Pharmaceutical Waste Management for Minnesota Veterinary Facilities

Minnesota Veterinary Medical Association
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Jeff Hollar
President – PharmWaste Technologies, Inc.
515-276-5302 – jhollar@pwaste.com
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Regulations apply when discarding drugs.

- Scope of waste = pharmaceutical drugs.
- Does not include infectious or bio-hazardous medical waste.
- Some drugs are considered hazardous and stricter disposal regulations apply as opposed to being non-hazardous.
- States can enforce stricter rules than what is considered federally hazardous waste.
- Minnesota considers more drugs as hazardous than what is federally recognized by the EPA.
- In Minnesota: MPCA – Minnesota Pollution Control Agency
Additional Considerations

- The American Veterinary Medical Association’s (AVMA) Best Management Practices for pharmaceutical disposal indicates incineration as the preferred method of drug disposal and that no drugs should ever be drained disposed. [https://www.avma.org/KB/Policies/Documents/bmp_rxdisposalposter.pdf](https://www.avma.org/KB/Policies/Documents/bmp_rxdisposalposter.pdf)

- Minnesota’s Hazardous Waste Rules requires all hazardous waste generators to properly manage waste and that no municipal solid waste landfill in Minnesota is approved to take VSQG hazardous waste. (MN 7045.0208)
Why a pharmaceutical waste program?

- **Regulatory Compliance**
  - Federal Regulations: EPA – Environmental Protection Agency
  - State Regulations: MPCA – Minnesota Pollution Control Agency
  - County Regulations: 7 metropolitan counties in MN

- **Environmental Stewardship**
  - Reduce the amount of drugs in our water supply
Federally Hazardous Waste

- P-Listed – Carries EPA codes starting with P
- U-Listed – Carries EPA codes starting with U
- Characteristic Waste – Carries EPA codes starting with D
  - Ignitable
  - Toxic
  - Reactive
  - Corrosive
P-Listed Waste

- EPA defines this type of waste as acute.
- Since P-Listed waste is considered more hazardous than other types of waste generated, EPA requirements are more strict if you generate more than 1 kg (2.2 pounds) cumulatively.
- Example: WARFARIN SODIUM
U-Listed Waste

- Also an EPA listed waste, but considered not as hazardous as an acute waste.
- Example: DIETHYLSTILBESTROL
**Ignitability** 40 CFR 261.21

- Aqueous Solution containing at least 24% alcohol by volume and a flash point of <140° F (<60° C).
- Includes flammable aerosols
- EPA Waste Code is D001
- Example: BAYTRIL SOLUTION

**Corrosivity** 40 CFR Part 261.22

- Aqueous Solution whose pH is >= 12.5 or <=2.
- Acid if <= 2, Base if >=12.5
- EPA Waste Code is D002.
Reactivity (40 CFR Part 261.23)

- Wastes that are not stable under normal conditions.
- Nitroglycerin was exempted August 14, 2001 under Federal Register: May 16th 2001.
- EPA Waste Code is D003.
40 Chemicals and heavy metals that meet certain leaching concentrations as determined by a TCLP (Toxicity Characteristic Leaching Procedure)

Regulatory concentrations are measured in mg/l.
- M-cresol 200mg/l (D024), Silver 5mg/l (D011), Mercury .2mg/l (D009), more...

Example: DURAMUNE MAX 5-CVK/4L (Thimerosal preservative)
Generator status is determined by the type and amount of hazardous waste generated.

### EPA Generator Status

<table>
<thead>
<tr>
<th>Generator Status</th>
<th>P-Listed Waste Generated Monthly</th>
<th>All Hazardous Waste Generated Monthly</th>
</tr>
</thead>
<tbody>
<tr>
<td>CESQG</td>
<td>&lt; 1Kg (or)</td>
<td>&lt; 100 Kg</td>
</tr>
<tr>
<td>SQG (Small Quantity Generator)</td>
<td>&lt; 1Kg (or)</td>
<td>&gt; 100 Kg and &lt; 1000 Kg</td>
</tr>
<tr>
<td>LQG (Large Quantity Generator)</td>
<td>1 Kg = 2.2 lbs</td>
<td>&gt; 1000 Kg</td>
</tr>
<tr>
<td></td>
<td>100 Kg = 220 lbs</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1000 Kg = 2200 lbs</td>
<td></td>
</tr>
</tbody>
</table>
Benefits of a CESQG versus SQG and LQG

- Less paperwork and documentation
- Less regulations
- Easier compliance
- Easier implementation

MN – VSQG designation
State Hazardous Waste – Minnesota Lethal

- MPCA – Minnesota Pollution Control Agency
- MN01 – Minnesota Lethal
- Lethality Characteristic
  - Oral LD50 (rat) < 500 mg/kg
  - Dermal LD50 (rabbit) < 1000 mg/kg
  - Inhalation LC50 (rat) < 2000 mg/m³ or 1000 ppm
  - Problem: LD50 and LC50 data is not readily available
Alternate Method to Evaluate Pharmaceutical Waste for the Lethality Characteristic

- Proposed by MHA.
- Acceptable to MPCA
- Generator must petition the MPCA if the alternate method is wanting to be used.
The Alternate Method

- Lethal if any of the following are applicable to the drug:
  1. Carcinogen
  2. Chemotherapy agent
  3. Combination U/P-List drug
  4. Endocrine disruptor
  5. NIOSH hazardous drug
  6. OSHA hazardous drug

Generator must also check to see if drug is federally hazardous by the EPA.
Hazardous Drug Waste Disposal Options

- Licensed hazardous waste vendor
  - $$$
  - Drug waste not inventoried
- Licensed Reverse Distributor
  - Specific regulations must be followed
Reverse Distributor Considerations:

1. Licensed by Minnesota Pharmacy Board & DEA
2. Dispose of MN01 as hazardous waste
3. Management Plan by RD
4. Disposal Record:
   - Identify and inventory all drugs
   - Waste Codes
   - Disposal Method

- Additional MPCA requirements: Refer to MPCA guidance document Waste/Hazardous Waste #3.36b
Resources

- Minnesota Pollution Control Agency - www.pca.state.mn.us
- PharmWaste Technologies, Inc. – www.pwaste.com
- National Pharmaceutical Returns, Inc. – www.npreturns.com

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Why a pharmaceutical waste program?
- Compliance
- Environmental Stewardship

Federally Hazardous Waste
- P-Listed
- U-Listed
- D Waste Codes – Ignitability, Corrosivity, Reactivity, Toxicity

EPA Generator Status
- Determined by the type and amount of waste generated.

State Hazardous Waste – Minnesota Lethal (MN01)
- MPCA – Minnesota Pollution Control Agency – regulates state hazardous waste
- Lethality Characteristic defined
- Alternate Method
  - Carcinogen
  - Chemotherapy agent
  - Combination U/P-List drug
  - Endocrine disruptor
  - NIOSH hazardous drug
  - OSHA hazardous drug

Hazardous Drug Waste Disposal Options
- Licensed hazardous waste vendor
- Reverse Distributor
  - Licensed
  - Dispose MN01 as hazardous
  - Waste Management Plan
  - Disposal Record
  - More requirements

To learn more about disposal options, contact:

Jeff Hollar – Exhibit Booth #214
President – PharmWaste Technologies, Inc.
515-276-5302
jhollar@pwaste.com