STATE OF CONNECTICUT
DEPARTMENT OF ENVIRONMENTAL PROTECTION

Gina McCarthy, Commissioner

Managing Pharmaceutical Waste
Connecticut Hospital Roundtable
September 8th, 2005

Charlotte Smith, R. Ph., M.S.
csmith@pharmecology.com
www.pharmecology.com
262-814-2635

Goals for Today's Program

- To develop a better understanding of the regulatory and environmental reasons for managing pharmaceutical waste more stringently
- To understand how federal hazardous waste rules impact pharmaceutical waste management in hospitals
- To consider specific Connecticut requirements
- To examine tools to assist in assessing current policies and procedures and developing a compliant and cost-effective pharmaceutical waste management plan

Increasing Focus on Pharmaceutical Waste

- "Cradle-to-Cradle Stewardship of Drugs for Minimizing Their Environmental Disposition While Promoting Human Health."
  - Dr. Christian Daughton, Chief, Environmental Chemistry Branch, USEPA National Exposure Research Laboratory
  - http://www.h2e-online.org/tools/chem-pharm.htm
- Warning: Side Effects Can Be Severe, Common drugs are seeping into our lakes, fish, and water supply. May 5, 2005 Milwaukee Journal/Sentinel
- Pharmaceuticals in Waterways Raise Concern: Effect on Wildlife, Humans Questioned. Washington Post, July 23, 2005

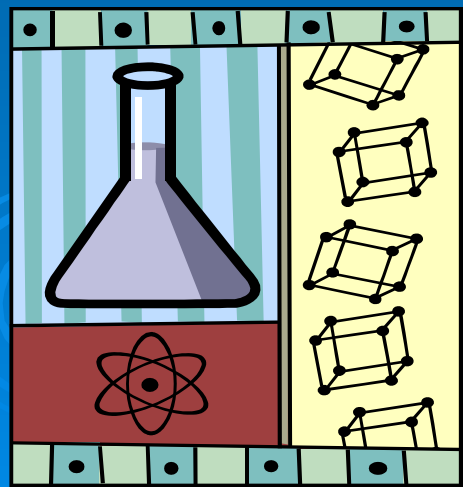
USGS Water Quality Study*

- First nationwide reconnaissance of occurrence of pharmaceuticals, hormones, other organic wastewater contaminants – March, 2002
- 139 streams in 30 states, analyzed for 95 different OWCs
- 82 of the 95 detected in at least one sample
- One or more OWCs found in 80% of stream samples
- 13% of sites had more than 20 OWCs
- Feature in Time Magazine, August 25, 2003 on continuing research
- Minnesota Study: Found 79 out of 92; 23 were pharmaceuticals

*http://toxics.usgs.gov/pubs/OFR-02-94/index.html

Below the Dose/Response Curve: Endocrine Disruptors

- Endocrine Disruptors: chemicals that interfere with the normal function of the endocrine system (glands including thyroid, adrenals, ovaries, testicles)
- Mimic hormone, trigger identical response, block a hormone
- Do not follow the normal dose/response curve
- Active at much lower doses, especially in the fetus and newborn
- Estradiols, progesterone, testosterone
- Lindane



Playing in an Ecosystem Near You

- Low sperm counts(50% reduction since 1939)
- Infertility
- Genital deformities
- Hormonally triggered human cancers
- Neurological disorders in children
  - Hyperactivity, attention deficit
  - Lowered IQ, rage reaction
- Developmental & reproductive problems in wildlife
- www.ourstolenfuture.org

Effects of Pharmaceuticals on Aquatic Organisms

- Drugs tested
  - Clofibric acid and naproxen sodium at 1000 nanograms/l (1 ppb) and 100 nanograms/l
- Test was to have been run for one week
- Had to terminate after 24 hours
- Clofibric acid induced milky, mucous response, difficulty with respiration, severe motility inhibition
- Naproxen effected behavior (slower), not as dramatic
- Also examined gene expression

Courtesy of Rebecca Klaper, Great Lakes WATER Institute

Impact on Exposure to Multiple Drugs on Daphnia

- Daphnia – the lab animal for water research
- Test involved clofibric acid, fluoxetine, erythromycin, triclosan, and trimethoprim
- Reproduction was disrupted to varying degrees indicating stress on organisms
- Most dramatic effect: significant increase in mortality in combo solutions

Colleen M. Flaherty, Stanley I Dodson. Effects of pharmaceuticals on Daphnia survival, growth, and reproduction. Chemosphere, In press, 2005.

Are We in Trouble…..Or Not???

- In the absence of definitive data, the argument has been made that the presence of EDCs, (including but not limited to drugs), and other drugs, many of which are not EDCs but include antibiotics, anti-cholesterol products, psychoactives, etc. is not an issue.
- In the absence of definitive data, others promote the Precautionary Principle

Precautionary Principle

- "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically." Wingspread Conference, Racine, WI 1998

EPA Conference on Pharmaceuticals in the Environment

- First ever conference of this nature, held August 23rd – 25th, 2005 in Las Vegas, EPA National Exposure Research Lab
- Multiple research reports on the ocurrence of common drugs in surface, ground and drinking water
- Multiple stakeholders in attendance, including EPA, DEA, PhARMA, Veterans Administration (Pharmacy, Safety), academia, private industry
- Developed priority action items to be explored involving regulatory changes, voluntary take-back programs, better research methods, etc.

Hospitals for a Healthy Environment

2004 Champion for Change Award

- Enhanced focus on hazardous waste and pharmaceutical waste
  - http://www.h2e-online.org/tools/chem-hwm.htm
  - http://www.h2e-online.org/tools/chem-pharm.htm
- EPA grant to H2E to develop a pharmaceutical waste management blueprint
- EPA grant to H2E to train JCAHO inspectors on environmental issues
- www.h2e-online.org

Hospitals for a Healthy Environment™

- Healthcare Environmental Resource Center
- Funded by EPA Office of Enforcement and Compliance Assistance and H2E
- Launched in April, 2005
- Environmental Compliance and Improvement Guide
  - "To improve compliance with JCAHO Environment of Care Standards"
  - http://www.hercenter.org/regsandstandards/jcahointro.html
- Hazardous waste determination
  - http://www.hercenter.org/hazmat/hazdeterm.html

Increasing USEPA Regulatory Activity

- EPA Region 2 (NY, NJ, Puerto Rico, VI) contacted 480 hospitals in 2003; Rx waste included.
- Region 2 Website: http://www.epa.gov/region02/healthcare/
  - North Shore University Hospital, Manhasset, NY fined $40,000 (July 2003)
    - http://www.epa.gov/Region2/news/2003/03066.htm
  - Nassau University Medical Center, East Meadow, NY fined $279,900 (Oct. 2003)
    - http://www.epa.gov/region2/news/2003/03127.htm
  - Mountainside Hospital, Montclair, NJ fined $64,349 (Nov. 2003)
    - http://www.epa.gov/Region2/news/2003/03139.htm
  - Memorial Sloan Kettering Cancer Center, New York , NY, fined $214,420
    - http://www.epa.gov/region02/news/2004/04008.htm

Region II Statement

“Hospitals and healthcare facilities must consider the proper handling of hazardous waste an integral part of their mandates to protect people's health,” said Jane M. Kenny, EPA Regional Administrator.

“Chemotherapy waste is an especially toxic waste produced by many medical facilities. Hazardous waste regulations are in place to help to ensure that facilities like Sloan-Kettering do not release these or other toxic chemicals into the environment.”

Region I Activity

- EPA Region 1 New England contacted 250 hospitals in April, 2004
- Website: http://www.epa.gov/NE/pr/2004/apr/040407.html
  - Enforcement initiative in New England
  - H2E grants: Pharmaceutical Waste and JCAHO inspector training
- Veterans Administration Hospital, White River, Vermont, August 5th, 2005
  - Cited and fined $372,254 for hazardous waste violations
  - Largest fine issued to a federal facility by Region I
- “It is critical that all federal facilities which use or generate hazardous wastes, including VA hospitals, comply with laws designed to protect public health and the environment,” said Robert W. Varney, regional administrator of EPA’s New England regional office. "The proper storage and handling of hazardous wastes really translates to ensuring protection for people, for the environment and for property."

Increasing State Regulatory Activity

- **Florida**
  - Hospitals, drug wholesalers, and reverse distributors audited and fined in the past several years
- **Washington State**
  - Managing Pharmaceutical Waste website: http://www.ecy.wa.gov/programs/hwtr/pharmaceuticals/index.html
  - Offered pharmaceutical waste training program October, 2003
- **California**
  - Management of Pharmaceutical Medical Waste, October, 2002
  - Memo on sewer disposal of drugs, September, 2003 Tri-TAC
- **Minnesota**
  - Offered pharmaceutical waste training program, October, 2003
  - Inspections began summer of 2004
  - Enforcement began July 1, 2005

Joint Commission
on Accreditation of Healthcare Organizations

New Initiatives at JCAHO

- Adding healthcare engineers to survey teams
- Beginning to ask questions about waste disposal
- H2E training JCAHO surveyors on environmental issues

Relationship to JCAHO Standards: Medication Management

- Standard MM.4.80
  - *Medications returned to the pharmacy are appropriately managed.*
- Elements of Performance MM.4.80
  - 3. *The organization has a process in place that addresses how outside sources, if any, are used for destruction of medications.*

Relationship to JCAHO Standards: Environment of Care

- **Standard EC.3.10**
- ***The organization manages its hazardous materials and waste[1] risks.***

[1] Hazardous materials (HAZMAT) and wastes. Materials whose handling, use, and storage are guided or regulated by local, state, or federal regulation. Examples include OSHA's Regulations for Bloodborne Pathogens (regarding the blood, other infectious materials, contaminated items which would release blood or other infectious materials, or contaminated sharps), the Nuclear Regulatory Commission's regulations for handling and disposal of radioactive waste, management of hazardous vapors (such as glutaraldehyde, ethylene oxide, and nitrous oxide), ***chemicals regulated by the EPA, Department of Transportation requirements***, and hazardous energy sources (for example, ionizing or non-ionizing radiation, lasers, microwaves, and ultrasound.)

Relationship to JCAHO Standards: Environment of Care

- **Rationale for EC.3.10**
- ***Organizations must identify materials they use that need special handling and implement processes to minimize the risks of their unsafe use and improper disposal.***

Relationship to JCAHO Standards: Environment of Care

- **Elements of Performance for EC.3.10**
- ***1. The organization develops and maintains a written management plan describing the processes it implements to effectively manage hazardous materials and wastes.***
- ***2. The organization creates and maintains an inventory that identifies hazardous materials and waste used, stored, or generated using criteria consistent with applicable law and regulation (for example, the Environmental Protection Agency [EPA] and the Occupational Safety and Health Administration [OSHA]).***

Relationship to JCAHO Standards: Environment of Care

- **Elements of Performance for EC.3.10**
- ***3. The organization establishes and implements processes for selecting, handling, storing, transporting, using, and disposing of hazardous materials and waste from receipt or generation through use and/or final disposal, including managing the following:***
- ***Chemicals***
- ***Chemotherapeutic materials***
- Radioactive materials
- Infectious and regulated medical wastes, including sharps
- See also 4. through 10

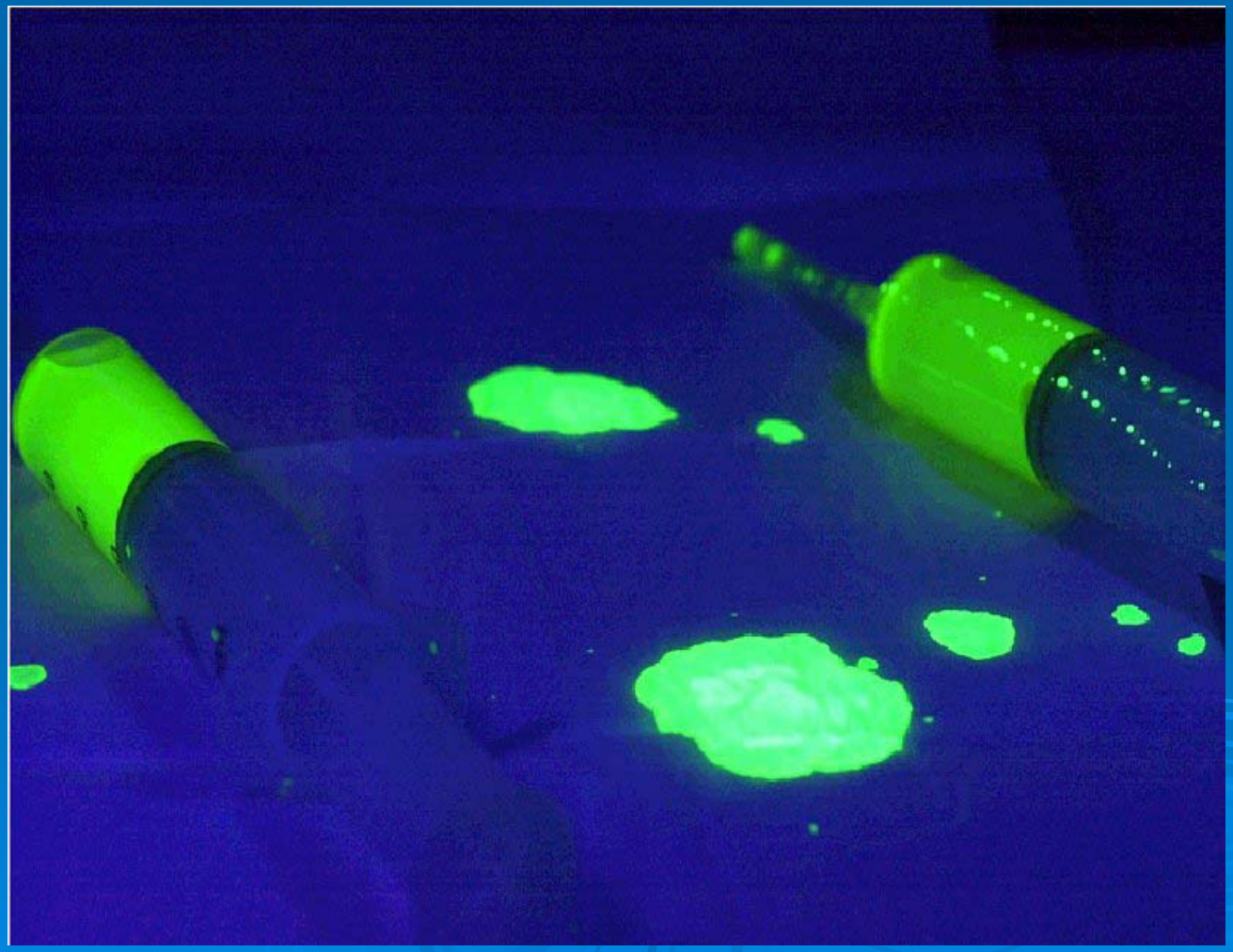
NIOSH Hazardous Drug Alert

- National Institutes of Occupational Safety & Health
- Non-enforcement arm of OSHA, administered under Centers for Disease Control (CDC)
- Hazardous Drug Work Group met for 4 years
- Recently released comprehensive new guidelines for total life cycle management of OSHA “Hazardous Drug”
- Identifies “hazardous waste” and need for appropriate disposal
- http://www.cdc.gov/niosh/topics/hazdrug/

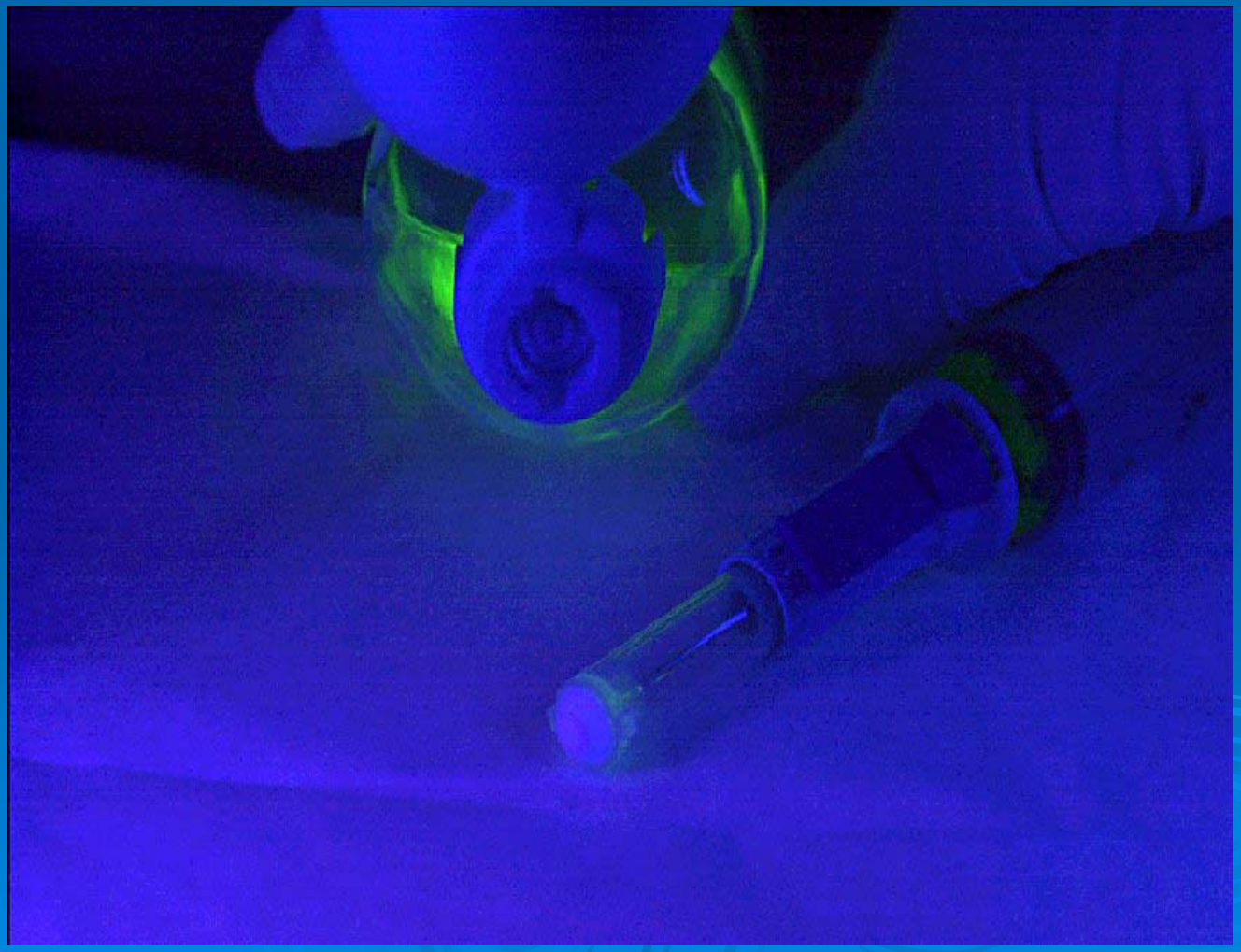
Fluorescein Study

- Conducted at MD Anderson Cancer Center
- Performed with fluorescent dye
- Inspected with UV light
- Evaluated contamination during
  - Drug reconstitution
  - Drug transfer
  - Drug administration

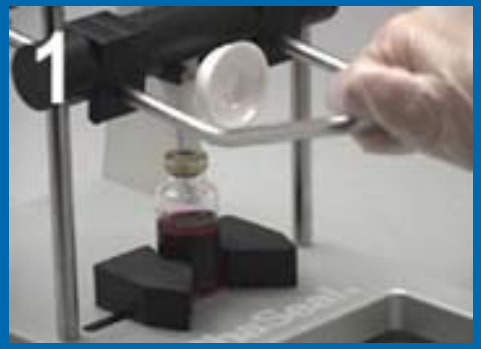
Drug Reconstitution with Needle and Syringe



Drug Preparation with Closed System



Using the PhaSeal Closed Transfer System



http://www.phaseal.com/siteUS/default.asp

Chemo Decontamination

- Clean work surfaces with an appropriate deactivation (if available) and cleaning agent before and after each activity, at the end of the workday
- Decontamination should be done with sodium hypochlorite followed by sodium thiosulfate to deactivate the chemo agent. SurfaceSafe offers a convenient towelette system (http://www.supergen.com/subpages/products/products.asp)
- Dispose of trace contaminated items in yellow/white chemo container

How is Pharmaceutical Waste Generated at the Healthcare Facility?

- IV Preparation
- General Compounding
- Spills/Breakage
- Partially Used Vials
- Partially Used Syringes/IVs
  - If Contaminated, Biohazardous
- Discontinued, Unused Preparations
- Unused Repacks (Unit Dose)
- Patients' Personal Medications
- Outdated Pharmaceuticals

When is an Outdated Drug a Waste?

- At the time and place the decision is made to discard it
- Two EPA guidance letters to the industry:
  - Merck & Co., 1981
  - BFI Pharmaceutical, 1991

  Note: These letters are being revisited by EPA and states.
- Enables shipping of potentially creditable outdates to a reverse distributor as product
- PROHIBITS the shipping of waste-like items, such as unused IVs, partial vials, expired repacks, samples
- Hospital is responsible for doing due diligence in the selection of a reverse distributor

Where is Pharmaceutical Waste Generated?

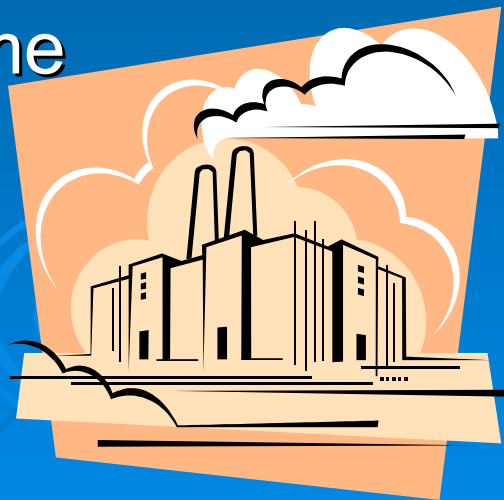
- Pharmacy/Satellites
- Patient Care Units
- ER/OR
- ICU/CCU/NICU
- Oncology/Hematology and other outpatient clinics
- Long Term Care Facilities
- Home Health Care Services

What Departments Get Involved in Generating and Managing Pharmaceutical Waste?

- Pharmacy
- Nursing
- Infection Control
- Environmental Services
- Safety
- Facility Management
- Risk Management
- Purchasing

Everything You NEVER Wanted to Know About Incinerators…..

- Municipal Incinerator
  - Permitted to burn municipal “garbage”
  - Usually not permitted to handle infectious waste
  - May be permitted to handle non-hazardous pharmaceuticals, with certain volume restrictions



Regulated Medical (Infectious) Waste Incinerators

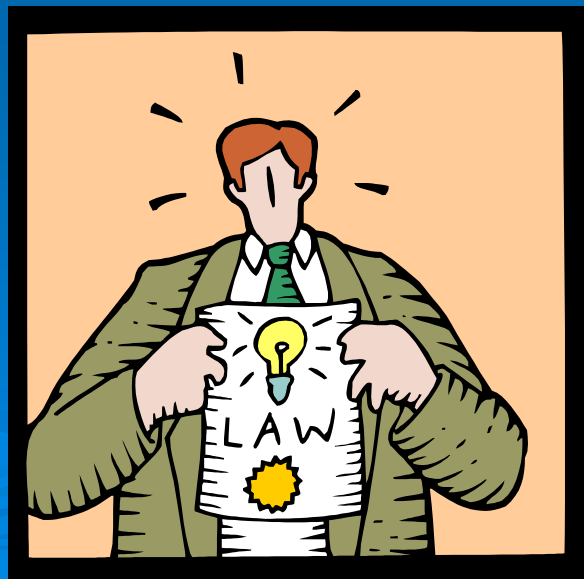
- Permitted by USEPA and the state to accept pathology waste, red bag and red sharps waste, trace chemo waste
- May be permitted to accept non-hazardous pharmaceutical waste
- Regulated under the Clean Air Act
- Lower temperature, less controls than TSDF
- Ash disposed of in a municipal (non-hazardous) landfill; may or may not be lined

Hazardous Waste Incinerators

- Permitted by USEPA, known as a Treatment, Storage and Disposal Facility (TSDF)
- High temperature, molecular bonds broken
- Pollutants scrubbed, emits only water vapor, ash stored in a lined, hazardous waste landfill
- Authorized to accept the “worst of the worst” hazardous chemicals, shipped on a 5-part manifest
- Examples:
  - Clean Harbors
  - Heritage
  - Onyx
  - Teris

RCRA: The Defining Regulation

- Resource Conservation & Recovery Act
  - Enacted in 1976, enforced by the EPA
  - Federal regulation of the disposal of solid wastes
  - Encourages the minimization of waste generation
- Defines “hazardous waste”
- “Cradle to Grave” tracking of hazardous waste
- Households are exempt



RCRA Risk Management & Liability

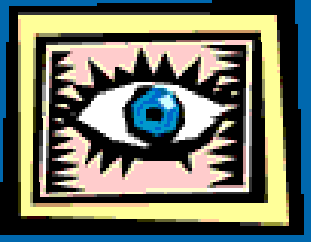
- Civil and criminal liability
  - Civil: State/USEPA enforcement
  - Criminal: FBI, Chief State's Atty., Grand Jury
- Corporate fines: up to $100,000 per violation per day
- Personal liability: fines and/or imprisonment
- No statute of limitations (civil)
- Managers up through CEO

Which Discarded Drugs Become Hazardous Waste?

- P-listed chemicals
  - Sole active ingredient
- U-listed chemicals
  - Sole active ingredient
- Characteristic of hazardous waste
  - Ignitability
  - Toxicity
  - Corrosivity
  - Reactivity

Hazardous Waste Segregation Can be FUN!

- Mix and Match opportunity to apply hazardous waste information to real life simulations
- Keep an eye out for the "All Seeing Eye"
- Watch for **BOLDED ITEMS**

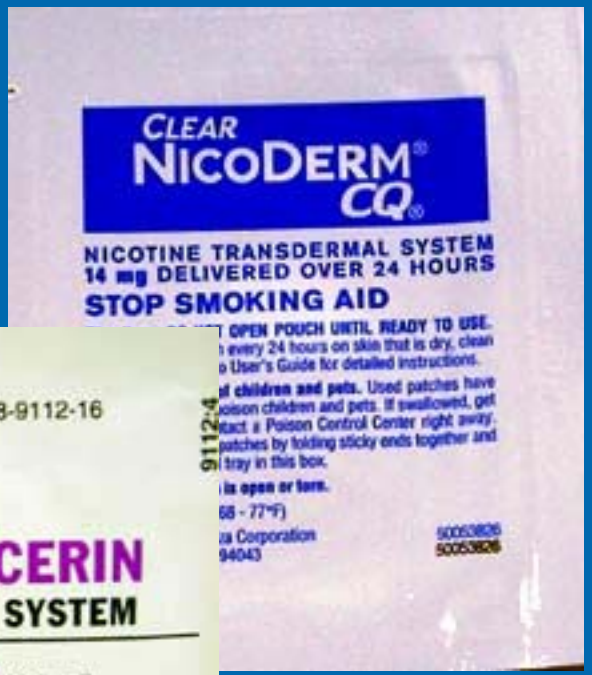


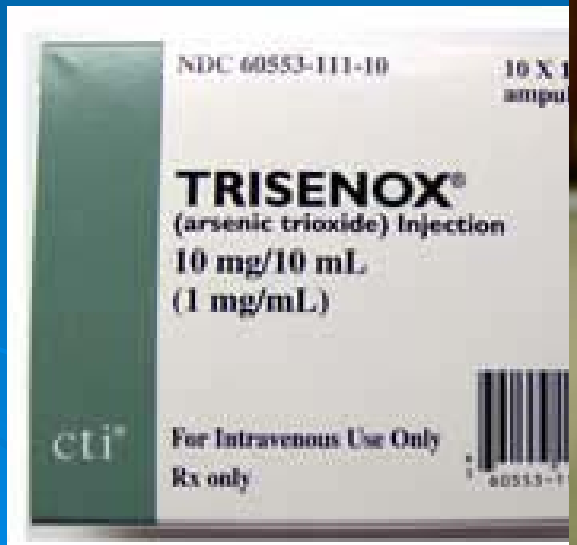
Examples of P-Listed Pharmaceutical Waste

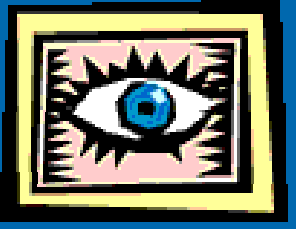
Arsenic trioxide	P012
Epinephrine	P042
Nicotine	P075
Nitroglycerin*	P081
Phentermine (CIV)	P046
Physostigmine	P204
Physostigmine Salicylate	P188
Warfarin >0.3%	P001

*Excluded from the P list federally; not yet in CT, planned for 2006

Examples of P-Listed Pharmaceuticals



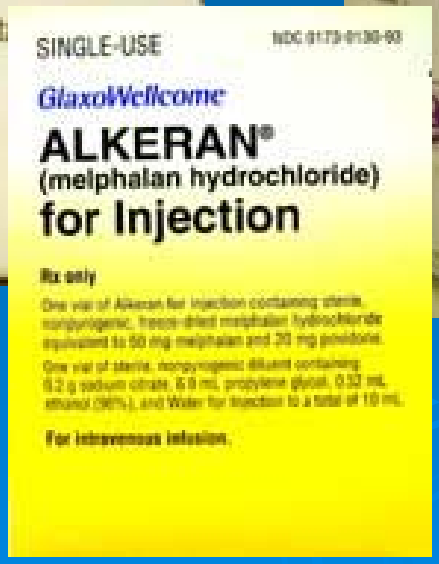




Examples of U-listed Pharmaceutical Waste

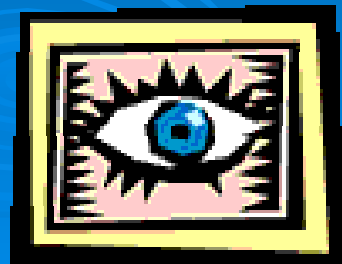
- Chloral Hydrate(CIV) U034
- *Chlorambucil* U035
- ***Cyclophosphamide*** **U058**
- *Daunomycin* U059
- *Diethylstilbestrol* U089
- ***Melphalan*** **U150**
- *Mitomycin C* U010
- *Streptozotocin* U206
- **Lindane** **U129**
- Saccharin U202
- Selenium Sulfide U205
- *Uracil Mustard* U237
- Warfarin<0.3% U248

Examples of U-Listed Pharmaceuticals

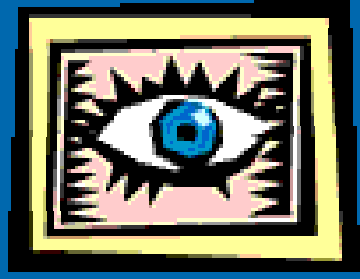


Chemotherapy Waste Summary

- Eight chemotherapy agents are U-listed; one is P-listed
- Medical waste hauler protocols for “Chemo Waste”
  - Empty vials, syringes, IV’s
  - Treated as infectious medical waste preferably through regulated medical waste incineration
- **If not empty, should be placed into Hazardous Waste container**



Definition of “Empty”



- “P” List

  Containers of “P” listed chemicals are considered hazardous waste, **unless they have been rinsed three times and the rinsate discarded as hazardous waste.**

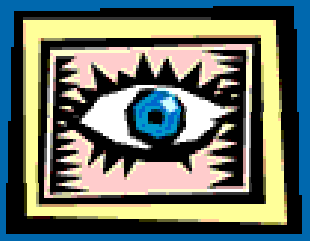
- “U” List

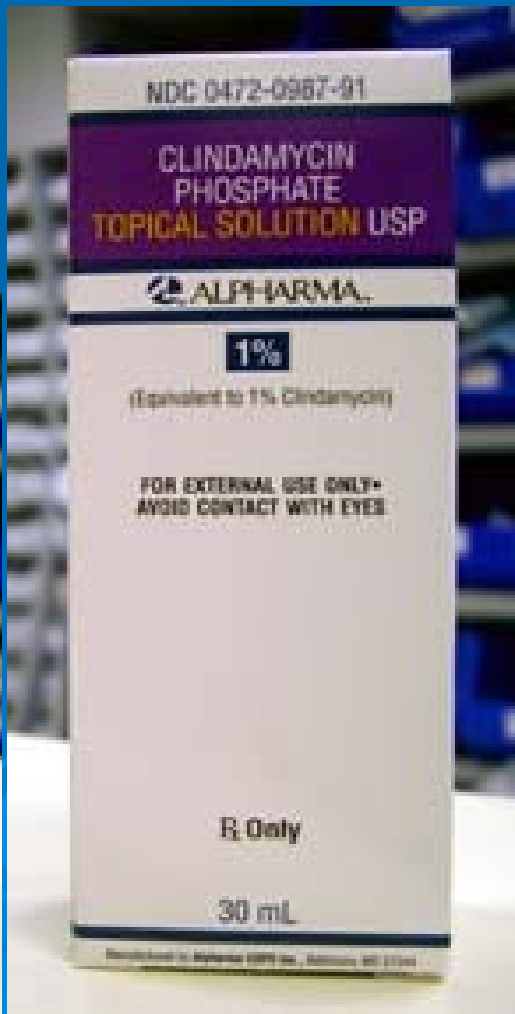
  Containers of “U” listed chemicals are empty only when

  - **All contents removed that can be removed through normal means**
  - **And no more than 3% by weight remains**

Characteristic of Ignitability

- Aqueous Solution containing 24% alcohol or more by volume & flash point<140° F.
- Hazardous Waste Number: D001
- Rubbing Alcohol
- Topical Preparation
- Injections





Characteristic of Corrosivity

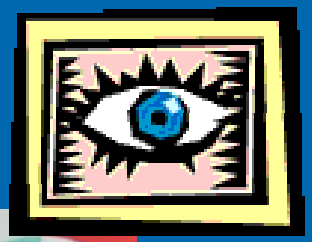
- An aqueous solution having a pH < or = 2 or > or = to 12.5
- Examples: Primarily compounding chemicals
  - Glacial Acetic Acid
  - Sodium Hydroxide
- Hazardous waste number: D002

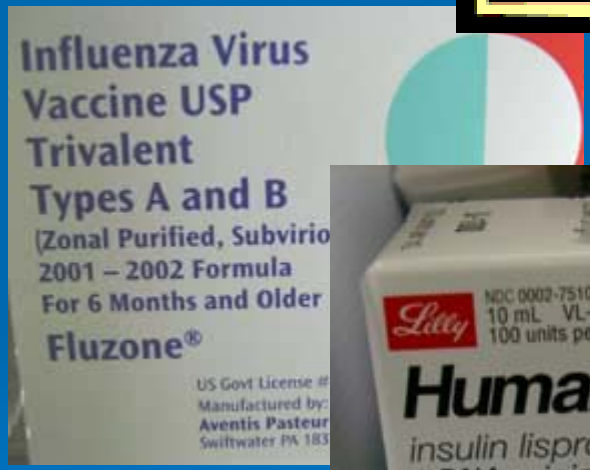
Characteristic of Toxicity

- Approximately 40 chemicals which meet specific leaching concentrations
- Examples of potential toxic pharmaceuticals:
- Arsenic
- Barium
- Cadmium
- Chloroform
- Chromium
- Lindane
- m-Cresol
- **Mercury (thimerosal)**
- (phenylmercuric acetate)
- Selenium
- Silver

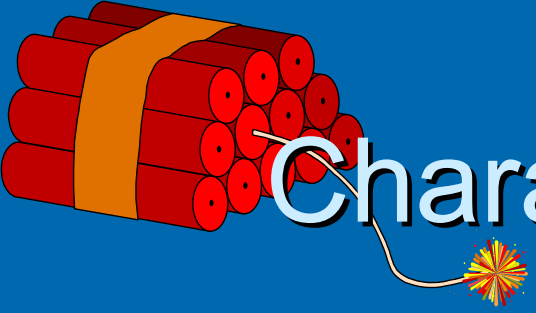
Examples of Pharmaceuticals Exhibiting the Characteristic of Toxicity

Heavy Metals: Selenium, Chromium and Silver



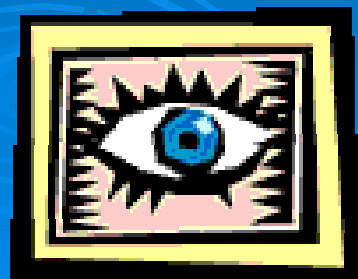


Preservatives: thimerosal & m-cresol



Characteristic of Reactivity

- Meet eight separate criteria identifying certain explosive and water reactive wastes
- Nitroglycerin formulations may be considered excluded federally from the P081 listing as non-reactive as of August 14, 2001 under FR: May 16, 2001, unless they exhibit another characteristics, such as ignitability.
- Connecticut has not yet adopted the federal exemption, but will be doing so in 2006. **Nitroglycerin must continue to be managed as P listed hazardous waste.** Some preparations are also ignitable, which takes precedence for packing purposes.
- Hazardous Waste Number for reactives: D003



Hazardous Waste Generation Status in CT

- Large Quantity Generator (LQG): (1) generates more than 1000 kg/month of hazardous waste or >1 kg/month “P” listed waste, OR (2) accumulates more than 1000 kg of hazardous waste at any one time.
- Small Quantity Generator (SQG):Generates <1000 kg/month but >100 kg/month of hazardous waste & < or = 1 kg/month “P” listed waste.
- Conditionally Exempt Small Quantity Generator (CESQG): Generates < or = 100 kg haz waste/month, < or = 1kg “P” listed waste/month

Impact of P-listed Waste on Generator Status

- Only 1 kg or 2.2 pounds/month cause facility to become a large quantity generator
- Weights of P-listed drug waste must be combined with any other P-listed waste generated at the facility in a given month
- Technically, containers that have held P-listed wastes are not “RCRA empty” unless they are triple rinsed and the rinsate discarded as hazardous
  - **Exception: EPA Hotline guidance exempts used epinephrine syringes which can be discarded as infectious waste**

Documenting Generator Status

- Large quantity generator: no need to record P waste separately.
- Small or conditionally exempt small quantity generator: need to segregate all P-listed including empty containers and document weights per calendar month
- Cannot exceed 1 kg or 2.2 lbs/month for any given month

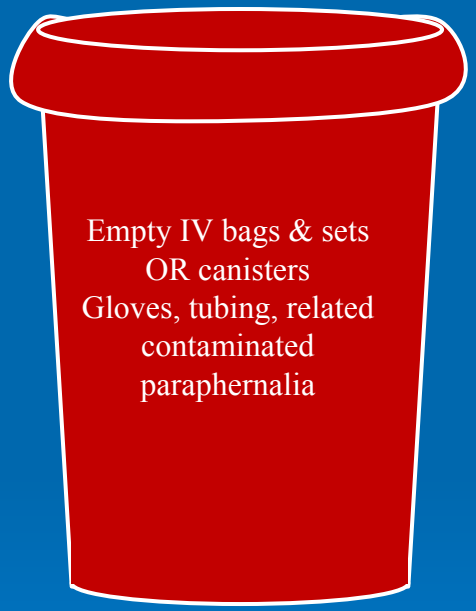
Where are Waste Drugs Going Today?

- Sewer System
  - Unused, partial IVs, including antibiotics
  - Compounding residues
  - Liquids
- Red Infectious Waste Sharps Containers, Bags
- Yellow or White Chemotherapy Sharps Containers, Bags
- Hazardous Waste Containers ????

Hospital Waste Management: A World Unto Itself

- Red-bag, red sharps: infectious, blood borne
- Yellow or White sharps: trace chemotherapy vials
- Yellow or White bags: trace chemotherapy gowns, gloves, goggles, tubing, etc.
- Black or Dark Blue: RCRA Hazardous waste: chemicals (pharmaceuticals) defined as hazardous by USEPA;
- White with Blue Top: Non-hazardous pharmaceutical waste (Best Management Practice)
- Drain: In CT, concentrated wastes not allowed.
- DEP permit required to discharge pollutants in quantities that will not adversely affect POTW/ cause pollution.

Red Bag Waste



Regulation:	CT BMW Regs., RCSA 22a-209-15 Blood Borne Pathogens, OSHA
Acronym:	RMW: Regulated Medical Waste
Contents:	Pourable, squeezable, flakable, drippable, blood, body fluids (state specific)
Treatment:	Primarily autoclave, microwave
Purpose:	Render materials non-infectious, non-recognizable (most states)
Final Disposition:	Non-hazardous landfill

Red Sharps Waste

Regulation: CT BMW Regs., RCSA 22a-209-15
Blood Borne Pathogens, OSHA

Acronym: BMW: Biomedical Waste

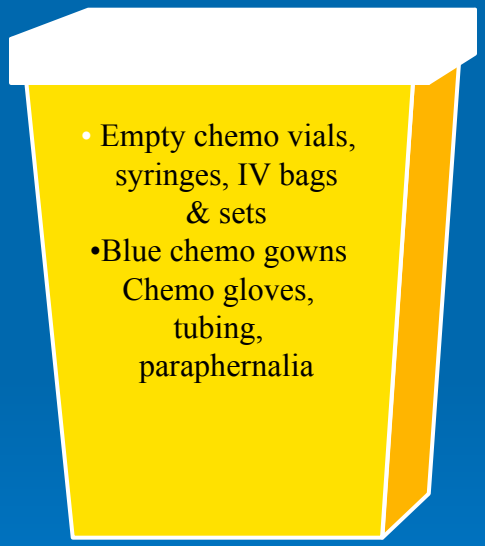
Contents: Pourable, squeezable, flakable blood; Sharps – used/unused (state specific)

Treatment: Primarily autoclave, microwave

Purpose: Render materials non-infectious, non-recognizable (most states)

Final Disposition: Non-hazardous landfill

Trace Chemotherapy Waste



Regulation: CT BMW Regs., RCSA 22a-209-15

Acronym: Trace Chemo/BMW

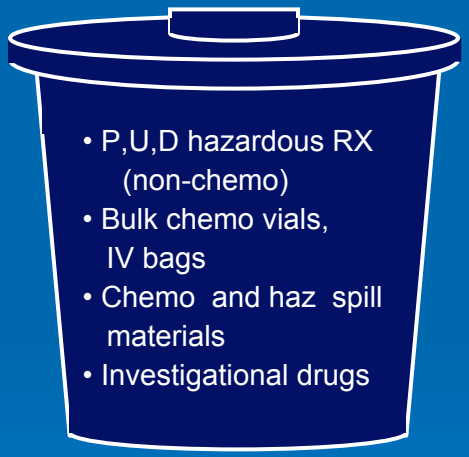
Contents: Trace contaminated chemo paraphernalia/RMW

Treatment: ***Incineration at an RMW facility***

Purpose: Deactivation of chemo; disinfection

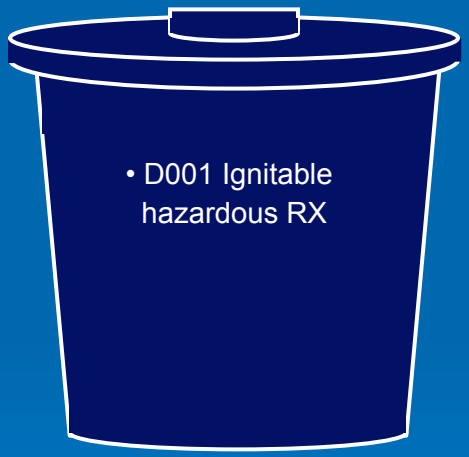
Final Disposition: ***Non-hazardous landfill***

Hazardous Waste - Toxic



Regulation:	Resource Conservation & Recovery Act
Acronym:	RCRA
Contents:	Toxic Hazardous Waste
Treatment:	Incineration at a RCRA hazardous waste incinerator
Purpose:	Destroy chemical compound entirely
Final Disposition:	Lined hazardous waste landfill

Hazardous Waste - Ignitable



Regulation:	Resource Conservation & Recovery Act
Acronym:	RCRA
Contents:	Ignitable Hazardous Waste
Treatment:	Incineration at a RCRA hazardous waste incinerator
Purpose:	Destroy chemical compound entirely
Final Disposition:	Lined hazardous waste landfill

Traditional Chemo Waste Containers

Empty vials, syringes, IVs, tubing, gowns, gloves,etc.

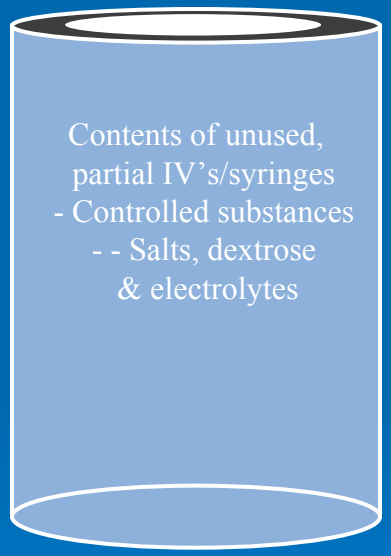
New Hazardous Waste Containers

Bulk chemo in vials, unused IV's, P, U. toxic D

Hospitec

Kendall

Sewer System



Regulation: Clean Water Act & RCSA 22a-430

Acronym: CWA

Contents: Wastewaters only
(no concentrated wastes)

Treatment: Pretreatment, then discharge to sewer

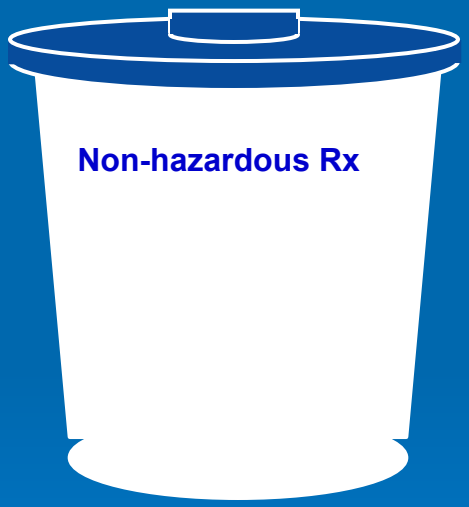
Purpose: Remove solids/pH adjustment, etc.

Final Disposition: Surface water, land disposal (sludge)

Sewering Hazardous Waste

- Permit required from CT DEP Water Bureau
  - Will require pre-treatment prior to discharge to sewer
  - Wastewaters only (no concentrated wastes)
- Notification of local POTW
  - 40 CFR 403.12 (p) and RCSA 22a-430-3(11)(A)
  - http://www.gpoaccess.gov/ecfr/
- Strongly discouraged at EPA Conference

Non-Hazardous Rx Waste



Regulation: CGS 22a-454 (CT-regulated waste
RCSA 22a-209-8 (Special Waste)

Acronym: Non-hazardous Rx

Contents: All Rx not RCRA

Treatment: Disposal at a CT-regulated waste facility or comparable out-of state facility; Disposal or incineration at an approved landfill or incinerator

Purpose: Prevent drain disposal and untreated landfilling

Final Disposition: Non-hazardous landfill

How should non-hazardous drugs be stored and disposed?

- Consider segregating into a non-red, non-yellow container, such as beige or white with blue top (California Pharmaceutical Waste)
- Label “Non-hazardous Pharmaceutical Waste – Incinerate Only”
- Dispose at a CT-regulated waste facility or municipal incinerator that is permitted to accept non-hazardous pharmaceutical waste

Managing Specialty Wastes

- Controlled substances:
  - May be handled by Onyx Environmental as a transfer between DEA registrants
  - Can be shipped to a reverse distributor as a transfer between registrants (non-hazardous waste)
  - Sewering not allowed w/o a DEP permit
- Mixed wastes:
  - Clean Harbors can accept mixed hazardous and infectious waste
  - Onyx can also accept mixed hazardous and infectious waste with some restrictions

How Should RCRA Hazardous Waste be Handled?

- Need a new waste stream in Pharmacy, certain Patient Care Areas, Oncology Clinics
- RCRA Hazardous Waste: Toxic
  - P, U, toxic Ds, (all Chemotherapy Residues, Chemo Spills)
- RCRA Hazardous Waste: Ignitable (D001)
- Can also use hazardous waste buckets available from brokers and disposal firms

Satellite Accumulation

- Segregated, labeled and contained in areas where it is generated
- Available in all units in which hazardous waste is generated
- Label each container as “Hazardous Waste” with the appropriate waste stream noted
- Waste containers must be in good condition, kept closed, and compatible with waste.
- Keep separated from incompatible wastes/materials.
- No time limit to fill the container
- No more than 55 gallons of U listed and characteristic waste or 1 quart of P listed waste may be accumulated
- Must be moved to storage accumulation within three days after these quantities are reached

Storage Accumulation

Hazardous Waste Storage Accumulation Site:

- Provides a safe and secure storage area for hazardous waste while it awaits shipping.
- Same locked area as mercury, xylene, formaldehyde, lab chemicals
- Maximum storage time: 90 or 180 days based on generator status

How Should RCRA Hazardous Waste Be Disposed?

- Either contract with a hazardous waste broker or develop internal expertise for:
  - Lab packing
  - Manifest preparation
  - Land ban preparation
- Contract with a federally permitted RCRA hazardous waste incineration facility (TSDF: Treatment, Storage & Disposal Facility)

How Can Hazardous RX Waste Generation Be Minimized?

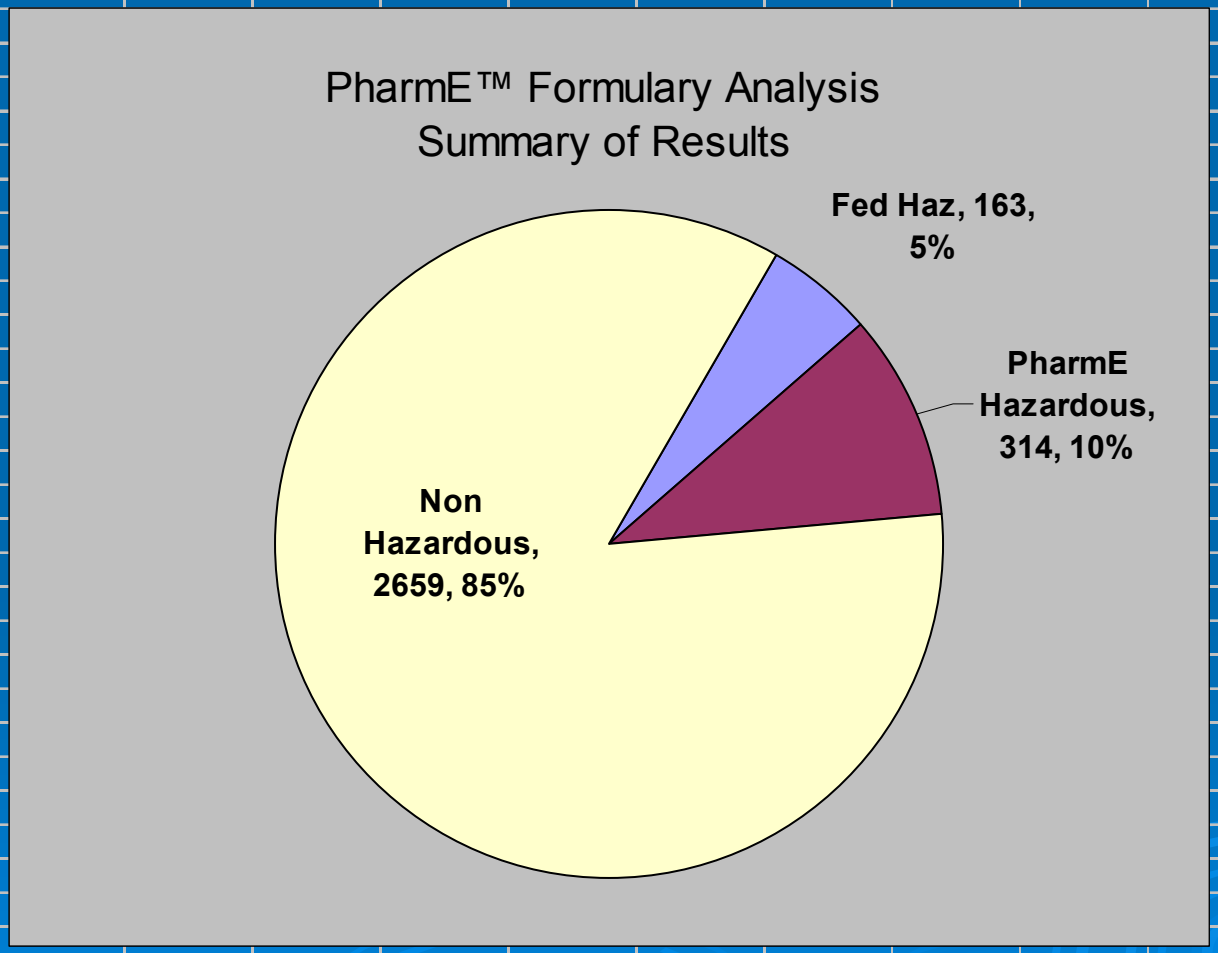
- Inherent limitations on substitution of a less hazardous drug since the hazardous nature of the chemical often provides the therapeutic effect
- Tighter inventory control to reduce outdate generation, both original manufacturers' containers and repacks
- Pre-labeling of multi-dose items such as ointments, inhalers, as take-home meds – works best in smaller, primary care hospitals
- Single dose vials vs. multiple dose vials
- Patient specific oral syringes vs. 10 cc. repacks (e.g. choral hydrate for pediatric use)

Solutions to Help Identify & Manage Pharmaceutical Hazardous Waste

- PharmE™ Formulary Analysis
  - A detailed analysis report of your formulary with complete pharmaceutical waste stream recommendations identifying all federally hazardous and PharmE Hazardous™ waste.

- PharmE™ Waste Wizard
  - On-line subscription to over 135,000 items, updated with an average of 300 new items weekly; over 1,000 new hazardous items added in the past six months.

Memorial Hospital



PharmE Formulary Analysis

Formulary Output

NDC	Product	Waste Class	Waste Stream	Waste Code
00074492134	ADRENALINE 0.1MG/ML ABBJCT	Fed Hazardous	Toxic	P042 - Epinephrine
00904777035	MEDIHALER-EPI INHALER	Fed Hazardous	Ignitable	D001 - Ignitable
49502050001	EPIPEN 0.3MG AUTO-INJECTOR	Fed Hazardous	Toxic	P042 - Epinephrine
11980011915	EPIFRIN 0.5% EYE DROPS	Fed Hazardous	Toxic	P042 - Epinephrine
11980012215	EPIFRIN 1%EYE DROPS	Fed Hazardous	Toxic	P042 - Epinephrine
6157				

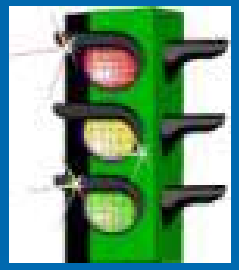
NDC	Product	Waste Class	Waste Stream	Waste Code
66479013929	METHOTREX SOD 1 GM P/F VL	PharmE hazardous	Toxic	NIOSH - Antineoplastic
65483059010	IMURAN 50 MG 100	PharmE hazardous	Toxic	NIOSH- Immunosuppressive
00015301238	BICNU 100 MG VL	Federal hazardous	Ignitable	Alcohol > 24%

**Sample Data. Results truncated for presentation purposes*

Detailed Information by Therapeutic Category

		Fed Haz	PharmE Hazardous	Non Hazardous	Total
01	Anti_Infective Agents		30	274	304
17	Biologicals	4		29	33
21	Antineoplastic Agents	27	89	5	121
22	Endocrine and Metabolic Drugs	13	54	144	211
31	Cardiovascular Agents	29	2	340	371
41	Respiratory Agents	15	27	180	222
46	Gastrointestinal Agents	1		236	237
53	Genitourinary Products	1	12	29	42
57	Central Nervous System Drugs	10		239	249
64	Analgesics and Anesthetics	2	23	396	421
72	Neuromuscular Drugs		32	86	118
77	Nutritional Products	3	6	148	157
82	Hematological Agents	9	5	100	114
86	Topical Products	39	18	306	363
92	Miscellaneous Products	10	16	147	173
Total		163	314	2659	3136

Identifying Hazardous Pharmaceutical Waste



- **Federal Hazardous Waste**
- **PharmE Hazardous Waste**
- **Non-Hazardous Waste**

PharmEcology - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Pharm@cology® Associates, LLC

Providing Environmental Consultation to the Healthcare Industry™
A 2004 H2E "Champion for Change" Award Winner

CONTACT US SITE MAP

ABOUT PHARM@COLOGY® FAQs RESOURCES NEWS SERVICES

Pharm@™ Waste Wizard Subscribers

Email: jmccauley@busarch.c

Password: ••••••••

Remember me

LOGIN

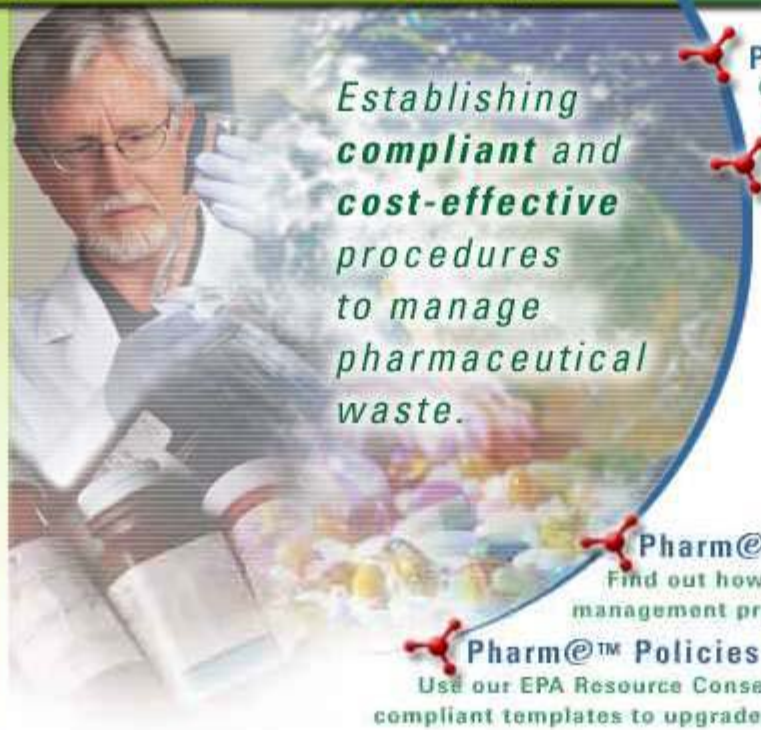
Pharm@™ Waste Wizard Signup

SUBSCRIBE

Tour Pharm@cology®

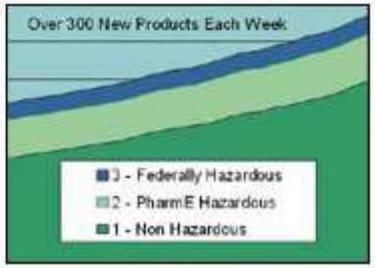
TOUR

Forgot your Password?



Pharm@™ Formulary Analysis
Get started by identifying your hazardous waste pharmaceuticals

Pharm@™ Waste Wizard
Keep up-to-date on-line with our weekly database updates



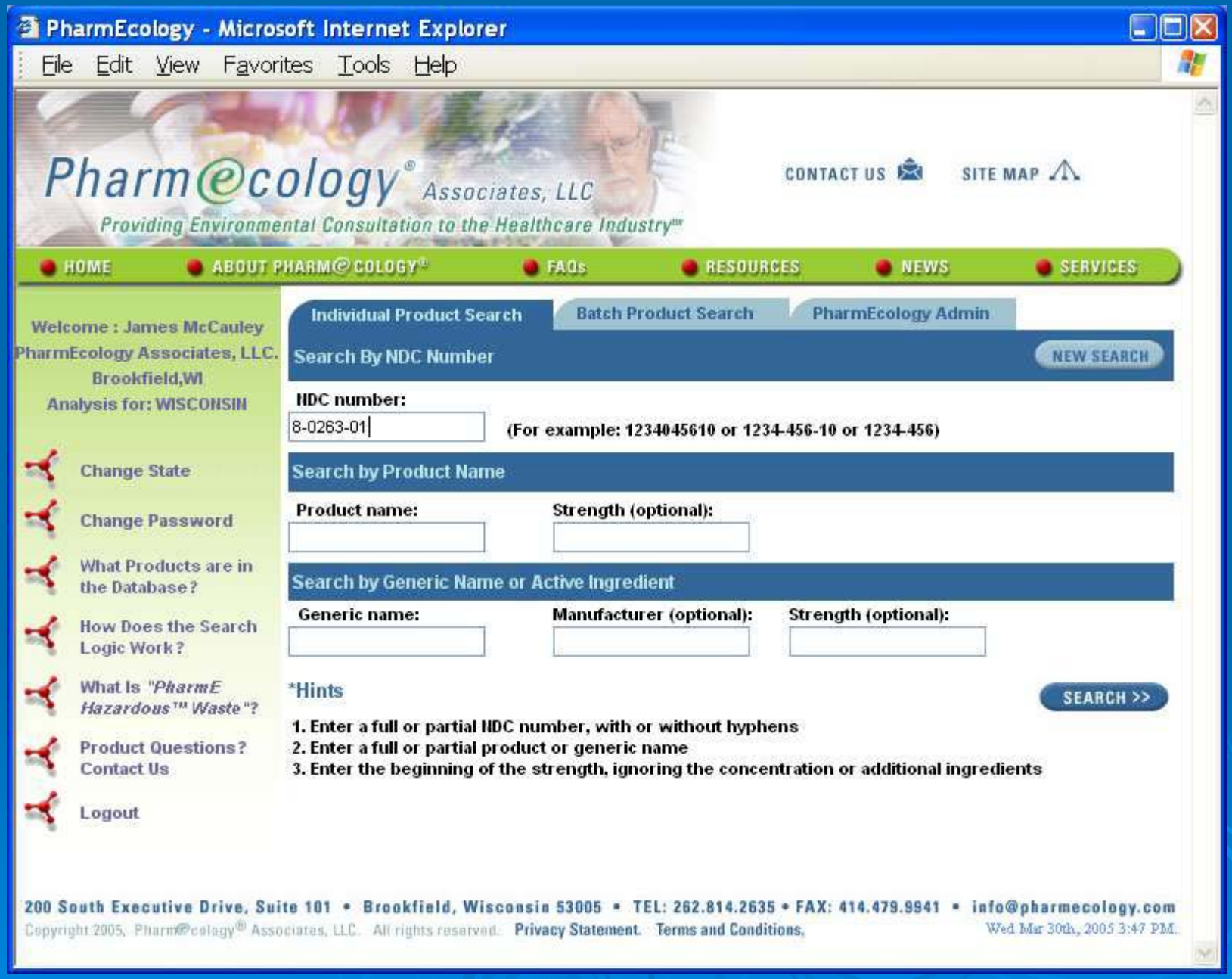
Pharm@™ On-Site Risk Assessment
Find out how your current pharmaceutical waste management practices can be improved

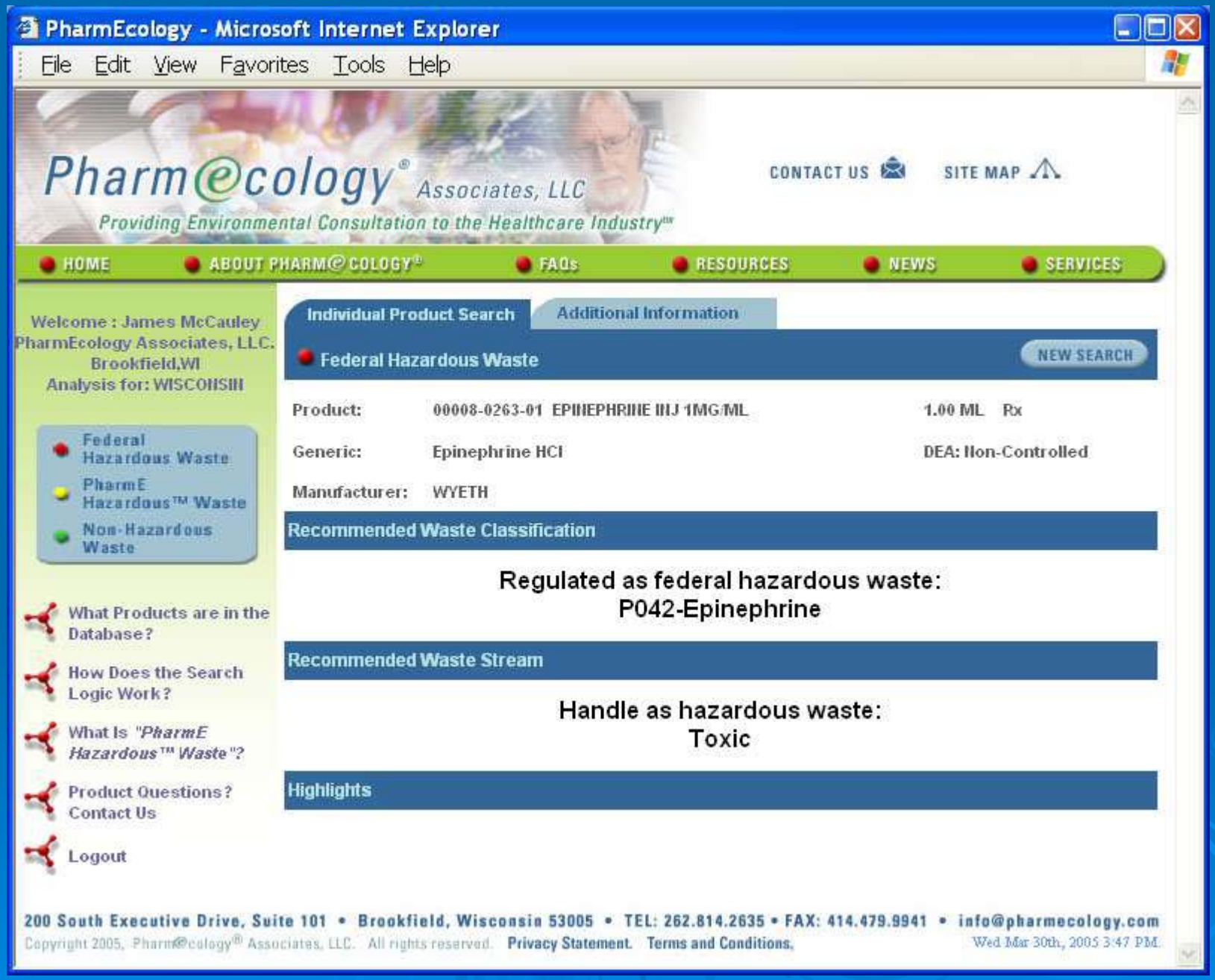
Pharm@™ Policies and Procedures
Use our EPA Resource Conservation and Recovery Act (RCRA) compliant templates to upgrade your policies and procedures

News Alert: PharmEcology® Announces a New Brand, a New Wizard, and New Waste Categories!

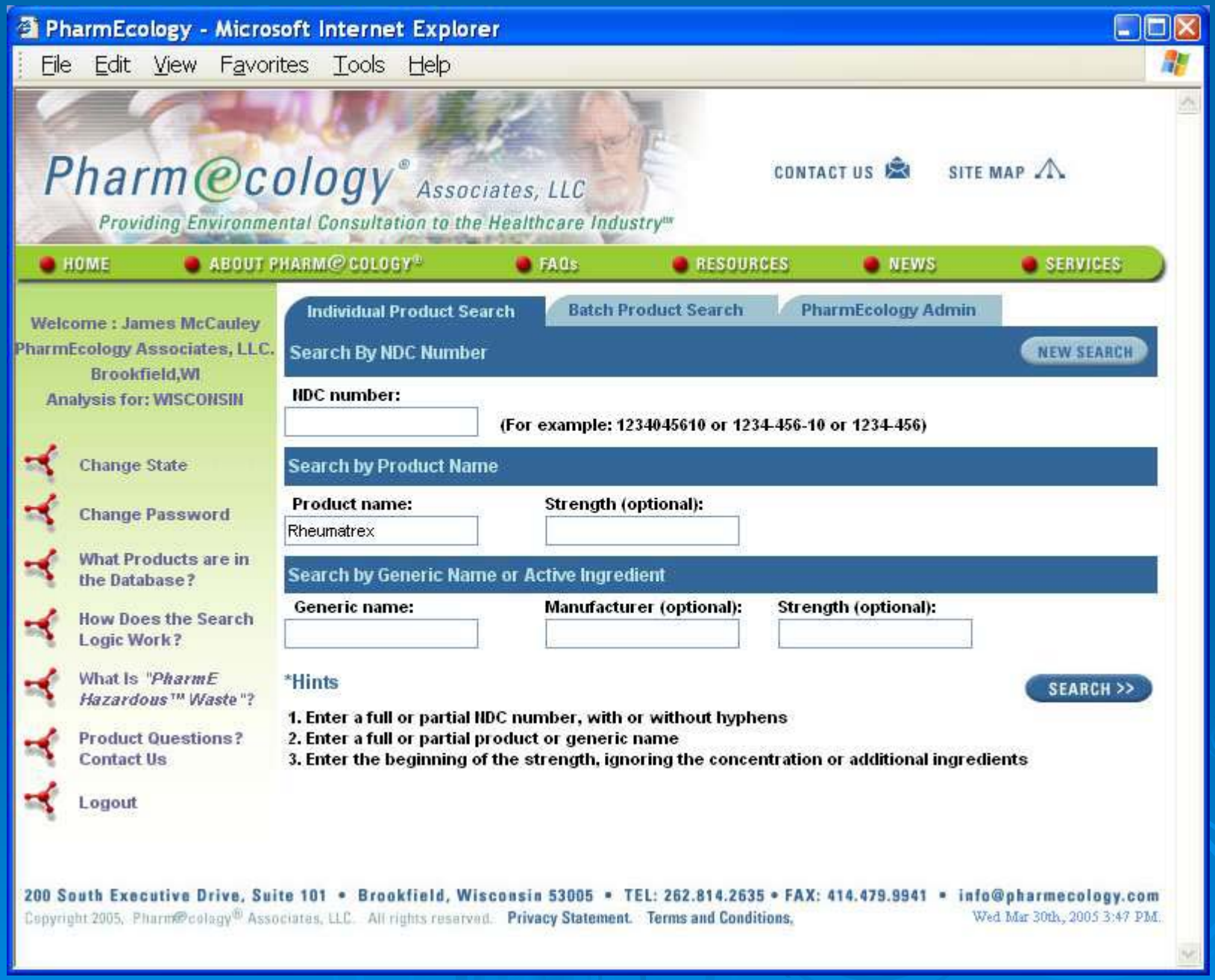
200 South Executive Drive, Suite 101 • Brookfield, Wisconsin 53005 • TEL: 262.814.2635 • FAX: 414.479.9941 • info@pharmecology.com

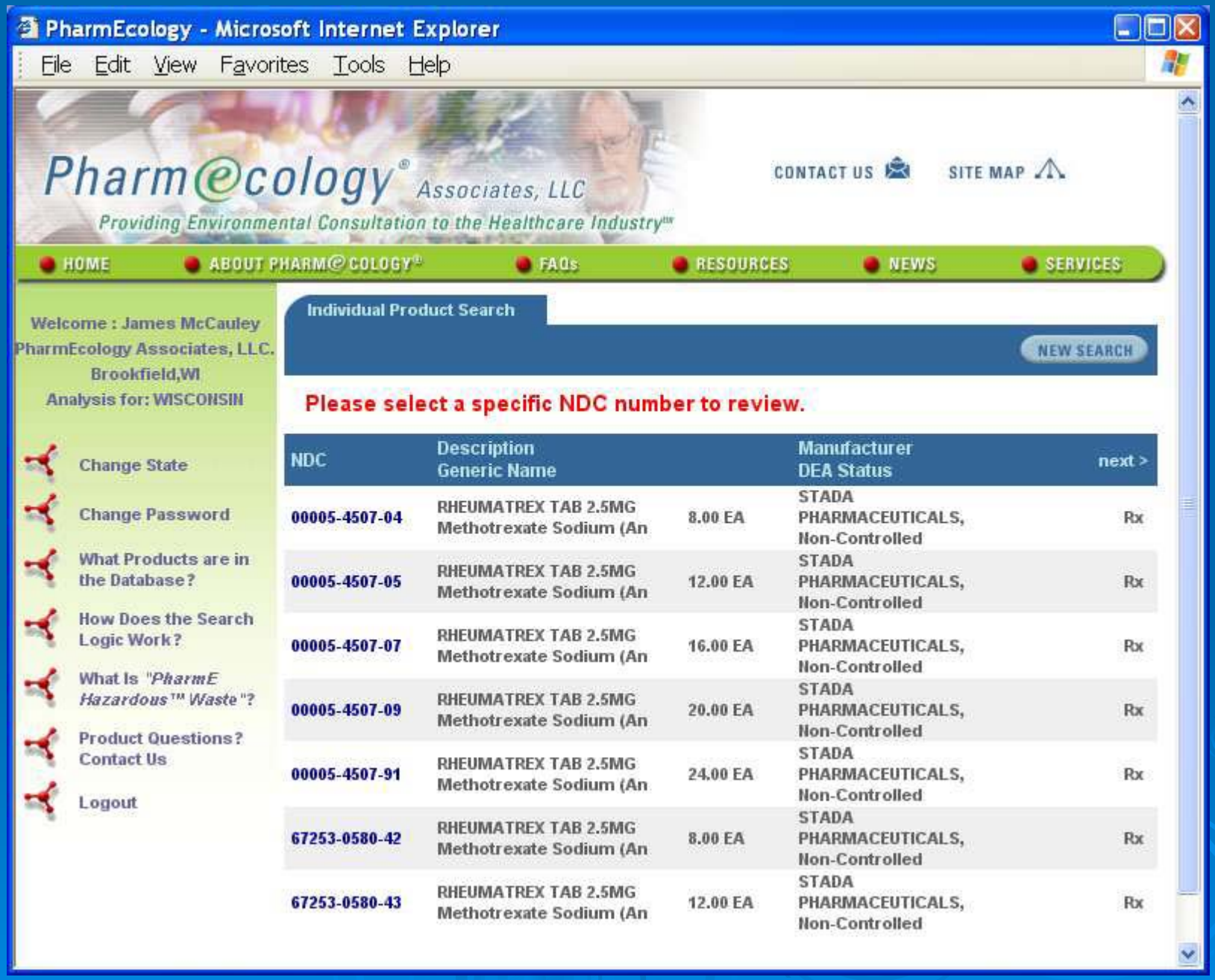
Wed Mar 30th, 2005 3:35 PM

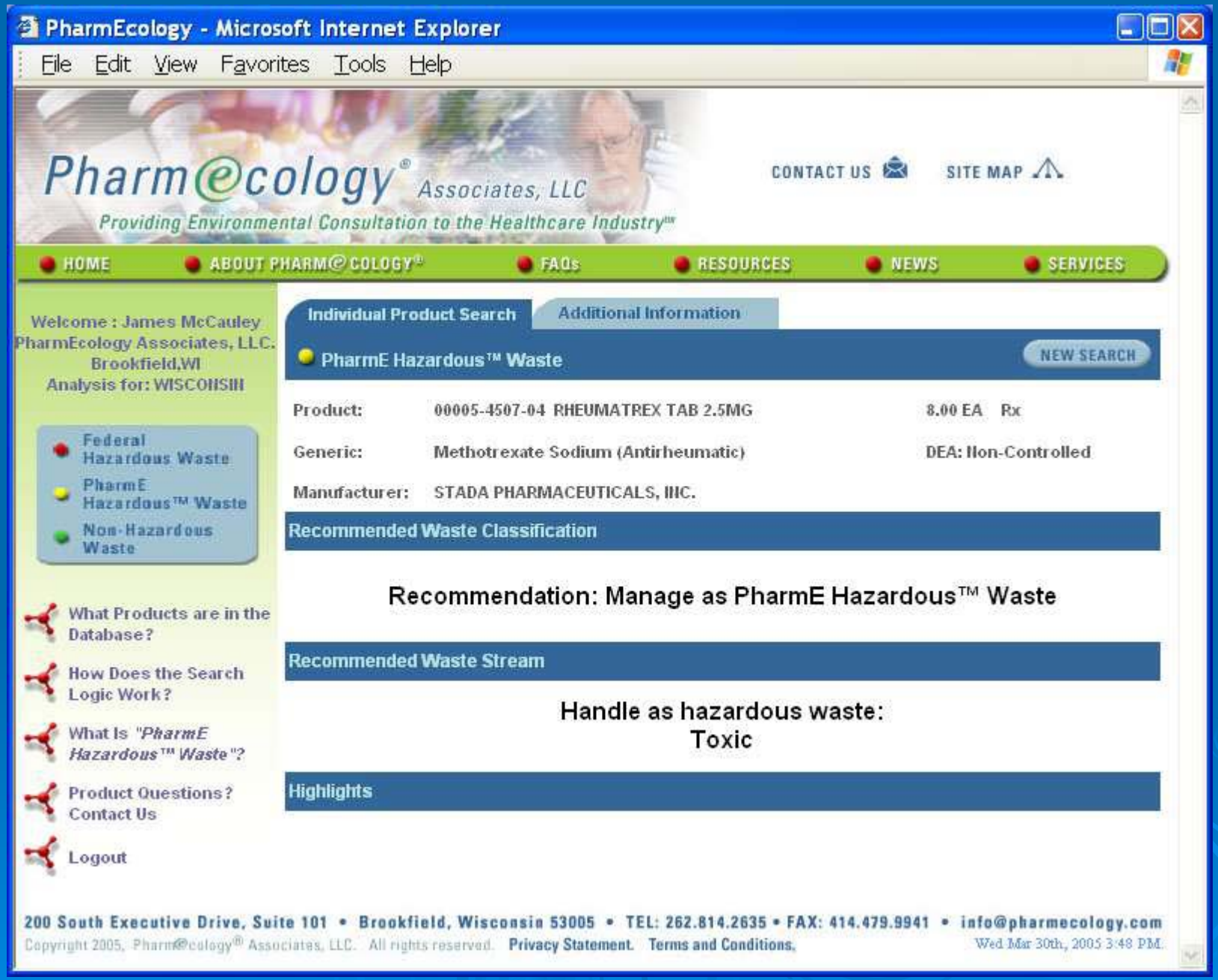

PharmEcology - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Pharm@cology® Associates, LLC
Providing Environmental Consultation to the Healthcare Industry℠
CONTACT US
SITE MAP
HOME
ABOUT PHARM@COLOGY®
FAQs
RESOURCES
NEWS
SERVICES
Welcome : James McCauley
PharmEcology Associates, LLC.
Brookfield,WI
Analysis for: WISCONSIN
Change State
Change Password
What Products are in the Database?
How Does the Search Logic Work?
What Is "PharmE Hazardous™ Waste"?
Product Questions? Contact Us
Logout
Individual Product Search
Batch Product Search
PharmEcology Admin
Search By NDC Number
NEW SEARCH
NDC number:
8-0263-01
(For example: 1234045610 or 1234-456-10 or 1234-456)
Search by Product Name
Product name:
Strength (optional):
Search by Generic Name or Active Ingredient
Generic name:
Manufacturer (optional):
Strength (optional):
*Hints
SEARCH >>
1. Enter a full or partial NDC number, with or without hyphens
2. Enter a full or partial product or generic name
3. Enter the beginning of the strength, ignoring the concentration or additional ingredients
200 South Executive Drive, Suite 101 • Brookfield, Wisconsin 53005 • TEL: 262.814.2635 • FAX: 414.479.9941 • info@pharmecology.com
Copyright 2005, Pharm@cology® Associates, LLC. All rights reserved. Privacy Statement. Terms and Conditions.
Wed Mar 30th, 2005 3:47 PM.


PharmEcology - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Pharm@cology® Associates, LLC
Providing Environmental Consultation to the Healthcare Industry℠
CONTACT US
SITE MAP
HOME
ABOUT PHARM@COLOGY®
FAQs
RESOURCES
NEWS
SERVICES
Welcome : James McCauley
PharmEcology Associates, LLC.
Brookfield,WI
Analysis for: WISCONSIN
Federal Hazardous Waste
PharmE Hazardous™ Waste
Non-Hazardous Waste
What Products are in the Database?
How Does the Search Logic Work?
What Is "PharmE Hazardous™ Waste"?
Product Questions? Contact Us
Logout
Individual Product Search
Additional Information
Federal Hazardous Waste
NEW SEARCH
Product: 00008-0263-01 EPINEPHRINE INJ 1MG/ML 1.00 ML Rx
Generic: Epinephrine HCl DEA: Non-Controlled
Manufacturer: WYETH
Recommended Waste Classification
Regulated as federal hazardous waste:
P042-Epinephrine
Recommended Waste Stream
Handle as hazardous waste:
Toxic
Highlights
200 South Executive Drive, Suite 101 • Brookfield, Wisconsin 53005 • TEL: 262.814.2635 • FAX: 414.479.9941 • info@pharmecology.com
Copyright 2005, Pharm@cology® Associates, LLC. All rights reserved. Privacy Statement. Terms and Conditions.
Wed Mar 30th, 2005 3:47 PM.


PharmEcology - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Pharm@cology® Associates, LLC
Providing Environmental Consultation to the Healthcare Industry℠
CONTACT US
SITE MAP
HOME
ABOUT PHARM@COLOGY®
FAQs
RESOURCES
NEWS
SERVICES
Welcome : James McCauley
PharmEcology Associates, LLC.
Brookfield,WI
Analysis for: WISCONSIN
Federal Hazardous Waste
PharmE Hazardous™ Waste
Non-Hazardous Waste
What Products are in the Database?
How Does the Search Logic Work?
What Is "PharmE Hazardous™ Waste"?
Product Questions? Contact Us
Logout
Individual Product Search
Additional Information
Federal Hazardous Waste
NEW SEARCH
Product: 00008-0263-01 EPINEPHRINE INJ 1MG/ML 1.00 ML Rx
Full name: EPINEPHRINE HCL TUBEX 1.00 MG/ML
Reference: eFACTS (Facts & Comparisons Online)
Page: Epinephrine
EPINEPHRINE
Epinephrine, is a P listed chemical, defined by USEPA as acutely hazardous waste when present as the sole active ingredient (P042).
Other then the exception noted below, all containers that have held P-listed waste must be managed as hazardous waste unless triple rinsed. If triple rinsed, all rinsate must also be treated as hazardous waste. The rinsed RCRA-empty container may then be disposed of as non-hazardous waste.
Based on a 1994 USEPA Hotline Report, epinephrine residue in a syringe used for administration is not regulated as a hazardous waste. The syringe is considered a "dispensing instrument", and, therefore, the contents were used for their intended purpose.

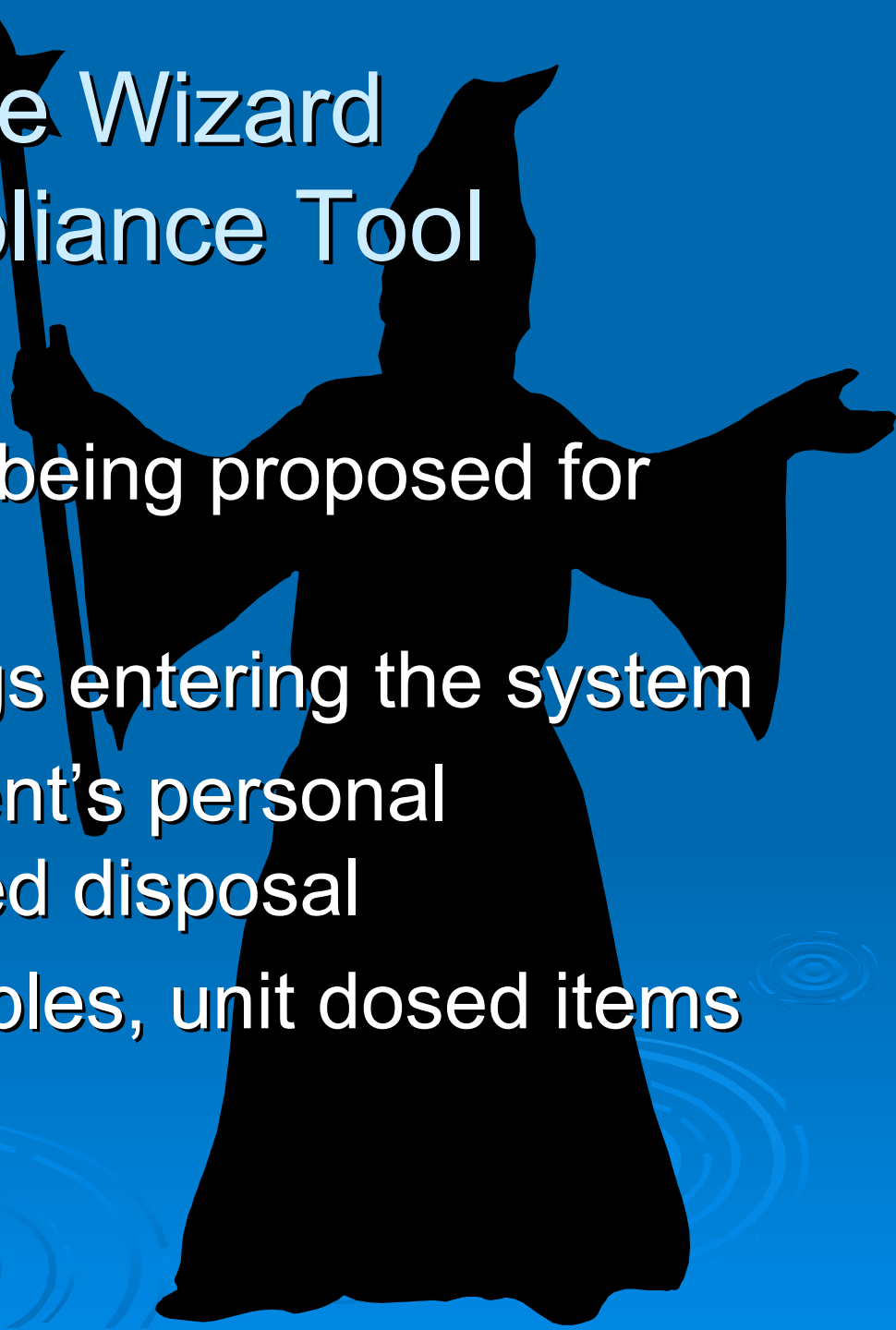

PharmEcology - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Pharm@cology® Associates, LLC
Providing Environmental Consultation to the Healthcare Industry℠
CONTACT US
SITE MAP
HOME
ABOUT PHARM@COLOGY®
FAQs
RESOURCES
NEWS
SERVICES
Welcome : James McCauley
PharmEcology Associates, LLC.
Brookfield,WI
Analysis for: WISCONSIN
Change State
Change Password
What Products are in the Database?
How Does the Search Logic Work?
What Is "PharmE Hazardous™ Waste"?
Product Questions? Contact Us
Logout
Individual Product Search
Batch Product Search
PharmEcology Admin
Search By NDC Number
NEW SEARCH
NDC number:
(For example: 1234045610 or 1234-456-10 or 1234-456)
Search by Product Name
Product name:
Rheumatrex
Strength (optional):
Search by Generic Name or Active Ingredient
Generic name:
Manufacturer (optional):
Strength (optional):
*Hints
SEARCH >>
1. Enter a full or partial NDC number, with or without hyphens
2. Enter a full or partial product or generic name
3. Enter the beginning of the strength, ignoring the concentration or additional ingredients
200 South Executive Drive, Suite 101 • Brookfield, Wisconsin 53005 • TEL: 262.814.2635 • FAX: 414.479.9941 • info@pharmecology.com
Copyright 2005, Pharm@cology® Associates, LLC. All rights reserved. Privacy Statement. Terms and Conditions.
Wed Mar 30th, 2005 3:47 PM.


PharmEcology - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Pharm@cology® Associates, LLC
Providing Environmental Consultation to the Healthcare Industry℠
CONTACT US
SITE MAP
HOME
ABOUT PHARM@COLOGY®
FAQs
RESOURCES
NEWS
SERVICES
Welcome : James McCauley
PharmEcology Associates, LLC.
Brookfield,WI
Analysis for: WISCONSIN
Change State
Change Password
What Products are in the Database?
How Does the Search Logic Work?
What Is "PharmE Hazardous™ Waste"?
Product Questions? Contact Us
Logout
Individual Product Search
NEW SEARCH
Please select a specific NDC number to review.
NDC
Description
Generic Name
Manufacturer
DEA Status
next >
00005-4507-04 RHEUMATREX TAB 2.5MG Methotrexate Sodium (An 8.00 EA STADA PHARMACEUTICALS, Non-Controlled Rx
00005-4507-05 RHEUMATREX TAB 2.5MG Methotrexate Sodium (An 12.00 EA STADA PHARMACEUTICALS, Non-Controlled Rx
00005-4507-07 RHEUMATREX TAB 2.5MG Methotrexate Sodium (An 16.00 EA STADA PHARMACEUTICALS, Non-Controlled Rx
00005-4507-09 RHEUMATREX TAB 2.5MG Methotrexate Sodium (An 20.00 EA STADA PHARMACEUTICALS, Non-Controlled Rx
00005-4507-91 RHEUMATREX TAB 2.5MG Methotrexate Sodium (An 24.00 EA STADA PHARMACEUTICALS, Non-Controlled Rx
67253-0580-42 RHEUMATREX TAB 2.5MG Methotrexate Sodium (An 8.00 EA STADA PHARMACEUTICALS, Non-Controlled Rx
67253-0580-43 RHEUMATREX TAB 2.5MG Methotrexate Sodium (An 12.00 EA STADA PHARMACEUTICALS, Non-Controlled Rx


PharmEcology - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Pharm@cology® Associates, LLC
Providing Environmental Consultation to the Healthcare Industry℠
CONTACT US
SITE MAP
HOME
ABOUT PHARM@COLOGY®
FAQs
RESOURCES
NEWS
SERVICES
Welcome : James McCauley
PharmEcology Associates, LLC.
Brookfield,WI
Analysis for: WISCONSIN
Federal Hazardous Waste
PharmE Hazardous™ Waste
Non-Hazardous Waste
What Products are in the Database?
How Does the Search Logic Work?
What Is "PharmE Hazardous™ Waste"?
Product Questions? Contact Us
Logout
Individual Product Search
Additional Information
PharmE Hazardous™ Waste
NEW SEARCH
Product: 00005-4507-04 RHEUMATREX TAB 2.5MG
8.00 EA Rx
Generic: Methotrexate Sodium (Antirheumatic)
DEA: Non-Controlled
Manufacturer: STADA PHARMACEUTICALS, INC.
Recommended Waste Classification
Recommendation: Manage as PharmE Hazardous™ Waste
Recommended Waste Stream
Handle as hazardous waste:
Toxic
Highlights
200 South Executive Drive, Suite 101 • Brookfield, Wisconsin 53005 • TEL: 262.814.2635 • FAX: 414.479.9941 • info@pharmecology.com
Copyright 2005, Pharm@cology® Associates, LLC. All rights reserved. Privacy Statement. Terms and Conditions.
Wed Mar 30th, 2005 3:48 PM.


PharmEcology - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Pharm@cology® Associates, LLC
Providing Environmental Consultation to the Healthcare Industry℠
CONTACT US
SITE MAP
HOME
ABOUT PHARM@COLOGY®
FAQs
RESOURCES
NEWS
SERVICES
Welcome : James McCauley
PharmEcology Associates, LLC.
Brookfield,WI
Analysis for: WISCONSIN
Federal Hazardous Waste
PharmE Hazardous™ Waste
Non-Hazardous Waste
What Products are in the Database?
How Does the Search Logic Work?
What Is "PharmE Hazardous™ Waste"?
Product Questions? Contact Us
Logout
Individual Product Search
Additional Information
PharmE Hazardous™ Waste
NEW SEARCH
Product: 00005-4507-04 RHEUMATREX TAB 2.5MG 8.00 EA Rx
Full name: RHEUMATREX 2.50 MG
Reference: eFACTS (Facts & Comparisons Online)
Page: Methotrexate Sodium Monograph
NIOSH - Antineoplastics
A NIOSH Hazardous Drug Alert was initially released on March 25, 2004 as a result of the efforts of the NIOSH Hazardous Drug Working Group. The 1990 ASHP definition of hazardous drug was expanded to include the following categories: carcinogenicity, teratogenicity or other developmental toxicity, reproductive toxicity, organ toxicity at low doses, genotoxicity, and structure and toxicity profiles of new drugs which mimic existing drugs as determined hazardous by the above criteria. Based on these expanded definitions, this antineoplatic drug has been listed as a hazardous drug in Appendix A of the Hazardous Drug Alert. Best management practices encourage handling as a "Risk Management" toxic hazardous waste.
For additional information, refer to:
http://www.cdc.gov/niosh/docs/2004-HazDrugAlert/#

Using the Wizard as a Compliance Tool



- Evaluate new drugs being proposed for the formulary
- Categorize new drugs entering the system
- Categorize any patient's personal medications that need disposal
- Categorize any samples, unit dosed items being disposed

Benefits of a Comprehensive Hazardous Waste Disposal Plan

- JCAHO Environment of Care Performance Improvement Initiative
  - See both Medication Management and Environment of Care
- Reduces CT DEP and EPA liability and risk exposure to a minimum
- Protects employees and patients
- Demonstrates responsible care in dealing with hazardous substances, hazardous wastes

Goals of Rx Waste Management Review Risk Assessment

- Assess the current situation
- Present Findings and Recommendations
- Develop an Action Plan
- Provide implementation assistance as needed
- Assist the organization to achieve cost-effective compliance with CT DEP and JCAHO/CMS

Specific Resources

- NIOSH Hazardous Drug Alert
  - http://www.cdc.gov/niosh/topics/hazdrug/
  - See Appendix A for a list of hazardous drugs
- PhaSeal™ closed transfer system
  - http://www.supergen.com/subpages/products/products.asp
- Hazardous Pharmaceutical Waste Containers
  - Hospitec: Christopher Hahn, 561) 833-2296, chris@hospitecinc.com
  - Kendall: Mike Liscio, (508) 261-8493, mike.liscio@tycohealthcare.com

General References

- www.pharmecology.com
- Pharmaceutical Waste: http://www.h2e-online.org/tools/chem-pharm.htm
- http://www.pca.state.mn.us/industry/healthcare.html
- RCRA On-Line http://www.epa.gov/rcraonline/
- Pharmaceuticals and Personal Care Products as Environmental Pollutants: http://www.epa.gov/nerlesd1/chemistry/pharma/index.htm