Briefing on RCRA and Pharmacies
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Robert Schick, Division of Environmental Remediation
Andrew English, Division of Environmental Remediation
William Ottaway, Division of Environmental Remediation
Monica Kreshik, Office of General Counsel

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

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
Typical Retail RCRA Facilities

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

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

DEC Guidance to be Released

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

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
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

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

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.

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).
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)

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

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

Penalty Waiver

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