Compliance with USP Chapter <800>

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Conflict of Interest Disclosure

- No conflict of interest to disclose.
- No one in control of the content of this activity has a relevant financial relationship with an ineligible company.

Learning Objectives

- Upon completion of this educational session, the Pharmacist learner will be able to:
  - Describe changes to the 2024 NIOSH Hazardous Drug List
  - Describe the entity's minimum health and safety requirements for handling HDs
  - Develop alternative containment strategies necessary for an Assessment of Risk

- Upon completion of this presentation, the Pharmacy Technician learner will be able to:
  - Describe changes to the 2024 NIOSH Hazardous Drug List
  - Describe safe practices associated with handling hazardous drugs in compliance with USP <800>
  - Describe support processes that ensure compliance with USP <800> requirements for employee safety

Abbreviations

- ACPH- Air Changes Per Hour
- AoR- Assessment of Risk
- AHSF- American Hospital Formulary Service
- ASTM- American Society for Testing Materials
- BSC- Biological Safety Cabinet
- CACI- Compounding Aseptic Containment Isolator
- C-PEC- Containment Primary Engineering Control
- C-SCA- Containment Segregated Compounding Area
- C-SEC- Containment Secondary Engendering Control
- CSP- Compounded Sterile Product
- EPA- Environmental Protection Agency
- HD- Hazardous Drug

Abbreviations Cont.

- ISO- International Organization for Standardization
- NIOSH- National Institute for Occupational Safety & Health
- OSHA- Occupational Safety and Health Administration
- PAPR- Powered Air-Purifying Respirator
- PPE- Personal Protective Equipment
- RCRA- Resource Conservation Recovery Act
- SDS- Safety Data Sheets
- sIPA- sterile Isopropyl Alcohol
- SOP- Standard Operating Procedure
- USP- United States Pharmacopeia
- ” w.c.- inches water column

2016 NIOSH Hazardous Drugs (HD)

- **NIOSH Group 1**: Antineoplastic drugs (AHFS Classification 10:00). Note that many of these drugs may pose a reproductive risk for susceptible populations.
- **NIOSH Group 2**: Non-antineoplastic drugs that meet one or more of the NIOSH criteria for a hazardous drug. Note that some of these drugs may also pose a reproductive risk for susceptible populations.
- **NIOSH Group 3**: Drugs that primarily pose a reproductive risk to men and women who are actively trying to conceive and women who are pregnant or breast feeding because some of these drugs may be present in breast milk.
- Drugs that are considered to be hazardous include those that exhibit one or more of the following six characteristics in humans or animals.
  - Carcinogenicity
  - Teratogenicity or other developmental toxicity
  - Reproductive toxicity
  - Organ toxicity at low doses
  - Genotoxicity
  - Structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the above criteria.

2024 NIOSH HD

1. Approved for use in humans by FDA CDER
2. Not otherwise regulated by the U.S. Nuclear Regulatory Commission, and
3. Either
    a. Is accompanied by prescribing information in the “package insert” that includes manufacturer’s special handling information (MSHI) to protect workers handling the drug, or
    b. Is identified as a carcinogenic hazard, developmental hazard, reproductive hazard, genotoxic hazard, or other health hazard by exhibiting one or mor of the following toxicity criteria in humans, animal models, or in vitro systems
        i. Carcinogenicity
        ii. Developmental toxicity (including teratogenicity)
        iii. Reproductive toxicity
        iv. Genotoxicity
        v. Organ toxicity at low doses, or a
        vi. Structure and toxicity profile that mimic existing drugs determined hazardous by exhibiting any one of the previous five toxicity types.

- However, if a drug also exhibits a molecular property that may limit the potential for adverse health effects from exposure to the drug in healthcare workers, it may be determined it is not a hazard.

2024 NIOSH Criteria for Tables 1 & 2

Table 1 includes drugs that have MSHI in the package insert and/or meet the NIOSH definition of a hazardous drug and one or mor of these criteria:

- Are classified by the National Toxicology Program (NTP) as “known to be a human carcinogen”
- Are classified by the International Agency for Research on Cancer (IARC) as Group 1“carcinogenic to humans” or Group 2A “probably carcinogenic to humans”

Table 2 includes drugs that meet one or more of the criteria in the NIOSH definition of a hazardous drug and

- Do not have MSHI
- Are not classified by the NTP as “known to be a human carcinogen”
- Are not classified by the IARC as Group 1 “carcinogenic to humans” or Group 2A“probably carcinogenic to humans”

Table 2 now also includes drugs that only meet the NIOSH criteria as a developmental (including teratogenicity) and/or reproductive hazard (RR). In the 2016 update of the *List*, this table did not include drugs that only posed a developmental and/or reproductive hazard.

Drugs Removed from the 2024 NIOSH List

Drug	Notation
Bacillus Calmette Guerin (BCG)	NIOSH removed BCG from the *List* because it is an infectious agent and not classified as a drug by FDA. For handling recommendations, see drug package insert.
ergonovine	Ergonovine was never approved for use in humans by the FDA in the United States.
liraglutide	NIOSH reviewed data from studies provided by the manufacturer and determined it is unlikely that liraglutide poses a carcinogenic, reproductive, or developmental hazard to workers in a healthcare setting and is no longer considered a hazardous drug by NIOSH.
paliperidone	NIOSH reviewed data from studies provided by the manufacturer and determined it is unlikely that paliperidone poses a carcinogenic, reproductive, or developmental hazard to workers in a healthcare setting and is no longer considered a hazardous drug by NIOSH.
pertuzumab	NIOSH reviewed data from studies provided by the manufacturer and determined it is unlikely that pertuzumab poses a carcinogenic, reproductive, or developmental hazard to workers in a healthcare setting and is no longer considered a hazardous drug by NIOSH.
risperidone	NIOSH reviewed data from studies provided by the manufacturer and determined it is unlikely that risperidone poses a carcinogenic, reproductive, or developmental hazard to workers in a healthcare setting and is no longer considered a hazardous drug by NIOSH.
telavancin	NIOSH removed telavancin from the *List* based on data from reproductive studies provided by the manufacturer concerning its lack of reproductive toxicity.

Change from Group 1 to Table 2: Oral &Topical

2024 - Table	RR	Current NIOSH Group	drug generic name	drug ahfs class	administration
2	RR	1	abiraterone	Antineoplastic Agents	Oral Solid | Oral Liquid
2		1	afatinib	Antineoplastic Agents	Oral Solid
2	RR	1	anastrozole	Antiestrogens; Antineoplastic Agents	Oral Solid
2		1	axitinib	Antineoplastic Agents	Oral Solid
2	RR	1	bexarotene	Antineoplastic Agents; Antiproliferants	Oral Solid | Topical
2		1	bicalutamide	Antineoplastic Agents	Oral Solid
2	RR	1	bosutinib	Antineoplastic Agents	Oral Solid
2	RR	1	cabozantinib	Antineoplastic Agents	Oral Solid
2		1	crizotinib	Antineoplastic Agents	Oral Solid
2		1	dabrafenib	Antineoplastic Agents	Oral Solid
2	RR	1	enzalutamide	Antineoplastic Agents	Oral Solid
2	RR	1	erlotinib	Antineoplastic Agents	Oral Solid
2	RR	1	exemestane	Antineoplastic Agents; Antiestrogens	Oral Solid
2		1	flutamide	Antineoplastic Agents	Oral Solid
2	RR	1	letrozole	Antineoplastic Agents; Antiestrogens	Oral Solid
2		1	megestrol	Antineoplastic Agents; Progestins	Oral Solid | Oral Liquid
2	RR	1	nilotinib	Antineoplastic Agents	Oral Solid
2	RR	1	PAZOPanib	Antineoplastic Agents	Oral Solid
2		1	PONATinib	Antineoplastic Agents	Oral Solid
2	RR	1	regorafenib	Antineoplastic Agents	Oral Solid
2	RR	1	SORAfenib	Antineoplastic Agents	Oral Solid
2		1	SUNItinib	Antineoplastic Agents	Oral Solid
2		1	trametinib	Antineoplastic Agents	Oral Solid
2	RR	1	tretinoin, systemic	Antineoplastic Agents	Oral Solid
2		1	vemurafenib	Antineoplastic Agents	Oral Solid
2	RR	1	vismodegib	Antineoplastic Agents	Oral Solid

Change from Group 1 to Table 2: Injectables

2024 - Table	RR	Current NIOSH Group	drug generic name	drug ahfs class	administration
2	RR	1	carfilzomib	Antineoplastic Agents	Injectable
2	RR	1	degarelix	Antineoplastic Agents; Gonadotropins	Injectable
2	RR	1	fulvestrant	Antineoplastic Agents	Injectable
2	RR	1	goserelin	Antineoplastic Agents; Gonadotropins	Injectable
2	RR	1	histrelin	Antineoplastic Agents; Gonadotropins	Injectable
2	RR	1	leuprolide	Antineoplastic Agents; Antiestrogens	Injectable
2	RR	1	triptorelin	Antineoplastic Agents, Gonadotropins	Injectable
2	RR	1	ziv-aflibercept	Antineoplastic Agents	Injectable

Change from Groups 2 & 3 to Table 1 Non-Antineoplastic

2024 - Table	drug group	drug generic name	drug ahfs class	administration
1	2	azaTHIOprine	Antimetabolites, Immunosuppressive Therapy, Miscellaneous	Oral Liquid | Oral Solid
1	2	chloramphenicol	Chloramphenicol	Topical
1	2	cidofovir	Nucleosides and Nucleotides	Injectable
1	2	conjugated estrogens	Estrogens	Injectable | Oral Solid
1	2	conjugated estrogens topical	Estrogens	Topical
1	2	cycloSPORINE	Calcineurin Inhibitors, Miscellaneous; Anti-inflammatory Agents	Injectable | Oral Liquid | Oral Solid
1	2	cycloSPORINE ophthalmic	Anti-inflammatory Agents; Calcineurin Inhibitors, Miscellaneous	Topical
1	2	desogestrel-ethinyl estradiol	Contraceptives; Estrogens; Progestins	Oral Solid
1	2	dexrazoxane	Chemotherapy antidotes/protectants	Injectable
1	2	esterified estrogens	Estrogens	Oral Solid
1	3	**esterified estrogens**-methyltestosterone	Estrogens	Oral Solid
1	2	estradiol-norethindrone	Estrogens; Progestins	Oral Solid
1	2	ethinyl estradiol-norethindrone	Contraceptives; Estrogens; Progestins	Oral Solid
1	2	ganciclovir (no waste code)	Nucleosides and Nucleotides	Injectable | Oral Liquig | Oral Solid
1	2	ganciclovir ophthalmic	Antivirals; - Nucleosides and Nucleotides	Topical
1	2	lenalidomide	Antineoplastic Agents; Immunomodulatory Agents	Oral Solid
1	2	mycophenolate mofetil	Antimetabolites, Immunosuppressive Therapy, Miscellaneous	Injectable | Oral Liquid | Oral Solid
1	2	thalidomide	Immunomodulatory Agents; Antineoplastic Agents	Oral Solid
1	2	valGANciclovir (no waste code)	Nucleosides and Nucleotides	Oral Liquid | Oral Solid

Monoclonal Antibodies: Table 1

AHFS	**NIOSH/Ochsner Grouping**	MAB	MAB Trade Name	Conjugate	MSHI
Antineoplastic	NIOSH 24 Table 1	ado-trastuzumab emtansine	Kadcyla	yes	yes
Antineoplastic	NIOSH 24 Table 1	belantamab mafodontin	Blenrep	yes	yes
Antineoplastic	NIOSH 24 Table 1	brentuximab vedontin	Adcetris	yes	yes
Antineoplastic	NIOSH 24 Table 1	enfortumab vedotin	Padcev	yes	yes
Antineoplastic	NIOSH 24 Table 1	fam-trastuzumab deruxtecar	Enhertu	yes	yes
Antineoplastic	NIOSH 24 Table 1	gemtuzumab ozogamicin	Mylotarg	yes	yes
Antineoplastic	NIOSH 24 Table 1	inotuzumab ozogamicin	Bensponsa	yes	yes
Antineoplastic	NIOSH 24 Table 1	loncastuximab tesirine	Zymlonta	yes	yes
Antineoplastic	NIOSH 24 Table 1	mirvetuximab soratansine	Elahere	yes	yes
Antineoplastic	NIOSH 24 Table 1	polantuzumab vedotin	Polivy	yes	yes
Antineoplastic	NIOSH 24 Table 1	sacituzumab govitecan	Trodelvy	yes	yes
Antineoplastic	NIOSH 24 Table 1	tisotumab vedotin	Tivdak	yes	yes

Monoclonal Antibodies Con.

AHFS	NISOH	MAB	MAB Trade Name	Teratogenic /Developmental Toxicity	Embryo-Fetal Toxicity	Reproductive Toxicity	OrganToxicity	Genotoxicity
Antineoplastic	NIOSH 24 Table 2	blinatumomab (powder)	Blincyto	no	n/a	no	no	no
Antineoplastic		atezolizumab	Tecentriq	no	yes	yes, Weekly ad	no	no
Antineoplastic		bevacizumab	Avastin	yes. Reproducti	n/a	yes, Female cyr	no	no
Antineoplastic		cetuximab	Erbitux	yes, in an anim	yes	no	no	no
Antineoplastic		ipilimumab	Yervoy	yes, In animal r	yes	no	no	no
Antineoplastic		margetuximab	Margenza	yes, In postmar	yes	no	no	no
Antineoplastic		panitumumab	Vectibix	no	n/a	see insert, Men	no	no
Antineoplastic		ramucirumab	Cyramza	no	n/a	In a 39 week an	no	no
Antineoplastic		Dostarlimab-gxy	Jemperi	no	yes	no	yes	no
Antineoplastic		trastuzumab	Herceptin	In post-marketi	yes	no	no	no
Antineoplastic		hyaluronidase/trastuzumab	Herceptin Hylecta	No. HERCEPTIN	yes	no	no	no
Antineoplastic		hyaluronidase/pertuzumab/	Phesgo	marketing	yes	no	no	no

Monoclonal Antibodies Con.

AHFS	NIOSH	MAB	MAB Trade Name	Teratogenic /Developmental Toxicity	Embryo-Fetal Toxicity	Reproductive Toxicity	OrganToxicity	Genotoxicity
Antineoplastic		amivantamab	Rybrevant	no	yes	no	no	no
Antineoplastic		avelumab	Bavencio	no	yes	no	no	no
Antineoplastic		cemiplimab-rwlc	Libtayo	no	yes	no	no	no
Antineoplastic		daratumumab-hyaluronidase	Darzalex Faspro	no	yes	no	no	no
Antineoplastic		daratumumab	Darzalex	no	yes	no	no	no
Antineoplastic		dinutuximab	Unituxin	no	yes	no	no	no
Antineoplastic		durvalumab	Imfinzi	no	yes	no	no	no
Antineoplastic		epcoritamab-bysp	Epkinly	no	yes	no	no	no
Antineoplastic		hyaluronidase/rituximab	Rituxan Hycela	no	n/a	no	no	no
Antineoplastic		mogamulizumab-kpkc	Poteligeo	no	n/a	no	no	no
Antineoplastic		naxitamab-gqgk*	Daylenza	no	yes	no	no	no
Antineoplastic		necitumumab	Portrazza	no	yes	no	no	no
Antineoplastic		nivolumab	Opdivo	no	yes	no	no	no
Antineoplastic		nivolumab-relalimab	Opdualag	no	yes	no	no	no
Antineoplastic		obinutuzumab	Gazyva	no	n/a	no	no	no
Antineoplastic		ofatumumab	Arzerra	no	n/a	no	no	no
Antineoplastic		pembrolizumab	Keytruda	no	yes	no	no	no
Antineoplastic		pertuzumab	Perjeta	no	yes	no	no	no
Antineoplastic		rituximab	Rituxan	no	n/a	no	no	no
Antineoplastic		Rituximab-abbs	Truxima	no	yes	no	no	no
Antineoplastic		Siltuximab	Sylvant	no	no	no	no	no
Antineoplastic		tafastiamab (powder)	Monjuvi	no	yes	no	no	no
Antineoplastic		Talquetamab-tgvs	Talvey	no	yes	no	no	no
Antineoplastic		teclistamab	Tecvayli	no	yes	no	no	no
Antineoplastic		tremelimumab	Imjudo	no	yes	no	no	no

HD that must follow USP <800>

- Drugs on the NIOSH list that must follow the requirements of USP Chapter <800> include:
  - Any HD Active Pharmaceutical Ingredients (API)
  - Any antineoplastic requiring HD manipulation

- Drugs on the NIOSH list that do not have to follow all of the containment strategies of USP Chapter <800> if an Assessment of Risk (AoR) is performed and implemented include:
  - Final dosage forms of compounded HD preparation and conventionally manufactured HD 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 HD on the NIOSH list, the entity may perform an AoR to determine alternative containment strategies and/or work practices

Topic Outline

1. USP <797> Pressure Differential and Viable Sampling
2. Personnel Training and Evaluation
3. Viable Sampling
4. Cleanroom Structure
5. Reducing HD Exposure
6. Initial Considerations for USP <800>
7. Designated Person Responsibilities
8. C-PEC and C-SEC
9. Standard Operational Procedures
10. Elements of an Assessment of Risk

1. USP <797> Pressure Differential and Viable Sampling

- Pressure differential Positive Buffer to Ante Room: minimum 0.02” w.c.
- Pressure differential Ante Room to unclassified: minimum 0.02” w.c.
- Pressure differential Negative Buffer to adjacent area: between -0.01 and -0.03” w.c.

- Action level for surface samples

ISO Class	Surface Sampling Action Levels (cfu/device)
5	>3
7	>5
8	>50

- Action level for air samples

ISO Class	Air Sampling Action Levels [cfu/cubic meter (1000 liters) of air/plate]
5	>1
7	>10
8	>100

2. Personnel Training and Evaluation

- Training required initially and at least every 3, 6 or 12 months

- Core Competency Skills
  - Hand Hygiene
  - Garbing
  - Cleaning and disinfection
  - Calculations, measuring, and mixing
  - Aseptic technique
  - Achieving and maintaining sterility
  - Use of equipment
  - Documentation of the compounding process
  - Proper use of PECs
  - Principles of movement of materials and personnel within compounding area

Personnel Training and Evaluation Cont.

- Garbing Competence Evaluation
  - Visual observation
    - Hand hygiene
    - Garbing procedures
    - GFT of both hands
  - Must pass 3 in succession on initial competency
    - Failure requires repeating until achieving 3 successful in a row

- Aseptic Manipulation Competency Evaluation
  - Visual observation
    - Hand Hygiene
    - Garbing procedures
    - Media-fill testing
    - GFT of both hands
    - Surface sampling of direct compounding area

- Frequency of competencies
  - Ongoing garbing and aseptic technique
    - Category 1 and 2: every 6 months
    - Category 3: every 3 months
    - Non-compounders providing oversight: every 12 months

Personnel Training and Evaluation Cont.

Box 1. Gloved Fingertip and Thumb Sampling Procedures

- Use one sampling media device (e.g., plates, paddles, or slides) per hand, containing general microbial growth agar (e.g., trypticase soy agar [TSA]) supplemented with neutralizing additives (e.g., lecithin and polysorbate 80) as this agar supports both bacterial and fungal growth.
- Label each media device with a personnel identifier, right or left hand, and the date and time of sampling.
- Do not apply sterile 70% isopropyl alcohol (IPA) to gloves immediately before touching the media device because this could cause a false-negative result. Using a separate media device for each hand, collect samples from all gloved fingertips and thumbs from both hands by rolling fingertip pads and thumb pad over the agar surface.
- Incubate the media device at 30°–35° for no less than 48 h and then at 20°–25° for no less than 5 additional days. Samples must be incubated in an incubator. Handle and store media devices to avoid contamination and prevent condensate from dropping onto the agar during incubation and affecting the accuracy of the cfu reading (e.g., invert plates).
- Record the number of cfu per hand (left hand, right hand).
- Determine whether the cfu action level is exceeded by counting the total number of cfu from both hands.

United States Pharmacopeial Convention. General chapter <797> pharmaceutical compounding—sterile preparations. USP-NF 2023, Issue 1, November 1, 2022, official as of November 1, 2023.

Personnel Training and Evaluation Cont.

Box 2. Media-Fill Testing Procedures

- If all of the starting components are sterile to begin with, manipulate them in a manner that simulates sterile-to-sterile compounding activities, and transfer the sterile soybean–casein digest media into the same types of container closure systems commonly used at the facility. Do not further dilute the media unless specified by the manufacturer.
- If some of the starting components are nonsterile to begin with, dissolve a commercially available nonsterile soybean–casein digest powder in nonbacteriostatic water to make a 3% nonsterile solution. Manipulate it in a manner that simulates nonsterile-to-sterile compounding activities. Prepare at least 1 container as the positive control to demonstrate growth promotion, which is indicated by visible turbidity upon incubation.
- Once the compounding simulation is completed and the final containers are filled with the test media, perform a gloved fingertip and thumb sample on each hand and surface sample of the direct compounding area inside the PEC. Take the samples prior to disinfecting gloves and PEC. Handle and store samples to avoid contamination and prevent condensate from dropping onto the agar during incubation and affecting the accuracy of the cfu reading (e.g., invert containers).
- Incubate the final containers at 20°–25° and 30°–35° for a minimum of 7 days at each temperature band to detect a broad spectrum of microorganisms. The order of the incubation temperatures must be described in the facility's SOPs. Final containers must be incubated in an incubator.
- Failure is indicated by visible turbidity or other visual manifestations of growth in the media in one or more container closure unit(s) on or before 14 days.

United States Pharmacopeial Convention. General chapter <797> pharmaceutical compounding—sterile preparations. USP-NF 2023, Issue 1, November 1, 2022, official as of November 1, 2023.

3. Viable Sampling

Surface sampling

1. Remove the cover from the surface sampling media device. Using a rolling motion, firmly press the media surface onto the surface to be sampled. The media device will leave a residue of growth media on the sample site. After sampling, clean and disinfect the sampled area to remove the residue from the surface.
2.Cover each media device. Handle and store media devices to avoid contamination and prevent condensate from dropping onto the agar during incubation and affecting the accuracy of the cfu reading (e.g., invert plates).
3. Incubate media device(s) at 30°–35° for no less than 48 h. Examine for growth. Record the total number of discrete colonies of microorganisms on each media device as cfu per media device on an environmental sampling form based on sample type (i.e., surface), sample location, and sample date.
4. Incubate the media device at 20°–25° for no less than 5 additional days. Examine for growth. Record the total number of discrete colonies of microorganisms on each media device (cfu per sample) on the environmental sampling record based on sample type (i.e., surface), sample location, and sample date.
5.Alternatively, to shorten the overall incubation period, two surface sampling media devices may be collected for each sample location and incubated concurrently.

A. Both media devices could be TSA or one media device could be TSA and the other fungal media (e.g., malt extract agar [MEA] or Sabouraud dextrose agar [SDA]). Media must be supplemented with neutralizing additives (e.g., lecithin and polysorbate 80).
B. Incubate each media device in a separate incubator. Incubate one media device at 30°–35° for no less than 48 h, and incubate the other media device at 20°–25° for no less than 5 days. If fungal media are used, incubate the fungal media device at 20°–25° for no less than 5 days.
C. Count the total number of discrete colonies of microorganisms on each media device, and record these results as cfu per media device.
D. Record the results of the sampling on an environmental sampling form based on sample type (i.e., surface), and include the sample location and sample date.

United States Pharmacopeial Convention. General chapter <797> pharmaceutical compounding—sterile preparations. USP-NF 2023, Issue 1, November 1, 2022, official as of November 1, 2023.

Viable Sampling Cont.

Air sampling

1. Follow the manufacturer's instructions for operation of the impaction air sampler, including placement of media device(s).

2. Using the impaction air sampler, test at least 1 cubic meter or 1000 L of air from each location sampled.

3. At the end of each sampling period, retrieve the media device and cover it. Handle and store media devices to avoid contamination and prevent condensate from dropping onto the agar during incubation and affecting the accuracy of the cfu reading (e.g., invert plates).

4. Incubate the media device at 30°–35° for no less than 48 h. Examine for growth. Record the total number of discrete colonies of microorganisms on each media device as cfu per cubic meter of air on an environmental sampling form based on sample type (i.e., viable air), sample location, and sample date.

5. Then incubate the media device at 20°–25° for no less than 5 additional days. Examine for growth. Record the total number of discrete colonies of microorganisms on each media device as cfu per cubic meter of air on an environmental sampling form based on sample type (i.e., viable air), sample location, and sample date.

6. Alternatively, to shorten the overall incubation period, two sampling media devices may be collected for each sample location and incubated concurrently.

   A. Both media devices could be TSA or one media device could be TSA and the other fungal media (e.g., malt extract agar [MEA] or Sabouraud dextrose agar [SDA]).

   B. Incubate each media device in a separate incubator. Incubate one media device at 30°–35° for no less than 48 h, and incubate the other media device at 20°–25° for no less than 5 days. If fungal media are used as one of the samples, incubate the fungal media sample at 20°–25° for no less than 5 days.

   C. Count the total number of discrete colonies of microorganisms on each media device, and record these results as cfu per cubic meter of air.

   D. Record the results of the sampling on an environmental sampling form based on sample type (i.e., viable air), and include the sample location and sample date.

United States Pharmacopeial Convention. General chapter <797> pharmaceutical compounding—sterile preparations. USP-NF 2023, Issue 1, November 1, 2022, official as of November 1, 2023.

4. Cleanroom Structure

Aluminum Honeycomb Panels

- *Strength*
- *Corrosion resistance*
- *Easily cleanable*

Get a written statement from vendor that the products are resistant to your cleaning chemicals



"Why Choose Aluminum Honeycomb Panels for Clean Rooms?" *Puracore*, 30 Jan. 2018, www.puracore.com/page/3/?p=a

Cleanroom Structure Cont.

- Single component epoxy paints contain an epoxy resin as primary component
- Typically contain solvents to help evaporate moisture and create a hard finish
- Frequently used on concrete, metal, and wood
- Not as durable as two-component epoxy paints and can be less resistant to impact, physical and chemical abrasion

- Two component epoxy paint
- Combine a base resin and hardening agent to create a powerful lasting coating
- Harder and can be more expensive than their single component counterparts
- Typically, longer lasting and more durable

- Have the paint vendor provide an official document attesting the epoxy will survive your selected cleanroom cleaning chemicals (e.g., peracetic acid, hydrogen peroxide, sodium hypochlorite)

Cleanroom Structure Cont.

- Flooring standards:
  - Vinyl flooring is generally tested in accordance with ASTM 970 – Standard Test Method of Static Load Limit
  - Resilient floor covering institute defines a dynamic load as “dynamic loads created when a load is placed on a floor, and then moved around the floor’s surface by rolling, sliding or dragging motion.”

- Epoxy adhesive for vinyl flooring
  - Epoxy flooring adhesive is selected in industrial, and residential setting because of it’s ability to withstand heavy loads
  - Need to make a conscious decision on where to use epoxy-based adhesive versus water-born adhesive due to cost

Ardex Technical Department. (2013, April 26). *High Rolling and High Point Loads – Vinyl Flooring Installation*. WW Henry.

Boudreau, M. (2019). Epoxy Flooring Systems - A Comprehensive Guide. [Ebook]. Florock Polymer Flooring.

Mannington. (n.d.) V-88 Adhesive. [Product Information Sheet}

5. Reducing HD Exposure

Engineering controls

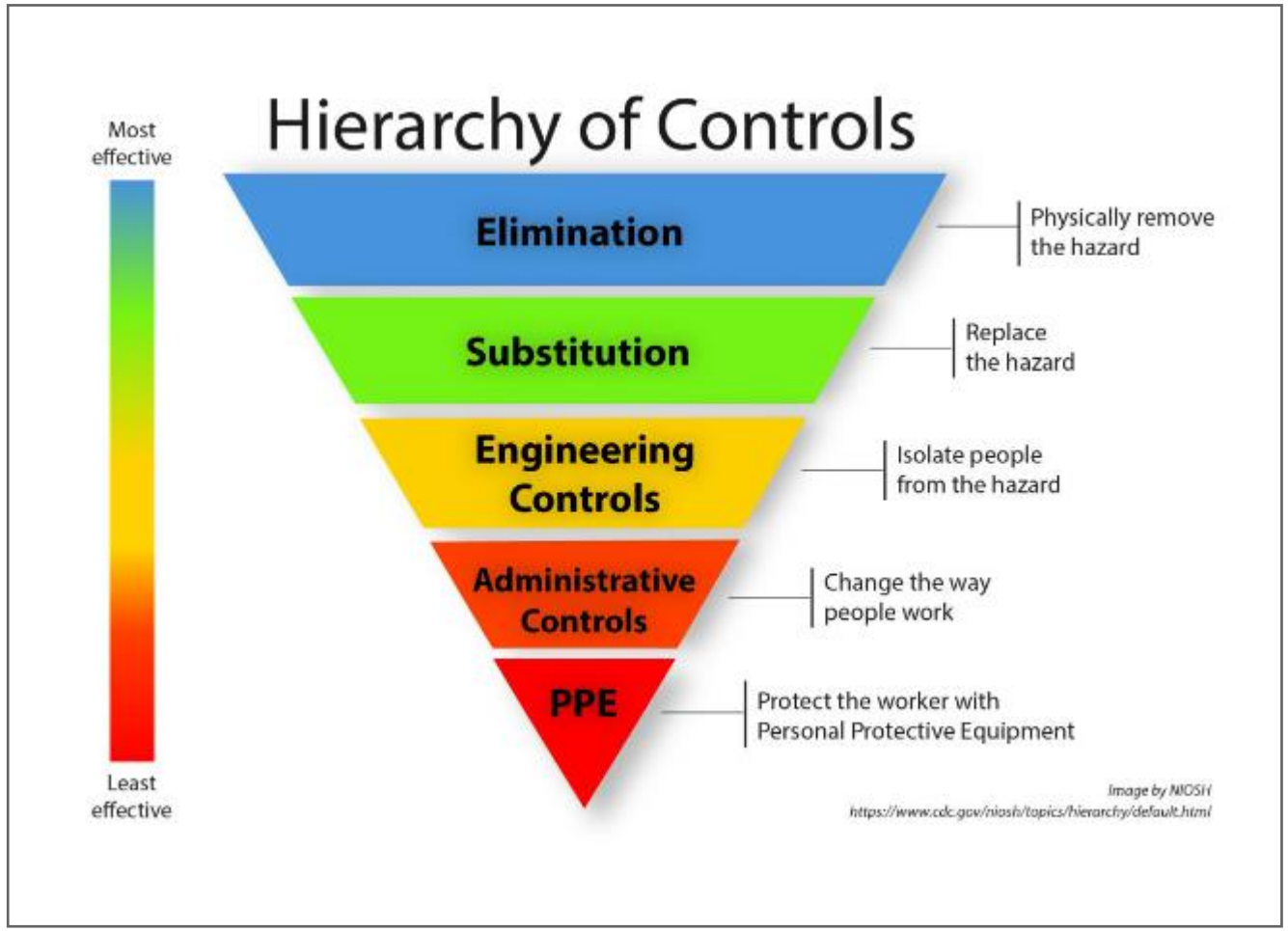
Personal protective equipment

Safe work practices

Competent personnel

Policies

Reducing HD Exposure Cont.



Centers for Disease Control and Prevention. (n.d.). Hierarchy of Controls. Centers for Disease Control and Prevention.

6. Initial Considerations for USP <800>

- Appointment of a Designated Person
- Adoption of the NIOSH 2016 list
  - Adopt updated NIOSH list when published
- Evaluation of current formulary meeting NIOSH criteria
- Process to evaluate new hazardous drugs added to the formulary
- Evaluation of pharmacy environment to accommodate USP <800> requirements
- Evaluation of pharmacy processes to accommodate USP <800> requirements
- Hazardous medication waste stream review

7. Designated Person Responsibilities: USP <797>

1. Monitor all activities in the pharmacy for USP Chapter <797> compliance and maintain documentation of sterile compounding area monitoring, findings, and actions.
2. Participate in developing of SOPs related to USP Chapter <797>.
3. Assure compliance with all applicable SOPs related to USP Chapter <797>.
4. Create and implement a training program for personnel and ensure that compounders, personnel who have direct oversight of compounder, and personnel who perform restocking and cleaning and disinfection duties are trained and qualified.
5. Provide oversite of ordering and usage of USP Chapter <797> compliant products within the pharmacy.
6. Review all certification and recertification records to ensure that the classified environments comply with minimum requirements in the USP <797> chapter
7. In collaboration with the pharmacy leadership, the DP shall execute and document appropriate actions following PEC or SEC certification failures and/or viable results with growth.
8. Ensure that any person who enters the sterile compounding area maintains the quality of the environment
9. Determine if employees at high risk of contaminating the CSPs shall be allowed to perform sterile compounding activities.

a) Personnel that may have a higher risk of contaminating the CSP and the environment include, but not limited to, individuals with rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory infection and should not be allowed to participate in sterile compounding activities.

Designated Person Responsibilities: USP <800>

- Develop and implement appropriate pharmacy standard operational procedures
- Ensure compliance with this chapter and other applicable laws, regulations, and standards
- Ensure competency of pharmacy personnel
- Ensure environmental control of the storage and compounding areas within pharmacy
- Maintain reports of testing/sampling performed in pharmacy and acting on the results
- Responsible for completion and annual review of AoRs

8. C-PEC and C-SEC

- ISO Classified
  - ISO Class 7 buffer room
  - ISO Class 7 ante-room
  - C-PEC: externally vented
  - C-SEC: externally vented, 30 ACPH, pressure -0.01 to -0.03” w.c. relative to adjacent areas
- Unclassified (C-SCA)
  - C-PEC: externally vented
  - C-SEC: externally vented, 12 ACPH, pressure -0.01 to -0.03” w.c. relative to adjacent areas



C-PEC and C-SEC Cont.

- BSC
  - Class II A2: provides ISO 5, canopy
  - Class II B2: provides ISO 5, 100% external exhaust
- CACI
  - Provides ISO 5
  - Canopy or 100% external exhaust



9. Standard Operational Procedures

- PPE and Garbing
  - *NOTE: Appropriate PPE should be addressed in each of the following SOPs*
- Receiving
- Storage
- Transport
- Compounding
- Cleaning and Disinfecting
  - Standardizing cleaning products and processes
- Spill management
- Waste management: understanding of NIOSH hazardous drug vs RCRA Regulated Waste

SOP for PPE

- Must be compliant with both USP <797 and <800>
  - Shoe covers
  - Head and facial hair covers
  - Face masks
  - Gowns
  - Gloves
  - Eye shields

SOP for PPE Cont.

- Respirator: prevents harmful materials from entering the respiratory system, usually by filtering hazardous agents, and meeting NIOSH and OSHA standards for use with hazardous drugs
- N95: removes at least 95% of airborne particles, respectively, but not resistant to oil
- R95: removes 95% of airborne particles, and somewhat resistant to oil
- P100: removes 99.97% of airborne particles, and strongly resistant to oil and provides protection for most harmful vapors
- Responders should undergo annual fit test for N95 and/or half face respirator with P100 filters





SOP for PPE Cont.

- Safety goggles (not glasses)

Correct



Incorrect



2020

[redacted] Hazardous Drug Handling PPE Guide

Personnel Protective Equipment (PPE) required for administration or spill of a Hazardous Drugs (HazD) for non-pharmacy staff:

Types of PPE	Gloves	Gown	Eye/Face Protection	Respiratory	Other: Hair/Beard Cover, Shoe Cover
Medication Administration Form	HazD Group 1 **All Gloves- ASTM D6978**		HazD Group 2		HazD Group 3
Intact pill, capsule, tablet	Single Gloves		Single Gloves		Single Gloves
Non-intact capsule or tablet-crushed or manipulated (Contact Pharmacy)	Double Gloves		Double Gloves		Double Gloves
Oral solution, syrup, suspension, Eye Drops, Feeding Tube	Double Gloves	for splash concern	Double Gloves	for splash concern	Double Gloves	for splash concern
Injectable: Intravenous (IV), Intra-muscular (IM), Subcutaneous, Intrathecal	Double Gloves	for splash concern	Double Gloves	for splash concern	Double Gloves	for splash concern
Topical gel/cream/powder, Suppository, Vaginal inserts/creams, Transdermal patch, Subcutaneous implant	Double Gloves	for splash concern; for inhalation potential	Double Gloves	for splash concern; for inhalation potential	Double Gloves	for splash concern; for inhalation potential
Intravesical (Bladder Instillation), Intra Cavity	Double Gloves		Double Gloves		Double Gloves	
Inhalation/Aerosol treatment	Double Gloves		Double Gloves		Double Gloves	

SOP for Donning and Doffing

- **Donning procedure**
  1. Don head, beard, and face covers.
  2. Don 1 regular blue shoe cover followed by 1 white (polyethylene) shoe cover on one foot.
  3. Put foot over Line of Demarcation (LOD).
  4. Repeat application of shoe covers with other foot.
  5. Perform hand hygiene.
  6. Don a non-HD gown.
  7. Don HD gown over non-HD gown.
  8. Don first pair of new sterile ASTM D6978 gloves. Gloves should go over the cuff of the inner non-HD gown.
  9. Don second pair of new sterile ASTM D6978 gloves.
  10. Gloves should go over the cuff of the outer HD gown.

SOP for Donning and Doffing Cont.

- **Doffing procedure**
  - Prior to crossing doffing line
  1. Doff HD gown with gloved hands.
  2. Remove HD gown slowly and carefully so that HD gown removal does not spread contamination.
  3. Grasp the HD gown at the hip and pull until the gown comes down from the shoulder.
  4. Sleeves of the HD gown must be pulled off carefully and then the entire gown is removed while gradually turning it inside out.
  5. Do not pull or reach around the neck of the HD gown.
  6. Discard HD gown in the yellow trace RCRA waste container.

SOP for Receipt of HD

- **General Notes:**
  - HDs should be received from suppliers in impervious plastic bags.
  - Unpack in an area that is neutral/normal or negative pressure.
  - Never unpack in sterile compounding area.
- **Procedure for unpacking NIOSH Category 1 drugs**
  1. Don a single pair of white (polyethylene) shoe covers, HD gown, two pairs of ASTM D6978 gloves (over the cuff of the gown), respiratory protection (N95, R95, or half mask), and eye protection if there is a risk of spill or splash (if not wearing a full mask).
  2. Unpack in negative pressure receiving room.
  3. Examine all packages for signs of breakage.
  4. Wipe the exterior surfaces of HD cartons with EPA-registered disinfectant and cleaner with sporicidal activity.
  5. Dispose of PPE in yellow trace RCRA waste containers.
- **Procedure for unpacking NIOSH Category 2 or 3 Drugs**
  1. Don two pairs ASTM D6978 gloves.
  2. Follow same unpacking procedures as for non-HD.
  3. Dispose of PPE in regular trash.

SOP for Storage of HD

- **General Notes**
  - Antineoplastic HDs that require manipulation must be stored in an externally ventilated, negative pressure room with at least 12 ACPH.
  - Sterile and non-sterile HD may be stored together, but not recommended to store non-sterile HD in sterile compounding area.
  - Antineoplastic HDs must be stored in dedicated refrigerator in negative pressure room with at least 12 ACPH.
  - Bins, drawers, or containers used to routinely store HDs must be of such configuration that reduce the risk of breakage (drawers may be used instead of shelves, or shelves must have front, back, and side lips to prevent falling) and must facilitate spill containment in the case of container leakage.
- **Procedure for storage NIOSH Category 1 drugs**
  1. Don 2 pair of ASTM D6978 gloves to store HDs unless handling an intact pill, capsule, or tablet where only 1 pair of gloves is required.
  2. Stored in resealable clear plastic bags or in bins identified by yellow (chemotherapy, cytotoxic) hazardous drugs labels or stickers.
  3. Dispose of PPE in yellow trace RCRA waste containers.
- **Procedure for storage of NIOSH Category 2 or 3 drugs**
  1. NIOSH Group 2 or 3 Drugs will be stored in resealable clear plastic bags or in bins identified by blue HD labels or stickers.
  2. Dispose of PPE in regular trash.

SOP for Transport of HD

- **General notes**
  - HDs must be transported in containers that minimize the risk of breakage or leakage.
  - Pneumatic tubes must not be used to transport any liquid HDs or antineoplastic.
  - When shipping HDs outside of facility, consult the Transport Information on the SDS.
- **Procedure for transporting HDs:**
  1. Don 2 pair of ASTM D6978 gloves to transport HDs unless transporting an intact pill, capsule, or tablet where only 1 pair of gloves is required.
  2. Place the HD in the appropriate resealable clear plastic bag.
  3. Ensure that the bag is tightly closed to facilitate spill containment.
  4. If the HD is a liquid or has been manipulated, then the resealable plastic bag must be placed into a hard-sided closeable container that reduces the risk of breakage and facilitates spill containment.
  5. The container must be clearly marked with the appropriate HD label or sticker.
  6. Prior to leaving the transport destination and 2 pair of ASTM D6978 gloves are worn, doff outer pair of gloves and discard them in the yellow trace RCRA waste container.
  7. Return the hard-sided closeable container to pharmacy and wipe with EPA-registered disinfectant and cleaner with sporicidal activity.
  8. Doff the remaining gloves and discard them in the yellow trace RCRA waste container.

SOP for Compounding and Manipulation of HD

- **General Notes**
  - Sterile compounding of HD will take place in a C-PEC within a C-SEC unless otherwise noted in an Assessment of Risk (AoR).
  - All sterile HD compounding shall be performed in compliance with USP Chapters <797> and <800>.
  - Sterile HD compounding must be compliant with UPS <797> standards.
  - A plastic-backed preparation mat should be placed on the work surface of the C-PEC.
- **Procedure for compounding and manipulation**
  1. Don head, beard, and face covers, two pair of shoe covers with outer pair made from polyethylene, non-HD gown covered by HD gown, two pairs of ASTM D6978 gloves with outer pair sterile.
  2. The outer, sterile gloves must be changed every 30 minutes (unless otherwise recommended by the manufacturer's documentation) during continuous compounding/manipulation, between preparations for different patients, and immediately if defect, puncture, or tear is suspected.
  3. The outer HD gown must be changed every 3 hours during continuous compounding/manipulation and immediately if it becomes damaged or contaminated.
  4. Doff HD gown with gloved hands prior to exiting C-SEC.
  5. Prior to crossing doffing line, remove the white (polyethylene) shoe cover with gloved hands.

SOP for Compounding and Manipulation of HD Cont.

- **Option one: Decontamination of final product**
  1. At the conclusion of compounding/manipulation, doff the outer gloves inside of the C-PEC.
  2. Place the gloves into a sealable receptacle or resealable clear plastic bag (located in the C-PEC) with yellow (chemotherapy, cytotoxic) HD label or sticker.
  3. Wipe the finished product with EPA-registered disinfectant and cleaner with sporicidal activity followed by sIPA and place on cleanest side of the C-PEC deck.
  4. Wipe the inner gloved hands with EPA-registered disinfectant and cleaner with sporicidal activity prior to removing finished product from the C-PEC.
  5. Remove finished product from the C-PEC, label, and place into a resealable clear plastic bag with yellow (chemotherapy, cytotoxic) HD labeling or sticker.

SOP for Compounding and Manipulation of HD Cont.

- **Option two: Decontamination of final product**
  1. At the conclusion of compounding/manipulation, doff the outer gloves inside of the C-PEC.
  2. Place the gloves into a sealable receptacle or resealable clear plastic bag (located in the C-PEC) with yellow (chemotherapy, cytotoxic) HD label or sticker.
  3. Wipe the inner gloved hands with EPA-registered disinfectant and cleaner with sporicidal activity prior to removing finished product from the C-PEC.
  4. Remove finished product from the C-PEC and place on a disposable chemo prep pad.
  5. Wipe the finished product with EPA-registered disinfectant and cleaner with sporicidal activity followed by sIPA and place on clean surface.
  6. Wipe the inner gloved hands with EPA-registered disinfectant and cleaner with sporicidal activity.
  7. Label finished product and place into a resealable clear plastic bag with yellow (chemotherapy, cytotoxic) HD labeling or sticker.

SOP for Cleaning and Disinfecting

Type of Agent	Purpose
Cleaning	An agent, usually containing surfactant, used for the removal of substances (e.g., dirt, debris, microbes, and residual drugs or chemicals) from surfaces.
Disinfectant	A chemical or physical agent used on inanimate surfaces and objects to destroy fungi, viruses, and bacteria.
Sporicidal	A chemical or physical agent that destroys bacterial and fungal spores when used at a sufficient concentration for a specified contact time. It is expected to kill all vegetative microorganisms.

When reviewing products ensure that they are EPA-registered per the USP <797> 2023 chapter.

United States Pharmacopeial Convention. General chapter <797> pharmaceutical compounding—sterile preparations. USP-NF 2023, Issue 1, November 1, 2022, official as of November 1, 2023.

SOP for Cleaning and Disinfecting Cont.

Site	Cleaning	Disinfecting[b]	Applying Sporicidal Disinfectant
PEC(s) and equipment inside the PEC(s)	• Equipment and all interior surfaces of the PEC daily on days when compounding occurs and when surface contamination is known or suspected	• Equipment and all interior surfaces of the PEC daily on days when compounding occurs and when surface contamination is known or suspected	• Monthly for entities compounding Category 1 and/or Category 2 CSPs • Weekly for entities compounding Category 3 CSPs
Removable work tray of the PEC, when applicable	• Work surface of the tray daily on days when compounding occurs • All surfaces and the area underneath the work tray monthly	• Work surface of the tray on days when compounding occurs • All surfaces and the area underneath the work tray monthly	• Work surfaces of the tray monthly • All surfaces and the area underneath the work tray monthly
Pass-through chambers	• Daily on days when compounding occurs	• Daily on days when compounding occurs	• Monthly for entities compounding Category 1 and/or Category 2 CSPs • Weekly for entities compounding Category 3 CSPs
Work surface(s) outside the PEC	• Daily on days when compounding occurs	• Daily on days when compounding occurs	
Floor(s)	• Daily on days when compounding occurs	• Daily on days when compounding occurs	
Wall(s), door(s), and door frame(s)	• Monthly	• Monthly	• Monthly
Ceiling(s)[c]			
Storage shelving and bin(s)			
Equipment outside the PEC(s)			

United States Pharmacopeial Convention. General chapter <797> pharmaceutical compounding—sterile preparations. USP-NF 2023, Issue 1, November 1, 2022, official as of November 1, 2023.

SOP for Cleaning and Disinfecting Cont.

- Deactivation: The act of rendering a HD inert of less hazardous. No one agent can deactivate all HDs
- Decontamination: The act of removing HD residues by transferring it to disposable wipes or mop pads.
- Disinfecting: the chemical process that uses specific products to destroy harmful microorganisms, but not necessarily their spores, on inanimate surfaces.
- Cleaning: The mechanical process (scrubbing) using soap or detergent to remove contaminants such as soil, microbes, and drug residues.

SOP for Cleaning and Disinfecting Cont.

- Cleaning equipment first time prior to entering compounding area
- Cleaning inside of the C-PEC
- Cleaning the outside of the C-PEC and the C-SEC
  - Daily
  - Weekly
  - Monthly
- Removing HD residue from finished product (bags and syringes)
- Removing HD residue from gloved hands
- Removing HD residue from carton or container
- Sanitizing gloved hands

SOP Spill Management of HD

- **General notes:**
  - Availability of Safety Data Sheets (SDS) for all NIOSH HDs.
  - Spills must be contained and cleaned immediately.
  - Document observational competency in spill management upon hire and annually thereafter.
  - Perform at least one HD spill drill annually.
- **Procedure for spills less than 30 mL inside of the C-PEC:**
  1. Don appropriate PPE.
  2. If the spill is a solid, wet absorbent towels with sterile water and place on top of the spill.
  3. Place sterile absorbent wipe over the spill.
  4. Wipe any spill residual and discard the saturated wipe in a black RCRA waste container.
  5. Doff outer glove and discard in a yellow trace RCRA waste container.
  6. Prior to donning second pair of gloves, sanitize gloved hands by applying sIPA, rub gloved hands together, and allow to dry. Then sanitize outer glove prior to re-entering the C-PEC.
  7. Clean the deck and any other affected area in the C-PEC by wiping with EPA-registered one-step cleaner and disinfectant.
  8. Discard all pads, sponges, and wipes in yellow trace RCRA waste containers.

SOP Spill Management of HD Cont.

- ASTM D6978 gloves
- Caution sign
- Goggle
- Yellow hazardous waste disposal bag
- Bags and ties
- Shoe covers
- Poly-coated gown
- Scoop with detachable scraper
- N95 mask
- Absorbent pads (gel forming pads)
- Absorbent towels



SOP Spill Management of HD Cont.

Additional Supplies

- ASTM D6978 gloves various sizes
- HD (chemo) gowns various sizes
- Shoe covers
- Yellow (trace) RCRA waste container
- 1 pack low-linting wipes
- 70% isopropyl alcohol
- EPA-registered disinfectant and cleaner
- Half Facepiece with P100 filters
- Full-Face-Piece Respirator with P100 Filter
- PAPR
- Bottle of Sterile Water

SOP for Handling HD Waste



Courtesy of Vizient

SOP for Handling HD Waste Cont.

- **General notes:**
  - All HD waste shall be disposed of according to Resource Conservation and Recovery Act (RCRA) waste characterization.
  - RCRA HD waste must be kept inside covered waste containers in a designated area.
- **Procedure for RCRA HD Waste:**
  1. All containers with more than 3% of the container's volume and syringes containing more than trace amounts of the HD shall be discarded in black bulk RCRA waste containers.
  2. All containers and syringes that are empty or contain less than 3% of the container’s original volume are considered to contain trace waste and shall be discarded in a yellow chemo waste container.
  3. PPE used in preparation of antineoplastics in NIOSH Table 1 shall be discarded in a yellow chemo waste bag or container.
  4. Needles and other sharps used in the preparation of antineoplastics in NIOSH Table 1 shall discarded in a hard-sided yellow chemo waste container.

STEP 1:
Witness and waste controlled substances

If this is not a controlled substance, proceed to Step 2

No controlled substances go in any of the RCRA waste containers.

If this medication is a controlled substance (waste code "DEA"), witness and waste the medication per your facility's policy and dispose of the controlled substance in either [redacted] sites)

[redacted] tory sites)

Then, proceed to Step 2 to dispose of the medication container and/or syringe

STEP 2:
Disposal of Medication, Medication Containers, and/or Medication Preparation or Administration Supplies*

*Supplies include include IV tubing, syringes, needles that were used to prepare and/or administer the medication

Is this medication or container/supply considered a sharp?

YES → Is >3% of the original medication volume remaining within the sharp?

YES → 2-gallon Black BKC Sharps Bin / Yellow Chemo Bin (Either bin is acceptable for empty "CHEMO" sharps)

NO → Was this sharp used to prepare or administer a CHEMO drug?

YES → 2-gallon Black BKC Sharps Bin / Yellow Chemo Bin (Either bin is acceptable for empty "CHEMO" sharps)

NO → Red Sharps Bin

NO → Is >3% of the original medication volume remaining?

YES → What is the RCRA disposal code?

NO CODE → Is this a "plain" IV fluid?

YES → Fluid poured down the drain, empty container in regular trash

NO → Blue Waste Bin

BKC → Black BKC Bin

CHEMO → Black Bulk Chemo Bin

SPO, SPLP SP, SPC, → Place in resealable plastic bag and send to pharmacy

PBKC → Black PBKC Container

NO → Is the RCRA disposal code PBKC or CHEMO?

NO → Regular Trash

YES → What is the RCRA disposal code?

PBKC → Black PBKC Container

CHEMO → Yellow Chemo Bin/Bag

STEP 3:
PPE Disposal**

**PPE Disposal guide is for PPE used for medication preparation or administration. PPE used for isolation precautions should be disposed in a red biohazard bag.

Did you prepare or administer a CHEMO drug?

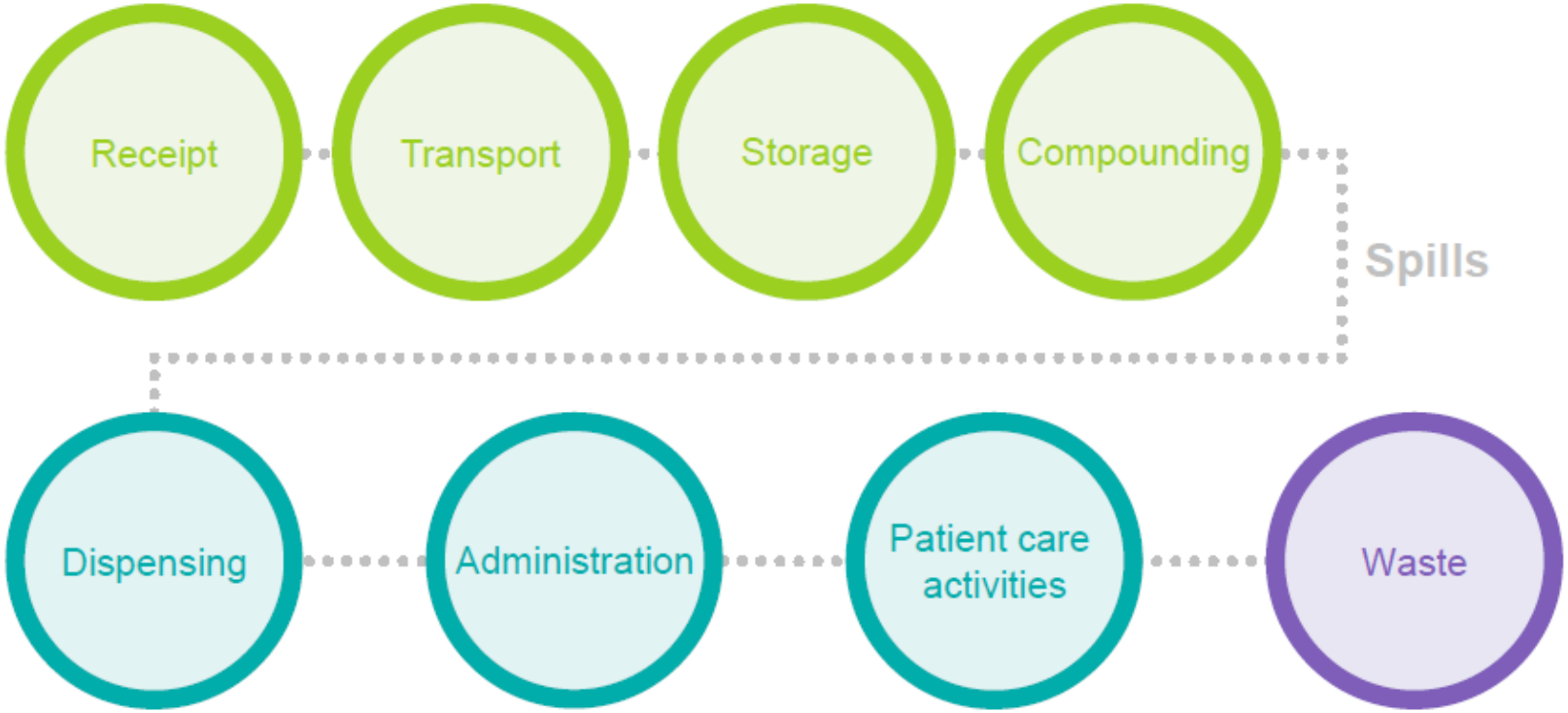
YES → Yellow Chemo Bin/Bag

NO → Regular Trash

If your department does not have the indicated waste container, consult pharmacy for disposal instructions

DRAFT

10. Elements of an Assessment of Risk (AoR)



Assessment of Risk (AoR)		
NIOSH Group 1,2, 3 Oral Solids		
Alternative Containment Strategies, if applicable		
HANDLING	**INPATIENT/AMBULATORY**	**RETAIL/SPECIALTY**
Receipt	Don 2 pair ASTM D6978 gloves; unpack using same procedure as nonhazardous drugs.	
Transport within Pharmacy	Don 1 pair ASTM D6978 gloves for intact pill, capsule, or tablet. Transport HazD in appropriate resealable clear plastic bag or bin to reduce risk of breakage and facilitate spill containment.	
Storage	NIOSH Group 1 Drugs shall be stored separately from non-HazDs, in resealable clear plastic bags or in bins identified by yellow (chemotherapy/cytotoxic) hazardous drugs labels or stickers. NIOSH Group 2 or 3 Drugs may be stored with non-HazDs, in resealable clear plastic bags or in bins identified by blue HazD labels or stickers. HazDs may be stored in automated dispensing machine as per OHS.PHARM.SOP.055 USP 800: Storage.	
Repackaging	Automated Repackaging equipment shall not be used for repackaging HazDs. Manually repackage in a designated area with dedicated equipment. Repacking in negative pressure room within a powder containment hood is preferred. Don 2 pair of ASTM D6978 gloves and appropriate fluid resistant, polyethylene coated spunbound fabric ASTM rated (F739-12, F1670, F1671) gown, such as a chemo gown. Don 1 pair white (polyethylene) shoe covers if entering Negative Pressure Room. Don an N95 respirator if in neutral pressure and/or not within a powder containment hood. If repackaging in a neutral pressure area, reasonable efforts should be made to minimize the production of powder/dust and aerosolization of any particulate, as well as any residual dust present in the tray. Only the number of tablets/pills/capsules necessary to accomplish the task should be emptied from the bottle into the tray. Deactivate, decontaminate, clean, and disinfect area and equipment after use and between HazDs by wiping twice with XXX and allow a 3-minute dwell time after the second wipe. Follow wiping with 70% Isopropyl Alcohol.	
Counting	Count in a designated area with dedicated equipment. Don 1 pair of ASTM D6978 gloves to count intact pills, capsules, or tablets. Don an N95 respirator if there is a reasonable risk of exposure to dust. Only the number of pills, capsules, or tablets necessary to accomplish this task should be emptied from the bottle onto the counting tray. Deactivate, decontaminate, clean, and disinfect area and equipment after use and between HazDs by wiping with XXX followed by 70% Isopropyl Alcohol.	
Splitting or crushing tablets	NIOSH Group 1 Drugs shall not be split or crushed outside of pharmacy.	

	The following may not be transported via pneumatic tube: NIOSH Group 1 Drugs, NIOSH Group 2 and 3 Drugs that have been manipulated into their final dosage form.	
Transport product to holding area for patient pick-up	N/A	Don 2 pair of ASTM D6978 gloves to transport HazDs unless transporting an intact pill, capsule, or tablet where only 1 pair of gloves is required. NIOSH Group 1 Drugs shall be transported in a resealable clear plastic bag with yellow (chemotherapy, cytotoxic) HazD labeling or sticker. NIOSH Group 2 or 3 Drugs shall be transported in a resealable clear plastic bag or bin with blue HazD labeling or stickers. The following may not be transported via pneumatic tube: NIOSH Group 1 Drugs, NIOSH Group 2 and 3 Drugs that have been manipulated into their final dosage form.
Storage waiting for patient pick-up	N/A	NIOSH Group 1 Drugs shall be stored in a resealable clear plastic bag with yellow (chemotherapy, cytotoxic) HazD labeling or sticker. NIOSH Group 2 or 3 Drugs shall be stored in a resealable clear plastic bag with blue HazD labeling or stickers. Use additional pharmacy paper bag if needed for delivery to patient.
Transport product to off-site administration area	Refer to OHS.PHARM.SOP.054 USP 800: Hazardous Drug (HazD) Transport	
Ship prescription to locations outside the entity	N/A	Ensure that labels and accessory labeling for the HazD include storage, disposal, and HazD category information in a format consistent with carrier's policies.
Preparation at Bedside	NIOSH Group 1 Drugs (capsules) should not be opened outside of pharmacy. Don 2 pair of ASTM D6978 gloves and N95 respirator. Deactivate, decontaminate, clean, and disinfect area after administration.	
Administration	Refer to Ochsner Health Hazardous Drug Handling PPE Guide.	N/A
Disposal	If handling NIOSH Group 1 Drugs, dispose of PPE in yellow RCRA waste container. If handling NIOSH Group 2 or 3 Drugs, dispose of PPE in regular trash.	

Review of Learning Objectives

- Upon completion of this educational session, the Pharmacist learner is now able to:
  - Describe changes to the 2024 NIOSH Hazardous Drug List
  - Describe the entity's minimum health and safety requirements for handling HDs
  - Develop alternative containment strategies necessary for an Assessment of Risk

- Upon completion of this presentation, the Pharmacy Technician learner is now able to:
  - Describe changes to the 2024 NIOSH Hazardous Drug List
  - Describe safe practices associated with handling hazardous drugs in compliance with USP <800>
  - Describe support processes that ensure compliance with USP <800> requirements for employee safety

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Question