

# Pulling It All Together Implementing the Standards

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# Preventing Occupational Exposure

## Warning!

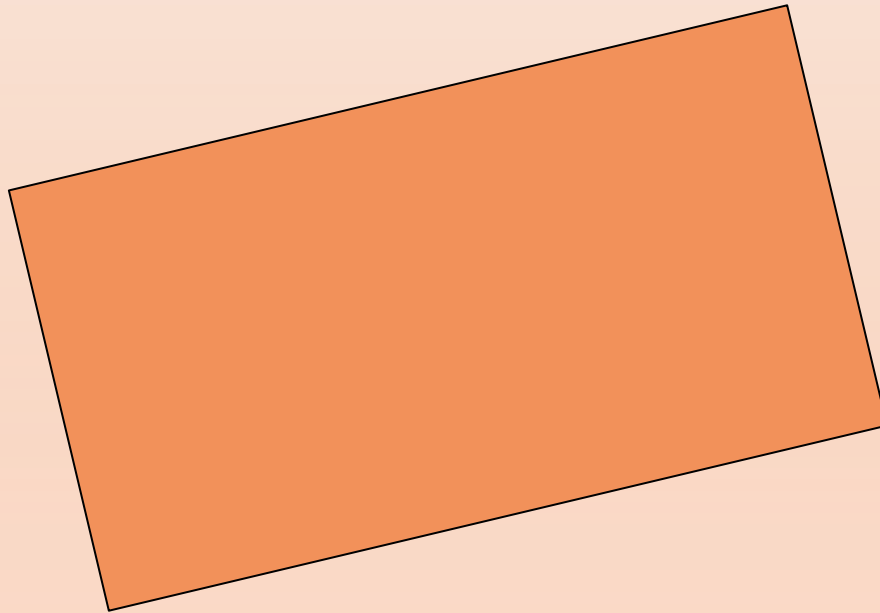
Working with or near hazardous drugs in health care settings may cause skin rashes, infertility, miscarriage, birth defects, and possibly leukemia or other cancers

# What Needs to Get Done?

- Create list of hazardous drugs
- Develop policies and procedures
- Design proper facility
- Use correct PPE
- Use CSTDs for administration of chemo
- Decontaminate surfaces
- Initiate and maintain medical surveillance
- Handle spills

# Your Specific Questions

- Write your question on a card



# List of Hazardous Drugs

- NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016
- This is a team sport!
- Antineoplastics
- Non-antineoplastics
- Reproductive hazards

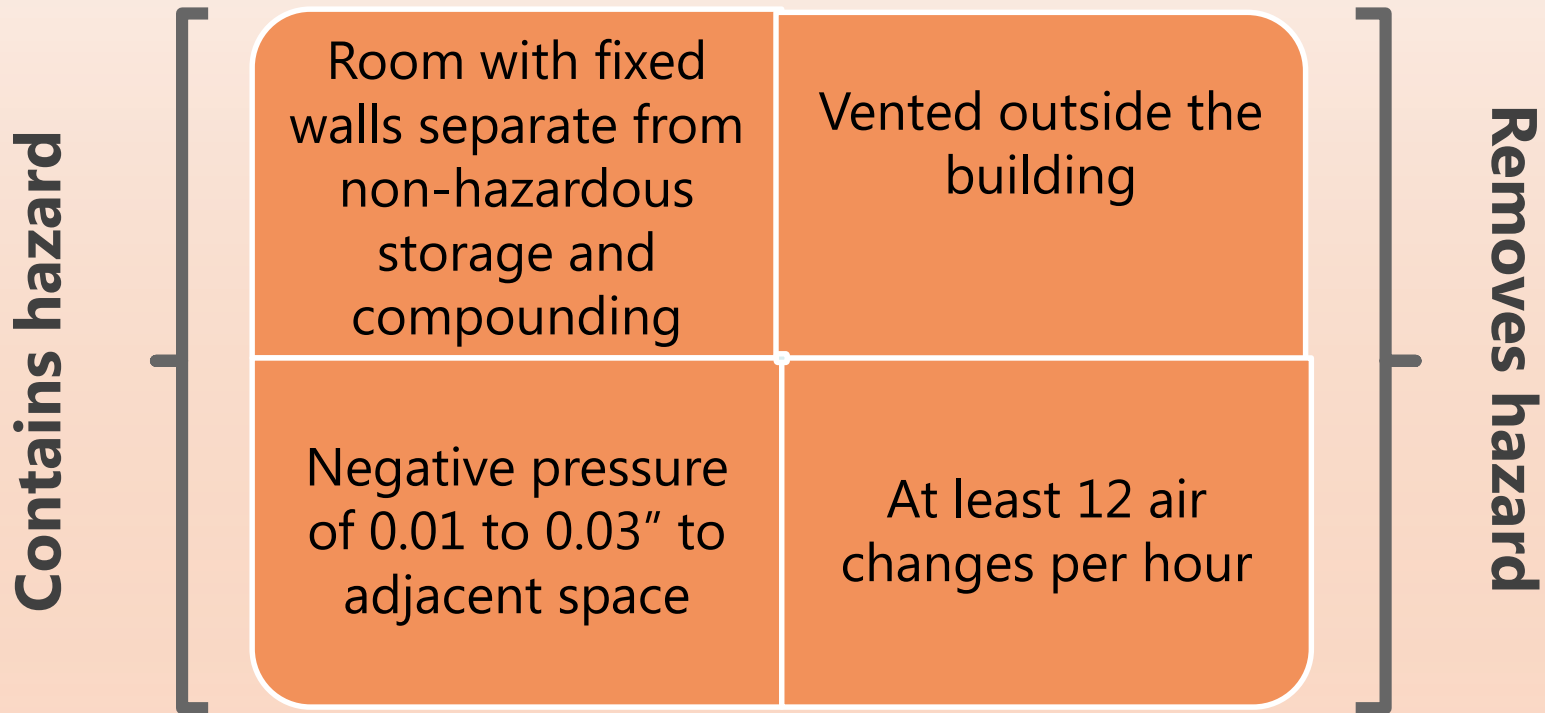
# Dosage Forms Matter

- Not all dosage forms produce the same risk
- Powder
- Vials
- Injections with closed systems
- Tablets

# Facility Design

- Antineoplastic admixtures require a proper hood (Biological Safety Cabinet) and negative pressure room
- Others can potentially be exempted if alternative strategies are identified and implemented

# Minimum Room Requirements








# What's Allowed - What's Not

Configuration	Allowed in <797>	Allowed in <800>
Cleanroom suite: ISO 7 positive anteroom opening into ISO 7 negative buffer room (30 ACPH)	Yes, with negative pressure of at least 0.01" negative to adjacent space	Yes, with pressure range of 0.01 to 0.03" negative to adjacent space
Low use exemption	Yes	No
Containment Segregated Compounding Area	Not addressed in <797>	Yes if externally vented and pressure range of 0.01 to 0.03" negative to adjacent space, but limited to 12 hour BUD
CACI in negative room with 12 ACPH	Yes, optimally vented	
BSC outside of cleanroom	No	

# Policies and Procedures (SOPs)

- Address all aspects of HD handling
  - Loading dock to handling HD waste
  - Review every 12 months
  - Communicate revisions
- Decisions (Pros and Cons)
  - Discipline or Department-wide?
  - Institution-wide?
  - Organization-wide?

# Links...

- Policy 
- Define Practice 
- Expect Compliance 
- Case study: "Not an Option"

# Policy Resource

- Esparza, D.M. (Ed.). (2014) Oncology Policies and Procedures. Pittsburgh, PA: Oncology Nursing Society.

# Personal Protective Equipment

- Gloves
- Gown
- Other PPE when necessary
  - Goggles
  - Respirator
  - Hair cover
  - Shoe covers

# Closed System Drug Transfer Devices

- How they work
- Why they should be applied by Pharmacy

# Decontamination of Surfaces

- How surfaces get contamination
- Decontamination and cleaning
- Wipe sampling

# Cleaning Solutions

<b>Activity</b>	<b>Solution</b>
Decontamination	Oxidizer – bleach or other solution designed for use with hazardous drugs
Cleaning	Detergent
Disinfecting	Alcohol



# Spills

- Misconception:
  - Case study:  
“Spills Don’t Happen”
- High-risk, Low volume:
  - Spill Drills



Wipe  
Sampling

**Worker  
Safety**



Medical  
Surveillance

# Wipe Sampling

- USP<800> specifies sites for wipe sampling in HD preparation areas
- Where are the risks in drug administration areas?

# Challenges: Wipe Sampling

- Results
  - Case study:  
“Don’t ask/ Don’t tell”
- Remediation
  - Case study:  
“Terminally Clean”

# Acknowledgement of Risk

- Standard says:

“Personnel of reproductive capability must confirm in writing that they understand the risks of handling HDs” (USP, 2016, p.92)

# Acknowledgement of Risk (2)

- What it is:
  - *Hazard Communication*
- What it is *Not*:
  - Legal document
  - Waiver
- Have a policy
- Have a form
- Consult your Risk Manager

# Sample Form

## Handling of Hazardous Drugs Employee Agreement

**All care providers** (RN, MD, NP, PA, LPN, Tech, housekeeping staff, patient observer):

I have read the Handling of Hazardous Drugs policy and procedure, and I understand:

- There are possible risks to my health and the health of other staff members who work in the environment when I handle hazardous medications.
- Medications are classified as hazardous when they possess any of the following characteristics: genotoxicity, carcinogenicity, teratogenicity or fertility impairment. Investigational drugs are considered hazardous until proven otherwise.
- Safety Data Sheets (SDS) are accessible to me if exposure occurs.
- Proper application of personal protective equipment and safe handling are required when handling hazardous medications to avoid risk to my health and the health of other staff members working in the environment.
- Proper apparel and safe handling are required when handling body fluids during the first 48

(Example: ONS, in press)



# Medical Surveillance

- Acute exposure
- Chronic exposure



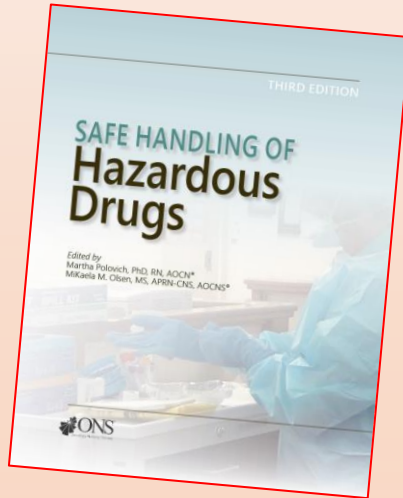
# Challenges: Medical Surveillance

- Cost concerns
- Fear of Liability
- What will it tell us anyway?

# Resources

- USP <800> FAQs
  - <http://www.usp.org/frequently-asked-questions/hazardous-drugs-handling-healthcare-settings>
- [www.readyfor800.com](http://www.readyfor800.com)
  - One hour panel discussion (physician, nurse, pharmacist)
  - Short (~5 minute) videos targeted to specific audiences
  - Ready for 800 checklist
- *Perform an Assessment of Risk to Comply with USP <800>*
  - Pharmacy Purchasing and Products ([www.pppmag.com](http://www.pppmag.com)), March 2017

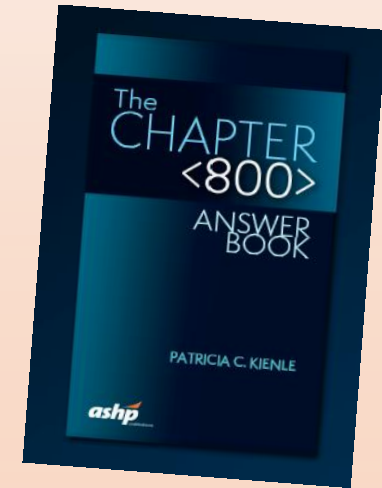
# References



[www.ons.org](http://www.ons.org)



[www.hazmedsafety.com](http://www.hazmedsafety.com)



[www.ashp.org](http://www.ashp.org)