ACCREDITATION UNIVERSITY

COMPLIANCE

USP <800> & PROPOSED <797>

MAY 2018

ACHC

PCAB PHARMACY COMPOUNDING ACCREDITATION BOARD

AccreditationUniversity.com

ACCREDITATION COMMISSION *for* HEALTH CARE

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PHARMACY

COMPLIANCE
USP <800> & PROPOSED <797>

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COMPLIANCE – USP <800> & PROPOSED <797>

WELCOME

- Housekeeping Items

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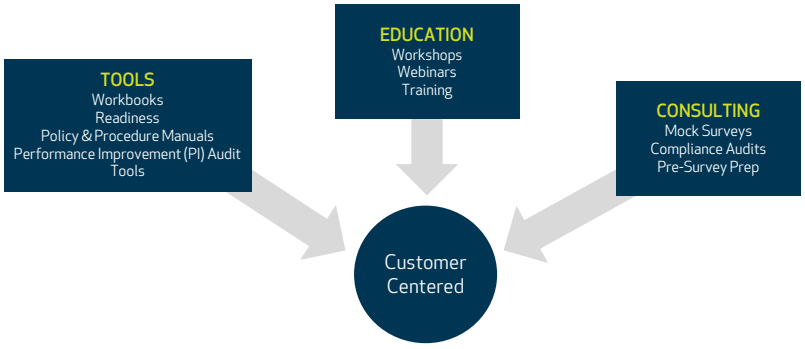

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PHARMACY

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PHARMACY

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PCAB AND ACHC

- PCAB Accreditation became a service of ACHC in July 2014

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PCAB ACCREDITATION

- Can additional accreditations be combined with PCAB ?
- How does ACHC Inspection Services (AIS) compare to accreditation?
- Who now requires accreditation?

Pharmacy Services:
AIC – Ambulatory Infusion Center
IRN– Infusion Nursing
IRX– Infusion Pharmacy
SRX– Specialty Pharmacy
SRX Only – SRX without DMEPOS
LTC - Long Term Care Pharmacy
PCAB Accreditation
CFNS – Non-Sterile Compounding (Ref. USP <795>)
CFST – Sterile Compounding (Ref. USP <797>)
AIS - ACHC Inspection Services
Distinctions*
ONC – Distinction in Oncology
HDH – Distinction in Hazardous Drug Handling
HIV– Distinction in Infectious Disease Specific to HIV
NTS – Distinction in Nutrition Support

*The provider must be accredited with ACHC to be eligible for a distinction service.

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OUR PROGRAM

- Introduction to USP <800>
- What's new in the proposed USP <797>?
- Today is your opportunity to ask questions about how these changes will impact your pharmacy

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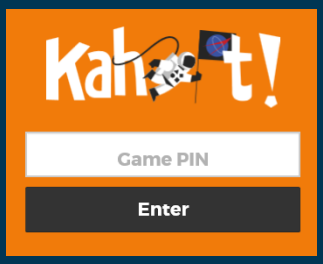
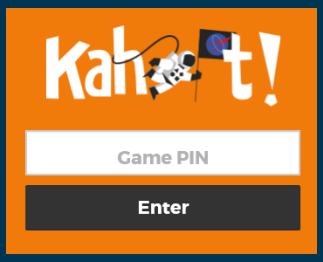
TEACHING TOOL: Kahoot!

- To create your nickname use your initials and your zip code
  - Example: AU27513



TEACHING TOOL: Kahoot!

- Cell phone or laptop
- Go to Kahoot.it
- Enter game PIN
- Enter your nickname
- See "You're in"
- You're ready!



INTRO TO USP<800>

- Overview of <800>
- Why worry about hazardous drug (HD) exposure?
- How to read a Safety Data Sheet (SDS)
- The HD list
- The compounding environment
- Primary Engineering Controls (PECs)
- Deactivation and decontamination
- Personal protective equipment (PPE)
- Personnel
- Receiving, shipping, and storage
- Occupational Safety and Health Administration (OSHA) hazard
- Communication program
- Disposal

COMPLIANCE – USP <800> & PROPOSED <797>

USP<800>

- Establishes quality and practice standards for handling HDs
- Promotes worker and patient safety
- Defines processes to minimize exposure to HDs
- Eliminates previous exemptions for handling HDs

- Applies to all healthcare personnel who handle HDs:
  - Pharmacists
  - Techs
  - Delivery personnel

PROTECTION FROM HDs IS NOT NEW

- Current USP <797> requires a negative pressure buffer room:
  - There is an undefined "low volume exemption"
  - **There is no low volume exemption in <800>**
- Current USP <795> addresses HDs:
  - In very general terms
- OSHA's *Controlling Occupational Exposure to Hazardous Drugs* references <800>, <797>, <795>
- Existing HD standards have not been strictly enforced
- USP <800> consolidates and expands existing requirements

WHAT IS HAZARDOUS

1. Appears on current "NIOSH List of Antineoplastic and Other Hazardous Drugs"
2. Meets National Institute for Occupational Safety and Health (NIOSH) list criteria for HDs
3. Treat as hazardous if there is insufficient information

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THE NIOSH LIST CATEGORIES

- Antineoplastic drugs:
  - Tamoxifen
  - Fluorouracil
  - Cyclophosphamide
- Non-Antineoplastic Drugs:
  - Estradiol
  - Progesterone
  - Testosterone
  - Apomorphine
  - Cyclosporine
- Reproductive Hazards:
  - Misoprostol
  - Spironolactone
  - Human chorionic gonadotropin (HCG)

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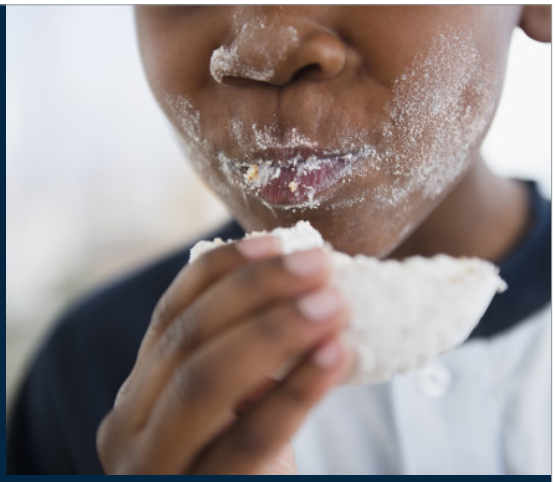
Why Should I Care?



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EVIDENCE FROM INDUSTRY

- Diethylstilbestrol (DES):
  - Loss of libido and gynecomastia in males
  - Occurred at very low exposure levels
- Synthetic estrogens:
  - Breakthrough bleeding 4x more than controls
- Corticosteroid factories: ← Not on NIOSH List!
  - Adrenal suppression
- OC *packaging into blister packs:*
  - Women: Elevated estrogens
  - Men: Decreased testosterone

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OK–BUT IS IT A PROBLEM FOR PHARMACY PERSONNEL?

- 2010 Healthcare Worker Study (including pharmacy:)
  - Chromosome 5&7 abnormalities
  - Breast and prostate cancer both linked to C-5
- 1999: Pharmacists, techs, & nurses handling HDs:
  - 40% higher risk of stillbirths and spontaneous abortions
- 2014: Pharmacy student dies of fentanyl overdose at a compounding pharmacy:
  - After only four days on the job ← Not on NIOSH List!

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VIDEO - HTTPS://VIMEO.COM/18804273

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SAFETY DATA SHEETS

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HOW TO READ AN SDS

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161
Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

Material Name: Cyclophosphamide Powder for Injection

Trade Name: SYKLOFOSFAMID, CYCLOBLASTIN, CYCLOPHOSPHAMIDE, CYCLOPHOSPHAMID, CYCLOSTIN, NEOSAR
Chemical Family: Alkylating Agent
Intended Use: Pharmaceutical product used as Antineoplastic

2. HAZARDS IDENTIFICATION

Appearance: White crystalline powder
Signal Word: DANGER

Statement of Hazard:
Toxic if swallowed.
May cause cancer.
May damage fertility or the unborn child.
May cause genetic defects.

Additional Hazard Information:
Long Term: The use of this drug during pregnancy has resulted in birth defects. Animal studies have shown a potential to cause adverse effects on the fetus. Repeat-dose studies in animals have shown a potential to cause adverse effects on reproductive system.
Known Clinical Effects: Effects on blood and blood-forming organs have also occurred.
EU Classification
EU Indication of danger:
Toxic
Toxic to reproduction: Category 1
Carcinogenic: Category 1
Mutagenic: Category 1

EU Hazard Symbols:
T

EU Risk Phrases:
R25 - Toxic if swallowed.
R45 - May cause cancer.
R46 - May cause heritable genetic damage.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Cyclophosphamide	50-18-0	200-015-4	T;R25 Repr.Cat.1;R60-61 Carc. Cat.1;R45 Mut. Cat.1;R46	100

4. FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

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5. FIRE FIGHTING MEASURES

Extinguishing Media:	Use carbon dioxide, dry chemical, or water spray.
Hazardous Combustion Products:	Carbon dioxide, carbon monoxide, and oxides of nitrogen phosphorous
Fire Fighting Procedures:	During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Fire / Explosion Hazards:	Fine particles (such as dust and mists) may fuel fires/explosions.

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
Measures for Cleaning / Collecting:	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
Measures for Environmental Protections:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Additional Consideration for Large Spills:	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

No Occupational Exposure Limit (OEL) or Short Term Exposure Limit (STEL) has been identified.

Engineering Controls:	Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. All operations should be fully enclosed. No air recirculation permitted.
Environmental Exposure Controls:	Refer to specific Member State legislation for requirements under Community environmental legislation.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands:	Wear impervious, disposable gloves as minimum protection (double recommended).
Eyes:	Wear safety glasses as minimum protection.
Skin:	Wear impervious disposable protective clothing when handling this compound.
Respiratory protection:	Whenever excessive air contamination (dust, mist, vapor) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure.

9. PHYSICAL AND CHEMICAL PROPERTIES

10. STABILITY AND REACTIVITY

Chemical Stability:	Stable under normal conditions of use.
Conditions to Avoid:	Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers

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11. TOXICOLOGICAL INFORMATION

Carcinogen Status: See below

Cyclophosphamide

IARC:	Group 1 (Carcinogenic to Humans)
NTP:	Known Human Carcinogen
OSHA:	Listed

12. ECOLOGICAL INFORMATION

Environmental Overview:	Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:	Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

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14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

This material is regulated for transportation as a hazardous material/dangerous good.

UN number:	UN 2811
UN proper shipping name:	Toxic solid, organic, n.o.s. (cyclophosphamide)
Transport hazard class(es):	6.1
Packing group:	III

15. REGULATORY INFORMATION

OSHA Label:
DANGER
Toxic if swallowed.
May cause cancer.
May damage fertility or the unborn child.
May cause genetic defects.

Cyclophosphamide

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	10 lb 4.54 kg
California Proposition 65	carcinogen initial date 2/27/87 developmental toxicity initial date 1/1/89 female reproductive toxicity 1/1/89 male reproductive toxicity initial date 1/1/89

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

R25 - Toxic if swallowed.
R45 - May cause cancer.
R46 - May cause heritable genetic damage.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

Data Sources:	Pfizer proprietary drug development information. Publicly available toxicity information.
Reasons for Revision:	Updated Section 3 - Composition / Information on Ingredients.
Prepared by:	Product Stewardship Hazard Communication Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet

COMPLIANCE – USP <800> & PROPOSED <797>

THE HAZARDOUS DRUG LIST

ACHC | CUSTOMER CENTRAL

- OSHA requirement (29 CFR 1910.1200)
- Guides all activities for handling and disposal of HDs
- Must be used to train employees
- An ongoing reference for employees

- Must include all NIOSH-listed drugs
- Must be reviewed at least annually
- Must be updated with new HDs
- Recommendation: Keep an electronic version

RESOURCES TO CREATE YOUR LIST

- NIOSH List
- SDS:
  - **Create an SDS file for all HDs stocked!**
  - Risks
  - Transport requirements
- Package inserts:
  - Special handling requirements

WHAT SHOULD BE ON THE LIST?

Drug	Form	CAS#	Category	Hazard	Location
Estradiol	API	50-28-2	Non-Antineoplastic	May cause cancer. May damage fertility or the unborn child.	HD Storage HD NS Compounding
	Capsules	50-28-2		May cause cancer. May damage fertility or the unborn child.	HD Storage Pick up HD NS Compounding
Cyclophosphamide	Vials	50-18-0	Antineoplastic	Toxic if swallowed. May cause cancer. May damage fertility or the unborn child. May cause genetic defects.	HD ST Buffer Pick Up

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WHAT SHOULD BE ON THE LIST?

Drug	Form	Location	Receiving	Compounding	Counting FD	Transport
Estradiol	API	HD Storage HD NS Compounding	Full Precautions per SOP XXX	Full Precautions	N/A	N/A
	Capsules	Storage Pick up HD NS Compounding	N/A	Full Precautions	Dedicated Utensils Std HD precautions per SOP XXXX	HD Precautions per SOP XXXX
Cyclophosphamide	Vials	HD ST Buffer Pick Up	Full Precautions per SOP XXX	Full Precautions	Gown/Double gloves	HD Precautions per SOP XXXX

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WHAT SHOULD BE ON THE LIST?

Drug	Shipping	Disposal	Pregnant	Alternative Containment Strategy
Estradiol	Not Dangerous Goods	HD Waste	PR Protocol	N/A
	Not Dangerous Goods	HD Waste	PR Protocol	N/A
Cyclophosphamide	UN2811 Toxic solid, organic, n.o.s. (cyclophosphamide) Hazard Class: 6.1 Packing Group 3 Air Cargo: 30ml or less per inner container Upto 1 liter total in box "E" Label Ground 4 Liters per inner container 5kg if solid	HD Waste	PR Protocol	N/A

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CONTAINMENT REQUIREMENTS

- What qualifies?
- What are environmental requirements?
- Engineering controls?
- Additional equipment?

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WHAT REQUIRES CONTAINMENT?

- NIOSH-list drugs that must follow <800>'s containment requirements:
  - HD API
  - Antineoplastics requiring *further manipulation*
- NIOSH-list drugs that do not have to follow containment requirements *if an assessment of risk is performed and implemented:*
  - Final dosage forms of compounded HD preparations
  - Conventionally manufactured HD products that require no further manipulation than counting or repackaging
  - Non-antineoplastic HD dosage forms on the NIOSH list

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ALTERNATIVE/ NO CONTAINMENT

- Final dosage forms that only require counting/repackaging:
  - Avoid automated counting or packaging machines
  - Consider manufacturer exceptions

To minimize the risk of dermal exposure, always wear impervious gloves when handling vials containing CYTOXAN sterile powder for injection, or bottles containing CYTOXAN tablets. This includes all handling activities in clinical settings, pharmacies, storerooms, and home healthcare settings, including during unpacking and inspection, transport within a facility, and dose preparation and administration.

- Assessment of Risk must include the following:
  - Type of HD
  - Dosage form
  - Risk of exposure
  - Packaging
  - Manipulation

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ALTERNATIVE/ NO CONTAINMENT

- Assessment of Risk (cont.:)
  - Must list each drug and dosage form individually:
    - May have same information for multiple drugs or dosage forms
  - Must document **what** alternative containment strategies or work practices are being employed
  - Must be reviewed every 12 months:
    - Review must be **documented**!

NON-STERILE HD COMPOUNDING

Containment Secondary Engineering Control (C-SEC):

- Dedicated room for HD compounding
- Negative pressure -0.01 to 0.03 inches water
- 12 ACPH
- Unclassified air
- Externally vented

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NON-STERILE HD COMPOUNDING

Smooth, seamless, and impervious surfaces:
- Avoid particle board
- Floor laid seamlessly
- Epoxy drywall or other wall material
- Coved moldings
- Impervious ceiling tiles and lighting fixtures

Must be able to stand decontamination with sodium hypochlorite solution

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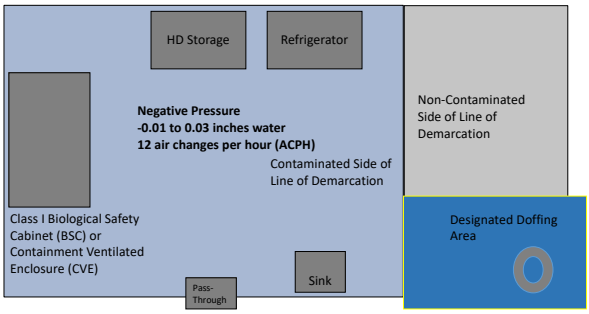
NON-STERILE HD COMPOUNDING



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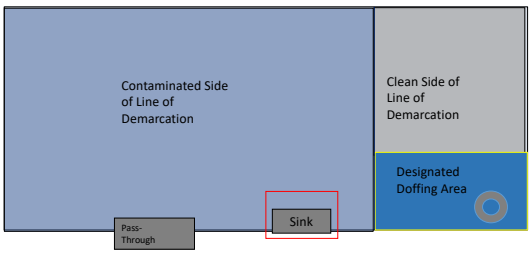
NON-STERILE HD COMPOUNDING



- Water must be accessible; does not specify must be in C-SEC
- USP <800> not specific about sink location
- Option: Sink in C-SEC for equipment washing

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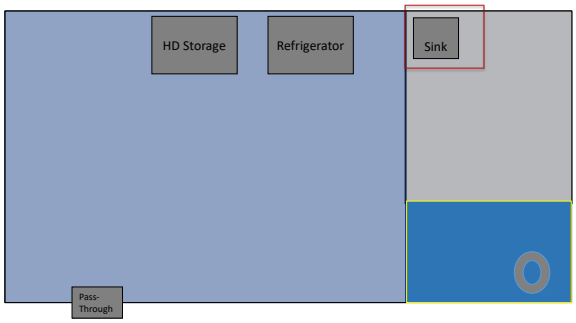
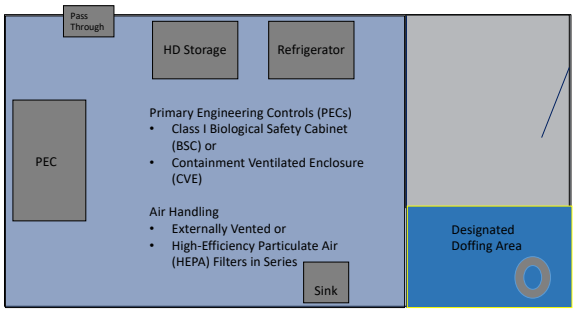
NON-STERILE HD COMPOUNDING



- Option: Sink for handwashing in C-SEC

NON-STERILE HD COMPOUNDING



CLASS I BSCS FOR NON-STERILE COMPOUNDING

- Protect the operator from exposure to HDs
- Do not protect HDs from exposure to the compounder

Image used with permission of AirClean Systems

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Class I BSC – Externally Vented

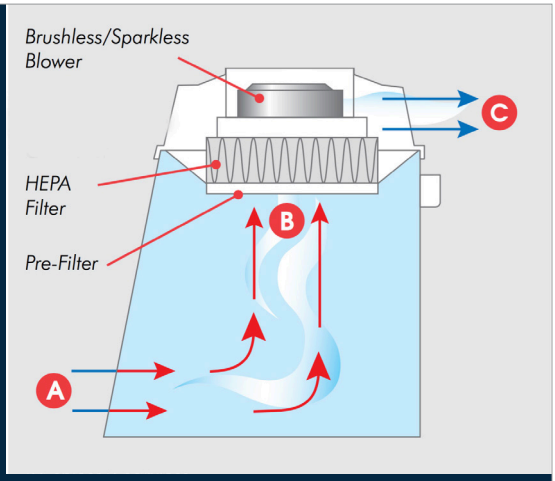

Image courtesy AirClean Systems

Class I BSC – Redundant HEPA Filter

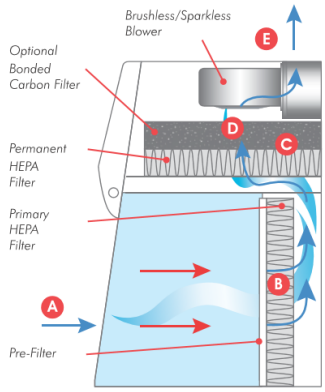

Image courtesy AirClean Systems

KEY POINTS ABOUT C-PECS – NS

- C-PEC may be either externally vented or go through redundant HEPA filters in series
- These devices can include:
  - Class I or II BSCs
  - Vented balance safety enclosures
  - Compounding Aseptic Containment Isolators (CACIs)
- The C-PEC must operate continuously if it supplies some or all of the negative pressure for the C-SEC

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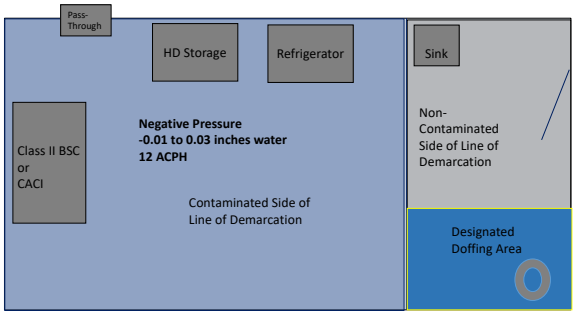
MORE TO THINK ABOUT

- A pass-through will save time and money
- What are you going to do with all that contaminated equipment?
  - Dirty side sink: Equipment never leaves the room
- Schedule your HD compounding:
  - It may not be time or PPE cost-effective to make one hormone capsules or gel Rx
- Use your old internally vented BSC to unpack
- Suggestion: Do not build in any fixtures:
  - Decontamination processes may be more difficult with drawers and cabinets
  - Use flat shelves, stainless steel tables, etc.

STERILE HD COMPOUNDING – CATEGORY 1



CONTAINMENT SEGREGATED COMPOUNDING AREA (C-SCA)

- Surfaces: Smooth, seamless, and impervious
- Pressure: 0.01-0.03 inches negative water column
- Air changes: 12 per hour
- Unclassified air
- May be used for storage (sterile HDs) and compounding
- **Only for Category 1 CSPs**

COMPLIANCE – USP <800> & PROPOSED <797>

C-SCA BUDs ARE LIMITED

- Beyond-Use Date (BUD) per USP<797> for HD Compounded Sterile Preparations (CSPs) prepared in a segregated compounding area
- Current USP:
  - Class II BSC/CACI: Low-risk CSPs with 12 hour BUD
  - Standalone CACI: Low, medium, maybe high risk
- USP revision:
  - Class II BSC or CACI: ≤12h room temperature, ≤24h refrigerated

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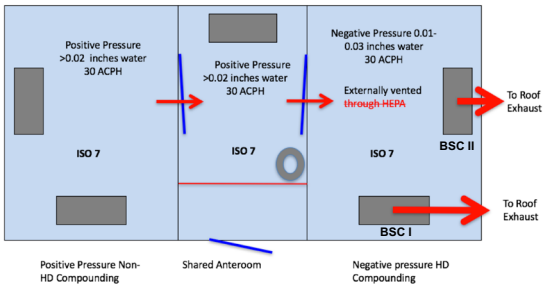
DESIGNS FOR BOTH CATEGORY 1 & 2 COMPOUNDING



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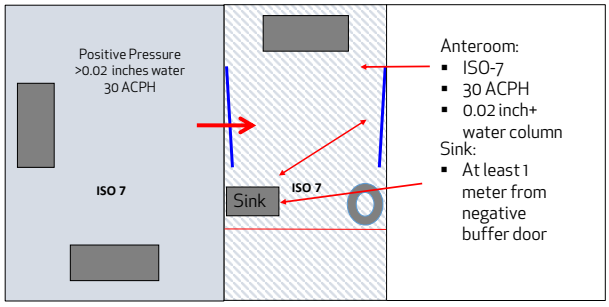
THE SHARED ANTEROOM



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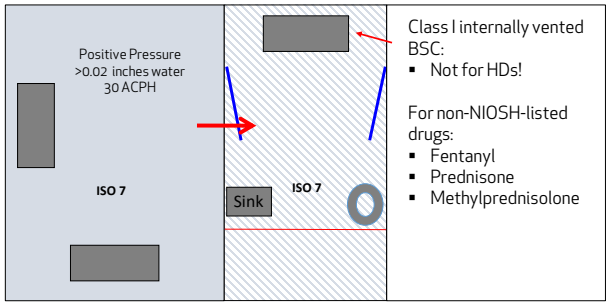
THE SHARED ANTEROOM



Class I internally vented BSC:
- Not for HDs!

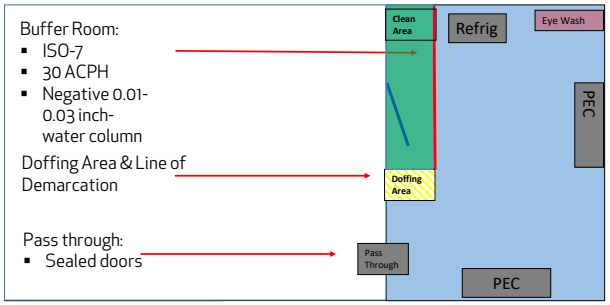
For non-NIOSH-listed drugs:
- Fentanyl
- Prednisone
- Methylprednisolone

THE BUFFER ROOM

Buffer Room:
- ISO-7
- 30 ACPH
- Negative 0.01-0.03 inch-water column

Doffing Area & Line of Demarcation

Pass through:
- Sealed doors

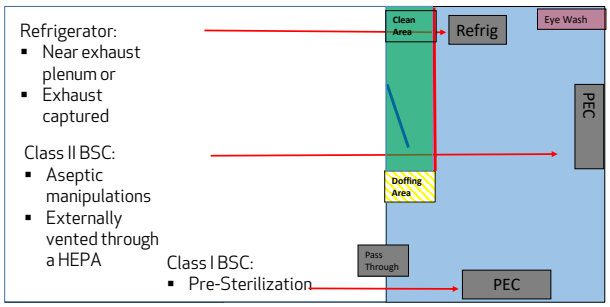


THE BUFFER ROOM

Refrigerator:
- Near exhaust plenum or
- Exhaust captured

Class II BSC:
- Aseptic manipulations
- Externally vented through a HEPA

Class I BSC:
- Pre-Sterilization



COMPLIANCE – USP <800> & PROPOSED <797>

STERILE HD COMPOUNDING

- Smooth, seamless, and impervious surfaces
- Avoid particle board
- Floor laid seamlessly
- Epoxy drywall or other wall material
- Coved moldings
- Impervious ceiling tiles and lighting fixtures
- Must be able to stand decontamination with sodium hypochlorite solution
- Can ruin stainless steel if not inactivated

BUFFER ROOM

- **Dedicated room for HD compounding:**
  - Negative pressure 0.01 to 0.03 water column
  - ISO-7
  - 30 ACPH
  - Externally vented
- **Buffer room may be used for:**
  - Compounding sterile HDs
  - May be used for storing HDs
- **ISO-7 Anteroom is required!**
  - Different than the typical ISO-8 anteroom
  - 30 ACPH for ISO-7 vs. 20 ACPH for ISO-8

CLASS II BSC TYPES

- Type A1:
  - 75 ft./min. inflow velocity
  - Exhaust into lab or canopy:
    - Into lab would be non-compliant
  - 70% of the air recirculated/30% exhausted
  - Have positive-pressure exhaust ducts - NOT SUITABLE FOR HDs
- Type A2:
  - 100 ft./min. inflow velocity
  - Exhaust into lab or through canopy:
    - Into lab would be non-compliant

NOTES

NOTES

CLASS II BSC TYPES

- Type B1:
  - 100 ft./min. inflow velocity
  - Exhaust to outside via direct duct connection
  - 30% of the air recirculated/70% exhausted
  - Suitable for minute quantities of volatile drugs
- Type B2:
  - 100 ft./min. inflow velocity
  - Exhaust to outside via direct duct connection
  - 100% of the air is exhausted
  - Suitable for volatile drugs

VOLATILE DRUGS

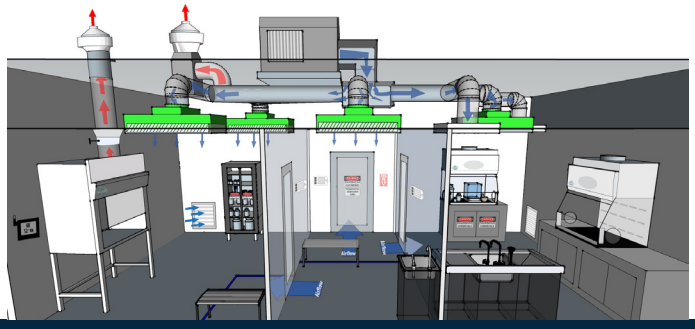
- Turn into gas at room temperature:
  - Fluorouracil (5-FU)
  - Carmustine
  - Nitrogen mustard
  - Cyclophosphamide
  - Cisplatin
  - Ifosfamide
- Class I BSCs:
  - Internally vented are not suitable
- Class II BSCs:
  - Type A: only minute quantities
  - Type B2 – (100% vented): designed for volatile HDs

COMPOUNDING ASEPTIC CONTAINMENT ISOLATORS (CACI)

- Various flavors of ventilation:
  - Internally vented
    - Not suitable for HD compounding under USP <800>
  - Externally vented:
    - Required under USP <800>

COMPLIANCE – USP <800> & PROPOSED <797>

FACILITY DESIGN FOR COMPLIANCE WITH USP <800>



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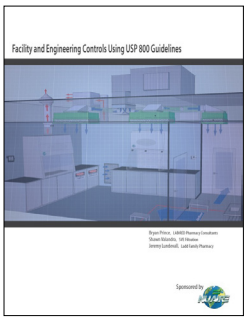
ADDITIONAL RESOURCE



November 2016

Free Article: *"Facility and Engineering Controls Using USP 800 Guidelines"*
Available at: PPPmag.com

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How to Calculate Supply and Exhaust CFMs

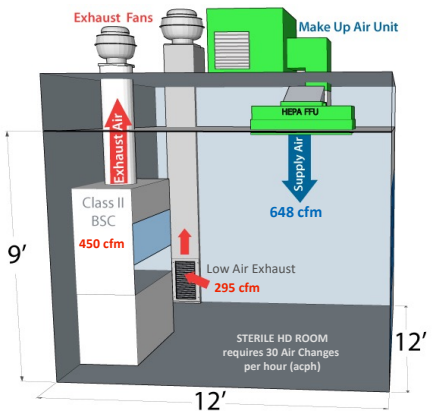
Supply Air for Sterile HD Room
12′ x 12′ x 9′ = 1,296 ft3
1,296 x 30 acph / 60 = **648 cfm**

Exhaust for Sterile HD Room
648 cfm x 1.15 = **745 cfm**

Class II BSC exhaust = 450 cfm

Low Air Exhaust = 745 - 450= 295 cfm

*The room is supplying more cfm than is being exhausted by the Class II BSC, so a supply surplus requires the use of the Low Air Exhaust for additional exhaust for balance.



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NOTES

NOTES

How to Calculate Supply and Exhaust CFMs

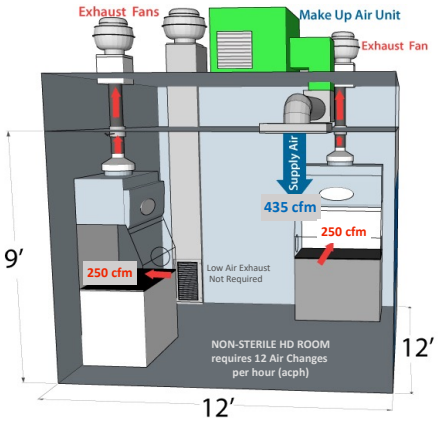
Supply Air for Sterile HD Room
12′ x 12′ x 9′ = 1,296 ft3
1,296 x 12 acph / 60 = **260 cfm**

Exhaust for Non-Sterile HD Room
260 cfm x 1.15 = **299 cfm**

Class-I C-PEC exhaust = 250 cfm
x 2 C-PECs= 500 cfm

500 / 1.15 = **435 cfm required supply**

*The room is supplying less cfm than is being exhausted by the Class-I C-PECs, so a supply shortage requires more supply air for balance.



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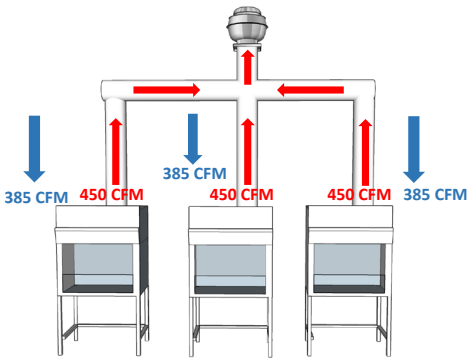
Each Incremental Unit

Each hood added in the future will affect both EXHAUST and SUPPLY

Each incremental hood:
- Exhausts 450 cfm
- Requires 385 cfm of supply for balance

Think about the future with your design and engineering controls



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ACHIEVING NEGATIVE PRESSURE

- Remember:
  1. The Containment Primary Engineering Control (C-PEC) will be the primary source of exhaust for the sterile HD room
  2. The C-PEC may or may not be the primary source of exhaust for the nonsterile HD room:
     - Refer to information about "redundant HEPA" hoods
  3. To make a room negative pressure, exhaust cfm must be approximately 10% - 15% greater than the supply cfm, based on the envelope construction

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COMPLIANCE – USP <800> & PROPOSED <797>

ADDITIONAL INFORMATION

- Fan Filter Units (FFUs) in the Sterile HD room ceiling are a must for guaranteeing ISO classification
- FFUs in the Nonsterile HD room ceiling are not necessary, but are a better way to get consistent airflow (called "cfm")
- If you rely solely on your custom Make-Up Air (MAU) unit with HEPA filtration, your ductwork could still fail you during certification
- Metal ductwork, although more expensive, is less likely to leak – unlike flexible commercial ductwork, which can be damaged
- Metal ductwork can also be decontaminated, whereas flexible ductwork has to be trashed because it contains porous materials

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TEMPERATURE AND HUMIDITY

- When you balance, commission, and certify the HD room, make sure all the equipment in place because dynamic conditions create heat
- Look back at your Temperature and Humidity logs throughout the year and see if there are times (e.g. July / August) when your air-handling system has fallen outside of range:
  - New <797> temperature target is 68 degrees
- Your existing HVAC system is not going to be able to keep up with the demands of USP <800>:
  - Adding a Sterile HD room (30 acph) to the same system as your current 797 cleanroom (30+) acph, and both hitting target temperature/humidity ranges is almost impossible
  - Adding a Non-sterile HD Room (12 acph) to the same commercial unit (typ. 4 to 8 acph) is over-stressing a system that wasn't designed for that and is a bad idea

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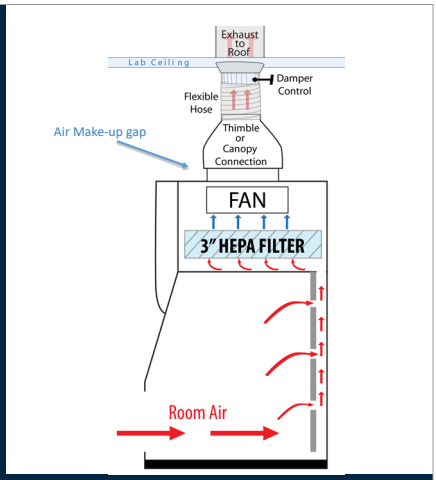
Can I use my existing hoods?

Yes - Class I C-PECs with Single HEPA -
Must be externally exhausted
- Class II C-PECs (A2 and B2)
Must be externally exhausted

Remember:

1. Do NOT hard duct the C-PEC to the exhaust system. Use a "thimble" connection to allow an air make-up gap
   - Contact the hood manufacturer and get their specific "thimble" or "canopy" connection
2. Use a local damper control to make air balancing easier for the Certifier



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NOTES

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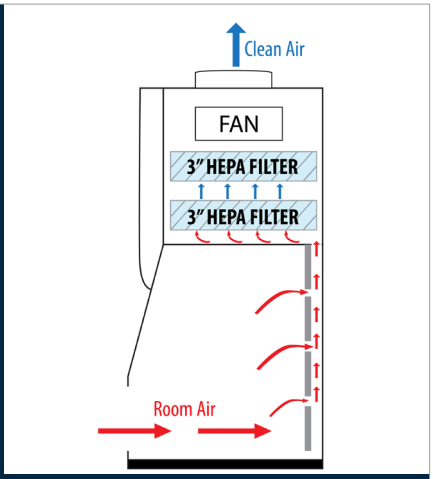
What is a C-PEC with Redundant HEPA Filtration?

A Class I BSC (also called Containment Ventilated Enclosures - CVE) with:

1. Two HEPA filters in the exhaust downstream
2. Both HEPA filters have a capture rate of 99.97%
3. Both HEPA filters are tested and certified

*Opinion: A CVE with a HEPA pre-filter and a HEPA primary filter should not qualify as redundant filtration.



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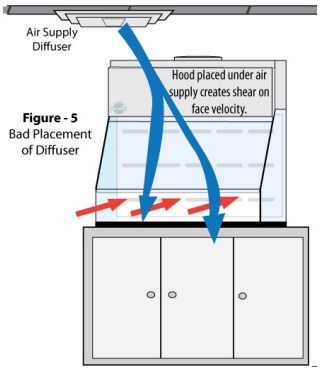
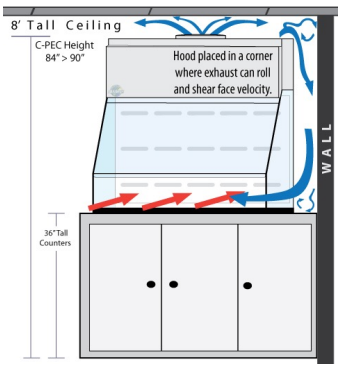


Figure - 5
Bad Placement of Diffuser



How the C-SEC Influences the C-PEC

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ADDITIONAL POINTS AND ENERGY RECOMMENDATIONS

1. As previously mentioned, it is very unlikely that your existing HVAC system will be able to handle the engineering demands of USP <800> compliance, and old air-handling systems can be energy hogs
2. Class I C-PECs with Redundant HEPA filtration can minimize the size of a roof-mounted exhaust fan and will save some energy costs:
   - *Disclaimer: Your state's BOP will make the final determination on acceptability of recirculation*
3. In a situation where the Non-sterile HD room has three or more Class I C-PECs, consider redundant HEPA recirculation because more hoods equal more supply air when exhausting
4. In the Sterile HD room, there is no opportunity for redundant HEPA filtration, so more C-PECs require more supply:
   - Plan for the future when purchasing a new Make Up Air Unit (MAU)

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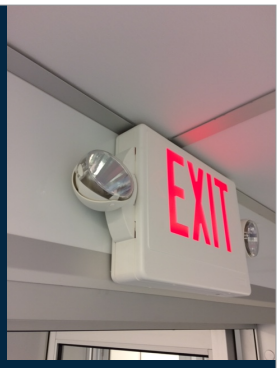
COMPLIANCE – USP <800> & PROPOSED <797>

Plumbing

Ceiling Tiles



Signage

What's Wrong Here?

MATERIALS OF CONSTRUCTION - WALLS

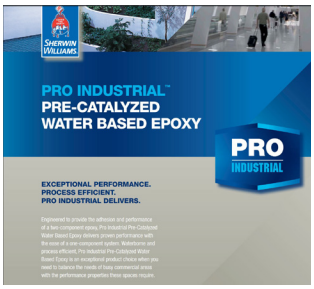
Due to the difficulty of cleaning HD contamination, surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the nonsterile compounding area must be smooth, impervious, free from cracks and crevices, and non-shedding.

Modular walls can be reconfigured or move with you to new locations.

MATERIALS OF CONSTRUCTION – WALLS

Epoxy Paint:

- Use Low VOC
- Water based
- Pre-catalyzed epoxy paint



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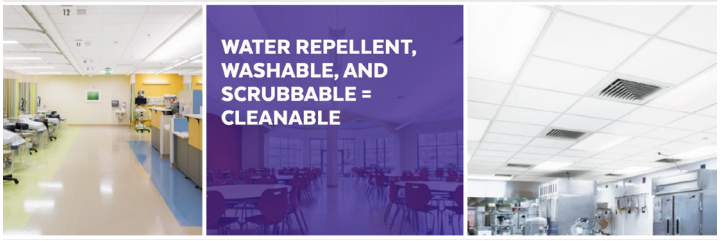
MATERIALS OF CONSTRUCTION – CEILING TILES

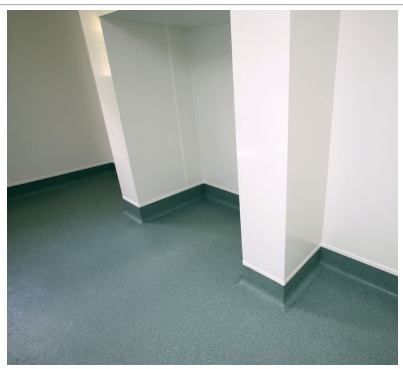


MATERIALS OF CONSTRUCTION - LIGHTING

Surface mount LED light is easier to clean and more energy efficient.

MATERIALS OF CONSTRUCTION - FLOORING

- Heat Welded
- Rolled up wall 4" - 6"



COMPLIANCE – USP <800> & PROPOSED <797>

MATERIALS OF CONSTRUCTION - CASEWORK

"Due to the difficulty of cleaning HD contamination, surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the nonsterile compounding area must be smooth, impervious, free from cracks and crevices, and non-shedding."
[USP <800> Section 5.3.1]

Polypropylene

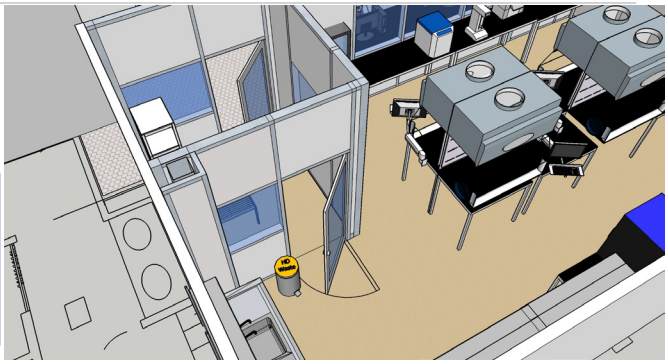
Stainless Steel

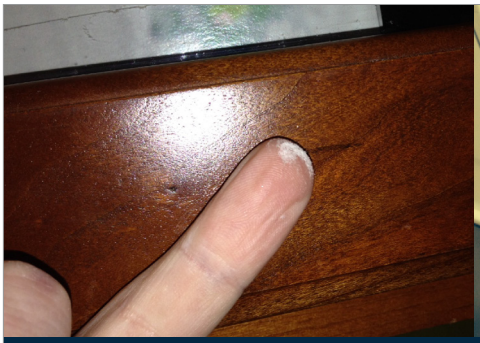
Epoxy or Phenolic

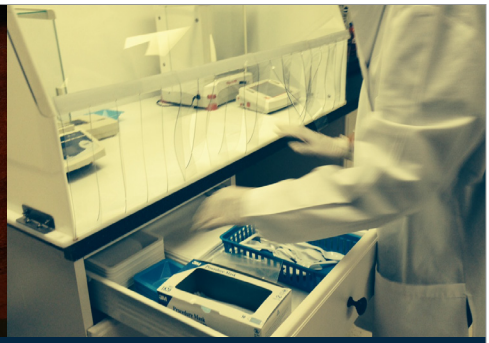
Powder coated metal

NONSTERILE-HD: THE GOWNING ROOM

A separate room for gowning is not required for USP 800. **However**, it is a best practice to teach pharmacists and technicians that donning and doffing both primary and secondary PPE in different places are good lab practices.







Engineering Controls and Good Lab Practices are Interdependent

NOTES

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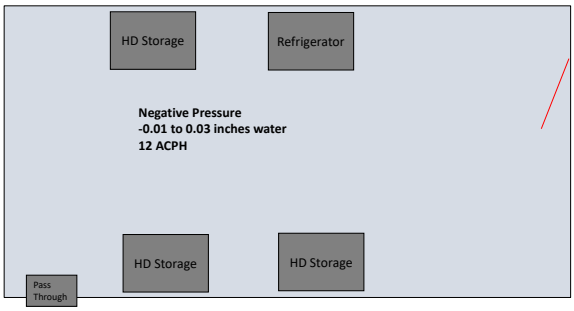
A SEPARATE HD STOREROOM



To HD buffer room or non-sterile HD compounding

STORAGE EXEMPTIONS

- Not exempted:
  - HD active pharmaceutical ingredients (APIs)
  - Any antineoplastic requiring HD manipulation
- NIOSH-listed drugs exempted if:
  - Final dosage forms not requiring additional manipulation except counting or repackaging of
    - Compounded HDs
    - Manufactured preps
  - **…and an assessment of risk is performed**
- Other dosage forms of NIOSH-listed drugs:
  - Based on risk assessment

OTHER EQUIPMENT

- Spill kits
- Eye washes:
  - OSHA requirement: Handling materials that are "corrosive"
  - ANSI: Eye wash where employees are exposed to HDs
- Closed system transfer devices should be used:
  - MUST be used for administration if the dosage form allows
- Plastic-backed prep mat on surface of PEC
- Dedicated equipment is required:
  - Mortars
  - Pestles
  - Spatulas

COMPLIANCE – USP <800> & PROPOSED <797>

THINK ABOUT WORKFLOW

- Where will we deactivate/decontaminate equipment?
- Can we afford to go in and out of the room all day?
- Can we deactivate/decontaminate efficiently through scheduling?
- Dosage forms:
  - Where do we transfer batched creams and ointments into dispensing containers?
  - Do our hormone capsules have powder residue on the outside?

✓ Deactivating NEW
✓ Decontaminating NEW
✓ Cleaning
✓ Disinfecting

DEACTIVATION & DECONTAMINATION

- Deactivation:
  - Treatment of an HD contaminant on surfaces with a chemical, heat, ultraviolet light, or another agent to transform the HD into a less hazardous agent
- Decontamination:
  - Inactivation, neutralization, or removal of HD contaminants on surfaces, usually by chemical means
- Don't forget about Cleaning <795/797> and Disinfection <797>!

NOTES

NOTES

WHAT RECEIVES DDC?

- DDC MUST occur in all areas where HDs are handled:
  - Receiving
  - Storage
  - Compounding
- DDC MUST occur on reusable equipment:
  - PECs
  - Capsule machines
  - Balances
- Sterile compounding areas MUST also be DISINFECTED per <797>

CLEANING - SOPs AND PPE

- Written procedures for cleaning MUST include:
  - Procedures:
    - Must include training
    - PPE must be impermeable to agents and include double chemotherapy-type gloves and impermeable disposable gowns
    - If splashing likely = eye and face protection
  - Agents used
  - Dilutions
  - Frequency (see next slide)
  - DOCUMENTATION

FREQUENCY - FOLLOW <795> AND <797>

What	When
PECs	Between different HDs Daily Before/after certification After voluntary interruptions If moved
Equipment	Daily Between different HDs
Counters	Daily
Floors	Daily
Walls, ceilings, shelving, and storage	Monthly
Under BSC work trays	Monthly

COMPLIANCE – USP <800> & PROPOSED <797>

WE ARE NOT QUITE DONE YET!

- Spills, splashes, and suspected contamination may require additional deactivation and decontamination
- After deactivation and decontamination:
  - Non-sterile: Cleaning per <795>
  - Sterile: Cleaning and disinfecting per <797>

HOW?

- 2% sodium hypochlorite followed by 1% sodium thiosulfate:
  - Sodium hypochlorite ruins stainless steel
  - Inactivate thoroughly with thiosulfate
  - Clean and/or disinfect surfaces thoroughly
- As recommended by manufacturer
- Commercial products:
  - Surface Safe®
  - HD Clean®
  - PeridoxRTU® Sporicidal Disinfectant and Cleaner
- Apply to cloth and wipe; do not spray on surfaces

WHAT SHOULD I WEAR?

- PECs:
  - Routine sterile/non-sterile HD garb
- BSC trays:
  - Sterile/non-sterile garb plus full face cartridge respirator with multi-gas cartridge and P100 filter
- Floors/ceilings/equipment:
  - Sterile/non-sterile garb plus N95
  - Risk of splashing: goggles/face shield

NOTES

NOTES

PPE FOR HD COMPOUNDING - WHEN

- MUST be worn while handling HDs during:
  - Receipt
  - Transport
  - Storage
  - Compounding
  - Administration
  - Deactivation, decontamination, cleaning, disinfecting
  - Spill cleanup
  - Waste disposal

PPE FOR HD COMPOUNDING - WHAT

- Required for compounding:
  - Gowns
  - Gloves - two pairs
  - Hair/head covers:
    - Sterile: Facial hair cover
  - Shoe covers - two pairs
  - Eye, face, and respiratory protection
  - Sterile compounders may need two layers of PPE
- Table 5 of NIOSH 2016 can provide guidance on developing you own PPE policies

COMPLIANCE – USP <800> & PROPOSED <797>

CONSIDER A TABLE FOR PPE

Activity	Where	Double Gloves	Gown	Eye Protect	Respiratory Protect
Receiving	NS HD PEC	Y	Y	N*	N*
Compounding	ST/NS PEC	Y	Y	N*	N*
Filling: Creams Ointments Liquids	NS HD PEC	Y	Y	N*	N*
Counting: Tablets Capsules	Dedicated Trays	N – use single gloves	N	N	N

- *If done in a PEC, the PEC provides respiratory and eye protection
- Counting: Capsules contaminated with HD or powdery tablets may require protection during handling

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Does your PPE fit properly?

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GOWNS – Non-sterile

- Disposable
- Polyethylene-coated polypropylene or laminate
- Must close in back
- Closed cuffs

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NOTES

NOTES

GOWNS - Sterile

- Disposable
- Polyethylene-coated polypropylene or laminate
- Must close in back
- Closed cuffs
- Two layers is best practice

Changing Gowns

- Must change:
  - Every 2-3 hours or
  - Per manufacturer's instructions
  - If spill or splash
- Same for sterile/non-sterile

GLOVES

- Meet American Society for Testing and Materials (ASTM) standard D6978
- For sterile compounding:
  - Outer gloves must be sterile
- Outer gloves must be changed every 30 minutes unless otherwise recommended by manufacturer:
  - Applies to both sterile and non-sterile compounding
- Change if:
  - Torn
  - Punctured
  - Contaminated

COMPLIANCE – USP <800> & PROPOSED <797>

RESPIRATORY PROTECTION

- **The PEC is your friend!**
- It will provide essential:
  - Eye protection
  - Face protection
  - Respiratory protection
- Doing everything in a PEC will save a lot of trouble!
  - Less strict respiratory protection requirements
  - Lower risk of contaminating facility
  - Lower risk of personnel exposure
  - Less cleanup
  - Containment of HD spills
  - Saves money

N95 MASKS

- Removes dust and small particles:
  - Does not remove vapors
  - Two types:
    - Surgical and non-surgical (surgical type is FDA cleared for use in healthcare settings)
- Each employee must be fit tested!
  - Performed by a "qualified person"
- Single use/disposable
- Wear whenever there is a risk of exposure:
  - Small-spill cleanup

Full Face Cartridge Respirator with Multi-Gas Cartridge & P100 Filter

- Protects against particles and vapors
- Each employee must be fit tested
- Device is reusable
- Filter cartridges are replaceable
- Wear when:
  - Unpacking HDs not enclosed in plastic
  - Cleaning up large spills (> 5ml)
  - Deactivating/decontaminating under work surface of a C-PEC
  - Reusable PPE must be cleaned/decontaminated after use

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Eye Protection

- Goggles are required:
  - Not acceptable:
    - Safety glasses
    - Prescription eyeglasses
- Wear (with resp. protection) when:
  - Risk of spills or splashes
  - Cleaning spills
- Full face respirator is an alternative
- Face shield with goggles can protect full face

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Possible Gowning Process-NS

- Entering the room:
  - Hair cover
  - Eye protection (maybe)
  - Respiratory protection (maybe)
  - Shoe covers (two pairs on each foot)
  - Wash hands
  - Put on one pair of gloves
  - Put on gown
  - Put on second pair of gloves over sleeves

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Possible Gowning Process-ST

- Entering the room:
  - Hair cover
  - Eye protection (maybe)
  - Mask (or respiratory protection - maybe)
  - Step over line of demarcation while donning shoe covers:
    - Two pairs on each foot
  - Wash hands
  - Disinfect with waterless surgical scrub
  - Don one pair of sterile chemo gloves
  - Don sterile compounding inner gown
  - Don chemo gown or apron with sterile sleeves
  - Disinfect gloves with sterile isopropyl alcohol (SIPA)
  - Don sterile chemo gloves over sleeves

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COMPLIANCE – USP <800> & PROPOSED <797>

LEAVING THE HD COMPOUNDING AREA

- Remove the outer set of gloves in the PEC:
  - Plastic bag or suitable container in PEC
- Move to doffing area
- Remove gown:
  - Sterile compounders - the outer gown only!
- Remove first layer of shoe covers while placing each foot into "clean" zone
- Step out of HD area
- Remove mask, hair cover, and shoe cover:
  - Sterile compounders remove gown – outside of anteroom or in "dirty" side

ADMINISTRATION OF HDs

- Must use protective medical devices and techniques:
  - Needleless systems
  - Closed system transfer devices
  - Pill crushing devices with a plastic pouch
- PPE must be worn and properly disposed of:
  - Two pairs of chemotherapy gloves a MUST
  - Gowns showing resistance to HD permeability a MUST when administering injectable antineoplastics

PERSONNEL

NOTES

NOTES

SAFETY OFFICER (A "MUST")

- Trained and qualified for developing procedures
- Oversees compliance with USP <800>
- Ensures personnel competency
- Monitors environmental controls
- Tracks spills and personnel exposures

PERSONNEL TRAINING

- Review the list of HDs and their risks
- How to read HD labels and SDSs
- The pharmacy's Standard Operating Procedures (SOPs) related to handling of HDs
- Proper use of PPE including respiratory protection
- Techniques for compounding with HDs
- Response to known or suspected HD exposure (including use of eye washes)

PERSONNEL TRAINING

- Deactivating and decontaminating
- Spill prevention and management (including use of spill kits)
- Proper disposal of HDs and trace-contaminated materials

COMPLIANCE – USP <800> & PROPOSED <797>

PERSONNEL COMPETENCIES

- Reading an SDS – written test
- Observational:
  - PPE – observational competency
  - Location and use of spill kits and eye washes
  - Use of closed system transfer devices
  - Signed acknowledgement of handling HDs

PROTECTING PERSONNEL

- Develop a policy for your facility
- Should address personnel that are:
  - Pregnant
  - Breastfeeding
  - Imminently conceiving

The WHY for Safety

NOTES

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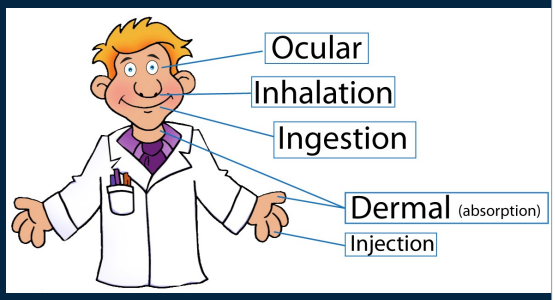
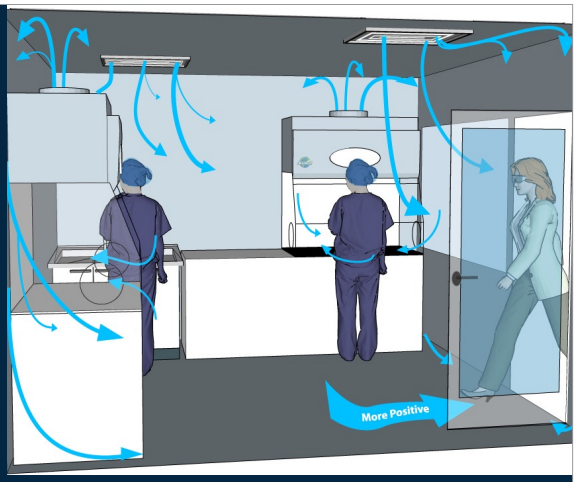
Notice Where the Micronized Powder Collects

Exposure Routes for Chemicals



The WHY for Negative Pressure



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Environmental Exposure

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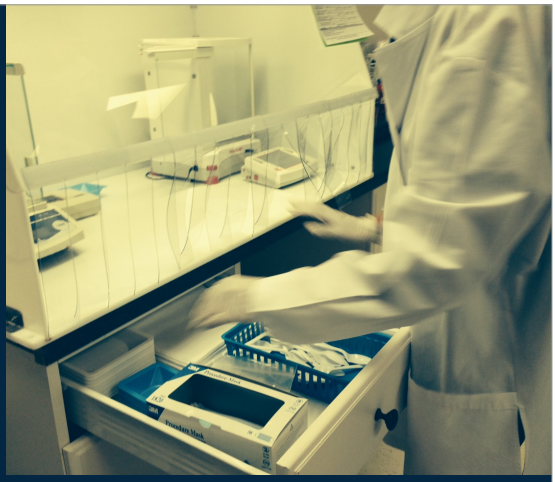
Breaching Containment is the #1 Safety Violation



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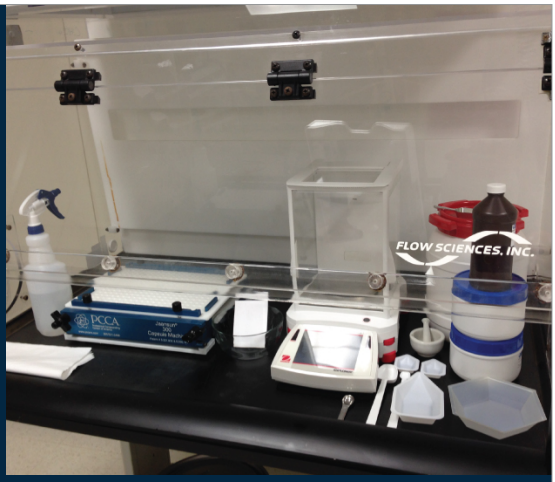
Stage Everything First Inside the C-PEC



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NOTES

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Recommended Setup if you use Formulation Software

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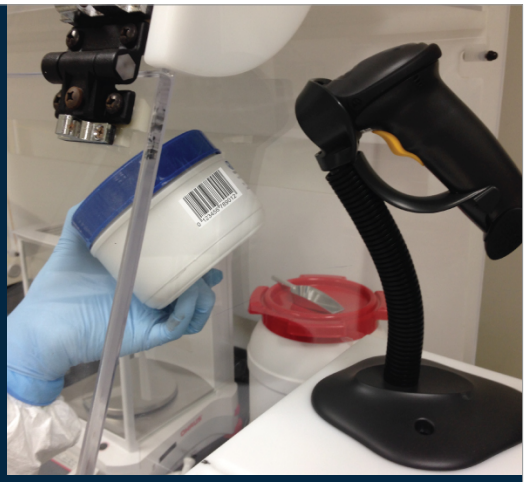
Chemicals are Scanned Through the Sidewall of the Hood Prior to Weighing

Quality Control:

SCAN – WEIGH / SCAN – WEIGH / SCAN – WEIGH



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The Mouse Belongs Inside of the Hood

Cover the mouse with clear sticky wrap (dental supply product)

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Under Normal Light

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Under Black Light

Contaminated keyboard
= Contaminated lab

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Cover With Sticky Wrap or Cellophane

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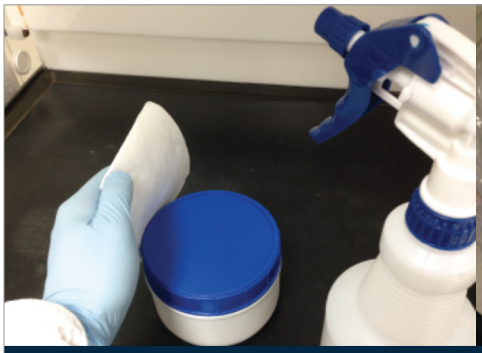
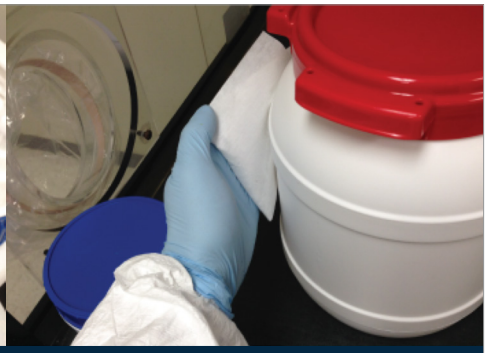
EVERY C-PEC SHOULD HAVE A SPRAY BOTTLE OF ISOPROPYL ALCOHOL

- That is where it permanently resides



A Spray Bottle of 70/30 IPA Lives Inside of the Hood



All Chemical Containers Must be Sprayed and Wiped Down Prior to Removal From Hood

Protecting Labels

Place clear packing tape over bottle labels to prevent damage to the label

COMPLIANCE – USP <800> & PROPOSED <797>

Contaminated Chemicals = **Contaminated Storage Area**

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The C-PEC is NOT a Chemical Storage Cabinet

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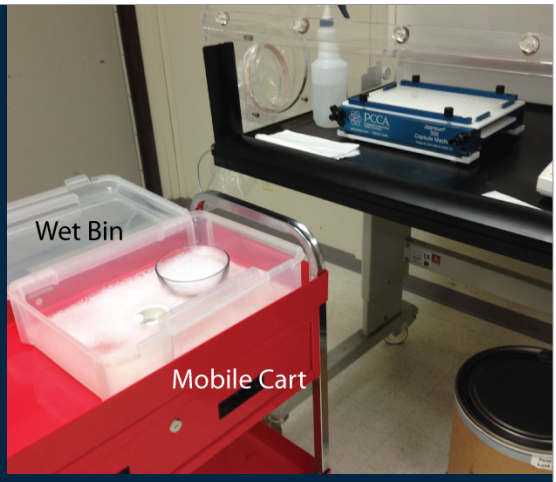
Wet-to-Wet Transfer Method



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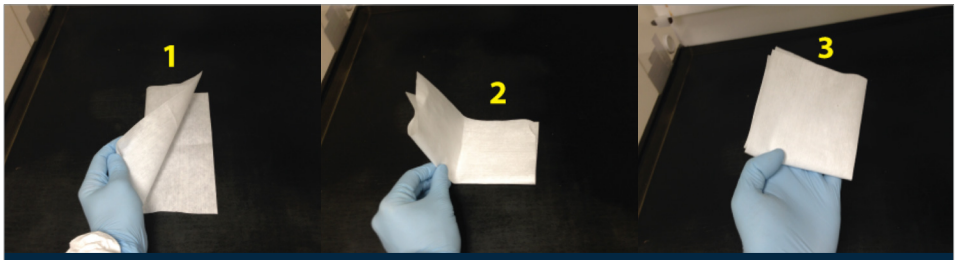
As Script Volume Grows, so do Safety Processes



Proper Cleaning Procedure

Proper Cleaning Procedure

COMPLIANCE – USP <800> & PROPOSED <797>

Doff Proper Procedure:
Deglove and desleeve inside hood

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The Wrong Method for Disposal of Contaminated Items

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Proper Disposal of Contaminated Materials

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NOTES

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Acceptable Alternative Disposal Method:

- Introduce a zip lock bag into the hood in the beginning
- Place all contaminated materials into bag and zip closed
- Spray and wipe outside of bag with IPA
- Remove from hood and place in general trash

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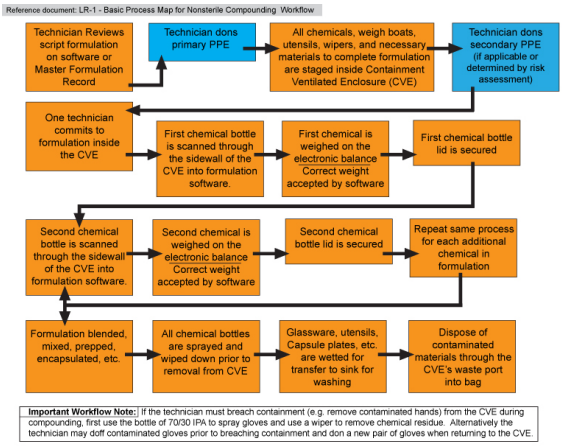

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Exiting the Lab

- Dispose of shoe booties
- Potentially contaminated coats never leave the lab

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COMPLIANCE – USP <800> & PROPOSED <797>

Staging the Script Baskets Outside the Lab

Labs are for Lab Personnel Only

Home Shoes vs. Lab Shoes

Home shoes = dirt, dander, contaminants

Work shoes = dedicated, cleanable, comfortable

RECEIVING, SHIPPING, AND STORAGE

NOTES

NOTES

RECEIVING OF HDs

- Neutral or negative pressure area
- Supplier should package in impervious plastic
- If they do not:
  - Must unpack wearing full face cartridge respirator with multi-gas cartridge and P100 filter
  - Until safety is established
- If shipping container is damaged:
  - Seal container and contact supplier
  - If returning – enclose in impervious packaging and label hazardous, or discard as HD waste

RECEIVING OF HDs

- If damaged shipping container must be opened:
  - Seal in impervious container
  - Move to PEC
  - Remove undamaged items and wipe down
  - Package the damaged goods in impervious container, mark hazardous, and return; or
  - Dispose of as HD waste
- PPE must be worn during unpacking:
  - Gloves
  - Gown

RECEIVING OF HDs

- Move to storage as soon as unpacked
- Damaged or leaking packages must be treated as spills:
  - Make sure you log these
- The receiving area must be cleaned, deactivated, and decontaminated

COMPLIANCE – USP <800> & PROPOSED <797>

SHIPPING OF HDs

- It is complicated:
  - Based on the specific HD
  - Based on the quantity or volume
  - Air or ground?
- It is simple:
  - A lot of HDs are exempt/partially exempt due to the quantity
- How can I tell?

SDS SPECIFIES SHIPPING REQUIREMENTS

- Estradiol - not regulated for transport

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

- Cyclophosphamide - more complicated!

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

This material is regulated for transportation as a hazardous material/dangerous good.

UN number:	UN 2811
UN proper shipping name:	Toxic solid, organic, n.o.s. (cyclophosphamide)
Transport hazard class(es):	6.1
Packing group:	III

DECIPHERING CYCLOPHOSPHAMIDE

- UN number:
  - Assigned by United Nations Committee of Experts on the Transport of Dangerous Goods
  - 2811 indicates a toxic solid, organic, not otherwise specified
- Proper shipping name:
  - Required on labeling if not exempt
- Packing group:
  - Packing Group I = great danger
  - Packing Group II = medium danger
  - Packing Group III = minor danger

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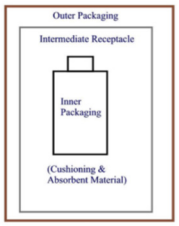
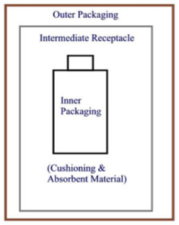
SO WHAT DOES THIS ALL MEAN?

- Shipping by air:
  - 30 gm/ml or less per inner container
  - Up to 1 liter total in box
  - Triple packing:
    - Inner pack
    - Intermediate package
    - Outer package
- Exempt labeling:
  - "E" label
  - 6.1 indicates the 30g/30ml exemption



SO WHAT DOES THIS ALL MEAN?

- Shipping by ground:
  - 4 liters or 5 kg or less per inner container
  - Triple packing:
    - Inner packaging
    - Intermediate receptacle
    - Outer packaging
- Exempt labeling:
  - Limited quantity label



SHIPPING HDs

- Limited quantities:
  - Do not require dangerous goods paperwork
  - Some changes in paperwork required
  - FedEx airbills need to say "Dangerous Goods in Excepted Quantities"
- FedEx/UPS have hazardous goods hotlines:
  - They are your best resource for shipping HDs
  - Have the UN number when you call!
  - Recording shipping information on your HD list will save time
- Delivery vehicle placarding:
  - May be required if certain exemptions exceeded

COMPLIANCE – USP <800> & PROPOSED <797>

SOPs

Hazard Communication Program	Dispensing
Occupational safety program	Transport
Receipt	Environmental Monitoring
Storage	Medical Surveillance
Compounding	Medical Surveillance
Spills	HD Waste & Disposal
Disposal	
Deactivation/Decontamination	

If we talked about it today, it requires an SOP!

BEST PRACTICE – WIPE SAMPLING

- Used to detect presence of HD residues:
  - Consider all places where HDs may be present:
    - PEC
    - Pass-thru
    - Staging areas
    - Storage
    - Receiving
- Limitations:
  - Cost
  - Unknown OEL – limits usefulness of data – BUT can help validate Deactivation and Decontamination

BEST PRACTICE – MEDICAL SURVEILLANCE

- Purpose – to minimize adverse health events in exposed personnel
- Looks at symptoms, complaints, labs for deviations
- Seeks to validate HD protections – PPE, engineering, practices
- Don't forget about HIPAA!
- Voluntary – employees may choose to not participate

NOTES

NOTES

OSHA HAZARDOUS COMMUNICATIONS PROGRAM

OSHA® Occupational Safety and Health Administration
www.osha.gov

*This is a regulatory **requirement** today!*

STEP 1: BASICS

- Learn the requirements:
  - https://www.osha.gov/Publications/OSHA3695.pdf
- Identify who is responsible for activities:
  - Hint: the safety officer!

STEP 2: PREPARE A WRITTEN PROGRAM

- Resources
- Requirements:
  - Written list of HDs
  - How personnel are trained and notified
  - How HDs are labeled
  - How SDSs are maintained
- Resource and template
- www.lni.wa.gov/Safety/Topics/AtoZ/HazardousDrugs/resources.asp

COMPLIANCE – USP <800> & PROPOSED <797>

KEEP IN MIND…

- NIOSH and OSHA have **different definitions** of what is hazardous
- OSHA includes all NIOSH HDs and some things that are not:
  - Skin corrosion/irritation:
    - Hydrochloric acid/sodium hydroxide
  - Respiratory or skin sensitization:
    - Ketoprofen
    - Cantharidin
  - Gases under pressure

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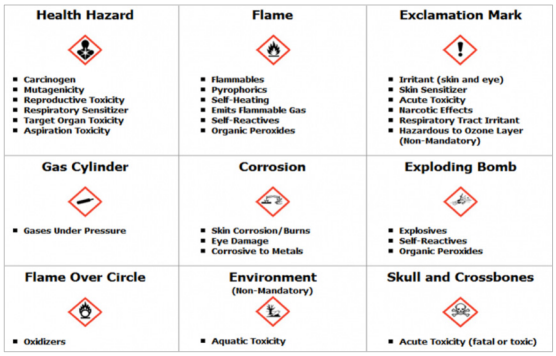
STEP 3: ENSURE PROPER LABELING

- Vendors
- Stock containers



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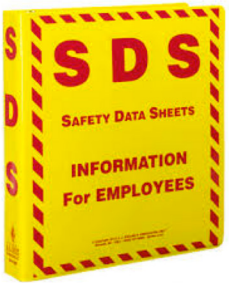
STEP 4: MAINTAIN SDSs

- Keep SDSs on file:
  - An electronic system is acceptable to OSHA
  - *However, local fire department rules may require hard copies*
- Keep SDSs accessible to employees:
  - All employees must be able to access the electronic SDSs



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STEP 5: TRAIN EMPLOYEES

- We already covered this one!

STEP 6: KEEP UPDATED

- Review and update annually along with HD list
- Update when:
  - New chemicals
  - Changes in processes/procedures

HD DISPOSAL

COMPLIANCE – USP <800> & PROPOSED <797>

DISPOSAL OF HDs

This is a regulatory requirement today!

SURPRISE!

- Environmental Protection Agency's (EPA) hazardous list is different than NIOSH's and OSHA's
- EPA uses several categories for hazardous materials, including:
  - P-List – acutely hazardous if >3%
  - U-List – toxic
  - D-List – products that contain residues that exceed a minimum concentration

SURPRISE! EPA'S HAZARDOUS LIST IS DIFFERENT THAN NIOSH'S AND OSHA'S

Environmental Protection Agency (EPA) Resource and Conservation and Recovery Act[11]

Regulated Pharmaceutical Wastes and Corresponding EPA Code Type[a]

P-LISTED

EPA Code	Regulated Agent
P012	Arsenic trioxide
P042	Epinephrine
P075	Nicotine
P081	Nitroglycerin
P204	Physostigmine
P188	Physostigmine salicylate
P001	Warfarin >0.3%

U-LISTED

EPA Code	Regulated Agent
U034	Chloral hydrate
U035	Chlorambucil
U044	Chloroform
U058	Cyclophosphamide
U059	Daunomycin
U075	Dichlorodifluoromethane
U089	Diethylstilbestrol
U122	Formaldehyde
U129	Lindane
U150	Melphalan
U151	Mercury
U010	Mitomycin C
U182	Paraldehyde
U188	Phenol
U200	Reserpine
U201	Resorcinol
U202	Saccharine
U205	Selenium
U206	Streptozotocin
U237	Uracil mustard
U248	Warfarin <0.3%

D-LISTED

EPA Code	Regulated Agent
D004	Arsenic (5 mg/L)
D005	Barium (100 mg/L)
D022	Chloroform (6 mg/L)
D007	Chromium (5 mg/L)
D024	M-cresol (200 mg/L)
D013	Lindane (0.4 mg/L)
D009	Mercury (0.2 mg/L)
D101	Selenium (1 mg/L)
D011	Silver (5 mg/L)

[a] This list is not all inclusive; items listed may be additives to primary formulations.

Source- Managing Pharmaceutical Waste, ASHP.
http://www.ashpadvantage.com/docs/pharmawaste-discussion-guide.pdf.
Accessed March 25, 2016

NOTES

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ANOTHER WAY TO LOOK AT IT

- More than one P- or U-listed drug
- Chemo drugs
- NIOSH or OSHA HDs
- Drugs with LD50 less than 50mg/kg
- Endocrine disrupters
- Immunosuppresants
- Vitamins and minerals with chromium, selenium, or cadmium

- Oh … and is it infectious waste?

SUMMARY OF PHARMACEUTICAL WASTE STREAMS

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Hazardous Drug Risk Assessment

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COMPLIANCE – USP <800> & PROPOSED <797>

RISK MANAGEMENT

"…Risk is defined as the combination of the probability of occurrence of harm and the severity of that harm."

Source: Guidance for Industry. Q9 Quality Risk Management. U.S. Department of Health and Human Services Food and Drug Administration. June 2006 ICH

THE DESIGNATED PERSON

USP <800> excerpt: *"The designated person must thoroughly understand the rationale for risk-prevention policies, risks to themselves and others, risks of noncompliance that may compromise safety, and the responsibility to report potentially hazardous situations to the management team."*

(Sect. 4. RESPONSIBILITIES OF PERSONNEL HANDLING HAZARDOUS DRUGS)

THE DESIGNATED PERSON

- **Common question:** "Do we need to hire another employee to manage our Hazardous Drug Program?"
  - HD Script volume (current versus future projected)
  - Script ratios? (sterile to nonsterile; HD to non-HD)
  - How many different locations does your pharmacy own/operate?
  - Current status of SOPs?
  - Will the HD rooms need to be located off-site due to special constraints?
  - Will hiring an additional PIC alleviate other tasks?
  - Will a dedicated "compliance person" handle other job functions?

Risk Management and Risk Assessment is better accomplished with a team approach versus the "designated" person only looking at it from their Stakeholder position

NOTES

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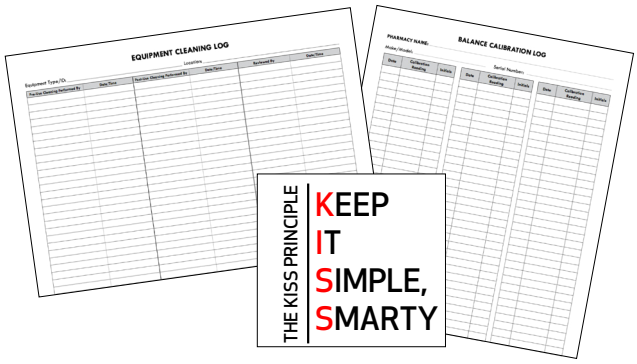
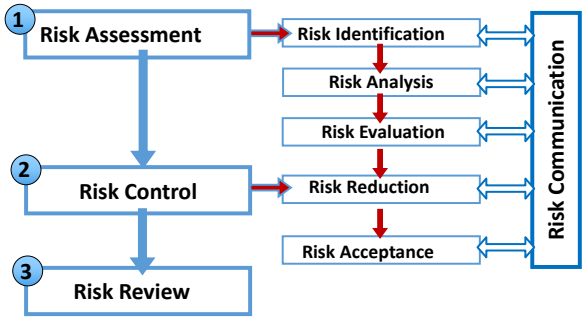
BENEFITS OF RISK MANAGEMENT

- Product Quality and Consistency (Quality Assurance-USP 797, 795, 1163)
- Set Internal Standards (PPE, workflow processes:)
  - Additional Resources:
    - Article: *Workflow Strategies to Minimize Exposure to Hazardous Drugs in the Compounding Pharmacy (learn.nuaire.com)*
- Decision-making gets better (learning curve, established corporate policy, SOPs)
- Regulatory Assurance (documentation makes them happy)
- Reputation (Patients and Providers)
- Competitive Advantage (use as a marketing tool)

EVERYDAY EXAMPLES OF RISK MGT.



RISK MANAGEMENT PROCESS



COMPLIANCE – USP <800> & PROPOSED <797>

RISK ASSESSMENT

RISK IDENTIFICATION

- Inventory Hazardous Drugs → Print or Digital copy Safety Data Sheets
- Examine the Processes → Receipt, Compounding, Labeling, Cleaning, Disposal, etc.
- Identify Opportunities and Routes of Exposure → Ex: Unpacking-Inhalation
- Document

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Hazardous Drug Risk Assessment Worksheet

Drug Name:
Chemical Form:
SDS Attached: Yes___ No___
Antineoplastic:_____ Carcinogen:_____ Reproductive Risk:_____

		Exposure Route					
		Injection	Eye exposure	Ingestion	Inhalation	Dermal exposure	Notes: PPE Recommend.; Containment; Process
Task	Receipt						
	Storage						
	Compounding						
	Labeling and Packaging						
	Transport / Dispensing						
	Administering						
	Deactivating and Cleaning						
	Disposal						
	Spill Handling						
	Other:						

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Hazardous Drug Risk Assessment Worksheet

Drug Name: Progesterone Date Performed: 18March2017
Chemical Form: Powder
SDS Attached: Yes✓ No___
Antineoplastic:_____ Carcinogen:✓ Reproductive Risk:✓

		Exposure Route					
		Injection	Eye exposure	Ingestion	Inhalation	Dermal exposure	Notes: PPE Recommend.; Containment; Process
Task	Receipt		✓		✓	✓	Follow Appendix# - Process Map: Receiving Hazardous Drugs
	Storage						Follow Appendix# - Process Map: Receiving Hazardous Drugs
	Compounding		✓	✓	✓	✓	Reference Yesterday's Presentation on Safe Workflow Ha...
	Labeling and Packaging				✓	✓	
	Transport / Dispensing						
	Administering						
	Deactivating and Cleaning		✓	✓	✓	✓	
	Disposal		✓	✓	✓	✓	R...ence ...OP- Workflow Doc# - ...Disposing of HD's
	Spill Handling		✓	✓	✓	✓	Reference SOP- Workflow Doc# - HD Chemical Spill Clean Up Procedures
	Other:						

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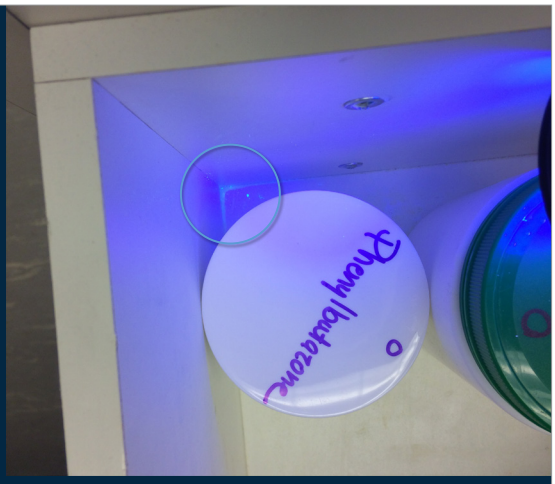
RISK ASSESSMENT
RISK IDENTIFICATION

RISK ANALYSIS (CONTINUED)

1. What is the problem or risk question?
   (could be qualitative or quantitative)
   Example: *Why is powder residue detected in the HD storage drawer?*
2. What is the potential harm?
   Example 1: *Environmental contamination can lead to cross-contamination, which could adversely affect the quality (potency) and/or cause an adverse patient reaction.*

   Example 2: *Environmental contamination can lead to personnel exposure, which could adversely affect their health.*



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RISK ASSESSMENT
RISK IDENTIFICATION

RISK ANALYSIS (CONTINUED)

3. What are the immediate and long-term corrective/mitigation actions?
   Example-Immediate: *Initiate a thorough facility cleaning.* (Ref: SOP for PPE)

   Example- Long-Term:
   1. *Implement GLP Process Map*
   2. *Training*
   3. *Documentation (for Risk Review)*

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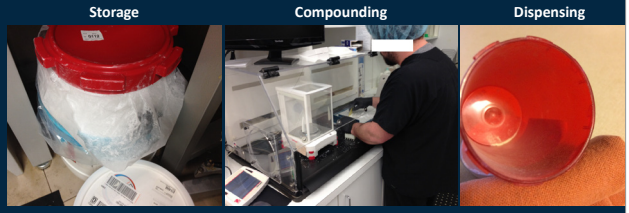
RISK ASSESSMENT
RISK IDENTIFICATION
RISK ANALYSIS

RISK EVALUATION

Risk evaluation compares the identification and analysis against the "risk criteria." There is no established risk criteria in our industry, so we start our own.

It looks like a **Gap Analysis:** Current State vs. Future State

Suggestion:
Take pictures now to document the pre-USP <800> implementation to establish what the *Current State* looks like.
*The pictures will be used during periodic "Risk Review."



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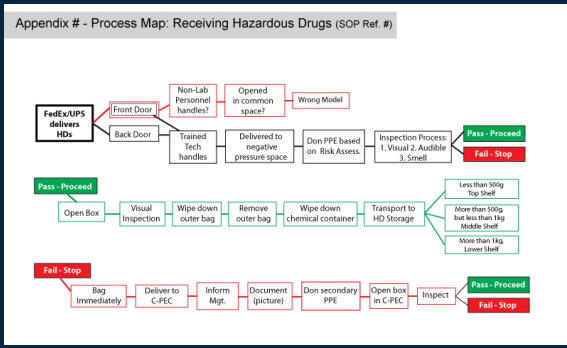
2 RISK CONTROL

RISK REDUCTION

Risk Control = reduce the risk to an acceptable level



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1 RISK CONTROL

RISK REDUCTION

OSHA Respirator Fit Test

Hypothetical Example: Risk Assessment performed on hormone encapsulation compounding process revealed multiple exposure points and technicians advised (or required) to wear a Half Mask respirator with N100 cartridges.

- ☐ **Step 1:** Technician is explained risk and reason for the need for a respirator *(document and sign.)*
- ☐ **Step 2:** Technician fills out OSHA Respirator Medical Evaluation Questionnaire and sends confidentially to a local healthcare provider.
- ☐ **Step 3:** Healthcare provider determines if technician is approved or requires additional examination prior to approval.
- ☐ **Step 4:** If approved, technician is trained on proper-use of respirator *(manufacturers have YouTube videos that can serve as training supplements).*
- ☐ **Step 5:** Technician dons fit hood without respirator. Trainer sprays nebulizer (with sweet fluid provided in kit) into hood while tech. opens mouth.
- ☐ **Step 6:** Technician washes out mouth, waits five minutes, dons respirator, dons hood, and nebulizer process repeated. If tech has no detectable smell or taste then they pass fit test and are approved to work inside respirator (if fail, adjust straps for fit and repeat).

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1 RISK ASSESSMENT
RISK REDUCTION

3 RISK REVIEW

Medical Surveillance

- ☐ Establishes hazardous communication to personnel
  Required under USP <800> Section 8
- ☐ Evaluates engineering controls
  Required under USP <800> Section 5
- ☐ Identifies HD exposure processes
  Required under USP <800> Section 8
- ☐ Establishes PPE Standards
  Required under USP <800> Section 7
- ☐ Observation of personnel health on consistent timeline
  Visual and/or physical (medical participation is voluntary)
- ☐ Current results versus desired future results
  GAP Analysis performed during Risk Evaluation
- ☐ Environmental monitoring
  "Must" for engineering control monitoring; "should" for wipe sampling

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3 RISK REVIEW

MEDICAL SURVEILLANCE

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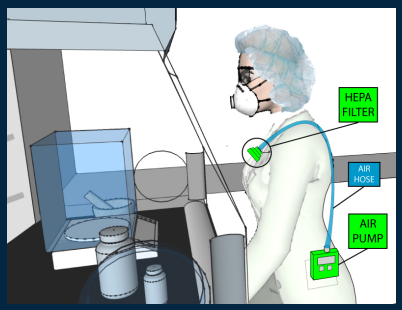
3 RISK REVIEW

COMPOUNDING PROCESS AIR MONITORING

Additional Benefits:
1. Risk Analysis
2. Risk Reduction
3. Competency Evaluation
4. Risk Mitigation



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RISK REVIEW

Risk assessments must be audited:
- -Qualitative Observation:
  Are processes working?
- -Quantitative Observation:
  Environmental monitoring
- -Review Incidents:
  Adverse employee or patient reports?

★ Required:
"at least every12 months"
★ Good Recommendation:
Quarterly
★ Best Recommendation:
Monthly

Quick Tip: If you pick one area (receiving process) per month (approx. 45 minutes) to audit, then the risk review process will be a lot less cumbersome by December 2019.

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RISK CONTROL AND RISK REVIEW

The best way to manage risk after implementation of USP <800>:

1. Training
2. Reinforce Culture
3. Re-training
4. Reinforce Culture

Culture Statement

If the pharmacy owner and the Pharmacist in Charge and management do not all cohesively and consistently reinforce the "culture change," then the employees will not adopt the compliance changes.

Training Statement

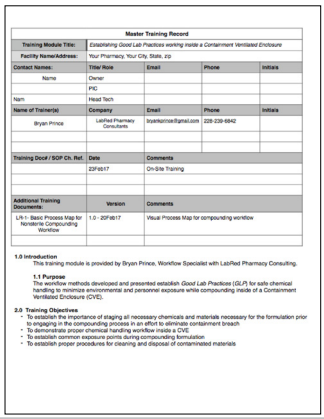
USP Ch.<1163> excerpt: Personnel involved in nonsterile or sterile compounding require additional, specific training and periodic retraining beyond the training needed for routine dispensing duties. A thorough quality assurance program for compounded preparations requires documentation of both training and skill competency.

KEY POINT: "*IF IT'S NOT DOCUMENTED,* IT NEVER HAPPENED."

PCAB Surveyors and FDA Inspectors both agree that a major area of concern is lack of documentation on Personnel Training and Competency Evaluation.

If you are a pharmacy owner or PIC, you can build multiple training modules from this education conference.

If you are a Technician, you can document this training for your employee record to show proficiency in multiple areas.



Master Training Record

Training Module Title:	*Establishing Good Lab Practices working inside a Containment Ventilated Enclosure*
Facility Name/Address:	Your Pharmacy, Your City, State, zip

Contact Names:	Title/ Role	Email	Phone	Initials
Name	Owner			
	PIC			
Nam	Head Tech			

Name of Trainer(s)	Company	Email	Phone	Initials
Bryan Prince	LabRed Pharmacy Consultants	bryanmorriss@gmail.com	228-239-6842	

Training Docd / SOP Ch. Ref.	Date	Comments
	22Feb17	On-Site Training

Additional Training Documents:	Version	Comments
LN 1- Basic Process Map for Nonsterile Compounding Workflow	1.0 - 20Feb17	Visual Process Map for compounding workflow

1.0 Introduction
This training module is provided by Bryan Prince, Workflow Specialist with LabRed Pharmacy Consulting.

1.1 Purpose
The workflow methods developed and presented establish *Good Lab Practices (GLP)* for safe chemical handling to minimize environmental and personnel exposure while compounding inside of a Containment Ventilated Enclosure (CVE).

2.0 Training Objectives
- To establish the importance of staging all necessary chemicals and materials necessary for the formulation prior to engaging in the compounding process in an effort to eliminate containment breach
- To demonstrate proper chemical handling workflow inside a CVE
- To establish common exposure points during compounding formulation
- To establish proper procedures for cleaning and disposal of contaminated materials

RISK ACCEPTANCE

- **And finally, after all the:**
  - Identification documents have been thoroughly filled out
  - Processes analyzed and evaluated for exposure points
  - New processes put in place to minimize exposure
  - Training modules implemented and documented
  - SOPs updated for hazardous drug handling
  - Engineering controls certified …

… there is still an opportunity for risk!

Remember: This is all very new to you and everyone, so be diligent, consistent, and patient.

NOTES

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USP <797>: WHAT'S NEW?

INTRO-USP <797>

- CSP categories
- Sterility and endotoxins
- In-use time
- The compounding environment
- Garbing and gowning
- Personnel competencies
- Environmental monitoring
- Cleaning and disinfecting

OVERVIEW

- Two CSP categories:
  - 1&2
  - Big changes to BUDs
- Increased surface and air sampling requirements
- Personnel:
  - Increased media-fill testing and GFTs
  - Sterile garb

COMPLIANCE – USP <800> & PROPOSED <797>

OVERVIEW

- CAI and CACIs are now restricted access barrier systems (RABs); new category: Isolator
- Sterility and endotoxin testing:
  - Relaxed sterility testing
  - Endotoxin monitoring/testing for all CSPs compounded with APIs
  - Container closure integrity required for frozen CSPs

CATEGORY 1 CSPs

- Definition:
  - CSPs prepared in an ISO-5 PEC located in a non-classified environment

Storage Conditions		
Controlled Room Temperature (20°–25°)		Refrigerator (2°–8° degrees)
BUD	≤12 hours	≤24 hours
*The BUDs specified in the table indicate the hours after the Category 1 CSP is prepared beyond which the CSP cannot be used. The BUD is determined from the time the CSP is compounded.		

CATEGORY 2 CSPs

- Definition:
  - CSPs prepared in an ISO-5 PEC in a classified environment meeting certain requirements
- Preserved CSPs:
  - Must do antimicrobial effectiveness test
- Frozen CSPs:
  - Must demonstrate container closure integrity

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CATEGORY 2 CSPs

	Preparation Characteristics			Storage Conditions		
	Method of Achieving Sterility	Sterility Testing Performed	Preservative Added	Controlled Room Temperature (20°–25°)	Refrigerator (2°–8°)	Freezer (–25° to –10°)[3]
BUD	Aseptically prepared CSPs	No	No	Prepared from one or more nonsterile starting component 4 days	Prepared from one or more nonsterile starting component 7 days	Prepared from one or more nonsterile starting component 45 days
				Prepared from only sterile starting components 6 days	Prepared from only sterile starting components 9 days	Prepared from only sterile starting components 45 days
			Yes[4]	28 days	42 days	45 days
		Yes	No	28 days	42 days	45 days
			Yes[4]	42 days	42 days	45 days
	Terminally Sterilized CSPs	No	No	14 days	28 days	45 days
			Yes[4]	28 days	42 days	45 days
		Yes	No	28 days	42 days	45 days
			Yes[4]	42 days	42 days	45 days

STERILITY TESTING

- Batch size 1-39:
  - Test 10% of units in batch rounded to next whole number
- Larger batch:
  - Per USP <71>
- SOP required for release at risk

ENDOTOXIN TESTING

- Any CSP made with non-sterile ingredients
- Exceptions:
  - Topical ophthalmics
  - Inhaled CSPs
- If Certificate of Analysis (COA) lists endotoxin burden:
  - Can calculate for finished prep and omit testing
- Can pre-determine endotoxin burden of ingredients

COMPLIANCE – USP <800> & PROPOSED <797>

TABLE 9.

- In-use time for conventionally manufactured products and CSPs opened, stored, and used for sterile compounding in ISO class 5 or better air quality

Components	In-Use Time
Conventionally Manufactured Sterile Product	
Ampules	Use immediately after opening and passing through sterile particulate filter.
Pharmacy Bulk Package	As specified by the manufacturer.
Single-dose container (e.g., bag, bottle, syringe, or vial)	6 hours.
Multiple-dose container	28 days, unless otherwise specified by the manufacturer.
CSP	
Compounded single-dose container	6 hours.
Compounded stock solutions	6 hours.
Compounded multiple-dose containers	28 days, unless otherwise specified by the original compounder.
*The particular CSP formulation must pass antimicrobial effectiveness testing in accordance with (51) at the completion of the sterility test (if conducted) or at the time of preparation (if sterility testing is not performed). The test must be completed and the results obtained on the specific formulation before any of the CSP is released or dispensed. The test needs to be conducted only once on each formulation in the particular container-closure system in which it will be stored or released/dispensed.	

TABLE 10.

- In-use times for conventionally manufactured products and CSPs opened and/or stored in worse than ISO class 5 air

Components	In-Use Time
Conventionally Manufactured Sterile Product	
Ampules	Use immediately after opening and passing through a sterile particulate filter.
Pharmacy Bulk Package	Not applicable. Contents of pharmacy bulk packages must be used only in an ISO Class 5 or better environment.
Single-dose container (e.g., bag, bottle, syringe, or vial)	Use for a single patient within the time specified by the manufacturer, or by the end of the case or procedure, whichever comes first. Discard remainder.
Multiple-dose container	28 days, unless otherwise specified by the manufacturer.
CSP	
Compounded single-dose container	Use for a single patient immediately. Discard remainder.
Compounded multiple-dose container [b]	28 days, unless otherwise specified by the original compounder.
[a] Compounding or repackaging must not occur in worse than ISO Class 5 air. [b] The particular CSP formulation must pass antimicrobial effectiveness testing in accordance with (51) at the completion of the sterility test (if conducted) or at the time of preparation (if sterility testing is not performed). The test must be completed and the results obtained of the specific formulation before any of the CSP is released or dispensed. The test needs to be conducted only once on each formulation in the particular container-closure system in which it will be stored or released/dispensed.	

COMPOUNDING ENVIRONMENT: CATEGORY 2 CSPs

- **Traditional anteroom/buffer room – remains the same:**
  - Pressure >0.02 inch water column
  - Humidity 30-60%
  - Temperature 68° F or lower
- **CAIs and CACIs:**
  - Are now "Restricted Access Barrier Devices" (RABs)
  - Must "live" in ISO-7 environment
- **Different:**
  - A RAB cannot "live" in an ISO-8 room for Category 2 compounding

NOTES

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SINGLE ROOM SETUP IS STILL POSSIBLE

- **Replace RAB with "Isolator:"**
  - High-integrity transfer ports
  - Decontaminated using a sporicidal generator
  - Maintains 0.05 inch water column
  - Continuously meets ISO-5, even during materials transfer
  - Sink at least 1 meter from isolator

GARBING AND GOWNING

- Gowns as usual:
  - Can be re-used for a shift
- New: sterile sleeves:
  - Must be discarded after each use
- RABs and isolators:
  - Do not require sterile gowns
  - Does not require a mask (omission?)
- Disinfecting hands:
  - Wash: Unscented soap and water
  - Old: Waterless surgical scrub
  - New: Alcohol-based hand rub with sustained antimicrobial activity

COMPETENCIES

- GFTs:
  - Post media-fill: Quarterly
- Media-fill:
  - Must simulate most difficult and challenging compounding: Quarterly
- Visual observation - hand hygiene and garb: Quarterly
- If any of above is deficient: Must pass 3x consecutively
- Cleaning and disinfecting:
  - Annually and when processes change

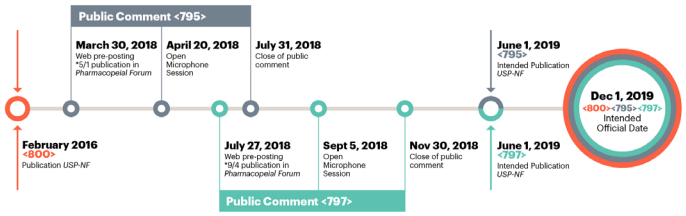
COMPLIANCE – USP <800> & PROPOSED <797>

STAY ABREAST OF USP <797>

- Sign up for updates at www.usp.org/hqs-signup-form
- Expected date of final publication is June 1, 2019; becomes official December 1, 2019:
  - Harmonizes with USP<800> official date

USP <795> AND <797> UPDATE TIMELINE

www.usp.org/compounding/updates-on-standards, accessed 3/9/2018



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THANK YOU

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ADDITIONAL RESOURCES

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ROOT CAUSE ANALYSIS REPORT FORM[1]

Pharmacy Name:		Author:								
Department:										
Consumer ID:		Age:	Gender: M F							
City/Town:		Date of Event:		Date RCA Completed:						
1.	**THE EVENT** – *Describe what happened and any harm that resulted. Identify the proximate cause, if known.*	Team Members Involved: Team Leader:								
2.	**BACKGROUND & FACTORS SUMMARY–** *Answer the following questions (brief summary only- attach supporting documents).*									
2.1	What was the sequence of events that was expected to take place? Attach flowchart if available.	Description:								
2.2	Was there a deviation from the expected sequence?	☐ Yes ☐ No	If YES, describe the deviation. Attach flowchart if available.							
2.3	Was any deviation from the expected sequence likely to have led to or contributed to the adverse event?	☐ Yes ☐ No ☐ NK	If YES, describe with causal statement.							
2.4	Was the expected sequence described in policy, procedure, written guidelines, or included in staff	☐ Yes ☐ No	If YES, cite source.							

[1] Adapted from a template utilized by the Australian Department of Human Services for use by Health Care Organizations and Hospitals [see http://clinicalrisk.vic.gov.au/rca/htm for original form]

	training?	☐ NK	
2.5	Does the expected sequence or process meet regulatory requirements and/or practice standards? Cite references and/or literature reviewed by the team.	☐ Yes ☐ No ☐ NK	If NO, describe deviation from requirements/standards.
2.6	Did human action or inaction appear to contribute to the adverse event?	☐ Yes ☐ No ☐ NK	If YES, describe the actions and how they contributed.
2.7	Did a defect, malfunction, misuse of, or absence of equipment appear to contribute to the event?	☐ Yes ☐ No ☐ NK	If YES, describe what equipment and how it appeared to contribute.
2.8	Was the procedure or activity involved in the event being carried out in the usual location?	☐ Yes ☐ No ☐ NK	If NO, describe where and why a different location was utilized.
2.9	Was the procedure or activity being carried out by regular staff familiar with the consumer?	☐ Yes ☐ No ☐ NK	If NO, describe who was carrying out the activity and why regular staff were not involved.
2.10	Was the procedure or activity being carried out by regular staff familiar with the activity?	☐ Yes ☐ No ☐ NK	If NO, describe the perceived inadequacy.
2.11	Were staff trained to carry out their respective responsibilities?	☐ Yes ☐ No ☐ NK	If NO, describe the perceived inadequacy.
2.12	Were staffing levels considered to have been adequate at the time of the incident?	☐ Yes ☐ No ☐ NK	If NO, describe why.

2.13	Were there other staffing factors identified as responsible for or contributing to the adverse event?	☐ Yes ☐ No ☐ NK	If YES, describe those factors.
2.14	Did inaccurate or ambiguous information contribute to or cause the adverse event?	☐ Yes ☐ No ☐ NK	If YES, describe what information and how it contributed.
2.15	Did a lack of communication or incomplete communication contribute to or cause the adverse event?	☐ Yes ☐ No ☐ NK	If YES, describe who and what and how it contributed.
2.16	Did any environmental factors contribute to or cause the adverse event?	☐ Yes ☐ No ☐ NK	If YES, describe what factors and how they contributed.
2.17	Did any organizational or leadership factors contribute to or cause the adverse event.	☐ Yes ☐ No ☐ NK	If YES, describe what factors and how they contributed.
2.18	Did any assessment or planning factors contribute to or cause the adverse event?	☐ Yes ☐ No ☐ NK	If YES, describe what factors and how they contributed.

2.19	What other factors are considered relevant to the adverse event?	Describe:	
2.20	Rank order the factors considered responsible for the adverse event, beginning with the proximate cause, followed by the most important to less important contributory factors. Attach Contributory Factors Diagram, if available.		
	Was a root cause identified? Unqualified personnel in the position of handling Rxs	☐ Yes ☐ No ☐ NK	If YES, describe the root cause.

3.	**RISK REDUCTION ACTIONS TAKEN** – List the actions that have already been taken to reduce the risk of a future occurrence of the event under consideration. Note the date of implementation.	
	Action Taken - Description	**Date Implemented**

4.	**PREVENTION STRATEGIES** – List from highest priority to lowest priority the recommended actions designed to prevent a future occurrence of the adverse event. Begin with a rank of 1 (highest). For each strategy or action provide an estimated cost, if known, and any additional considerations or recommendations for implementing the strategy (e.g., phase-in, immediate need, triage by risk).		
Rank	**Strategy**	**Estimated Cost**	**Special Considerations**
1			
2			
3			
4			
5			
6			
7			

5	**INCIDENTAL FINDINGS** – List and describe any incidental findings that should be carefully reviewed for corrective action.

6.	**APPROVAL** – After review of this summary report, all team members should notify the team leader of either their approval or recommendations for revision. Following all revisions the report should be signed by the team leader prior to submission.
Signature of Team Leader:	Date Signed:

The information contained in this report is confidential and is intended solely to promote safety and reduce consumer risk.

Forward this report to all RCA team members and to the following individuals:

Name	Title	Organization	Address	Email

AccreditationUniversity.com

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F (919) 785-3011

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