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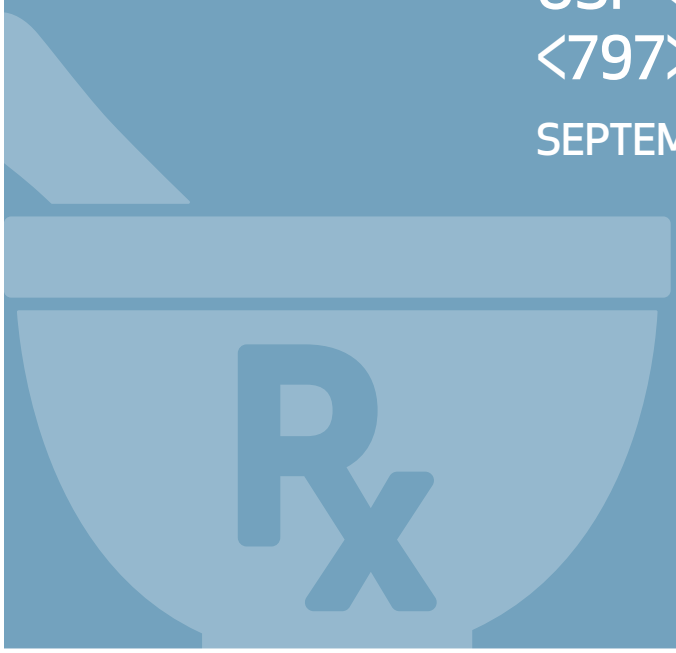
COMPLIANCE

USP <800> & PROPOSED <797>

SEPTEMBER 2018



ACHC

PCAB PHARMACY COMPOUNDING ACCREDITATION BOARD

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ACCREDITATION COMMISSION *for* HEALTH CARE

ACCREDITATION UNIVERSITY

COMPLIANCE
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WELCOME

- Housekeeping Items

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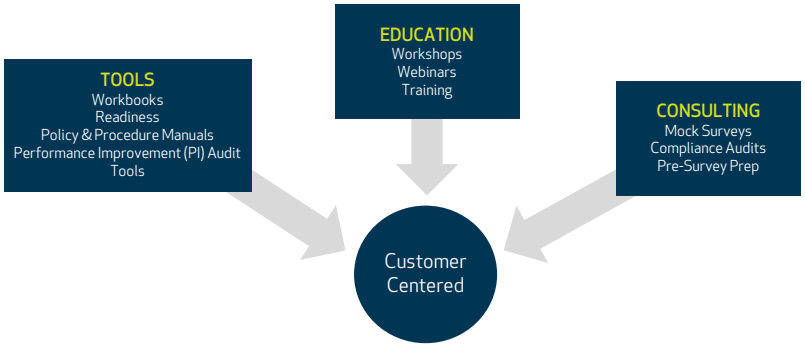

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COMPLIANCE – USP <800> & PROPOSED <797>

OUR PROGRAM

- Introduction and implementation of USP <800>
- What's new in the proposed USP <795> and <797>?
- Today is your opportunity to ask questions about how these changes will impact your pharmacy
- *Network with your colleagues!*

ACHC PHARMACY ACCREDITATION

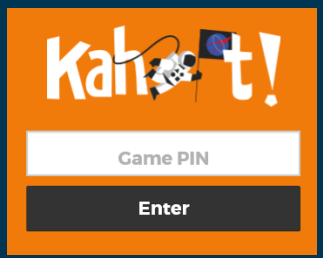
- Hazardous Drug standards are currently incorporated into PCAB and IRX standards
- The *Distinction in Hazardous Drug Handling* provides standards built from USP <800>

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 (Ref. USP <800>)
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.

TEACHING TOOL: Kahoot!

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



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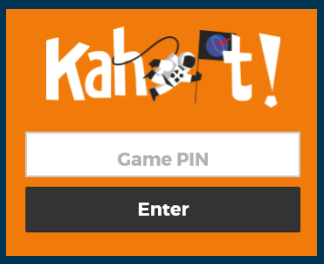
TEACHING TOOL: Kahoot!

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



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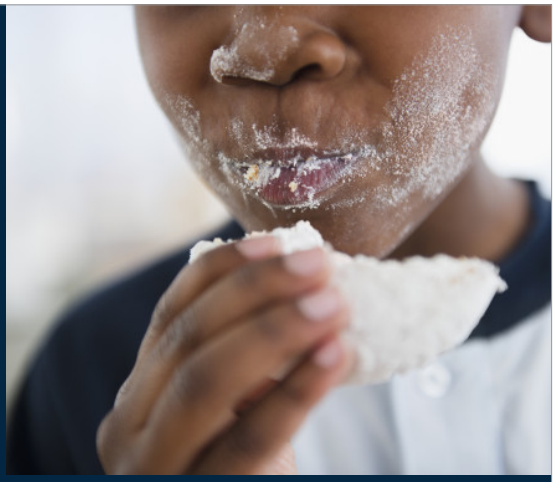
Exposure to Hazardous Drugs:

Why Should I Care?



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WHY SHOULD I CARE? – INDUSTRY EVIDENCE

- 1999: Pharmacists, techs, & nurses handling HDs
  - 40% higher risk of stillbirths and spontaneous abortions
- 2010: Healthcare Worker Study (including pharmacy)
  - Chromosome 5&7 abnormalities
  - Breast and prostate cancer both linked to C-5
- 2014: Pharmacy student dies of fentanyl overdose at a compounding pharmacy
  - After only four days on the job
- 2014: Evaluation of manufacturing practices finds drug residue on external packaging of containers of 5-FU and cisplatin

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WHY SHOULD I CARE? – EXTERNAL FACTORS

- HD protection is growing as a regulatory requirement
  - State Boards of Pharmacy
  - FDA
  - OSHA – *Controlling Occupational Exposure to Hazardous Drugs*
- Growing interest in waste-streams
- Liability?

Hartford News

OSHA cites New Haven pharmacy for multiple violations

Posted: 10/23/2014, 03:00pm | WTNH

New Haven, Conn. (WTNH) — The Occupational Safety and Health Administration (OSHA) has cited a New Haven pharmacy for multiple violations during their most recent inspections following a July chemical spill that sent four employees to the hospital.

In all, OSHA's proposed fines total $77,220.

HISTORY

- Concern over exposure to hazardous drugs (HDs) is not new!
  - 1986 – first OSHA guidelines for cytotoxic drugs
  - 1990 – ASHP technical assistance bulletin on handling cytotoxic and hazardous drugs
  - 2004 – NIOSH Alert - Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings
  - 2008 – USP Chapter <797> included sterile hazardous drug guidance
  - March 2014 – USP Chapter <800> draft released
  - February 2016 – final version of Chapter <800> released
  - December 1, 2019 – "Effective Date" for *<800> Hazardous Drugs – Handling in Healthcare Settings*

VIDEO - HTTPS://VIMEO.COM/18804273

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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

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INTRO TO USP <800>

- 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

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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

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COMPLIANCE – USP <800> & PROPOSED <797>

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

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)

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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7. HANDLING AND STORAGE

General Handling:	Restrict access to work area. Designate a change area to facilitate 'good manufacturing' decontamination practices. Ground and bond all bulk transfer equipment. No open handling permitted. All operations should be fully enclosed. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
Storage Conditions:	Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

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.

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9. PHYSICAL AND CHEMICAL PROPERTIES

Melting/Freezing Point (°C): 41

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.

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.

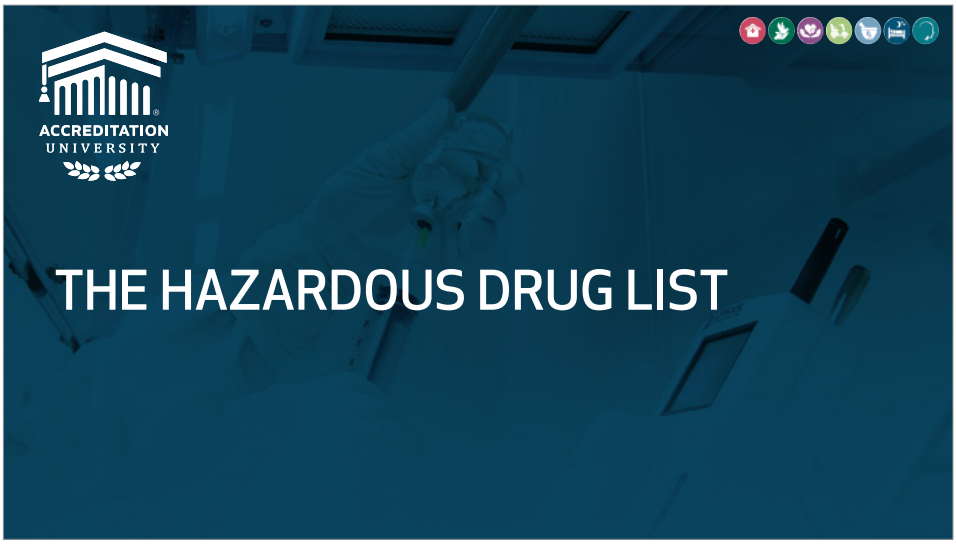
Reasons for Revision: Updated Section 3 - Composition / Information on Ingredients.

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

- 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

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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 HD NS Compounding Pick Up
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

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

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

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

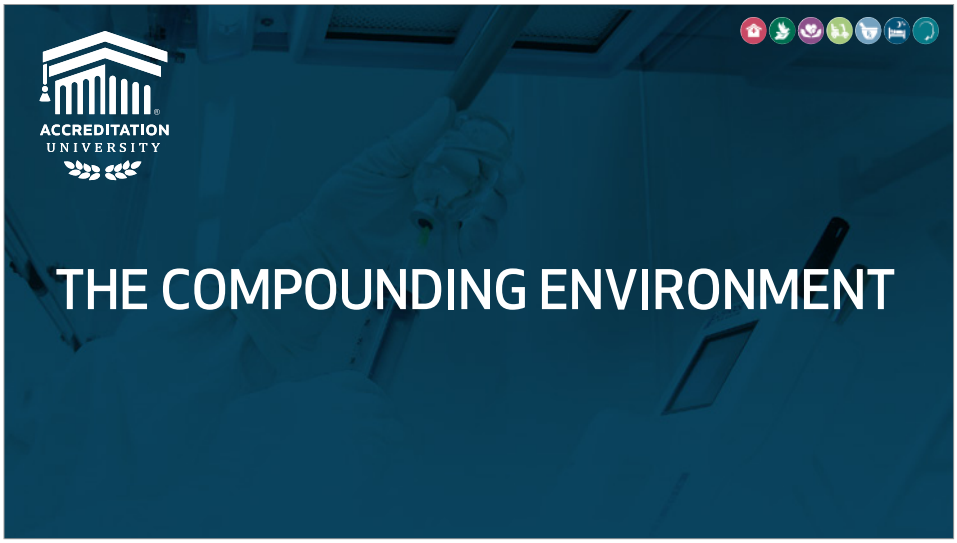
- Final dosage forms that only require counting/repackaging:
  - Avoid automated counting or packaging machines
  - Consider manufacturer exceptions

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

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**!



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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

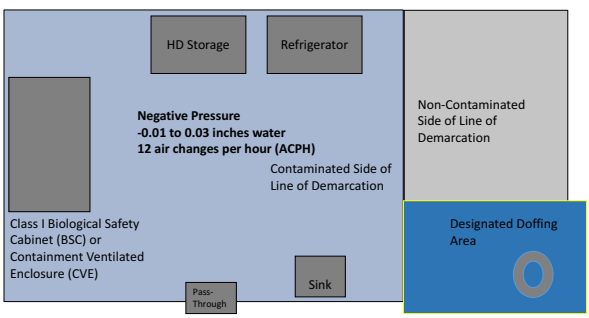
NON-STERILE HD COMPOUNDING

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

NON-STERILE HD COMPOUNDING



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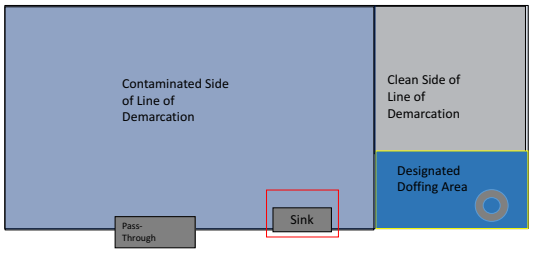
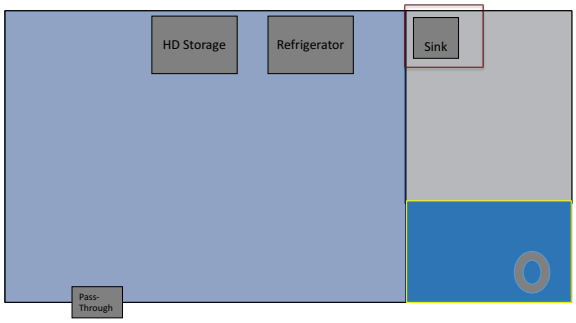
NON-STERILE HD COMPOUNDING



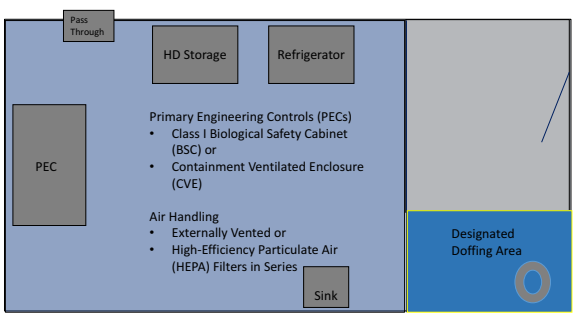
- Water must be accessible; does not specify must be in C-SEC
- USP <800> not specific about sink location
- Option: Sink in C-SEC for equipment washing

NON-STERILE HD COMPOUNDING



- Option: Sink for hand-washing in C-SEC

NON-STERILE HD COMPOUNDING



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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

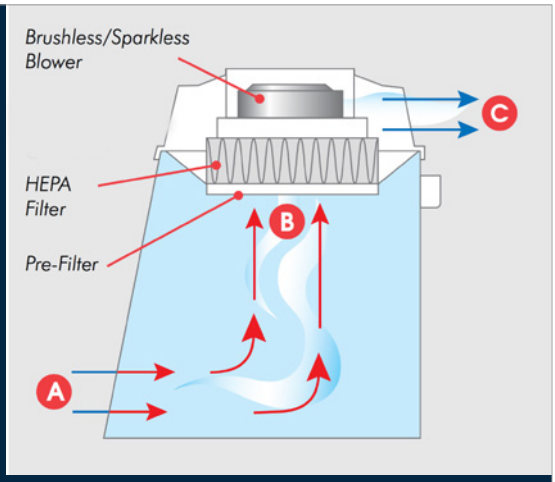

Image courtesy AirClean Systems

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Class I BSC – Redundant HEPA Filter

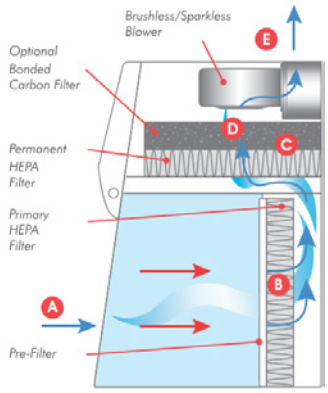

Image courtesy AirClean Systems

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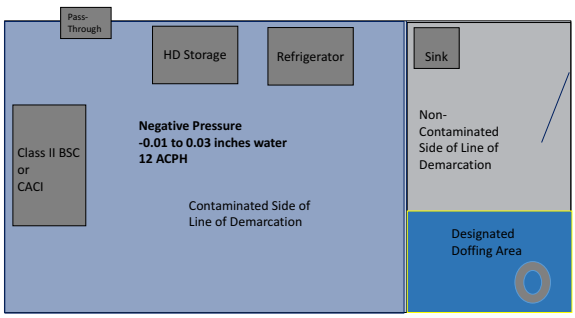
KEY POINTS ABOUT C-PECS – NS

- 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

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



COMPLIANCE – USP <800> & PROPOSED <797>

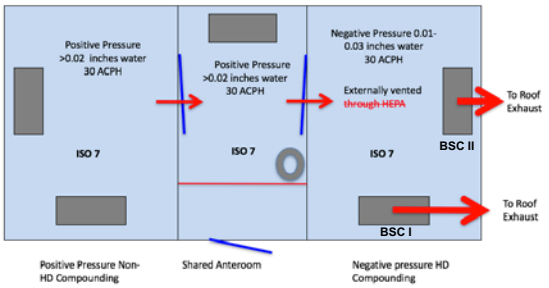
CONTAINMENT SEGREGATED COMPOUNDING AREA (C-SCA)

- 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**

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 <797>:
  - Class II BSC/CACI: Low-risk CSPs with 12-hour BUD
  - Stand-alone CACI: Low, medium, maybe high risk
- USP <797> revision:
  - Class II BSC or CACI: ≤12h room temperature, ≤24h refrigerated

DESIGNS FOR BOTH CATEGORY 1 & 2 COMPOUNDING



NOTES

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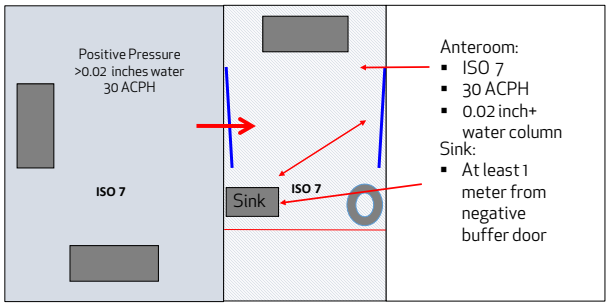
THE SHARED ANTEROOM



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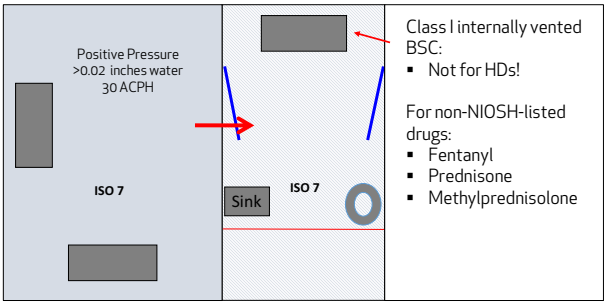
THE SHARED ANTEROOM



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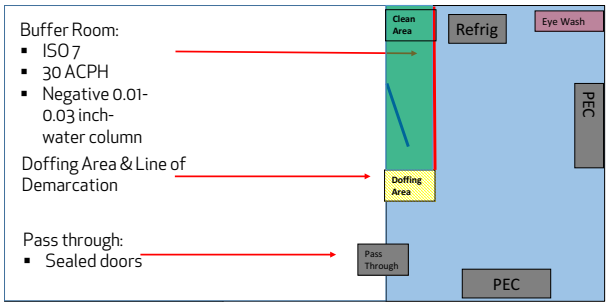
THE BUFFER ROOM



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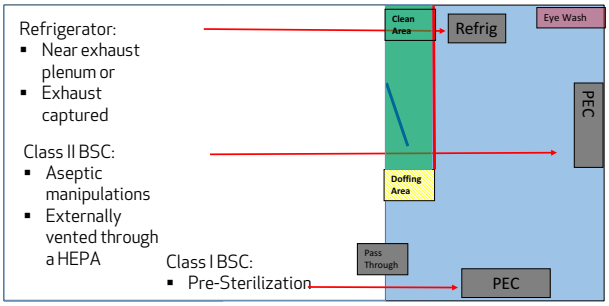
COMPLIANCE – USP <800> & PROPOSED <797>

THE BUFFER ROOM



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

NOTES

NOTES

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

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

COMPLIANCE – USP <800> & PROPOSED <797>

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>

FACILITY DESIGN FOR COMPLIANCE WITH USP <800>

ADDITIONAL RESOURCE

November 2016

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

NOTES

NOTES

How to Calculate Supply and Exhaust CFMs

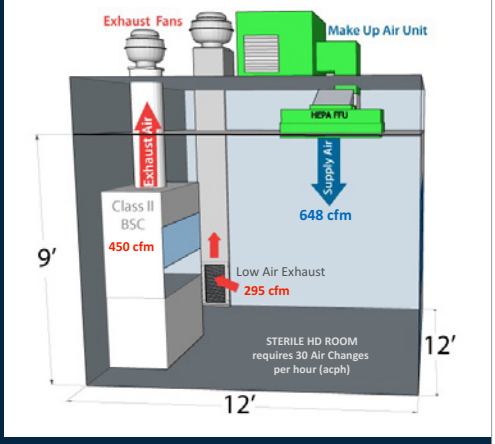
Supply Air for Sterile HD Room
12′ x 12′ x 9′ = 1,296 ft3
1,296 x 30 acph / 60 = **648 cfm**

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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How to Calculate Supply and Exhaust CFMs

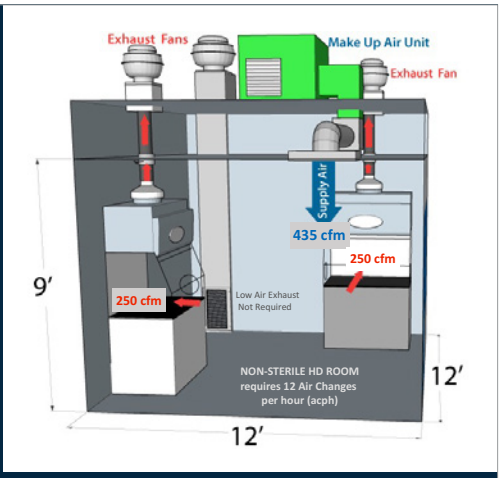
Supply Air for Sterile HD Room
12′ x 12′ x 9′ = 1,296 ft3
1,296 x 12 acph / 60 = **260 cfm**

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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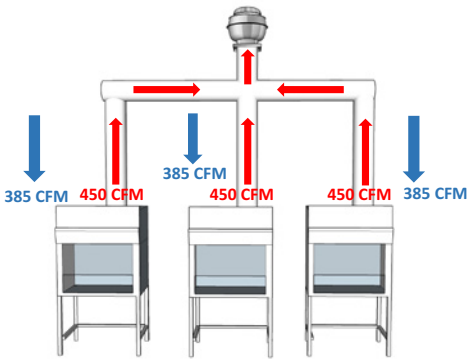
Each Incremental Unit

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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COMPLIANCE – USP <800> & PROPOSED <797>

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 non-sterile 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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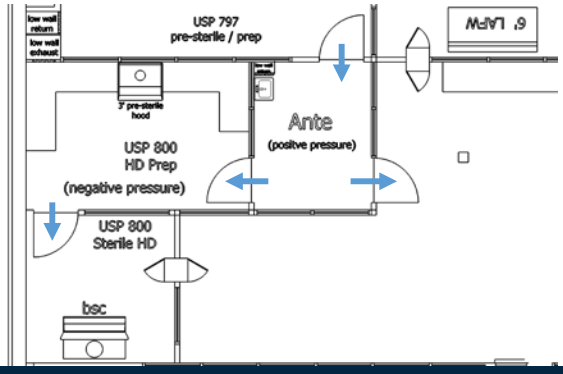
THE PROBLEM WITH NEGATIVE PRESSURE

- Consider door locations
- Consider airlocks between rooms
- CFUs come from everywhere



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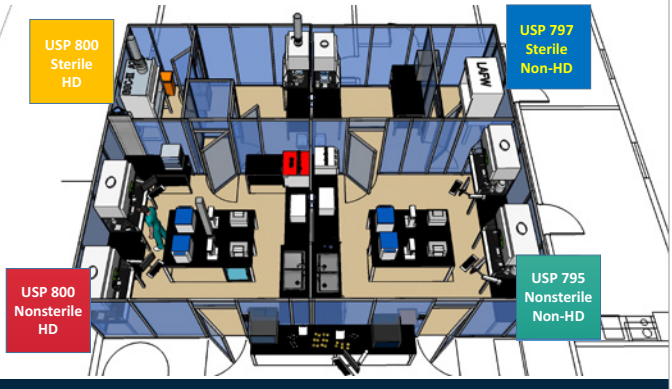
FOUR DIFFERENT ASPECTS OF COMPOUNDING

SEPARATE HAZARDOUS FROM NON-HAZARDOUS



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NOTES

NOTES

ADDITIONAL INFORMATION

- Fan Filter Units (FFUs) in the Sterile HD room ceiling are a must for guaranteeing ISO classification
- FFUs in the non-sterile 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

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

MAKE-UP AIR UNIT (MAU)

A MAU provides 100% fresh make-up air from outside, conditions temperature and humidity, and supplies air into the hazardous drug room

COMPLIANCE – USP <800> & PROPOSED <797>

CONSIDER METAL DUCTWORK

Standard commercial flex duct with fiberglass lining gets damaged, leaks, will not sustain pressures.

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EXHAUST BLOWER MOUNTED ON ROOF

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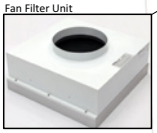
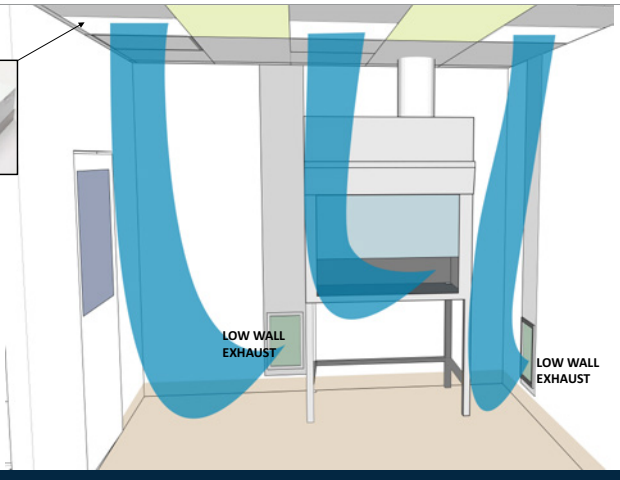


Design Goal:
Get air from the ceiling to the floor.
Moves particles down and out.
For Sterile and Non-sterile



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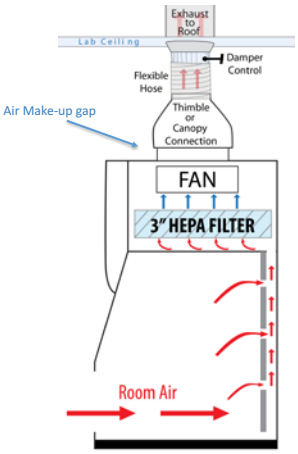
NOTES

NOTES

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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Example of hard-ducted hoods. -This is <u>not</u> acceptable because the external exhaust fan and the C-PEC's fan will fight each other.

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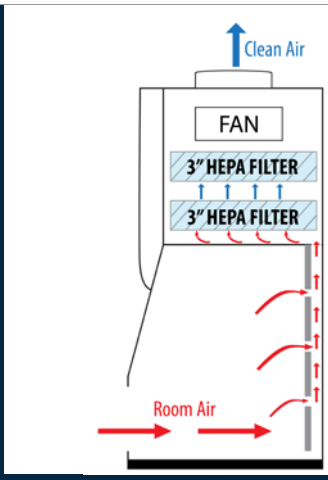
What is a C-PEC with Redundant HEPA Filtration?

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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COMPLIANCE – USP <800> & PROPOSED <797>

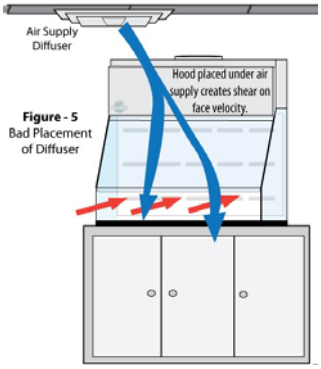
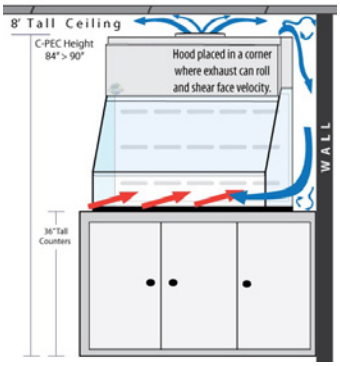


Figure - 5
Bad Placement of Diffuser



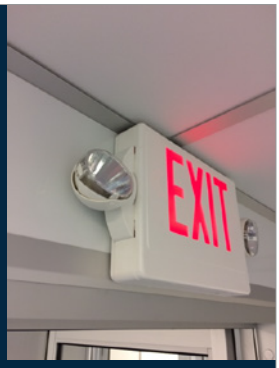
How the C-SEC Influences the C-PEC

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)

Plumbing

Ceiling Tiles



Signage

What's Wrong Here?

NOTES

NOTES

MATERIALS OF CONSTRUCTION - WALLS

Due to the difficulty of cleaning HD contamination, surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the non-sterile 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.

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STICK FRAMED

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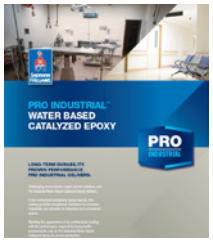
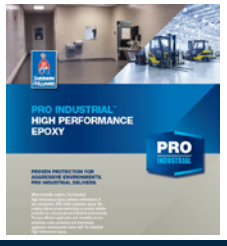
MATERIALS OF CONSTRUCTION – WALLS

Epoxy Paint:





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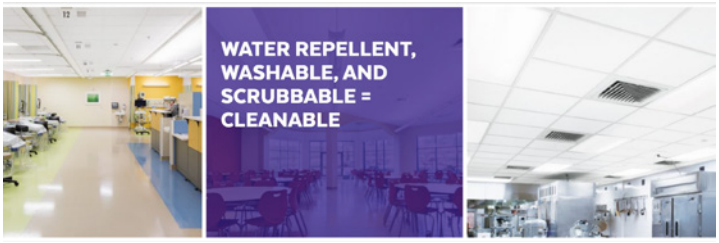
COMPLIANCE – USP <800> & PROPOSED <797>

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"

NOTES

NOTES

MATERIALS OF CONSTRUCTION – CASEWORK

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

Damaged laminate cabinet

Polypropylene

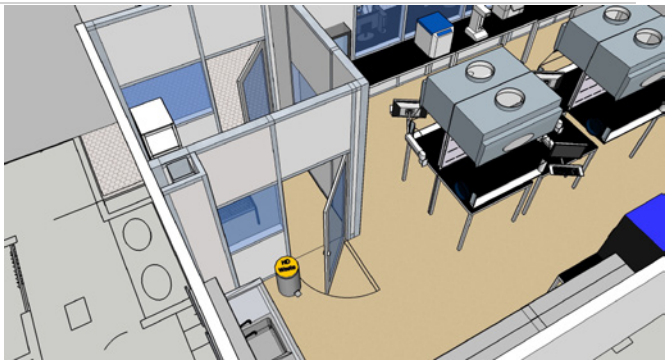
Stainless Steel

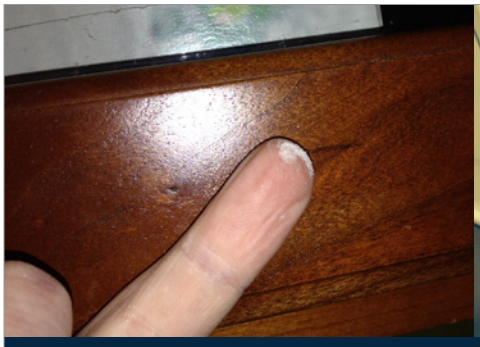
Epoxy or Phenolic

Powder coated metal

NON-STERILE 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.

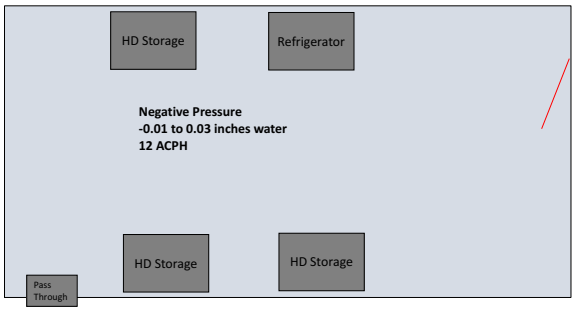




Engineering Controls and Good Lab Practices are Interdependent

COMPLIANCE – USP <800> & PROPOSED <797>

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 assessment of risk

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

NOTES

NOTES

SOME THINGS TO THINK ABOUT …

- Externally vented rooms move a lot of air …
- 10'x10'x8' example:
  - 12 ACPH: enough to fill a typical hot-air balloon in 12 hours
  - 30 ACPH: fills the balloon in three hours
  - The air will weigh three tons
- External venting is usually done at the roof:
  - There may be local requirements for the venting
  - Landlord permission will be required

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

COMPLIANCE – USP <800> & PROPOSED <797>

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>!

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

NOTES

NOTES

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

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

COMPLIANCE – USP <800> & PROPOSED <797>

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

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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

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NOTES

NOTES

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

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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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COMPLIANCE – USP <800> & PROPOSED <797>

GOWNS – Non-sterile

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

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GOWNS – Sterile

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

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Changing Gowns

- Must change:
  - Every two to three hours, or
  - Per manufacturer's instructions
  - If spill or splash
- Same for sterile/non-sterile

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NOTES

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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

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

COMPLIANCE – USP <800> & PROPOSED <797>

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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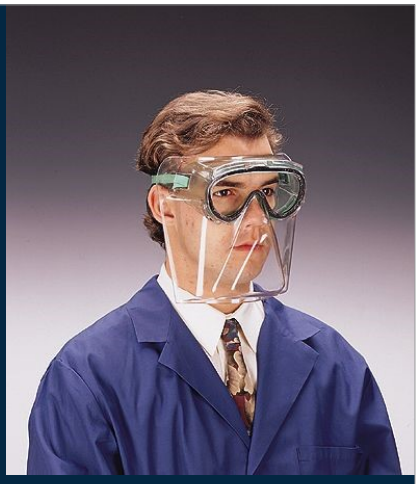
Eye Protection

- 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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NOTES

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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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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

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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

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COMPLIANCE – USP <800> & PROPOSED <797>

PERSONNEL

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 eyewashes)

NOTES

NOTES

PERSONNEL TRAINING

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

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

COMPLIANCE – USP <800> & PROPOSED <797>

The WHY for Safety

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Notice Where the Micronized Powder Collects

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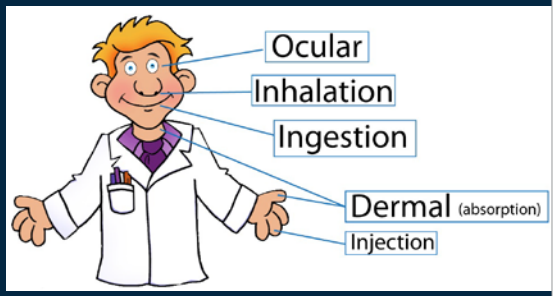
Exposure Routes for Chemicals



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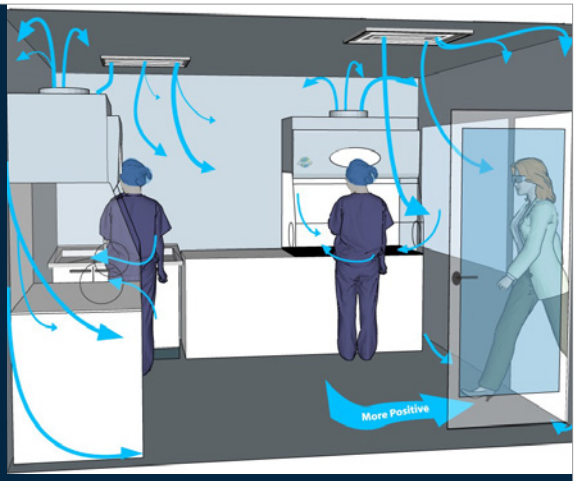
The WHY for Negative Pressure

Look more closely at your facility.



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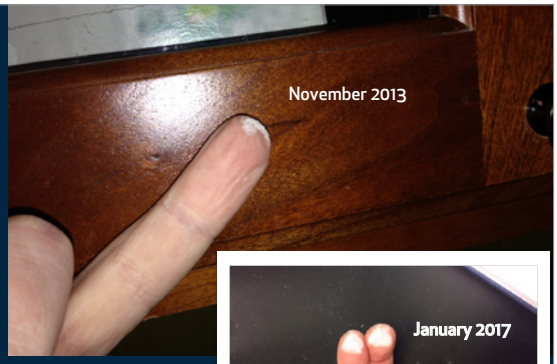
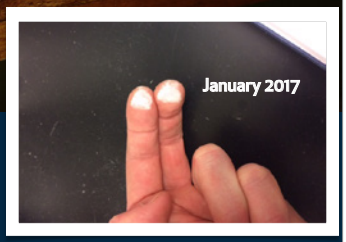
Environmental Exposure



Look more closely at your facility.



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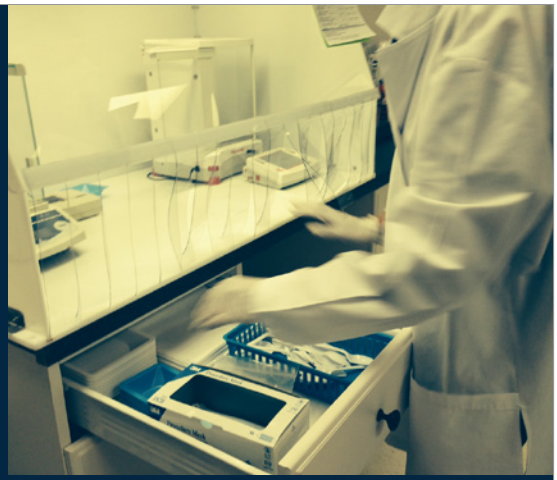
Breaching Containment is the #1 Safety Violation



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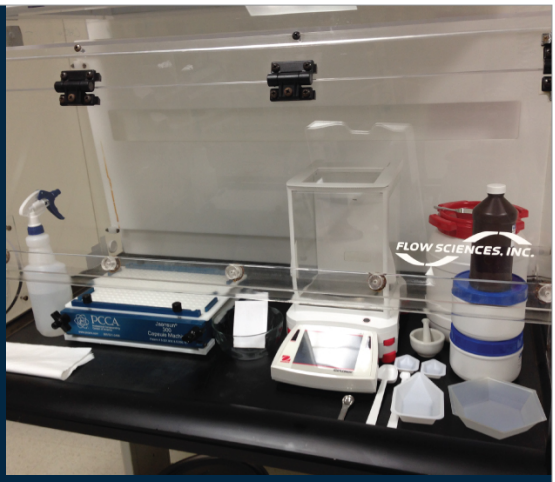
COMPLIANCE – USP <800> & PROPOSED <797>

Stage Everything First Inside the C-PEC



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Recommended Setup if you use Formulation Software

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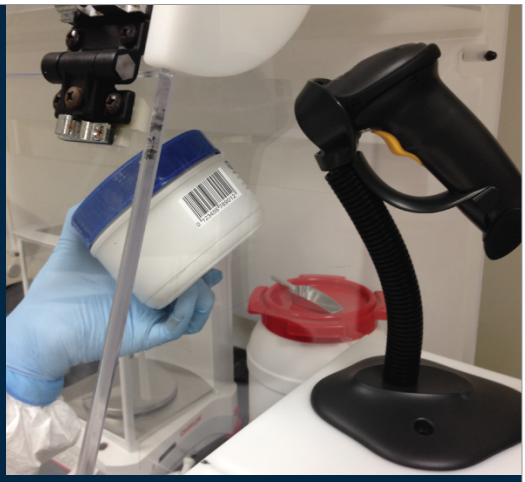
Chemicals Are Scanned Through the Sidewall of the Hood Prior to Weighing

Quality Control:

SCAN – WEIGH / SCAN – WEIGH / SCAN – WEIGH



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NOTES

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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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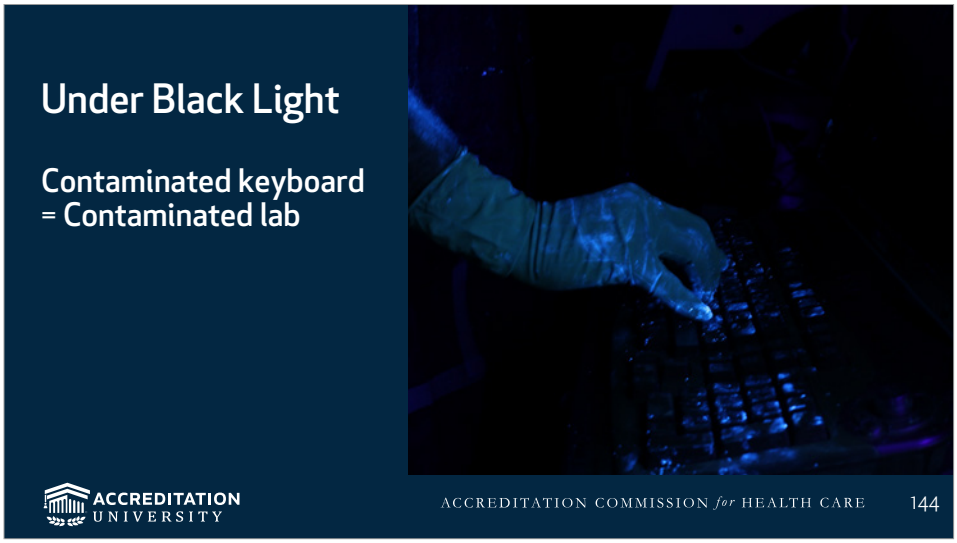
143


Under Black Light
Contaminated keyboard = Contaminated lab
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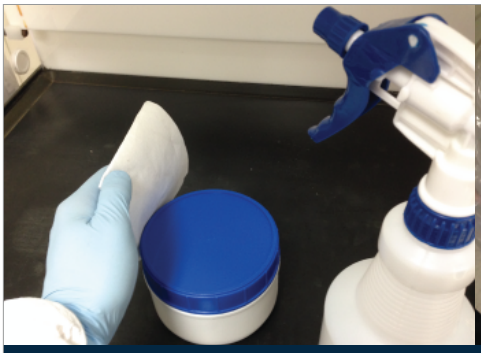
144

COMPLIANCE – USP <800> & PROPOSED <797>

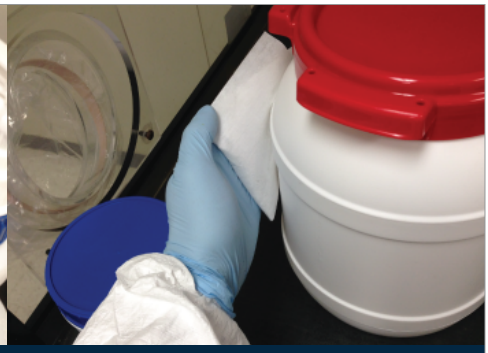
Cover With Sticky Wrap or Cellophane

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

NOTES

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Protecting Labels

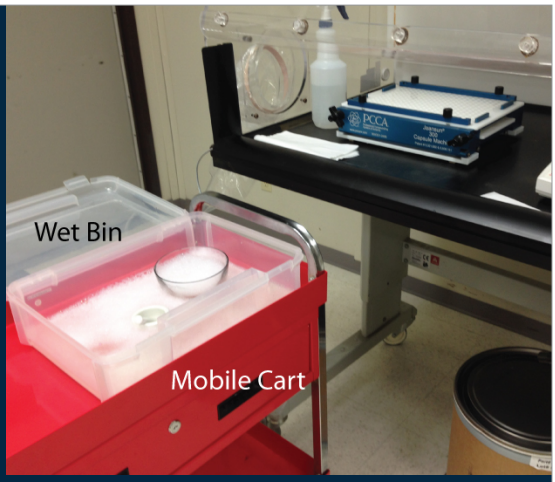
Place clear packing tape over bottle labels to prevent damage to the label

Contaminated Chemicals = **Contaminated Storage Area**

The C-PEC is NOT a Chemical Storage Cabinet

COMPLIANCE – USP <800> & PROPOSED <797>

Wet-to-Wet Transfer Method



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As Script Volume Grows, So Do Safety Processes

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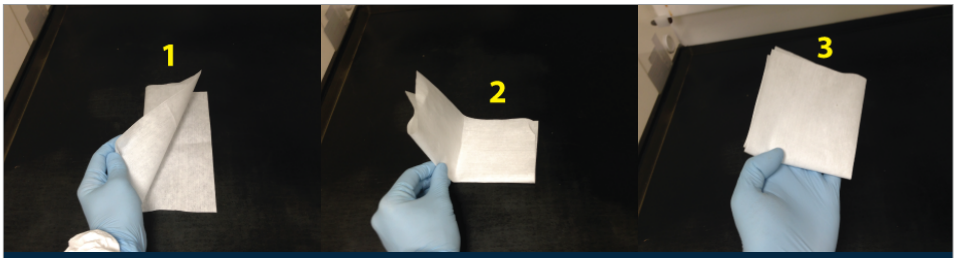

Proper Cleaning Procedure

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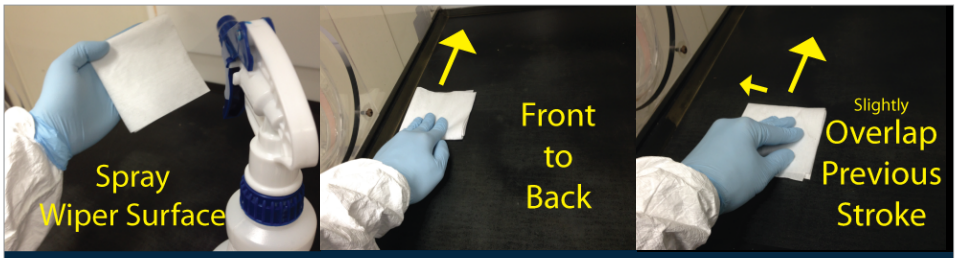

Proper Cleaning Procedure for Class-I Powder Hood

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Doff Proper Procedure:
Deglove and Desleeve Inside Hood

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The Wrong Method for Disposal of Contaminated Items

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COMPLIANCE – USP <800> & PROPOSED <797>

Proper Disposal of Contaminated Materials

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Acceptable Alternative Disposal Method:

- Introduce a Ziploc 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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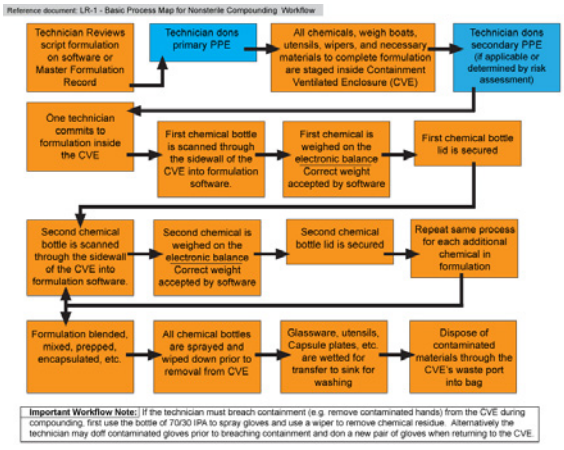

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NOTES

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Exiting the Lab

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

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Staging the Script Baskets Outside the Lab

Labs Are for Lab Personnel Only

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Home Shoes vs. Lab Shoes

Home shoes = dirt, dander, contaminants

Work shoes = dedicated, cleanable, comfortable

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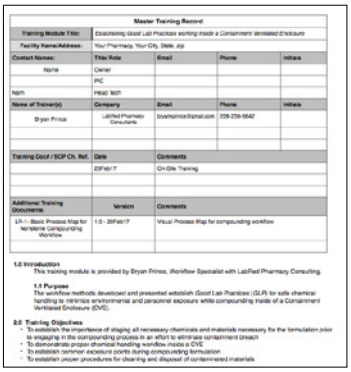
COMPLIANCE – USP <800> & PROPOSED <797>

"*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.



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	LabRad Pharmacy Consultants	brankonnor@gmail.com	228-239-5842	

Training Docs / SOP Ch. Ref.	Date	Comments
	23Feb17	On-Site Training

Additional Training Documents:	Version	Comments
LR-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 LabRad 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

RECEIVING, SHIPPING, AND STORAGE

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

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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

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?

COMPLIANCE – USP <800> & PROPOSED <797>

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 – refers to level packaging required:
  - Packing Group I = great danger
  - Packing Group II = medium danger
  - Packing Group III = minor danger

SO WHAT DOES THIS ALL MEAN?

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

NOTES

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SO WHAT DOES THIS ALL MEAN?

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

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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

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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!

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COMPLIANCE – USP <800> & PROPOSED <797>

BEST PRACTICE – WIPE SAMPLING

- Used to detect presence of HD residues:
  - Consider all places where HDs may be present:
    - PEC
    - Pass-through
    - 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

OSHA HAZARDOUS COMMUNICATIONS PROGRAM

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

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

NOTES

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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

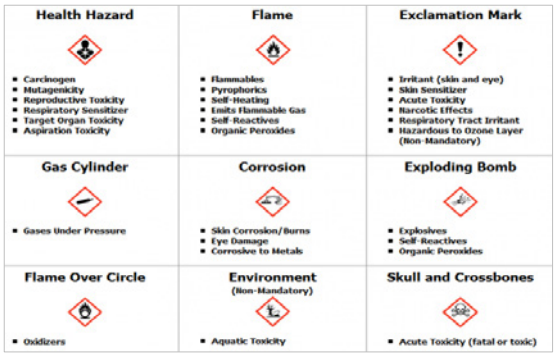
KEEP IN MIND …

- 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

COMPLIANCE – USP <800> & PROPOSED <797>

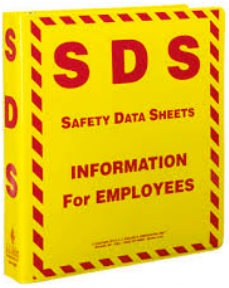
STEP 3: ENSURE PROPER LABELING

- Vendors
- Stock containers



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



STEP 5: TRAIN EMPLOYEES

- We already covered this one!

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STEP 6: KEEP UPDATED

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

HD DISPOSAL

DISPOSAL OF HDs

This is a regulatory requirement today!

COMPLIANCE – USP <800> & PROPOSED <797>

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

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
- Immunosuppressants
- Vitamins and minerals with chromium, selenium, or cadmium

- Oh … and is it infectious waste?

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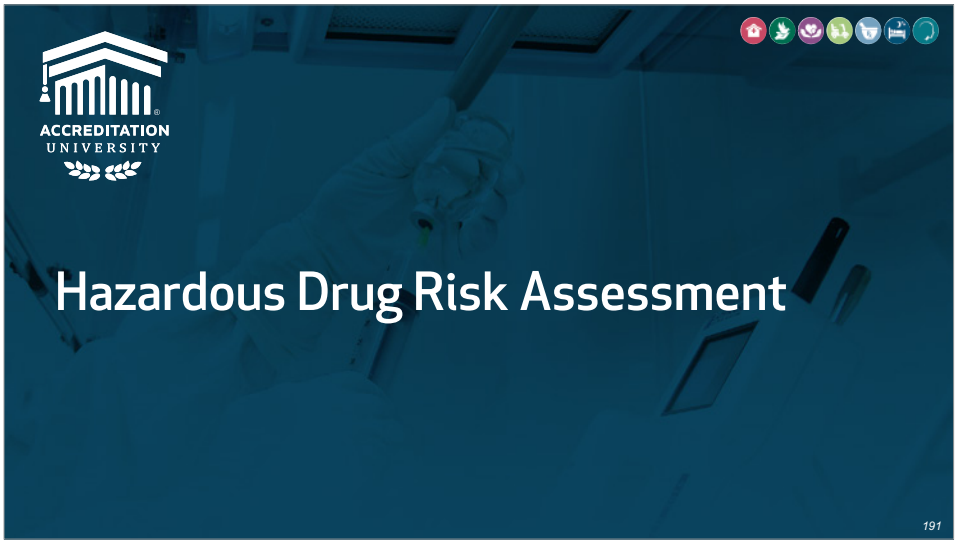
SUMMARY OF PHARMACEUTICAL WASTE STREAMS



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

COMPLIANCE – USP <800> & PROPOSED <797>

BENEFITS OF RISK MANAGEMENT

- Product Quality and Consistency (Quality Assurance – USP <797>, <795>, <1163>)
- Set Internal Standards (PPE, workflow processes:)
- Decision-making gets better (establish/update corporate policies and SOPs)
- Regulatory Assurance (documentation makes them happy)
- Reputation (Patients and Providers)
- Competitive Advantage (use as a marketing tool)

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EVERYDAY EXAMPLES OF RISK MGT.

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SUPPLEMENTAL READING

ARTICLE:

HOW TO PERFORM A HAZARDOUS DRUG RISK ASSESSMENT IN THE COMPOUNDING PHARMACY

https://learn.nuaire.com

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RISK ASSESSMENT PROCESS

Risk Identification = *Inventory hazardous drugs on hand*

↓

Risk Analysis = *Walk around and examine the processes.*

↓

Risk Evaluation = *Why?*

↓

Risk Reduction = *Implementation of new HD standards (SOPs, training, etc.)*

RISK IDENTIFICATION

Hazardous Drug Risk Assessment Worksheet

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

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

Source: Hazardous Drug Consensus Statement (HDCS)

Hazardous Drug Risk Assessment Worksheet

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

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

Suggestion: *Staple a copy of the Safety Data Sheets (SDS) to the back of this worksheet.*

COMPLIANCE – USP <800> & PROPOSED <797>

RISK ANALYSIS AND RISK EVALUATION

The "risk evaluation" compares the identification and analysis against a set of "risk criteria."

The problem is 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

Storage | Compounding | Dispensing

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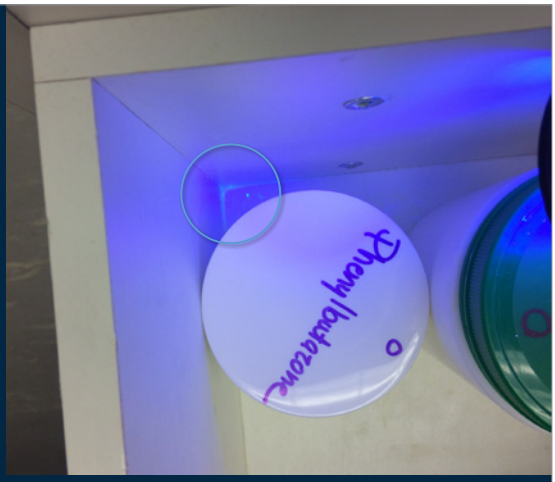
RISK EVALUATION AND RISK REDUCTION

"Why is powder residue detected in the HD storage drawer?"

"How do we mitigate (reduce) this situation?"



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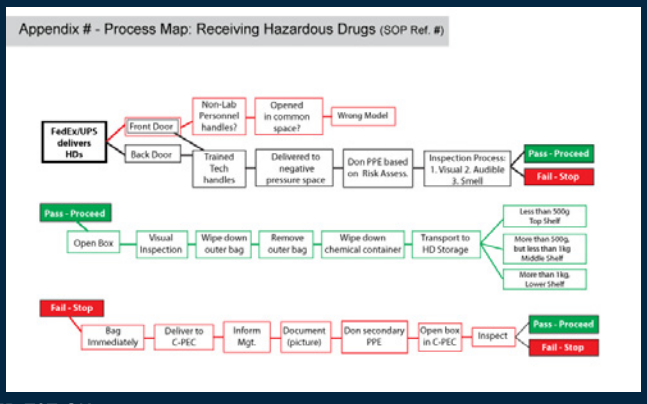
EXAMPLE-1: RISK ANALYSIS TO RISK EVALUATION TO RISK REDUCTION



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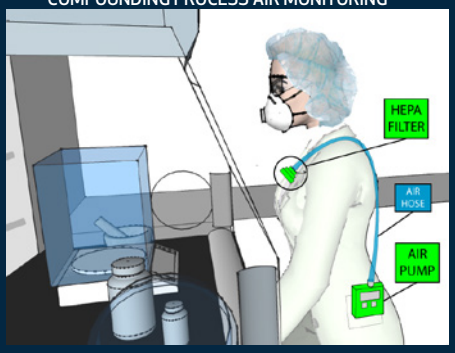
EXAMPLE-2: RISK ANALYSIS TO RISK EVALUATION TO RISK REDUCTION

COMPOUNDING PROCESS AIR MONITORING



The "breathing pump" monitors are available from third-party analytical testing labs.

**additional benefit: technician competency evaluation*

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EXAMPLE OF RISK REDUCTION

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).

OSHA Respirator Fit Test

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MEDICAL SURVEILLANCE

"Medical surveillance is part of a comprehensive exposure control program complementing engineering controls, safe work processes, and use of PPE. Healthcare workers who handle HDs as a regular part of their job assignment should be enrolled in a medical surveillance program."

- ☐ 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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COMPLIANCE – USP <800> & PROPOSED <797>

MEDICAL SURVEILLANCE

USP <795> AND <797>: WHAT'S NEW?

HAZARDOUS DRUGS

- Both <795> and <797> revisions refer to <800> in regards to HDs
- *Do you live in, or carry a license in, a state that requires <795>/<797> compliance?*

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USP <795> REVISION

- New term – **CNSP** – Compounded Non-sterile Preparation
  - Includes nasal and sinus preparations intended for local application
- Designated person – similar to <800> requirement
- Increased formality around hygiene and garbing
  - Hand-washing before a new CNSP – if gloves on , wash with gloves
  - Gloves required, other garb "as appropriate"

USP <795> REVISION

Table 1. Minimum Frequency for Cleaning and Sanitizing Surfaces in Nonsterile Compounding Areas

Site	Minimum Frequency
Floors	Daily, after spills, and when surface contamination (e.g., splashes) is known or suspected
Walls	Every 3 months, after spills, and when surface contamination (e.g., splashes) is known or suspected
Ceilings	Every 3 months, after spills, and when surface contamination (e.g., splashes) is known or suspected
Storage shelving	Every 3 months, after spills, and when surface contamination (e.g., splashes) is known or suspected

USP <795> REVISION

- Containment – any weighing, measuring, or other manipulation of an API must occur inside a containment device
  - **Previously only required for HDs**
- Ingredient selection – conforms more closely with DQSA language

COMPLIANCE – USP <800> & PROPOSED <797>

USP <795> REVISION

- Labels to contain:
  - Assigned internal identification number (e.g., prescription or lot number)
  - Chemical and/or generic name(s), or active ingredient(s), and amounts or concentrations
  - Dosage form
  - Total amount or volume
  - Storage conditions
  - BUD
  - Indication that the preparation is compounded

USP <795> REVISION

- BUDs

Type of Preparation	BUDs (days)	Storage Temperature[a]
Solid dosage forms[b]	180	Controlled room temperature
Preserved aqueous dosage forms[c]	30	Controlled room temperature
Non-preserved aqueous dosage forms[c]	14	Refrigerator
Nonaqueous dosage forms[d]	90	Controlled room temperature

[a] See *Packaging and Storage Requirements* ⟨659⟩.
[b] Capsules, tablets, granules, powders.
[c] An aqueous preparation is one that has a water activity (Aw) of >0.6 (e.g., emulsions, gels, creams, solutions, sprays, or suspensions).
[d] Any preparation other than solid dosage forms that have a reduced Aw of ≤0.6 (e.g., suppositories, ointments, fixed oils, or waxes).

Maximum 180-day BUD!

USP <797> REVISION – ROUND 2!!!

- First draft – Sep 2015
- Second draft – July 2018
  - Second draft SIGNIFICANTLY different than first
- HDs – see USP <800>
- Radiopharmaceuticals – draft of USP <825>
- Allergenic extracts – not in first draft, exempt from requirements of the chapter if certain criteria are met

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USP <797> REVISION – ROUND 2!!!

- Definition of CSP
  - "Sterile compounding is defined as combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug or bulk drug substance to create a sterile medication."
  - "Preparing a conventionally manufactured sterile product in accordance with the directions contained in approved labeling provided by the product's manufacturer is **not compounding** as long as the product is for an **individual patient** and follows the **provisions for administration** below."

USP <797> REVISION – ROUND 2!!!

- Risk Categories:
  - Low, Medium, High-risk… GONE!
  - New terminology based on environment
    - Category 1 – PEC in a non-ISO space
    - Category 2 – PEC in an ISO 7 or better buffer *and* ISO 8 or better anteroom
      - Note – this includes all PECs…. *RABS are not exempt*

USP <797> REVISION - BUDS

- Category 1: limited to ≤ 12 hours room temp, ≤ 24 hours refrigerated
- Category 2:

Table 12. BUDs for Category 2 CSPs

Preparation Characteristics		Storage Conditions		
Sterilization Method	Sterility Testing Performed and Passed	Controlled Room Temperature (20°–25°)	Refrigerator (2°–8°)	Freezer (−25° to −10°)
Aseptically prepared CSPs	No	Prepared from one or more nonsterile starting component(s): 1 day	Prepared from one or more nonsterile starting component(s): 4 days	Prepared from one or more nonsterile starting component(s): 45 days
		Prepared from only sterile starting components: 4 days	Prepared from only sterile starting components: 9 days	Prepared from only sterile starting components: 45 days
	Yes	30 days	45 days	60 days
Terminally sterilized CSPs	No	14 days	28 days	45 days
	Yes	45 days	60 days	90 days

COMPLIANCE – USP <800> & PROPOSED <797>

USP <797> REVISION – TRAINING AND COMPETENCY

- Hand hygiene
- Garbing
- Cleaning and disinfection
- Calculations, measuring, and mixing
- Aseptic technique
- Achieving and/or maintaining sterility and apyrogenicity
- Use of equipment
- Documentation of compounding process
- Principles of unidirectional airflow
- Use of PECs
- Principles of movement of materials

USP <797> REVISION – TRAINING AND COMPETENCY

- Garbing and hand hygiene
  - Initial – 3x, ≥1 cfu
  - Post media-fill – every six months, >3 cfu
  - Visual observation – six months
- Media-fill – every six months (examples have been removed)
- Cleaning and disinfecting – retrain and requalify with change in procedure

USP <797> REVISION

- Hand hygiene, garbing, and gloving
  - Order to be determined by facility
  - Revision allows for sink to be in or out of anteroom
- Presterilization
  - ISO 8 environment
  - Must be in a PEC

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USP <797> REVISION

- Certification – CETA is a *must*
- Six-month cycle for viable and nonviable air sampling
- Surface sampling
  - Monthly requirement in each classified area

USP <797> REVISION

- Compounding Records
  - MFR – required if:
    - CSP prepared in a batch for more than 1 patient
    - CSP prepared from non-sterile ingredients
  - CR – created for all CSPs
    - May be in the form of an Rx order, compounding log, or label
- Recalls, complaints, adverse event reporting – all covered by the chapter

STAY UP TO DATE WITH USP <795> AND <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

COMPLIANCE – USP <800> & PROPOSED <797>

USP <795> AND <797> UPDATE TIMELINE

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

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THANK YOU

Accreditation Commission for Health Care
139 Weston Oaks Court
Cary, NC 27513
(855) 937 2242 | achc.org

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ADDITIONAL RESOURCES

ACCREDITATION COMMISSION *for* HEALTH CARE

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

T (919) 228-6559
F (919) 785-3011

139 Weston Oaks Ct., Cary, NC 27513

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