

Briefing and Panel Discussions on RCRA, Pharmacies, and DEC's Audit Policy

December 18, 2014

Moderated By: Darren Suarez, NYS Business Council

NYS Department of Environmental Conservation



Welcome and Introductions

- Representatives of:
 - Chain Pharmacy Association of NYS
 - Food Industry Alliance of NYS
 - Retail Council of NYS
 - Pharmacists Society of the State of NY
 - National Federation of Independent Business
 - The Business Council of NYS
 - NYS Department of Environmental Conservation

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Agenda

- ❖ Welcome and Introductions
- ❖ Applicability of RCRA to Pharmacies/Retail Sector
- ❖ Panel Discussion: RCRA Issues & Audience Questions
- ❖ NYSDEC Audit Policy: How it Works for You
- ❖ Panel Discussion: Audit Program & Audience Questions
- ❖ Summary and Next Steps

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Speakers and Panelists

- NYSDEC
 - Bill Ottaway, Div. of Environmental Remediation
 - Monica Kreshik, Office of General Counsel
 - Andrew English, Div. of Environmental Remediation
- Panelists
 - Joe Berman, Price Chopper
 - Richard Walka, Ellen DeOrsay, & Brian Veith, D&B Engineers & Architects, P.C.
 - Ted Wolf, Manatt, Phelps & Phillips, LLP

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Applicability of RCRA to Pharmacies/Retail Sector

Background and Basics

William Ottaway, P.E., Division of Environmental Remediation

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Resource Conservation and Recovery Act

- Enacted in 1976
- Subtitle C addresses hazardous waste
 - “Cradle to grave”
- Subtitle D addresses solid waste

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Any generator of HW, regardless of size, must:

1. Make HW determinations;
2. Direct HW to an authorized facility
 - (CESQG’s have more choices);
3. Meet transportation requirements (Part 364)
 - CESQGs can self-transport small amounts.
 - Note manifesting

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Generator Responsibility

- Any generator is ultimately responsible for the appropriate management of their hazardous waste, even if they engage a 3rd party to make the HW determination.

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Common Problems at Retail Facilities

- Not making a hazardous waste determination
 - waste pharmaceuticals, ignitables (e.g., alcohols, solvents), corrosives (e.g., drain cleaner, batteries)
- Manifesting hazardous wastes
- Adequate training of staff to manage HW
- 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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Hazardous Waste Determinations



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Overview

- To be a hazardous waste, a material must:
 - Meet the definition of solid waste
 - Not be exempted/excluded
 - Meet the definition of a listed or characteristic waste
- Generators of solid waste must determine whether their wastes are hazardous or nonhazardous.

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Is It a Solid Waste? 371.1(c)

EXAMPLES

- Discarded solid, semi-solid, liquid or gas
- Abandoned
- Inherently waste-like
- Recycled, burned for energy, reclaimed?



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Is It an Excluded Waste? 371.1(e)

- Domestic sewage
- Industrial wastewater discharges
- Radioactive wastes
- Reclaimed and reused spent wood preserving solutions
- Processed scrap metal
- Irrigation return flow
- In-situ mining waste
- Material reclaimed and reused in the original process

MORE EXAMPLES

- Some recycled materials
- Lab samples
- 'Empty' containers
- Household wastes



Is It a Listed Waste? 371.4(b)-(e)

EXAMPLES

- P- and U-Listed Wastes
 - F-Listed Wastes
 - K-Listed Wastes
 - PCB-Containing Wastes (NYS)
- P- and U-Listed (Unused): pesticides, pharmaceuticals, intermediaries
 - F-Listed (Used): Halogenated, non-halogenated solvents, wastewater treatment sludges from electroplating operations
 - K-Listed: (specific processes) API separator sludge, tank bottoms from petroleum refiners

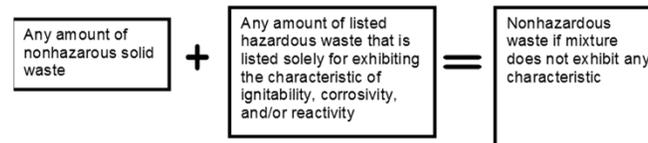
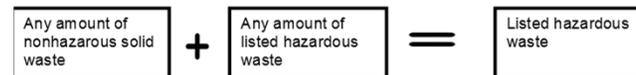


Is It a Characteristic Waste? 371.3 (b)-(e)

- Ignitable
 - Corrosive
 - Reactive
 - Toxic
- EXAMPLES
- >24% Alcohol
 - Spent sulfuric acid
 - Cyanide waste
 - Exceed Toxicity Characteristic Leaching Procedure (TCLP)



Is It Subject to the Mixture Rule? 371.1(d)(1)(d)



Summary

- To be a hazardous waste, a material must:
 - Meet the definition of solid waste
 - Not be exempted/excluded
 - Meet the definition of a listed or characteristic waste
- Generators of solid waste must determine whether their wastes are hazardous or nonhazardous.



HAZARDOUS WASTE DETERMINATION FORM

HAZARDOUS WASTE DETERMINATION FORM

SECTION I: WASTE DESCRIPTION

SECTION II: WASTE PROPERTIES, CHARACTERISTICS, AND COMPOSITION

SECTION III: REQUESTOR'S CERTIFICATION

On-Site Document Review

Waste Determination Forms/Records



Missing Waste Determinations

- Non-routine operating wastes
 - relamping
- Maintenance wastes
- Emissions control device waste
- Expired or unused products
- Aerosol cans
- Universal wastes
- Electronic wastes for recycling
- Spent solvents
- Photo or films
- Wastewater
- Plating wastes/sludges
- Floor sweepings



Common Wastes



- Pharmaceuticals
 - Warfarin
 - Nicotine
 - Some vaccines (mercury)
- Special notes
 - Phentermine
 - Epinephrine
 - Nitroglycerine

http://www.ecy.wa.gov/programs/hwtr/pharmaceuticals/pages/pu_metals.html



Note on Collections

- NYSDOH Bureau of Narcotics Enforcement
- *The Department of Health is working to update its regulations to allow for a program for the safe disposal of unused controlled substances by consumers in accordance with federal law. However, until such time as the corresponding State regulations are adopted, mail-back programs and collection receptacle locations for purposes of controlled substance disposal is not yet permissible in New York State.*



Common Wastes



MAINTENANCE ACTIVITIES

- Housekeeping
 - Aerosols
 - Unused or expired disinfectants
 - Paint or floor finishes



Common Wastes

MAINTENANCE GARAGES

- Oils
- Antifreeze
- Fuels such as gasoline
- Paints
- Aerosols
- Used rags
- Solvents
- Metal dusts
- Air Bags



Universal Waste (UW)

- Lamps – FLTs, CFLs, Metal halide, High pressure sodium, some incandescent bulbs, lead in solder
- Mercury containing equipment
- Batteries
- Certain pesticides



UW Notes

- Wastes managed as universal wastes don't count in determining generator category.
- e-waste is not a universal waste, but if directed for recycling doesn't count and is generally exempt from most HW regulations.



Your Generator Status

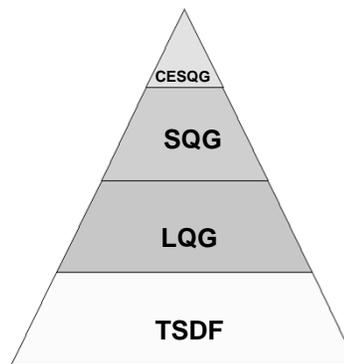


Generator Rules

- Facility category is determined on a monthly basis and based on amount generated NOT shipped.
- A generator can be classified as multiple facility categories during a calendar year.



HW Generation Rate



	Non-Acute HW (kg)	Acute HW (kg)	Acute HW Spill Clean Up (kg)
CESQG	≤100	≤1	≤100
SQG	>100 – <1,000	≤1	≤100
LQG	>1,000	>1	>100
TSDF	See permit		



RCRA Generator Requirements			
REQUIREMENT	*LQG	*SQG	*CESQG
WASTE DETERMINATION	Yes	Yes	Yes
EPA ID NUMBER	Required	Required	Not Required
NON-ACUTE WASTE LIMITS	Greater or equal to 1000 kg/mo (2200 lb/mo).	Between 100-1000 kg/mo (220-2200 lb/mo).	Less than or equal to 100 kg/mo (220 lb/mo).
ACUTE WASTE LIMITS	More than 1 kg/mo (2.2 lb/mo) and more than 100kg/mo. Of contaminated spill cleanup materials	Less than or equal to 1 kg/mo (2.2 lb/mo)	Less than or equal to 1 kg/mo (2.2 lb/mo)
ON-SITE ACCUMULATION LIMITS	No Limit.	6000 kg. (13,200 lbs) Or less.	1000 kg. (2200 lbs) or less.
ACCUMULATION TIME LIMITS	90 days or less.	180 days or less. 270 days or less (if transported more than 200 miles).	None
SATELLITE ACCUMULATION AREA	55 gallons non-acute or 1 quart acute HW at or near the point of generation.	55 gallons non-acute or 1 quart acute HW at or near the point of generation.	Same as on-site accumulation.
HAZARDOUS WASTE STORAGE AREA	Full requirements for management of tanks and containers.	Basic requirements with technical standards for tanks and containers.	None
MANIFEST	Required	Required	Not Required
ANNUAL HAZARDOUS WASTE REPORT	Required	Not Required	Not Required
SECONDARY CONTAINMENT	Storage of greater than 185 gallons of liquid over sole source aquifers.	Storage of greater than 185 gallons of liquid over sole source aquifers.	None
CLOSURE PLAN	Storage of greater than 185 gallons of liquid over sole source aquifers.	Not Required	Not Required
PERSONNEL TRAINING	Written Training Program Required	Basic Training Required	Not Required
CONTINGENCY PLAN	Required	Not Required	Not Required
PREPAREDNESS AND PREVENTION	Required	Required	Not Required
LAND DISPOSAL RESTRICTION	Required	Required	Not Required



Nicotine Products

- Acute HW
 - If you generate more than 2.2 lbs. in a month, you are a LQG
 - Many of the most significant LQG requirements kick in when you store a hazardous waste



Note on Containers

- Containers for P-Listed wastes
 - Policy DSH-HW-03-17 Counting of Container and Packaging Weights
 - Triple rinsing is often not a reasonable alternative



FINAL POINT

- Laws and regulations change
- Compliance officers must keep current with changes
- A variety of resources are available to help keep current
 - Our Universal Waste page will be updated soon



Panel Discussion: RCRA Issues

- Panelists
 - Bill Ottaway, NYSDEC
 - Joe Berman, Price Chopper
 - Ellen DeOrsay, & Brien Veith, D&B Engineers & Architects, P.C.
 - Ted Wolf, Manatt, Phelps & Phillips, LLP

Responses to Audience Questions



NYSDEC Audit Policy: How it Works for You

Obtaining an Audit Agreement

Monica Kreshik, Esq., Office of General Counsel



Environmental Audit Incentive Policy Goals

- Make it easier for the regulated community to come into compliance and stay in compliance
- Provide time for facilities to come into compliance while maintaining a strong enforcement position
- Encourage and reward companies that go beyond compliance



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 or multiple violations
 - Violations discovered pursuant to an 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
- Policy Implementation to Date
- For more information, visit the DEC website

<http://www.dec.ny.gov/regulations/93791.html>



Obtaining an Audit Agreement

- **Steps**
 - Invitation to participate in Audit Program (January)
 - Opt-in period (45 days)
 - Sign Audit Agreement
 - Template on DEC Website
 - Scope (RCRA, P2 commitments, other)
 - Identify qualified personnel or consultant to conduct Audit
 - Complete Audit and Submit Disclosure Report
 - Implement Corrective Action
 - Acknowledge Corrective Action Complete
 - Final sign off and release from penalties by DEC



Conducting Compliance Audits

Implementation Options

Andrew English, P.E., Division of Environmental Remediation

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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 & monitoring

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DEC Online Guidance

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

<http://www.dec.ny.gov/chemical/99555.html>

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Options for Conducting Audits

- Outside Resources
- Inside Resources
- Driven Internally with Outside Assistance

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Audits Driven w/Outside Resources

- Least short-term impact on internal staff
- Important to find a consultant w/NY RCRA experience
- Less long-term impact/sustainability



Audits Driven w/Inside Resources

- High short-term impact on internal staff
 - May need time to develop internal expertise
 - Less capacity for other tasks
- Greater risk of errors
- Longer to complete audit process but more sustainable



Audits Driven Internally Supplemented by Outside Resources

- Significant short-term impact on internal staff
 - May need time to develop internal expertise
 - Less capacity for other tasks
- Moderate risk of errors
- Intermediate time to complete audit & significant sustainability



Outside Resources: Issues to Consider

- How many consultants?
- Consistency among consultants
- Training/preparation of consultants
- It always comes down to individuals
- DEC assistance



Inside Resources: Issues to Consider

- RCRA is one of many environmental/health & safety programs to manage
- RCRA is complicated and specialized
- Cost of training (and cost of non-compliance)
- It always comes down to individuals
- DEC assistance



Panel Discussion: Audit Program

• Panelists

- Monica Kreshik & Andrew English, NYSDEC
- Joe Berman, Price Chopper
- Richard Walka, D&B Engineers & Architects, P.C.
- Ted Wolf, Manatt, Phelps & Phillips, LLP

Responses to Audience Questions



Summary and Next Steps

