

Briefing on RCRA and Pharmacies

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Agenda

- ❖ Welcome and Introductions
(Robert Schick, Director, Division of Environmental Remediation)
- ❖ Review of Technical Issues and Common Problems; Draft RCRA Guidance Document; Q & A
(Andrew English, Division of Environmental Remediation)
- ❖ Pharmaceutical Take Back – Issues and Opportunities; Q & A
(Bill Ottaway, Division of Environmental Remediation)
- ❖ Solutions:
 - ❖ Global Consent Order
(Robert Schick)
 - ❖ Environmental Audit Program
(Monica Kreshik, Office of General Counsel)
- ❖ Discussion
(Marc Gerstman, Executive Deputy Commissioner)
- ❖ Wrap up and next steps

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Common RCRA-C Violations and How to Prevent Them

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Common RCRA-C Violations at Retail Facilities

- Failure to make a hazardous waste determination
 - waste pharmaceuticals, ignitables (e.g., alcohols, solvents), corrosives (e.g., drain cleaner, batteries)
- Failure to properly manifest hazardous wastes
- Failure to properly train staff to manage HW
- Failure to properly manage universal wastes
- Incomplete/Incorrect understanding of rules for reverse distribution/reverse logistics
- Less than fifty-foot setback for storing ignitable wastes

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Typical Retail RCRA Facilities

- Pharmacies
- Food Suppliers with Pharmacies
- Home Improvement Stores
- Big-Box Stores
- Paint Suppliers

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Five Keys to RCRA Compliance Success

- Leadership Commitment to Compliance
 - corporate, regional, store
 - understanding of the requirements
- Individuals tasked/accountable for compliance
- Deliberate planning (Facility Compliance Plan)
- Deliberate training (Facility Training Plan)
- Deliberate implementation

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DEC Guidance to be Released

- Outline of Facility Compliance Plans
- Outline of Facility Training Plans
- Universal Waste Checklist
- Guidance on Reverse Distribution/Logistics

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Facility Compliance Plans

- How to accurately identify HW
- Determination of Facility Category
- Identify applicable facility standards
- Develop specific compliance measures
- Implement, Audit, Refine, and Repeat

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Facility Training Plans

- List Compliance Duties
- Assign Duties to Job Titles
- Identify Specific Employees
- Determine Training Content
- Determine Best Training Methods
- Implement Training
- Evaluate, Refresh, Refine



Universal Waste Management

- Identify waste managed
 - lamps, batteries, pesticides, mercury-containing equipment
- Labeling and Dating
- Storage Procedures
- Transportation
- Disposal



Reverse Distribution/logistics

- Definitions
- Common Pharmaceutical HW
 - Coumadin/warfarin, nicotine, multivitamins
- Eligibility for Reverse Distribution
 - Product or Waste?
 - Point of Determination
- Anticipated USEPA Proposal
- Reverse Logistics



Pharmaceutical Collection

Coordination with the New DEA Rule



Three Disposal Options

- Take-back events,
- Mailback programs, and
- **Collection receptacles.**
 - Retail pharmacies
 - Long term care facilities

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Collection receptacles at Retail Pharmacies

- Households only
- Accept comingling of controlled substances, hazardous waste pharmaceuticals and all other pharmaceuticals
- Encouraged to dump pills in loose
 - Dispose of packaging separately

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New DEA Rule

- Register with DEA as “Collectors”
- Cannot sort or handle (inner liner).
- Ship by common carrier or contract carrier to a reverse distributor (RD)
- RD would transport to MSW incinerator under 364 permit.

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Communication with USEPA

- EPA and DEC concur that the household hazardous waste exemption carries through
- We believe that DEA and EPA worked together to develop the proposed program and that it will be consistent with upcoming, EPA proposed rule (12/14).

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Existing Impediments

- HHW 373.4:
 - Must receive a permit or written approval
 - Transportation (4.2.c) 364 permit
 - Disposal (4.2.g) as hazardous
 - SEQR requirements
- Approval through household pharmaceutical collection variance request
- NYSDOH BNE (January 2015)

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Commissioner's Policy

- Regulations will be revised, but that takes time
- For now, a commissioner's policy will be drafted providing enforcement discretion to facilitate the collection practices provided by DEA's new rule
- Estimate 6 months to complete

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Environmental Audit Incentive Policy Goals

- Make it easier for the regulated community to return to compliance and stay in compliance
- Encourage and reward companies that go beyond compliance
- Maintain Robust Enforcement

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Penalty Waiver

- Waives gravity portion of potential civil penalty for those who voluntarily disclose
- Economic benefit portion may be waived
 - Where de minimus (\leq \$5,000)
 - By the amount invested in pollution prevention

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Voluntary Disclosure

- Scope:
 - Single violation
 - Multiple violations
 - Violations discovered pursuant to a partial or comprehensive Audit Agreement
 - Violations discovered through P2 and compliance assistance
- Must be disclosed:
 - Prior to government inspection
 - Prior to filing of report or complaint by third party
 - Within 30 days of discovery



Eligibility

- Any regulated entity, no matter the size
- Excluded violations
 - Repeat violations or disclosures (5 year look back)
 - Violations of Commissioner's order, Consent Order
 - Violations of written clean up agreements
 - Alleged criminal conduct
 - Violations discovered through inspection
 - Violations reported by a third party
 - Violations required to be self-reported
 - Violations resulting in NRD, serious actual harm, imminent and substantial endangerment



- Manner of Disclosure
- Correcting Violations
 - Includes measures to prevent future violations
 - Environmental management system are encouraged
 - P2 measures are encouraged
- New Owners
- Pollution Prevention Incentives
- For more information, visit the DEC website
<http://www.dec.ny.gov/regulations/93791.html>



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