Meeting the USP <797> / <800> Challenge

Performing a gap analysis and operationalizing the conversion

New York State Healthcare Facilities Conference

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AIA Buffalo/WNY Chapter

A001

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Performing a gap analysis and operationalizing the conversion

BUF2016-

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Learning Objectives

At the end of the this course, participants will be able to:

1. Review USP 797/ USP 800

2. Discuss process for performing an assessment of risk to determine compliance to USP <800>

3. Discuss strategies and/or work practices for operationalizing the conversion to USP <800>

1. Understand the challenges involved

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Smilow Cancer Hospital - Yale New Haven Health

- YNHH - 1541 bed Academic Medical Center
- Smilow Cancer Hospital
    - 168 inpatient beds
    - 160 infusion chairs
    - National Cancer Institute (NCI) Designated Cancer Hospitals
    - National Comprehensive Cancer Network Hospitals (NCCN)
- Smilow Cancer Hospital Care Centers and Network
    - 13 Cancer Hospital Care Centers throughout CT
    - 4 Community Hospitals
- Affiliate of Yale University
- Specialty Pharmacy for Oral Chemotherapy
- Investigational Research – 450 open Investigational studies
    - Active Phase I, II, III

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Who are we?– Oncology Pharmacy Services

- Department of Oncology Pharmacy
  - 140 fte's
    - 71 Clinical Oncology Pharmacists - 80% BCOP
    - 52 Certified Pharmacy Technicians
    - 4 Oncology PGY2 residents
    - 6 Medication Assistance Coordinators (MAPs)
    - 7 Support Staff
  - Collaborative practice model - Clinical Pharmacists practice on oncology disease teams assisting with medication selection, treatment plans, order verification, education
  - Pharmacy Technicians manage distribution logistics

- Drug expenses
  - $164 million - FY 2017

- 173,132 chemotherapy doses were compounded in FY 2017
  - 21.1% increase from previous year

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United States Pharmacopeia

- United States Pharmacopeia (USP)
  - Non-governmental non-profit organization
  - Primary activities are creation of standards, patient safety, healthcare information, and verification of products
    - Quality and consistency of medicines
    - Safe and proper use of medications

United States Pharmacopeia

- Each general chapter of the USP/NF is assigned a number which appears in brackets

- Chapter <1> to <999> are required and enforceable
  - Pharmacies are subject to inspection for compliance with required standards by:
    - State Boards of Pharmacy
    - FDA
    - Joint Commission on Accreditation of Healthcare Organizations (TJC)
    - Includes Chapter <797> and <800>

- Chapter <1000> to <1999> are informational

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USP Chapter <797>

- Goal of USP Chapter <797> is to prevent potential patient **harm** or **death** that could result from:
  - Microbial contamination
  - Excessive toxins produced by bacteria (endotoxins)
  - Compounding errors
  - **For USP <797> - Think Sterility**

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Setting the Stage - Personnel Cleansing and Gowning

- A human person in a cleanroom is considered a broad spectrum particle generator enclosed by inefficient mechanical filters that may also be sources of particles
- The human body harbors an average of 150-200 different classes of bacteria
- Hands have an average of 100,000 organisms / sq mm
- Even though we can't "see" it, we shed over 1 million skin cells per hour and those cells contain microorganisms!
- Personnel - "Our greatest asset and also our biggest liability!"

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USP Chapter <800>

- The United States Pharmacopeia Convention (USP) published General Chapter <800> *Hazardous Drugs – Handling in Healthcare Settings* on February 1, 2016 with a planned delayed implementation date of July 1, 2018.

- However as of September 29th, 2017 the USP Expert Committee in an effort to align both USP 797 and USP 800 standards extended the dating USP 800 implementation to December 1, 2019.

- The standard applies to all healthcare personnel (i.e., physicians, nurses, veterinarians, pharmacists and technicians) and all healthcare facilities where hazardous drugs are handled or manipulated, including their compounding, dispensing, and administration — with a goal of preventing and/or limiting residual exposure.

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What is the rationale for USP <800>?

- Safety of the employee is a paramount. The processes listed in USP <800> are intended to provide containment of Hazardous Drugs (HDs) to as low a limit as reasonably achievable
- 8 million healthcare workers are exposed annually to HD
- In 2010, it was determined that 75% of the surfaces of pharmacies were contaminated with HDs
- Over 20 studies have been published linking exposure to HDs to medical risks
- **For USP <800> - Think Exposure**

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For hospitals that handle HDs – systems must be in place that include:

- Facility and engineering controls
- Safe work practices that address exposure to HDs (SOP's)
- Competencies for personnel
- Proper use of appropriate Personal Protective Equipment (PPE)
- Policies for HD waste, segregation and disposal
- Current list of Hazardous Drugs (HDs)

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The Challenge

- What are my options to update my facility to be in compliance with USP 800?
- Do I have to make changes to my facility per USP 800?

- The simple answer is Yes! If you are compounding hazardous drugs as listed in the National Institute for Occupational Safety and Health (NIOSH), then your facility is required to meet the USP 800 standards.

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Conversion to USP Chapter <800> must address:

- Receipt
- Storage
- Compounding
- Use and maintenance of proper engineering controls (e.g. C-PECs, C-SECs and C-SCA)
- Hand hygiene and use of PPE
- Hazardous Drug List
- Transport
- Cleaning, and disinfection
- Deactivation and decontamination
- Administration
- Environmental monitoring
- Disposal
- Spill control
- Medical surveillance

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How did we prepare for USP 800 Conversion

- Perform a gap analysis
- Educate staff and leadership
- Obtain capital funding ($$$$$)
- Perform risk assessment
- Develop Plan – Develop Timeline - Assemble a team
  - Pharmacy Mechanical Engineering
  - Facilities Architect
  - Nursing Quality and Risk
- Create operational plan to operate during construction –
  - Update SOPs
  - Temporary cleanroom (C-SCA -Contained Segregated Compounding Area)
  - Mobile cleanroom
  - Outsourcing
- Maintain strong communications
- Deadline 12/1/2019

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Preparing for USP 800 Conversion - Perform Gap Analysis

Utilized to prioritize items and includes:

- Facility needs and/or upgrades
  - Understand the requirements and options
    - both state and federal
  - Educate leadership and Secure Capital dollars
- Perform Assessment of Risk
- Review Hazardous Drug list
- Review workflow
  - Containment of HDs
  - Techniques to limit exposure
  - Decontamination of areas exposed to HDs
- Evaluate Monitoring processes and certification
- Evaluate staff understanding of standards
  - PPEs

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Properly Garbed for Compounding Sterile Products!

- Double gloved
- Facemask
- Chemo Gown
- Double boots

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Perform a Gap Analysis- Facility Design

- Facility assessment must include an understanding:
  - C-PEC and C-SEC containment requirements to control hazardous drug contamination
  - Engineering controls (HVAC)
- Understand the Options for Sterile Compounding
  - Hazardous Cleanroom
    - Positive pressure ISO 7 (class 10,000) anteroom opening into negative pressure ISO 7 buffer room with ISO 5 (class 100) biological safety cabinet (BSC) or compounding aseptic containment isolator (CACI)
  - Containment Segregated Compounding Area
    - Separate space with BSC or CACI – non ISO rated room
    - Negative pressure – 12 air exchanges, 100% externally vented
    - Limited to 12 hour beyond-use date (BUD)

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Understand the required USP Facility Design and Engineering Controls

- Containment Primary Engineering Control (C-PEC)
  - must be 100% externally vented
- Containment Secondary Engineering Control (C-SEC – HD cleanroom)
  - 100% externally vented
  - Monitored negative pressure range - (–) 0.01-0.03 inches of water column (WC) relative to adjacent areas
  - Appropriate air changes per hour – minimum 30 ACPH of HEPA filtered supply air
  - ISO 7 environment (10,000 particles per ft^3)
  - Monitored temperature 20C (68 F)
  - Target ≤60% humidity
- ISO 7 ante room, positive pressure, proper ACPH – Minimum of 30 ACPH of HEPA filtered air, line of demarcation
  - Maintain a positive pressure of at least 0.02 inches WC relative to adjacent unclassified areas

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Understand the required USP Facility Design and Engineering Controls

Separation of HDs and non-HDs

- A C-PEC and C-SEC used for the preparation of HDs shall NOT be used for the preparation of a non-HDs.
    - All hazardous drug compounding shall be prepared in a separate area designated for hazardous drug compounding only
        - must be in a negative pressure room
    - All non-hazardous drug compounding must be separated from HD compounding
        - must be in a positive pressure room

HD Storage

- HDs must be stored separately from non-HDs
- Must be 100% externally ventilated, negative pressure room, 12 ACPH

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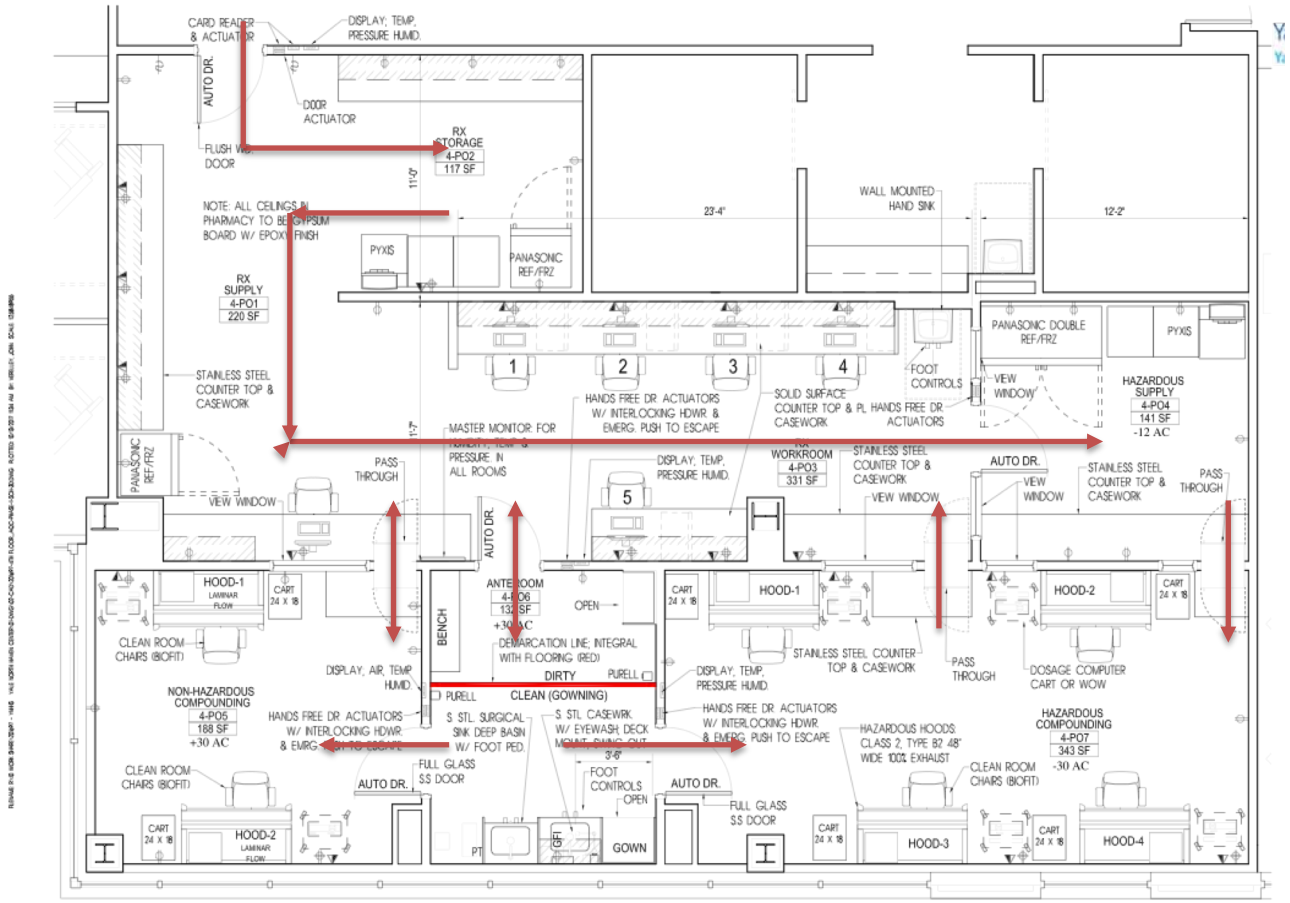
Understand the required USP Facility Design and Engineering Controls as It Relates to Workflow



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C-PEC Considerations – which type is best

Containment Primary Engineering Control (C-PEC)

- Biological Safety Cabinet (BSC)
  - Class II, Type A2
  - Class II, Type B2
- Compounding Aseptic Containment Isolator (CACI or “Glove box”)

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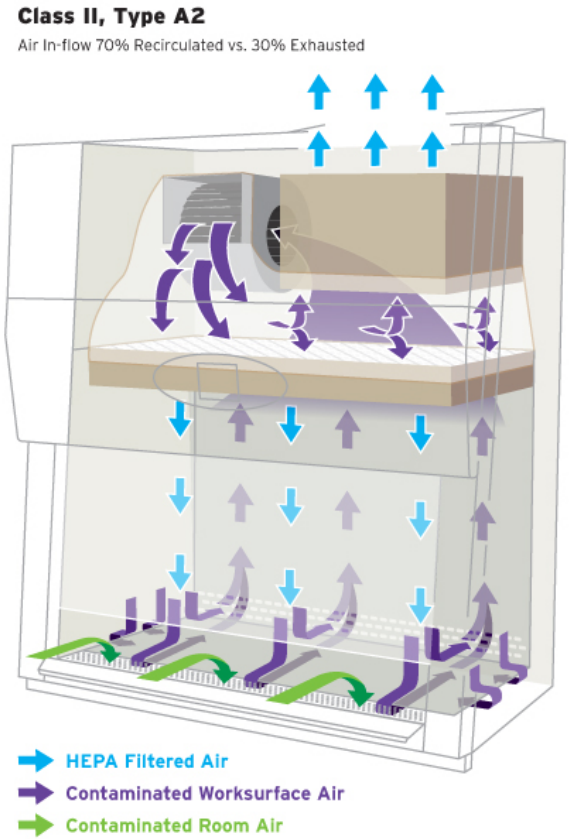
Why a Class II Type A2?

Class II Type A2

HEPA air moves downward and captured in front

- Protects product and personnel.
- 30% externally vented through HEPA filter 70% re-circulated through HEPA
- Requires exhaust canopies
- Less expensive option



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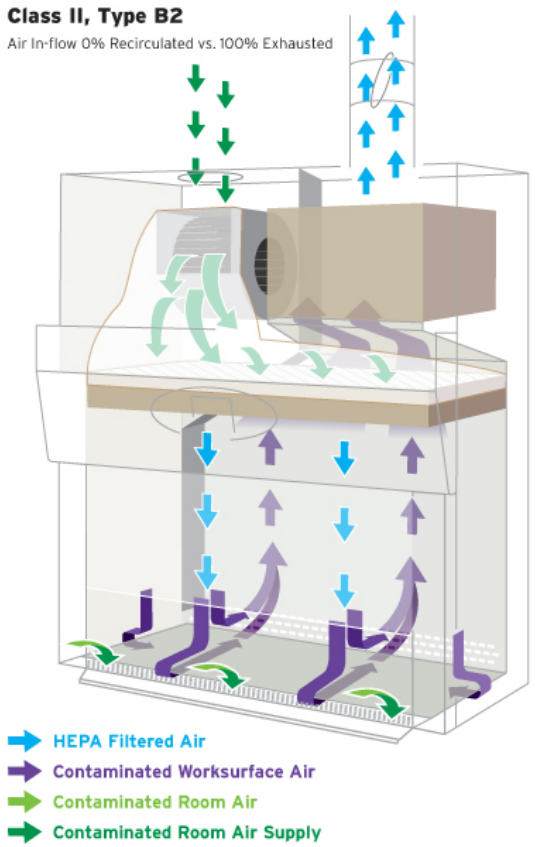
Why a Class II Type B2?

Class II Type B2

HEPA air moves downward and captured in front

- Protects product and personnel.
- No recirculation and 100% externally vented through HEPA filter.
- More expensive alternative



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Environmental Quality and Control

- Cleanroom - Critical Site
  - Any opening providing a direct pathway between a sterile product and the environment or any surface coming into direct contact with the product and the environment
  - Must protect these sites from environmental contamination

- Air Quality
  - ISO Class 5 (Class 100) required in critical area (area where sterile products are directly exposed, e.g. containment hood)
  - ISO Class 7 (Class 10,000) required for buffer area or clean room
  - Anteroom - ISO Class 8 (Class 100,000) adjacent to non HD cleanroom; ISO Class 7 (Class 10,000) adjacent to HD cleanroom
  - Minimize air currents from open doors, personnel traffic
  - Temperature and humidity control required

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Develop standard SOPs and Policies

- USP<800> establishes the personnel and operational requirements.
- SOPs should be developed that include:
    - Staff competencies – finger tip and media fill testing
    - Aseptic technique and proper workflow
    - Garbing – Protective Equipment (PPE)
        - Standardizing of garbing supplies
        - Updating nursing garbing compliance to align with USP 800
    - Cleaning
    - Closed System Transfer Devices (CSTD)
    - Monitoring
        - Remediation planning
        - Report structure for System Infection Prevention

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How do we protect staff from HDs exposure?

Receipt	Residue	Labeling Gloves and Spill procedure
Transport	Moving HDs	Labeling, Gloves and spill procedures
Compounding	Manipulating HDs	HD garbing/doffing Engineer controls Cleaning/HD spills CSTD
Administration	Various routes	Labeling, gloves, gowns, googles, spill procedures, CSTD, needleless
Waste	Collecting and disposal	Labeling, Gloves, spill procedures

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Responsibility of personnel handling HDs

- Educate staff - All personnel who handle HDs are responsible for understanding practices and precautions and for continually evaluating these and the quality of the final HD product
  - To prevent harm to patients
  - Minimize exposure to personnel
  - Minimize contamination of the compounding environment
  - Minimize contamination of patient-care environment

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Develop a Hazardous Drug List

- Perform an Assessment of Risk of Exposure for drugs on the NIOSH list
- Review NIOSH list of Hazardous Drugs
  - Antineoplastics
  - Non-antineoplastics
  - Reproductive hazardous drugs
- Handle every drug and dosage form on the NIOSH list with all the precautions and work practices listed in <800>
  - Is that possible in every case?
  - Is that practical in every case?

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Create facility options during construction

Creating alternative containment strategies and/or work practices during construction

1) Mobile Cleanroom

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Create facility options during construction

Creating alternative containment strategies and/or work practices during construction

2) Temporary Cleanroom
   - Contained Segregated Compounding Area (C-SCA)

3) Outsourcing

4) Compound from other sites within Health System

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Specifications

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BSC’s – 100% externally exhausted

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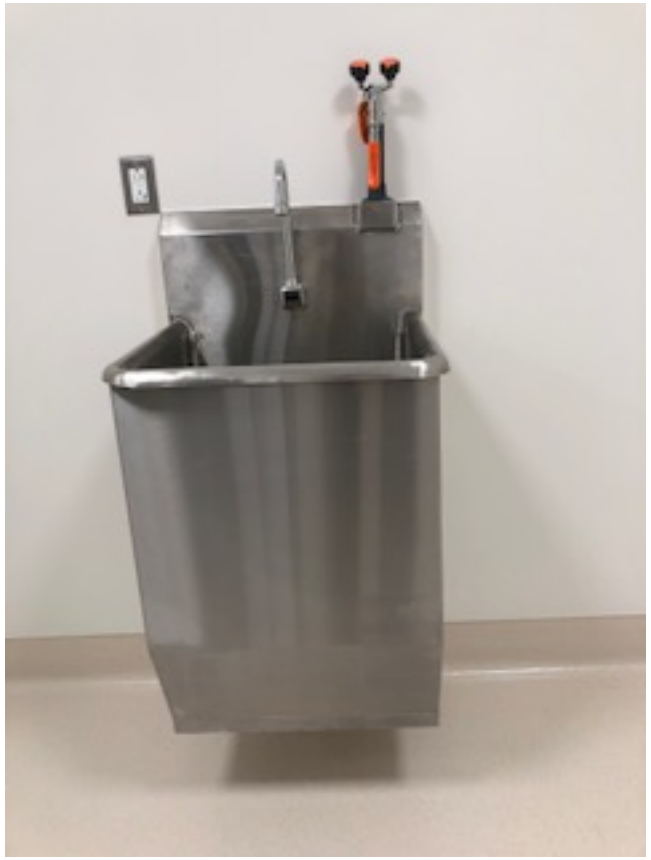
Cleanroom Sink



Hands Free
Deep basin’
Stainless steel
eyewash

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Cleanroom Window

Cleanroom Window
Borderless
Flush mount (cleanroom side)
Glass panel

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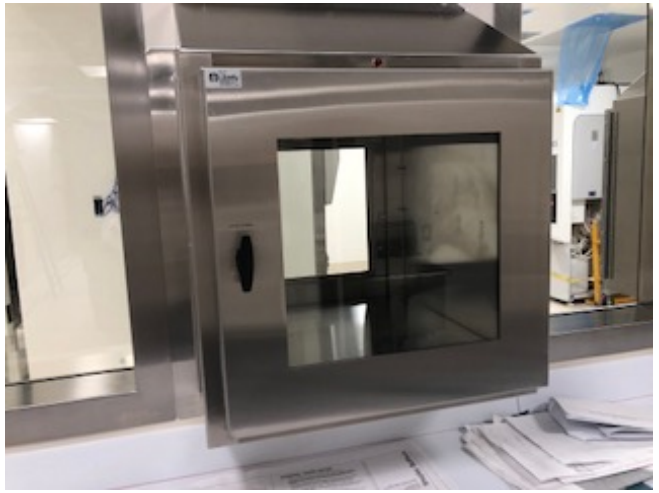
Cleanroom Pass-Through



- Stainless steel
- Gasketed
- Interlocking
- HEPA filtration (optional)

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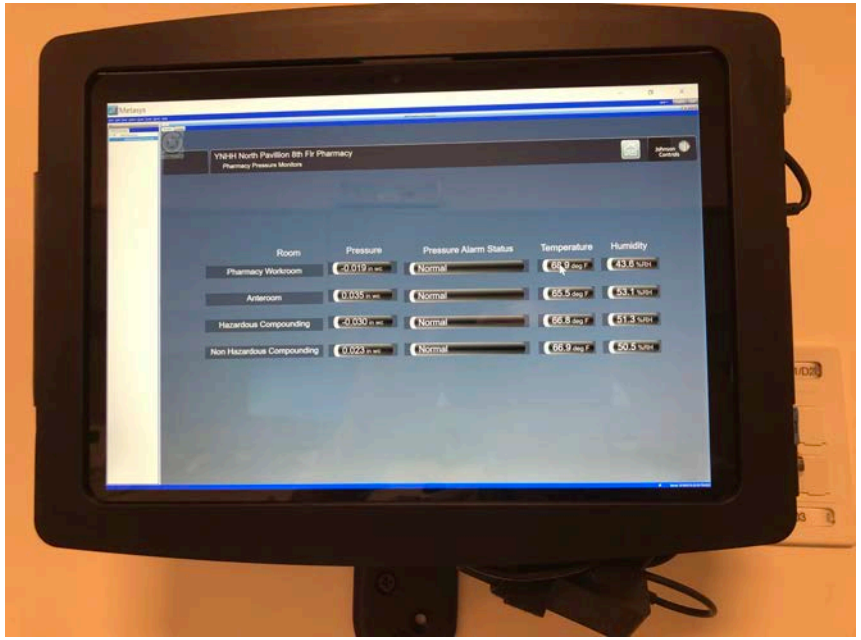
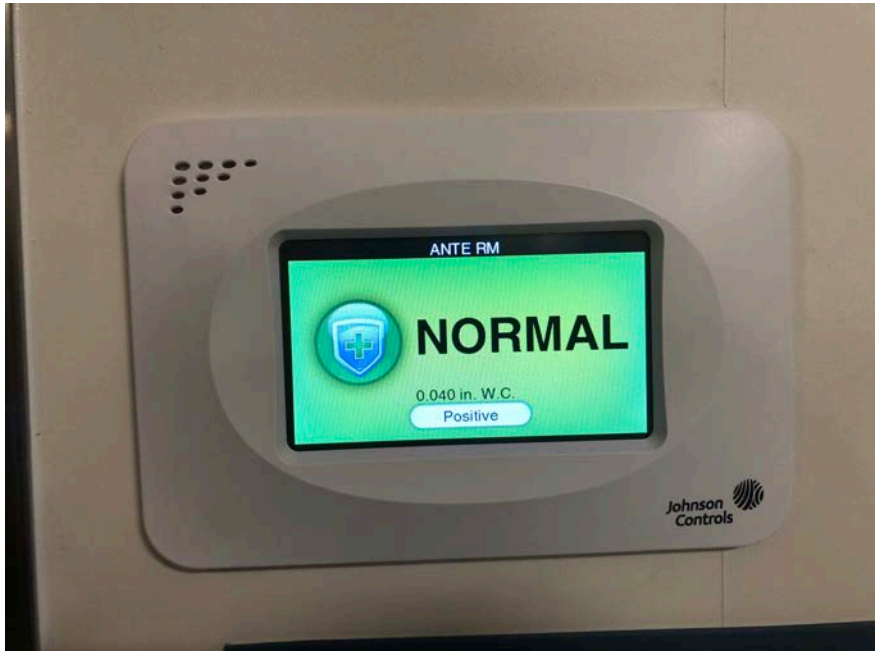
Proper Monitoring



Temperature
Pressure
Humidity
Monitored 24/7



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Cleanroom Telephone

Hands Free
Flush Mount
Cleanable surface
Speed Dial

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Cleanroom Doors

- Swing doors or sliders
- Hands free operation
-Interlocking

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Technology/Robotics – Understand the Impact Of Technology

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FAQ: How often do the Bio-safety cabinets and Laminar flow hoods and cleanrooms need to be certified?

- The Laminar Flow Hoods and BSC's are considered primary engineering control units and need to be inspected and certified at least every 6 months
- The cleanrooms are considered secondary engineering control units and are required to be certified at least every 6 months
- If a "hood" has to be moved or has broken down and out of production and may have compromised it's performance it needs to be recertified before it can be placed back in service.

Note: Some states may require more frequent certifications

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FAQ: Is Chemotherapy Considered a High Risk Compounded Sterile Product?

- No
  - Chemotherapy is considered a biohazard drug
  - High Risk CSPs are ones made from non-sterile components and need to be sterilized

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FAQ: What is a line of demarcation and where is it in the ante-room?

- The concept is to have a dirty side and a clean side of the ante-room
- Where you begin to garb is the “dirty side”
- Where you finish garbing is the “clean side”

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FAQ: How Often should I perform environmental sampling? When is action required.

Answer
Whenever the cleanroom room is compromised and at least every 6 months as part of the Ceta-Certification

USP <797> Class and Action levels

ISO Clean Room Classification	ISO, 0.5 u/m_3 Particulate	Viable Air Sampling 400-1000 CFU/m_3	Surface Contact CFU/plate	Gloved Fingertip CFU/plate	Gloved Fingertip CFU/plate Gown Validation
Class 5	3,520	>1	>3	>3	>0
Class 7	352,000	>10	>5	N/A	N/A
Class 8 or worse	3,520,000	>100	>100	N/A	N/A

Note: any mold or fungal growth on air or surface is considered actionable

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FAQ: Why don't I shut the hood off when I go home at night?

- It is important to maintain the air balance in the room and prevent the HEPA filter from becoming clogged up by allowing dust to settle from the vents for the bio-safety cabinets.

- Even though you may be tempted to save electricity, the "hood" may need to run an hour or more in the morning to assure sterility and room balance if it is turned off.

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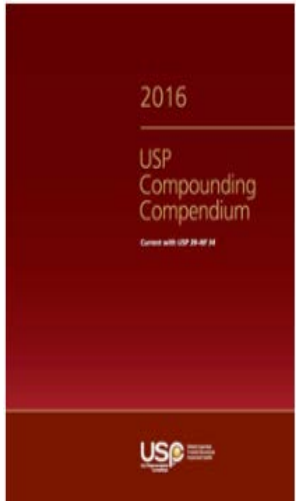
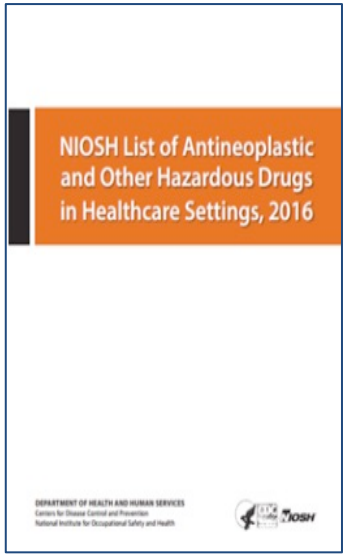
Resources





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Thank you

This concludes The American Institute ofArchitects Continuing Education Systems Course

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