loaded lid) or with a self closing swing door;
- Bags can be used, provided they meet the standard (i.e. the neck of the bag is tightly bound and sealed, the bag is able to contain liquids, and is non-leaking).

Examples that do not meet the standard:

- Bags leaving a trail of liquid on the ground;
- Cardboard boxes.
Labeling

- Containers of solvent-contaminated wipes must be labeled: “Excluded Solvent-Contaminated Wipes”

- Containers must be labeled during accumulation, storage, and transportation
Solvent Wipes Rule

Accumulation Time Limit

• Solvent-contaminated wipes may be accumulated by the generator for up to 180 days from the start date of accumulation for each container.

• Generators must keep documentation that the 180-day accumulation time limit is being met.
Solvent Wipes Rule

No free liquids – the Heart of the Rule

• Solvent-contaminated wipes may not contain free liquids at the point of being sent for cleaning onsite or sent offsite for cleaning or disposal.

• “No free liquids” is defined in 260.10 and is determined using the paint filter liquids test (Method 9095B in SW-846).

• Generators must document the process they are using to meet the no free liquids condition.

• Free liquid spent solvent that is removed from the wipes is subject to hazardous waste regulation.
Solvent Wipes Rule

Recordkeeping

Generators must maintain the following documentation at their site:

• Name and address of the destination facility (laundry, combustor, or landfill) that is receiving the solvent-contaminated wipes;

• Documentation that the 180-day accumulation time limit is being met:
  – Could include a service contract specifying frequency of pick-up, a log that lists the start date of each container, or container labels with the start date.

• Description of the process the generator is using to meet the “no free liquids” condition:
  – Description of technologies, methods, sampling, or knowledge that a generator is using to ensure wipes container no free liquids at the point of transport.
Handling Facilities

- **Reusable wipes** must be sent to a laundry or dry cleaner whose discharge, if any, is regulated under section 301 (effluent discharge restriction) and 402 (permitting requirements) or section 307 (indirect discharge to a POTW) of the clean water act.

- **Disposable wipes** must go to either
  - A combustor regulated under section 129 of the clean air act or a hazardous waste combustor, boiler, or industrial furnace regulated under 40 CFR 264, 265, or 266 subpart H; or
  - A municipal solid waste landfill regulated under 40 CFR 258 or a hazardous waste landfill regulated under 40 CFR 264 or 265.

- **Storage/labeling requirement** continue to apply if solvent-contaminated wipes are stored at handlers.

**Any free liquids found by handling facilities must be removed and managed as hazardous waste!**
Solvent Wipes Rule

For more information on this rulemaking, (website includes a summary chart of the rule as well as FAQs) go to:

http://www.epa.gov/epawaste/hazard/wastetypes/wasteid/solvents/wipes.htm
Upcoming Regulations
Questions?

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