

# USP <800> PRACTICAL COMPLIANCE STRATEGIES FOR ALL PRACTICE SETTINGS

NYSCHP Annual Assembly  
The Saratoga Hilton, Saratoga Springs, NY  
Sunday, April 22th at 8 AM

**NYSCHP** | New York State  
Council of Health-system  
Pharmacists

**LOU DIORIO, RPH, FAPHA**

*PRINCIPAL*

*LDT HEALTH SOLUTIONS, INC.*



# DISCLOSURES -

- MR. DIORIO IS A SHAREHOLDER OF *LDT HEALTH SOLUTIONS, INC.*, A NJ BASED QUALITY MANAGEMENT & MEDICATION SAFETY CONSULTANCY, ADVISING CLIENTS INTERNATIONALLY ON MATTERS OF REGULATORY COMPLIANCE, COMPOUNDING TECHNOLOGY, MEDICATION SAFETY AND EXTEMPORANEOUS COMPOUNDING.
- THE OPINIONS PRESENTED ARE THAT OF THE SPEAKER AND NOT THAT OF NYSCHP.

# SESSION OBJECTIVES-

- DESCRIBE THE COMPONENTS AND STRATEGIES AVAILABLE TO PROTECT ALL COMPOUNDING AND ADMINISTRATION PERSONNEL IN HANDLING HDS.
- OUTLINE THREE MAJOR CHARACTERISTICS OF A FULLY COMPLIANT HD COMPOUNDING LOCATION / PHARMACY / PHYSICAL PLANT.
- DESCRIBE THE CRITICAL CHARACTERISTICS OF A COMPLIANT HD DRUG STORAGE PLAN.

# ARE YOU COMFORTABLE KNOWING HOW ALL THE PIECES FIT TOGETHER?



# CLEANROOM CLEANING & DISINFECTING- FOR NON-HD CSPS

FROM USP <797>

SWFI

Per <797> when dissolution of messy spills is in order

70%  
Sterile IPA

Per <797> this is the primary disinfect agent in your cleanroom

Quat  
Ammonium  
Cleaner

Needed when a “soap” is indicated. Sticky spills etc.

Sporicidal  
Agent

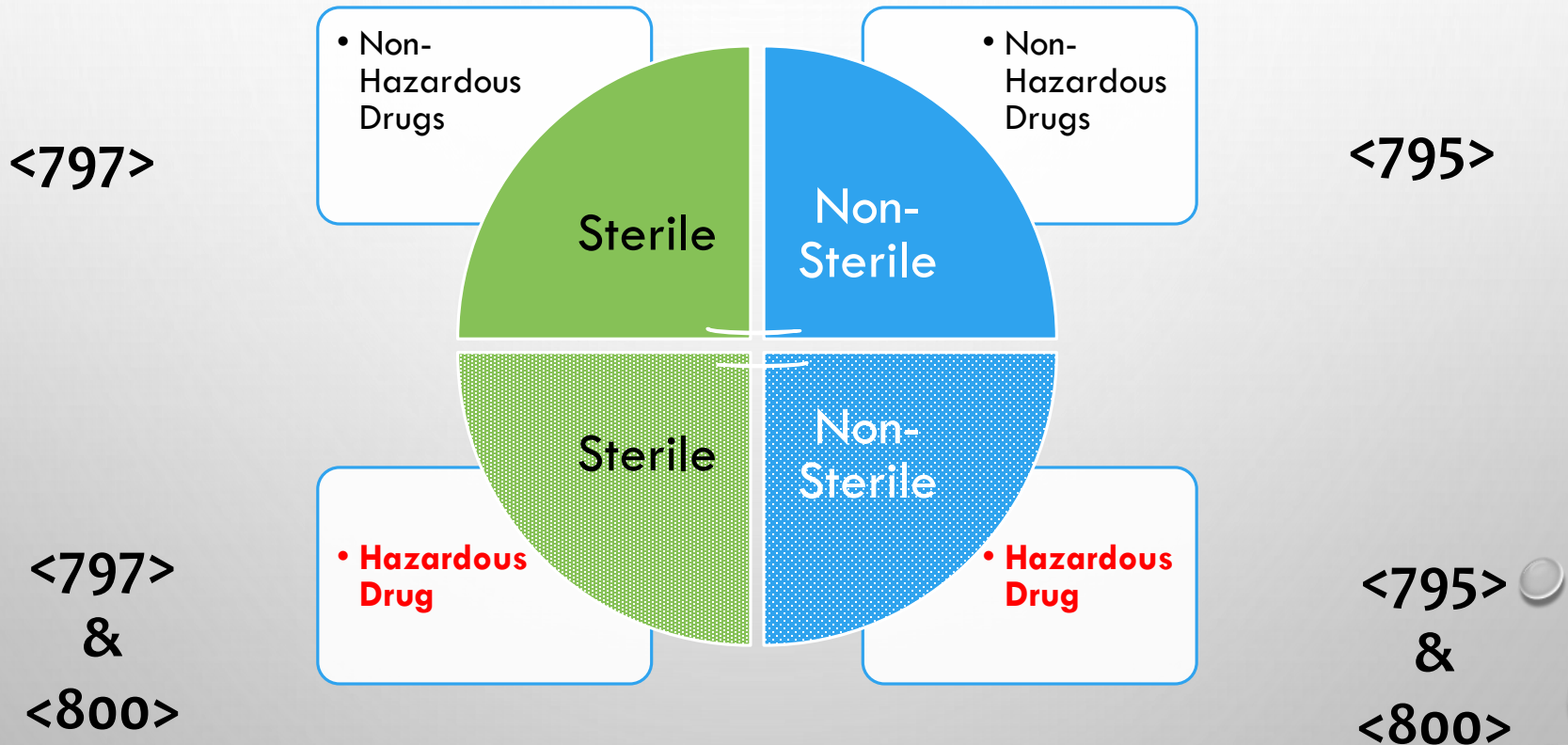
FDA is advocating the regular use of a sporicidal agent, regardless of ENV monitoring. POINTS to REMEMBER- dilution strength & contact time. [as well as residues]

2% Sterile  
Bleach

A good economical disinfectant, especially if a large volume of solution is needed. Can be used to remove Sporicidal residues. OSHA- Corrosive , S Steel could have issues

**<797> - Primary concern is  
Maintaining Sterility**

# ASSESS YOUR COMPOUNDING OPERATION



# Hierarchy of Controls



# QUESTION 1 -

- **TRUE OR FALSE : COMPLIANCE TO USP GENERAL CHAPTER <800> EXEMPTS A PHARMACY FROM THE RIGORS OF COMPLYING WITH USP <797> ?**



# USP <800> HAZARDOUS DRUGS – HANDLING IN HEALTHCARE SETTINGS

- “THIS CHAPTER DESCRIBES PRACTICE AND QUALITY STANDARDS FOR HANDLING OF HAZARDOUS DRUGS (HDS) TO PROMOTE PATIENT SAFETY, WORKER SAFETY, AND ENVIRONMENTAL PROTECTION.”

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## ● USP <800> - A WORD ABOUT DATES...

- USP GENERAL CHAPTER <800> WILL BE COME OFFICIAL ON DECEMBER 1, 2019
- HOWEVER, THE BODY OF INFORMATION AROUND THESE DRUGS IS LONG-STANDING, SUBSTANTIAL, AND WELL KNOWN.
- SINCE AN HD HANDLING COMPLIANCE PROGRAM IS MULTI-FACETED, IMPLEMENTATION TIMELINES WILL COMPLEX. DELAYING ANY EFFORTS UNTIL 2018 - 2019 WILL BE PROBLEMATIC.



USP-NF

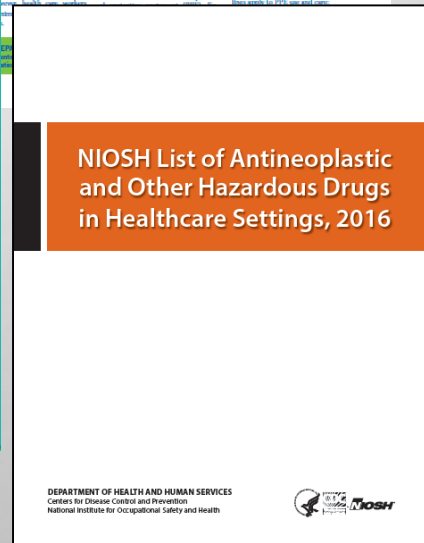
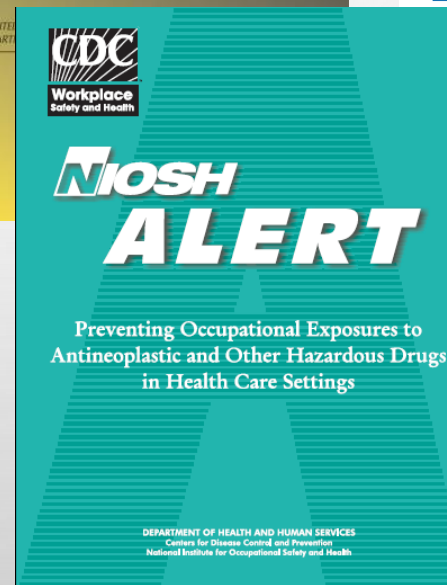
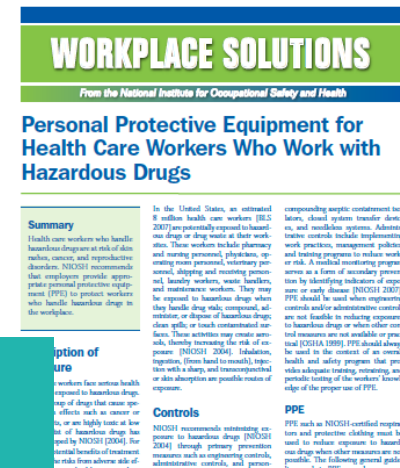
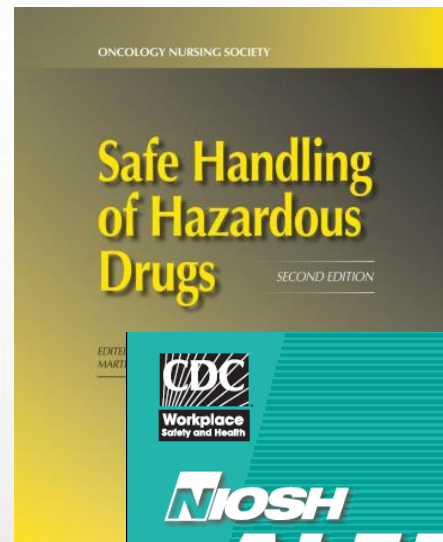
# USP TIME LINE FOR COMPOUNDING CHAPTERS -



USP-NF

# USP <800> HAZARDOUS DRUGS – HANDLING IN HEALTHCARE SETTINGS

- BASED UPON EXISTING DOCUMENTS:
  - NIOSH ALERTS
    - LIST OF ANTINEOPLASTIC AND OTHER HAZARDOUS DRUGS IN HEALTHCARE SETTINGS 2016
  - ASHP GUIDELINES
  - OTHER REGULATORY & PROFESSIONAL GUIDANCE



# USP <800> HAZARDOUS DRUGS - SCOPE

- “THIS CHAPTER APPLIES TO ALL HEALTHCARE PERSONNEL WHO HANDLE HD PREPARATIONS AND ALL ENTITIES WHICH STORE, PREPARE, TRANSPORT, OR ADMINISTER HDS (E.G., PHARMACIES, HOSPITALS, AND OTHER HEALTHCARE INSTITUTIONS, PATIENT TREATMENT CLINICS, PHYSICIANS’ PRACTICE FACILITIES, OR VETERINARIANS’ OFFICES.”



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# USP <800> HAZARDOUS DRUGS – SIGNIFICANT CHANGES

- ELIMINATES CURRENT ALLOWANCE FOR “LOW VOLUME” PROVIDERS IN A “NON-NEGATIVE” SPACE.
- ALL HAZARDOUS DRUG COMPOUNDING SHALL BE DONE IN A SEPARATE AREA SPECIFICALLY DESIGNED FOR THAT PURPOSE.
- ADDITION OF A ALLOWANCE FOR LOW/MEDIUM HD COMPOUNDING IN A “CONTAINMENT SEGREGATED COMPOUNDING AREA” (C-SCA) WITH AT LEAST 12 ACPH WITH A BUD NOT TO EXCEED 12 HOURS.

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# USP <800> HAZARDOUS DRUGS – RECEIVING OF HDS

- MUST BE RECEIVED IN A “NEUTRAL” **OR** “NEGATIVE” PRESSURE AREA RELATIVE TO ADJACENT SPACES.
- MUST HAVE APPROPRIATE/ADEQUATE PERSONAL PROTECTIVE EQUIPMENT (PPE) AVAILABLE:
  - GLOVES
  - GOWNS
  - RESPIRATOR
  - EYE PROTECTION
  - SPILL KIT
- MUST NOT BE UNPACKAGED IN STERILE COMPOUNDING AREAS!



# USP <800> HAZARDOUS DRUGS –

- LIST OF HAZARDOUS DRUGS-

- MUST BE MAINTAINED WHICH INCLUDE ITEMS ON THE CURRENT NIOSH LIST. *[CURRENTLY THE 2016 EDITION, RELEASED 9/2016]*
- **PLUS –**
  - HDS THAT ENTER THE MARKET AFTER THE MOST RECENT VERSION OF THE LIST HAS BEEN PUBLISHED.
  - INVESTIGATIONAL DRUGS-
    - IF THE INFORMATION AVAILABLE ON ANY DRUG IS DEEMED INSUFFICIENT TO MAKE AN INFORMED DECISION, CONSIDER THE DRUG HAZARDOUS UNTIL MORE INFORMATION IS AVAILABLE.



## QUESTION 2 -

- **HAZARDOUS DRUGS (HDS) CAN ONLY BE COMPOUNDED;**
- (A) IN A SEPARATE AREA DESIGNED FOR THAT PURPOSE.
- (B) UNDER “NEGATIVE PRESSURE” IN SOME TYPE OF CONTAINMENT ROOM / AREA.
- (C) BOTH A & B
- (D) NEITHER A NOR B

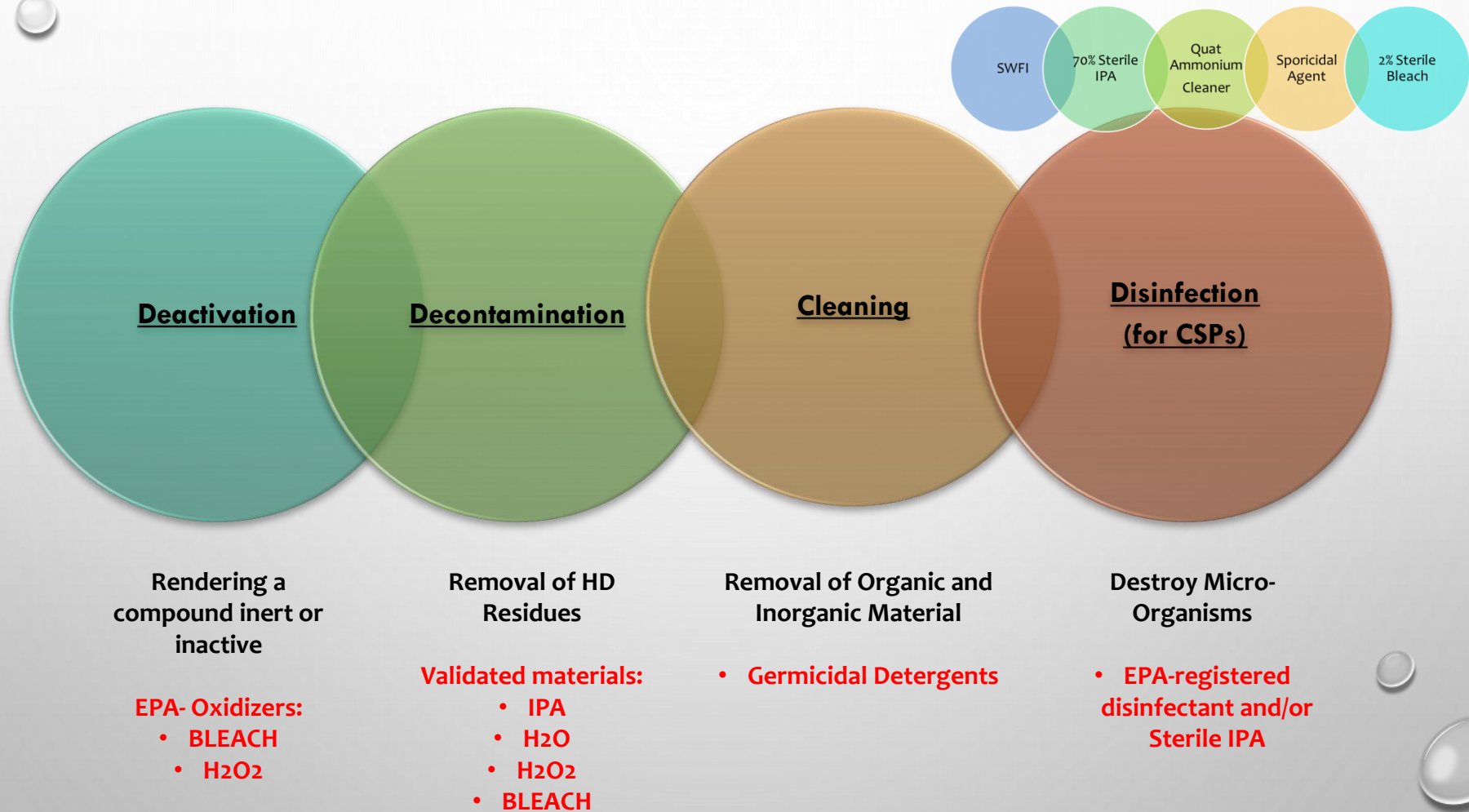
# USP <800> HAZARDOUS DRUGS- STORAGE

- STORAGE OF ANTINEOPLASTIC HDS MUST BE IN A CONTAINMENT ROOM THAT IS:
  - SEPARATE FROM NON-HD STORAGE
  - EXTERNALLY VENTILATED
  - UNDER NEGATIVE PRESSURE
  - MAINTAINS AT LEAST 12 AIR CHANGES PER HOUR (ACPH)
- REFRIGERATED HDS MUST BE IN A SEPARATE REFRIGERATOR
  - MAY BE LOCATED IN THE BUFFER ROOM
  - YOUR DESIGN MUST ACCOUNT FOR THE HEAT / PARTICULATE LOAD(S)

# QUESTION 3 -

- **WHEN CONSIDERING CLEANING OF AN HD COMPOUNDING AREA (FOR STERILE OR NON-STERILE OPERATIONS), WHICH OF THE FOLLOWING IS FALSE:**
- (A) ALL PERSONNEL MUST BE PROPERLY TRAINED TO DO SO.
- (B) ALL PERSONNEL MUST WEAR ALL APPROPRIATE PPE.
- (C) ALL DISPOSABLE SUPPLIES, CLEANING PRODUCTS, AND PPE MUST BE DISPOSED OF PROPERLY.
- (D) ALL DEACTIVATION AGENTS, CLEANERS, AND DISINFECTANTS, MUST HAVE SEPARATE SPRAY BOTTLES FOR APPLICATION.

# CLEANROOM CLEANING & DISINFECTING- FOR HD CSPS



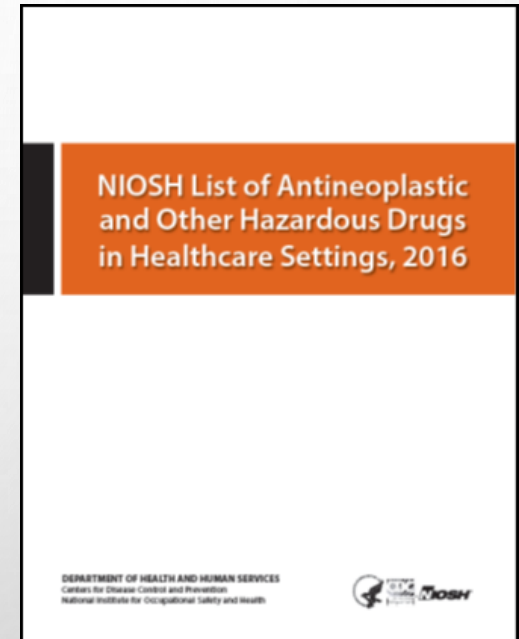
# USP <800> HAZARDOUS DRUGS –

- DOSAGE FORMS OF DRUGS DEFINED AS HAZARDOUS MAY NOT POSE A SIGNIFICANT RISK OF DIRECT OCCUPATIONAL EXPOSE BECAUSE OF THEIR DOSAGE FORMULATION.
  - **SOLID TABLETS OR CAPSULES**
    - IF ADMINISTERED INTACT WITHOUT MODIFICATION!
    - FOLLOW THE MANUFACTURER'S INSTRUCTIONS / RECOMMENDATIONS
  - MIND THE “DUST!”
  - CONSIDER ALTERNATIVE CONTAINMENT STRATEGIES / WORK PRACTICES.



# USP <800> HAZARDOUS DRUGS -

- THE NIOSH LIST OF ANTINEOPLASTIC AND OTHER HAZARDOUS DRUGS IN HEALTHCARE SETTINGS 2016
  - 2016 LIST OF HDS RELEASED 9/2016
- ASSESSMENT OF RISK CAN BE CONDUCTED ON:
  - ANTINEOPLASTIC HDS REQUIRING NO MANIPULATIONS OTHER THAN COUNTING OR PACKAGING (TABLE 1)
  - NON-ANTINEOPLASTIC HDS (TABLE 2)
  - REPRODUCTIVE-ONLY RISK HDS (TABLE 3)
  - CONDUCTED AS AN ANNUAL ACTIVITY



# SAMPLE HD COLLECTION TOOL -

| Drug Name | NDC # | NIOSH Category | Alternate Work Practice Established? | Deactivation Agent | Decontamination Agent | RCRA Hazardous Waste Category | Notes | Alternative Work Practice Description |
|-----------|-------|----------------|--------------------------------------|--------------------|-----------------------|-------------------------------|-------|---------------------------------------|
|           |       |                |                                      |                    |                       |                               |       |                                       |
|           |       |                |                                      |                    |                       |                               |       |                                       |
|           |       |                |                                      |                    |                       |                               |       |                                       |
|           |       |                |                                      |                    |                       |                               |       |                                       |
|           |       |                |                                      |                    |                       |                               |       |                                       |
|           |       |                |                                      |                    |                       |                               |       |                                       |
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|           |       |                |                                      |                    |                       |                               |       |                                       |
|           |       |                |                                      |                    |                       |                               |       |                                       |

# USP <800> HAZARDOUS DRUGS –

- **PERSONNEL TRAINING FOR HDS –**

- TRAINING MUST OCCUR BEFORE THE EMPLOYEE INDEPENDENTLY HANDLES HDS
  - ANNUAL RE-ASSESSMENT, WHEN NEW OF SIGNIFICANT PRACTICE CHANGES OCCUR.
  - EACH EMPLOYEE TRAINING MUST BE RETURN DEMONSTRATED.
- THE TRAINING PROGRAM MUST INCLUDE THE FOLLOWING:
  - OVERVIEW OF THE ENTITY'S LIST OF HDS & THEIR RISKS
  - REVIEW OF THE ENTITY'S SOPS RELATED TO THE HANDLING OF HDS
  - PROPER USE OF PPE
  - SPILL MANAGEMENT
  - RESPONSE TO KNOWN OR SUSPECTED HD EXPOSURES



# USP <800> HAZARDOUS DRUGS – KEY DESIGN ELEMENTS-

- **COMPOUNDING OF HDS-**

- ENGINEERING CONTROLS ARE REQUIRED TO PROTECT THE PREPARATION FROM CROSS-CONTAMINATION & MICROBIAL CONTAMINATION (IF A CSP)
- **PRIMARY** – VENTILATED DEVICE OR “HOOD.”
- **SECONDARY** – THE ROOM WHERE THE DEVICE IS PLACED.
- **SUPPLEMENTAL** – ADJUNCT CONTROLS OFFERING ADDITIONAL LEVELS OF PROTECTION [CSTDS]

# ENGINEERING CONTROLS -



- **PEC examples NOT endorsements**
  - *Images used by permission*

# USP <800> STERILE COMPOUNDING

## Engineering Controls for Sterile HD Compounding

| Configuration   | C-PEC  | C-SEC   |
|---|--|---|
| <b>ISO Class 7 buffer room with ISO Class 7 ante-room</b> | <ul style="list-style-type: none"><li>Externally vented</li><li>Examples: Class II BSC or CACI</li></ul> | <ul style="list-style-type: none"><li>Externally vented</li><li>30 ACPH</li><li>Negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas</li></ul> |
| <b>Unclassified C-SCA</b>                                 | <ul style="list-style-type: none"><li>Externally vented</li><li>Examples: Class II BSC or CACI</li></ul> | <ul style="list-style-type: none"><li>Externally vented</li><li>12 ACPH</li><li>Negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas</li></ul> |

# EXAMPLE: C-PEC WITHIN A C-SEC



Photo © LDT Health Solutions, Inc.

# ENGINEERING CONTROLS – (NON-STERILE COMPOUNDING)



- **PEC examples NOT endorsements**
- Photos © LDT Health Solutions, Inc

# USP <800> NONSTERILE COMPOUNDING

## Engineering Controls for Nonsterile HD Compounding

| C-PEC   | C-SEC Requirements   |
|---|--|
| <ul style="list-style-type: none"><li>Externally vented (preferred) or redundant-HEPA filtered in series</li><li>Examples: CVE, Class I or II BSC, CACI</li></ul> | <ul style="list-style-type: none"><li>Externally vented</li><li>12 ACPH</li><li>Negative pressure between 0.01 and 0.03 inches water column relative to adjacent areas</li></ul> |

Chapter <800> Hazardous Drugs- Handling in Healthcare Settings *USP39–NF34 Supplement* : No. 1

# STERILE & NON-STERILE HD COMPOUNDING TOGETHER?

- FOR ENTITIES THAT COMPOUND **BOTH NONSTERILE AND STERILE HDS**, THE RESPECTIVE C-PECS MUST BE PLACED IN SEPARATE ROOMS, UNLESS THOSE C-PECS USED FOR NONSTERILE COMPOUNDING ARE SUFFICIENTLY EFFECTIVE THAT THE ROOM CAN CONTINUOUSLY MAINTAIN ISO 7 CLASSIFICATION THROUGHOUT THE NONSTERILE COMPOUNDING ACTIVITY.
- IF THE C-PECS USED FOR STERILE AND NONSTERILE COMPOUNDING ARE PLACED IN THE SAME ROOM, THEY MUST BE PLACED AT LEAST **1 METER APART** AND PARTICLE-GENERATING ACTIVITY MUST NOT BE PERFORMED WHEN STERILE COMPOUNDING IS IN PROCESS.

From -USP <800> © US Pharmacopeial Convention 2017

# USP <800> HAZARDOUS DRUGS – KEY DESIGN ELEMENTS-

- ENGINEERING CONTROLS FOR HDS-

- **MUST-**

- ALWAYS BE A C-PEC INSIDE A C-SEC
- RUN CONTINUOUSLY
- BE EXTERNALLY VENTED THROUGH HEPA FILTRATION
  - (BEWARE THE USP ERRATA PUBLISHED IN MARCH 2016)
- BE PHYSICALLY SEPARATED (A DIFFERENT ROOM)
- BE RUN AT NEGATIVE PRESSURE BETWEEN 0.01” – 0.03” WATER COLUMN
- HAVE A SINK & EYE WASH AVAILABLE





# USP <800> HAZARDOUS DRUGS – (KEY DESIGN ELEMENTS & ADMINISTRATION)

- CONTAINMENT SUPPLEMENTAL ENGINEERING CONTROLS FOR HDS-
  - **CLOSED SYSTEM TRANSFER DEVICES (CSTDS) -**
    - PROVIDE ADJUNCT CONTROLS & OFFER ADDITIONAL PROTECTION ESPECIALLY IN ELIMINATING THE POTENTIAL OF GENERATING AEROSOLS DURING COMPOUNDING.
    - **THERE ARE NO PUBLISHED UNIVERSAL PERFORMANCE STANDARDS**
    - CSTDS ARE NOT A SUBSTITUTE FOR C-PECS.
    - CSTDS “SHOULD” BE USED FOR COMPOUNDING...
    - CSTDS “MUST” BE USED FOR ADMINISTRATION...



# QUESTION 4 -

- **WHEN CONSIDERING AN HD DRUG COMPOUNDING PROGRAM, WHICH OF THE FOLLOWING IS TRUE? [FOR BOTH STERILE OR NON-STERILE]**
- (A) PPE USED IN COMPOUNDING OF HD DRUGS CANNOT BE INCORPORATED INTO THE REGULAR TRASH / WASTE PROCESS.
- (B) TRAINING OF ALL STAFF, INCLUDING JANITORIAL STAFF IS REQUIRED.
- (C) TWO PAIRS OF GLOVES ARE REQUIRED IN BOTH THE COMPOUNDING & ADMINISTRATION OF HDS
- (D) ALL ARE TRUE

# USP <800> HAZARDOUS DRUGS –

- **PERSONAL PROTECTIVE EQUIPMENT –**

- GLOVES [ASTM STANDARD D6978]
- GOWNS [POLYETHYLENE, COATED OR LAMINATES]
- HEAD, HAIR SHOE, AND SLEEVE COVERS
- EYE AND FACE PROTECTION – [GOGGLES]
- RESPIRATORY PROTECTION – [SURGICAL N95 RESPIRATOR]

**DONNING &  
DOFFING**

- DISPOSAL OF PPE
- SPILL CONTROL
- TRAINING OF PERSONNEL



# QUESTION 5 -

- **WHEN UNPACKING HD DRUGS AT THE PHARMACY, PRACTICE, OR FACILITY; WHICH OF FOLLOWING IS FALSE:**
- (A) ONLY A NEGATIVE PRESSURE AREA IS SUITABLE.
- (B) EMPLOYEES MUST WEAR APPROPRIATE PPE, INCLUDING GLOVES & EYE PROTECTION.
- (C) ALL DRUG PACKAGING SHOULD BE WIPED DOWN BEFORE PLACING INTO YOUR STORAGE AREA (INVENTORY).
- (D) A SPILL KIT & EYE WASH MUST BE READILY AVAILABLE.

# USP <800> HAZARDOUS DRUGS –

## • ENVIRONMENTAL QUALITY AND CONTROL-

### • **ENV WIPE SAMPLING SHOULD BE PERFORMED ROUTINELY -**

- INITIALLY AS A BASELINE
- MINIMUM OF SEMI-ANNUALLY TO VERIFY CONTAINMENT

### • **KEY LOCATIONS –**

- INTERIORS OF C-PECS AND EQUIPMENT CONTAINED WITHIN
- STAGING AREA(S) NEAR C-PECS
- PATIENT ADMINISTRATION AREA(S)

### • **COMPLIANCE BARRIERS –**

- CURRENTLY THERE ARE NO ACCEPTABLE LIMITS FOR SURFACE CONTAMINATION!
- THERE ARE NO CERTIFYING AGENCIES FOR VENDORS OF WIPE KITS!
- COMMON MARKERS - CYCLOPHOSPHAMIDE, IFOSFAMIDE, METHOTREXATE, FLUOROURACIL, AND PLATINUM-CONTAINING DRUGS



# SELF-ASSESSMENT TOOLS (SAT) OR “GAP” ANALYSIS-

- USE A SAT OR GAP ANALYSIS TO IDENTIFY ORGANIZATIONAL POINTS OF COMPLIANCE AND OPERATIONAL GAPS.
  - HIGH LEVEL SITUATIONAL ANALYSIS OF CURRENT STATE OF READINESS.
  - SHOULD ADDRESS-
    - **USP <71> <85> <795> <797> <800>**
    - **FDA CPGS 503A & HOSPITAL AND HEALTH SYSTEM COMPOUNDING**
    - **STATE AND LOCAL REGULATION**
- SAT OR GAP ANALYSIS WILL SERVE AS A PLACEHOLDER FOR REGULATORY AND ACCREDITATION AGENCIES.
  - IT IS ONLY A STARTING POINT!
  - BUT THE BEST PLACE TO START IS AT THE BEGINNING!

# DEVELOPING AN ACTION PLAN-

- FOCUS SHOULD BE ON:
  - “CHANGING THE BUSINESS CULTURE” -
    - CONTROLLED PROCESSES AND DOCUMENTATION
    - SOLID WRITTEN POLICY & PROCEDURES
    - COMPETENCY BASED TRAINING AND EDUCATION
    - COMPLIANCE TO LOCAL, STATE, AND FEDERAL REGULATIONS
    - EMPLOYEE / COMPOUNDER SAFETY IS KEY!
    - PATIENT SAFETY IS ALWAYS YOUR GOAL!

# SUMMARY / CONCLUSIONS -

- THERE IS NO SUBSTITUTE FOR CONSTANT VIGILANCE ON THE PART OF ANY PROFESSIONAL, COMPOUNDER, OR HEALTHCARE PROVIDER OF COMPOUNDED PREPARATIONS.
- ***A USP <800> COMPLIANCE PROGRAM WILL REQUIRE A MULTI-FACETED APPROACH. DEPENDING ON YOUR PARTICULAR PRACTICE SETTING, RESOURCES OUTSIDE OF PHARMACY WILL BE REQUIRED!***



# QUESTION 1 -

- **TRUE OR FALSE : COMPLIANCE TO USP GENERAL CHAPTER <800> EXEMPTS A PHARMACY FROM THE RIGORS OF COMPLYING WITH USP <797> ?**
- **FALSE – BOTH ARE ENFORCEABLE & APPLICABLE!**

## QUESTION 2 -

- **HAZARDOUS DRUGS (HDS) CAN ONLY BE COMPOUNDED;**
- (A) IN A SEPARATE AREA DESIGNED FOR THAT PURPOSE.
- (B) UNDER “NEGATIVE PRESSURE” IN SOME TYPE OF CONTAINMENT ROOM / AREA.
- (C) BOTH A & B
- (D) NEITHER A NOR B
- (C) BOTH A & B

# QUESTION 3 -

- **WHEN CONSIDERING CLEANING OF AN HD COMPOUNDING AREA (FOR STERILE OR NON-STERILE OPERATIONS), WHICH OF THE FOLLOWING IS FALSE:**
- (A) ALL PERSONNEL MUST BE PROPERLY TRAINED TO DO SO.
- (B) ALL PERSONNEL MUST WEAR ALL APPROPRIATE PPE.
- (C) ALL DISPOSABLE SUPPLIES, CLEANING PRODUCTS, AND PPE MUST BE DISPOSED OF PROPERLY.
- (D) ALL DEACTIVATION AGENTS, CLEANERS, AND DISINFECTANTS, MUST HAVE SEPARATE SPRAY BOTTLES FOR APPLICATION.
- **(D) IS FALSE**

# QUESTION 4 -

- **WHEN CONSIDERING AN HD DRUG COMPOUNDING PROGRAM, WHICH OF THE FOLLOWING IS TRUE? [FOR BOTH STERILE OR NON-STERILE]**
- (A) PPE USED IN COMPOUNDING OF HD DRUGS CANNOT BE INCORPORATED INTO THE REGULAR TRASH / WASTE PROCESS.
- (B) TRAINING OF ALL STAFF, INCLUDING JANITORIAL STAFF IS REQUIRED.
- (C) TWO PAIRS OF GLOVES ARE REQUIRED IN BOTH THE COMPOUNDING & ADMINISTRATION OF HDS
- (D) ALL ARE TRUE
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# QUESTION 5 -

- **WHEN UNPACKING HD DRUGS AT THE PHARMACY, PRACTICE, OR FACILITY; WHICH OF FOLLOWING IS FALSE:**
- (A) ONLY A NEGATIVE PRESSURE AREA IS SUITABLE.
- (B) EMPLOYEES MUST WEAR APPROPRIATE PPE, INCLUDING GLOVES & EYE PROTECTION.
- (C) ALL DRUG PACKAGING SHOULD BE WIPED DOWN BEFORE PLACING INTO YOUR STORAGE AREA (INVENTORY).
- (D) A SPILL KIT & EYE WASH MUST BE READILY AVAILABLE.
- **(A) IS FALSE – NEGATIVE OR NEUTRAL AREAS ARE ACCEPTABLE.**

• **QUESTIONS -**



**Thank You !**

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# **QUALITY PROCESS-**

## **COURTESY OF LDT HEALTH SOLUTIONS, INC.**

- **PERSONNEL ARE CAPABLE AND QUALIFIED TO PERFORM THEIR ASSIGNED DUTIES.**
- **INGREDIENTS USED IN COMPOUNDING HAVE THEIR EXPECTED IDENTITY, QUALITY, AND PURITY .**
- **CRITICAL PROCESSES ARE VALIDATED TO ENSURE THAT PROCEDURES, WHEN USED, WILL CONSISTENTLY RESULT IN THE EXPECTED QUALITIES IN THE FINISHED PREPARATION.**
- **THE ENGINEERING CONTROLS AND PRODUCTION ENVIRONMENT IS SUITABLE FOR ITS INTENDED PURPOSE (ADDRESSING SUCH MATTERS AS ENVIRONMENTAL CLEANLINESS, CONTROL, MONITORING, STAFF ATTIRE, AND THE SETTING OF ACTION LIMITS, AS APPROPRIATE).**
- **THERE IS ASSURANCE THAT PROCESSES ARE ALWAYS CARRIED OUT AS INTENDED OR SPECIFIED AND ARE UNDER CONTROL.**
- **APPROPRIATE STABILITY EVALUATION IS PERFORMED OR DETERMINED FROM THE LITERATURE FOR ESTABLISHING RELIABLE EXPIRATION DATING TO ENSURE THAT FINISHED PREPARATIONS HAVE THE EXPECTED POTENCY, PURITY, QUALITY AND CHARACTERISTICS AT LEAST UNTIL THE LABELED EXPIRATION DATE.**
- **APPROPRIATE RELEASE CHECKS OR TESTING PROCEDURES ARE PERFORMED TO ENSURE THAT FINISHED CSPS HAVE THEIR EXPECTED POTENCY, PURITY, QUALITY AND CHARACTERISTICS AT LEAST UNTIL THE LABELED BEYOND USE DATE.**
- **PREPARATION CONDITIONS AND PROCEDURES ARE ADEQUATE FOR PREVENTING MIX-UPS.**
- **THERE ARE ADEQUATE PROCEDURES AND RECORDS FOR INVESTIGATING THE PRODUCT, CORRECTING FAILURES OR PROBLEMS IN PREPARATION, TESTING, OR IN THE PREPARATION ITSELF.**

# READING LIST / BIBLIOGRAPHY -

- GENERAL CHAPTER USP <795> <797> <800> - [WWW.USP.ORG](http://www.usp.org)
- CONTROLLED ENVIRONMENTAL TESTING ASSOCIATION (CETA) – [WWW.CETAINTERNATIONAL.ORG](http://www.cetainternational.org)
- CENTERS FOR DISEASE CONTROL & PREVENTION [WWW.CDC.GOV](http://www.cdc.gov)
- PHARMACY PURCHASING AND PRODUCTS MAGAZINE- [WWW.PPPMAG.COM](http://www.pppmag.com)
- FDA WEBSITE – [WWW.FDA.GOV](http://www.fda.gov)
  - NECC FDA FORM 483 -  
[HTTP://WWW.FDA.GOV/DOWNLOADS/ABOUTFDA/CENTERSOFFICES/OFFICEOFGLOBALREGULATORYOPERATIONSANDPOLICY/ORA/ORAELECTRONICREADINGROOM/UCM325980.PDF](http://www.fda.gov/downloads/aboutfda/centersoffices/officeofglobalregulatoryoperationsandpolicy/ora/oraelectronicreadingroom/ucm325980.pdf)
  - DRUG QUALITY & SAFETY ACT -
    - [HTTP://WWW.FDA.GOV/DRUGS/GUIDANCECOMPLIANCEREGULATORYINFORMATION/PHARMACYCOMPOUNDING/UCM376732.HTM](http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm376732.htm)
  - GUIDANCE – PHARMACY COMPOUNDING -
    - [HTTP://WWW.FDA.GOV/DOWNLOADS/DRUGS/GUIDANCECOMPLIANCEREGULATORYINFORMATION/GUIDANCES/UCM377052.PDF](http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm377052.pdf)
  - GUIDANCE – HOSPITAL & HEALTH SYSTEM COMPOUNDING-
    - [HTTP://WWW.FDA.GOV/DOWNLOADS/DRUGS/GUIDANCECOMPLIANCEREGULATORYINFORMATION/GUIDANCES/UCM496287.PDF](http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm496287.pdf)
- OSHA / NIOSH RESOURCES –
  - HD DRUG LIST - [HTTP://WWW.CDC.GOV/NIOSH/DOCS/2016-161/DEFAULT.HTML](http://www.cdc.gov/niosh/docs/2016-161/default.html)
  - NIOSH DRUG ALERT- [HTTP://WWW.CDC.GOV/NIOSH/DOCS/2004-165/DEFAULT.HTML](http://www.cdc.gov/niosh/docs/2004-165/default.html)
  - WORKPLACE SOLUTIONS – PPES- [HTTP://WWW.CDC.GOV/NIOSH/DOCS/WP-SOLUTIONS/2009-106/PDFS/2009-106.PDF](http://www.cdc.gov/niosh/docs/wp-solutions/2009-106/pdfs/2009-106.pdf)
  - DONNING & DOFFING – (VIDEOS) [HTTP://WWW.CDC.GOV/VHF/EBOLA/HCP/PPE-TRAINING/](http://www.cdc.gov/vhf/ebola/hcp/ppe-training/)
  - CSTD- (DRAFT FOR COMMENT) - [HTTP://WWW.CDC.GOV/NIOSH/DOCKET/REVIEW/DOCKET288/DEFAULT.HTML](http://www.cdc.gov/niosh/docket/review/docket288/default.html)