1. **Purpose** 
   1. The purpose of this SOP is to establish minimum safety standards and requirements for management of Hazardous Drugs (HD) spills
2. **Responsibility** 
   1. It is the responsibility of the Designated Person to ensure this procedure meets local, state, and federal regulations as required
   2. It is the responsibility of the Designated Person to ensure all staff that encounter HD are trained on and adhere to this SOP should a spill occur
3. **Scope** 
   1. This SOP applies to all personnel who respond to a HD spill
4. **References** 
   1. USP General Chapter <800> – Hazardous Drugs – Handling in Healthcare Settings, published in the May 31, 2019 USP Committee Revision Bulletin
5. **Acronyms & Definitions** 
   1. HD – Hazardous Drugs - The National Institute for Occupations Safety and Health (NIOSH) considers a drug to be hazardous if it exhibits one or more of the following properties in humans or animals; carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity, organ toxicity at low doses, genotoxicity, or structure and toxicity profiles of new drugs that mimic existing hazardous drugs
   2. USP – United States Pharmacopeia
   3. Designated Person – A trained and qualified person designated by [company] to be responsible for developing and implementing appropriate HD procedures, overseeing entity compliance with local, state and federal HD regulations, ensuring personnel HD competency, and ensuring environmental control of HD storage and handling areas
6. **Frequency** 
   1. This procedure must be followed for all HD spills at [company]
7. **General Information**
   1. Care must always be taken to avoid spills an accidental exposure to HD
   2. Always:
      1. Where appropriate PPE when handling HD
      2. Tightly close all open HD containers
      3. Do not open more HD containers than necessary
      4. Store HD according to company policy and procedure
         1. Off the ground, on shelving units/ in cabinets of appropriate material with raised edges
      5. Dispose of HD material (i.e. used garb, disposable equipment & devices, used spill kits, HD waste, etc.) in appropriate HD waste disposal areas and in accordance with all local, state, and Federal regulations
8. **Procedure** 
   1. Personnel trained and qualified to clean HD spills must be available while HDs are being handled
   2. Spills must be contained and cleaned immediately only by qualified personnel wearing appropriate PPE.
      1. Signs must be available for restricting access to the spill area and should be displayed immediately upon notice of a spill
   3. PPE for cleaning spills may vary depending on the type and severity of the spills.
      * 1. For spills larger than what a spill kit can contain, additional precautions may need to be taken
      1. PPE for spill control may include:
         1. Respiratory protection
         2. N95 or better NIOSH certified respirators
         3. Elastomeric half masks with P100 cartridges
         4. Full facepiece with chemical cartridge respirators
         5. Eye and face protection
         6. Two pairs of chemotherapy gloves
         7. Impermeable gown with back closure and long sleeves
         8. Head, hair, shoe and sleeve covers
   4. All spill clean up materials must be disposed of in appropriate HD waste receptacles. All HD waste must be disposed of in accordance with local, state and federal regulations
   5. Spill areas must be immediately deactivated, decontaminated, cleaned, and disinfected (as appropriate) once spill cleanup is complete
   6. Spills must be immediately reported to the Designated Person
      1. The Designated person must document the circumstance of the spill and spill cleanup
   7. Spill kits containing all materials needed to clean HD spills are readily available in all areas where HDs are routinely handled and/ or stored
      1. Spill kits for [HD type(s) and size(s)] are located [list locations]

^ enter based on spill kits purchased

* + - 1. For spills larger than [max spill size], contact the Designated Person
  1. If HDs are being prepared or administered in a non-routine healthcare area (i.e. patient home), a spill kit and respirator must be available

1. **Training Requirements** 
   1. Personnel must be trained on this procedure:
      1. Prior to HD exposure/ spill cleanup,
      2. Every 12 months,
      3. Each time there is a significant change to this procedure,
      4. In response to an accidental exposure of HD during spill cleanup that resulted in documented changes in employee health, and
      5. Any other time deemed necessary by the Designated Person

1. **Attachments** 
   1. N/A
2. **History**

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| SOP: *XX.XX:* - RETAIL - Hazardous Drugs; Spill Control | | |
| Date Approved | Version Number | Revision Summary |
| XX/XX/XXXX | 1 | N/A – Origination |
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