STANDARD OPERATING PROCEDURE OVERVIEW	
SOP TITLE:	USP 800: Hazardous Drug (HazD) Compounding, Manipulation, and Repackaging
ISSUANCE DATE:	December 1, 2019
REVISION DATE:	DECEMBER 10, 2021
PROCESS OWNER:	System Pharmacy Operations
SOP NUMBER:	OHS.PHARM.SOP.056

BACKGROUND:

Engineering controls are required to protect the preparation form cross-contamination and microbial contamination if a preparation is intended to be sterile. Engineering controls consist of primary, secondary, and supplementary levels of control. A containment primary engineering control (C-PEC) is ventilated device designed to minimize worker and environmental HazD exposure when directly handling HazDs. The containment secondary engineering control (C-SEC) is the room in which the C-PED is placed. Supplemental engineering controls such as a closed-system drug-transfer device (CSTD) are adjunct controls to offer additional levels of protection. Personal Protective Equipment (PPE) also provides worker protection and reduces the risk of HazD exposure. This SOP is intended to establish standard procedures for sterile and non-sterile hazardous drug (HazD) preparations performed by pharmacy personnel.

NOTES (ASSUMPTIONS, EXCEPTIONS, ETC.):

- Sterile compounding of HazD will take place in a C-PEC within a C-SEC unless otherwise noted in an Assessment of Risk (AoR).
- Nonsterile HazD compounding will take place in a C-PEC within a C-SEC, preferentially separate from sterile preparations, unless otherwise noted in an AoR.
- All sterile HazD compounding shall be performed in compliance with USP Chapters <797> and <800>.
- All nonsterile HazD compounding shall be performed in compliance with USP Chapters <795> and <800>.

USP 800 SOPs:

- OHS.PHARM.SOP.038 – USP 800: Hazardous Drug (HazD) Receiving
- OHS.PHARM.SOP.050 – USP 800: Garbing for Hazardous Drug (HazD) Compounding and Manipulation
- OHS.PHARM.SOP.051 – USP 800: Hazardous Drug (HazD) Spill Management in Pharmacy
- OHS.PHARM.SOP.052 – USP 800: Hazardous Drug (HazD) Waste Management in Pharmacy
- OHS.PHARM.SOP.053 – USP 800: Hazardous Drug (HazD) Formulary Review and Assessment of Risk
- OHS.PHARM.SOP.054 – USP 800: Hazardous Drug (HazD) Transport
- OHS.PHARM.SOP.055 – USP 800: Hazardous Drug (HazD) Storage
- OHS.PHARM.SOP.056 – USP 800: Hazardous Drug (HazD) Compounding, Manipulation, and Repackaging
- OHS.PHARM.SOP.057 – USP 800: Hazardous Drug (HazD) Surface Wipe Analysis in Pharmacy
- OHS.PHARM.SOP.058 – USP 800: Designated Person
- OHS.PHARM.SOP.059 – USP 800: Supply List
- OHS.PHARM.SOP.060 – USP 800: Hazardous Drug (HazD) Crushing and Splitting
- OHS.PHARM.SOP.061 – USP 800: 3M Rugged Comfort-Quick Latch Half Facepiece Reusable Respirator 6500 QL Series
- OHS.PHARM.SOP.062 – USP 800: 3M Particulate Respirator R95
- OHS.PHARM.SOP.063 – USP 800: 3M Versaflo TR-600 Series Powered Air Purifying Respirators (PAPR)
- OHS.PHARM.SOP.014 – USP 795/797/800: Labeling of Compounded Sterile and Nonsterile Preparations
- OHS.PHARM.SOP.114 – USP 800: Cleaning and Disinfecting of the Hazardous Drug (HazD)Compounding Area
- OHS.PHARM.SOP.115 – USP 800: OnGuard™ Closed Medication System with TEVADAPTOR®

PROCESS STEP:	DESCRIPTION:
1. PPE	• Refer to OHS.PHARM.SOP.050 – USP 800: Garbing for Hazardous Drug (HazD) Compounding and Manipulation.
2. PRE-COMPOUNDING	• Upon receipt of a label for a HazD, personnel will select the appropriate: o medication o fluid o administration set • A disposable chemo prep pad may be used when compounding within a C-PEC (BSC/CACI), however, one must be used when compounding within a PEC (LFWB/CAI). • The medication and fluid should be scanned into Epic Dispense Prep or into BD Pyxis IV Prep to ensure that the correct fluid and medication are being used. • Tubing for HazD sterile products should be primed in the pharmacy with the primary fluid. Exceptions are as follows: o HazDs that, according to their AoR, do not have to be primed. o Titratable HazDs that should be primed with active drug.
3. DUAL VERIFICATION OF STERILE HAZD COMPOUNDED PREPARATIONS	• Cameras or gravimetric devices will be utilized for an independent second verification of the finished HazDs preparation. • In the absence of this technology or during technology downtime, the following items should be checked visually by a trained pharmacist who did not prepare the HazD: o Medication vial(s) o Appropriate concentrations for all dilutions and final products o Medication volume added to the bag o Diluent type and volume, if applicable o Tubing used for the preparation
4. CLOSED SYSTEM TRANSFER DEVICE (CSTD)	• CSTDs should be used when compounding HazDs and the dosage form allows. (refer to OHS.PHARM.SOP.115 OnGuard™ Closed Medication System with TEVADAPTOR®) Instructions for the OnGuard® CSTD OnGuard® CSTD for Pharmacy - YouTube
5. STERILE NIOSH GROUP 1 DRUGS	**Option 1:** • Perform sterile compounding in a C-PEC utilizing aseptic technique. • Don appropriate PPE for compounding sterile HazDs. (refer to OHS.PHARM.050 - USP 800: Garbing for Hazardous Drug (HazD) Compounding and Manipulation) • When the dosage form allows, a Closed System Transfer Device (CSTD) should be used. **Decontaminate finished product prior to removing from the C-PEC (Best Practice).** • At the conclusion of compounding/manipulation, doff the outer gloves inside of the C-PEC. • Place the gloves into a sealable receptacle or resealable clear plastic bag (located in the C-PEC) with yellow (chemotherapy, cytotoxic) HazD label or sticker. The receptable or resealable clear plastic bag will be disposed of as yellow trace RCRA waste. • Wipe the finished product with Peridox®RTU followed by sIPA and place on cleanest side of the C-PEC deck.

	• Wipe the inner gloved hands with Peridox®RTU prior removing finished product from the C-PEC. • Remove finished product from the C-PEC, label, and place into a resealable clear plastic bag with yellow (chemotherapy, cytotoxic) HazD labeling or sticker. • Prior to donning second pair of gloves, sanitize inner gloved hands by applying sterile 70% Isopropyl Alcohol (sIPA), rub gloved hands together, and allow to dry. **Option 2:** • Perform sterile compounding shall take place in a C-PEC utilizing aseptic technique. • Don appropriate PPE for compounding sterile HazDs. (refer to OHS.PHARM. USP 800: Garbing for Hazardous Drug (HazD) Compounding and Manipulation) • When the dosage form allows, a CSTD should be used. **Decontaminate finished product after removing from the C-PEC.** • At the conclusion of compounding/manipulation, doff the outer gloves inside of the C-PEC. • Place the gloves into a sealable receptacle or resealable clear plastic bag (located in the C-PEC) with yellow (chemotherapy, cytotoxic) HazD label or sticker. The receptable or resealable clear plastic bag will be disposed of as yellow trace RCRA waste. • Wipe the inner gloved hands with Peridox®RTU prior removing finished product from the C-PEC. • Remove finished product from the C-PEC and place on a disposable chemo prep pad. • Wipe the finished product with Peridox®RTU followed by sIPA and place on clean surface. • Wipe the inner gloved hands with Peridox®RTU. • Label finished product and place into a resealable clear plastic bag with yellow (chemotherapy, cytotoxic) HazD labeling or sticker. • Prior to donning second pair of gloves, sanitize inner gloved hands by applying sterile 70% Isopropyl Alcohol (sIPA), rub gloved hands together, and allow to dry. • **Note:** If the finished product is labeled prior to removing from the C-PEC, the finished product and label must be decontaminated prior to placing into a resealable clear plastic bag with yellow (chemotherapy, cytotoxic) HazD labeling or sticker.
6. STERILE NIOSH GROUPS 2 AND 3 DRUGS	• When available, sterile compounding shall take place in a C-PEC utilizing aseptic technique. • Don appropriate PPE for compounding sterile HazDs. (refer to OHS.PHARM. USP 800: Garbing for Hazardous Drug (HazD) Compounding and Manipulation) • CSTDs are not required for NIOSH Groups 2 and 3 sterile compounding. • In the absence of a C-PEC, Groups 2 and 3 sterile preparations may be compounded in a PEC, preferrable at the end of the shift, on a disposable chemo prep pad. Don same PPE as for NIOSH GROUP 1 sterile compounding with the addition of an N95 mask. • Remove finished product from the PEC and place on a disposable chemo prep pad. • Doff outer glove and discard in a yellow trace RCRA waste container • Wipe the finished product with Peridox®RTU followed by sIPA and place on clean surface. • Wipe the inner gloved hands with Peridox®RTU. • Label finished product and place into a resealable clear plastic bag with blue HazD labeling or sticker.

	• If additional compounds will be prepared, prior to donning second pair of gloves, sanitize inner gloved hands by applying sterile 70% Isopropyl Alcohol (sIPA), rub gloved hands together, and allow to dry.
	• If compounding is complete, the PEC and surrounding area shall be cleaned utilizing the following steps:
	  ○ Wipe with Peridox®RTU
	  ○ Wipe with Peridox®RTU (3-minute dwell time)
	  ○ Wipe with sIPS
	• Doff remaining PPE and discard in a yellow trace RCRA waste container.
	• If a spill occurs in a Positive Buffer Room, refer to OHS.PHARM.SOP.051 – USP 800: Hazardous Drug (HazD) Spill Management in Pharmacy, and follow procedure for Spill Cleanup Outside of the C-PEC and clean the Ante and Positive Buffer Rooms.

7. NONSTERILE NIOSH GROUP 1 DRUGS	• Nonsterile compounding and manipulation shall take place in a C-PEC.
	• A dedicated sterile C-PEC may be used in lieu of a dedicated nonsterile C-PEC but will require appropriate cleaning before sterile HazD manipulation may resume.
	• A C-PEC is not required for unit dose repackaging if the medication does not emit particles, aerosols, or gasses.
	• A C-SEC or neutral pressure room designated for nonsterile manipulation of HazDs may be used for repackaging of nonsterile HazD medications.
	• Don 2 pair of ASTM D6978 gloves, HazD (Chemo) gown, 1 pair white (polyethylene) shoe covers if in negative pressure room.
	• Don an N95 respirator and eye protection if there is a risk of spill or splash and not working within a C-PEC.
	• Automated prepackaging machines will not be used in the repackaging of HazD.
	• Utilize disposable or designated equipment for HazD compounding, such as mortars, pestles, or spatulas.
	• Upon completion of compounding and manipulation, clean the C-PEC, equipment, and surrounding area utilizing the following steps:
	  ○ Wipe with Peridox®RTU
	  ○ Wipe with Peridox®RTU (3-minute dwell time)
	  ○ Wipe with sIPS
	• Doff PPE and discard in yellow trace RCRA waste container
	• Wash hands with soap and water.

8. NONSTERILE NIOSH GROUP 2 AND 3 DRUGS	• If an AoR permits, compounding, manipulation, and repackaging can occur in a designated neutral pressure HazD handling area on a disposable chemo prep pad.
	• Don 2 pair of ASTM D6978 gloves, HazD (Chemo) gown, 1 pair white (polyethylene) shoe covers if in negative pressure room
	• Don an N95 respirator and eye protection if there is a risk of spill or splash and not working within a C-PEC.
	• Upon completion of compounding and manipulation, clean equipment and surrounding area utilizing the following steps:
	  ○ Wipe with Peridox®RTU
	  ○ Wipe with Peridox®RTU (3-minute dwell time)
	  ○ Wipe with sIPS
	• Doff PPE and discard in yellow trace RCRA waste container.

	• Wash hands with soap and water.

Approval

Deborah Simonson, VP Pharmacy 1-19-2022

Deborah Simonson, VP Pharmacy **Date**

Reviewer	Date of Review	Notes
DOP System Policy Committee	*11/11/21*	*Approved*
DOP	*12/10/21*	*Approved*