

## North Carolina Board of Pharmacy

### Guidance on USP 800 Assessment of Risk and Other Educational Information

Board Staff has received several questions concerning compliance with USP<800> for non-compounding pharmacies who handle and dispense medications, designated as hazardous in the NIOSH Alert, in their final dosage form. The following information addresses identification of Hazardous Drugs, instructions on conducting an Assessment of Risk, and templates for non-compounding pharmacies to develop Standard Operating Procedures (SOPs) addressed in USP<800>. This informational material is for pharmacies that **DO NOT** compound with hazardous medications.

**Step 1: Download a copy of the NIOSH Alert 2016 and review USP 800 FAQ:**

[https://www.cdc.gov/niosh/topics/antineoplastic/.../hazardous-drugs-list\\_2016-161.pdf](https://www.cdc.gov/niosh/topics/antineoplastic/.../hazardous-drugs-list_2016-161.pdf)

<http://www.usp.org/frequently-asked-questions/hazardous-drugs-handling-healthcare-settings>

<https://www.usp.org/usp-chapter-800-download> (Currently available to download for free from USP)

**Step 2: Identify all Hazardous Drugs in stock**

- Identify other Hazardous Drugs that may not be on the NIOSH List.
- Develop a system of evaluating new drug inventory
- Hazardous Drug Risk Acknowledgement Form

**Step 3: Use the Assessment of Risk tool to evaluate the handling of Hazardous Drugs in your pharmacy during: (See attached Assessment of Risk Template and PPE/Mitigation Consideration information sheet).**

- Receiving
- Transportation
- Storage
- Dispensing
- Waste

**Step 4: Develop Policy and Procedures that address Handling and containment strategies for: (See the attached sample Policy and Procedure Templates)**

- Receipt of Hazardous Drugs
- Occupational Safety Program
- Storage of Hazardous Drugs

- Dedicated Hazardous Drug Area
- Hand Hygiene and Personal Protective Equipment based on activity
- Dispensing of Hazardous Medication
- Proper Disposal of Hazardous Drugs
- Deactivation, decontamination, cleaning, and disinfection
- Spill Control for Hazardous Drugs
- Hazard Communication

**Step 5: Develop a Pharmacy Specific Training Program for all Employees who handle HDs based on their job functions, and must include:**

- Overview of the Pharmacy's HD list and their risks
- Review of the Pharmacy's SOPs related to the handling of HDs
- Proper Use of PPE
- Proper Use of Equipment
- Response to known or suspected HD exposure
- Spill Management
- Proper Disposal of HDs and trace contaminated material

**USP Chapter <800> Hazardous Drug Finished Dosage Form Assessment of Risk Template**

Generic Drug Name: \_\_\_\_\_ Date Assessed: \_\_\_\_\_

Finished Dosage Form: (Circle one)

Tablet   
  Capsule   
  Oral Liquid   
  Topical   
  Inhalation   
  Irrigation   
  Suppository   
  Transdermal   
  Not Applicable

Assessor: \_\_\_\_\_ Referenced SOP(s): \_\_\_\_\_

**Note: This assessment must be performed for each separate dosage form for each drug listed on the NIOSH Lists of Hazardous Drugs.**

1. Find the drug to be assessed on the [NIOSH List of Hazardous Drugs](#).
2. Is the drug listed in NIOSH Table 2 or 3? (Circle one, If choose “no”, skip to Question 5) **YES**      **NO**
3. Will this finished dosage form require further manipulation beyond repackaging for dispensing? (e.g. tablets split or crushed, capsules opened, liquids or injections diluted, or used as an ingredient in a compound). (circle one) **YES**      **NO**      **NOT APPLICABLE**
4. Will this finished dosage form be handled by vulnerable healthcare workers (e.g. personnel with reproductive capability, pregnant or lactating women, employees trying to conceive, immunosuppressed employees, etc.)? (circle one) **YES**      **NO**      **NOT APPLICABLE**

**Action required based on response to questions above for drugs listed in NIOSH Tables 2 and 3:**

<b>Question 3 Response</b>	<b>Y</b>	<b>Y</b>	<b>N</b>	<b>N</b>
<b>Question 4 Response</b>	<b>Y</b>	<b>N</b>	<b>Y</b>	<b>N</b>
<b>Actions Required:</b>	<b>Follow ALL &lt;800&gt; strategies</b>	<b>SOP and suggested mitigation strategies</b>	<b>SOP and suggested mitigation strategies</b>	<b>Consider suggested mitigation strategies</b>

5. Is the drug listed in NIOSH Table 1? (Circle one, If “no” to this Question and “no” to Question 2 above, skip to Question 8 below) **YES**      **NO**
6. Will this finished dosage form require further manipulation beyond repackaging for dispensing? (e.g. tablets split or crushed, capsules opened, liquids or injections diluted, or used as an ingredient in a compound). (Circle one) **YES**      **NO**
7. Will this finished dosage form be handled by vulnerable healthcare workers (e.g. personnel with reproductive capability, pregnant or lactating women, employees trying to conceive, immunosuppressed employees, etc.)? (Circle one) **YES**      **NO**

**Action required based on response to questions above for drugs listed in NIOSH Table 1:**

<b>Question 6 Response</b>	<b>Y</b>	<b>Y</b>	<b>N</b>	<b>N</b>
<b>Question 7 Response</b>	<b>Y</b>	<b>N</b>	<b>Y</b>	<b>N</b>
<b>Actions Required:</b>	<b>Follow ALL &lt;800&gt; strategies</b>	<b>Follow ALL &lt;800&gt; strategies</b>	<b>SOP and suggested mitigation strategies</b>	<b>Consider suggested mitigation strategies</b>

8. Is the drug not listed on the NIOSH Tables but is similar to a drug listed in the NIOSH? (Circle one) **YES**      **NO**  
 If yes, repeat steps 2-7 to assess risk.

**USP 800 PPE & Mitigation Considerations for Non-Compounding Pharmacies**

The following chart provides general guidelines and considerations to protect staff in a non-compounding pharmacy setting. The pharmacy should complete an Assessment of Risk (AOR) based on the individual needs of the facility.

<b>Dosage Form</b>	<b>Applicable NIOSH Table(s)</b>	<b>Activity or Manipulation</b>	<b>Double Chemotherapy Gloves</b>	<b>Gown</b>	<b>Mask</b>	<b>Eye Protection</b>	<b>Separate Area, Separate Tray &amp; Spatula, or Mitigation SOP based on AOR</b>
All unopened containers for HDs	All tables (1, 2, 3)	Receiving, Unpacking, Stocking shelves, Returning Over-stocked product	No (Single gloves may be used. <b>Use Double gloves when spills occur.</b> )	Spills only	Spills only	Spills only	NA
<b>Intact</b> tablets & capsules	All tables	Counting & placing in patient vial	No (Single gloves may be used.)	No	No	No	Yes
Tablets & Capsules	All tables	Crushing, Splitting, Opening, Uncoated tablets that produce powdered residue	Yes	Yes	Yes	No	Yes
Tablets & Capsules	Compounding with tablets or capsules – <b>Compounding requires full USP 800 compliance.</b>						
Commercially Available <b>Antineoplastic</b> Oral Liquids	1	Pouring (into patient vial)	Yes	Yes	Yes	Yes	Yes
Commercially Available <b>Non-Antineoplastic</b> Oral Liquids	2, 3	Pouring (into patient vial)	Yes	No	No	No	Yes
Oral Reconstitution Powders	2,3	Reconstitution	Yes	Yes	Yes	Yes	Yes

## USP 800 PPE & Mitigation Considerations for Non-Compounding Pharmacies

The following chart provides general guidelines and considerations to protect staff in a non-compounding pharmacy setting. The pharmacy should complete an Assessment of Risk (AOR) based on the individual needs of the facility.

Commercially Available Topical Cream or Ointment	All tables	Dispensing in manufacturer's container	Yes	No	No	No	Yes
Commercially Available Topical Cream or Ointment	Compounding with a commercially available topical cream or ointment – <b>Compounding requires full USP 800 compliance.</b>						
<b>Continued on Next Page</b>							
<b>Dosage Form</b>	<b>Applicable NIOSH Table(s)</b>	<b>Activity or Manipulation</b>	<b>Double Chemotherapy Gloves</b>	<b>Gown</b>	<b>Mask</b>	<b>Eye Protection</b>	<b>Separate Area, Separate Tray &amp; Spatula, or Mitigation SOP</b>
Injectable Products (Sub Q/IM) (Ex: Testosterone Cypionate or Medroxyprogesterone Acetate)	All tables	Dispensing Commercially available vials/containers	No (Single gloves may be used.)	No	No	No	Yes
All Dosage Forms	All tables	Spills & Waste associated w/ HD product(s)	Yes	Yes	Yes (if products present inhalation potential)	Yes (if splash potential is present)	NA – Use HD disposal bin
All Dosage Forms	All tables	Cleaning	Yes	Yes	Yes (if products present inhalation potential)	Yes (if splash potential is present)	NA

### **Additional Considerations:**

Always consult the manufacturer's safe handling guidelines for the product(s) in question.

Purchase items such as unit-dose packaging that do not require handling unpackaged product.

Discontinue stocking product(s) if mitigation strategies/alternative purchasing options are not feasible for the facility.

Hazardous Drug Risk Acknowledgement Form

Employee: \_\_\_\_\_

I understand **Sample Pharmacy** receives and dispenses drugs determined hazardous by the NIOSH List, USP<800>, and OSHA.

I understand that working with, or near, hazardous drugs in a pharmacy setting may cause cancers, birth defects, miscarriage, infertility, and skin irritations.

**Sample Pharmacy** has implemented best practice methodologies for receiving, storage, handling, and disposal of hazardous drugs to reduce occupational exposure to hazardous drugs. **Sample Pharmacy** will continue to revise and update methodologies to reflect appropriate standards of care.

I agree to immediately contact my Pharmacy Manager, or direct supervisor should I have any questions or concerns pertaining to handling of Hazardous Drugs.

I understand failure to follow best practice methodologies may put me at risk of exposure to hazardous drugs, and may lead to adverse effects such as cancers, birth defects, miscarriage, infertility, and skin irritations.

\_\_\_\_\_  
Employee Signature

\_\_\_\_\_  
Date

# NCBOP SAMPLE PHARMACY POLICY AND PROCEDURE

## Internal Document – USP<800> Workgroup – Not for Distribution

Document Number: 4  
Document Name: Receipt of HD Medications  
Effective Date: July 1, 2018

### 1.0 Purpose

The receipt of HD medications represent a potential risk of exposure for employees through contact with outer containers, storage containers and individual dosage units. Employees receiving HD medications should so wearing one (1) pair of ASTM D6978 rated gloves unless a spill has occurred (See Table 5 of NIOSH 2016 and Table 4 of USP 800). All shipping containers must be checked for damage upon receipt, and a spill kit should be present in the receiving area. Employees involved in receiving HD medications should be trained in spill control, decontamination, cleaning, and disposal of HD waste

### 2.0 Policy Details

(Describe, specifically, policy implementation in pharmacy operations)

All Employees of (PHARMACY NAME HERE) must participate in annual training/review of proper response to HD spills while receiving medications. Proficiency in following proper procedures in accordance pharmacy SOPs must be demonstrated by pharmacy staff. Annual training will be observed, and documented, by the Designated Person. Documentation will be kept on file in the pharmacy in accordance with all state and federal requirements.

### 3.0 Reference Documents/Related Policies

List all documents, articles etc. referenced to create this SOP, and other pharmacy SOPs used in conjunction with this one.

*e.g. NIOSH [2016]. NIOSH list of antineoplastic and other hazardous drugs in healthcare settings, 2016. By Connor TH, MacKenzie BA, DeBord DG, Trout DB, O'Callaghan JP. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication Number 2016-161 (Supersedes 2014-138).*

### 4.0 Documentation

List documents the pharmacy staff needs to have completed in order to show compliance with this SOP.

*e.g. Signed Observational Checklist showing employee demonstrated competency in cleaning an HD spill during receipt of HD medications*

Last Modified By: Enter Text  
Document Owner: Enter Text

Last Modified On: Select Date  
Original Date: Select Date

Page: 1

**NCBOP SAMPLE PHARMACY POLICY AND PROCEDURE**  
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## 5.0 Document History

List a summary of changes made to the SOP since creation. Include the date, section changed, and type of change made.

*e.g. August 2017 - Section 4.0 – Several typos corrected*

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Last Modified On: Select Date  
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Page: 2



# NCBOP SAMPLE PHARMACY POLICY AND PROCEDURE

## Internal Document – USP<800> Workgroup – Not for Distribution

Document Number: 2  
Document Name: Occupational Safety Program  
Effective Date: July 1, 2018

### 1.0 Purpose

The Occupational Safety Program ensures employee safety while working with, and around, Hazardous Drugs (HDs), within the pharmacy setting, and in an emergent situation, such as a spill or broken bottle. All employees must receive training, and demonstrate competency, based on their job functions, before independently handling HDs. Employee competency will be reassessed annually. Employees must be aware of potential opportunities for exposure to HDs in their daily tasks, and demonstrate competency in the use of pharmacy equipment designated for use with HDs. The Designated Person will be responsible for observing and documenting competencies.

### 2.0 Policy Details

(Describe, specifically, policy implementation in pharmacy operations)

All Employees of (PHARMACY NAME HERE) must participate in training and competency assessment prior to independently handling HDs. In addition, employees must participate in training prior to the introduction of a new HD, new equipment, and prior to a significant change in pharmacy work practice or SOP. Review of proper response to HD spills while receiving medications. Proficiency in following proper procedures in accordance pharmacy SOPs must be demonstrated by pharmacy staff. All training will be observed, and documented, by the Designated Person. Documentation will be kept on file in the pharmacy in accordance with all state and federal requirements.

### 3.0 Reference Documents/Related Policies

List all documents, articles etc. referenced to create this SOP, and other pharmacy SOPs used in conjunction with this one.

*e.g USP<800> Section 7 – Personal Protective Equipment*

### 4.0 Documentation

List documents the pharmacy staff needs to have completed in order to show compliance with this SOP.

Last Modified By: Enter Text  
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Last Modified On: Select Date  
Original Date: Select Date

Page: 1

## NCBOP SAMPLE PHARMACY POLICY AND PROCEDURE

### Internal Document – USP<800> Workgroup – Not for Distribution

*e.g. Training Records for all Employees Receiving HD Spill Response Training and observational checklists*

## 5.0 Document History

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*e.g. August 2017 - Section 4.0 - Several typos corrected*

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Last Modified On: Select Date  
Original Date: Select Date

Page: 2

# NCBOP SAMPLE PHARMACY POLICY AND PROCEDURE

## Internal Document – USP<800> Workgroup – Not for Distribution

Document Number: 5  
Document Name: Storage of HD Medications  
Effective Date: July 1, 2018

### 1.0 Purpose

Non-antineoplastic, reproductive risk only, and final dosage forms of antineoplastic HD Medications may be stored with other inventory if existing pharmacy policy does not dictate otherwise. All HD medications must be clearly labelled with the identity of the medication and appropriate hazard warnings.

### 2.0 Policy Details

(Describe, specifically, policy implementation in pharmacy operations)  
All Employees of (PHARMACY NAME HERE) must participate in annual training/review of identification and storage of HDs in accordance with USP 800, the NIOSH List, and Pharmacy SOPs. Proficiency in following proper procedures in accordance pharmacy SOPs must be demonstrated by pharmacy staff. Annual training will be observed, and documented, by the Designated Person. Documentation will be kept on file in the pharmacy in accordance with all state and federal requirements.

### 3.0 Reference Documents/Related Policies

List all documents, articles etc. referenced to create this SOP, and other pharmacy SOPs used in conjunction with this one.

*e.g. USP<800> - Section 5.2 - Storage*

### 4.0 Documentation

List documents the pharmacy staff needs to have completed in order to show compliance with this SOP.

*e.g. Signed Training records for proper identification of HD medications*

### 5.0 Document History

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*e.g. August 2017 - Section 4.0 – Several typos corrected*

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Original Date: Select Date

Page: 1

# NCBOP SAMPLE PHARMACY POLICY AND PROCEDURE

## Internal Document – USP<800> Workgroup – Not for Distribution

Document Number: 3  
Document Name: Designation of HD Areas  
Effective Date: July 1, 2018

### 1.0 Purpose

The designation of HD areas within a retail pharmacy setting is limited to an area where final dosage forms are counted, repackaged, and labeled. To protect employees and prevent cross contamination, the HD area should be clearly marked, have dedicated equipment for use within the HD area, and have a procedure for decontamination and cleaning.

### 2.0 Policy Details

(Describe, specifically, policy implementation in pharmacy operations)

All Employees of (PHARMACY NAME HERE) must participate in annual training/review of cleaning and decontamination of the HD area and HD designated equipment. Proficiency in following proper procedures in accordance pharmacy SOPs must be demonstrated by pharmacy staff. Annual training will be observed, and documented, by the Designated Person. Documentation will be kept on file in the pharmacy in accordance with all state and federal requirements.

### 3.0 Reference Documents/Related Policies

List all documents, articles etc. referenced to create this SOP, and other pharmacy SOPs used in conjunction with this one.

*e.g. USP<800> Section 12 – Dispensing Final Dosage Forms*

### 4.0 Documentation

List documents the pharmacy staff needs to have completed in order to show compliance with this SOP.

*e.g. Signed Observational Checklist showing employee was observed working within, decontaminating, and cleaning the HD area, and all equipment designated for use with HDs, in accordance with pharmacy SOPs.*

### 5.0 Document History

Last Modified By: Enter Text  
Document Owner: Enter Text

Last Modified On: Select Date  
Original Date: Select Date

Page: 1

## NCBOP SAMPLE PHARMACY POLICY AND PROCEDURE

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*e.g. August 2017 - Section 4.0 – Several typos corrected*

Last Modified By: Enter Text  
Document Owner: Enter Text

Last Modified On: Select Date  
Original Date: Select Date

Page: 2

**NCBOP SAMPLE PHARMACY POLICY AND PROCEDURE**  
**Internal Document – USP<800> Workgroup – Not for Distribution**

Document Number:	1
Document Name:	Hand Hygiene and Personal Protective Equipment (PPE)
Effective Date:	July 1, 2017

## 1.0 Purpose

**Describe the purpose for the policy and rationale for its implementation.**

*e.g. To establish the appropriate measures required to complete hand hygiene and identify personal protective equipment (PPE) necessary to protect facility personnel while handling hazardous drugs (HDs).*

## 2.0 Policy Details

**(Describe, specifically, policy implementation in pharmacy operations)**

*e.g. All employees of pharmacy (INSERT PHARMACY NAME HERE) that handle HDs or compound using HDs must demonstrate proper hand hygiene and use of PPE.*

*The employee must wash hands thoroughly using a facility approved soap and water prior to donning necessary PPE.*

*Gloves must be worn when handling HDs or touching surfaces that may be contaminated with HD residue (e.g. HD containers, HD counting equipment, shipping totes, etc.). Note the type(s) of gloves to be used by employees and indicate instances in which more than one pair may be necessary.*

*Gowns must be worn to protect the employee from splashes of HDs and HD waste. Specify gown & specific garbing considerations.*

*Eye and Face protection must be worn when the HD has the potential to splash into the eyes of the employee (e.g. compounding or cleaning a spill). Describe the items that should be used within the pharmacy and note garbing considerations.*

*All PPE worn while handling HDs or HD waste must be considered “contaminated” therefore disposable PPE must be contained and disposed of according the Hazardous Drug Disposal policy.*

*All employees must wash hands thoroughly using a facility approved soap and water after handling HDs, HD waste, or contaminated PPE.*

Last Modified By:	Enter Text
Document Owner:	Enter Text

Last Modified On:	Select Date
Original Date:	Select Date

Page:	1
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**NCBOP SAMPLE PHARMACY POLICY AND PROCEDURE**  
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### 3.0 Reference Documents/ Policies

Reference all documents, articles, and policies used to create this policy.  
*e.g. Hazardous Drug Disposal Policy, USP <800>, etc.*

### 4.0 Documentation

If specific documentation is required, list it here and indicate specific forms that must be completed to demonstrate compliance with this SOP. Reference applicable policies as necessary.

### 5.0 Document History

Provide a list of changes made to the policy since its implementation. Include the date, section changed, and detail of changes made.

Last Modified By: Enter Text  
Document Owner: Enter Text

Last Modified On: Select Date  
Original Date: Select Date

Page: 2

# NCBOP SAMPLE PHARMACY POLICY AND PROCEDURE

## Internal Document – USP<800> Workgroup – Not for Distribution

Document Number: 1  
Document Name: Dispensing Hazardous Drugs  
Effective Date: July 1, 2017

### 1.0 Purpose

**Describe the purpose for the policy and rationale for its implementation.**

*e.g. Hazardous Drugs (HDs) may pose serious health risks to employees that handle them regularly. The following policy details appropriate handling measures when dispensing HDs.*

### 2.0 Policy Details

**(Describe, specifically, policy implementation in pharmacy operations)**

*e.g. All HDs identified in (INSERT PHARMACY NAME HERE) must be counted, or measured within the designated HD area. Employees that count or measure HDs must don the appropriate personal protective equipment (PPE) as identified by the drug Assessment of Risk and Hand Hygiene and Personal Protective Equipment policy. Once counted or measured, the HD must be appropriately labeled with a pharmacy label. The designated HD area must be decontaminated after every use as described in the Deactivation Decontamination and Cleaning Policy. Should any spills occur, consult the Hazardous Drug Spill policy.*

### 3.0 Related Documents/ Policies

**Reference all documents, articles, and policies used to create this policy.**

*e.g. Hand Hygiene and Personal Protective Equipment; Deactivation, Decontamination, and Cleaning; Hazardous Drug Disposal, etc.*

### 4.0 Documentation

**Indicate specific forms that must be completed to demonstrate compliance with this SOP. Reference other applicable policies as necessary.**

Last Modified By: Enter Text  
Document Owner: Enter Text

Last Modified On: Select Date  
Original Date: Select Date

Page: 1



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## 5.0 Document History

Provide a list of changes made to the policy since its implementation. Include the date, section changed, and detail of changes made.

Last Modified By: Enter Text  
Document Owner: Enter Text

Last Modified On: Select Date  
Original Date: Select Date

Page: 2

# NCBOP SAMPLE PHARMACY POLICY AND PROCEDURE

## Internal Document – USP<800> Workgroup – Not for Distribution

Document Number: 1  
Document Name: Hazardous Drug Disposal  
Effective Date: July 1, 2017

### 1.0 Purpose

**Describe the purpose for the policy and rationale for its implementation.**

*e.g. Appropriate safety measures must be used to protect the employee from Hazardous Drugs (HDs), their waste, and trace contamination on equipment and personal protective equipment (PPE). The following policy details measures to be taken when disposing of HDs, their waste, and supplies which are presumed to have trace contamination.*

### 2.0 Policy Details

**(Describe, specifically, policy implementation in pharmacy operations)**

*e.g. All employees of (PHARMACY NAME HERE) that dispose of HDs, HD waste, or materials presumed to have trace contamination (e.g. cleaning materials and contaminated PPE) must wear appropriate PPE according to the Hand Hygiene and Personal Protective Equipment policy. Hazardous drugs must be placed in the waste bin labeled “\_\_\_\_\_”. Trace waste and contaminated PPE must be placed in the disposal bin labeled “\_\_\_\_\_”. Do not over-fill or force waste items into a bin. Include routine waste pick-up information in this policy as needed.*

### 3.0 Related Documents/Policies

**Reference all documents, articles, and facility policies used to create this policy.**

*e.g. Hand Hygiene and Personal Protective Equipment; USP <800>,*

### 4.0 Documentation

**Indicate specific forms that must be completed to demonstrate compliance with this SOP. Reference other applicable policies as necessary.**

Last Modified By: Enter Text  
Document Owner: Enter Text

Last Modified On: Select Date  
Original Date: Select Date

Page: 1

**NCBOP SAMPLE PHARMACY POLICY AND PROCEDURE**  
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Last Modified By: Enter Text  
Document Owner: Enter Text

Last Modified On: Select Date  
Original Date: Select Date

Page: 2

**NCBOP SAMPLE PHARMACY POLICY AND PROCEDURE**  
**Internal Document – USP<800> Workgroup – Not for Distribution**

Document Number:	1
Document Name:	Hazardous Drug Deactivation, Decontamination, and Cleaning
Effective Date:	July 1, 2017

## 1.0 Purpose

**Describe the purpose for the policy and rationale for its implementation.**

*e.g. Hazardous Drugs (HDs) in the workplace may pose significant risks to the health of employees that handle them regularly. The following policy details appropriate cleaning measures for areas and equipment used when handling HDs.*

## 2.0 Policy Details

**(Describe, specifically, policy implementation in pharmacy operations)**

*Deactivation measures render a HD or its residue(s) inactive. Decontamination removes a HD or its residue(s) from a contaminated surface. Cleaning removes other contaminants from the surface, (e.g. organic and inorganic contaminants).*

*All areas and reusable equipment used when handling HDs must be deactivated, decontaminated, decontaminated, and cleaned after handling is complete. Appropriate personal protective equipment (PPE) must be worn during deactivation, decontamination, and cleaning activities according policy.*

**Step 1.** *Deactivate the contaminated surface. Apply a deactivating agent to a disposable wipe (or pre-saturated wipe) and apply thoroughly to all surfaces to be deactivated. Deactivating agents typically include, but are not limited to EPA-registered oxidizing agents.*

**Step 2.** *Decontaminate affected surface(s). Decontamination agents may include, but are not limited to peroxide and sodium hypochlorite.*

**Step 3.** *Clean the affected surfaces with a facility approved germicidal detergent to remove contaminants other than HD residue(s).*

*Discard disposable supplies and PPE according to the Hazardous Drug Disposal Policy.*

## 3.0 Related Documents/ Policies

**Reference all documents, articles, and policies used to create this policy.**

*e.g. Hand Hygiene and Personal Protective Equipment, Hazardous Drug Disposal, etc.*

Last Modified By:	Enter Text
Document Owner:	Enter Text

Last Modified On:	Select Date
Original Date:	Select Date

Page:	1
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**Internal Document – USP<800> Workgroup – Not for Distribution**

## 4.0 Documentation

Indicate specific forms that must be completed to demonstrate compliance with this SOP. Reference other applicable policies as necessary.

## 5.0 Document History

Provide a list of changes made to the policy since its implementation. Include the date, section changed, and detail of changes made.

Last Modified By: Enter Text  
Document Owner: Enter Text

Last Modified On: Select Date  
Original Date: Select Date

Page: 2

# NCBOP SAMPLE PHARMACY POLICY AND PROCEDURE

## Internal Document – USP<800> Workgroup – Not for Distribution

Document Number: 1  
Document Name: Hazardous Drug Spill  
Effective Date: July 1, 2017

### 1.0 Purpose

**Describe the purpose for the policy and rationale for its implementation.**

*e.g. Hazardous Drugs (HDs) may pose serious health risks to employees that handle them. The following policy details appropriate measures to safely contain and clean spills of HDs.*

### 2.0 Policy Details

**(Describe, specifically, policy implementation in pharmacy operations)**

*All HDs must be stored off of the floor in an organized manner such that shelves do not become cluttered and create a risk for spills. In the event of a spill, use the following measures to contain, deactivate, decontaminate, and clean the affected area(s).*

*All HD spills must be contained and cleaned immediately. Prior to containing and cleaning a spill, the employee(s) must don appropriate personal protective equipment (PPE) as determined by the Assessment of Risk (AOR) and Hand Hygiene and Personal Protective Equipment policy. Obtain a spill kit, which contains all supplies that may be required to contain and manage a HD spill (include a list of supplies). (Include the location of the spill kit.)*

*Provide spill containment and cleaning measures, for dosage forms used by the pharmacy (e.g. uncoated tablets, liquids, etc.). If the Assessment of Risk (AOR) identifies a unique risk posed by a specific drug, reference the AOR as well as the Deactivation, Decontamination, and Cleaning policy.*

### 3.0 Related Documents/ Policies

**Reference all documents, articles, and policies used to create this policy.**

*e.g. USP Chapter <800>, Hand Hygiene and Personal Protective Equipment; Deactivation, Decontamination, and Cleaning; Hazardous Drug Disposal, etc.*

Last Modified By: Enter Text  
Document Owner: Enter Text

Last Modified On: Select Date  
Original Date: Select Date

Page: 1

**NCBOP SAMPLE PHARMACY POLICY AND PROCEDURE**  
**Internal Document – USP<800> Workgroup – Not for Distribution**

## 4.0 Documentation

Indicate specific forms that must be completed to demonstrate compliance with this SOP. Reference other applicable policies as necessary.

## 5.0 Document History

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Last Modified By: Enter Text  
Document Owner: Enter Text

Last Modified On: Select Date  
Original Date: Select Date

Page: 2

# NCBOP SAMPLE PHARMACY POLICY AND PROCEDURE

## Internal Document – USP<800> Workgroup – Not for Distribution

Document Number: 1  
Document Name: Hazard Communication Program  
Effective Date: July 1, 2018

### 1.0 Purpose

The Hazard Communication Program is designed to ensure employee safety during all phases of Hazardous Drug (HD) handling. Employees must receive training in proper labelling, transport, storage and disposal of HDs, and use of Safety Data Sheets (SDS). Employees of reproductive capability must confirm, in writing, that they understand the risks of handling HDs.

### 2.0 Policy Details

(Describe, specifically, policy implementation in pharmacy operations)

All Employees of (PHARMACY NAME HERE) must participate in annual training/review of the NIOSH List and all SDS kept on file in the pharmacy pertaining to HDs. Employees of reproductive capacity must confirm in writing that they understand the risks of handling HDs. Proficiency in following proper procedures in accordance pharmacy SOPs must be demonstrated by pharmacy staff. Annual training will be observed, and documented, by the Designated Person. Documentation will be kept on file in the pharmacy in accordance with all state and federal requirements.

### 3.0 Reference Documents/Related Policies

List all documents, articles etc. referenced to create this SOP, and other pharmacy SOPs used in conjunction with this one.

*e.g. USP<800> Section 8 – Hazard Communication Program*

### 4.0 Documentation

List documents the pharmacy staff needs to have completed in order to show compliance with this SOP.

*e.g. Signed Acknowledgment of Risk for employees of reproductive age*

### 5.0 Document History

Last Modified By: Enter Text  
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Last Modified On: Select Date  
Original Date: Select Date

Page: 1



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List a summary of changes made to the SOP since creation. Include the date, section changed, and type of change made.

*e.g. August 2017 - Section 4.0 – Several typos corrected*

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Page: 2