Sterile Compounding and Aseptic Technique: Reviewing the basics and preparing for USP <800>.

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SDSHP Annual Conference
April 7-8, 2017

Disclosure
The views and opinions expressed are those of the speaker and are not endorsed by or affiliated with USP.

Conflict of Interest
I have no financial relationships with any commercial sponsor with a vested interest in this presentation

Technician Learning Objectives
1. Review definitions related to compounding.
2. Explain proper hand-hygiene procedures and garbing order.
3. Discuss when to deactivate, decontaminate, clean and/or disinfect the PEC and C-PEC.
4. Locate the direct compounding area within the PEC and C-PEC.
Pharmacist Learning Objectives

1. Review new acronyms introduced in USP <800>.
2. Explain appropriate clean room behavior.
3. Identify requirements for environmental monitoring.
4. Determine how to establish a BUD.

United States Pharmacopeia (USP)

USP <795> Nonsterile Compounding
USP <797> Sterile Compounding
USP <800> Nonsterile and Sterile Hazardous Drugs
Related chapters <71>, <85>, <1163>, etc.

Chapters numbered under 1000 are enforceable.
Chapters numbered over 1000 are informational.

Shall or Must – Requirement
Should - Recommendation

CSP – Compounded sterile preparation
HD – Hazardous Drug (as defined by NIOSH)
BUD – Beyond-use date

Ante-Room – ISO-7 or ISO-8 classified room where hand hygiene and garbing occur.
PEC - Primary engineering control is where CSPs are compounded. 
Examples: LAFW and CAI 
LAFW – Laminar Airflow Workbench 
CAI – Compounding Aseptic Isolator 

SEC – Secondary engineering control is where PEC is located. 
Examples: Positive pressure ISO-7 buffer room or segregated compounding area (SCA).

C-PEC – Containment primary engineering control is where hazardous CSPs are compounded. 
Examples: BSC and CACI. 
BSC – Biological Safety Cabinet 
CACI - Compounding Aseptic Containment Isolator 

C-SEC - Containment secondary engineering control is where C-PEC is located. 
Examples: Negative pressure ISO-7 buffer room or containment segregated compounding area (C-SCA).

Technician Learning Assessment 
An LAFW is an example of a C-PEC. 
True or False
False
An LAFW is an example of a PEC.

**Pharmacist Learning Assessment**
Compounding is performed in a C-SEC located within a C-PEC.
True or False

False
Compounding is performed in a C-PEC located within a C-SEC.
Hand-Hygiene and Garbing

Why is it important?

Individuals shall not work in sterile compounding areas with:
- Rashes
- Sunburn
- Weeping sores
- Conjunctivitis
- Active respiratory infection

Before entering ante-room or segregated compounding area remove:
- Outer garments
- Cosmetics
- Hand, wrist, visible jewelry and piercings (e.g., earrings, lip or eyebrow piercings)
- Nail polish
- Artificial nails

Natural nails shall be kept neat and trimmed.
Don garb dirtiest to cleanest

- Dedicated shoes or shoe covers on clean side of line of demarcation. Dirty shoes should never touch clean side.
- Head and facial hair covers (e.g., beard covers)
- Face masks
- Eye shields.

Eye shields are optional unless working with irritants such as germicidal disinfecting agents or when preparing hazardous drugs.

Perform hand hygiene

Hand washing procedure shall be performed by removing debris from underneath fingernails using a nail cleaner under running warm water followed by vigorous hand washing. Hands and forearms shall be washed to the elbows for at least 30 seconds with soap (either nonantimicrobial or antimicrobial) and water while in the ante-room. The use of antimicrobial scrub brushes is not recommended because they can cause skin irritation and skin damage. Hands and forearms to the elbows will be completely dried using either lint-free disposable towels or an electronic hand dryer.

After completion of hand washing, a nonshedding gown with sleeves that fit snugly around the wrists and enclosed at the neck is donned. Gowns designated for buffer room use shall be worn, and preferably they should be disposable. If reusable gowns are worn, they should be laundered appropriately for buffer room use. Once inside the buffer room or segregated compounding area, and prior to donning sterile powder-free gloves, antiseptic hand cleansing shall be performed using a waterless alcohol-based surgical hand scrub with persistent activity. Hands are allowed to dry thoroughly before donning sterile gloves. Sterile gloves shall be the last item donned before compounding begins.
Disinfection of contaminated gloved hands may be accomplished by wiping or rubbing sterile 70% IPA to all contact surface areas of the gloves and letting the gloved hands dry thoroughly.

Routine application of sterile 70% IPA to sterile gloves shall occur throughout the compounding process and whenever nonsterile surfaces (e.g. vials, counter tops, chairs, carts) are touched.

Properly garbed and gloved compounding personnel who are exposed to air quality that is either known or suspected to be worse than ISO Class 7 shall re-garb PPE along with washing their hands properly, performing antiseptic hand cleansing with a waterless alcohol-based surgical hand scrub, and donning sterile gloves upon reentering the ISO Class 7 buffer room.

When compounding personnel exit the ante-room or segregated compounding area during a work shift, the exterior gown may be removed and retained in the ante-room or segregated compounding area if not visibly soiled, to be re-donned during that same work shift only.

However, shoe covers, hair and facial hair covers, face masks/eye shields, and gloves shall be replaced with new ones before re-entering the ante-room or segregated compounding area, and proper hand hygiene shall be performed.
Doff garb on the clean side of line of demarcation in ante-room or segregated compounding area.
- Remove gloves and perform hand hygiene.
- Remove gown and discard it, or hang it on hook if it is to be reused within the same work shift.
- Remove and discard mask, head cover, and beard cover.
- Remove shoe covers or shoes one at a time, ensuring that uncovered foot is placed on the dirty side of the line of demarcation and perform hand hygiene again. (Remove and discard shoe covers every time the ante-room or segregated compounding area is exited).

Additional PPE for Hazardous Compounding
(per <800>)
Don and doff within negative pressure buffer room or containment-segregated compounding area. HD PPE must not be worn outside of negative pressure room.
- Second set of shoe covers.
- Chemo gown (may not be re-used)
  Change per manufacturer or every 2-3 hours or after splash/spill
- Two pairs of chemotherapy gloves.
  Change per manufacturer or every 30 minutes or after tear. Remove and discard outer glove while in BSC or CACI.

Technician Learning Assessment
Nails must be cleaned under running water before washing hands.
True or False
True

Nails must be cleaned under running water before washing hands.

Pharmacist Learning Assessment

Pharmacists _____ need to garb to enter a segregated compounding area.

a. do  b. do not

a. do

Pharmacists do need to garb to enter a segregated compounding area.
Types of Primary Engineering Controls

- **LAFW** – Laminar Airflow Workbench (PEC)
  Protects the product or preparation. No personnel protection. May be either horizontal or vertical air flow.

- **BSC** – Biological Safety Cabinet (C-PEC)
  Protects personnel. Used for hazardous drugs. Vertical air flow.
  Class II Type A2, B1, or B2
  Class III
  Best to run PEC (LAFW) continuously. C-PEC (BSC) must run continuously (per <800>). LAFW/BSC must run 30 minutes before use after being off.

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Types of Primary Engineering Controls

- **RABS** – Restricted Access Barrier System

- **CAI** – Compounding Aseptic Isolator (PEC)
  Protects the product or preparation. No personnel protection.
  Vertical air flow, positive pressure.

- **CACI** – Compounding Aseptic Containment Isolator (C-PEC)
  Protects personnel. Used for hazardous drugs.
  Vertical air flow, negative pressure.
  **Isolator**
  Contains an internal system to decontaminate interior with sporicidal agent.

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Cleaning and Disinfection of PEC

At the beginning of each shift, before each batch, not longer than 30 minutes following the previous surface disinfection when ongoing compounding activities are occurring, after spills, and when surface contamination is known or suspected.

Items shall be removed from areas to be cleaned, and surfaces shall be cleaned by removing loose material and residue from spills; e.g., remove water-soluble residues with sterile water (for injection or irrigation) using low shedding wipes then wipe with a residue-free disinfecting agent such as sterile 70% IPA, which is allowed to dry before compounding begins.
Clean and disinfect PEC from cleanest to dirtiest using overlapping strokes and a new side of the cloth for each location. Start by carefully cleaning the grid covering the HEPA filter.

**LAFW** (horizontal air flow)
Clean top then sides then work surface.

**BSC and LAFW** (vertical air flow)
Clean back then then work surface.

**CAI and CACI** with the front panel closed:
Follow manufacturer’s instructions or if not stated start with the work chamber then move to the ante chamber. Start by carefully cleaning the grid covering the HEPA filter being careful not to let any liquid enter. Clean back wall, sides, front wall and work surface.

Clean the gauntlet sleeves. Apply sterile gloves over gauntlet gloves. Sanitize gloves frequently with sterile 70% isopropyl alcohol.

**CAI** with the front panel open:
Follow manufacturer’s instructions or if not stated open front panel and start with the work chamber then move to the ante chamber. Start by carefully cleaning the grid covering the HEPA filter being careful not to let any liquid enter. Clean back wall, sides, areas under the work surface (if applicable), work surface, and front wall.

Clean the gauntlet sleeves. Apply sterile gloves over gauntlet gloves. Sanitize gloves frequently with sterile 70% isopropyl alcohol.
Use sporicidal agent on ISO-5 surfaces (including under the work surface) at least monthly. Reminder: do not open the front panel on CACI. Document cleaning and disinfecting agents (and contact time as applicable).

Follow manufacturer’s recommendations on changing gauntlet sleeves and gauntlet gloves. Don’t forget to document when this is done.

Need to know recovery time to return to ISO 5 after CAI is turned off. CACI should never be turned off. Also need to know purge time before moving items from ante chamber to work chamber.

Deactivation, decontamination, cleaning and disinfection of C-PEC (per <800>).

Deactivation renders a compound inactive. If no specific information is available on SDS then use sodium hypochlorite 5000 - 6000 ppm or other EPA registered oxidizer.

Decontamination removes inactivated substances. May use 70% IPA, water, peroxide or sodium hypochlorite 5000 – 6000 ppm.

C-PEC must be deactivated/decontaminated (and cleaned and disinfected) at least daily, any time a spill occurs, before and after certification, any time voluntary interruption occurs, and if moved. Work surface between compounding of different hazardous drugs.

Area under the work surface monthly.
Document agents used and contact time.
Ante-Room and Buffer Room and Segregated Compounding Area

Clean and disinfect work surfaces at least daily. Clean and disinfect floors daily at a time when no aseptic operations are in progress. Mopping shall be performed by trained personnel using approved agents and procedures described in the written SOPs.

Using mop labeled ‘floor’ start at area furthest from door (cleanest) moving to door (dirtiest). Buffer room first then ante-room. Floor mops may be used in both the buffer room and ante-room, but only in that order.

Clean and disinfect ceiling, walls, carts, equipment exteriors storage and anything not covered in daily cleaning monthly. Ceiling first then walls, area furthest from door (cleanest) moving to door (dirtiest). Buffer room first then ante-room. Clean and disinfect equipment exteriors, storage and any other areas not covered in daily cleaning/disinfection. Must be done all in one day when no aseptic operations are in progress. Document date, time, cleaning agent, disinfectant and contact time.

Use sporicidal agent on all surfaces at least monthly.

A full cleaning is required anytime the clean room is compromised including
- Inappropriate garbing or staging
- When HEPA fans are off (for any reason including maintenance and power outages)
- Walls/ceiling have been opened
**Additional requirements for C-SEC (per <800>)**

All areas where hazardous drugs are handled and all reusable equipment and devices must be deactivated, decontaminated, cleaned and disinfected.

It is incumbent on compounding personnel to ensure that such cleaning is performed properly. Schedules of use and methods of application shall be in accordance with written SOPs and followed by custodial or compounding personnel.

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**Environmental Monitoring**

**Daily**
- Temperature (< or equal to 77F ideally < 68F)
- Humidity (recommend < 60%)
- Pressures
  - Positive (non-HD rooms) at least 0.02
  - Negative (HD rooms) -0.01 to -0.03
- Refrigerator/Freezer temperatures
  - Refrigerators 2 to 8C (36 to 46F)
  - Freezers -25 to -10C (-13 to 14F)

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**Periodic**

Surface testing in all ISO-classified and segregated compounding areas.

Use TSA with lecithin and polysorbate 80.

Incubate 30-35C for 48 to 72 hours.

Recommended action levels
- ISO 5 > 3 cfu
- ISO 7 > 5 cfu
- ISO 8 > 100 cfu
Every 6 months
Nonviable air counts under dynamic conditions.

Viable air counts (400-1000L volumetric air sample) using TSA (and MEA for high-risk) under dynamic conditions with growth identified/reported as CFU per cubic meter.
Recommended action levels
ISO 5 > 1 cfu
ISO 7 > 10 cfu
ISO 8 > 100 cfu

Air changes of at least 30 (15 may come from the PEC).

Regardless of the number of cfu identified in the compounding facility, further corrective actions will be dictated by the identification of microorganisms recovered (at least the genus level) by an appropriate credentialed laboratory of any microbial bioburden captured as a cfu using an impaction air sampler.

Highly pathogenic microorganisms (e.g., Gram-negative rods, coagulase positive staphylococcus, molds and yeasts) can be potentially fatal to patients receiving CSPs and shall be immediately remedied, regardless of cfu count, with the assistance of a competent microbiologist, infection control professional, or industrial hygienist.

Technician Learning Assessment

_________ renders a drug inactive.

a. cleaning
b. disinfection
c. decontamination
d. deactivation
d. deactivation

Deactivation renders a drug inactive.

Pharmacist Learning Assessment

Ante-room air sample reveals 1 cfu of coag + s.aureus. Is this a problem?  
Yes  No

Yes

Highly pathogenic microorganisms (e.g., Gram-negative rods, coagulase positive staphylococcus, molds and yeasts) can be potentially fatal to patients receiving CSPs and shall be immediately remedied, regardless of cfu count, with the assistance of a competent microbiologist, infection control professional, or industrial hygienist.
**Staging**
Remove supplies from shipping cartons. No shipping or other external cartons may be taken into the buffer room or segregated compounding area (or C-SCA).

Stage equipment and supplies by wiping with sterile 70% IPA and a low lint wipe before entering each ISO area.

When sterile supplies are received in sealed pouches designed to keep them sterile until opening, the sterile supplies may be removed from the covering pouches as the supplies are introduced into the ISO Class 5 PEC without the need to disinfect the individual items.

### Clean room behavior and aseptic technique reminders
- First air shall touch critical points of vials, syringes, needles, etc.
- Do not touch critical points or allow critical points to touch nonsterile surfaces.
- Avoid shadowing. Hands/objects should never come between critical point and HEPA filter.

### Critical Points
- **Vial**
- **Stoppers**
- **Syringes**
  - Tip, Piston Plunger, Inner Shaft
- **Needles**
  - Hub, Bevel, Tip, Heel, Shaft, Lumen

Taking apart vials or syringes adds risk.
Where's the first air?

LAFW  BSC  

DCA 6 inches from front  DCA 4 inches above work surface

Clean room behavior and aseptic technique reminders

- Keep trash out of direct compounding area (DCA).
- Use slow purposeful movements.
- Disinfect gloves every time they leave the PEC.
- Work in the direct compounding area (DCA).
- Do not rest hands/arms on DCA.
- Avoid sneezing, coughing, excessive talking.
- Keep head from entering PEC.
- Compound one preparation at a time.

Disinfecting vials, injection ports, etc.

Wiping with small sterile 70% IPA swabs that are commercially available in individual foil-sealed packages is preferred for disinfecting entry points on bags and vials, allowing the IPA to dry before piercing stoppers with sterile needles and breaking necks of ampuls. The surface of the sterile 70% IPA swabs used for disinfecting entry points of sterile packages and devices shall not contact any other object before contacting the surface of the entry point. Sterile 70% IPA wetted gauze pads or other particle-generating material shall not be used to disinfect the sterile entry points of packages and devices.
**Additional requirements for handling HDs** (per <800>)

- Wipe down HD containers to reduce the amount of contamination introduced into the C-PEC.
- Supplemental engineering controls (CSTD) should be used when the dosage form allows. CSTDs must be used when administering antineoplastic HDs when the dosage form allows.
- When CSTD not available, use negative pressure technique to withdraw liquid from vials.
- Seal in impervious plastic bags with cautionary label.
- Transport in impact-resistant and/or water-tight containers. Do not use pneumatic tubes for hazardous liquids or antineoplastic drugs.

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**Single dose vials and containers opened outside an ISO 5 environment may be used up to ONE hour.** This includes Sodium Chloride, Sterile Water for Injection and Sterile Water for Irrigation.

**Single dose vials and containers opened inside an ISO 5 environment may be used up to SIX hours.**

Open ampules must be filtered and used immediately.

**Multi-dose vials (including compounded MDV) may be used up to 28 days unless specified otherwise by manufacturer.** Vials must be labeled.

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**HD Storage**

(per <800>)

Antineoplastic hazardous drugs requiring manipulation other than counting or repackaging of final dosage forms and any hazardous drug API must be stored separately from non-hazardous drugs in a manner that prevents contamination and personnel exposure.

These hazardous drugs must be stored in an externally ventilated, negative-pressure room with at least 12 air changes per hour (ACPH). Non-antineoplastic, reproductive risk only, and final dosage forms of antineoplastic hazardous drugs may be stored with other inventory if permitted by entity policy.
Definition of low-, medium- and high-risk and USP <797> storage

**Low-Risk** compounding involves not more than three commercially manufactured packages of sterile products and not more than two entries into any one sterile container or package.
- Controlled Room Temp 20-25C or 68-77F <= 48 hrs
- Cold Temp 2-8C or 36-46F <= 14 days
- Frozen -25 to -10C or -13 to 14F <= 45 days

**Medium-Risk** compounding involves more than three commercially manufactured packages of sterile products, more than two entries into any one sterile container or package, complex manipulations or unusually long duration.
- Controlled Room Temp 20-25C or 68-77F <= 30 hrs
- Cold Temp 2-8C or 36-46F <= 9 days
- Frozen -25 to -10C or -13 to 14F <= 45 days

**High-Risk** (1) compounding involves nonsterile components or devices or (2) compounding personnel are improperly garbed or gloved or (3) any of the following are exposed to air quality worse than ISO Class 5 for more than 1 hour: sterile contents of commercially manufactured products, CSPs that lack effective antimicrobial preservatives, and sterile surfaces of devices and containers for the preparation, transfer, sterilization, and packaging of CSPs.
- Controlled Room Temp 20-25C or 68-77F <= 24hrs
- Cold Temp 2-8C or 36-46F <= 3 days
- Frozen -25 to -10C or -13 to 14F <= 45 days

Note: Repackaging and biologics have their own rules.
Immediate-use is for emergency or immediate patient administration of a CSP where patient is subject to risk from delays in therapy.
- Nonhazardous low risk only.
- No batch compounding.
- No Storage. Under continuous supervision.
- Must follow aseptic technique
- Prepared & administration started within one hour.
- Must be discarded if administration has not begun within 1 hour from the start of preparation.
- If not prepared/witnessed by administrator, must be labeled with names/amounts of ingredients, initials of the preparer and the exact 1-hour BUD and time.

Low-risk with 12-hour BUD if the PEC is a CAI/CACI that does not meet the exception requirements or LAFW/BSC that is not located within an ISO Class 7 buffer room.
- Low-risk nonhazardous and radiopharmaceutical only.
- Pursuant to a physician’s order for a specific patient.
- PEC located in segregated compounding area restricted to sterile compounding activities that minimize the risk of contamination.
- Segregated compounding area shall be located away from unsealed windows or doors that connect to the outdoors, high traffic areas, construction sites, warehouses, food preparation areas.

Low-risk with 12-hour BUD
Personnel shall follow <797>
- Hand hygiene and garbing
- Cleaning and disinfection
- Aseptic technique
- Environmental monitoring
- Training and competency
CAI/CACI Exception Requirements
CAI/CACI outside of an ISO 7 buffer room needs
documentation from manufacturer and certification
company (every six months):
1) CAI shall provide isolation from the room and
maintain ISO Class 5 during dynamic operating
conditions, including transferring ingredients,
components, and devices into and out of the isolator
and during preparation of CSPs.
2) Particle counts sampled approximately 6 to 12
inches upstream of the critical exposure site shall
maintain ISO Class 5 levels during compounding
operations.

3) Not more than 3520 particles (0.5 mm and larger)
per m³ shall be counted during material transfer, with
the particle counter probe located as near to the
transfer door as possible without obstructing the
transfer.

Make sure documentation from manufacturer is for
your specific model.

CAI/CACI Exception Requirements
• Only authorized personnel and materials in the
  compounding area.
• Presterilization procedures for high-risk, such as
  weighing & mixing, shall be completed in no worse
  than an ISO Class 8 environment.
• PECs located out of traffic patterns/air currents.
• CACIs for hazardous must be in a compounding area
  that maintains a minimum negative pressure of 0.01-
  inch water column and have a minimum of 12 ACPHs.
• Appropriate personnel protective equipment (PPE)
  shall be worn.
When CAIs and CACIs are the source of the ISO Class 5 environment, the garbing and gloving requirements for compounding personnel should be as described above, unless the manufacturer can provide written documentation based on validated environmental testing that any component(s) of PPE or personnel cleansing are not required.

When is a sterility test needed?
- All risk levels require a sterility test when exceeding USP <797> storage limits.
- All high-risk level CSPs that are prepared in groups of more than 25 identical individual single-dose packages or in multiple-dose vials for administration to multiple patients or that are exposed longer than 12 hours at 2° to 8° and longer than 6 hours at warmer than 8° before they are sterilized shall meet the sterility test before they are dispensed or administered.
- [NOTE—Sterility tests for autoclaved CSPs are not required unless they are prepared in batches >25]
  Sterility Tests must be comply with USP <71>

- Extending BUD requires sterility AND stability assurance.
- Stability is not the same as potency.
- BUDs and expiration dates are not the same.
  -Expiration dates for the chemical and physical stability of manufactured products are determined from rigorous testing.
  -BUDs for compounded preparations are assigned on the basis of direct testing or extrapolation from reliable literature sources and other documentation.
Technician Learning Assessment

The direct compounding area in a BSC is __________.

a. six inches from the front
b. four inches from the front
c. six inches above the surface
d. four inches above the surface

The direct compounding area in a BSC is four inches above the surface.

Pharmacist Learning Assessment

Drug X has a stability (in a syringe) of 15 days refrigerated. One vial is used to prepare four pediatric syringes. What BUD should be assigned?

a. 15 days
b. 14 days
c. 9 days
d. 3 days
c. 9 days

Use the shorter of stability (15 days) and sterility assurance (9 days for medium-risk).

Training and Competency
Initially: GFS x 3 with zero cfus
Initially & Annually for Low-, Medium-risk
Initially & Q6mo for High-risk
• Didactic review/test and media-fill
• GFS after garbing and after completing media-fill.
  (One plate for each hand. Total of 3 or fewer cfus.)
• Visual observation
  - Hand Hygiene and Garbing (Appendix III)
  - Aseptic Technique (Appendix IV)
  - Cleaning and Disinfection (Appendix V)
• Post media fill surface test (3 or fewer cfus) to validate staging and disinfection process.

Media-fill tests represent the most challenging or stressful conditions actually encountered by the personnel being evaluated when they prepare particular risk level CSPs and when sterilizing high-risk level CSPs.

Compounding personnel who fail written tests or whose media-fill test vials result in gross microbial colonization shall be immediately re-instructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic practice deficiencies.
Training/Competency requirements for HDs (per <800>)

- All personnel who handle HDs or who perform custodial waste removal or cleaning activities must be trained based on job functions. Training must occur before independently handling HDs.
- Personnel must be trained prior to the introduction of a new HD or new equipment and prior to a new or significant change in process or SOP.
- Effectiveness of training must be demonstrated.
- Competency must be reassessed at least annually.
- All training and competency assessments must be documented according to OSHA standards and other applicable laws and regulations.

Training/Competency requirements for HDs (per <800>)

- Overview of HDs in use and their risks
- Use of Safety Data Sheets
- Storage
- Review of SOPs related to handling of HDs
- Use of equipment and devices
- Use of PPE including use of NIOSH respirators
- Prevention of HD contamination
- Labeling and transport
- Disposal of HDs and trace-contaminated materials
- Spill management and use of a spill kit
- Response to known or suspected HD exposure

Additional requirements for HDs (per <800>)

Must maintain a list of HDs, which must include any items on the current NIOSH list. List must be reviewed at least every 12 months.

Drugs on the NIOSH list that must follow the requirements of USP <800> include:
- Any HD API
- Any antineoplastic requiring HD manipulation
Additional requirements for HDs (per <800>)

- Drugs on the NIOSH list that do not have to follow all the containment requirements of USP <800> if an assessment of risk is performed and implemented include:
  - Final dosage forms of compounded HD preparations and conventionally manufactured HD products, including antineoplastic dosage forms that do not require any further manipulation other than counting or repackaging (unless required by the manufacturer).

- For dosage forms of other HDs on the NIOSH list, the entity may perform an assessment of risk to determine alternative containment strategies and work practices.

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Additional requirements for HDs (per <800>)

The assessment of risk must consider the following:

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

If an assessment of risk approach is taken, the entity must document what alternative containment strategies and work practices are being employed for specific dosage forms to minimize occupational exposure. If used, the assessment of risk must be reviewed at least every 12 months and the review documented.

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Additional requirements for HDs (per <800>)

All personnel who may be required to clean up a spill of hazardous drugs must receive proper training in spill management and the use of PPE and NIOSH-certified respirators.

Spills must be contained and cleaned immediately only by qualified personnel with appropriate PPE.

Qualified personnel must be available at all times while hazardous drugs are being handled.
**Additional requirements for HDs** (per <800>)

Signs must be available for restricting access to the spill area.

Spill kits containing all of the materials needed to clean hazardous drug spills must be readily available in all areas where hazardous drugs are routinely handled.

SDS must be retrievable in hazardous drug handling areas.

All spill materials must be disposed of as hazardous waste.

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**Additional requirements for HDs** (per <800>)

EPA provides information on environmental hazards. P- and U-listed drugs must be segregated and disposed of as hazardous waste to comply with EPA regulations. Note that these drugs are different than the drugs on the NIOSH list. EPA defines hazardous as related to the disposal of hazardous drugs so aims to protect the environment. Section 13 of the Safety Data Sheet lists disposal considerations. Keep in mind that state and local laws may be even more restrictive.

DOT defines hazardous from a shipping perspective. Section 14 of the Safety Data Sheet lists transport information. Also check vendor requirements.

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**Reference**

United States Pharmacopeia USP 39 - NF 34

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