



**Michigan Department of Environmental Quality &  
Michigan Health and Hospital Association**



# **MHA Health Care Pharmaceutical Waste Management Guide**

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Air & Waste Specialist  
September 12, 2013  
517-373-0590**



# Environmental Assistance Center



**Phone:** 1-800-NO2-WASTE  
(1-800-662-9278)

**Hours:** 8:00 AM to 4:30 PM  
Monday – Friday

## Compliance Assistance Services Include:

Air  
Waste  
Water  
Site Clean-up

Environmental Audit Privilege  
Brownfield Redevelopment  
Release Reporting  
Permit Coordination

- Development Background
- Benefits
- Overview
- Survey. Results, & Updates



## Why the concern –

- **Pharmaceuticals are an emerging contaminant**
- **Since 1999 USGS samples have detecting low levels of pharmaceuticals in the environment**
- **No know human health impacts**
- **Concern due to their presence in source waters used for our drinking water**

**October 2009 - MHA approached DEQ seeking regulatory clarification on...**

**– confusing disposal options**

**hazardous waste, liquid industrial waste, non-hazardous solid waste, medical waste, universal waste, mixed or dual waste, controlled substance?**

**– conflicting disposal recommendations**

**Hazardous/liquid industrial waste that is a controlled substance: should it be incinerated or sewerred?**

## December 2009 – DEQ & MHA developed a forum with 17 health care systems

- **Beaumont**
- **Bostford**
- **Bronson**
- **Covenant Health Care System**
- **Detroit Medical Center**
- **Henry Ford Health System**
- **Karmanos Cancer Center**
- **Michigan Health Association**
- **Mid Michigan**
- **McLaren**
- **Munson**
- **Northern Michigan Regional**
- **Promedica/Bixby**
- **St John Providence**
- **Sparrow**
- **University of Michigan**
- **VA Health System**

**August 2011 –  
9 disposal  
vendors joined  
to the forum  
providing input  
to make  
guidance  
effective for all  
users**

- **Chemical Analytics**
- **IWRS**
- **Stericycle**
- **Clean Harbors**
- **Drug & Laboratory Disposal (DLD)**
- **MARSH, Inc. Health Care Consultant**
- **Waste Management Health Care Solutions**
- **Heritage Environmental Service**
- **Veolia**



# MHA Guide Delivery



## January 2012

- DEQ/MHA Initial MHA Guide Workshop (117 attended)

## July 2012

- DEQ/MHA Revised MHA Guide Webinar (212 viewed)

## July 2012

- DEQ Pharmaceutical Waste Tutorial (146 viewed)
- Direct Mailing to Health Care Providers (10,000 mailed)

## July 2013

- DEQ Performed MHA Guide Survey



## Why Do I Need to Know All of This?



**Hazardous waste and liquid industrial waste regulations...**

- ☑ Apply to all businesses, including health care, municipalities, and service industries**
- ☑ Approximately 15% of pharmacy's inventory meets the definition of hazardous waste**



# Why Do I Need to Know All of This?



## MHA Guide & Tools help health care:

- understand pharmaceutical & medical waste compliance options
- identifying common waste types and classifications
- identifying common options for segregating or commingling



## Why Do I Need to Know All of This?



**MHA Guide & Tools help health care determine the compliance path with the best “fit” based on site specific details like:**

- **real estate**
- **staff level**
- **containers & locations**
- **drug labeling information systems**
- **training capabilities**



# Why Do I Need to Know All of This?



## MHA Guide & Tools help health care:

- easily find what they need at [www.michigan.gov/deqhealthcare](http://www.michigan.gov/deqhealthcare) under Waste Health Care Resources
- have a common understanding when working with waste vendors
- have a common understanding across health care systems



# Why Do I Need to Know All of This?



## Mixing different waste types:

- changes the handling/disposal requirements
- can have significant disposal cost implications
- can result in exposure or non-compliance liabilities



# Why Do I Need to Know All of This?



**Understanding the management requirements for common health care wastes is key to...**

- **protecting workers**
- **protecting our water resources**
- **achieving compliance**
- **reducing liabilities**
- **reducing costs**

## Commingled (universal waste)

- Directs cost ↑ (disposal)
- Indirect costs ↓ (training and handling)
- Error factor ↓
- Accumulation flexibility ↑ ↑ ↑
  - ☒ **ALLOWS USE OF MORE THAN ONE CONTAINER** at or near point of generation of hazardous waste
  - ☒ 1 year storage allowance
  - ☒ No required secondary containment for storage area

## Segregated (haz, liquid industrial, non-haz solid)

- Directs cost ↓ (disposal)
- Indirect costs ↑ (training and handling)
- Error factor ↑
- Accumulation *flexibility* ↓ ↓ ↓
  - ☑ **ONLY ALLOWS USE OF ONE CONTAINER** at or near point of generation of hazardous waste - large or small quantity generators, then must move to storage with containment
  - ☑ Max 90 or 180 day storage

## Why was the guide developed –

- Provide a single resource to understand of Michigan's pharmaceutical waste regulations
- Highlight incineration as the preferred disposal option
- Streamline waste handling to help meet the many other requirements that apply to hazardous pharmaceuticals in health care (patient & worker protection, DEA requirements, etc.)

## Why was the guide developed –

- Encourage the use of best management practices in handling hazardous pharmaceuticals
- Provide a collective understanding of practical approaches used in health care to handle common pharmaceutical wastes
- Increase awareness and education on the Michigan pharmaceutical waste requirements



# MHA Guide Overview



**The guide is a tool for . . .**

- **understanding target compliance options for common health care wastes**
- **selecting the best management option(s) for a site**
- **understanding best management practices for handling hazardous pharmaceuticals**



# MHA Guide Overview



## The Guide...

- is completely optional
- does not constitute any new rulemaking or new requirements
- does not cover *waste characterization & generator status; recordkeeping; training & contingency planning; etc.*

Going “off-guide” is completely appropriate, acceptable, and anticipated; however, the waste must be managed to meet the statute and rules.

**Guide Background/Purpose**

**How to Use the Guide**

**Regulations Considered**

**Guide Glossary**

**Guide Sheets -**

- Waste category defined
- Include/exclude tables
- Storage and labeling requirements
- Transport requirements
- Recordkeeping requirements
- Disposal requirements



# General Guide Use Tips



- Review guide
- Determine your waste types
- Evaluate options (segregate vs. commingle)
- Evaluate vendor costs
- Select compliance option(s)
- Implement compliance option(s)
- Perform self audits

## Bulk Haz Pharm –

Includes hazardous waste (characteristic & listed) pharmaceuticals, NIOSH hazardous drugs, investigative chemo agents, hazardous pharmaceutical spill clean-up material, hazardous pharmaceutical contaminated PPE, and may include P-listed compounding sharps if vendor approved as non-infectious



## Bulk Haz Pharm –

Outlines management standards for meeting the Rule 306, Part 111 generator exemption for (LQG 90 day and SQG 180 day)

Includes BMP to manage NIOSH hazardous drugs and investigational chemo as a hazardous waste

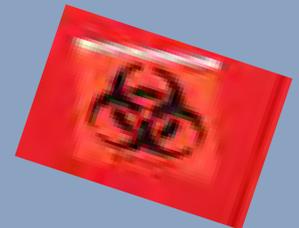


## Trace Chemo –

Includes materials exposed during chemo administration but not known to be contaminated with chemo agents, may include medical waste if preferred



Guide Sheet outlines management standards for solid waste in Part 115 and medical waste generators per Part 138 of Public Health Code



## Universal Waste Pharm –

includes all Bulk Haz Pharm wastes  
except spill material and contaminated  
PPE



may include non-haz pharm if desired

Guide sheet outlines management standards for meeting Part 111, Rule 228, universal waste standards, and meeting the liquid industrial waste generator standards found under Section 12103 of Part 121

## Universal Waste Pharm –

Primary benefits of managing materials as universal waste include:

- Longer storage time (1 year)
- Weight of waste not counted in hazardous waste generator status
- Not subject to satellite accumulation requirements (can “double satellite”)
- Less labeling

## Universal Waste Pharm –

Potential benefit in managing materials as universal waste include a reduction in the site's generator status and a reduction in the environmental compliance requirements

See Table 2.6 in Chapter 2 of the DEQ guidebook at [www.michigan.gov/ehsguide](http://www.michigan.gov/ehsguide) to compare the compliance requirements for the different hazardous waste generator types

## Non-Haz Pharm

Includes all non-hazardous pharmaceutical wastes, solid, liquid, paste or aerosol



BMP provisions exclude NIOSH haz drugs and investigative chemo agents from management under this Non-haz Pharm Guide Sheet and recommends they be managed under the Bulk Haz or Universal Pharm Guide Sheet.



# Guide Waste Categories



## Non-Haz Pharm

Can include exempt hazardous waste from a Conditionally Exempt Small Quantity Generator (CESQG) waste - site maintains generation records proving exempt status and otherwise lawfully handles/disposes of waste

CESQG waste exempted from hazardous waste regulations still has unique handling requirements, so check your vendor on CESQG waste



# Guide Waste Categories



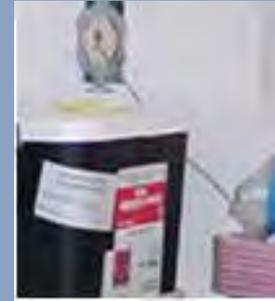
## Non-Haz Pharm

Guide sheet outlines management standards for meeting the liquid industrial waste generator requirements found under Section 12103 of Part 121

## Mixed/Dual Pharm –

Includes vaccinations with a live or attenuated virus preserved with

thimerosal, pharm waste inadvertently mixed with medical waste may include P-listed sharps from compounding and/or intracavity chemo and body fluids (check with disposal vendor)



**Recommend establishing provisions to prevent mixing of medical waste and pharm waste to prevent unanticipated cost overruns!**



# Guide Waste Categories

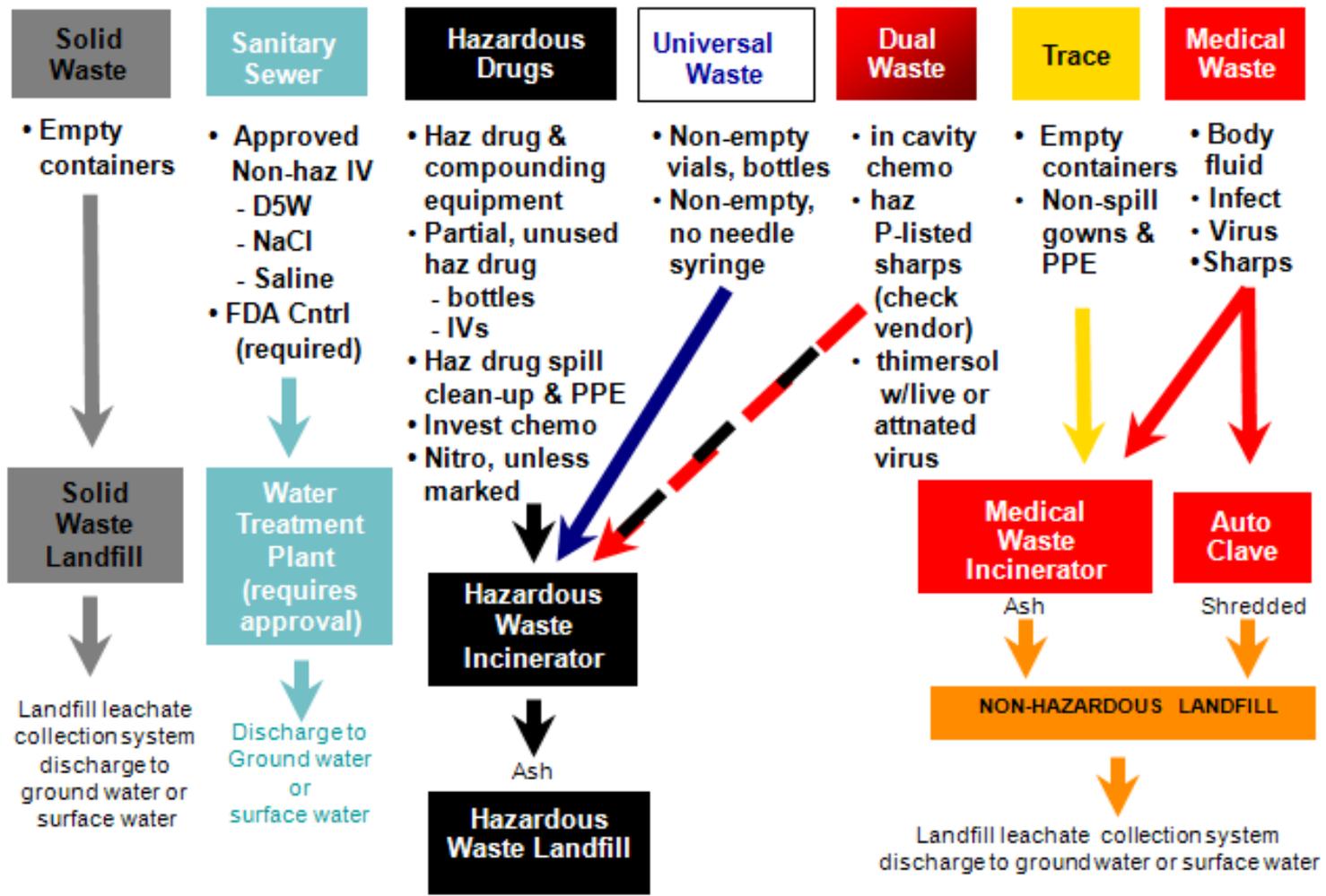


## Mixed/Dual Pharm –

Guide sheet outlines management standards for both the hazardous waste regulations under Rule 306 of Part 111 and medical waste provisions under the public health code.

Intracavity chemo (after use/administration) is managed as a hazardous waste as a BMP

## Example Pharmaceutical Chart





# How to Use the Guide



**Pick your compliance option (on or off guide) –**

- **Segregate or commingling hazardous and non-hazardous pharmaceutical waste?**
- **Some sites segregate haz from non-haz, then manage segregated haz as Universal Waste for the greater flexibility in handling and reducing their generator status**



# How to Use the Guide

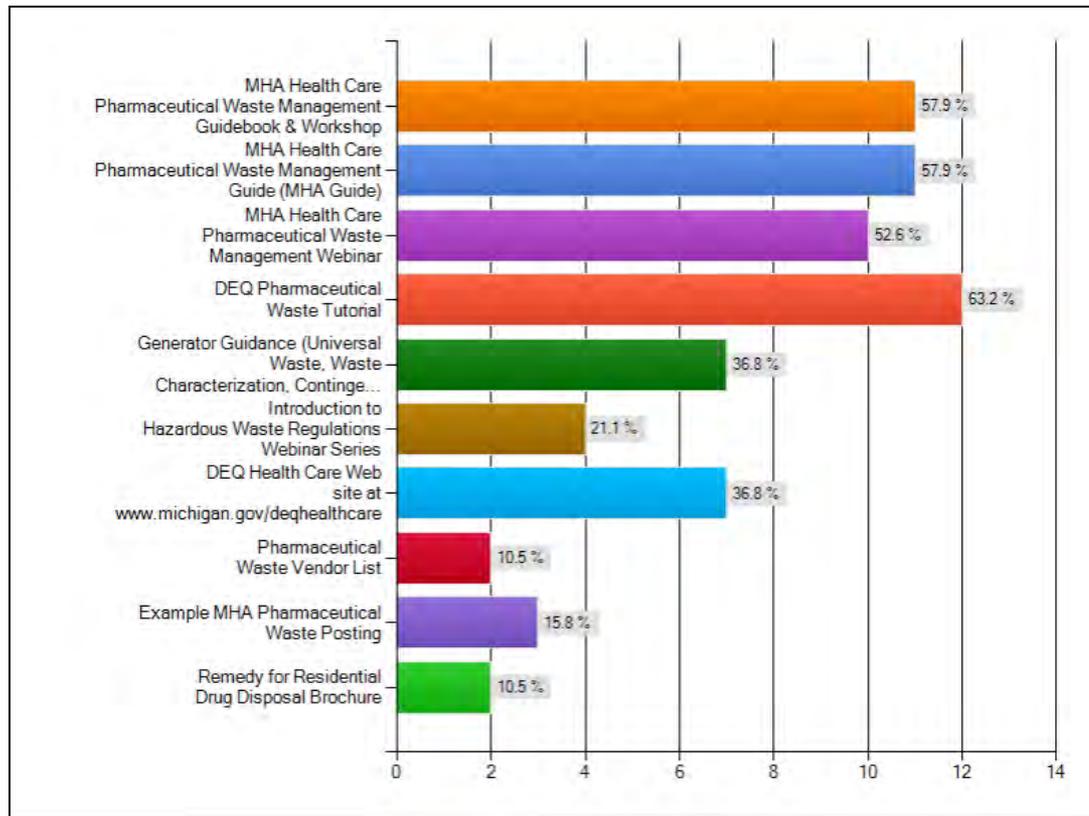


- Segregation –
  - Use Bulk Haz Pharm, Trace Chemo, Non-haz Pharm, and Mixed/Dual Pharm Guide Sheets
- Commingling –
  - Use Universal Waste Pharm, Trace Chemo, and Mixed Medical Waste Guide Sheets

## How to use the guide –

- View the on-line, on-demand recorded webinars in the ***Introduction to Hazardous Waste Regulations Webinar Series*** at [www.michigan.gov/deqworkshops](http://www.michigan.gov/deqworkshops) to fill any knowledge gaps
- Drill down into more information in the guide at [www.michigan.gov/deqhealthcare](http://www.michigan.gov/deqhealthcare) under “Waste Health Care Resources”

## Respondents Reported Using Most All of the Pharmaceutical Waste Management Tools

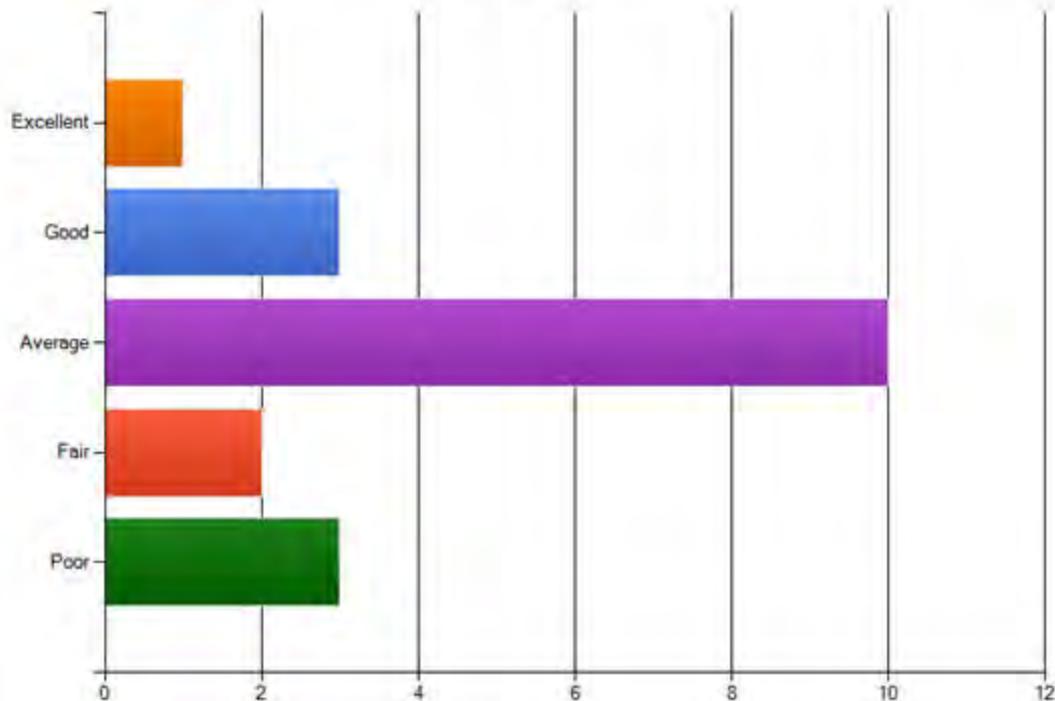


## Respondents Reported Tools...

- **Increased Knowledge of Regulations - 95%**
- **Increased Knowledge of Environmental Impact of Pharmaceutical Chemicals - 90%**
- **Caused Change in Disposal Method - 58%**
- **Helped in Developing/improving their Pharmaceutical Waste Program - 65%**
- **Helped Save Money - 26%**

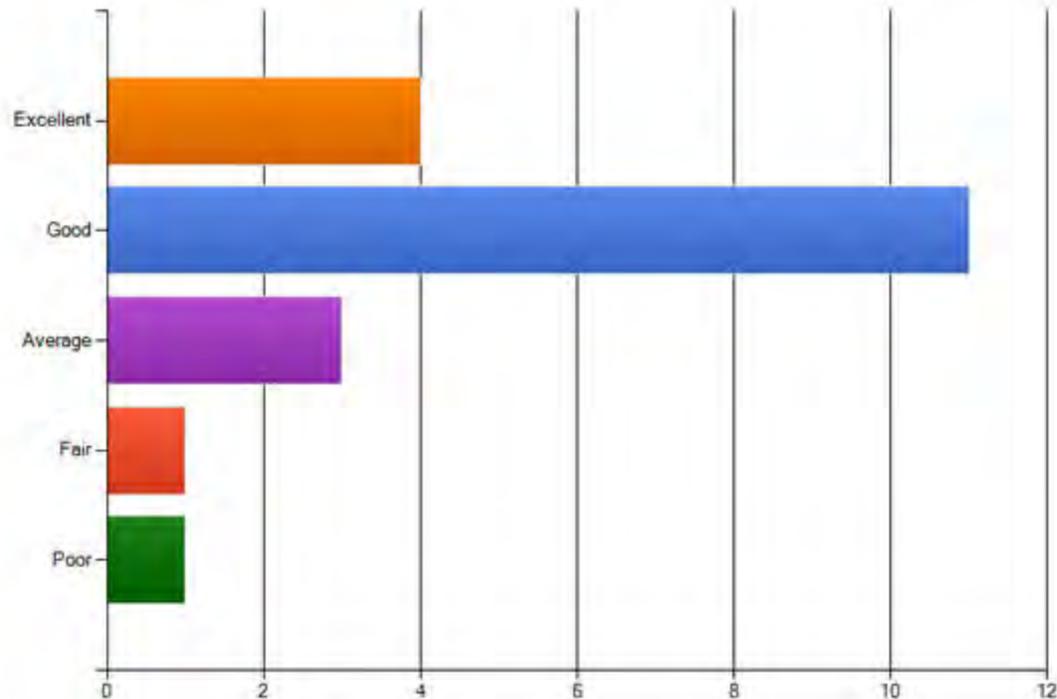
## Rank of Knowledge of Pharmaceutical Waste Regulations BEFORE Using Tools

How would you rate your knowledge of pharmaceutical waste requirements prior to using these tools?

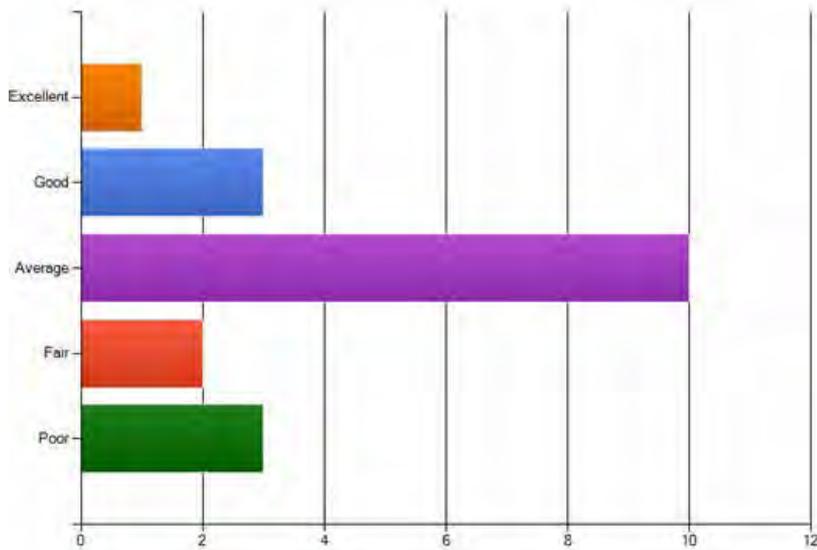


## Rank of Knowledge of Pharmaceutical Waste Regulations AFTER Using Tools

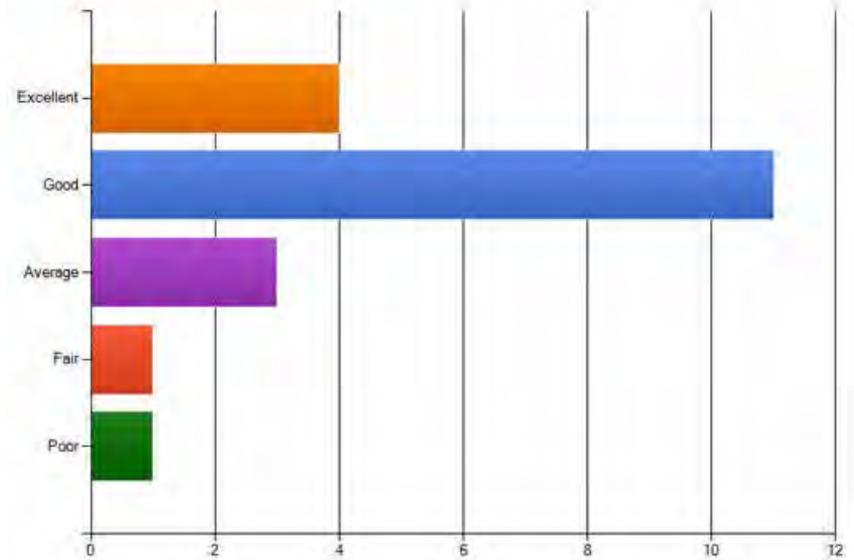
How would you rank your knowledge of pharmaceutical waste requirements after using these tools?



## Rank of Knowledge of Pharmaceutical Waste Before and After Using Tools



**Before**



**After**

## 75% Reported Using the MHA Guide and...

- **Format was easy to follow - 92%**
- **Glossary was helpful - 71%**
- **Guide Sheets were helpful - 92%**
- **No additional Guide Sheets are necessary - 62%**
- **Included/Excluded tables are helpful - 85%**
- **Storage guidelines are clear - 100%**
- **Transportation guidelines are clear - 93%**
- **Disposal guidelines are clear - 85%**

## Comments suggested...

- **Adding a table of contents would be helpful**
- **Adding a definition for “empty” for hazardous waste and liquid industrial waste would be helpful**
- **Confusion exists on what is “empty” for nitroglycerine in Michigan**
- **Additional spill guidance would be helpful**
- **Only instruction on disposal of chemotherapy agents is covered in collegiate curriculums**

## Next Steps for OEA...

- **Work with OWMRP and MHA to...**
  - ◊ **Add a table of contents**
  - ◊ **Add a definition for “empty” and clarify what is “empty” for nitroglycerine**
- **Evaluate adding details on expected protocol for spill response for pharmaceuticals**
- **Respond & share details on EPA and DEA rulemaking as they proceed**



# EPA Rulemaking Update



- **December 2008 EPA proposed rules to make pharmaceuticals a federal universal waste type**
- **January 2009 EPA public comment period closed on proposed rules**
- **June 2012 EPA announced they were abandoning adding pharmaceuticals as a federal universal waste type due to public comment**
- **EPA projects by March 2014 proposed rules specific to health care will be issued**



# DEA Update



- **Definitive answer to DEA issues cannot be provided yet since regulations are currently being written on the disposal issue as required under the Secure and Responsible Drug Disposal Act**
- **Notice of proposed DEA rulemaking is expected to be published in the Federal Registrar sometime in 2014**

## Questions?

**Go to [www.michigan.gov/deqhealthcare](http://www.michigan.gov/deqhealthcare)**

**Contact the Environmental Assistance Center at  
1-800-662-9278 or [deq-assist@michigan.gov](mailto:deq-assist@michigan.gov)**

**Contact Christine Grossman at 517-373-0590**

A young child with light hair, wearing a bright red hoodie and blue jeans, stands on a rocky beach. The child is facing away from the camera, looking out over a large body of water. In the background, a large suspension bridge with two tall towers spans across the water. The sky is clear and blue. The water is a deep blue-green color with white foam from the waves. The beach is covered in small, light-colored rocks.

**THANK YOU  
FOR PROTECTING  
MICHIGAN'S  
ENVIRONMENT!**