Abbott Northwestern Hospital
The Journey To A Successful Pharmaceutical Waste Management Program

Washington State Department of Ecology
Pharmaceutical Waste Seminar
June 21, 2007

Steven A. Waderich
Safety & Hazardous Waste Program Manager
Haz Mat Emergency Coordinator
steven.waderich@allina.com

Abbott Northwestern Hospital

- Allina Hospitals and Clinics (11 hospitals and 42 Allina Medical Clinics)
- 621 beds on main campus
- 43,061 Inpatient admissions
- 247,636 Outpatient registrations
- 39,504 Emergency Department visits
- 32,222 Surgical procedures
- 5,330 Employees
- Largest not-for-profit hospital in Twin Cities

Introduction

This presentation contains components of a Hazardous Pharmaceutical Waste Management Program that has been developed over a period of three years to come into compliance with federal, state, and local hazardous waste rules including

A three year collaborative effort between metro and regional hospitals and clinics, Minnesota Hospital Assoc., state and county regulators, Minnesota Pollution Control Agency, hazardous waste vendors, and consultants from the pharmaceutical waste arena.

Introduction

Healthcare produces enormous volumes of hazardous waste, which, if not handled properly, threaten our lakes, streams, and rivers.

Reducing the amount of pharmaceutical & other waste from hospitals that goes into our sewers and landfills diminishes the risk of surface water contamination.

Pre-2004 RCRA Management

- Experience with RCRA was very limited
  - Mostly Lab related hazardous waste
  - Still a Small Quantity Generator (SQG)
  - Haz waste budget $35,000 in 2003
  - Inspected every two years
- Pharmacy (extensive use of Reverse Distribution process)
  - Credits
  - Reverse distribution destruction of non-creditable products as waste

National RCRA Activity '03

- US healthcare facilities generate an estimated 2.7 million tons of waste annually
- Regulations for handling and disposing of hospital waste are confusing
- EPA crackdown on non-complying hospitals gaining attention in Region I
  - *Oct. of 2003, our regulators were conducting information meetings and training sessions.*

Implementing the 10 Step Blueprint

- Charting the Abbott Northwestern Hospital journey and comparing program to the 10-Step Blueprint Template
- Why it is important to use the tool and not to wait for regulatory enforcement before applying the blueprint to your facility

Step 1: Start Now… The Time is Right

- Pull together key stakeholders and plan a Hazardous Pharmaceutical Waste Collection Program that works for you.
  - Safety/Risk Management
  - Pharmacy
  - Lab
  - Consultants (PharmEcology)

- Plan for a two year implementation timeframe
- Budget now for your Pharmaceutical Waste Program

Step 1: Getting Started

- Review your existing program using these resources and tools.
  - Hospitals for a Healthy Environment is a great place to start.
    - http://www.h2e-online.org/reqsandstandards/jcahotoc.html#EC
    - Complete checklists to identify gaps
  - Table of Common Waste in the Health Care Industry and other MPCA fact sheets.
    - http://www.pca.state.mn.us/publications/w-hw3-34a.pdf
    - http://www.pca.state.mn.us/publications/w-hw3-34.pdf
  - Use a consultant if you are stuck

Inspection Findings

- Our first inspection was in April 2004
- We were cited with a Letter of Warning with 60 days to comply
  - Failure to properly evaluate our waste (lab, pharmacy, radiology)
  - Failure to evaluate for Minnesota Lethality
  - Improper waste disposal practices
  - Strict restriction of reverse distribution
  - Failure to evaluate lab processors that discharge directly to the sewer

More Citations

- Improper labeling
- Recycling containers mislabeled
- Failure to close containers
  - Unattended lab container with funnel
- Manifest discrepancy reports related to Minnesota Lethality
- LQG instead of SQG (epinephrine)
- Failure to have in place LQG requirements

The Challenges

- Little expertise within the healthcare community in handling hazardous waste
- Decentralized management of waste streams
- Healthcare is highly regulated
  - JCAHO *(Joint Commission Accreditation of Healthcare Organizations)*
  - OSHA
  - MPCA/EPA/County
  - DOT
  - DEA

Challenges Continue to Grow!

- We hired PharmEcology as a consultant to bring awareness to key stakeholders, conduct a facility waste review, and to evaluate 4100 formulary drugs
  - The MPCA was unwilling to accept third party evaluations
  - Not allowing third party evaluations would result in inconsistencies from hospital to hospital and county to county
  - Time was running out

Step 2: Understanding the Regulations

- As more hospitals were inspected, enforcement differed from county to county and state levels
- End facility incinerators did not understand healthcare issues
- Waste haulers weren't licensed to haul dual waste (hazardous and infectious)
- The POTW issues also had to be addressed

MN Approach – A Good Idea!

- Metro County and State agencies reach consensus on standards and approach
  - SWMCB Counties
  - POTW (Metropolitan Council Envir. Services (MCES)
  - MN Pollution Control Agency (MPCA)
  - MN Technical Assistance Program (MnTAP)
- Unified approach to standards and enforcement on hazardous waste
  - Fact sheets clarified requirements
- Developed and implemented training workshops
  - Information on this slide provided by Fawzi Awad (SWMCB).

Minnesota Hospital Association

"Statement"

- Hospitals are driven by the mission of caring for patients 24/7.
- Minnesota hospitals are committed to being good stewards of the environment and understand the important correlation between public health and protecting the environment.

-Ann Gibson, Minnesota Hospital Association

MPCA Regulatory Consensus

- Developed a strategy for working with healthcare and other stakeholders to achieve compliance and collaborate on solutions
  - Collaboration with Minnesota Hospital Assoc.
  - Regulatory Consensus of Healthcare Industry
- MHA Workgroups (comprised of representatives of various metro hospitals)
  - Safety
  - Pharmacy
  - Lab

During Lack of Regulatory Consensus We Show Good Faith

- Pulled stakeholders together
  - Safety, Pharmacy, Nursing & vendors
  - Come up with a waste collection plan
    - Pilot program
    - Collection containers
    - Process plan – flow charts, training, collection & sorting, checklists, and manifests
    - Must comply w/ waste hauler and end facility considerations

Collection Pilot for 30 days

- Three areas included in Pilot Program
  - Cardiovascular ICU
  - Inpatient Oncology
  - Pharmacy including two satellite pharmacies
- Collect all pharmaceutical waste and deem hazardous
- Required a checklist on container to indicate proper waste codes

Learning's of Pilot

- Waste generated: 1645 pounds/30 days
- Controlled substances in waste stream issue
- Heavy metals (thimerosal, Se/Cr in TPN's)
- Infectious & hazardous waste –Dual Waste
- Cost at the time were prohibitive considering issues
- Nursing staff didn't want to stop pilot program

Step 3: Considering BMP's for Non-Regulated Pharmaceutical Waste

- PharmEcology included Best Management Practices which complied with Minnesota Lethality applications
  - Second round of educational presentations
- All Allina hospitals applied "best practices" to pharmaceutical collection and disposal
  - No drugs disposed to sewer including non-haz
  - Non-haz drugs collected and incinerated for energy recovery
  - Managed DEA Controlled that missed "witness waste" as Minnesota Lethal (hazardous)

Step 4: Performing a Drug Inventory Review

- The MPCA accepted third party evaluation options under regulatory consensus
- We used the PharmEcology formulary evaluation which included regulatory consensus criteria
- Created training materials and formulary flipcharts for staff

Step 5: Minimizing Pharmaceutical Waste

- Epi irrigation process changes
  - Make up fewer large irrigation IV's in advance
- Limit P-listed waste (document)
- Prevent waste cross contamination
- Prevent free liquids in waste containers
- Prevent use of samples

Step 5: Minimizing Pharmaceutical Waste

- Ensure correct segregation to limit costly waste streams (in order of cost per pound)
  - DEA Controlled
  - Hazardous/Infectious "Dual Waste"
  - Hazardous Waste
  - Infectious (Red Bag) Waste
  - Trash
  - Sewer

Step 6: Assessing Current Practices

- Compliance deadline was looming (extension)
- An accurate waste segregation at point of generation created problems (checklists)
- Staff input for placement of containers and plan to replace them
- Easy access to staff to field questions and make adjustments to processes
- Data collection tools needed
- LQG impact is HUGE!

Step 7: Communication & Labeling Challenge

- Created training packets for caregivers
  - Collaborated with nurse educators
  - Agreed on plan to roll out by nursing community
  - Nursing staff required training before rollout
- Created training packets for waste collectors and transport to storage room
- Labeling on containers didn't contain all information required by regulators
  - Created our own labels

Step 8: Centralized Segregation Model II

- Implemented program to collect all waste in single container (hazardous)
  - Transported to central sorting for segregation by qualified vendor
  - Dual Infectious/Hazardous Sharps collected in additional sharps container.
- Storage Room and Satellite Accumulation Requirements

Step 9: Implementation

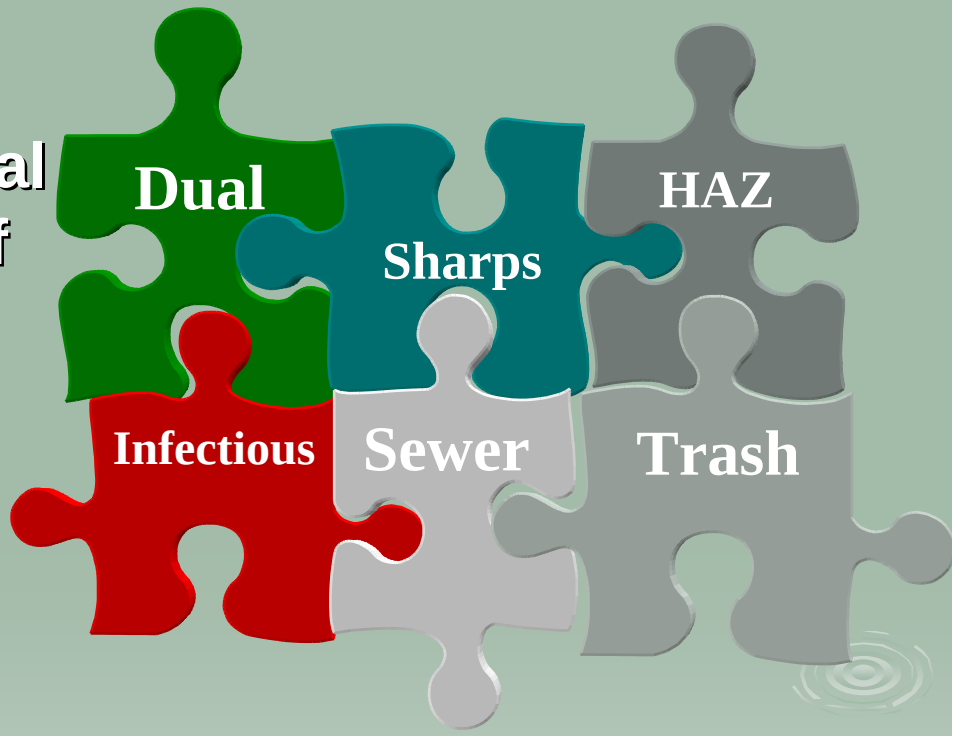
- Hazardous Pharmaceutical Waste Streams
  - Pharmaceutical Waste Stream Flow Chart
  - Waste Streams
  - Cart and Container disposal system
  - Waste Disposal Guidelines
  - Hazardous Pharmaceutical Drugs Flipchart
  - Examples of Labels

Pharmaceutical Waste Streams

Part 2

HOW WILL WE DISPOSE OF PHARMACEUTICAL WASTE?

- The proper handling and disposal of pharmaceutical wastes requires that all of us who work with and discard drug products follow proper waste stream management.
- The following slides explain the proper management of each waste stream.



Sewer

Dispose of non-hazardous liquids. (examples: soda, milk, IV solutions containing salts, sugars, lipids, amino acids, or witnessed waste of DEA controlled substances)

Dispose of Stock IV Solutions and TPN's into the drain or sink with water. (Examples: Stock IV Solutions, TPN's that only contain electrolytes, salts, lipids, K+, NA+, Dextrose, amino acids, etc.)

TPN's with drug additive (i.e. insulin or epinephrine) are disposed to the BLACK Pharmaceutical Hazardous Waste container.

Dispose of pills that patients ingested then expelled by any means to the sewer.

Trash

- Dispose of non-hazardous solids (example: garbage, plastic bags, Styrofoam cups, etc.)
- Dispose of empty containers, boxes, paper and packaging materials

Black Pharmaceutical Container

CONTAINER MUST BE CLOSED WHEN NOT IN USE

All pharmaceutical drugs that are wasted will be disposed of in the designated BLACK pharmaceutical waste container's on each patient care unit/area (Note: *NO SHARPS!*).

This includes drug vials, bottles, loose tablets, capsules, partial IV's and tubing with drug additives including any IV's with insulin or epinephrine.

All IV bags and tubing need to be placed in Ziploc bag to prevent free floating liquid at the bottom of the container.

The containers will be collected when full and taken to a central sorting room to separate the hazardous pharmaceutical waste from the non-hazardous waste stream.

Regular Sharps Container

- Used syringes with sharps
- <u>DEA Controlled Substances</u> (Narcotics) witnessed wasted in sewer *but* empty syringe with sharp can go in regular sharps container

Controlled Substance empty vial or amps will go in Black Pharmaceutical container.

Dual Waste With Sharp

<u>Hazardous Drug waste with sharps</u> (needles) will be placed in a special Hazardous "Pharmaceutical Waste" Sharps container.

This container is WHITE with a BLUE top and labeled "Hazardous Pharmaceutical Waste".

It is important to reference the hazardous drug list to verify that the drug with sharp is on the list. If it is not on the list it should be disposed in a regular sharps container.

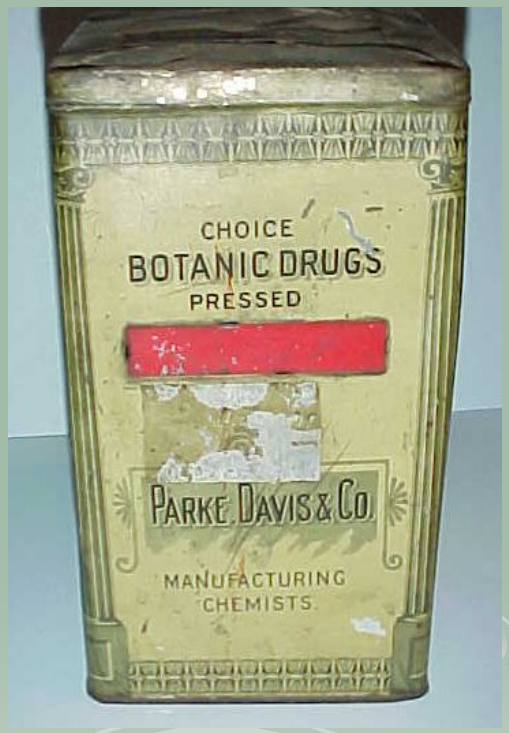
Hazardous Drug mixed with Infectious Waste

Hazardous Drug waste mixed with Infectious waste will be placed in a RED bag and then placed in a separate BLACK hazardous pharmaceutical waste container labeled with a biohazard sticker. These containers will be on hand in the soiled utility room.

An example of this waste stream would be IV tubing containing a drug (identified on the Hazardous Drug list) and the patient blood mixed together. By regulation this has to be handled separately and not just thrown into Infectious Waste.

WHAT ABOUT OUTDATED DRUGS?

Outdated medications that are in the manufacturer's original containers will be returned for possible credit through the pharmacy's reverse distributor. This is managed by pharmacy personnel.



Rollout Plan
(By Nursing Community)

- Week 1: Woman Care
- Week 2: Behavior Health, Emergency Dept., Radiology/CT/MRI
- Week 3: Med/Surg
- Week 4: Neuro/Rehab
- Week 5: Ortho/Spine
- Week 6: Cardiovascular
- Week 7: Surgical Services
- Week 8: Outpatient Clinics

Pharmaceutical Waste…

The Good,
The Bad, and The Ugly

Part 3

Zip Loc Bags

- Prevents free liquids in container
- Prevents contamination to container
- Cuts sorting time
- Prevents IV tubing mess

Before Zip Loc Bags

- Tangled IV tubing
- Fluids leak
- Contaminate container
- Safety hazard for sorting staff

Free Liquids

Zip Loc Bags Work!

Infectious Waste

No Sharps In Waste Stream

- Creates safety hazard for sorters

Compressed Aerosols

Orientation and Training Programs

- Related to hazardous (pharmaceutical) waste duties
  - General Employee Right to Know
  - Hazardous Pharmaceutical Waste Handler
    - Required for employees who handle and dispose of hazardous waste specific to pharmaceuticals at the point of care (nurses), in pharmacies, and pharmacy satellites (pharmacists and pharmacy technicians).
  - Hazardous Waste Collector
    - Required for employees who collect and replace waste containers and take to storage rooms.
  - HAZWOPER – Emergency Response Team
  - Hazardous Waste Management & DOT

Employee Training Documentation, Summary of Hazardous Waste Training

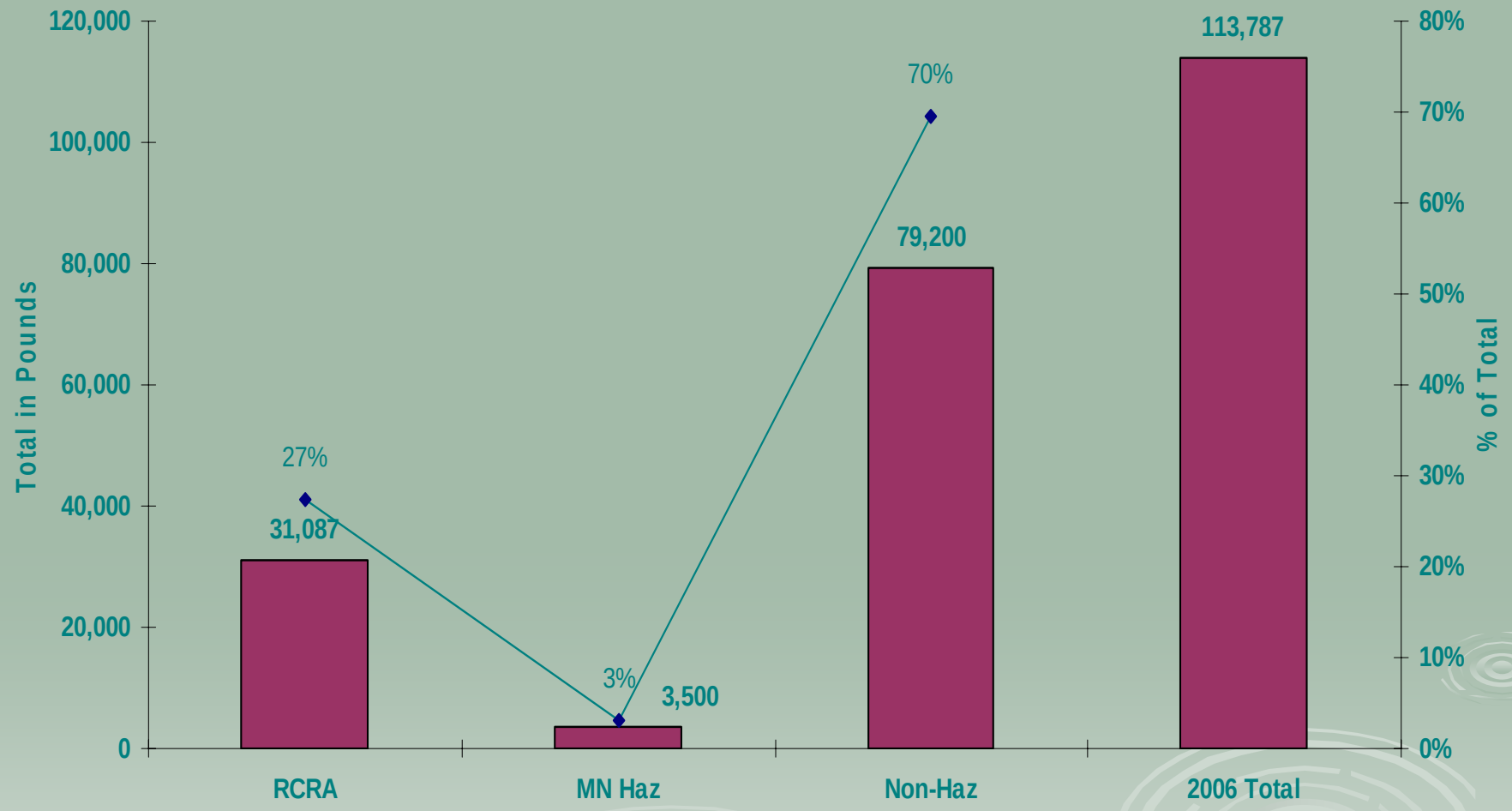
Adopted from MPCA
The Hazardous Waste Compliance Guide, Appendix G

- License Requirements
  - Management Plans
  - License posted
- Manifests
  - Proper completion
- Accumulation of Wastes
  - Hazards of each waste
  - Storage time limits
  - Satellite accumulation
- Containers
  - Marking & labeling
  - Keeping containers closed
  - Weekly inspections
- Emergency Response
  - Use and location of equip
  - Telephone postings
  - Local authority arrangements
  - Evacuation routes
- Record Keeping
  - Container inspections
  - Personnel Training
  - Annual Reports
  - Manifests and shipping papers
- Waste Reduction
  - Reduce, reuse, recycle

Pharmaceutical Waste Data 2006

- Total collected, 113,400 pounds
  - A total of 156,000 pounds since 2004
- Total Hazardous, 34,500 pounds (30%)
  - RCRA Haz, 31,090 pounds, (27%)
    - P-listed, 314 pounds
    - Dual Haz/infectious, 20,970 pounds (18%)
  - MN lethal, 3500 pounds (4%)
- Total Non-haz, 60,616 pounds (55%)
- Total trash, 18,500 pounds (16%)

Pharmaceutical Waste Data 2006



Waste Projection Costs

- Based on current data we estimate annual waste disposal at Abbott Northwestern Hospital to be:
  - $400,000 - $450,000
    - Includes Haz, Haz/Dual & Non-Haz pharm. disposal
    - Includes Lab waste disposal
    - Includes containers & vendor charges
    - Includes outside vendor sorting fees
  - Does not include
    - Additional staff time commitment (est. 2.3 FTE's)
    - Training (est. $66/employee)
    - Off site clinics
    - Evaluation processes

Waste Projections

- Waste generated at ANW for 2006:
  - Hazardous Waste
    - 34,525 pounds Pharmaceutical Waste
    - 41,000 pounds of Lab Waste
  - Non Hazardous Pharmaceutical Waste
    - 60,625 pounds incinerated for energy recovery
  - Infectious Waste Disposal
    - 365,000 pounds
  - Solid Waste Disposal
    - 1900 Tons

Positive Outcomes

- Recycling opportunities
  - Currently being rolled out
- Lab chemical reduction
  - Successful Recycling program
- Pharmaceuticals (proper management)
  - Evaluated 4100 formulary drugs
  - Epi Irrigation process changes
  - Collection program fully rolled out

Positive Outcomes Standardization

- Allina Hospitals and Clinics
  - Regulated & Hazardous Waste Committee
  - Standardized Training material
  - Standardized collection & handling processes
  - Data gathering
  - Waste streams and profiles
  - RFP & resource management initiatives
  - Drafted an Environmental Policy

A Closer Look at JCAHO

Part 4

Hazardous Pharmaceutical Waste Management Plan

Management of Information JCAHO

- Who maintains information and reports on performance indicators, spills, exposures, trending, etc.
  - Collaboration between Safety Officer, Pharmacy Manager, Lab Manager, Radiology Safety Officer, Environmental Services and Facilities Manager
- Indicate Organizational Roles and Responsibilities

New JCAHO Tracer Methodologies

- Hazardous Pharmaceutical Waste
  - Start w/ discontinued IV containing partial drug waste at patient bedside
    - Use of PPE
  - Proper waste container
    - Dual Haz w/Sharps or Haz w/Infectious
    - Hazardous waste container or non haz container
  - Hazardous Waste container full and call for removal
    - PPE
    - Training
    - Proper labeling

New JCAHO Tracer Methodologies

- Hazardous Pharmaceutical Waste cont.
  - Appropriate path through facility to storage
    - Security access to storage room
  - Storage room compliance
    - Aisle space
    - Storage limits
    - Emergency response

New JCAHO Tracer Methodologies

- Review Manifests
  - Copy distribution
- How is it placed on the truck for removal
  - DOT requirements
  - Security plans

PDSA - Plan Do Study Act

- Performance Improvement Model
- Make your goals measurable
- Document process, actions, and outcomes

Collaboration Works

- Most often regulators and the community that they are regulating only meet in an enforcement arena.
- An appreciation for the willingness of the Solid Waste Coordinating Board and Minnesota Pollution Control Agency to come to the table to discuss approaches for hospitals to achieve compliance with hazardous waste regulations while keeping in mind our important mission of quality patient care.
- Encouraged communication with local regulators

Summary

- The proper disposal of pharmaceutical and other hazardous wastes is required to protect ourselves, each other, our patients and the communities we serve.
- Caregivers have a key role making sure to consistently dispose of wastes properly.
- It can be done!

References

- Abbott Northwestern Hospital: http://www.abbottnorthwestern.com/ahs/anw.nsf/
- Hospitals for a Healthy Environment- *http://www.h2e-online.org/regsandstandards/jcahotoc.html#EC*
- H2E and PharmEcology Associates LLC, *"Implementing a Pharmaceutical Waste Management Program: Reviewing the 10 Step Blueprint":*

  http://www.h2e-online.org/docs/h2epharmablueprint41506.pdf
- PharmEcology: *www.pharmecology.com*
- EPA, Hazardous Waste Training Requirements:

  www.epa.gov/Region9/waste/rcra/ca/epafact.htm
- EPA, Profile of the Healthcare Industry: *http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/health.html*

References

- JCAHO Standards Information:

  www.jcaho.org/

- Minnesota Pollution Control Agency, Regulatory Consensus on Health Care Issues:

  http://www.pca.state.mn.us/publications/w-hw3-35.pdf

- MPCA Hazardous Waste Fact sheets Page:

  www.pca.state.mn.us/waste/pubs/business.html

- #3.34; Managing Waste From Health Care Providers:

  www.pca.state.mn.us/publications/w-hw3-34.pdf

- #3.34a; Table of Common Waste in the Health Care Industry:

  www.pca.state.mn.us/publications/w-hw3-34a.pdf

References

- **Solid Waste Management Coordinating Board**
  http://www.swmcb.org/
- **Minnesota Hospital Association:**
  http://www.mnhospitals.org/
- **Minnesota Technical Assistance Program, (MnTAP):**
  http://www.mntap.umn.edu/