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**#1 Go Live Date**
- December 1, 2019
- New Mexico Board of Pharmacy is currently rewriting Title 16, Chapter 19, Part 30 (Compounding of Non-Sterile Pharmaceuticals) and Part 36 (Compounded Sterile Preparations) to include USP <800> regulations
- What does this mean for hazardous compounding in New Mexico facilities?
- We have approximately 14 months to bring our facilities into compliance with the new regulations
- The New Mexico Board of Pharmacy will require compliance and will be inspecting for compliance as of December 1, 2019.
- Get it done early because you’ll have a lot of people to reach out to!

**#2 Introduction and Scope**
- **WHAT ARE WE DISCUSSING?**
  - Handling Hazardous Drugs (HDs)
- **WHY ARE WE DISCUSSING HANDLING HAZARDOUS DRUGS?**
  - To create standards for handling because we care about patient safety, employee safety and protecting the environment
  - **WHO IS AFFECTED?**
    - Anyone and any institution that handles HD preparations
  - **SHARE WHAT WE HAVE AT UNMH**

**#3 Designated Person**
LIST OF HAZARDOUS DRUGS

- ENTITY MUST CREATE AND MAINTAIN A LIST OF HDs
  - A list of HDs is maintained by The National Institute for Occupational Safety and Health (NIOSH)
  - A list of HDs is maintained at the facility
  - NIOSH List plus a proposed addition list for 2018
  - #4 LIST OF HAZARDOUS DRUGS

ASSESSMENT OF RISK

- IT IS ADVISABLE TO PERFORM AN ASSESSMENT OF RISK (AOR) ON ALL DRUGS ON YOUR HAZARDOUS DRUG LIST
  - Why? Provides for alternative containment strategies and work practices
  - NIOSH List that must follow containment requirements of USP <800>
  - Any HD API (Antineoplastics)
  - Any HD requiring manipulation
  - Alternative containment strategies and work practices are allowed for drugs on the NIOSH list if an AOR is completed
  - Final dosage forms of compounded HD preparations
  - Conventionally manufactured HD products that do not require any further manipulation

ASSESSMENT OF RISK

- TOPICS TO INCLUDE IN THE AOR:
  1. Type of HD
  2. Dosage form (Every form of every drug on the NIOSH list)
  3. Risk of exposure
  4. Packaging
  5. Manipulation
  6. Administration (IFPE)

- EXAMPLES
  1. Final dosage form of compounded antineoplastics (An AOR may reveal the need for less restrictive storage requirements)
  2. Finasteride (snorting tablets on the floor) (An AOR may reveal the need for more restrictive requirements)

Step 1: Create an Algorithm

- Present it to your group and discuss
- Pick other topics in important and order up with a recommendation of work
- You can try to evaluate each drug and each form separately
- After you include all of the forms of one drug you are looking at a list 300 lines long
- Divide and conquer for group discussion
- Bring in and compare it to the final
- Make sure it's not too long
- Finalize and upper management can lead to maintenance
Step 2: Load Your Algorithm Rules into Excel

- This is a Great Way to Get Pharmacy out there in your Facility!

**Requirements for Receiving HDs**

1. Visually examine the shipping container for signs of damage or breaches and follow the facility’s developed procedure for handing damaged or broken containers.
2. The supply chain should package HDs in temperature-stable containers prior to transportation to separate them from other drugs. Leave the HDs in the packaging and deliver to the HD storage area for further unpacking.
3. PPE, including gloves and gowns, must be worn when unpacking HDs (also known as AOR, as in to unpack).
4. Review HDs, then external shipping containers, in an area that is either positive or negative pressure relative to the surrounding area.
5. Do not unpack in a sterile compounding area or in any positive pressure area.
6. A spill kit must be accessible in the receiving area.

Step 3 Collaborate!

This is a Great Way to Get Pharmacy out there in your Facility!

- Use it as an excuse to get on agendas and network!
- Adult Nurse/Pharmacy
- Med Safety
- Safety Directors meeting
- O&E
- IPC
- Management Coffee
- Make sure it is safe AND practical!
- Participate in Nursing Education on USP 800
- Build it into your MAR and on to Pyxis
- Work with it and make it user friendly!
PROCEDURE REQUIRED FOR STORING HDs

1. Do not store on the floor. Store on secure shelves with raised front lips to prevent falling and breaking.

2. Antineoplastic HDs and HD API requiring physical manipulation must be stored in an externally vented, negative pressure room with at least 12 air changes per hour (ACPH). Example: Hazardous Ante or Clean room.

3. Non-antineoplastic, reproductive risk only, and final dosage forms of antineoplastic HDs may be stored with other inventory if permitted by entity policy. Examples: methotrexate, finasteride and warfarin tabs.

REFRIGERATED HDs

4. Refrigerated antineoplastic HDs must be stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH. Examples: storage room, buffer (clean) room or containment segregated compounding area (C-SCA). Note: It is recommended to place the refrigerator in front of an exhaust vent if the refrigerator is located in a negative pressure buffer (clean) room.

5. The most simple approach to take (if your procedures allow) is to store sterile HDs that require manipulation in a properly designed storage room, hazardous ante or clean room or C-SCA. Store non-sterile HDs such as tablets or suspensions with other inventory.

COMPOUNDING HDs

#7

PURPOSE

• Training
• Personal Protective Equipment
• Facilities and Engineering Controls
• Containment Supplemental Engineering Controls
• Non-sterile compounding

Definitions

Engineering Control: NIOSH/OSHA term that describes a barrier between the worker and HD

• Primary Engineering Control
  • Containment Primary Engineering Control (C-PCEC): Haz-ht
  • Secondary Engineering Control
  • Containment Secondary Engineering Control (C-SEC): Haz-room
  • Unclassified area: Everywhere else in the world
  • Supplemental Engineering Control: Closed-System Drug Transfer Device (CSTD)

• Equashield, Phaseal, etc

TRAINING

STERILE HAZARDOUS COMPOUNDING

1. TRAINING IN NON-HAZARDOUS STERILE COMPOUNDING IS REQUIRED PRIOR TO BEGINNING HAZARDOUS STERILE COMPOUNDING TRAINING

2. Once non-hazardous compounding training is complete and employee demonstrates competency then hazardous compounding training can begin

3. The following are required areas of training for any type of hazardous compounding:
   • Overview of entity’s list of HDs and risks
   • Review of entity’s policies and procedures for handling HDs
   • Proper Use of Personal Protective Equipment
   • Proper Use of equipment and devices
   • Response to known or suspected HD exposures
   • Spill Management
   • Proper disposal of HDs and tissue-contaminated materials
PERSONAL PROTECTIVE EQUIPMENT

1. GLOVES (American Society for Testing and Materials (ASTM) D6978)
   - Two pairs of gloves are required. The outside gloves must be sterile.
   - Change gloves every 30 minutes or when torn, punctured or contaminated.
   - Wash hands with soap and water after removing gloves.

2. GOWNS (Polyethylene-coated polypropylene or other laminate materials)
   - Disposable.
   - Long-sleeved.
   - Closed cuffs that are elastic or knit.
   - Change every 2-3 hours or per the manufacturer's information. Change immediately after a spill or splash.
   - Do not wear the gown outside of the hazardous medication preparation area.

3. HEAD, HAIR, SHOE, AND SLEEVE COVERS
   - Cover head and hair. Cover beard and moustache with a beard cover.
   - When entering the hazardous compounding area a second set of shoe covers must be donned before entering and doffed when exiting the compounding area.
   - Disposable sleeve covers may be used if polyethylene-coated polypropylene or other laminate materials offer better protection.

4. EYE AND FACE PROTECTION
   - Eye protection is typically not used when compounding inside an appropriate biological safety cabinet.
   - Goggles must be worn when eye protection is needed.
   - Face shields in combination with goggles provide full protection against splashes to the eyes and face.

5. RESPIRATORY PROTECTION
   - Interestingly enough – USP <800> doesn't give a recommendation for respiratory protection if working with a face shield in an appropriate biological safety cabinet.
   - USP <800> does state that “surgical masks do not provide respiratory protection from drug exposure and must not be used when respiratory protection from HD exposure is required”.
   - Remember a mask ensures sterility of the product but even an N-95 doesn’t do much to protect the worker.

6. DISPOSAL OF PPE USED DURING COMPOUNDING
   - Place in an appropriate waste container inside the containment secondary engineering control area (C-SEC) also known as the hazardous clean room and dispose of per local, state, and federal regulations.
   - Remove chemotherapy gloves and sleeve covers used during compounding and discard immediately into an appropriate waste container outside of the C-PEC. You may also place gloves and sleeves into a sealable bag and discard into an appropriate waste container outside of the C-PEC such as an appropriate container located in the C-SEC. This second option is a little more practical due to space inside the C-PEC.
   - Need to don PPE upon entering and doff PPE BEFORE leaving the haz room.
   - Can’t run things out of the haz room and re-enter anymore.

PERSONAL PROTECTIVE EQUIPMENT

FACILITIES AND ENGINEERING CONTROLS

In order to compound appropriately and safely understand the facility, design and engineering controls is crucial.

USP <797> AND <800> FACILITY DESIGN FOR STERILE COMPOUNDING

- Unclassified Containment-Segregated Compounding Area (C-SCA) – Requires 12 hour BUD

USP <797> AND <800> FACILITY DESIGN FOR HD STERILE COMPOUNDING – Unclassified Containment-Segregated Compounding Area (C-SCA) – Requires 12 hour BUD

- Negative pressure – Relative to adjacent area (0.01 – 0.03 in WC), externally vented to outside air.

Class II B2 BSC

Laminar Air Flow Hood (LAFH)

Class II B2 BSC

Shared Isol Room – ISO 5

Positive Pressure Buffer Room ISO 7 – Non-Hazardous Compounding. Recirculate Air through HEPA Filters or Vent to the Outside.

Negative Pressure – ISO 7 – Hazardous Compounding. Externally Vent to Outside Air.

Class II B2 BSC
PRIMARY ENGINEERING CONTROL
Containment Primary Engineering Controls (C-PECS) NOT ALLOWED for STERILE compounding of HDs

- Laminar Air Flow Hood (LAFH)
- Containment Ventilated Enclosure (CVE)
- Can be used for Non-Sterile Compounding
- Class I BSC (preferred) must be used to protect product.

PRIMARY ENGINEERING CONTROL – One more!
Compounding aseptic containment isolator (CACI)

- Note that 797 update will require that you put disposable gloves on your hands, then put your gloved hands into the gloves then put gloves on top of the gloves
- 3 pair of gloves
- You still need to put it into a negative pressure room

CONTAINMENT SUPPLEMENTAL ENGINEERING CONTROLS (CSTDs)
Keyword: Supplemental Not a substitute for a C-PEC

- Offer an additional level of protection during compounding and administration
  - A “Should” for preparation, but a “Must” for administration?
  - Many Brands in the Marketplace. Examples:
    - Equashield
    - Icumedical
    - ChemoLock
    - BD Phaseal
    - Tevadaptor

NON-Sterile Compounding
- Must also follow standards set in Pharmaceutical Compounding-Nonsterile Preparations <795>
- Handling of final dosage forms in a C-PEC is not required unless you are manipulating in such a way that produces particles, aerosols or gasses
- If you are manipulating a non-sterile HD then the following table is helpful to determine where to compound:

<table>
<thead>
<tr>
<th>Engineering Controls for Nonsterile HD Compounding</th>
<th>C-PEC Requirements</th>
<th>C-SEC Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>C-PEC Requirements</td>
<td></td>
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<tr>
<td>Externally vented</td>
<td></td>
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<tr>
<td>HEPA Filtered in series</td>
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<td></td>
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<tr>
<td>Examples: CVE, Class I or II BSC, CACI</td>
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<td></td>
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<tr>
<td>Externally vented</td>
<td></td>
<td></td>
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<tr>
<td>Class I BSC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Negative Pressure (0.01 and 0.03 inches of water column relative to adjacent areas)</td>
<td></td>
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</tr>
</tbody>
</table>

- A C-PEC designed for sterile compounding may be used to nonsterile compounded non-sterile HD. However, the C-PEC must be decontaminated, cleaned and disinfected before resuming sterile compounding.

Other Recommendations
Engineering Controls: Preferred ISO Class 7 buffer room with ISO Class 7 ante room
- Not recommended to enter the haz room through the non-haz room (ante-room preferred)
- Use if you do, a method of transportation of HD is required. It’s basically required to have a pass-through
- When sampling twice per year
- Talk with your CSTD rep!
#8 ADMINISTERING HDs

- No NIOSH medications should be crushed on the units?
- What about paediatric patient education (methotrexate)?
- It's a SHOULD NOT in USP 800, use a plastic pouch and PPE if absolutely necessary
- Now you have a Do-Not Crush list and the NIOSH list
- Time to put this info onto the MAR and Pysc.
- Use CSTDs for administration where possible (US mandatory)
- Use Chem-experienced nurses to administer chemo
- PPE all of our gloves at UNMH are “Chem gloves”
- 2 pair for anti-neoplastic HDs
- 0 versus 1 for the rest depends on your assessment of risk
- Eye, face, and respiratory protection is optional
- Refer to Oncology Nursing Society guidelines ONS for more details on PPE

#9 SPILL CONTROL of HDs

- In addition to PPE requirements described, it's up to you to work with EVS and Safety on this one!
- Develop SOPs and train your staff at UNMH
- Our Spill SOP is built into our USP 800 guideline
- Double-bag contaminated/soiled linen blue then yellow on the outside
- Spills less than 5ml
  - No spill kit necessary
- Spills greater than 5ml
  - Use a spill kit

#10 MEDICAL SURVAYLANCE

- Does every person exposed to chemo need a trip to the ED?
- Consider running this by the ED before putting it in writing
- Our ED does not feel that every drop of chemo requires an emergency visit
- Eye exposure, ingestion, symptomatic skin and symptomatic inhalation require immediate treatment
- Send patients, visitors and workers to Oc Health or ED
- Injections, rectal, nasal exposure need immediate help as well
- Work with your Occupational Health team

Help the Nurses!

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Spills!

In addition to PPE requirements described, it's up to you to work with EVS and Safety on this one!
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Accidental Exposure!

- Does every person exposed to chemo need a trip to the ED?
- Consider running this by the ED before putting it in writing
- Our ED does not feel that every drop of chemo requires an emergency visit
- Eye exposure, ingestion, symptomatic skin and symptomatic inhalation require immediate treatment
- Send patients, visitors and workers to Oc Health or ED
- Injections, rectal, nasal exposure need immediate help as well
- Work with your Occupational Health team
Conclusion

Christina Kim

USP 800 is a big deal and its our time to shine!

- Recruit a multidisciplinary team
- Come up with your own procedure and make it practical and specific for your institution
- Parade around your work!
- Use it as a networking opportunity for your department and our profession!

Wow them with Pharmacy!

References


Thank You

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