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USP Standards & Practice Considerations

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Presenter Bio

Derek Burns PharmD, BCPS, BCSCP
Clinical Oncology Specialist

Current Role
Clinical Oncology Specialist serving as a subject matter expert for the McKesson Advisory Services team. Within his current role, he provides clinical and operational insight and supports strategic initiatives for oncology and multispecialty practices within the Western region.

Previous Experience
Prior to joining McKesson, served as the Director of Pharmacy & Admixture Services for Rocky Mountain Cancer Centers - a multi-site outpatient oncology practice in Colorado and part of the US Oncology Network. He has also worked as a Clinical Pharmacist and IV Room Supervisor for two hospital institutions.

Education & Training
With nearly two decades of experience, Derek expanded his familiarity of USP Standards by completing onsite education directly from USP, received Compounded Sterile Preparations certification from ASHP, and holds Board certification in Sterile Compounding and Pharmacotherapy.

No conflicts of interest to disclose

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Current State: *Managing Complication?*

USP 797

USP 800

Agenda

Timeline of USP Standards

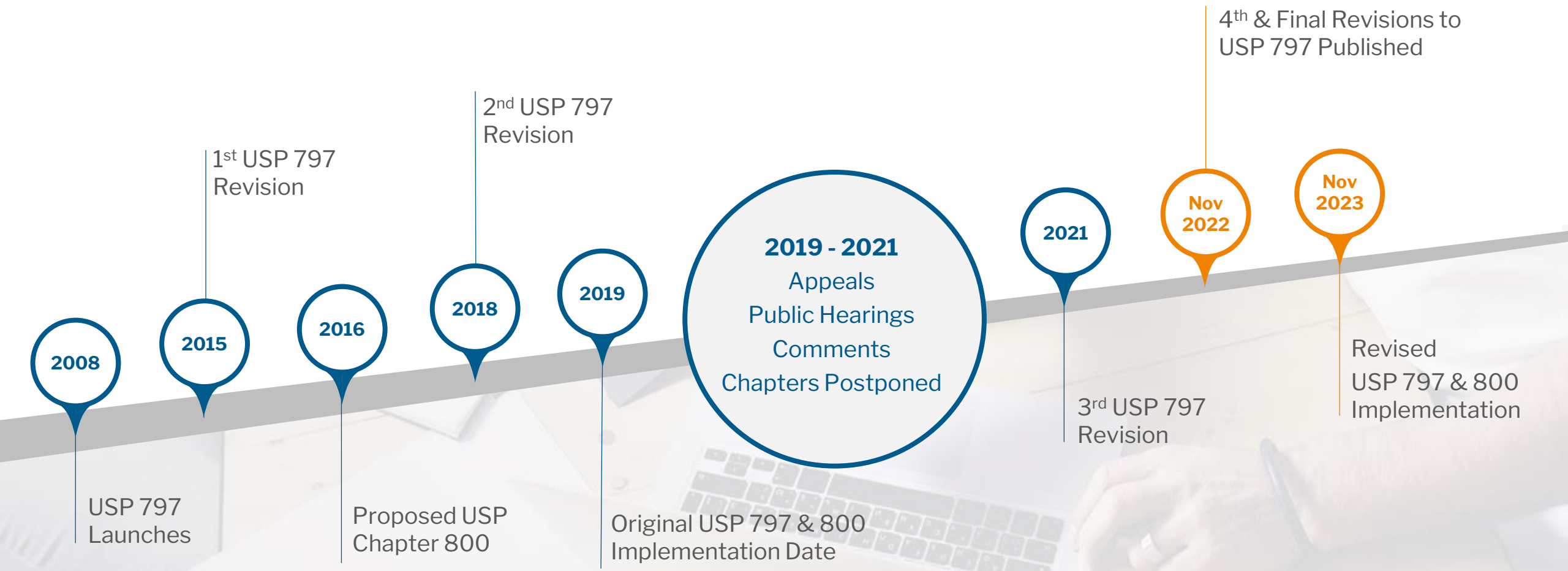
Foundational Concepts

Summary of Latest Changes

Critical Components

Developing a Roadmap

Timeline of USP Chapters



Final Revisions: USP Chapters <797> & <800>[7]

Summary of Updates, Changes & Additions

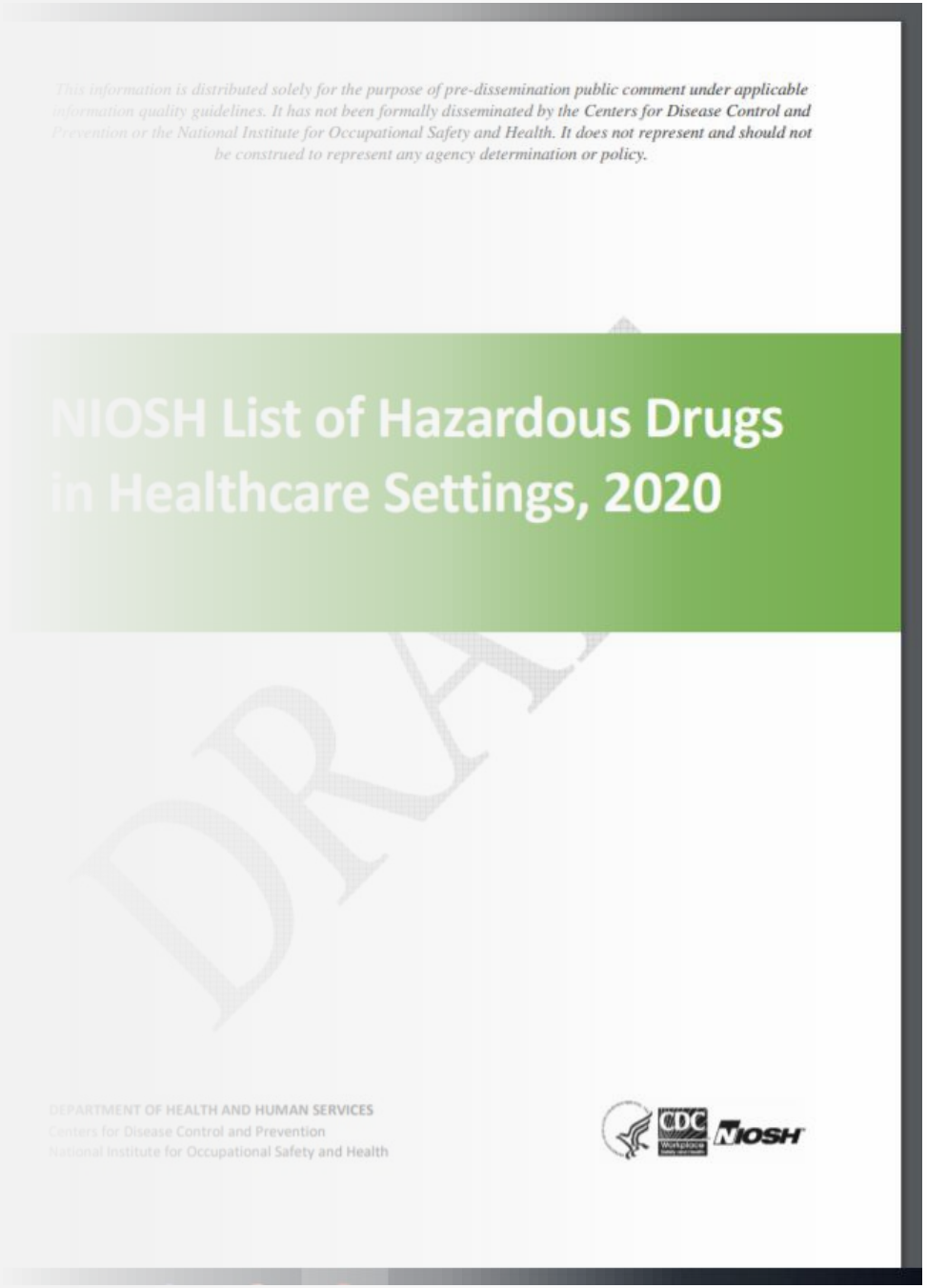
- No new revisions to Chapter <800> from the previous 2018 version
- Addition of the following statement to <797> : "***Sterile compounding is defined as combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug bulk substance to create a sterile preparation.***"
- Clarification that prepared **bladder irrigations** must be sterile
- Switch to Category 1, 2 & 3 along with Immediate-Use **Beyond-Use Dating**.
- **Training** and **competency validation** for personnel preparing immediate use CSPs
- More frequent visual observation of **hand hygiene and garbing**
- Practice SOPs to address disinfection of **re-useable PPE** and use of **"low-lint" PPE**
- Additional requirements for maintaining **master formulation** and **compounding records**
- More frequent **surface, media-fill** and **glove-fingertip sampling** during personnel competency testing
- **Viable particulate sampling** within all classified spaces
- **Designated person** with direct oversight responsible and accountable for employee training, facility operation, and preparation of CSPs

NIOSH Background [5,6]

- National Institute for Occupational Safety & Health
- Part of the CDC in the Department of Health & Human Services
- These are **standards** (like USP Chapters) not recommendations
- Neither NIOSH nor the CDC are regulators, but the standards can be enforceable
- USP Chapter <800> references the NIOSH list

> *"For the purposes of this chapter, the term antineoplastic only refers to the antineoplastic drugs included in Table 1 of the most current NIOSH List"*

- Last official published NIOSH list was in 2016
- NIOSH 2020 List of Hazardous Drugs remains **pending**



NIOSH 2020 Update: Proposed Additions/Removals [5,6]

Proposed Oncology Drugs to be Added ***Injectables***	Proposed Oncology Drugs to be Added ***Orals***	Removed or No Longer Considered for Addition
• **Besponsa** (inotuzumab ozogamicin)	• **Cotellic** (cobimetinib)	• **Aranesp** (darbepoetin)
• **Blincyto** (blinatumomab)	• **Lenvima** (lenvatinib)	• **Avastin** (bevacizumab)
• **Enhertu** (trastuzumab deruxtecan)	• **Lynparza** (olaparib)	• **BCG Vaccine**
• **Padcev** (enfortumab vedotin)	• **Odomzo** (sonidegib)	• **Botulinum Toxin**
• **Polivy** (polatuzumab vedotin)	• **Zykadia** (ceritinib)	• **Herceptin** (trastuzumab)
• **Tivdak** (tisotumab vedotin)		• **Interferon**
• **Trodelvy** (sacituzumab)		• **Perjeta** (pertuzumab)
• **Yondelis** (trabectedin)		• **Tagrisso** (Osimertinib)
• **Zynlonta** (loncastuximab tesirine)		

A total of 21 new drugs are proposed to be added, of which 14 are classified as antineoplastic or oncology related.

Difference Between Chapters[1,2]

USP 797

Standards for Sterile Compounding within Healthcare Settings

Prevention of Microbial Contamination

Focused on Patient Safety

VS.

USP 800

Standards for the Handling of Hazardous Drugs within Healthcare Settings

Prevention of Hazardous Contamination

Focused on Healthcare Worker, Patient, and Workplace Safety

Difference Between Sterility & Stability [1,8]

Sterility

Beyond Use Dating based on potential for microbial contamination

Only applies to CSPs

The date and hour after which a CSP must not be used.

Based on level of containment and determined by when the CSP was prepared

VS.

Stability

Expiration Dating based on chemical stability

Applies to all conventionally manufactured products

The time during which a product can be expected to maintain quality provided it is kept under specified storage conditions

Determined by the manufacturer

Enforcement

FDA

State BOPs

State Medical Boards

OSHA

CMS

The Joint Commission

ACHC

Regulatory
(Enforces)

Advisory
(Interprets)

USP

NIOSH / CDC

ASHP

ASCO / COA / AUA

Physical Plant vs. Personnel Considerations

Capital Expenditures / Renovations

- Primary Engineering Controls (Hoods)
- Secondary Engineering Controls (Cleanrooms)
- ISO Classification (Air Quality)
- Air Changes Per Hour (Air Quality)
- HVAC; HEPA Filters; Air Returns (Ventilation)
- Pressure Gradients (Containment)
- Interlocking Pass-Throughs (Containment)

VS.

Time Commitment / Culture Change

- Policies, Procedures & Workflows (Consistency)
- Education & Training (Expectations)
- Employee Competencies (Documentation)
- Personal Protective Equipment (Protection)
- Quality Assurance & Quality Control (Safety)
- Routine Certification (Validation)
- Cleaning & Decontamination (Containment)

Maintaining a State of Control [1,2,8]

Goal – Reduction in both microbial and hazardous contamination

Ventilation	Hardware	People	Processes
• Dedicated Air Supply • HEPA Filtration • Pressure Gradients • Air Changes Per Hour • Low Air Returns • ISO Classification	• Room Configuration • Hoods • CSTDs • Pass-Throughs	• Hand Hygiene • PPE • Traffic & Workflows	• Cleaning, Decontamination & Disinfection • SOPs • Training & Competencies • Hood & Room Certification

Primary Engineering Controls[1,2,9,10]

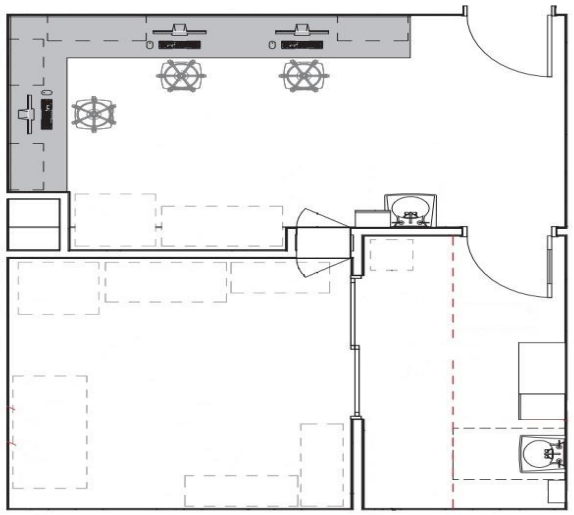
- **Hazardous Admixture Preparation**
- Class II Type A2 Biological Safety Cabinet
- Vertical flow
- Various Sizes: 3ft; 4ft; 5ft; 6ft
- Direct connect to external exhaust w/ alarm
- Internal HEPA Filter
- Negative Pressure / ISO 5 environment

- **Non-Hazardous Admixture Preparation**
- Laminar Airflow Cabinet
- Horizontal flow
- Various Sizes: 3ft; 4ft; 5ft; 6ft
- Internal HEPA Filter
- Positive Pressure / ISO 5 environment

Important Considerations

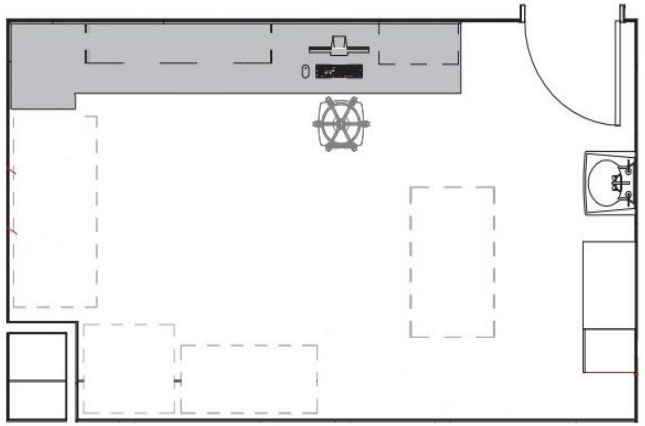
Workflows
Staffing
Current Volume
Potential Growth
Lead Times
Cost
Space
Position for Cleaning

Secondary Engineering Controls [1,2]



- **Full Cleanroom Suite**
- Admin Work Area (non-classified)
- Ante Room (ISO 7, Positive Pressure)
- IV Room (ISO 7, Negative Pressure)
- 30 air changes per hour
- Category 2 BUD's

- **Containment - Segregated Compounding Area**
- Single room design (non-classified)
- Negative Pressure
- 12 air changes per hour
- Category 1 BUDs



Important Considerations

Workflows
Staffing
Current Volume
Potential Growth
Building Lease
Budget
Space

Additional Cleanroom Features[1,8]

Goal – Cleanable surfaces with minimal particulate generation

Flooring

- Welded sheet vinyl
- Seamless epoxy
- Incorporated LOD and separate colors for clean/dirty areas

Walls

- Gypsum board with epoxy paint
- Laminate/polycarbonate wall sheet coverings

Celling

- Smooth/flush ceiling
- Sealed non-porous tiles
- Ceiling mounted HEPA filters and testing port
- Dimmable lighting

Sink Station

- Proximity to hood(s)
- Handsfree operation
- Eye wash station

Additional Cleanroom Fixtures [1,8,12,13,14]

Goal – Convenience, Containment, & Reporting

Refrigerators

Single vs. Double

Inventory separation

Dispensing Cabinets

Single vs. Double

Inventory separation

Wire rack or shelving

Supply Storage

Moveable

Cleanable

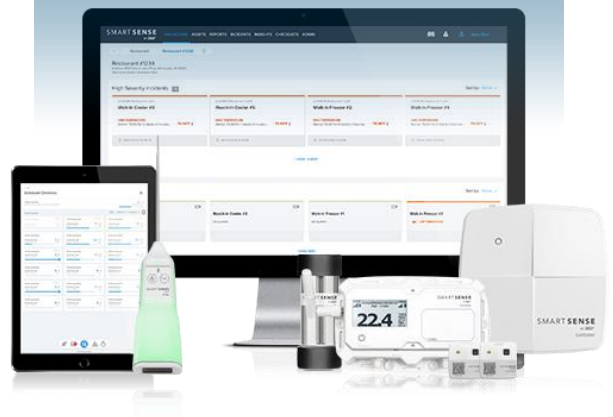
Stainless Steel vs. Plastic

Temp. Monitoring

Refrigerated storage

Ambient storage

Continuous reporting



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Viable Air Sampling [1,8]

Requirements

Purpose: Checking for unacceptable levels and confirming effectiveness of cleaning and that personnel practices are being followed

- Microbiological air sampling must include viable volumetric airborne particulate sampling
- Each sample is 1 cubic meter of air and tests for microbial particulates through incubation
- Must test classified areas Q6 months
- Selection of areas tested matter to ensure accurate representation of compounding conditions

Viable Air Sampling is commonly completed by outside certifiers, but corrective action plans are the responsibility of the practice.

Corrective Action Plan (*Options*)

ISO 5	> 1 CFU / 1 CM
ISO 7	> 10 CFU / 1 CM
ISO 8	> 100 CFU / 1 CM

When CFU counts exceed allowable levels:

- Cause must be investigated
- Retraining
- Cleaning and disinfection
- Suspension of operations
- Lower BUDs temporarily
- HEPA filter replacement
- Recertification to confirm corrective action effective
- Attempt to identify microorganism w/ microbiologist

Surface Sampling & HD Wipe Sampling[1,2,8]

Surface Sampling
(Required for Category 1 & 2)

Vs.

HD Residue Wipe Sampling
(Suggested)

Purpose:
Identifies microbial burden on surfaces. Evaluates work surface cleaning, disinfection procedures, material handling procedures and personnel competencies

Sample Areas:
- Each classified area
- Pass through chamber
- Equipment within the PEC
- Staging and work areas

ISO 5	> 3 CFU
ISO 7	> 5 CFU
ISO 8	> 50 CFU

Frequency: Monthly

Purpose:
Identifies hazardous residue containment. Verifies decontamination procedures, material handling, and personnel competencies

Sample Areas:
- Interior of C-PEC
- Pass through chamber
- Work area surfaces
- Patient administration areas
- Infusion pumps

Frequency: Every 6 months

Environment Validation [1,2,8]

Airflow Testing	ISO Classification	HEPA Filters	Surfaces	Temp/Humidity
ACPH *Pressures* *Smoke Testing*	*Particulate Counts*	Integrity Leak Testing	High Touch Areas	Gauges & Recording Devices
Q6 months	Q6 months	Q6 months	Monthly	Q12 months

Common Cleanroom & C-SCA Failures [8]

1. **Meeting ISO Classification**
   Solutions: Low air returns; Leak test HEPAs
2. **Achieving Adequate ACPH**
   Solutions: Dedicated Airflow; No VAV
3. **Maintaining Proper Pressure**
   Solutions: Adjustable air handler; Door sweeps
4. **Accommodation of Future Growth**
   Solutions: 2nd Hood; Wi-Fi; Power; Data; Tech
5. **Viable Particulate Growth**
   Solutions: Cleaning; PPE; Training; Traffic

Designated Person(s) [2]

What USP Chapter <797> says:

Designated person(s): One or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of CSPs. Training and observation may be performed by the designated person of an assigned trainer.

Responsibilities – Oversight of drug preparation (USP 797); hazardous drug handling (USP 800); implementation of training program; employee competencies; creation of SOPs; staff education; Quality Assurance & Quality Control; maintenance/monitoring/certification of cleanroom(s); cleaning; corrective action plans; can oversee all employee training or assign duties to a designated trainer

Action Items

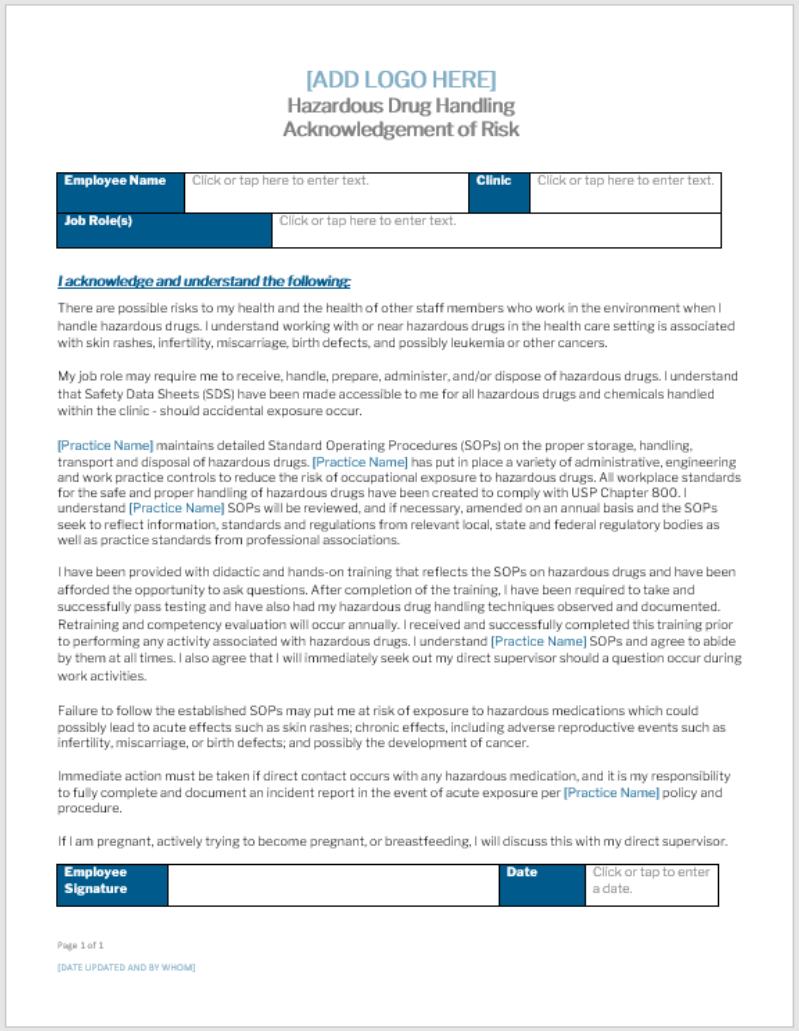
- Select a designated person(s) – *(Pharmacist, Practice Admin., Clinical Nurse Mgr., Admixture Technician)*
- Create a policy and job description
- Demonstrate knowledge and understanding through qualified program – *(USP, Critical Point LLC, ASHP)*
- Consider creating a Task Force comprised of key stakeholders *(nursing, pharmacy, physician, etc.)*
- Provide sufficient time for development and oversight of program
- Meet regularly and conduct compliance audits

Training & Competency Assessments [1,2,8,10]

Essential components of a compliant employee training program

- Create and implement a training program for personnel
- The training program must be written and specify who will receive training, what will be included in the training program, how often training will occur, and outline the process for evaluation
- Training and competency must occur initially and then annually
- Training program must demonstrate both knowledge and competency
- Designated supervisor (or assigned trainer) must observe and document skills to successfully complete employee competencies
- All hands-on training and competencies should mimic typical work environment
- Must cover all elements of preparing CSPs and the handling of hazardous drugs, and include all personnel involved in the above tasks

Acknowledgement of Risk [2,19]



[ADD LOGO HERE]
Hazardous Drug Handling
Acknowledgement of Risk

Employee Name	Click or tap here to enter text.	Clinic	Click or tap here to enter text.
Job Role(s)	Click or tap here to enter text.		

I acknowledge and understand the following:

There are possible risks to my health and the health of other staff members who work in the environment when I handle hazardous drugs. I understand working with or near hazardous drugs in the health care setting is associated with skin rashes, infertility, miscarriage, birth defects, and possibly leukemia or other cancers.

My job role may require me to receive, handle, prepare, administer, and/or dispose of hazardous drugs. I understand that Safety Data Sheets (SDS) have been made accessible to me for all hazardous drugs and chemicals handled within the clinic - should accidental exposure occur.

[Practice Name] maintains detailed Standard Operating Procedures (SOPs) on the proper storage, handling, transport and disposal of hazardous drugs. [Practice Name] has put in place a variety of administrative, engineering and work practice controls to reduce the risk of occupational exposure to hazardous drugs. All workplace standards for the safe and proper handling of hazardous drugs have been created to comply with USP Chapter 800. I understand [Practice Name] SOPs will be reviewed, and if necessary, amended on an annual basis and the SOPs seek to reflect information, standards and regulations from relevant local, state and federal regulatory bodies as well as practice standards from professional associations.

I have been provided with didactic and hands-on training that reflects the SOPs on hazardous drugs and have been afforded the opportunity to ask questions. After completion of the training, I have been required to take and successfully pass testing and have also had my hazardous drug handling techniques observed and documented. Retraining and competency evaluation will occur annually. I received and successfully completed this training prior to performing any activity associated with hazardous drugs. I understand [Practice Name] SOPs and agree to abide by them at all times. I also agree that I will immediately seek out my direct supervisor should a question occur during work activities.

Failure to follow the established SOPs may put me at risk of exposure to hazardous medications which could possibly lead to acute effects such as skin rashes; chronic effects, including adverse reproductive events such as infertility, miscarriage, or birth defects; and possibly the development of cancer.

Immediate action must be taken if direct contact occurs with any hazardous medication, and it is my responsibility to fully complete and document an incident report in the event of acute exposure per [Practice Name] policy and procedure.

If I am pregnant, actively trying to become pregnant, or breastfeeding, I will discuss this with my direct supervisor.

Employee Signature		Date	Click or tap to enter a date.

Page 1 of 1

[DATE UPDATED AND BY WHOM]

What USP Chapter <800> says:

Hazard Communication Program: Personnel who may be exposed to hazardous drugs when working must be provided information and training before the initial assignment to work with a hazardous drug, and whenever hazards change.

Personnel of reproductive capability must confirm in writing they understand the risks of handling HDs

Goal – Transparency, Safety, Compliance

Recommendations

- Acknowledgement customized for your practice
- Set expectations and responsibilities of all parties
- Have legal counsel review
- Have all employees sign that handle or may come in contact with HDs
- Provide robust training and education

Assessment of Risk [2,5,6,8]

Hazardous drugs on the NIOSH list that do not have to follow all containment requirements:

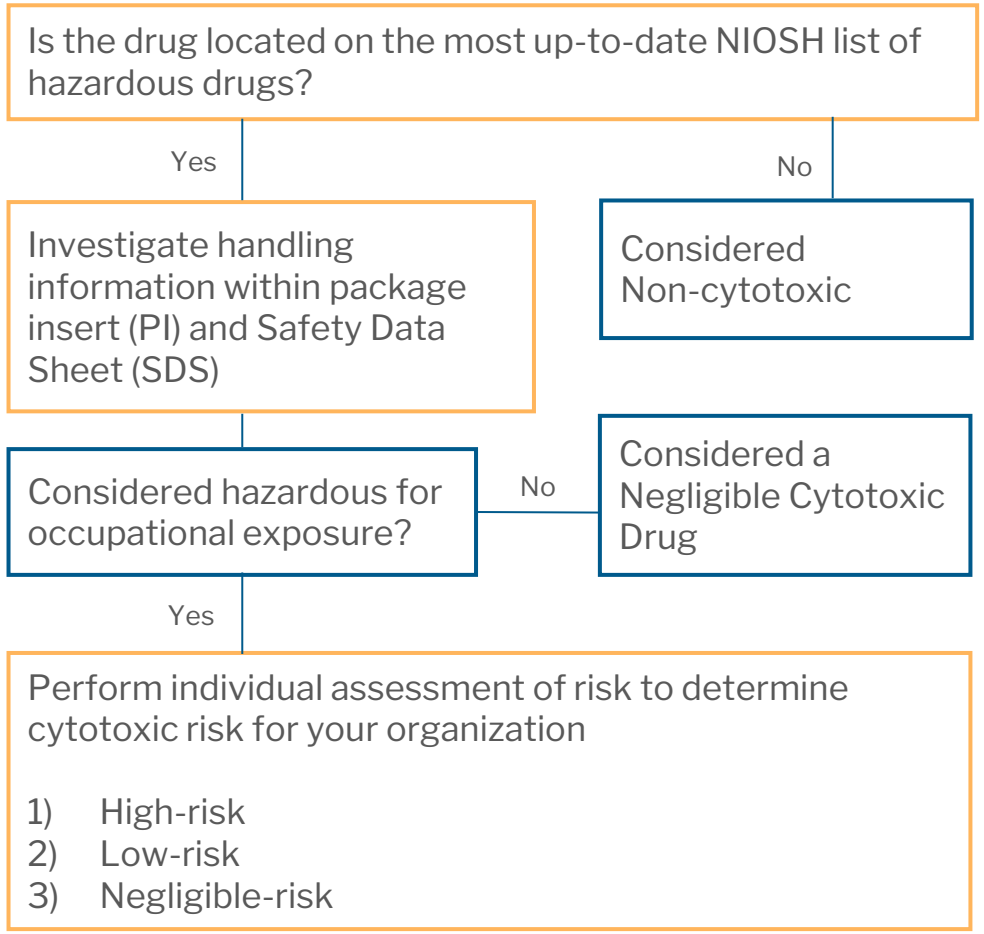
- Table 1 injectable drugs manufactured in a final dosage form where no manipulation is necessary
- Table 1 drugs in solid dosage form
- Table 2 drugs

Practice may perform and implement an Assessment of Risk for all of the above which must include at a minimum:

- Type of HD
- Dosage form
- Risk of Exposure
- Packaging
- Manipulation

1	Create a hazardous drug list for your practice. Review inventory of drugs and compare to the most recent NIOSH Hazardous Drug List.
2	Complete an Assessment of Risk for all eligible hazardous drugs handled by the practice. Document alternative containment strategies and work practices.
3	Educate all stakeholders and set expectations for the handling of these hazardous drugs within your practice.
4	Review and update Assessments of Risk annually and whenever a new hazardous drug is added to practice inventory

Performing an Assessment of Risk – *Cytotoxic Drugs* [2,5,6,8]



High-Risk Cytotoxic Drug: A drug that is determined to pose a high risk to the safety of health care workers if exposure occurs.

- Located on Table 1 of NIOSH list
- Injectable antineoplastic drugs
- Injectable cytotoxic drugs with pharmacology consistent with drugs that may be carcinogenic

Low-Risk Cytotoxic Drug: A drug that is determined to pose a lower risk to the safety of health care workers if exposure occurs.

- Solid dosage forms of all cytotoxic drugs in unaltered state
- Injectable dosage forms not requiring manipulation (prefilled syringes)

Negligible-Risk Cytotoxic Drug: A drug that is determined to pose the lowest risk to the safety of health care workers if exposure occurs.

- Determination based on type of cytotoxic drug, dosage form, risk of exposure, packaging, or manipulation required prior to administration

Personal Protective Equipment [1,2,8,10,16,17,18]

Activities
Drug Receiving
CSP Preparation
Cleaning Duties
Drug Administration
HD Spill Cleanup & Waste Disposal
Conducting Inventory

Supplies
Gloves (ASTM-6978)
Protective Gowns
Shoe Covers
Hair Covers
Masks (Pleated and N95)
Respirators and Goggles

Reminder

PPE is the **last line of defense**

for employee protection against HD exposure, and patient protection against microbial contamination

Personnel Validation (Media Fill & GFTS) [1,8]

Purpose:
Measures aseptic skills of compounding personnel to validate ability to prepare CSPs without contamination

Frequency:
Q6M - Those who prepare Category 1 or 2 CSPs
Q12M - Designated person(s)

Important Considerations:

- Media-fill test should simulate the most difficult and challenging aseptic compounding procedures encountered by the person
- Results of the evaluation and corrective actions must be documented to provide a record and long-term assessment of personnel competency.
- Microbial identification is not required for media-fill or GFTS testing.

Media Fill
Actionable Levels
Any visible turbidity

Gloved Fingertip	
Actionable Levels	
After Garbing	> 0 Total CFUs
After Media Fill Testing	> 3 Total CFUs

Receiving HD Shipments [2,8,10]

SOP

SOP must include inspection of shipments looking for possible damage or leaks

Damaged packages must be opened in C-PEC, followed by full cleaning process

PPE

Gloves (ASTM-6978)

If leak or damage is expected…

Gown (impermeable)
N95 or Respirator

Spill kit must be in area

Transport

HDs must be delivered to dedicated storage area immediately after unpacking shipments

Drug Inventory Storage [1,2,12,13]

What USP Chapters <797> & <800> say:

Separation of HDs and Non-HDs

"Antineoplastic HDs requiring manipulation must be stored separately from non-HDs to prevent contamination or exposure."

"Antineoplastic HDs must be stored in an externally vented, negative pressure room with at least 12 air changed per hour."

"Refrigerated antineoplastic HDs must be stored in a dedicated refrigerator."

"HDs must be stored in a manner that prevents spillage or breakage if the container falls."

Temperature Monitoring

"…must monitor temperature where components are stored either manually once daily when open or by continuous recording device."

Access & Security

"Access to areas where HDs are handled must be restricted to authorized personnel…"

Labeling of MDV's

"…MDVs must not be used for more than 28 days."

Aseptic Technique – **Best Practices** [2,8,20]

Aseptic Technique is a set of specific practices and procedures performed by health-care personnel under carefully controlled conditions with the goal of minimizing the introduction of microbial contamination. Consistently practicing **Aseptic Technique** is critical to patient safety for the prevention of infection resulting from drug preparations for administration.

100%
of all involved personnel must be properly trained

Essential Components

- Hand hygiene practices and use of protective gloves
- Designated preparation area away from patient care areas and free from clutter
- Thorough cleaning and disinfection of preparation area
- Wiping all vial septums with isopropyl alcohol prior to needle puncture
- Avoiding touch contamination of all critical sites
- Using only single-use, sterile syringes and needles
- Practicing needle technique that prevents vial coring
- Inspection of final preparation for any particulates or leaks
- Ensuring disposal of all single-use items used for preparation to prevent reuse

Beyond-Use Dating[1]

Considers Environmental Control & Probability of Microbial Contamination

Designated Area

BUD ≤ 4 hrs

C-SCA

BUD ≤ 12 hr RT
BUD ≤ 24 hr Fridge

Full Cleanroom Suite
allows for CSP batching

BUD ≤ 4 d RT
BUD ≤ 10 d Fridge
BUD ≤ 45 d Freezer

Full Cleanroom Suite
w/ Sterility Testing Requirements

BUD ≤ 60 d RT
BUD ≤ 90 d Fridge
BUD ≤ 120 d Freezer

Considerations: C-PECs, SEC configuration, ISO classification, pressures, ACPH, personnel requirements

Immediate Use Criteria [1]

Designated Area

BUD ≤ 4 hrs

1. Aseptic technique, processes, and procedures are followed, and written SOPs are in place to minimize particulates and microbial contamination
2. Personnel are trained and demonstrate competency in aseptic processes
3. Preparations follow approved labeling, stability, and compatibilities in accordance with evidence-based information
4. The preparation does not involve more than 3 different sterile products
5. Unused portions of SDVs must be discarded and cannot be used for more than one patient
6. Administration of the CSP must begin within 4 hours following the start of preparation
7. Unless administered by the person who prepared, the CSP must be labeled with names and amounts of all ingredients, the name of the preparer, and the 4-hour BUD

Record Keeping of CSPs [1,8]

Compounding Records

Compounding Record (CR): Documents the compounding of all CSPs, Including Category 1, 2, and 3, along with immediate-use CSPs prepared for more than one patient.

Components - Name, strength and dosage form of the CSP; date and time of preparation; assigned internal order number; identity of the persons that prepared and verified the CSP; name of each component; strength/volume of each ingredient; assigned BUD and any storage requirements; and results of quality control (i.e., visual inspection).

Goal – Maintaining records for all CSPs prepared

Master Formulation Records

Master Formulation Record (MFR): A detailed record of procedures that describes how a CSP is to be prepared.

Components - Name, strength and dosage form of the CSP; identities and amounts of all ingredients; type and size of container closure system; complete instructions for preparation (including equipment, supplies, compounding steps in order and special precautions); BUD and storage requirements; references to support stability; filter or light protection requirements; and labeling instructions

Provides documentation of batched CSPs

Goal – Creating consistency/repeatability and reduction in compounding errors

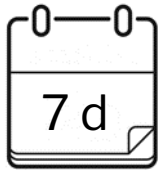
Determine Your Cleaning Schedule [1,2,8]

Each Shift

Hoods
Counters
Workspaces

Daily

plus
Floors



Weekly

plus
Under BSC Deck

Monthly

plus
Walls
Ceilings

Reminders

- Have a policy
- Create a schedule and audit
- No spray bottles near hood
- Use lint free wipes
- Have a full-face respirator
- Locking castors on shelving
- Closeness of hoods to walls

Who will clean?
Employee or outside company

What will be cleaned?
Hoods, counters, floors, walls, ceilings, pass-throughs, hardware, inventory, supplies

How often will it be cleaned?
Each shift, daily, weekly, or monthly

What will it be cleaned with?
Detergent, disinfectant, sporicidal

Handling Hazardous Drug Spills

[2,8,10,16,17,18,19,20]

Consistent **procedures** for safety, consistency; timely and optimal containment

Robust **education, training** and **competencies** conducted routinely

Spill kits available and located in all areas where HDs are stored and administered

Conduct **spill drills** randomly with employees to ensure readiness for response

HD Waste Handling [2,8,10116,17,18,20]

Plastic HD Waste Bags:
Trace hazardous waste with minimal hazardous contamination

- PPE used during HD receiving
- PPE used during HD preparation (exception of outer gloves)
- PPE used during HD administration
- PPE used during HD inventory tasks
- PPE used during transport of HD waste containers

Hard-Sided HD Waste Bins:
Anything that can break, poke or contains large volumes of hazardous waste

- All waste generated during HD preparation (vials, needles, syringes, CSTDs)
- Outer gloves used during HD preparation
- All waste generated from HD administration (bags, tubing, needles, syringes)
- Contents from used spill kits during spill cleanup
- Waste generated from cleaning inside C-PEC and IV-Room (wipes, mop heads)

Investigate disposal requirements per local, state and federal regulations
Waste Handlers may have additional requirements to follow
Have a dedicated storage area for holding HD waste

MID Pharmacies & USP 800 [12, 4, 5, 6, 7, 8, 10, 18]

Focus:
Risk of Exposure

Create SOPs / Develop Workflows
- PPE (receiving, counting, dispensing)
- HD Waste (packaging, PPE)
- Designated Equipment (counting trays, spatulas)
- Cleaning & Decontamination

Perform Training & Complete Competencies
- Performed annually
- Consider any accreditation requirements

Complete Assessment of Risk
- HD drug list (for all HDs in table 1 and 2)
- Solid Dosage Forms vs. Injectables
- Handling: Manipulation? Final dosage form? Ready to administer?
- Avoid altering solid dosage forms (splitting/crushing/opening capsules)
- Reviewed annually

Drug Inventory Storage
- Store and dispense in manufacturer bottles whenever possible
- Shelf labeling of HD medications

Conducting a GAP Analysis[1,2,8]

Once selected, the Designated Person(s) should conduct a Gap Analysis to ensure the highest level of success, safety, and overall efficiency for the initiative. Begin asking key questions to prioritize action items for the team.

Physical Plant

- ❑ C-PEC ventilated to outside w/ thimble alarm installed
- ❑ Negative pressure for C-SCA or HD Buffer Room
- ❑ Maintain ISO requirements for classified spaces
- ❑ Meet minimum ACPH
- ❑ Dedicated air supply to classified spaces
- ❑ Q6M – ACHP, Pressure, Particulate Sampling
- ❑ Q6M – Leak Test HEPA filters
- ❑ Q12M -Temperature & Humidity monitor calibration
- ❑ Ensure floors, walls, ceiling are of cleanable material
- ❑ Sink and Eyewash Station are available
- ❑ Commercial grade refrigerators used for drug storage
- ❑ Viable Sampling of classified spaced & Action Plan
- ❑ Storage of HDs in negative pressure

Personnel & Processes

- ❑ Select Designated Person
- ❑ Staff education and training
- ❑ Acknowledgment of Risk
- ❑ Create necessary SOPs
- ❑ Aseptic Technique followed
- ❑ Assessment of Risk performed
- ❑ Conduct competencies
- ❑ Personal Protective Equipment
- ❑ Fit testing (N95 and respirators)
- ❑ Gloves are ASTM-6978
- ❑ Gowns are impermeable
- ❑ HDs prepared in C-PEC
- ❑ Separation of HDs and Non-HDs
- ❑ BUDs followed
- ❑ Quality Control & Assurance routinely audited
- ❑ Schedule cleaning, decontamination & disinfection
- ❑ HD spill cleanup process
- ❑ HD waste disposal process
- ❑ Incorporate a Sporicidal
- ❑ Conduct Media Fill & GFTS
- ❑ Q1M -Surface Sampling
- ❑ Limited Access & Security
- ❑ Compounding records maintained

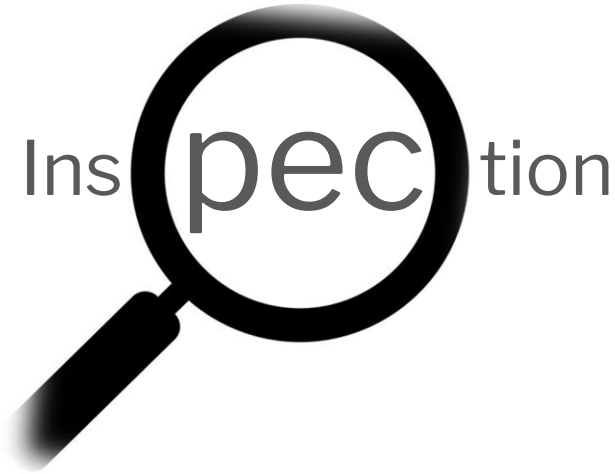
Define Your Roadmap?

1 Where we WERE

2 Where we ARE

3 Where we are GOING

- ✓ Can't just know it, you must understand it
- ✓ Believe it
- ✓ Be able to speak to it
- ✓ Current state and Future State
- ✓ Be passionate
- ✓ Tie to your efforts to your value proposition
- ✓ Tell your story



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Critical Next Steps and Takeaways

Select a Designated Person(s)
Should be someone that works in the environment and has influence
Invest in getting training and education for those overseeing

Conduct a GAP Analysis
Should be a separate analysis for each location
Each item is either compliant or not compliant

Develop a Roadmap
Prioritize your areas of focus
Create S.M.A.R.T. goals

Discuss Long-Term Budget Expenses
Research costs and plan ahead
Each location will likely require a different approach

Develop SOPs
Prioritize areas of focus. Suggest starting with Aseptic Technique, PPE, Cleaning, Assessment of Risk

Education & Training
Ensure all stakeholders are educated and trained
Set expectations and document competencies

Thank You!

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