Community Pharmacy

Hazardous Drug Program Guide

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Introduction

The intent of this guide is to provide employers who have “reasonably anticipated exposure” to hazardous drugs, an easy-to-use format for developing a comprehensive Hazardous Drug Control Program (HDCP). Each employer will need to customize their HDCP for their specific use, work tasks, and workplace.

This guide is not a standard or regulation, creates no new legal obligations, and does not change any existing standard or regulation. The guide is advisory in nature, is informational in content, and is intended to assist employers in providing a safe and healthful workplace.
Section I: How to Use This Guide

This guide is divided into three sections and two appendices. The first section provides information on how to use this guide. The second section provides guidance and examples on how to complete a hazard assessment for the hazardous drugs in your workplace. The third section describes how to write a comprehensive HDCP that will help organize and document your program. Appendices A and B contain tools, templates, and additional resources to help put together your HDCP.

To develop your HDCP you need to determine if your employees have a “reasonably anticipated” exposure to hazardous drugs. This means exposure that is expected during a normal course of your employees work tasks.

Once you have determined you have reasonably anticipated exposure you will need to establish an HDCP. The HDCP needs to be reviewed annually and have a way to recognize input from employees who may be exposed to hazardous drugs as a result of the performance of their duties regarding the quality and effectiveness of the Hazardous Drug Control Program.

Elements of your HDCP can be found in other programs such as your written Hazard Communication program. If so, you should note where the elements exist in your HDCP.

The following elements need to be included in your Hazardous Drug Control:

- Written inventory of hazardous drugs in your workplace.
- Current hazard assessment for hazardous drugs for which there is reasonably anticipated occupational exposure (see below for this assessment)
- Hazardous drug policies and procedures including, but not limited to:
  - Engineering controls (equipment use and maintenance) if required.
  - Personal protective equipment (gloves, respirators, eye protection, protective clothing, etc.)
  - Safe handling practices (receiving and storage, labeling, preparing, administering, and disposing of hazardous drugs).
  - Cleaning, housekeeping, and waste handling (body fluids and pharmaceutical wastes).
  - Spill control.
  - Personnel issues (such as exposure of pregnant workers).
  - Training.
• Also consider:
  – Purchasing drugs in a ready-to-use form to eliminate drug preparation work.
  – Purchasing the safest form possible.
  – Developing a procedure for administering hazardous drugs to patients that minimize exposure.
  – Reviewing health and safety information about the hazardous drug(s) before purchasing.
Section II: Hazard Assessment

The hazard assessment is conducted to help you identify what tasks have the potential for exposure, which employees may be exposed, and how to control exposure. It will form the foundation of your Hazardous Drug Control Program (HDCP).

After completing the below steps and summarizing your assessment, you will be ready to develop your written Hazardous Drug Control Program using the templates included in this guide. The following is a list of steps you must address to complete your assessment.

The rest of this section provides guidance for each of these steps.

A. WRITTEN HAZARD ASSESSMENT

Steps to help you conduct your hazard assessment:

1. Develop an inventory of hazardous drugs stored, transported, or otherwise handled in your facility.

2. Identify the tasks performed where an employee may be reasonably anticipated to have exposure to a hazardous drug.

3. Characterize the potential exposure for each task, including exposure by contact, injection, or inhalation.

4. Determine the preventive methods that will be used for each of the identified tasks and exposures for your work operations and worksites.

5. Complete a diagram of the physical layout of your work areas where hazardous drugs may be located or used; however, a diagram will not be needed for temporary worksites.

Step 1. Develop an inventory of hazardous drugs stored, transported, or otherwise handled in your facility.

You need to use at least the methods below to identify the hazardous drugs in your workplace as covered by the standard:

a.) Any drug listed on the NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings. The most recent list may be found at: http://www.cdc.gov/niosh/topics/hazdrug/
b.) Any drug that meets at least one of the below six adverse health effects criteria. You may use the manufacturer’s Safety Data Sheet - look under the sections “Hazard Identification” and “Toxicological”.

The supplier and manufacturer are required to provide you a copy of the Safety Data Sheet (SDS). If you need assistance in obtaining an SDS, you may contact your local DOSH office. You may also refer to the manufacture’s other material or medical related information that provides reliable toxicological information specific for the drug.

Adverse health effects criteria:

i.) Carcinogenicity.

ii.) Teratogenicity or developmental toxicity.

iii.) Reproductive toxicity in humans.

iv.) Organ toxicity at low doses in humans or animals.

v.) Genotoxicity.

You may use the example Written Inventory template found in Appendix A. You can add, delete, or edit this template so that it is tailored to your workplace.

You should also consider drugs that are non-routine or handled infrequently that you anticipate having on-site in the future.

You may not need to recreate your inventory if you have already established one for other state or federal programs, or as a part of your ordering procedures.

Step 2. Identify the tasks performed where an employee may be reasonably anticipated to have exposure to a hazardous drug.

Tasks that must be reviewed for potential employee exposure by handling or accident include: receiving, transporting, storing, preparing, administering, waste handling, decontamination/cleaning, housekeeping, maintenance, and spill control.

To be complete, you should list the specific sub-tasks for preparation and administration. All tasks with exposure will need to be included.

You may use the Hazard Assessment template in Appendix A to list the identified tasks and the form of the hazardous drug.

Step 3. Characterize the potential exposure for each task including exposure by contact, injection, or inhalation.

This characterization will aid you in determining the type and extent of preventive methods needed for each task.

Contact includes that which leads to skin absorption, ingestion, or contamination of other work areas or the home environment that may expose others.
Injection includes the accidental piercing of the skin with a needle containing a hazardous drug.

Inhalation of a hazardous drug may occur with the aerosolization of drugs in powder form, or from drugs in liquid form that are volatile.

You must also consider the volume and frequency of exposure, packaging, and the form of hazardous drugs handled (tablets, coated versus uncoated, powder versus liquid).

Capsules or coated tablets that are administered to patients without modification to their form may not pose a significant risk of occupational exposure, and may not require preventive methods during their normal handling.

However, they may pose a need for control if altered, for example, if tablets are crushed or dissolved, if capsules are pierced or opened, or if the tablet or capsule is accidentally crushed or damaged in a way that requires spill control and clean-up.

**Step 4. Determine the preventive methods that will be used for each of the identified tasks and exposures for your work operations and worksites.**

Preventive methods include engineering controls, safe handling practices, and personal protective equipment.

You may summarize the identified methods for each task by using the example Hazard Assessment Table below. A few examples of some typical tasks are provided in the table.

The preventive methods shown in the examples are those recommended by NIOSH for the listed tasks (see reference: NIOSH ALERT: Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings). The preventive methods will be more completely addressed in the written HDCP program through the development of specific policies as provided in the example table below.

**Engineering controls.**

An engineering control is a device designed to eliminate or reduce worker exposure to hazards. Examples for hazardous drugs include biological safety cabinets, laboratory fume hoods, containment isolators, closed system transfer devices, safer sharps devices, and safety interlocks.

The rule requires an employer to evaluate and implement appropriate engineering controls to eliminate or minimize employee exposure and for some tasks, provides for specific types of controls.

Chemotherapy drugs must be prepared in an appropriate ventilated cabinet with the exception of circumstances where the employer can document evidence of a clinical need.

Exposure during infrequent crushing and splitting tablets or drawing medication into a syringe, may be controlled by use of a ventilated cabinet or by temporarily designating...
a preparation area, use of appropriate personal protective equipment, and instituting cleaning procedures.

When handling hazardous drugs that are not intended for chemotherapy you will need to assess volume and frequency of use to determine your need for engineering controls.

In a clinic setting, it’s important to identify the types of tasks that will be conducted using hazardous drugs and consider the types of equipment or devices that are available and designed to help eliminate the possibility of exposure.

For instance, injections involve the handling of sharp objects and the possibility of exposure through accidental needle sticks. The use of safe-needle devices, needleless systems, dispensing pins, and closed-system devices reduces the likelihood of exposure by injection.

**Safe handling practices.**

This preventive method refers to several different areas, such as but not limited to: receiving and storage, labeling, preparing, administering, and disposing of hazardous drugs. Assessing safe handling practices provides a plan for the utilization of engineering controls, administrative, and personal protective equipment, and can include a number of specific practices within a facility. (One example would be techniques used by employees to remove PPE).

The practices set forth expected procedures and behaviors designed to prevent and minimize exposure. They work only as well as they are designed, and employees are trained and supervised.

You may summarize the practice in the Hazard Assessment Table below, or reference a specific policy.

**Personal protective equipment (PPE).**

Gloves will be needed for most tasks and double gloves in some circumstances. Other PPE such as gowns, booties, head cover, face shield, eye protection, and respirators will depend on a number of variables such as the form of the hazardous drug, formulation, engineering control used, extent of possible body contact, and the specific tasks performed.

The Hazardous Drugs rule does specify the use of gloves and other PPE under certain conditions and may guide you by example in determining the PPE requirements for other tasks.

The rule requires the use of powder-free chemotherapy gloves when handling chemotherapy drugs or when there is potential contact with chemotherapy contaminated items or surfaces.

The rule further requires the use of appropriate PPE as determined by the hazard assessment, whenever handling body fluids and contaminated laundry.
Gowns are to be worn whenever there is a reasonable possibility of a hazardous drug splash or spill such as in compounding, preparing and administering hazardous drugs.

A full-face shield or a mask, and eye protection, are to be used as appropriate when splashes to the eyes, nose, or mouth may occur; examples include cleaning a spill, or performing a procedure such as bladder instillation.

Booties may be required for walking into areas with fecal material contaminated with an excreted hazardous drug, as may occur in a veterinary setting.

Respiratory protection is required whenever there is a significant risk of inhalation exposure to hazardous drug particulates, such as the use of an N95 type respirator during spill clean-up. An appropriate chemical cartridge-type respirator is required for events such as large spills of volatile hazardous drugs, e.g., when an intravenous (IV) bag breaks or a line disconnects.

**Step 5. Complete a diagram of the physical layout of your work areas where hazardous drugs may be located or used; however, a diagram will not be needed for temporary worksites.**

Your layout should identify the areas where hazardous drugs will be received, stored, handled, processed, and disposed as appropriate to your operations. Consider locating hazardous drug work areas that best limit and control exposure and facilitate decontamination.

**B. EXAMPLES**

**Example Written Inventory (your specific inventory may differ)**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Form (tablets, capsule, liquid, gel, powder etc.)</th>
<th>Routes of Exposure</th>
<th>Volume and Frequency (daily, monthly, quarterly, annually)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tamoxifen</td>
<td>Tablet, liquid</td>
<td>Contact</td>
<td>90 tablets 12X monthly</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Example Hazard Assessment (your site specific tasks may differ)

<table>
<thead>
<tr>
<th>Task</th>
<th>Drug and Formulation</th>
<th>Engineering Controls for Exposure minimization</th>
<th>Administrative/Work Practice Controls¹ (reference your policy and procedure)</th>
<th>PPE Required</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Receiving:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Guidance:</strong> The employer should consider how drugs will be received and consider the types of activities or circumstances that could potentially expose staff to the drugs during their receipt. Below are some typical examples of tasks that should be included in your assessment.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Opening shipments</td>
<td>All drugs</td>
<td>Designated receiving area</td>
<td>Inspect packages for leaks; if leaking, initiate spill control.</td>
<td>Gloves</td>
</tr>
<tr>
<td>Dealing with damaged packaging (wet)</td>
<td>All drugs</td>
<td>Designated receiving area</td>
<td>Inspect packages for leaks; if leaking, initiate spill control.</td>
<td>Gloves</td>
</tr>
<tr>
<td><strong>Transport:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Guidance:</strong> If hazardous drugs will be transported within the facility to a work area, then some consideration should be given to those tasks in which potential exposure could occur. For instance, every effort should be given to maintaining proper control of the drugs packaged in such a fashion as to limit potential exposure from the point of preparation to final administration.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>All hazardous drugs</td>
<td>Secondary containment transport bin</td>
<td></td>
<td>Gloves</td>
</tr>
<tr>
<td><strong>Storing:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Guidance:</strong> Assessment of storing hazardous drugs should include an evaluation of the location where they will be stored along with suggested packaging and labeling that would help prevent exposures.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>All hazardous drugs</td>
<td>Separate antineoplastic agent storage area from others</td>
<td></td>
<td>Gloves</td>
</tr>
<tr>
<td><strong>Drug Manipulation (Activities listed below)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Guidance:</strong> Drug preparation represents a significant opportunity for exposure to hazardous drugs. Pharmacies must consider the types of tasks they will be conducting when preparing hazardous drugs. Examples of some common tasks are listed below. Pharmacies should include their own tasks and assess whether suggested engineering, work practices or PPE are provided and used during those activities.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pill/tablet splitting</td>
<td>All tablets</td>
<td>Pill splitting device</td>
<td>Designated/Decon/disposal waste area</td>
<td>Gloves</td>
</tr>
<tr>
<td>Counting pills/capsules</td>
<td>All drugs: Tablets, capsules</td>
<td>Pill counting device/stick</td>
<td>Designated/Decon/disposal waste area</td>
<td>Gloves</td>
</tr>
<tr>
<td>-------------------------</td>
<td>----------------------------</td>
<td>--------------------------</td>
<td>--------------------------------------</td>
<td>--------</td>
</tr>
<tr>
<td>Dispensing / distributing to customers</td>
<td>All drugs</td>
<td></td>
<td></td>
<td>Gloves</td>
</tr>
</tbody>
</table>

## Waste Handling:

**Guidance:** Pharmacies should consider the types of tasks they will encounter at their facility that generate waste products that would be contaminated with hazardous drugs.

<table>
<thead>
<tr>
<th>All hazardous drugs</th>
<th>Labeled, closed, compatible waste container</th>
<th>Hazardous waste policy</th>
<th>Gloves, eye protection, gown</th>
</tr>
</thead>
</table>

## Decontamination / Cleaning:

**Guidance:** Pharmacies must assess the potential hazards of surfaces and equipment that may come in contact with hazardous drugs during preparation and administration to ensure that appropriate safe work practices and PPE selections have been considered and are appropriate for those tasks involved.

<table>
<thead>
<tr>
<th>All hazardous drug handling areas</th>
<th>Hazardous drug handling area decontamination policy</th>
<th>Gloves, eye protection</th>
</tr>
</thead>
</table>

## Housekeeping:

**Guidance:** Pharmacies must assess those housekeeping activities in which workers may come in contact with hazardous drugs. (See also; waste handling above).

<table>
<thead>
<tr>
<th>Contracted Janitorial staff</th>
<th>No actual drug handling</th>
<th>Hazardous drug awareness training and PPE for all contracted janitorial staff</th>
<th>Gloves, eye protection</th>
</tr>
</thead>
</table>

## Maintenance:

**Guidance:** Pharmacies that use ventilated cabinets and other engineered exhaust systems for hazardous drugs must assess those routine maintenance tasks involved with maintaining that equipment to ensure that safe work practices have been developed and appropriate PPE selected to
reduce the potential exposure to workers. Below are some examples of typical tasks associated with those systems.

| Example: maintenance on ventilated cabinets or packaging contaminated equipment | No actual drug handling | Gloves, gown, eye protection, respirator |

**Spill Control / Spill Response:**

**Guidance:** Pharmacies that use hazardous drugs must evaluate credible spill events and assess whether safe work practices and supplies are in place along with the proper selection and availability of PPE.

| Gloves | eye protection | powder | Hazardous drug spill response kit | gloves, gown, respirators | Hazardous drug spill response training | Other |
Section III: Example Hazardous Drug Control Program Requirements

This example HDCP is only one EXAMPLE of how you might document and record your HDCP, and is not exhaustive. You may tailor the below example or create your own to best suit your workplace.

Note: Elements of the Hazardous Drug Control Program may be located in other documents such as the employer's accident prevention program or other policies and procedures as long as they are referenced in the program.

Instructions: You can use this section as part of documentation of your HDCP. You need to tailor this document to fit your task and work environment.

This is only an example and you may need to add additional information to address your specific workplace.

(Facility Name) is committed to providing a safe and healthful work environment for our entire staff. This is our program to eliminate or minimize occupational exposure to hazardous drugs. This HDCP is a key document to assist our firm in implementing and ensuring compliance with the standard, thereby protecting our employees.

This HDCP includes:

- Program Administration.
- Determination of employee exposure.
- Implementation of various methods of exposure control, including:
  - Universal precautions
  - Engineering and work practice controls
  - Personal protective equipment
  - Housekeeping
  - Training and communication of hazards to employees.
- Recordkeeping.
- The methods of implementation of these elements of the standard are discussed in the subsequent pages of this HDCP.
- Policies.
A. **PROGRAM RESPONSIBILITIES**

(Name of responsible person)_________________________ is (are) the HDCP Administrator responsible for:

- HDCP implementation.
- HDCP maintenance, review and updates (annually and whenever necessary to include new or modified tasks and procedures).
- Ensuring all necessary personal protective equipment (PPE such as gloves, gowns) is provided and available in the appropriate sizes.
- Ensuring all necessary engineering controls (e.g. closed system transfer device or controlled area) are properly maintained and used.
- Ensuring that employee HDCP training, (initial and whenever necessary to include new or modified tasks and procedures), is delivered and documented by an adequate person.

The Program Administrator may delegate, with documentation, any of the above responsibilities to a designated person.

Those employees who are determined to have occupational exposure to hazardous drugs must comply with the procedures and work practices outlined in this HDCP.

B. **EMPLOYEE EXPOSURE DETERMINATION**

Employees may be exposed to hazardous drugs during routine pharmacy tasks such as: drug handling, manipulating, crushing, splitting, opening, counting, and dispensing drugs to customers, hazardous drug disposal, cleaning/decontaminating designated hazardous drug handling areas and hazardous drug spill response activities. The exposure determination is made without regard to the use of personal protective equipment. This exposure determination lists all job classifications in which employees have occupational exposure, regardless of frequency.

The following is a list of all job classifications at our establishment in which all employees may have occupational exposure:

**JOB TITLE DEPARTMENT/LOCATION**
(Example: Pharmacist, Pharmacist Assistant, Customer Service/Front Desk personnel, Janitorial Staff /)
The following is a list of job classifications in which some employees at our establishment may have occupational exposure. Included is a list of tasks and procedures, or groups of closely related tasks and procedures, in which occupational exposure may occur for these individuals:

<table>
<thead>
<tr>
<th>JOB TITLE DEPARTMENT/LOCATION</th>
<th>TASK/PROCEDURE</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Example: Customer Service/Front Desk Personnel: handling customer ready drugs; Janitorial Staff: cleaning hazardous drug handling area, shipping and handling) Part-time, temporary, contract and per diem employees are covered by the standard. How the provisions of the standard will be met for these employees should be described in the HDCP.</td>
<td></td>
</tr>
</tbody>
</table>

C. METHODS OF IMPLEMENTATION FOR THE HDCP

**Hazardous Drug Control Program - Training**

(You may choose to omit the person’s name or department as it is not required by the rule)

Employees covered by the Hazardous Drugs standard receive an explanation of this during their initial training session. It will also be reviewed in their regularly scheduled training. All employees have an opportunity to review this program at any time during their work shifts by contacting__________________ (Name of responsible person or department). If requested, we will provide an employee with a copy of the program free of charge and within 15 days of the request.

**Engineering Controls**

Engineering controls will be used to prevent or minimize exposure to hazardous drugs. The specific engineering controls used are listed below: (Closed system transfer devices, safer sharps devices, enclosed crushing or cutting implements, ventilated cabinets)

This facility identifies the need for changes in engineering control through (Examples: employee interviews, committee activities, etc.) We evaluate new procedures or new products regularly by (Describe the process, literature reviewed, supplier info, products considered)

Both front line workers and management officials are involved in this process: (Describe how employees will be involved)

_________________________ (Name of responsible person or department) will ensure effective implementation of these recommendations.
Work Practices

Work practice controls will be used to prevent or minimize exposure to hazardous drugs. The specific work practice controls used are listed below. (Example: Drug preparation techniques, procedures for removing PPE, the use of closed system transfer devices, and enclosed crushing or cutting implements).

________________________________________________________________________

This facility identifies the need for changes in work practices through (Examples: employee interviews, committee activities, etc.)

________________________________________________________________________

We evaluate new procedures or new products regularly by (Describe the process, literature reviewed, supplier info, products considered)

________________________________________________________________________

Both front line workers and management officials are involved in this process: (Describe how employees will be involved)

_________ (Name of responsible person or department) ________________ will ensure effective implementation of these recommendations.

Personal Protective Equipment (PPE)

PPE is provided to our employees at no cost to them. Training is provided by

________________ (Name of responsible person or department) __________________ in the use of the appropriate PPE for the tasks or procedures employees will perform.

The types of PPE available to employees are as follows: (for example, gloves, gowns, and eye protection).

________________________________________________________________________

PPE is located ________________ (List location) ____________ and may be obtained through ___________ (Name of responsible person or department) ________________

(Specify how employees are to obtain PPE, and who is responsible for ensuring that it is available.)
Housekeeping

Regulated waste is placed in containers which are closable, constructed to contain all contents and prevent leakage, appropriately labeled or color-coded and closed prior to removal to prevent spillage or protrusion of contents during handling. The procedure for handling sharps disposal containers is: (may refer to specific agency procedure by title or number and last date of review)

________________________________________________________________________

The procedure for handling other regulated waste is: (may refer to specific agency procedure by title or number and last date of review)

________________________________________________________________________

Contaminated sharps are discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak-proof on sides and bottoms, and labeled or color-coded appropriately. Sharps disposal containers are available at __________________________ (must be easily accessible and as close as feasible to the immediate area where sharps are used).

Bins and pails (e.g., wash or emesis basins) are cleaned and decontaminated as soon as feasible after visible contamination.

Broken glassware which may be contaminated is picked up using mechanical means, such as a brush and dust pan.

D. EMPLOYEE TRAINING

All employees who have occupational exposure to hazardous drugs receive training conducted by (Name of responsible person or department). (Attach a brief description of their qualifications.)

________________________________________________________________________

All personnel involved in any aspect of the handling of hazardous drugs (shipment-receiving personnel, pharmacists, housekeepers, medical personal, vets and assistants, or employees involved in the transport or storage of drugs) must receive information and training to apprise them of the hazards of the hazardous drugs present in the work area. The information and training should include:

- Information on any operation/procedure in their work area where drugs that present a hazard are present: (such as pharmacy, area of a clinic where drugs are crushed)
• Methods used to detect the presence or release of a hazardous drug in the work area:  
  (such as monitoring conducted, continuous monitoring devices, visual appearance or odor)

• Physical and health hazards of the hazardous drugs, including carcinogenic and reproductive hazard potential:

• Measures employees can take to protect themselves from these hazards: (here you can refer to your policies)

• The hazard communication training as required by the _____ (Facility Name) __________ Communication Policy and Program.

This information should be provided at the time of an employee's initial assignment to a work area where hazardous drugs are present and prior to assignments involving new hazards, and when there is a new drug or change in procedures, or equipment.

E. RECORDKEEPING

Instructions: This section will allow you to record or track activities of your choice. The following is an example of tracking training.

Training records will be maintained for _______years.

Records must include:
• Dates of training
• Brief summary of training content
• Name(s) of the person conducting the training
• Names and job titles of individuals attending the training.
F. PHYSICAL LAYOUT

Instructions: This should contain a written description of your area where employees come into contact with hazardous drugs. Examples include but are not limited to: Receiving, Storage, Transportation, Drug Preparation and Administration, Cleaning and Disposal, Spill and Emergency Response.

In addition and only as an EXAMPLE you can include a map of your area to better show how hazardous drugs move through your workplace.
Example Lay Outs

Front End

Desk

Desk

Total Square Footage Approximately 633
G. POLICIES

Policies or Standard Operating Procedures (SOPs) provide detailed, written instructions to achieve uniformity of the performance of a specific function. SOPs can be used in training and insisting that they be followed can help keep employees safe at work and will reduce variation in job tasks. There is an example Personal Protective Equipment (PPE) policy in Appendix A.

You will need to develop and maintain policies for the following areas that pertain to your specific workplace. The following is a list of things you should considering when developing your policies:

- Engineering controls (equipment use and maintenance) if required.
- Personal protective equipment (gloves or respirators).
- Safe handling practices (receiving and storage, labeling, preparing, administering, and disposing of hazardous drugs).
- Safety for maintenance work
- Cleaning, housekeeping, and waste handling.
- Spill control.
- Personnel issues (such as exposure of pregnant workers).
- Training

1. ENGINEERING CONTROLS: Provide guidance to your employees concerning what engineering controls you have put into place. Include in your policy here or in a separate policy how you clean and maintain this equipment, as well as how you use it.

   Types of engineering controls to consider:
   - Closed system transfer devices.
   - Safer sharps devices.
   - Safety interlocks.
   - Self-contained pill crushing and splitting devices.
   - Ventilated cabinets.

2. PERSONAL PROTECTIVE EQUIPMENT (PPE): Provide guidance to your employees concerning what PPE is required, how it is accessed, and disposal methods, if applicable.

   Types of PPE to consider:
   - Types of PPE such as chemical or water proof.
   - Gloves (List types).
• Gowns.
• Eye Protection (safety glasses or safety goggles if there is a splash potential).
• Respirators:
  – Use N95 or equivalent respiratory protection during spill clean-up and whenever there is a significant risk of inhalation exposure to hazardous drug particulates.
  – Use an appropriate chemical cartridge-type respirator for events such as large spills of volatile hazardous drugs, e.g., when an intravenous (IV) bag breaks or a line disconnects.
• Donning/doffing PPE.
• PPE Storage.

3. SAFE HANDLING: Provide guidance to your employees concerning practices that provide the safest handling of hazardous drugs.

Areas to consider:
• Receiving and storage
• Preparation, administration and transporting
• Waste handling
• Personal hygiene (such as washing hands, and not eating in work area)

4. CLEANING AND DECONTAMINATION OF AREAS AND EQUIPMENT WHERE HAZARDOUS DRUGS ARE PRESENT.

Areas to consider:
• When and how to clean areas and equipment.
• What types of chemicals or equipment is used for cleaning
• Required PPE

5. SPILL CONTROL POLICY.

Areas to consider when writing your policy:
• Who will respond to the spill.
• How the spill will be cleaned.
• PPE required.
• Location of spill kits.
• Waste disposal.
• How you report and evaluate spills.
6. PERSONNEL ISSUES: When developing this policy you should consider reproductive concerns and how to address those issues, in addition to any other personnel issue you would like or need to address concerning handling of hazardous drugs.

7. TRAINING POLICIES: Train workers to recognize and understand the risks of working with hazardous drugs, or in an environment where these drugs are handled. It is essential that workers understand the carcinogenic potential and reproductive hazards of these drugs. Both females and males should understand the importance of avoiding exposure to the drugs, especially early in pregnancy, so that they can make informed decisions about the hazards involved.

In addition, the company’s policy regarding reproductive toxicity of hazardous drugs should be explained to workers. Updated information should be provided to employees on a regular basis and whenever their jobs involve new hazards.

Temporary or contract employees should be informed of the facilities hazardous drug policies and of the expectation that they will comply with these policies. In compliance with the Hazard Communication standard, all personnel involved in any aspect of the handling of hazardous drugs must receive information and training to apprise them of the hazards of hazardous drugs present in the work area.

Such information must be provided at the time of an employee’s initial assignment to a work area where hazardous drugs are present and prior to assignments involving new hazards and then on a regularly scheduled basis thereafter.

Employee training must include at least the following elements:

- Requirements of the Hazard Communication standard with particular attention to:
  - Any operation/procedure in their work area where drugs that present a hazard are present
  - The location and availability of the written hazard communication program including hazardous drug inventory and associated Safety Data Sheets
  - The location and availability of any other plan regarding hazardous drugs
  - Methods and observations that may be used to detect the presence or release of a hazardous drug in the work area (such as monitoring conducted by the employer, continuous monitoring devices, visual appearance or odor of covered hazardous drugs being released, etc.)
  - The physical and health hazards of the covered hazardous drugs in the work area.
  - The measures employees can take to protect themselves from these hazards. This includes specific procedures that the employer has implemented to protect the employees from exposure to such drugs, such as identification of covered drugs and those to be handled as hazardous, appropriate work practices and controls, emergency procedures, locations and proper use of spill kits, cleaning and
decontamination, and proper waste handling and disposal of contaminated materials.

- Personal protective equipment (use and care), and the details of the hazard communication program developed by the employer, including an explanation of the labeling system and the MSDS, and how employees can obtain and use the appropriate hazard information.

- Additional training:
  - For those tasks or procedures requiring employee use of respiratory protection, the company will ensure that employees receive the necessary training for respiratory protection.
  - The employer will ensure that for those employees that will respond to chemical emergency spills or releases, and will potentially conduct those operations where high levels of exposures to toxic substances could exist, or pose a serious danger to employees, that they receive the appropriate level of training based upon their anticipated duties according to the Emergency Response rule.

**Additional Guidance:** Train workers to recognize and understand the risks of working with hazardous drugs, and the risks of working in an environment where these drugs are handled. It is essential that workers understand the carcinogenic potential and reproductive hazards of these drugs.

Both females and males should understand the importance of avoiding exposure, especially early in pregnancy, to the drugs, so that they can make informed decisions about the hazards involved.

In addition, the facility's policy regarding reproductive toxicity of hazardous drugs should be explained to workers. Updated information should be provided to employees on a regular basis and whenever their jobs involve new hazards.

Medical staff and other personnel who are not hospital employees should be informed of hospital policies and of the expectation that they will comply with these policies.
Appendix A: Helpful Tools

These optional forms can help you meet the requirements of the Hazardous Drugs rule. Use these optional forms in your business by:

- Customizing them (choose the Word version)
  OR
- Printing them for direct use (choose the PDF (Acrobat) version)

Written Inventory (Template)

<table>
<thead>
<tr>
<th>Drug</th>
<th>Form (tablets, capsule, liquid, gel, powder etc.)</th>
<th>Routes of Exposure</th>
<th>Volume and Frequency (daily, monthly, quarterly, annually)</th>
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</thead>
<tbody>
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</tbody>
</table>
## Hazard Assessment (Template)

<table>
<thead>
<tr>
<th>Task</th>
<th>Drug and Formulation</th>
<th>Engineering Controls for Exposure minimization</th>
<th>Administrative/Work Practice Controls1 (refer to your policy and procedure)</th>
<th>PPE Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receiving</td>
<td></td>
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<tr>
<td>Transporting</td>
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<tr>
<td>Storing</td>
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<tr>
<td><em>Drug Manipulation</em></td>
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<tr>
<td><em>Activities listed below</em></td>
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<tr>
<td>Pill/Tablet Splitting</td>
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<tr>
<td>Counting pills/capsules</td>
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<tr>
<td>Dispensing / Distributing to customers</td>
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<tr>
<td>Waste Handling</td>
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<tr>
<td>Decontamination / Cleaning</td>
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<tr>
<td><strong>Housekeeping:</strong> contracted janitorial staff</td>
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<tr>
<td>Maintenance staff:</td>
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<td>(example: maintenance on ventilated cabinets or packaging contaminated equipment)</td>
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<tr>
<td>Spill Control / Spill Response Staff</td>
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<tr>
<td>Other</td>
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</tbody>
</table>
Example Policy for PERSONAL PROTECTIVE EQUIPMENT (PPE)

All employees using PPE must observe the following precautions:

Gloves

- Wash hands immediately or as soon as feasible after removal of gloves or other PPE.
- Remove PPE after it becomes contaminated, and before leaving the work area.
- Used PPE may be disposed of in ____________ (List appropriate containers for storage, laundering, decontamination, or disposal.)
- Wear appropriate gloves when it can be reasonably anticipated that there may be hand contact with hazardous drugs, or when handling or touching contaminated items or surfaces; replace gloves if torn, punctured, contaminated, or if their ability to function as a barrier is compromised.
- Utility gloves may be decontaminated for reuse if their integrity is not compromised; discard utility gloves if they show signs of cracking, peeling, tearing, puncturing, or deterioration.
- Never wash or decontaminate disposable gloves for reuse.

Gowns

- Wear gowns made of polyethylene-coated polypropylene or other nonabsorbent, non-linting protective material as determined by the PPE hazard assessment. Make sure the gown has a closed front, long sleeves, and elastic or knit cuffs.
- Remove and dispose of gowns at the end of hazardous drug handling activities, when leaving the hazardous drug handling area and as soon as possible when damaged or contaminated.
- If no permeation information is available, change gowns every two to three hours or when contaminated after a splash or spill.

Eye Protection

- Wear appropriate face and eye protection when splashes, sprays, spatters, of hazardous drugs pose a hazard to the eye, nose, or mouth.
- Remove immediately or as soon as feasible any garment contaminated with hazardous drugs in such a way as to avoid contact with the outer surface.
Respirators

- Use N95 or equivalent respiratory protection during spill clean-up and whenever there is a significant risk of inhalation exposure to hazardous drug particulates.

- Use an appropriate chemical cartridge-type respirator for events such as large spills of volatile hazardous drugs, e.g., when an intravenous (IV) bag breaks or a line disconnects.

The procedure for handling used PPE is as follows: *(This is the section for your policy and refers to specific agency procedure by title or number and last date of review)*

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*(For example: How and where to decontaminate face shield, eye protection, etc.)*
Appendix B: Resources & Reference Materials

Hazardous Drugs, WAC 296-62-500
Personal Protective Equipment, WAC 296-800-160
Hazard Communication, Chapter 296-901 WAC
Respirators, Chapter 296-842 WAC
Emergency Response, Chapter 296-824 WAC
Accident Prevention Program, Chapter 296-800-140
First Aid, WAC 296-800-150


Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings

Personal Protective Equipment for Health Care Workers Who Work with Hazardous Drugs


OSHA [1999]. OSHA technical manual, TED 1-0.15A, Sec VI, Chapt II: Categorization of drugs as hazardous

ASHP Guidelines on Handling Hazardous Drugs
## Abbreviations List

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDC</td>
<td>Center for Disease Control</td>
</tr>
<tr>
<td>DOSH</td>
<td>Division of Occupational Safety and Health</td>
</tr>
<tr>
<td>HDCP</td>
<td>Hazardous Drug Control Program</td>
</tr>
<tr>
<td>IV</td>
<td>Intravenous</td>
</tr>
<tr>
<td>NIOSH</td>
<td>The National Institute for Occupational Safety and Health</td>
</tr>
<tr>
<td>PPE</td>
<td>Personal Protective Equipment</td>
</tr>
<tr>
<td>SDS</td>
<td>Safety Data Sheets (formerly known as Material Safety Data Sheets or “MSDS”)</td>
</tr>
<tr>
<td>WISHA</td>
<td>Washington Industrial Safety and Health Act</td>
</tr>
</tbody>
</table>