

STANDARD OPERATING PROCEDURE OVERVIEW	
SOP TITLE:	USP 800: Hazardous Drug (HazD) Storage
ISSUANCE DATE:	December 1, 2019
REVISION DATE:	January 20, 2022
PROCESS OWNER:	System Pharmacy Operations
SOP NUMBER:	OHS.PHARM.SOP.055

BACKGROUND:

Hazardous drugs (HazDs) must be stored under conditions that promote patient safety, worker safety, and environmental protection.

Access to areas where HazD are stored must be limited to authorized staff only and be marked with a sign indicating HazD, Authorized Personnel Only.

Drugs listed in the following NIOSH groups are considered hazardous drugs (HazD).

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.

Drugs on the NIOSH list that must follow the requirements of USP Chapter <800> include:

- Any HazD Active Pharmaceutical Ingredients (API)
- Any antineoplastic requiring HazD 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 HazD preparation and conventionally manufacturer HazD 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 HazD on the NIOSH list, the entity may perform an AoR to determine alternative containment strategies and/or work practices.

NOTES (ASSUMPTIONS, EXCEPTIONS, ETC.):

NIOSH Group 1 Drugs will be stored in resealable clear plastic bags or in bins identified by yellow (chemotherapy, cytotoxic) hazardous drugs labels or stickers.

NIOSH Group 2 or 3 Drugs will be stored in resealable clear plastic bags or in bins identified by blue HazD labels or stickers.

HazD Containment strategies:

- Bins, drawers, or containers used to routinely store HazDs 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.
- HazDs must not be stored directly on the floor.

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 Dispensing
- 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 – 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. NIOSH GROUP 1 STORAGE	<ul style="list-style-type: none"> • Don 2 pair of ASTM D6978 gloves to store HazDs unless handling an intact pill, capsule, or tablet where only 1 pair of gloves is required. • NIOSH Group 1 Drugs requiring manipulation other than counting or repackaging of the final dosage form and any Active Pharmaceutical Ingredients (API) shall be stored: <ul style="list-style-type: none"> ○ Separately from non-HazDs ○ In an externally vented, negative pressure room with at least 12 air changes per hour (ACPH). • NIOSH Group 1 Drugs that require refrigeration shall be stored: <ul style="list-style-type: none"> ○ Separately from non-HazDs

	<ul style="list-style-type: none"> ○ In a dedicated refrigerator ○ In an externally vented, negative pressure room with at least 12 ACHP. ● NIOSH Group 1 Drugs received in the manufacturer’s final dosage form or in a form that requires only counting or repackaging may be stored as follows: <ul style="list-style-type: none"> ○ Preferably in a negative pressure room ○ Preferably separate from non-HazDs ● NIOSH Group 1 Drugs shall be stored in a resealable clear plastic bag or bin with yellow (chemotherapy, cytotoxic) hazardous drug labeling or sticker. ● Upon completion, doff gloves and dispose of in yellow trace RCRA waste container. ● Wash hands with soap and water.
<p>2. NIOSH GROUPS 2 AND 3 STORAGE</p>	<ul style="list-style-type: none"> ● Don 2 pair of ASTM D6978 gloves to store HazDs unless handling an intact pill, capsule, or tablet where only 1 pair of gloves is required. ● NIOSH Group 2 and 3 Drugs may be stored with non-hazardous inventory. ● NIOSH Group 2 and 3 Drugs may be stored in pharmacy carousel. ● NIOSH Group 2 or 3 Drugs shall be stored in a resealable clear plastic bag or bin with blue HazD labeling or stickers. ● Upon completion, doff gloves and dispose of in regular trash. ● Wash hands with soap and water.
<p>3. STORAGE IN AUTOMATED DISPENSING CABINET (ADC)</p>	<ul style="list-style-type: none"> ● ADC in nursing or procedural areas may be used for storage of NIOSH Group 2 and 3 Drugs in their final dosage form. The HazD will be designated by a Pyxis CDC (Clinical Data Category). ● ADC storage bins shall be identified by yellow (chemotherapy, cytotoxic) hazardous drug or blue HazD labels or stickers. ● Offsite and non-24-hour pharmacies which use ADC for inventory management may apply special considerations for storage of NIOSH Group 1 Drugs in their final dosage form within ADC with approval from the site Director of Pharmacy and/or Pharmacy Designated Person.

Approval

Deborah Simonson VP Pharmacy

1-20-2022

Deborah Simonson, VP Pharmacy

Date

Reviewer	Date of Review	Notes
DOP System Policy Committee	8/19/21	Approved
DOP	11/10/21	Approved