



Exposure Control Plan	UBC-RMS-OHS-ECP-17-001
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Exposure Control Plan for Cytotoxic Substances

1. PURPOSE

The University of British Columbia (UBC) is committed to providing a safe and healthy workplace by protecting all campus occupants from the potential adverse effects from exposure to cytotoxic substances in accordance with the Occupational Health and Safety (OHS) Regulations.

[Chapter 6](#) of the Occupational Health and Safety (OHS) Regulation lists “Cytotoxic drugs” as substances with specific requirements (Appendix A contains the section of the regulation pertaining to cytotoxic drugs). The requirements of the regulations are incorporated in this ECP.

Cytotoxic drugs are primarily used to treat cancer, frequently as part of a chemotherapy regime. Recently, their uses have expanded to treat certain skin conditions, rheumatoid and juvenile rheumatoid arthritis, and steroid-resistant muscle conditions. UBC research projects involving these medical conditions might involve working with cytotoxic drugs.

In addition, due to the largely inclusive definition of cytotoxic agents, other UBC employees might be exposed to chemicals classified as cytotoxic agents. Many common techniques in cellular biology, microbiology, biochemistry and molecular biology use reagents that fall into this classification.

If a worker is or may be occupationally exposed to a cytotoxic drug, the employer must develop and implement an Exposure Control Plan (ECP) meeting the requirements of section [5.54](#) of the regulation. This ECP is applicable to all UBC employees, contractors and students carrying out work with cytotoxic substances at UBC and where there is potential for cytotoxic exposure to occur.

The document contains the following appendices:

Appendix A – WorkSafe BC cytotoxic drugs regulation

Appendix B – Common cytotoxic drugs (WorkSafe BC and BC Cancer Agency lists)



Appendix C – Excretion rates of several cytotoxic drugs

Appendix D – Job tasks and controls table - acceptable control methods for specific job tasks

2. ROLES AND RESPONSIBILITIES

Employer

- Develop, implement and maintain a Cytotoxic Exposure Program to ensure exposure to cytotoxic substances is maintained As Low As Reasonably Achievable (ALARA) as per OHS Regulations
- Protect workers from hazards in the workplace by considering the hierarchy of controls (e.g. in order of elimination, substitution, engineering, administrative and personal protective equipment (PPE))
- Ensure workers are informed on the hazards of cytotoxics and trained on how to minimize exposure to cytotoxic substances
- Ensure resources are made available to ensure occupational exposure to cytotoxic substances is conducted, when required
- Ensure exposure control plans (ECPs) are developed and implemented, when required
- Provide workers with the necessary materials, tools and equipment, PPE and other resources required to minimize exposure to cytotoxic substances
- If an exposure incident occurs at the workplace, ensure it is investigated and, based on the findings, develop ways to prevent similar incidents from occurring.
- Ensure workers who exposed to cytotoxic substances participate in health monitoring, when required.

Department Manager/Supervisor Responsibilities

- Attend education and training sessions provided by the employer
- Identify and evaluate occupations, areas or tasks where the potential for exposure to cytotoxics exists
- Ensure necessary resources are available to conduct occupational monitoring for cytotoxics exposure, when required
- Ensure employees have the appropriate education and training for working with cytotoxics and demonstrate competency for identified tasks
- Ensure employees are able to identify the signs and symptoms associated with cytotoxics exposure
- Ensure the hierarchy of controls (e.g. elimination/substitution, engineering, administrative, PPE) are considered and implemented accordingly
- Ensure all equipment, PPE, and materials needed to control against exposure to cytotoxics are available
- Complete Site-Specific ECPs and provide to workers, when required



- Develop and provide safe work procedures to workers
- Provide workers with adequate supervision to ensure that work practices eliminate or minimize exposure to cytotoxics
- Ensure exposure to cytotoxics incidents are investigated appropriately.
- Report any incident *via* the UBC Centralized Accident / Incident Reporting System ([CAIRS](#)).

Worker Responsibilities

- Attend education and training sessions provided by the employer
- Adhere to the hierarchy of controls for cytotoxics (e.g. elimination / substitution, engineering, administrative, PPE)
- Follow the ECP and safe work practices established by the employer
- Ensure all equipment, PPE and materials needed to control against exposure to cytotoxics are in good working condition
- Understand the importance of evacuating work areas where signs of cytotoxics exposure arise
- Report unsafe cytotoxics exposure conditions to their supervisor
- Participate in incident/accident investigations, where required.

Risk Management Services (RMS) Responsibilities

- Assist in the implementation of this Cytotoxics Exposure Program through training and consultation
- Provide education and training on cytotoxics exposure including how to recognize early signs and symptoms associated with the exposure
- Assist with cytotoxics risk identifications and assessments, as requested
- Ensure occupational exposure monitoring for cytotoxics is conducted, when required
- Conduct respirator fit testing sessions for tight-fitting respirators
- Assist in the development of ECPs and conduct annual reviews of the ECPs
- Conduct annual reviews of the effectiveness of this Cytotoxics Exposure Program.

3. CYTOTOXIC SUBSTANCES - CHARACTERISTICS

This ECP applies to cytotoxic substances defined as any chemical substance confirmed or suspected of having a genotoxic, mutagenic or teratogenic effect in humans. This information can usually be obtained from the SDS of the chemical (sections 2 and 11).

A cytotoxic drug means an agent that possesses a specific destructive action on certain cells or that may be genotoxic, oncogenic, mutagenic, teratogenic, or hazardous to cells in any way and includes most anti-cancer drugs.

A number of drugs used in health care settings (e.g., hospitals, physician's offices, home healthcare agencies) may pose a risk to workers through acute or chronic occupational exposure.



The American Society of Hospital Pharmacists (ASHP) considers a drug hazardous if it:

- is genotoxic,
- is carcinogenic,
- is teratogenic (a substance that is capable of causing physical defects in a developing embryo) or impairs fertility, or
- causes serious organ or other toxic manifestations at low doses in experimental animals or treated patients.

Some common drugs that meet these criteria are listed in Appendix B. For drugs not included on this list, professional judgement by personnel trained in pharmacology and/or toxicology is needed to designate a drug as cytotoxic. The primary factors to be considered are as follows:

- Is the drug designated an antineoplastic agent in the American Hospital Formulary Service Drug Information? (An agent is antineoplastic if it inhibits or prevents the development of tumors)
- Does the manufacturer suggest the use of special isolation techniques in its handling, administration or disposal?
- Is the drug known to be a human mutagen, carcinogen, teratogen or reproductive toxicant? (An agent is mutagenic if it is capable of inducing genetic mutation.)
- Is the drug known to be carcinogenic or teratogenic in animals? (A drug known to be mutagenic in multiple bacterial systems or animals should also be considered cytotoxic.) or,
- Is the drug known to be acutely toxic to an organ system?

For any questions and help with identifying cytotoxic substances, contact the RMS [Chemical Safety Advisor](#).

4. HEALTH HAZARDS ASSOCIATED WITH EXPOSURE TO CYTOTOXICS

There is evidence that exposure to cytotoxic drugs can cause adverse effects in workers. There are reports that exposure to cytotoxic drugs:

- can cause an increased frequency of chromosome damage in exposed workers
- can produce some acute effects in workers which include skin, eyes, and mucous membrane irritations, allergic reactions upon contact with the skin, as well as subjective symptoms including nausea, headache, and dizziness
- has been associated with adverse reproductive outcomes (including higher incidences of spontaneous abortions and a higher risk of delivering malformed babies)

Repeated, long-term occupational exposure to small amounts of cytotoxic drugs has not been identified as a cause of cancer. However, because of the above-mentioned concerns, precautions must be followed to limit occupational exposure to all cytotoxic drugs.



5. RISK IDENTIFICATION AND ASSESSMENT

The degree of risk is dependent on the inherent toxicity of the drug, as well as the extent of exposure. Workers may be exposed *via* inhalation of dusts or aerosols, absorption through the skin, needle stick injuries, and ingestion (e.g., because of contact with contaminated food). Compliance with the personal hygiene requirements (sections [5.82 to 5.84](#)) should eliminate ingestion as a source of exposure.

Exposure may occur during preparation and administration and usage of cytotoxic substances, handling of body fluids from animals receiving cytotoxic drugs, handling and disposal of cytotoxic wastes and related trace contaminated material, and transportation of cytotoxic drugs. Some cytotoxic drugs have a direct irritant effect on the mucous membranes, eyes and skin. Spills onto skin surfaces that have cuts or abrasions and punctures of the skin with a contaminated needle or broken glass can lead to severe soft tissue injury.

Surface contamination is one of the main sources of occupational exposure to cytotoxic drugs in health care settings. Due to their chemical stability, residue from hazardous drugs can persist in the workplace and be spread far from their point of origin. Residue can also collect on items that are not directly used for handling hazardous drugs, such as pens, door handles, and elevators buttons. Since surfaces throughout the workplace may be contaminated, there is potential risk of exposure for anyone working in the space.

Table 1. Main routes of exposure to cytotoxic substances

Route of exposure	Examples of activities	Possible controls
Direct dermal contact	<ul style="list-style-type: none">• Handling oral or topical forms of cytotoxic substances• Contact with a leak or spill of cytotoxic substances	<ul style="list-style-type: none">• Wearing double chemotherapy-tested gloves• Using a closed-system transfer device
Indirect dermal contact	<ul style="list-style-type: none">• Handling contaminated animal excreta• Handling or touching contaminated materials, such as equipment, containers, work surfaces	<ul style="list-style-type: none">• Wearing double chemotherapy-tested gloves• Observing a precautionary period for handling animal excreta
Contact with eyes	<ul style="list-style-type: none">• Handling liquid forms of cytotoxic substances• Weighing out powders on top loading balances on the open bench	<ul style="list-style-type: none">• Wearing eye protection or a face shield• Weighing out powders in a fume hood
Inhalation	<ul style="list-style-type: none">• Inhaling aerosols or vapours released when breaking open	<ul style="list-style-type: none">• Performing activities inside a biological safety cabinet



Route of exposure	Examples of activities	Possible controls
	<ul style="list-style-type: none"> ampules, withdrawing needles from drug vials, transferring drugs with syringes, or expelling air from a drug-filled syringe Inhaling particulate material released when crushing tablets or opening capsules Using nutating mixers for staining and incubations 	<ul style="list-style-type: none"> Wearing an appropriate respirator Performing staining activities inside a fume hood Using cage changing stations for dumping
Percutaneous exposure	<ul style="list-style-type: none"> Preparing or administering cytotoxic substances using a needle Handling broken glass or overfilling sharps containers Reusing razor blades, scalpels or dissection pins 	<ul style="list-style-type: none"> Using a needless system or safety engineered medical sharp Use single use sharps and dispose of directly in a dedicated cytotoxic sharps container
Ingestion	<ul style="list-style-type: none"> Eating food that has been contaminated with cytotoxic substances 	<ul style="list-style-type: none"> Ensuring all food is stored away from areas where hazardous drugs are handled Proper hand washing

6. OCCUPATIONAL EXPOSURE LIMITS

There are no general occupational exposure limits (OEL) for cytotoxic drugs because it is not possible to determine safe exposure levels. According to the Occupational Health and Safety (OHS) Regulation if a substance identified as carcinogen, reproductive toxin, and/or sensitizer is present in the workplace, the employer must replace it, if practicable, with a material that reduces the risk to workers. If substitution is not practicable, the employer must implement an exposure control plan to maintain workers' exposure as low as reasonably achievable below the exposure limit established.

7. RISK CONTROL

Once a risk to cytotoxics has been identified and assessed, the appropriate hierarchy of controls must be implemented to ensure the risk is eliminated or mitigated. The hierarchy of controls is as follows (in priority of most effective to least effective):

1. Elimination or Substitution
2. Engineering
3. Administrative
4. Personal Protective Equipment



The types of controls needed will be dependent on the task being performed.

Substitution / Elimination

Though the most effective risk control, elimination or substitution are not possible when the cytotoxic substance itself is tested in a research setting (e.g. animal studies). For the cases where the cytotoxic substance is used in a chemical process or as a precursor in a synthesis, the supervisor must replace it, if practicable, with a material, which reduces the risk to workers ([WorkSafe BC Regulation 5.57\(1\)](#)).

Engineering

Engineering controls are those controls, which aim to minimize the exposure to cytotoxic substances through physical modifications to facilities, equipment and processes.

Biological Safety Cabinets (BSC) and Fume Hoods

Local Exhaust Ventilation is an engineering control designed to protect against exposure to cytotoxic substances *via* inhalation route. According to [WorkSafe BC Regulation 6.53](#):

All mixing, preparation and priming of administration sets with a cytotoxic drug must be performed in one centralized area in a specially designated **Class II Type B biological safety cabinet** that;

- is exhausted to the outside atmosphere in a manner that prevents recirculation into any work area,
- has exhaust and ventilation systems that remain in operation for a sufficient period of time to ensure that no contaminants escape from the biological safety cabinet into the workplace, and
- is equipped with a continuous monitoring device to permit confirmation of adequate airflow and cabinet performance.

Fume hoods, “clean benches” and other laminar flow devices such as horizontal flow cabinets that direct the air towards the operator, are not the same as biological safety cabinets. They are not considered appropriate for work with cytotoxic drugs.

The BSC must be inspected and certified by a competent person at least annually and when the cabinet is moved. The BSC must be cleaned, maintained, and used according to the manufacturer’s recommendations. The exhaust blower on the BSC should be operated continuously — even when not in use. The cabinet should be cleaned daily with 70% alcohol and decontaminated weekly or whenever spills occur. Decontamination should consist of surface cleaning with an alkaline detergent followed by thorough rinsing. Personal protective equipment as described later in this document should be used while decontaminating the cabinet. The ductwork attached to the cabinet should be labelled as to its hazardous content.



[WorkSafe BC Regulation 30.12](#) and related [Guidelines](#) detail the exact requirements for BSC operation and certification.

When work with cytotoxic substances is part of a chemical synthesis process, the use of a laboratory fume hood is recommended. The fume hood and its related ductwork must be designed, installed and maintained in accordance with the Industrial Ventilation, A Manual of Recommended Practice, published by the American Conference of Governmental Industrial Hygienists, as amended from time to time ([WorkSafe BC Regulation 30.8](#)).

Safety-engineered sharps

All activities involving handling the cytotoxic substance *via* a syringe (e.g. administration of medication, transfer of chemicals from sealed containers) must be done with safety-engineered sharps. Safety-engineered sharps are devices 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.

Administrative

Administrative controls are those that aim to control or minimize exposure to cytotoxic substances using work methods and work procedures. Several of these administrative controls are part of the regulatory requirements ([WorkSafe BC Regulation 6.44 to 6.58](#))

- Information - if a cytotoxic drug is received, prepared, administered, stored or disposed of at a workplace, the employer must maintain and make readily available to workers information on its acute and chronic toxicity, acute exposure treatment and safe handling.
- Labels - a container of a cytotoxic drug and a shelf or bin where a cytotoxic drug is regularly stored must be appropriately labelled.
- Signs - warning signs which are clearly visible and clearly state the identified hazards must be posted in all areas where cytotoxic drugs are stored or mixed.
- List - storage and preparation areas for cytotoxic drugs must be posted with a list of all cytotoxic drugs present in the workplace.
- Safe Work Procedures - when a cytotoxic drug is received, prepared, administered, stored or disposed of, written safe work procedures must be developed and implemented for applicable aspects of receiving, storage, preparation, administration and waste handling. The work safe procedures must be readily available for reference by workers.
- Reproductive toxins – if present in the work place, the policy and procedures must inform workers about the reproductive toxin and identify ways to minimize exposure to the reproductive toxin for a worker who has advised the employer of pregnancy or intent to conceive a child.



- Records - the employer must maintain a record of all workers who prepare or administer cytotoxic drugs, including the name of the drugs handled, and when practicable, the number of preparations or administrations per week. The exposure records must be maintained for the duration of employment plus 10 years.

Personal Protective Equipment (PPE) and Other Protective Clothing

PPE and protective clothing is the least effective control. However, when used in conjunction with other controls (e.g. engineering and administrative), PPE and protective clothing can help further reduce the worker's exposure to cytotoxic substances.

The specific PPE that is required for each task in the workplace is determined by a risk assessment. Workers should refer to the safe work procedures at their workplace for determining what types of PPE they are required to wear when handling hazardous drugs.

[WorkSafe BC regulation \(6.55\)](#) lists under personal protective equipment:

- medical gloves that are manufactured and designed for use when handling cytotoxic drugs,
- a moisture resistant, long-sleeved gown with cuffs,
- if there is a risk of contact with aerosols, an approved respirator, and
- if there is a risk of eye contact, eye and face protection.

Used gowns and gloves must not be worn outside the preparation, administration or storage area and must be handled as hazardous waste or contaminated linen. All other non-disposable personal protective equipment must be cleaned immediately after use.

Gloves

Nitrile or natural rubber latex is a preferred basic glove material, while vinyl is considered inappropriate because of its generally increased permeability. For extended exposure to cytotoxic substances, double gloving, the use of thicker gloves and the frequent change of gloves increases their protective power.

When following best practices for the use of gloves during handling of hazardous drugs, workers should:

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 gloves and during removal, including washing hands before and after wearing gloves
- Change gloves after 30 minutes of continuous compounding or if they have been contaminated or compromised
- Remove outer gloves before taking them out of a biological safety cabinet



Gown / lab coat

A gown made of low permeability fabric with a closed front (or back), long sleeves, and closed knitted cuffs is recommended. Cuffs should be tucked under gloves. Disposable gowns are recommended when cytotoxic drugs are prepared. Gowns should be immediately changed if contaminated or compromised. Wash hands immediately after removing a gown.

Face and eye protection

Eye protection, such as splash goggles, should be made available for use in any situation where there is a risk of splashing, which may occur when handling liquid forms of cytotoxic substance or contaminated body fluids and waste. Eye protection should also be used when cleaning up spills.

When following best practice for wearing face protection for hazardous drugs, workers should:

- 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 provide protection against exposure to hazardous drugs, such as by wearing closed shoes that are made of a material that prevents liquids from soaking through. Refer to [section 8.22](#) of the WorkSafe BC Regulation for more information on the requirements for footwear. Shoe covers are part of sterile preparation procedures but also help reduce exposure by preventing contamination being spread to other areas of the workplace on workers' shoes.

Best practices for footwear and shoe covers include, but are not limited to:

- Having a dedicated set of footwear that is only used in the preparation area
- Having all workers wear shoe covers when entering a sterile preparation room
- Removing shoe covers with gloved hands and disposing as hazardous waste upon exiting the preparation room
- Wearing shoe covers when cleaning up spills or broken containers on the floor

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. This type of exposure may occur when workers:

- Prepare cytotoxic drugs on a counter or some other place that is outside of an approved BSC
- Clean up spilled cytotoxic substances



- Decontaminate a BSC that has the sash raised

The respirator selected must provide protection from particulates as well as gases or vapours that can be generated from solid or liquid forms of cytotoxic substance, depending on the activity. This could include a half-or full-face air-purifying respirator that has a particulate filter (such as P100) 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 cytotoxic substance for each task in the workplace. Fit tests must also be carried out before a respirator is issued to a worker. The worker must perform a seal check before each use. Respirator fit testing is performed by [Risk Management Services](#).

More information on how to select an appropriate respirator can be found in the WorkSafe BC publication [Breathe Safer: How to Use Respirators Safely and Start a Respirator Program](#).

8. EDUCATION / TRAINING

A worker involved in any aspect of handling a cytotoxic drug must receive pre-job education and on-the-job training on the handling of this substance ([WorkSafe BC Regulation 6.50](#)).

As necessary, personnel will be trained to a level of “demonstrated competency”. While not necessarily an exhaustive list, education and training may include:

- known health risks, including any potential reproductive hazards,
- relevant techniques and procedures for safe handling,
- proper use of protective equipment and materials, and
- spill and waste disposal procedures
- procedures for reporting known exposures and suspected health effects.

The adequacy of instruction must be assessed when required by a change in the substance used, information available on the substance or a change in work procedures. Refresher training is required every 3 years.

According to the regulation, training records must be maintained for 3 years from the date that the training occurred.

The [Occupational & Preventive Health](#), on Vancouver UBC campus, provides services and programs to help UBC employees manage potential risks in the workplace.

9. WRITTEN WORK PROCEDURES

The OHS Regulation requires that an Exposure Control Plan (ECP) for cytotoxics substances be developed and implemented when a worker may be occupationally exposed to a cytotoxic substance.



The ECP must be reviewed at least annually and updated as necessary by the employer, in consultation with the joint committee or the worker health and safety representative, as applicable.

The employer must ensure site-specific ECPs and written safe work procedures are developed and implemented to ensure controls are in place to minimize the risk of exposure to cytotoxic substances. The ECPs and safe work procedures must be made readily available to workers. Refer to the following documents:

- Appendix D: Job Tasks and Controls Table
 - This table lists job tasks where exposure to cytotoxic substances may occur and respective controls that are to be implemented to avoid exposure to cytotoxic substances. Specific Safe Work Procedure are generated based on the identified tasks.
- Task-Specific Safe Work Procedures
 - Cytotoxics Spill Cleanup Procedure (UBC-RMS-OHS-SWP-17-004)
 - Receiving and Storage of Cytotoxic Substances (UBC-RMS-OHS-SWP-17-005)
 - Cytotoxic Waste Management (under development)

10. HYGIENE FACILITIES

Hygiene facilities must be made available to permit proper hand washing and cleaning of reusable personal protective equipment such as respirators and safety eyewear. Reusable gowns / lab coats must be laundered and changed regularly. Gowns / lab coats must not be worn outside the designated work area (ie. must be removed while eating lunch). Disposable gowns / lab coats must be discarded accordingly.

Eating, drinking, smoking, application of cosmetics or storage of food is prohibited in any area where a cytotoxic drug is mixed, administered or stored.

11. HEALTH MONITORING

Health monitoring may be required if workers are exposed to cytotoxic substances. The necessity of health monitoring will be decided from case to case by an occupational health professional. Contact [Occupational & Preventive Health](#), on Vancouver UBC campus, with any questions and concerns.

All personnel involved in any aspect of the handling of cytotoxic substances should be informed about the risks of occupational exposure to hazardous drugs. A worker who is pregnant or intends to conceive, should advise her supervisor. The supervisor must develop policy and procedures appropriate to the risk, which may include protective reassignment.



12. DOCUMENTATION

Documentation associated with the Cytotoxics Exposure Program will need to be maintained. The documentation includes, but not limited to:

- Cytotoxics Exposure Program, ECP and safe work procedures
- Project/task specific cytotoxics ECP and safe work procedures
- Cytotoxics education and training records
- First aid records pertaining to cytotoxics exposures
- Incident/accident investigation reports pertaining to cytotoxics exposures
- WorkSafeBC inspection reports, if applicable
- Respirator fit test records
- Safety meeting minutes

13. PROGRAM REVIEW

This program is to be reviewed at least annually by the responsible departmental representative in Risk Management Services.

14. REFERENCES

Occupational Health and Safety Regulations Part 5.54 – Exposure Control Plan
Occupational Health and Safety Regulations Part 6.42 – Cytotoxic Drugs
WorkSafe BC – Best Practices for the Safe Handling of Hazardous Drugs (2015)
Government of South Australia – Cytotoxic Drugs and Related Waste (2015)
Workplace Health and Safety Queensland – Guide for handling cytotoxic drugs and related waste (2017)
BC Cancer Agency – Cytotoxic chemicals handling and disposal (SOP: CYT-001, 2015)
Australian Medicines Handbook (2014)

15. DOCUMENT INFORMATION

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APPENDIX A: WORKSAFE BC CYTOTOXIC DRUGS REGULATION

6.42 Definition

In sections 6.43 to 6.58

"*cytotoxic drug*" means an agent that possesses a specific destructive action on certain cells or that may be genotoxic, oncogenic, mutagenic, teratogenic, or hazardous to cells in any way and includes most anti-cancer drugs.

6.43 Exposure control plan

If a worker is or may be occupationally exposed to a cytotoxic drug, the employer must develop and implement an exposure control plan meeting the requirements of section 5.54.

6.44 Information

If a cytotoxic drug is received, prepared, administered, stored or disposed of at a workplace, the employer must maintain and make readily available to workers information on its

- (a) acute and chronic toxicity, including any potential reproductive hazard,
- (b) acute exposure treatment, and
- (c) safe handling.

[Amended by B.C. Reg. 21/2006, effective May 17, 2006.]

6.45 Labels

A container of a cytotoxic drug and a shelf or bin where a cytotoxic drug is regularly stored must be appropriately labelled.

6.46 Signs

Warning signs which are clearly visible and clearly state the identified hazards must be posted in all areas where cytotoxic drugs are stored or mixed.

6.47 List

Storage and preparation areas for cytotoxic drugs must be posted with a list of all cytotoxic drugs present in the workplace.

6.48 Procedures

(1) When a cytotoxic drug is received, prepared, administered, stored or disposed of, written safe work procedures must be developed and implemented for applicable aspects of receiving, storage, preparation, administration and waste handling.



(2) The work procedures required by subsection (1) must be readily available for reference by workers and where practicable, summaries of relevant procedures must be posted in the appropriate work areas.

6.49 Reproductive toxins

(1) At any worksite where a worker is occupationally exposed to a cytotoxic drug that is a reproductive toxin, the employer must develop policy and procedures appropriate to the risk, which may include protective reassignment.

(2) The policy and procedures must inform workers about the reproductive toxin and identify ways to minimize exposure to the reproductive toxin for a worker who has advised the employer of pregnancy or intent to conceive a child.

6.50 Instruction

(1) A worker involved in any aspect of handling a cytotoxic drug must receive pre-job education and on-the-job training on the handling of this substance.

(2) The instruction required by subsection (1) must address the

- (a) known health risks, including any potential reproductive hazards,
- (b) relevant techniques and procedures for safe handling,
- (c) proper use of protective equipment and materials, and
- (d) spill and waste disposal procedures.

(3) The adequacy of instruction must be assessed when required by a change in the substance used, information available on the substance or a change in work procedures, and retraining provided where necessary.

6.51 Supervision

A worker involved in any aspect of cytotoxic drug handling must be effectively supervised.

6.52 Records

(1) The employer must maintain a record of all workers who prepare or administer cytotoxic drugs, including the name of the drugs handled, and when practicable, the number of preparations or administrations per week.

(2) Exposure records must be maintained for the duration of employment plus 10 years, and training records for 3 years from the date that the training occurred.

6.53 Drug preparation and administration

(1) All mixing, preparation and priming of administration sets with a cytotoxic drug must be performed in one centralized area in a specially designated Class II Type B biological safety cabinet that



- (a) is exhausted to the outside atmosphere in a manner that prevents recirculation into any work area,
- (b) has exhaust and ventilation systems that remain in operation for a sufficient period of time to ensure that no contaminants escape from the biological safety cabinet into the workplace, and
- (c) is equipped with a continuous monitoring device to permit confirmation of adequate airflow and cabinet performance.

(2) The administration of cytotoxic drugs must be done by following safe work procedures.

6.54 Disconnects

Syringes and intravenous sets used for cytotoxic drugs must have appropriate fittings, such as Luer locking fittings, which prevent accidental disconnection.

6.55 Personal protective equipment

(1) Adequate personal protective equipment must be provided and worn whenever there is a risk of contact with a cytotoxic drug.

(2) For the purposes of subsection (1) personal protective equipment includes

- (a) medical gloves that are manufactured and designed for use when handling cytotoxic drugs,
 - (b) a moisture resistant, long-sleeved gown with cuffs,
 - (c) if there is a risk of contact with aerosols, an approved respirator, and
 - (d) if there is a risk of eye contact, eye and face protection.
- (3) used gowns and gloves must not be worn outside the preparation, administration or storage area and must be handled as hazardous waste or contaminated linen.
- (4) all other non-disposable personal protective equipment must be cleaned immediately after use.

6.56 Personal hygiene

Eating, drinking, smoking, application of cosmetics or storage of food is prohibited in any area where a cytotoxic drug is mixed, administered or stored.

6.57 Waste disposal

(1) Adequate, leak-proof waste disposal containers, including sharps and solids containers, and distinctive plastic waste bags must be available in every area where cytotoxic drugs are prepared, administered or stored, and all cytotoxic drug-related waste must be placed into these containers or bags.

(2) Any excreta from a patient being treated with cytotoxic drugs that is handled by a worker must be treated as cytotoxic drug-related waste.



6.58 Spills

(1) Written emergency procedures to address spills of a cytotoxic drug must be developed and implemented which address requirements for small spill cleanup, both inside and outside the biological safety cabinet, large spill cleanup, and personal decontamination.

(2) Spill kits, clearly labelled, must be kept in or near cytotoxic drug preparation, administration and storage areas and a sign detailing spill procedures must be posted in all such areas.

**APPENDIX B: COMMON CYTOTOXIC DRUGS (WORKSAFE BC LIST)***

Altretamine	Estramustine	Mitoxantrone
Aminogluthethimide	Ethinyl Estradiol	Nafarelin
Azathioprine	Etoposide	Pipobroman
L-Asparaginase	Floxuridine	Plicamycin
Bleomycin	Fluorouracil	Procarbazine
Busulfan	Flutamide	Ribavirin
Carboplatin	Glanciclovir	Streptozocin
Carmustine	Hydroxyurea	Tamoxifen
Chlorambucil	Idarubicin	Testolactone
Chloramphenicol	Ifosfamide	Thioguanine
Chlorozotocin	Interferon-A	Thiotepa
Cyclosporin	Isotretinoin	Uracil Mustard
Cisplatin	Leuprolide	Vidarabine
Cyclo-phosphamide	Levamisole	Vinblastine
Cytarrabine	Lomustine	Vincristine
Dacarbazine	Mechlorethamine	Zidovudine
Dactinomycin	Medroxy-progesterone	
Daunorubicin	Megestrol	
Diethyl-stilbestrol	Melphalan	
Doxorubicin	Mercaptopurine	
Estradiol	Methotrexate	

* This is not an exhaustive list; consult the (M)SDS of the chemical compound to see if it qualifies as a cytotoxic substance.



BC CANCER AGENCY HAZARDOUS DRUGS LIST

Abiraterone ¹	Enzalutamide ¹	PACLitaxel ¹
Acitretin ³	Epirubicin ¹	PACLitaxel, nab ⁴
AFAtinib ¹	eriBULin ¹	Palbociclib ⁴
Amsacrine ¹	Erlotinib ¹	PAZOPanib ¹
Anastrozole ¹	Estramustine ¹	Pemetrexed ¹
Arsenic trioxide ¹	Etoposide ¹	PERTuzumab ¹
Atezolizumab ¹	Everolimus ¹	Plerixafor ³
aXitinib ¹	Exemestane ¹	Pomalidomide ¹
azaCITIDine ¹		PONATtinib ¹
		Procarbazine ¹
Bacillus Calmette – Guerin (BCG)* ¹	Fludarabine ¹	
Bendamustine HCl ¹	Fluorouracil ¹	
Bexarotene ¹	Flutamide ¹	
Bicalutamide ¹	Fulvestrant ¹	Quinagolide ⁴
Bleomycin ¹		
Blinatumomab ⁴	Gemcitabine ¹	Raltitrexed ⁴
Bortezomib ¹	Geserelin ¹	Regorafenib ¹
Bosutinib ¹		Retrovirus serotype 3 – Dearing strain* ⁴
Brentuximab vedotin ¹		romiDEPsin ¹
Buserelin ⁴	hydroxyUREA ¹	Ruxolitinib ⁴
Busulfan ¹		
Cabazitaxel ¹	IDArubicin ¹	
Cabergoline ³	Ifosfamide ¹	SORafenib ¹
Capecitabine ¹	iMATinib mesylate ¹	Streptozocin ¹
CARBOplatin ¹	Irinotecan HCl ¹	SUNItinib malate ¹
Carfilzomib ¹	Irinotecan, liposome ⁴	



Carmustine ¹	Ixabepilone ¹	
Chlorambucil ¹		Tamoxifen ¹
CISplatin ¹	Lanhreotide ⁴	Temozolomide ¹
Cladribine ¹	Lapatinib ⁴	Temsirolimus ¹
Cobimetinib ⁴	Lenalitimide ²	Teniposide ¹
Crizotinib ¹	Lenvatinib ⁴	Testosterone ³
Cyclophosphamide ¹	Letrozole ¹	Thalidomide ²
cycloSPORINE ²	Leuprolide acetate ¹	Thioguanidine ¹
cytarabine	Lomustine ¹	Thiotepa ¹
		Topotecan ¹
	Mechlorethamine ¹	Trametinib ¹
	medroxyprogesterone acetate ²	Trastuzumab (HERCEPTIN®) ¹
daBRAFeNib ¹	Megestrol ¹	TRC105 (carotuximab) ⁴
Dacarbazine ¹	Melphalan ¹	Tretinoin ³
DACTINomycin ¹	Mercaptopurine ¹	
Daratumumab ⁴	Methotrexate ¹	vanDETanib ¹
daSATinib ¹	Mitomycin ¹	vemURAFenib ¹
DAUNOrubicin HCl ¹	Mitotane ¹	vinBLAS tine sulfate ¹
Degarelix ¹	mitoXANTRONE ¹	vincristine sulfate ¹
Dexrazoxane ²		Vinorelbine tartrate ¹
DOCEtaxel ¹	niLOTinib ¹	Vismodegib ¹
DOXOrubicin ¹		
DOXOrubicin, pegylated ⁴	Olaparib ⁴	Zoledronic acid ³
	Oxaliplatin ¹	

* designated as *biohazardous* (BioHD) at BCCA

Numerical superscripts **1, 2, or 3** refer to tables contained within the NIOSH 2014 List as below:

1. NIOSH Table 1 (hazardous antineoplastic drugs)
 2. NIOSH Table 2 (hazardous non-antineoplastic drugs)
 3. NIOSH Table 3 (hazardous non-antineoplastic drugs with primarily reproductive effects)
- Numerical superscript **4** refers to drugs evaluated by BCCA per Provincial Pharmacy Directive VI-80 *Hazardous Drug List*



APPENDIX C: EXCRETION RATES OF SEVERAL CYTOTOXIC DRUGS*

Drug name	Excretion Rate**	Precautionary time period following cytotoxic drug treatment when handling body waste (excreta)***	
		Urine	Feces
Bleomycin	Urine: up to 68% in first 24 h	3 days	
Carboplatin	Urine: up to 60% in first 24 h	2 days	
Carmustine	Urine: up to 65% in first 24 h	4 days	
Chlorambucil		2 days	
Cisplatin	Urine: up to 75% in first 5 days	7 days	
Cyclophosphamide	Urine: up to 62% in first 48 h	3 days – in urine, sweat and saliva	5 days
Cytarabine	Urine: up to 90% in first 24 h	1 day	
Dacarbazine		1 day	
Daunorubicin		7 days	7 days
Docetaxel	Urine: up to 60% in first 24 h	1 day	2 days
Doxorubicin	Urine: up to 15% in first 5 days Feces: up to 85%	6 days	7 days
Epirubicin	Urine: up to 11% in first 24 h	3 days	
Etoposide	Urine: up to 50% in first 24 h Feces: up to 15% in first 24 h	3 days	5 days
Fludarabine	Urine: up to 60% in first 24 h	3 days	
Fluorouracil (5-FU)	Urine: up to 15% in first 24 h	2 days	5 days
Gemcitabine		1 day	
Idarubicin		3 days	2 days
Ifosfamide		2 days	
Melphalan	Urine: up to 60% over first 24 h	2 days	7 days
Mercaptopurine	Up to 40% in first 24 h	2 days	5 days
Methotrexate	Urine: up to 90% in first 48 h Feces: up to 9%	3 days	7 days



Mitomycin		1 day	
Mitozantrone	Urine: up to 6.5% over first 5 days Feces: up to 18%	6 days	7 days
Oxaliplatin	Urine: up to 50% in first 24 h	3 days	
Paclitaxel	Urine and feces: at least 13% in first 24 h	3 days	5 days
Procarbazine	Urine: up to 70% in first 30 days	3 days	
Teniposide		3 days	
Thioguanine		1 day	
Topotecan		2 days	
Vinblastine	Urine: up to 33% in first 3 days Feces: up to 41% in first 3 days	4 days	7 days
Vincristine	Urine: up to 8% in first 3 days Feces: up to 40% in first 3 days	4 days	7 days
Vinorelbine		4 days	7 days

* Data from Australian Medicines Handbook July 2014 (<http://www.amh.net.au>)

** The majority of cytotoxic drugs will be excreted within 7 days however some may require longer precautionary periods. If the cytotoxic drug excretion rate is not known use precautions for at least 48 hours following treatment.

*** May be unchanged drug or metabolite



APPENDIX D: JOB TASKS AND CONTROL TABLE - ACCEPTABLE CONTROL METHODS FOR SPECIFIC JOB TASKS

Work Activity	Control Methods	Personal Protective Equipment (PPE)	Comments
Receiving and storage of cytotoxic substances	<ul style="list-style-type: none"> • Restricted access area • Negative pressure with respect to surrounding rooms • Storage shelves with fall guards 	<ul style="list-style-type: none"> • Recommended gloves for use with cytotoxic substances • Gowns / lab coats • An approved and fit-tested respirator (if handling damaged packages containing cytotoxic substances) 	Surface contamination of containers and packaging is a potential source of exposure for workers as they unpack and store incoming shipments of cytotoxic substances (drugs).
Transport of cytotoxic substances	<ul style="list-style-type: none"> • Transport cytotoxic substances in equipment that reduces spills • Use equipment that is easy to clean 	<ul style="list-style-type: none"> • Recommended gloves for use with cytotoxic substances • Gowns / lab coats 	Workers who transport cytotoxic substances throughout a facility may be exposed if they come in contact with contaminated surfaces or a cytotoxic substances leak or spill.
Cytotoxic drug preparation	<ul style="list-style-type: none"> • Preparation is done in a designated and controlled area, all air should be exhausted externally • A closed-system transfer device is used when appropriate • Safety engineered needles are used to reduce the risk of percutaneous exposure • Furniture and equipment is made of materials that are easily cleaned and decontaminated (i.e. stainless steel) • Drug preparation is done only inside a BSC Type II B • Follow recommended procedures for handling waste and/or cleaning spills 	<ul style="list-style-type: none"> • Recommended gloves for use with cytotoxic substances • Disposable gown • Shoe covers • Eye and, if needed, face protection • An approved and fit-tested respirator (if necessary) 	Workers who prepare (compound, dilute, mix, etc.) cytotoxic drugs can be exposed



Work Activity	Control Methods	Personal Protective Equipment (PPE)	Comments
Cytotoxic drug administration	<ul style="list-style-type: none"> • Treatment of animals should be done in an area kept under neutral or negative air pressure; a BSC Type II B is recommended • A closed-system transfer device is used when appropriate • Safety engineered needles are used to reduce the risk of percutaneous exposure • Use disposable, absorbent pads to capture any possible spills • Use bandages over areas where a topical medication has been applied • Follow recommended procedures for handling waste and/or cleaning spills 	<ul style="list-style-type: none"> • Recommended gloves for use with cytotoxic substances • Gowns / lab coats • Eye and, if needed, face protection 	Administration of cytotoxic drugs can take many forms (i.e. IV, inhalation, injections, oral or topical) and workers can be exposed by using equipment that may leak or spill, by directly handling medication, by exposure to body fluids, etc.
Handling cytotoxic substances in a research lab (synthesis, tissue culture, etc.)	<ul style="list-style-type: none"> • All handling should be done inside a fume hood or a BSC • Use disposable, absorbent pads to capture any possible spills • Use safety engineered needles and disposable syringes when necessary • Follow recommended procedures for handling waste and/or cleaning spills 	<ul style="list-style-type: none"> • Recommended gloves for use with cytotoxic substances • Lab coat • Eye protection 	<p>Working with cytotoxic substances in a research laboratory requires</p> <ul style="list-style-type: none"> • Handling the container containing the substance • Transfer of the substance from original container to a secondary vessel • Cleaning the glassware used
Non-invasive monitoring of animals treated with cytotoxic drugs (during the precautionary period)	<ul style="list-style-type: none"> • Animals should be housed in microisolator type cages during the precautionary period (the period for which the animal excretes the drug or metabolites of the drug, see Appendix C) • Removal of animal from the cage should be done inside a BSC Type II B 	<ul style="list-style-type: none"> • Recommended gloves for use with cytotoxic substances • Gown or lab coat 	Non-invasive monitoring tasks include observing the animal without direct contact as well as procedures requiring physically handling the animal (i.e. weighing, injection site evaluation, and electrocardiogram).



Work Activity	Control Methods	Personal Protective Equipment (PPE)	Comments
Invasive monitoring of animals treated with cytotoxic drugs (during the precautionary period)	<ul style="list-style-type: none"> Procedures should be done in a BSC Type II B Use disposable, absorbent pads to capture any possible spills Use safety engineered needles and disposable syringes when necessary Follow recommended procedures for handling waste and/or cleaning spills 	<ul style="list-style-type: none"> Recommended gloves for use with cytotoxic substances Disposable gown Eye protection 	Invasive monitoring tasks involve direct contact with bodily fluids (i.e. surgery, IV treatment)
Bed changing and cage cleaning	<ul style="list-style-type: none"> Identify animals who have received cytotoxic drugs (name of drug and day/time of administration on cage) The use of pressure washers for cleaning purposes is prohibited Cleaning of contaminated cages (during the precautionary time) should be done inside a fume hood or BSC – See Appendix C. Contaminated waste should be disposed off according to procedures 	<ul style="list-style-type: none"> Heavy duty cleaning gloves on top of disposable gloves Gown / lab coat Eye protection An approved and fit-tested respirator (if task is not completed inside a fume hood or BSC during the precautionary period) 	Cleaning cages or changing bedding of animals receiving cytotoxic drugs exposes the worker to contaminated residues resulted from the animals excreting the drug or metabolites.
Waste disposal	<ul style="list-style-type: none"> Adequate, leak-proof waste disposal containers, including sharps and solids containers are available and labelled as “cytotoxic waste” Procedures for disposal of contaminated waste are in place Animal carcasses are disposed of as biohazardous waste 	<ul style="list-style-type: none"> Recommended gloves for use with cytotoxic substances Gown / lab coat 	Workers can be exposed to cytotoxic substances <i>via</i> contact with contaminated waste and/or waste containers
Spill response	<ul style="list-style-type: none"> Supply of spill kits are available in area where cytotoxic substances are handled Regular training on emergency spill procedures is provided 	<ul style="list-style-type: none"> Heavy duty cleaning gloves on top of disposable gloves Disposable gown Eye and face protection An approved and fit-tested respirator 	While responding to a spill, workers can be exposed to a leak, spill, or can inhale aerosols, vapours or particulates released.