Safe Work Practices for Handling Hazardous Drugs



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About this book

This book addresses the health and safety of workers who work with **hazardous drugs** and are at risk of exposure to these drugs. Its purpose is to provide clear instructions to employers on their obligation to eliminate or minimize worker exposure to hazardous drugs. This book is meant to be a starting point and a reference guide on the regulatory requirements.

This book has four parts:

- Part 1 gives an overview of current knowledge on hazardous drugs.
- Part 2 describes how to identify hazardous drugs and conduct a risk assessment.
- Part 3 gives an overview of control measures and exposure control plans (ECPs).
- Part 4 focuses on work procedures and the regulatory requirements for each stage of handling hazardous drugs.

Who should read this book?

This book is for employers in workplaces where workers are at risk of exposure to hazardous drugs. This includes industries such as health care, drug manufacturing and transportation, home-based care, and veterinary practices.

See "Who is at risk of exposure?" on page 6 for a list of occupations in which workers may be at risk of exposure to hazardous drugs. Workers will find information to help them work safely with hazardous drugs and waste related to those drugs.

Terminology

Appendix 2 contains a glossary of terms frequently used when handling hazardous drugs. When these terms first appear in the text of this book, they are indicated with bold type. If you place your cursor over the bold text in the electronic version of this book, a pop-up box will appear with the definition of the term.

Regulatory requirements for hazardous drugs

When hazardous drugs are present in the workplace, the employer must ensure that the regulatory requirements are being met. If a worker is or may be exposed to hazardous drugs, employers must do the following:

- Perform a risk assessment as outlined in section 6.45 of the Occupational Health and Safety Regulation.
- Develop and implement an ECP that meets the requirements of section 6.46 of the Regulation.



When you see this symbol, it indicates a specific requirement from the Regulation when a worker is or may be exposed to a hazardous drug in the workplace.

Use this book as a starting point

While the information in this book is meant to help you meet the requirements specified in the Regulation, it does not replace it. You will need to refer to the Regulation to determine the exact requirements that apply to your workplace.

Part 1:

Hazardous drugs in the workplace

The following chapters provide an overview of current knowledge on hazardous drugs. This will help you understand what hazardous drugs are, why they are hazardous, and who is at risk of exposure. Routes of occupational exposure and an overview of how to control exposure are also covered.

1. What are hazardous drugs?

Hazardous drugs are specific drugs used to treat cancer and other diseases in both people and animals.

These drugs provide essential treatment for patients. However, if workers are unintentionally exposed to hazardous drugs without proper protection, these drugs have the potential to cause harm. Continual or frequent exposures to low levels of hazardous drugs, or a single exposure to a larger amount, can put workers at risk of negative health effects.

But with proper control measures, workers who work with hazardous drugs can be protected from these adverse effects. This book outlines the regulatory requirements and makes recommendations for anyone who works with hazardous drugs.

2. Why are workers at risk?

For the past few decades, hazardous drugs have been increasingly used to treat diseases other than cancer. These drugs are now used to treat rheumatoid arthritis, skin psoriasis, multiple sclerosis, and some viral diseases, such as HIV. Hazardous drugs are also increasingly being administered in non-traditional settings, including community or home care settings and physician and veterinary practices. In these workplaces, there may not be well-established control measures in place to minimize occupational exposure.

With the growing potential for exposure to hazardous drugs, it is essential that all workplaces where hazardous drugs are present have effective measures in place to control worker exposure.

The Regulation states that the term *hazardous drug* means a drug that has one or more of the following characteristics:

- Carcinogenicity
- Teratogenicity
- Genotoxicity
- Reproductive toxicity
- Organ toxicity at low doses

A drug is also considered a hazardous drug if it is:

- A new drug that mimics an existing drug with one of the characteristics listed above.
- Listed in the NIOSH List of Hazardous Drugs in Healthcare Settings. The U.S. National Institute for Occupational Health and Safety (NIOSH) updates its list from time to time based on Food and Drug Administration approvals and newly published scientific data or other governmental agency evaluations.

For drugs not on the **NIOSH list**, employers can determine whether a drug is considered a hazardous drug by using the following sources of information:

- Drug information sheets provided by the manufacturer, such as safety data sheets
- Product monographs in Health Canada's Drug Product Database
- Health warnings from government or professional groups
- Drug information from the American Hospital Formulary Service

3. Who is at risk of exposure?

A wide range of people can be at risk of exposure to hazardous drugs in their workplaces, including:

- Pharmacy workers (pharmacists, technicians, and assistants)
- Laboratory workers
- Nurses
- Health care assistants
- Cleaners
- · Housekeeping and laundry staff
- Physicians and physician assistants
- · Veterinary and animal attendant workers
- Community health workers
- Workers in drug shipping, receiving, or transport services
- Workers in the hazardous drugs manufacturing industry

The work activities that may pose a high risk of exposure include:

- Preparing hazardous drugs
- Administering hazardous drugs
- · Cleaning up a hazardous drug spill
- · Handling excreta (feces and urine) of patients who have received hazardous drugs
- Handling and disposing of drug waste
- · Decontaminating equipment used with hazardous drugs

4. Routes of occupational exposure

Workers can be exposed to hazardous drugs in a number of ways. The potential route of exposure depends on the form of the drug being handled and the tasks being conducted. The table below shows the main routes of worker exposure and gives some examples of activities in which these exposures may take place. It also gives examples of **controls** that may be used to minimize worker exposure.

Route of exposure	Examples of activities	Possible controls
Direct dermal contact	 Handling oral or topical forms of hazardous drugs Contact with a leak or spill of hazardous drugs 	 Wear personal protective equipment (PPE) that provides appropriate protection from hazardous drugs. Use a closed system drug-transfer device.
Indirect dermal contact	 Handling contaminated patient excreta Handling or touching contaminated materials, such as equipment, containers, work surfaces, or patient laundry 	 Wear a gown, mask, and gloves that provide appropriate protection from hazardous drugs. Observe a precautionary period for handling patient excreta. Implement routine cleaning and decontamination procedures.
Contact with eyes	Handling liquid forms of hazardous drugs	Wear eye protection or a face shield.
Inhalation	 Inhaling aerosols or vapours released when priming an intravenous administration set Inhaling particulate material released when crushing tablets or opening capsules 	 Use an appropriate ventilated enclosure, such as a biological safety cabinet (BSC), that meets Regulation requirements. Wear an appropriate respirator.
Percutaneous exposure • Preparing or administering drugs using a needle		Use a needleless system or a safety-engineered medical sharp.
Ingestion • Eating food that has been contaminated with hazardous drugs		 Ensure all food is stored away from areas where hazardous drugs are handled. Practise proper handwashing.

Surface contamination can pose a risk of worker exposure to hazardous drugs. It can occur if a worker doesn't clean up spills properly or doesn't remove their gloves before leaving the work area. Due to the chemical stability of hazardous drugs, residue from these drugs can persist in the workplace and be spread far from their point of origin. Trace residue from hazardous drugs can be deposited on surfaces, such as vials and IV bags containing the drugs, work tables, and hazardous drug transport carts. Residue can also collect on items that are not directly used for handling hazardous drugs, such as pens, door handles, and elevator buttons. If proper controls are not adhered to, surfaces may be contaminated, leading to possible exposures for staff, other workers, and patients' family members.

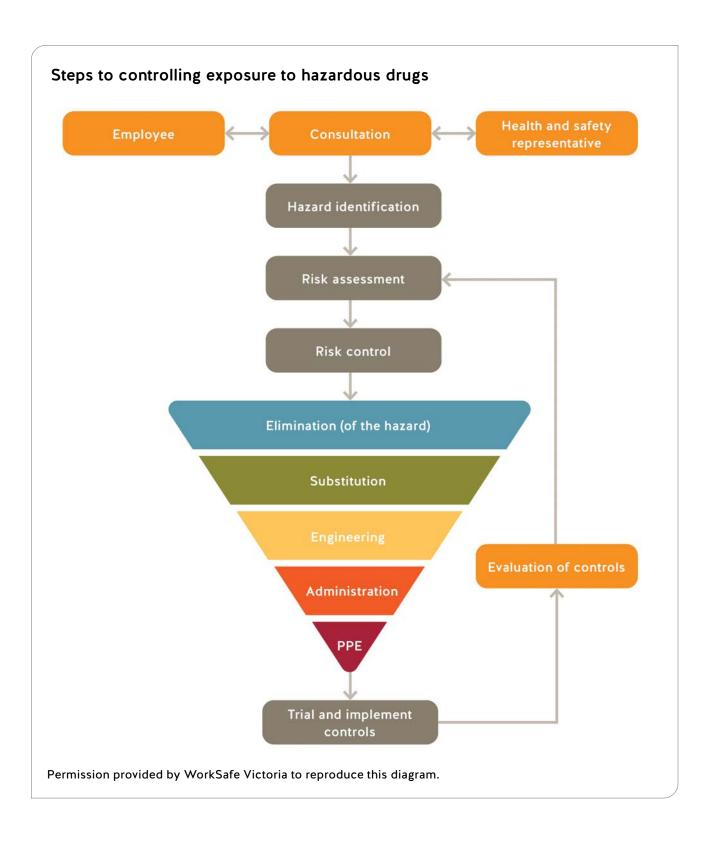
5. Controlling exposure to hazardous drugs

There are four steps to controlling exposure to hazardous drugs:

- 1. Identify the hazardous drugs in your workplace.
- 2. Assess the risks of those drugs.
- 3. Develop and implement measures to control the risks. This includes providing workers with instruction, training, and supervision on the control measures.
- 4. Evaluate the effectiveness of the control measures, and improve those that are not working as intended.

The remainder of this book focuses on steps 1 to 3.

Consult your joint health and safety committee or worker health and safety representative, as applicable, throughout the process.



Part 2:

Identifying hazardous drugs and conducting a risk assessment

Chapter 6 discusses the process of identifying hazardous drugs. Chapter 7 covers what is involved in conducting a risk assessment. Employers must ensure a **qualified person** prepares a written risk assessment if a worker is or may be exposed to a hazardous drug during a work activity.

6. Identifying hazardous drugs

Identifying hazards is the first step toward controlling exposure to hazardous drugs in your workplace.

If a worker is or may be exposed to a hazardous drug, the employer must do the following:

- Develop and maintain a written list of hazardous drugs.
- Review and update the list at least once a year.
- Make the list readily available to workers.

Create a list of hazardous drugs in your workplace

To develop a list of hazardous drugs, you can divide up the workplace and determine where hazardous drugs may be used. For example, in a hospital, hazardous drugs may be found in:

- The pharmacy, where drug preparation occurs
- The ward or treatment area, where drug administration occurs
- · Parts of the premises where handling, transport, and disposal of hazardous waste occur

The NIOSH List of Hazardous Drugs in Healthcare Settings can help with identifying hazardous drugs. If a drug in your workplace is not on the NIOSH list, review it to determine if it's hazardous. Use the criteria discussed in Part 1. Review your list at least once a year and update it as needed.



In the Regulation

Under section 6.44 of the Regulation, employers must do the following:

- Develop a written list of all hazardous drugs workers may be exposed to in the workplace.
- Review the list at least annually and update it if necessary.
- · Make the list readily available in the workplace.

7. Conducting a risk assessment

A **risk assessment** provides a foundation for eliminating or minimizing worker exposure to hazardous drugs in your workplace. It involves examining the level to which workers are being exposed to hazardous drugs and what can be done to prevent or reduce risks to workers.

If a worker is or may be exposed to a hazardous drug in the workplace, the employer must ensure that a qualified person prepares a written risk assessment to determine the level of risk. This involves determining how the drugs are used in the workplace and identifying which tasks place workers at risk of exposure.

Qualified person

Under section 1.1 of the Regulation, *qualified* "means being knowledgeable of the work, the hazards involved and the means to control the hazards, by reason of education, training, experience or a combination thereof."

The qualified person preparing the risk assessment for hazardous drugs will have:

- · A good understanding of hazardous drugs and the tasks and factors involved in working with them
- · Knowledge of assessing the hazards, risks, and controls associated with hazardous drugs
- Knowledge of the work processes
- Knowledge of equipment uses and limitations
- Education and training in risk-assessment methods

Employers are responsible for ensuring that the qualified person can competently conduct the risk assessment. The risk assessment forms the basis for other requirements, such as the employer's exposure control plan (ECP) (see pages 20–21), so it is an important process for protecting workers from exposure.

The qualified person does not necessarily have to be one individual. A qualified person may be a knowledgeable and experienced staff member in one workplace. In another workplace, a qualified person may be a team of people who bring different areas of knowledge about the Regulation, the hazardous drugs used, and the various work processes that may expose workers to a hazardous drug. For example, in a health care setting, a qualified team may consist of an occupational health and safety professional, a pharmacy representative, and a clinical practice representative.

A risk assessment involves analyzing the work environment, tasks, and activities performed, and any previous incidents where workers may have been exposed to hazardous drugs. This information can be gathered by performing a walk-through survey of the workplace, consulting with workers who are performing the tasks being evaluated, and reviewing employer health and safety records. Taking these steps will help the qualified person see what's happening on the floor and obtain worker feedback. See the table on the next page for more details.

Regulation requirement	Factors to consider
Determine the hazardous properties of the drug as provided by manufacturers, suppliers, pharmacists, or scientific publications.	 Consider the following: The active ingredients in the hazardous drug and their concentrations Health risks of exposure to the hazardous drug, including acute and chronic effects, and reproductive effects Available information on whether exposure to multiple hazardous drugs may increase the risk of harmful health effects Special precautions a worker should take, if any
Determine the scope, circumstances, and nature of the work activities.	 What to look for: How hazardous drugs are used in various jobs and activities The quantities and concentrations of the drug used (drug classification and formulation and quantity of the drug) Frequency and duration of exposure Whether the work activity involves crushing, dissolving, piercing, or mixing the hazardous drug, which increases the risk of exposure Whether opening a container or package of the hazardous drug increases the risk of exposure Whether another worker in the same work area may be at risk of exposure Any additional information needed to complete the risk assessment
Review information relating to the effectiveness of existing and planned control measures to eliminate or minimize exposure to hazardous drugs.	 What to do: Consider the time from when the drug is received to when it is disposed of. Include the time spent in storage and in transportation within the workplace. Find information about any spills or accidental exposures. Review environmental monitoring or exposure monitoring data, if applicable. Review hazard inspection reports and employer incident investigation reports. Identify any problems associated with storage and transport. Investigate reports of unsafe conditions.
Review and update the risk assessment if changes are introduced to the workplace.	 Update the risk assessment if any of the following apply: A new hazardous drug is introduced to the workplace. Drug handling practices, or other work activities that may cause a worker to be at risk of exposure to a hazardous drug, are changed. Information indicates that controls implemented under the ECP are not effective. Exposure monitoring or health monitoring of a worker (if conducted) indicates that a review of the risk assessment is necessary. Investigation of worker reports indicates that additional controls are required.
Determine the form of the substance.	This may include: • Liquid • Powder • Tablet • Cream, ointment, or lotion for topical application

Regulation requirement	Factors to consider
Determine the routes of exposure.	 These may include: Inhalation of aerosols, particulates, and droplets Skin or eye contact through splashing of liquid Skin contact with a contaminated surface Ingestion through poor personal hygiene or splashing of liquid Injection resulting from injuries from sharps
Ascertain the potential harmful effects.	 These may include: Carcinogenic, mutagenic, or teratogenic potential Alterations to normal blood cell count Fetal loss in pregnant women and malfunctions in the offspring of pregnant women Abnormal pain, hair loss, nasal sores, vomiting Liver damage Contact dermatitis, local toxic or allergic reaction, skin irritation



In the Regulation

A risk assessment must be performed where a worker is or may be exposed to a hazardous drug. See sections 6.45, 5.53(1)(a), and 5.54(2)(b) of the Regulation.

Consultation

The employer must consult with the joint health and safety committee or worker health and safety representative when preparing a risk assessment. Best practice is to also consult with workers who work with hazardous drugs. They can provide knowledge on how work is being done and insights into potential solutions. The most effective solutions for controlling exposure will take the needs and knowledge of workers into account.

Additional considerations for assessing risk

Some employers may find the following useful when preparing their risk assessments. Methods for assessing the risk posed by hazardous drugs in the workplace may include one or more of the following:

- · Grouping of hazardous drugs
- Environmental monitoring
- Health monitoring

Grouping of hazardous drugs

For workplaces that use a large number of hazardous drugs, it may be helpful to group them by nature and degree of risk of exposure. While the Regulation uses the singular form "a hazardous drug," this wording allows for the plural form in its interpretation. Grouping similar hazardous drugs may be more efficient than assessing one drug at a time. The groupings would be based on information about:

- The drug itself, such as the form of the drug, potential routes of exposure, and potential health effects
- How the drug is used in the workplace, as determined in the risk assessment

A risk assessment for a group of hazardous drugs can be conducted if a qualified person can do the following:

- Demonstrate a rationale for the grouping (e.g., the drugs have similar toxicological profiles and the forms of administration are the same).
- Adequately assess the risk of exposure.

Environmental monitoring

Some workplaces may conduct environmental monitoring (e.g., surface sampling) of hazardous drugs to evaluate the effectiveness of control measures. For example, pharmacies may conduct surface sampling to confirm cleaning and decontamination protocols.

In other workplaces, environmental monitoring may establish baseline measurements for possible hazardous drug contamination so future measurements can be compared. These comparisons can help evaluate interventions and set targets for future improvements.

Prior to setting up an environmental monitoring program, the employer should consider the following:

- Is there an acceptable surface limit for comparison?
- Is there a qualified person to conduct the sampling and interpret the results?
- Which hazardous drugs should be monitored?
- How will sampling be conducted?
- Is a commercial analytical method available?
- What locations should be monitored, and how many samples should be taken?
- · What should be done with the results?

Where an environmental monitoring program has been implemented, the risk assessment must consider the effectiveness of control measures by taking into account monitoring data.

For more information about environmental monitoring and guidance on surface contamination, see the Hazardous Drug Surface Contamination Guidance Document published by the American Industrial Hygiene Association.

Health monitoring

Generally, health monitoring (also known as biological monitoring or medical surveillance) is intended to assess worker exposure to specific substances and the potential health risks by detecting **biomarkers** usually found in blood or urine samples. For example, a blood lead level greater than an acceptable safe level is associated with adverse health effects and can be attributed to exposure to lead.

The Regulation does not currently require health monitoring for hazardous drugs. However, some employers may implement a health monitoring program as an additional part of an ECP.

It is possible to measure concentrations of certain hazardous drugs in the blood or urine (e.g., as is done to adjust patient prescriptions for clinical applications). However, implementing a health monitoring program for hazardous drugs may be challenging. First of all, there are hundreds of hazardous drugs, and analytical methods are not available for every drug. If there is a method, it may only be available in a research setting. The health outcomes of finding traces of a drug are not fully understood, and there are no reference limits to compare the results.

If an employer conducts health monitoring, a qualified person should interpret the test results.

Part 3:

Control measures

This part focuses on control measures to eliminate or reduce worker exposure to hazardous drugs. The content of each chapter is as follows:

- Chapter 8 focuses on exposure control plans (ECPs).
- Chapter 9 focuses on developing and implementing control measures.
- Chapter 10 provides information on engineering controls.
- Chapter 11 focuses on administrative controls and the written work procedures that are part
 of the ECP.
- Chapter 12 gives information on personal protective equipment.
- Chapter 13 is about the instruction, training, and supervision that employers must provide.
- Chapter 14 outlines the requirements for keeping records.

8. The exposure control plan (ECP)

An exposure control plan (ECP) describes the employer's plan for how workers will be protected from hazardous drugs in the workplace. An ECP must include information on:

- The nature of the hazard
- The risk associated with exposure
- Controls that the employer will use to protect workers

An ECP must be developed by a qualified person. (See page 13 for more information on a qualified person.)

An ECP includes the following components, which are detailed in sections 5.54(2) and 6.46 of the Regulation:

- · Statement of purpose and responsibilities
- Risk identification and assessment
- Risk controls
- Education and training
- Written work procedures
- Documentation
- Hygiene facilities and decontamination procedures

The written work procedures to include in an ECP are outlined in Chapter 11, "Administrative controls."

As long as the required components are covered, the Regulation allows employers to determine the format or style of written ECPs that are suitable for their workplaces. For example, one ECP can be written to include all of the hazardous drugs found at a workplace if the information is organized so it groups similar hazardous drugs for the risk assessment and controls.

An employer with multiple work locations may only need one ECP if the contents of the plan apply to all of those locations. However, an ECP may need to be customized to include site-specific content.

If a risk assessment is updated, the employer must ensure the ECP is updated to address any changes to the risk assessment.

The ECP and its written work procedures must be reviewed at least annually and updated as necessary by the employer. This must be done in consultation with the joint committee (or the worker health and safety representative, if applicable) for a workplace to which the ECP applies.

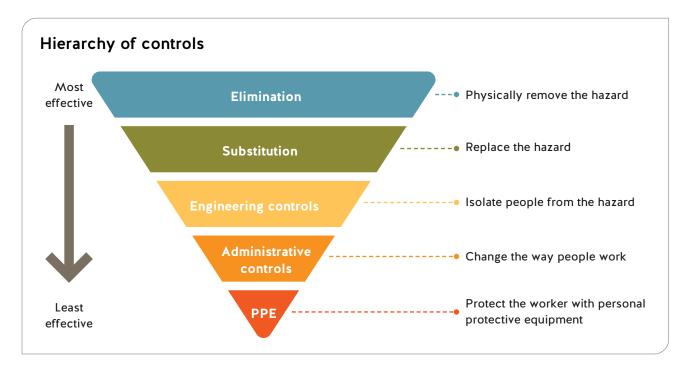


In the Regulation

Workplaces where a worker is or may be exposed to a hazardous drug must have an ECP in place. See sections 6.46 and 5.54 of the Regulation.

9. Developing and implementing control measures

Once all hazardous drugs have been identified and the risks assessed, the employer must choose appropriate controls. Controls aim to eliminate or minimize exposure to workers. As shown in the diagram below, one or more of these controls must be implemented in the workplace.



Elimination is at the top of the hierarchy of controls. The employer must first consider whether it's possible to eliminate the risk of exposure to a hazardous drug.

If elimination is not practicable, the employer must control the risk of exposure using **substitution**. (Under the Regulation, practicable means "that which is reasonably capable of being done.") Examples of substitution include using a less-hazardous drug or a different form of the drug that poses a lower risk of exposure to workers. For example, instead of crushing a pill (which could increase a worker's exposure to a hazardous drug) to make it easier to swallow, determine if using a liquid form is practicable.

If substitution is not practicable, the employer must keep the risk of exposure as low as reasonably achievable through engineering controls and administrative controls that are appropriate for the work activity.

Employers must provide workers with personal protective equipment (PPE) appropriate for the work activity.

A combination of the controls mentioned above often provides the most effective protection.



In the Regulation

In workplaces where a worker is or may be exposed to hazardous drugs, the employer must take steps to eliminate or control the risk of exposure. For more information, see section 6.48 of the Regulation.

The following table provides a description and one or more examples for each type of control.

Type of control	Description	Examples
Elimination	Eliminate the risk of worker exposure to a hazardous drug. Elimination of hazardous drugs from the workplace is not typically possible because these drugs may be the only treatments available.	Remove unneeded hazardous drugs from the workplace.
Substitution	Substitution includes using a drug that is less hazardous, either because of the form it is administered in or its toxicological properties (provided it is just as effective at treating the patient).	Use a form of the hazardous drug that has a lower risk of exposure, such as tablets instead of IV infusions (if clinically appropriate).
Engineering controls	Engineering controls protect workers by physically changing the work environment to minimize exposure to hazardous drugs.	 Have negative-pressure preparation rooms or anterooms. Use a ventilated enclosure such as an appropriate biological safety cabinet that meets Regulation requirements when working with any of the following: Antineoplastic drugs. Drugs that are IARC Group 1 or 2A carcinogens. Drugs for which the manufacturer recommends ventilated engineering controls. Use closed system drug-transfer devices where applicable. (See page 27 for more information.)

Type of control	Description	Examples
Administrative controls	Administrative controls aim to reduce exposure in the work environment by changing how work is carried out.	 Reduce the number of times hazardous drugs are handled. Limit access to the areas where hazardous drugs are present. Practise proper handwashing. Develop and implement safe work procedures. Implement an effective cleaning routine. Implement protective reassignment. Deliver drugs to the point of care in a form that's ready to administer.
PPE	PPE controls exposure at the point of the individual worker. It is last in the hierarchy of controls because it is the least effective way to limit worker exposure. Workers often have to wear PPE despite the presence of other control methods. PPE must not be worn outside of the work environment. Non-disposable PPE must be cleaned and decontaminated after use.	 Wear appropriate PPE, such as: Gloves and gowns designed to provide protection from hazardous drugs. Respirators. Eye and face protection. Appropriate footwear.

10. Engineering controls

Engineering controls, such as ventilated enclosures and closed system drug-transfer devices, protect workers by physically changing the work environment.

Engineering controls selected for use with hazardous drugs should:

- Be approved for use with hazardous drugs by the manufacturer
- · Eliminate or minimize the release of hazardous drugs in the form of liquids, solids, or vapours
- Be supported by evidence that demonstrates their effectiveness at reducing environmental contamination in the workplace

Employers should periodically review engineering controls for their effectiveness. If a control is not working effectively, take action to address it.

Ventilated enclosures

A ventilated enclosure is a local exhaust ventilation unit used to contain and extract aerosols, particulates, and vapours emitted during processes such as preparation of hazardous drugs. Some activities with certain hazardous drugs may pose greater risks to workers. These activities must be conducted inside a ventilated enclosure. This requirement applies to hazardous drugs:

- Identified in the NIOSH list as being antineoplastic
- For which the manufacturer recommends ventilated engineering controls
- Classified by the IARC Monographs as Group 1 or Group 2A carcinogens

For the types of hazardous drugs listed above, the following activities must be performed in a ventilated enclosure:

- Mixing
- Preparing
- Priming intravenous sets with hazardous drugs

The ventilated enclosure must meet the requirements outlined in section 6.50(4) of the Regulation. An example of a ventilated enclosure that meets these requirements is a Class II Type B2 biological safety cabinet that conforms to NSF/ANSI Standard 49-2018 Biosafety Cabinetry: Design, Construction, Performance, and Field Certification.

Biological safety cabinets (BSCs)

A biological safety cabinet (BSC) is a ventilated enclosure designed to protect workers, the product, and the environment.

BSCs are divided into three classes (Class I, Class II, and Class III) designed to meet different needs, depending on their intended uses. One of the key differences between the classes of BSCs is whether the air from inside the ventilated enclosure is fully discharged to the outdoors. The following table compares the BSC classes.

Class of BSC	Requires 100% discharge of the contaminated air to the outdoors?	Meets Regulation requirements?
Class I	No	No
Class II Type A1	No	No
Class II Type A2	No	No
Class II Type B1	No	No
Class II Type B2	Yes	Yes
Class II Type C1	No	No
Class III	Yes	Yes

A BSC used for the types of hazardous drugs listed under "Ventilated enclosures" (see page 25) must be equipped with a continuous airflow monitoring device. This device confirms adequate airflow and proper cabinet performance.

Workers who use a BSC should regularly monitor device readings, be able to recognize problems, and know what to do in response. Safe work procedures must be developed to ensure worker protection should a malfunction occur.

Section 30.12 of the Regulation sets out other BSC-related requirements. BSCs must be certified by a qualified person at the time of installation and then at least once a year. This requirement helps ensure that BSCs perform properly and conform with the manufacturer's specifications and Regulation requirements.

For more information on BSCs, refer to the Canadian Biosafety Handbook, Second Edition.

Compounding aseptic containment isolators (CACIs)

A compounding aseptic containment isolator (CACI) is a ventilated enclosure designed to:

- Protect the sterile compounding process
- Use air pressurization and isolation techniques to protect the user

There are currently no recognized performance and testing standards for CACIs. However, WorkSafeBC may recognize CACIs that meet or exceed regulatory requirements and are designed to prevent releases into the work environment. Employers are responsible for demonstrating that a ventilated enclosure that is not a BSC Class II Type B2 meets Regulation requirements.



In the Regulation

A minimum of a Class II Type B2 BSC must be used when preparing certain hazardous drugs (see "Ventilated enclosures" on page 25). Class II Type A1, A2, and B1 cabinets must not be used for these hazardous drugs. See sections 6.50(3) and (4) of the Regulation.

Closed system drug-transfer devices (CSTDs)

Closed system drug-transfer devices (CSTDs) are designed to contain hazardous drugs and minimize potential exposure when transferring them between containers or pieces of equipment.

A CSTD is not a substitute for compounding preparations inside a BSC. When using a CSTD during the preparation of hazardous drugs, it should always be inside a BSC.

Several studies have demonstrated that using a CSTD in addition to a BSC reduces surface contamination of hazardous drugs in the workplace. Whenever practicable, use a CSTD for transferring hazardous drugs between containers.

Other engineering controls

Many different types of equipment and supplies are used as engineering controls in the preparation and administration of hazardous drugs. Further examples include:

- Fittings that prevent accidental disconnection, such as luer lock fittings
- Appropriate needleless systems or safety-engineered needles that reduce the risk of workers getting a percutaneous exposure
- Filtered venting devices, such as chemotherapy-dispensing pins and chemotherapy vents, that can minimize the accidental release of hazardous drugs when reconstituting or withdrawing from a vial

11. Administrative controls

Administrative controls involve identifying and implementing safe work procedures that minimize worker exposure to hazardous drugs. The safe work procedures must be written in the exposure control plan (ECP).

Written safe work procedures in the ECP

The written safe work procedures in the ECP are an important part of ensuring that information on minimizing exposure is communicated to workers. A qualified person (see page 13) must ensure that the written work procedures are specific to the tasks performed at the workplace. The work procedures must be available for workers to reference.

A qualified person must ensure that the written work procedures include:

- Appropriate safe work procedures for all tasks and activities involving hazardous drugs, including but not limited to:
 - The manufacture, receipt, preparation, administration, storage, and disposal of a hazardous drug
 - Procedures for housekeeping
 - Procedures for emergency decontamination and any other work activity in which a worker is at risk of exposure to a hazardous drug
- Procedures for containing or enclosing work activities that involve hazardous drugs (if containment or enclosure is used as a control measure)
- Requirements for providing, selecting, using, caring for, maintaining, and disposing of personal protective equipment
- Requirements for personal hygiene where hazardous drugs are present, including:
 - Proper handwashing
 - The prohibition of eating, drinking, smoking, applying personal care products, and storing food
- Reporting and response procedures for accidental exposure, a spill, or the uncontrolled release of a hazardous drug
- Procedures for identification, removal, cleanup, and disposal of hazardous drug waste, including:
 - · Any materials that come into contact with a hazardous drug
 - Anything contaminated by excreta, vomit, or bodily fluids from a patient treated with a hazardous drug



In the Regulation

The employer must ensure that a qualified person includes written work procedures in an ECP. Section 6.46.1(2) of the Regulation sets out what the work procedures must address. See also page 28.

The work procedures must be readily available for workers to reference where hazardous drugs are in the workplace. See section 6.46.1(3) of the Regulation.

An employer must consult with the joint committee or the worker health and safety representative about the ECP. See section 6.46(3) of the Regulation.

Workers exposed to reproductive toxins: Protective reassignment

If a worker is or may be exposed to a hazardous drug that is a reproductive toxin, the employer must develop the following:

- A written policy about the availability of protective reassignment
- A procedure for determining if protective reassignment is appropriate for workers who advise the employer that they are pregnant or intend to conceive a child

Protective reassignment is an administrative control that involves assigning a worker to alternative tasks that reduce the risk of exposure to hazardous drugs. Some examples of protective reassignment include:

- Moving the worker to a different area that does not involve exposure to hazardous drugs
- Assigning the worker to tasks where they won't be exposed to hazardous drugs
- Reducing hours worked in areas where hazardous drugs are handled

12. Personal protective equipment (PPE)

The specific personal protective equipment (PPE) required for each task in the workplace is determined by a risk assessment carried out by a qualified person. Workers should refer to the safe work procedures for their workplace to determine what types of PPE they are required to wear when handling hazardous drugs.

The employer must provide workers with appropriate PPE and training on its correct use and disposal. Workers are responsible for wearing supplied PPE when it is needed.

PPE may include:

- Gloves designed for use with hazardous drugs
- · Gowns that are moisture resistant and have long sleeves and tight-fitting cuffs
- Respirators
- Face and eye protection

Part 8 of the Regulation states the requirements for personal protective clothing and equipment.

If the PPE is disposable, then once it's been used for hazardous drugs, it must be discarded as hazardous drug waste. Non-disposable PPE must be cleaned and decontaminated after each use.

Contaminated (or potentially contaminated) PPE must not be worn outside of areas where any of the following occurs:

- Hazardous drugs are manufactured, prepared, administered, or stored.
- Waste contaminated by a hazardous drug is handled.



In the Regulation

PPE that is consistent with the ECP's written work procedures must be used where there is exposure to hazardous drugs. See 6.46.1(2)(d) of the Regulation.

Employers must provide information, instruction, and training to workers on how to select, use, and maintain PPE. See sections 6.48(4)(b) and 6.51(2)(c) of the Regulation.

Also, see sections 8.40 and 8.41 of the Regulation for requirements on the use of respirators, if applicable.

Protective gloves

Where the risk assessment requires use of gloves, the gloves must provide effective protection from the hazard — for example, gloves meeting the requirements of ASTM Standard D6978-05 (as amended from time to time).

Protective gloves used for hazardous drugs should:

- Not be powdered, as the powder can become contaminated, fall off the gloves during removal, and lead to further contamination
- · Be compatible with cleaning and decontaminating agents used in the workplace
- Be latex free (e.g., neoprene, nitrile, polyurethane)
- Be able to maintain their resistance to permeation by hazardous drugs when disinfected (e.g., with alcohol)

Best practices for using gloves include the following:

- Wear double gloves when the risk for dermal contamination with hazardous drugs is high. (This is determined as part of your workplace risk assessment.)
- Follow steps to avoid contamination when putting on and removing gloves. This includes washing hands before and after wearing gloves.
- Change gloves if they have been contaminated or compromised.
- Remove outer gloves before taking them out of a biological safety cabinet.

Protective gowns

Workers should wear gowns designed for use with hazardous drugs when there is a risk of contact with hazardous drugs or contaminated bodily fluids and waste from patients during the precautionary period.

Gowns should meet the requirements of ASTM Standard F739 (as amended from time to time), or a comparable standard.

Gowns should:

- Be identified by the manufacturer as gowns for handling hazardous drugs
- Be moisture resistant, with long sleeves and tight-fitting cuffs
- Have a closed front that covers the worker from shoulders to knees and fastens in the back

Best practices for protective gowns include the following:

- Change the gown immediately when compromised (e.g., by a tear or a spill).
- Wash hands immediately after removing a gown.



In the Regulation

Employers must ensure the following:

- Contaminated or potentially contaminated PPE, including gowns and gloves, is not worn outside areas where any of the following occurs:
 - · Hazardous drugs are manufactured, prepared, administered, or stored.
 - · Waste contaminated by a hazardous drug is handled.
- Non-disposable PPE is cleaned and decontaminated after use in accordance with the written work procedures. See section 6.49 of the Regulation.

Respirators

An approved and fit-tested respirator must be worn when there is a risk of exposure to airborne particulates, aerosols, or vapours from hazardous drugs.

The respirator must protect against particulates and gases or vapours that can be generated from solid or liquid forms of hazardous drugs, depending on the chemical properties. This could include a half- or full-facepiece air-purifying respirator that has a particulate filter (e.g., N95 or better) and a **chemical cartridge** that removes vapour contaminants from air as it is inhaled.

The choice of respirator must be made as part of the risk assessment, based on the potential exposure to airborne particulates, aerosols, or vapours from hazardous drugs for each task in the workplace. Fit tests must be carried out before a respirator is issued to a worker. The worker must perform a seal check before each use.

Refer to the WorkSafeBC publication *Breathe Safer: How to Use Respirators Safely and Start a Respirator Program* for more information on how to select an appropriate respirator.

Refer to sections 8.32 to 8.45 of the Regulation for respirator requirements.

Face and eye protection

Face protection, such as full or partial face shields and goggles, should be worn when there is a risk of splashing. Splashing may occur when handling liquid forms of hazardous drugs or contaminated bodily fluids and waste.

When following best practices for wearing face protection for hazardous drugs, workers should do the following:

- · Wear full face shields.
- Use disposable face protection whenever practicable.
- Clean non-disposable face protection immediately after use.

Footwear and shoe covers

Workers must ensure their footwear is in a condition to protect against hazardous drugs. For example, workers need to wear closed shoes that are made of a material that prevents liquids from soaking through. Refer to section 8.22 of the Regulation for more information on footwear requirements.

Shoe covers are part of sterile preparation procedures. They also help reduce exposure by preventing contamination from being spread to other workplace areas on workers' shoes.

Best practices for footwear and shoe covers include the following:

- Have a dedicated set of footwear that is only used in the preparation area.
- Wear shoe covers when entering a sterile preparation room.
- Remove shoe covers with gloved hands and dispose of them as hazardous waste after exiting the preparation room.
- Wear shoe covers when cleaning up spills or broken containers on the floor.

13. Instruction, training, and supervision

Instruction, training, and supervision are essential components of reducing exposure to hazardous drugs in the workplace. Employers are responsible for ensuring that all workers who may be exposed to hazardous drugs receive information, instruction, and training on the safe handling of hazardous drugs. The instruction and training must address all of the following:

- Known health effects, including reproductive health effects, caused by exposure to hazardous drugs
- The written work procedures in the exposure control plan (ECP)
- · How to select, use, and maintain personal protective equipment and clothing

Employers must evaluate whether the instruction and training are still adequate if there is a change to any of the following:

- · The hazardous drug being used
- · Practices for handling it
- Work activities
- Information about the hazardous drug

If there are changes, employers must provide more instruction and training to workers, if necessary.

Employers must also ensure that a worker who is or may be exposed to a hazardous drug is effectively supervised and follows all applicable written work procedures from the ECP.



In the Regulation

For information on instruction and training, see section 6.51 of the Regulation.

For information on supervision, see section 6.52 of the Regulation.

The employer must review the instruction and training of workers as necessary, in consultation with the joint committee or the worker health and safety representative. See section 6.51(4) of the Regulation.

14. Keeping records

If a worker prepares a hazardous drug, the employer must keep records for the duration of that worker's employment plus 10 years. These records must include:

- Names of the hazardous drugs prepared
- Number of preparations of hazardous drugs per week, if practicable
- All risk assessments and exposure control plans (ECPs), including updates that are relevant to the worker's employment, that applied to the worker at any time during their employment

If a worker administers a hazardous drug, the employer must keep records for the duration of that worker's employment plus 10 years. These records must include the following:

- · Names of the hazardous drugs administered by the worker:
 - Parenterally
 - Orally, if capsules were opened or if the hazardous drug was in powder or liquid form
 - By topical application
- Number of administrations per week, if practicable
- All risk assessments and ECPs, including updates that are relevant to the worker's employment, that applied to the worker at any time during their employment

The employer must also keep records of all instruction and training of workers who are or may be exposed to hazardous drugs. These records must be kept for three years from the date that the instruction was given or the training was provided.



In the Regulation

For information on keeping records, see section 6.58 of the Regulation.

Part 4:

Work procedures for reducing exposure to hazardous drugs

The following chapters provide information on work procedures and Regulation requirements for each stage of handling hazardous drugs. These chapters also include information on best practices. The practices that your workplace chooses to adopt should be based on the findings of the risk assessment. The goal is to minimize worker exposure to hazardous drugs.

15. Drug preparation

Workers may work directly with hazardous drugs when they prepare, compound, and verify drugs before they are administered to patients. Care must be taken to minimize exposure during handling and to limit the spread of hazardous drug contamination.

Examples of activities that could result in exposure include:

- Compounding, diluting, or altering hazardous drugs
- Priming administration equipment with hazardous drugs, which can generate aerosol or particulate contamination
- Handling, crushing, cutting, or opening oral medications
- Handling hazardous drugs while verifying before they leave the pharmacy, as packaging may have surface contamination

Regulation requirements

There must be written work procedures to address the following:

- Preparation of hazardous drugs
- · Containment or enclosure of work activities related to working with hazardous drugs

A ventilated enclosure must be used when mixing, preparing, or priming certain hazardous drugs. Priming intravenous administrative sets with saline solution is permitted outside of a ventilated enclosure if the saline solution does not contain a hazardous drug.

For more information, see "Ventilated enclosures" on pages 25–27.



In the Regulation

Ventilated enclosures used for preparing, mixing, and priming certain hazardous drugs must meet or exceed the requirements for a Class II Type B2 biological safety cabinet. Type A1, A2, B1, or C1 cabinets must not be used for preparing, mixing, and priming hazardous drugs. See section 6.50(4) of the Regulation.

Considerations for safer work practices

Some examples of safer practices for the preparation of hazardous drugs include the following:

- Obtain hazardous drugs from the supplier in a form that is ready to administer.
- Use safety-engineered needles that do not produce spray when activated.
- Use closed system drug-transfer devices.
- · Use disposable plastic syringes.
- Use an approved biological safety cabinet (BSC) for preparations of hazardous drugs.

- Plan tasks to avoid leaving and re-entering the preparation room unnecessarily.
- Limit access to the preparation room to workers trained to work in the room (e.g., pharmacy and housekeeping staff).
- Limit equipment and materials in a BSC to those required to prepare one dose for one patient. This helps avoid overcrowding and mixing up drugs.
- Implement procedures for priming equipment with a hazardous drug solution in a BSC. (See the next chapter for priming with a non-hazardous drug solution.)
- Implement procedures to have all alterations of hazardous drug tablets or capsules (e.g., cutting, splitting, and crushing) performed inside an approved BSC.
- Don't use automated unit-dose packaging machines or automated counting machines with tablet or capsule forms of hazardous drugs.
- Implement procedures to reduce contamination of containers and IV bags after they leave the BSC (e.g., clean with a soap-moistened towel and place the product in a clear, resealable bag).



In the Regulation

Safety-engineered needles or needleless systems must be used when caring for or treating a person. This applies to all hazardous drugs. See section 6.36 of the Regulation.

Cleaning

The preparation room should be cleaned regularly as part of regular housekeeping and throughout the workday. This includes the following:

- Regular cleaning of the interior of the BSC
- Cleaning and decontaminating of the preparation room, moving from the cleanest areas to the most contaminated

16. Drug administration

Administration of hazardous drugs can take many forms. Examples include IV therapy, inhalation therapy, surgical procedures, injections, and oral and topical medications.

Examples of activities that could result in exposure include:

- Using administration equipment that may leak or spill, such as IV equipment
- Directly handling medications such as oral or topical treatments
- Removing air or priming equipment such as syringes
- Exposure to blood or bodily fluids during the precautionary period

Regulation requirements

There must be written work procedures to address the administration of hazardous drugs, including the containment or enclosure of work activities related to working with hazardous drugs.

Work area design

Hazardous drugs are administered in treatment areas in a number of different settings. The design of treatment areas should reflect the findings of the risk assessment.

Treatment areas where hazardous drugs are administered should:

- Be kept under neutral or negative air pressure to the surrounding rooms, where possible
- Use surfaces that are easy to clean (e.g., stainless steel), where possible
- Keep rest areas for workers or visitors isolated from administration areas

Drug administration equipment

Selecting appropriate equipment for the administration of hazardous drugs can help minimize the risk of exposure to workers.

All activities involving the administration of medication to a person must be done with safety-engineered medical sharps or a needleless system, where clinically appropriate.

Equipment used for the administration of hazardous drugs includes:

- Closed system drug-transfer devices (CSTDs) designed for such administration
- Safety-engineered needles
- Filtered venting devices, such as chemotherapy-dispensing pins and chemotherapy vents
- Administration equipment, such as IV pumps and continuous ambulatory delivery device (CADD) pumps
- Appropriate fittings, such as luer locks, to prevent accidental disconnection



In the Regulation

All activities involving the administration of medication to a person must be done using a safety-engineered medical sharp or a needleless system. See section 6.36 of the Regulation.

The written work procedures must address the preparation and administration of a hazardous drug. See section 6.46.1(2)(a)(i) of the Regulation.

Considerations for safer work practices

Some examples of safer practices for the administration of hazardous drugs include the following:

- Avoid priming IVs with a hazardous drug solution at the point of administration. (This must be done as part of the preparation step in an approved BSC.)
- If priming of administration sets cannot be done as part of the preparation step, implement procedures so that priming is performed with compatible dilutant and the drug is added afterwards.
- Avoid altering (e.g., crushing or cutting) oral medications at the point of administration. (This should be done as part of the preparation step in an approved BSC.)
- Avoid contact with oral medications during administration, where possible, by using medication cups or unit-dose packaging from the manufacturer, or by having patients administer their own medication.
- Use CSTDs for administration activities, including withdrawing and injecting hazardous drugs from syringes and IV systems.
- Place disposable, absorbent pads under the patient where administration is occurring.
- Use bandages that can be applied over an area where a topical medication has been applied to avoid spreading contamination to clothing or bedsheets.
- Limit access to administration areas. (This is extremely important for some administration forms, particularly aerosolization therapy. Only the patient should be in the room where treatment is taking place.)
- For veterinary clinics, have cages, kennels, or stalls dedicated for animals that are receiving or have recently received chemotherapy.
- Implement procedures for proper disposal of administration equipment (e.g., flush IV tubing with a dilutant before disconnecting, or discard tubing immediately as hazardous waste after use).



In the Regulation

Priming of administrative sets with certain hazardous drugs must be performed in a ventilated enclosure that meets Regulation requirements. See sections 6.50(3) and (4) of the Regulation.

Cleaning

Administration areas should be cleaned regularly. Each administration area should have a set of cleaning equipment dedicated for that area. Equipment and products used for housekeeping and emergency decontamination in relation to hazardous drugs must be designated for use with hazardous drugs only and kept readily available for use. The equipment and products should not be used in other areas.

Work areas (e.g., trays, carts, tabletops, chairs, and beds where hazardous drugs are administered) should be cleaned daily.

Administering hazardous drugs in home care settings

Administering hazardous drugs in home care settings poses additional challenges because there is less ability to change the physical work environment.

A qualified person must do a risk assessment to consider the scope, circumstances, and nature of the work activities. Where possible, an initial assessment of the home should be done to determine that there are appropriate facilities for the activities that will take place in the home. For example, the assessment should determine if there is:

- · Running water to allow for handwashing
- A properly functioning toilet with a lid
- Windows that can be opened for ventilation

The guidelines for safe work practices in administration settings discussed in the previous sections may also be applied in home care settings, where relevant. Additional best practices for administration in the home include the following:

- Avoid any alteration of hazardous drugs in the home as much as possible. (Activities such
 as cutting or crushing oral medications and dissolving powders into solutions should be
 done by pharmacy staff in a ventilated enclosure such as a BSC. See pages 22–27 for more
 information on BSCs.)
- Mixing, preparing, and priming certain hazardous drugs must be done in a designated BSC that is at least a Class II Type B2. (For more information, see page 25.)
- Provide the patient with instructions on the following:
 - How to use administration equipment, such as electronic diffusion devices.
 - Safe handling precautions during the precautionary period. These precautions include recommendations for the equipment and PPE required.
 - How to safely dispose of hazardous drug waste and contaminated medical sharps.

17. Patient care

Providing personal care for patients receiving hazardous drugs requires additional precautions. Bodily fluids have been shown to contain hazardous drugs during the precautionary period.

Examples of activities that could result in exposure include:

- Handling bodily fluids from a patient who has received hazardous drugs
- Bathing the patient
- Handling contaminated bedding or laundry
- Assisting with toileting, especially flushing toilets
- Cleaning the patient's room, washroom, or home

Work area design

The design of the patient care area must reflect the results of the risk assessment.

In general, care areas where patients are receiving or have received hazardous drugs should:

- Be isolated from other patient care areas, where possible
- · Have dedicated washroom facilities for patients who have received hazardous drugs
- Have appropriate laundry services

Equipment

Equipment used for caring for patients within the precautionary period includes:

- Bed pans that are disposable, when possible
- Carts and trays that are easy to clean and dedicated for use with patients who have received hazardous drugs

Considerations for safer work practices

Some examples of safe work practices when caring for patients receiving hazardous drugs include the following:

- Implement safe procedures for handling bodily fluids of patients during the precautionary period, such as covering toilets and double flushing.
- Implement safe procedures for handling laundry from patients during the precautionary period. Examples include refraining from shaking laundry, folding bedding so any contamination is trapped in the centre, and placing laundry in a plastic bag.
- Where possible, discard laundry or bedding that is heavily contaminated by bodily fluids, or wash such items separately from other laundry.

- On top of regular charting requirements, document the length of the precautionary period for the patient as per the treatment protocol.
- Ensure workers review patient history before providing care.

When patients are being cared for at home, either by a health care worker or the patient's family, safer work practices should be considered. For more information, see "Administering hazardous drugs in home care settings" on page 42.



In the Regulation

Employers must ensure that a qualified person prepares written work procedures for the disposal of excreta, vomit, or bodily fluids from patients who have been treated with a hazardous drug and are within the precautionary period. See section 6.46.1(2)(h)(ii) of the Regulation.

Cleaning

Patient care areas should be cleaned and decontaminated regularly. This includes the following:

- Regularly clean washrooms of patients receiving hazardous drugs.
- Immediately clean up spills of patients' bodily fluids.

The equipment and products for housekeeping, decontamination, and emergency decontamination must be readily available and must not be used for other purposes.

18. Drug storage and labelling

Surface contamination of containers and packaging is a potential source of exposure for workers as they unpack and store incoming shipments of hazardous drugs. Facilities should communicate with the drug suppliers to identify hazardous drugs during shipping to reduce exposure for the workers transporting and receiving the drugs. Hazardous drugs must be stored with clear labelling in a designated area.

Examples of activities that could result in exposure include:

- Handling incoming shipments of hazardous drugs that may have surface contamination
- Opening packages containing hazardous drugs, which could result in the generation of particulates or aerosols
- Handling individual containers or bags of hazardous drugs that may have surface contamination
- · Handling damaged packaging that has resulted in a leak or spill

If an incoming shipment is damaged or broken, follow proper spill response procedures (see Chapter 22).

Regulation requirements

There must be written work procedures to address storage of hazardous drugs.

Employers must ensure the following:

- Hazardous drugs are stored in a designated area, if practicable.
- Work activities related to storage are conducted in accordance with the written work procedures.

The designated area must:

- Be designed and constructed to ensure the hazardous drugs are safely contained
- Have clearly visible signs warning that hazardous drugs are stored in the area
- Not be located in any space used for eating or for changing or storing clothes
- Be restricted to authorized personnel only

All containers, bins, and shelves used to hold hazardous drugs must be correctly and clearly labelled.

It may not be practicable in all cases to provide a designated area for storage. A qualified person should make this determination based on the risk assessment. In such cases (e.g., in a home care setting), the designated area could be a suitable bin that is properly labelled and accessible only to authorized workers.

Examples of signs and labels for hazardous drugs

CAUTION CHEMOTHERAPYAuthorized Personnel Only

HAZARDOUS DRUG

Do not crush tablet or open capsule

CAUTION: ANTI-NEOPLASTIC MATERIAL HANDLE PROPERLY.

CHEMOTHERAPY DISPOSE OF PROPERLY



Equipment

Equipment used in receiving and storage areas should, where possible, be designed to minimize potential exposure to hazardous drugs. Examples of such design features include:

- · Storage shelves with fall guards, such as lipped edges or barriers
- Containers with lids for storage and transportation of hazardous drugs

Considerations for safer work practices

Some examples of safer practices to eliminate or minimize the risk of hazardous drugs during receiving and storage include the following:

- Check incoming shipments for damage before any container is opened.
- Implement a procedure to clean containers before they are moved to storage (e.g., wipe the exterior of containers with a single-use, disposable absorbent pad and a detergent and water solution).
- Limit access to the storage area and use signs to indicate entry is restricted to authorized personnel only.
- Store hazardous drugs in their original packaging (e.g., resealable bags or shrink wrap).
- Ensure storage containers are not overfilled.

19. Transport

Transport refers to both shipping hazardous drugs to facilities and the movement of drugs within facilities.

Examples of activities that could result in exposure during transport include:

- · Handling containers or packages with surface contamination
- · Handling containers or packages when there has been a leak or a spill

Regulation requirements

Drug suppliers and shipping companies handling hazardous drugs must ensure that appropriate procedures are in place to protect their workers from exposure. These requirements include the following:

- Transport hazardous drugs in a sealed container.
- Label the container with a unique, recognizable identifier to distinguish the hazardous drugs from other drugs.
- Package hazardous drugs in a way that minimizes environmental contamination if the hazardous drug is dropped or there is a spill, leak, or uncontrolled release.

Workers who transport a hazardous drug must be trained in procedures to follow in the event of a spill. Employers must ensure that clearly labelled spill kits are readily available to workers.

Considerations for safer work practices

The equipment used for transporting hazardous drugs should be designed to minimize exposure to workers during handling. This includes the following:

- Use equipment that reduces spills, such as carts with lipped edges and closed, hard-sided transport boxes.
- Use equipment that is easy to clean.
- Place hazardous drugs in resealable, clear plastic bags before transport.
- Use closed, hard-sided boxes for transporting hazardous drugs in the facility.
- Implement procedures for safe handling of products during transport.

20. Housekeeping and decontamination

Cleaners, housekeeping workers, and laundry staff may be at risk of exposure. There is also a risk of cross-contamination from housekeeping equipment. Workplaces may have contract workers who are responsible for cleaning activities. If this is the case, it is essential to coordinate with the contracting company to develop procedures to minimize hazardous drug contamination throughout the workplace.

Examples of activities that could result in exposure include contact with:

- Surfaces contaminated with hazardous drugs
- Bodily fluids or waste
- Cleaning solutions that have been applied to clean up hazardous drugs



In the Regulation

In the Regulation, decontamination "means the removal, inactivation or destruction of a hazardous drug that is or may be on a surface, material or thing."

Housekeeping includes the following:

- Routine cleaning
- · Routine decontamination
- Changing, handling, laundering, or other cleaning, and the disposing of things contaminated with the excreta, vomit, or bodily fluids of patients

See section 6.42 of the Regulation.

Regulation requirements

There must be written work procedures that address:

- Housekeeping
- The cleanup and disposal of anything contaminated during the precautionary period

To prevent cross-contamination, housekeeping equipment must be designated for use for hazardous drugs and must be readily available for use (e.g., close to where equipment will be used and not confused with equipment used for non-hazardous drugs).

Ensure workers are provided with training on hazardous drugs, including potential routes of exposure and how to minimize exposure.

Considerations for safer work practices

Best practices for cleaning activities in areas with hazardous drug contamination include the following:

- Change routine cleaning practices to minimize hazardous drug contamination.
- For veterinary clinics, prohibit the use of pressure washers to clean cages, kennels, and stalls of animals being treated with hazardous drugs to minimize the spread of aerosolized contamination.
- For veterinary clinics, supply disposable towels for cleaning cages, kennels, and animals, where practicable.

Cleaning agents

Effective cleaning and decontamination are key parts of reducing surface contamination. Hazardous drug contamination has been detected on surfaces even after cleaning using conventional methods and cleaning products. Hazardous drug contamination may accumulate in porous materials.

Multiple cleaning agents may be required to ensure effective cleaning and decontamination. The effectiveness of a cleaning or decontaminating agent depends on the chemical and physical properties of the hazardous drug, as well as the surface being cleaned.

When selecting cleaning and decontamination agents, consider:

- Current research on the effectiveness of different procedures and agents on the types of hazardous drugs being used
- Surfaces (e.g., stainless steel BSCs) that may have cleaning requirements specified by the manufacturer
- The characteristics of the surfaces that will be cleaned and decontaminated, such as porosity and texture
- The ease of use, such as having pre-packaged wipes soaked in solution
- The potential for hazardous by-products from cleaning and decontamination products, or products that are hazardous themselves

The following table provides more information on agents used for deactivating, decontaminating, disinfecting, and cleaning.

	Deactivating agent	Decontaminating agent	Disinfecting agent	Cleaning agent
Examples	Hypochlorite (household bleach).	Laboratory-grade detergents.	Ethyl alcohol, 70%.Isopropyl alcohol.	Chlorhexidine.
Mode of action	Breaks down hazardous drugs.	Physically removes hazardous drugs.	Disinfects surfaces.	Removes organic and inorganic material.
Benefits	Highly effective at deactivating several commonly used hazardous drugs.	 Safer than bleach. Convenient. Use of different agents can improve efficiency against different drugs. 	Commonly used in routine disinfection procedures.	Commonly used in routine cleaning procedures.
Challenges	 Can produce hazardous by-products. Known to corrode stainless steel. (This can be minimized by following with a neutralizing agent.) Can cause skin, eye, and respiratory irritation. 	 May be less effective when type of contamination is unknown. Higher concentrations may leave residues that can trap hazardous drugs. 	 Does not directly act on hazardous drugs. Should not be used as the sole agent for removing hazardous drug contamination. 	

21. Waste handling and disposal

Hazardous drug waste is a potential source of exposure to hazardous drugs. The employer must develop safe work procedures to ensure that all waste related to a hazardous drug is handled and disposed of in accordance with the manufacturer's instructions.

Hazardous drug waste may include:

- Hazardous drugs that are to be disposed of
- Disposable equipment used to administer hazardous drugs, such as syringes, needles, or IV tubing
- Disposable PPE used for protection against exposure to hazardous drugs
- Excreta, vomit, or bodily fluids from patients who are within the precautionary period
- Disposable materials contaminated with excreta, vomit, or bodily fluids from patients who are within the precautionary period



In the Regulation

The employer must develop written work procedures for the identification, removal, cleanup, and disposal of hazardous drug waste. See section 6.46.1(2)(h) of the Regulation.

For information on waste handling and disposal, see section 6.56 of the Regulation.

Examples of activities that could result in exposure include:

- Handling hazardous drug waste containers that may have surface contamination
- Handling materials that have come into contact with a hazardous drug
- Disposing of anything contaminated by excreta, vomit, or bodily fluids from a patient treated with a hazardous drug

Regulation requirements

There must be written work procedures that address the identification, removal, cleanup, and disposal of hazardous drug waste. This includes anything contaminated during the precautionary period by excreta, vomit, or bodily fluids from a patient treated with a hazardous drug.

All hazardous drug waste must be handled and disposed of in accordance with the manufacturer's instructions, if any.

Hazardous drug waste containers must be collected and transported in a facility only by workers trained in safe handling of hazardous drugs and the procedures to follow in the event of a spill.

Every area where hazardous drugs are manufactured, prepared, administered, or stored must have appropriate waste containers and, if appropriate, sealable plastic waste bags.

Hazardous drug waste containers or bags:

- Must be leak-proof and sealable
- · Must be puncture and fluid resistant
- Must be designated for use with hazardous drugs
- Should be clearly labelled as designated for hazardous drugs (e.g., by using a uniform colour for all such containers or bags in a workplace)

A bag used for disposal of soft materials (e.g., laundry, gloves, or gowns) contaminated with hazardous drugs should be:

- Made of thick, leak-proof plastic
- · Clearly labelled

All areas where there is potential for hazardous drug waste must have a hazardous drug waste container and, if appropriate, sealable plastic waste bags. These areas can be determined as part of a risk assessment.

During the precautionary period, excreta, vomit, and bodily fluids from a patient treated with a hazardous drug must be treated as hazardous drug-related waste and placed in a bag or container for disposal.



In the Regulation

A hazardous drug waste container or bag must be provided in areas where hazardous drugs are manufactured, prepared, administered, or stored. See section 6.56 of the Regulation.

Work area design

If hazardous drug waste is stored at the workplace before it is taken to be disposed of, it should be stored with appropriate precautions. These precautions are determined by the risk assessment and the written work procedures. Examples of precautions include the following:

- Store hazardous drug waste in a cool, locked, ventilated area until it is transported out of the facility.
- Isolate the storage area for hazardous drug waste from other workplace areas as much as possible.
- Store hazardous drug waste in a manner that reduces the risk of leaks and spills, such as by having shelves with lipped edges.
- Use materials that are easy to clean, such as stainless steel.

Considerations for safer work practices

Some examples of safer practices for disposal of hazardous drug waste include the following:

- Share information about hazardous drugs with external waste-collection companies.
- Send hazardous drug waste for disposal by a certified hazardous waste organization and in accordance with local regulations.
- Arrange for the collection of hazardous drug waste containers from a patient's home.
- Implement procedures to reduce the risk of leaks (e.g., place contaminated items in double plastic bags before placing in a hazardous drug waste container).
- Provide hazardous drug waste containers and bags to patients and animal owners who
 are receiving hazardous drugs or being cared for at home.

22. Spill response and emergency decontamination

Employers must develop emergency procedures for spills or uncontrolled releases of hazardous drugs. Signs detailing spill response procedures should be posted in all relevant areas of the workplace.



In the Regulation

Employers must develop written work procedures in an exposure control plan for emergency decontamination following a spill or an accidental exposure to hazardous drugs. See section 6.46.1(2)(a) and (g) of the Regulation.

Examples of activities that could result in exposure include:

- · Contact with a leak or spill
- Inhalation of aerosols, vapours, or particulates released as the result of a spill
- · Contact with contaminated cleaning supplies

Regulation requirements

The written work procedures must have reporting and response procedures for incidents that involve:

- Accidental exposure to a hazardous drug
- A spill, or the uncontrolled release, of a hazardous drug

Requirements for hazardous drug spill response include the following:

- Supply a clearly labelled spill kit in all areas where hazardous drugs are manufactured, received, prepared, administered, stored, or transported.
- Ensure the kits and spill procedures are readily available to workers.
- Provide training on emergency spill procedures or unintended exposure.
- Allow only workers trained to clean spills to do so.
- Ensure all spill-cleanup supplies are discarded as hazardous waste in clearly labelled, leak-proof, and sealable waste containers and sealable plastic waste bags.

A spill kit should include the following:

- · Laminated, written instructions
- Warning signs and plastic "caution" tape to alert other staff to the hazard and to isolate the spill area



In the Regulation

The employer must ensure that clearly labelled spill kits are:

- Kept in or near any area in which a hazardous drug is manufactured, received, prepared, administered, stored, or transported
- · Readily available to workers

See section 6.53 of the Regulation.

Appendices

Appendix 1: Resources

In-text resources

The following resources are mentioned throughout this book, and they may be amended from time to time.

American Society for Testing and Materials: ASTM D6978-05 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.

American Society for Testing and Materials: ASTM F739 Standard Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions of Continuous Contact.

Government of Canada: Canadian Biosafety Standards and Guidelines.

Health Canada: Drug Product Database.

International Agency for Research on Cancer (IARC): IARC Monographs on the Identification of Carcinogenic Hazards to Humans.

National Institute for Occupational Safety and Health (NIOSH): NIOSH List of Hazardous Drugs in Healthcare Settings.

NSF / American National Standards Institute: NSF/ANSI 49 Biosafety Cabinetry: Design, Construction, Performance and Field Certification.

WorkSafeBC: Breathe Safer: How to Use Respirators Safely and Start a Respirator Program.

Additional resources

The following resources offer more information on hazardous drugs.

American Society of Health-System Pharmacists (ASHP). 2018. Guidelines on Handling Hazardous Drugs.

Association paritaire pour la santé et la sécurité du travail du secteur affaires socials (ASSTSAS) [Joint Sector-based Association for Health and Occupational Safety for the Social Sector]. 2023. Prevention Guide: Safe Handling of Hazardous Drugs.

BC Cancer Agency (BCCA). 2023. Safe Handling of Hazardous Drugs — Module 1.

Canadian Association of Pharmacy in Oncology (CAPhO). 2009. Standards of Practice for Oncology Pharmacy in Canada.

Chaffee, B, Armitstead, J, Benjamin, B, Cotugno, M, Forrey, R, Hintzen, B, Pfeiffenberger, T, & Stevenson, J. Guidelines for the safe handling of hazardous drugs: Consensus recommendations. Am J Health-Syst Pharm 67 (2010): 1254–1546.

International Society of Oncology Pharmacy Practitioners (ISOPP). 2007. Standards of Practice — Safe Handling of Cytotoxics.

National Institute for Occupational Safety and Health (NIOSH). 2010. Safe Handling of Hazardous Drugs for Veterinary Workers. Workplace Solutions.

National Institute for Occupational Safety and Health (NIOSH). 2016. NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016.

Occupational Health and Safety Administration (OSHA). 2017. Controlling Occupational Exposure to Hazardous Drugs.

WorkSafeBC. 2022. Creating and Managing a Healthy and Safe Workplace.

WorkSafe Victoria. 2013. Handling cytotoxic drugs in the workplace: Handling health and safety risks associated with handling cytotoxic drugs in the healthcare industry.

Appendix 2: Glossary

administrative controls

The provision, use, and scheduling of work activities and resources in the workplace, including planning, organizing, staffing and coordinating, for the purpose of controlling risk.

antineoplastic

An agent that acts to prevent, inhibit, or prevent the development of a neoplasm (a tumour), and which is most often used to treat cancer.

biological safety cabinet (BSC)

An enclosed, ventilated containment device that provides protection for workers, the environment, and the product, depending on the BSC class.

biomarkers

Measurable, biological signs that indicate exposure to a substance or development of a disease. For example, a biomarker could be a metabolite of a chemical or a predicted change in normal body functioning.

carcinogenicity

The ability to cause cancer.

chemical cartridge

A cartridge that can be added to an elastomeric respirator designed to remove gases or vapours from the air a worker breathes. These cartridges contain chemical compounds that react with specific contaminants so they are removed from the air. Cartridges must be replaced following a specific schedule outlined by the manufacturer.

closed system drug-transfer device (CSTD)

A device that completely contains a substance it is carrying by preventing leaks, airborne particulates, and vapours from escaping.

controls

Methods of protecting against hazards. In the case of hazardous drugs, controls eliminate or minimize the risk of exposure to workers.

decontamination

The removal, inactivation, or destruction of a hazardous drug that is or may be on a surface, material, or thing.

emergency decontamination

Decontamination in response to a spill or an emergency that involves, or may involve, a hazardous drug. Does not include routine decontamination performed as part of housekeeping.

engineering controls

The physical arrangement, design, or alteration of workstations, equipment, materials, production facilities, or other aspects of the physical work environment, for the purpose of controlling risk.

environmental monitoring

The use of analytical techniques, such as surface wipe sampling, to measure contamination of an environment over a period of time.

exposure control plan (ECP)

A requirement in the Regulation that details how the employer will minimize exposure to hazardous drugs. Employers must ensure a qualified person develops an exposure control plan if their workers may be exposed to hazardous drugs.

genotoxicity

The ability to damage or mutate DNA.

hazardous drug

A drug that:

- (a) Has one or more of the following characteristics:
 - (i) Carcinogenicity
 - (ii) Teratogenicity
 - (iii) Genotoxicity
 - (iv) Reproductive toxicity
 - (v) Organ toxicity at low doses
- (b) Is a new drug that mimics, in structure or toxicity, an existing drug known to be a hazardous drug according to the characteristics listed in list item (a), or
- (c) Is identified in the NIOSH list as a hazardous drug

housekeeping

Routine cleaning for hygiene, including changing, handling, and laundering linens, and cleaning and disposing of things contaminated with the excreta, vomit, or bodily fluids of patients treated with hazardous drugs.

luer lock

A fitting for medical instruments that is designed to prevent leaking.

mutagenic

A substance that causes mutations to occur in the genetic material of cells.

NIOSH list

The NIOSH List of Hazardous Drugs in Healthcare Settings, prepared by the United States National Institute for Occupational Safety and Health and amended from time to time.

organ toxicity

The ability to seriously affect organs or organ systems.

percutaneous

A cut or puncture that breaks through the skin.

personal protective equipment (PPE)

A method of reducing occupational exposure to hazardous substances that involves wearing or using specialized clothing or equipment.

precautionary period

The period of time during which the excreta, vomit, or bodily fluids of a patient treated with a hazardous drug are contaminated by the hazardous drug or a hazardous metabolite of the hazardous drug, determined in accordance with any of the following information:

- Information provided by the manufacturer or a supplier of the hazardous drug
- Information provided by a pharmacist or physician
- Information in a scientific publication

priming

Running of fluid through tubing to remove air.

protective reassignment

Placing a worker in a role that is different than what they normally perform to reduce exposure to reproductive toxins.

qualified person

A person who is knowledgeable of the work, the hazards involved, and the means to control the hazards, by reason of education, training, experience or a combination thereof. Risk assessments, ECPs, and written work procedures must be developed by a qualified person.

reproductive toxicity

The ability to affect reproductive function in adults

risk assessment

The process of examining the workplace in order to understand where workers are exposed to a hazard and the level of risk. A risk assessment involves a qualified person analyzing how hazardous drugs are used in the workplace and identifying which tasks and activities place workers at risk of exposure. It is the foundation of an ECP.

safety-engineered medical sharp

A medical sharp with a built-in safety feature or mechanism that eliminates or minimizes the risk of accidental parenteral contact while or after the sharp is used (e.g., using a retracting mechanism or blunt tip).

substitution

A control measure used to minimize a hazard by replacing a substance or process with one that is less hazardous.

surface contamination

Refers to residues of hazardous drugs that are deposited on a surface.

surface sampling

A method of quantifying hazardous drug surface contamination by collecting hazardous drug residues on a wipe.

teratogenicity

The ability to affect the development of an embryo or fetus.