PART 6: SUBSTANCE SPECIFIC REQUIREMENTS

~~CYTOTOXIC DRUGS~~

~~**Definition**~~	~~**6.42**~~	~~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.~~
~~**Exposure control plan**~~	~~**6.43**~~	~~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.~~
~~**Information**~~	~~**6.44**~~	~~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.]~~
~~**Labels**~~	~~**6.45**~~	~~A container of a cytotoxic drug and a shelf or bin where a cytotoxic drug is regularly stored must be appropriately labelled.~~
~~**Signs**~~	~~**6.46**~~	~~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**~~	~~**6.47**~~	~~Storage and preparation areas for cytotoxic drugs must be posted with a list of all cytotoxic drugs present in the workplace.~~
~~**Procedures**~~	~~**6.48**~~	~~(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.~~ ~~[Amended by B.C. Reg. 21/2006.]~~
~~**Reproductive toxins**~~	~~**6.49**~~	~~(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.~~
~~**Instruction**~~	~~**6.50**~~	~~(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.

Supervision **6.51** A worker involved in any aspect of cytotoxic drug handling must be effectively supervised.

Records **6.52** (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.

Drug preparation and administration **6.53** (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.

[Amended by B.C. Reg. 21/2006.]

Disconnects **6.54** Syringes and intravenous sets used for cytotoxic drugs must have appropriate fittings, such as Luer locking fittings, which prevent accidental disconnection.

[Amended by B.C. Reg. 21/2006.]

Personal protective equipment **6.55** (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.~~

~~[Amended by B.C. Reg. 21/2006.]~~

~~**Personal hygiene** **6.56** Eating, drinking, smoking, application of cosmetics or storage of food is prohibited in any area where a cytotoxic drug is mixed, administered or stored.~~

~~**Waste disposal** **6.57** (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.~~

~~[Amended by B.C. Reg. 21/2006.]~~

~~**Spills** **6.58** (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.~~

~~[Amended by B.C. Reg. 21/2006.]~~

HAZARDOUS DRUGS

Definitions **6.42** **In this section and sections 6.43 to 6.58:**

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

"emergency decontamination" **means decontamination in response to a spill or an emergency that involves, or may involve, a hazardous drug, but does not include routine decontamination performed as part of housekeeping;**

"exposure control plan" **means an exposure control plan under section 6.46;**

"hazardous drug" **means 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 paragraph (a), or
		(c) is identified in the NIOSH list as a hazardous drug;
"housekeeping"		includes the following:
		(a) routine cleaning;
		(b) routine decontamination;
		(c) changing, handling, laundering or other cleaning and disposal of things contaminated with the excreta, vomit or bodily fluids of patients;
"NIOSH list"		means the ***NIOSH List of Hazardous Drugs in Healthcare Settings***, prepared by the United States National Institute for Occupational Safety and Health, as amended from time to time;
"precautionary period"		means 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:
		(a) information provided by the manufacturer or a supplier of the hazardous drug;
		(b) information provided by a pharmacist or physician;
		(c) information in a scientific publication;
"risk assessment"		means a risk assessment under section 6.45;
"work procedures"		means work procedures under section 6.46.1.
Application	6.43	Sections 6.44 to 6.58 apply in relation to a workplace at which a worker is or may be exposed to a hazardous drug.
Identifying hazardous drugs	6.44	An employer must do all of the following:
		(a) develop a written list of every hazardous drug that a worker is or may be exposed to at a workplace;
		(b) review the list at least annually and, if necessary, update the list;
		(c) ensure the list is made readily available for reference by workers at each of the workplaces to which the list applies.
Risk assessment	6.45	(1) An employer must ensure that a qualified person prepares a written risk assessment for the hazardous drugs identified in the list developed under section 6.44.
		(2) A risk assessment must consider at least the following:
		(a) information about the hazardous properties of the hazardous drug, including any information provided by manufacturers, suppliers or pharmacists, or in scientific publications, with respect to
		(i) the active ingredients of the hazardous drug and the concentration of those ingredients,

(ii) the potential harmful health effects of exposure to the hazardous drug, including both acute and chronic effects and reproductive effects,

(iii) whether exposure to multiple hazardous drugs may increase the risk of harmful health effects, and

(iv) any special precautions a worker is advised to take;

(b) the scope, circumstances and nature of the work activities related to a hazardous drug, including

(i) the classification, formulation and quantity of the hazardous drug,

(ii) the frequency and duration of exposure to the hazardous drug,

(iii) whether the potential for exposure may increase if the form of the hazardous drug is altered during a work activity by crushing, dissolving, piercing or mixing that hazardous drug or by opening a container or package that holds that hazardous drug, and

(iv) whether another worker in the same work area may be at risk of exposure to the hazardous drug;

(c) the effectiveness of existing and planned control measures to eliminate or minimize exposure to the hazardous drug, taking into account, if applicable,

(i) information respecting a spill, uncontrolled release or accidental exposure, and

(ii) environmental monitoring or exposure monitoring data;

(d) any additional information relevant to the risk from the hazardous drug.

(3) The employer must ensure that the risk assessment is reviewed and, if necessary, updated by a qualified person if any of the following occur:

(a) a new hazardous drug is introduced into a workplace to which the risk assessment applies;

(b) drug handling practices, or other work activities that may cause a worker to be at risk of exposure to a hazardous drug, are changed;

(c) available information indicates that controls implemented under the exposure control plan are not effective.

(4) A risk assessment must be prepared in consultation with a joint committee or worker health and safety representative, as applicable, for a workplace to which the risk assessment applies.

Exposure control plan	6.46	(1) An employer must

(a) ensure that a qualified person develops an exposure control plan that

(i) meets the requirements of section 5.54(2), and

(ii) addresses the hazards identified in the risk assessment, and

(b) implement the exposure control plan developed and updated under this section.

(2) The employer must

(a) review an exposure control plan at least annually, and, if necessary, update the exposure control plan, and

(b) if necessary, update an exposure control plan to address any changes to a risk assessment for the workplace.

(3) An exposure control plan must be developed, reviewed and updated in consultation with a joint committee or worker health and safety representative, as applicable, for a workplace to which the exposure control plan applies.

Work procedures **6.46.1** (1) For the purposes of complying with section 5.54(2)(d), an employer must ensure that written work procedures required to be incorporated into an exposure control plan are prepared by a qualified person.

(2) Work procedures must address the following, as applicable:

(a) a work activity relating to

(i) the manufacture, receipt, preparation, administration, storage and disposal of a hazardous drug,

(ii) housekeeping, and

(iii) emergency decontamination;

(b) any other work activity in which a worker is or may be exposed to a hazardous drug;

(c) the containment or enclosure, as a control measure, of a work activity or a work process;

(d) the provision of, and the correct selection, use, care, maintenance and disposal of, any required personal protective equipment and clothing;

(e) prohibitions on eating, drinking, storing food and applying personal care products in an area in which a hazardous drug is present;

(f) handwashing and related protocols;

(g) reporting and response procedures for incidents that involve

(i) accidental exposure to a hazardous drug, or

(ii) a spill or uncontrolled release of a hazardous drug;

(h) the identification, removal, cleanup and disposal of waste related to a hazardous drug, which waste may include

(i) anything contaminated by the hazardous drug, and

(ii) anything contaminated during the precautionary period applicable to the hazardous drug by excreta, vomit or bodily fluids from a patient treated with the hazardous

		drug.
		(3) The employer must ensure that work procedures are made readily available for reference by workers at each of the workplaces to which the work procedures apply.
Reproductive toxins	6.47	If a worker is or may be exposed to a hazardous drug that is a reproductive toxin, an employer must develop (a) a written policy about the availability of protective reassignment, and (b) a procedure for determining if protective reassignment is appropriate for workers who advise the employer of a pregnancy or an intent to conceive a child.
Eliminating or controlling exposure	6.48	(1) An employer must, if practicable, eliminate the risk of worker exposure to a hazardous drug. (2) If elimination under subsection (1) is not practicable, the employer must control the risk of worker exposure to a hazardous drug using substitution. (3) In selecting a suitable substitute, the employer must ensure that the hazards of the substitute are known and that the risk to workers is reduced by its use. (4) If substitution under subsection (2) is not practicable, the employer must control the risk of worker exposure to a hazardous drug, keeping the risk as low as reasonably achievable, by doing the following: (a) applying engineering controls and administrative controls that are appropriate in relation to the work activity and consistent with the risk assessment for the workplace; (b) ensuring that a worker who is or may be exposed to a hazardous drug (i) is provided with personal protective equipment appropriate to the work activity as identified in the applicable work procedures, and (ii) uses the personal protective equipment in accordance with the instruction and training provided under section 6.51.
Contaminated personal protective equipment	6.49	(1) An employer must ensure that contaminated or potentially contaminated personal protective equipment, including gowns and gloves, is not worn outside an area in which a hazardous drug is manufactured, prepared, administered or stored or in which waste contaminated by a hazardous drug is handled. (2) An employer must ensure that non-disposable personal protective equipment is cleaned and decontaminated after use in accordance with the work procedures applicable to the workplace.
Preparation and administration of certain hazardous drugs	6.50	(1) In this section, "IARC Monographs" means the *IARC Monographs on the Identification of Carcinogenic Hazards to Humans* published by the International Agency for Research on Cancer, as amended from time to time.

(2) This section applies to the following hazardous drugs:

(a) a hazardous drug that is identified in the NIOSH list as being antineoplastic;

(b) a hazardous drug for which the manufacturer recommends ventilated engineering controls;

(c) a hazardous drug that is classified by the IARC Monographs as a Group 1 or Group 2A carcinogen.

(3) An employer must ensure that all of the following work activities are performed in a ventilated enclosure that meets the requirements set out in subsection (4):

(a) mixing a hazardous drug to which this section applies;

(b) preparing a hazardous drug to which this section applies;

(c) priming an intravenous administration set with a solution containing a hazardous drug to which this section applies.

(4) For the purposes of subsection (3), a ventilated enclosure must

(a) meet or exceed the requirements for a Class II Type B2 biological safety cabinet that conforms to NSF/ANSI Standard 49-2018 ***Biosafety Cabinetry: Design, Construction, Performance, and Field Certification***,

(b) have exhaust and ventilation systems that remain in operation for a period of time sufficient to ensure that no contaminants escape into the workplace,

(c) be connected to the exhaust ventilation system, which system must discharge to the outdoors in a manner that prevents contaminants from being recirculated in the workplace or an adjacent workplace, and

(d) be equipped with a continuous monitoring device to permit confirmation of adequate airflow and cabinet performance.

(5) An employer must ensure that hazardous drugs to which this section applies are administered in accordance with the applicable work procedures.

Instruction and training	6.51	(1) An employer must ensure that a worker who is or may be exposed to a hazardous drug is provided with instruction and training on the safe handling of the hazardous drug.

(2) The instruction and training under subsection (1) must address all of the following:

(a) known health effects, including reproductive health effects, caused by exposure to the hazardous drug;

(b) the applicable work procedures, including the procedures to be followed in the event of a spill, uncontrolled release or accidental exposure to the hazardous drug;

(c) the correct selection, use, care, maintenance and disposal of personal protective equipment and clothing.

(3) The employer must

(a) review the adequacy of the instruction and training provided under this section if there is a change to

(i) the hazardous drug, or

(ii) handling practices, work activities or the information available respecting the hazardous drug, and

(b) if necessary, ensure that further instruction or training is provided.

(4) Instruction and training under subsection (1) must be provided in consultation with a joint committee or worker health and safety representative, as applicable, for a workplace in relation to which the instruction and training are provided.

Supervision 6.52 An employer must ensure that a worker who is or may be exposed to a hazardous drug at a workplace is

(a) effectively supervised, and

(b) required to follow all work procedures applicable to the workplace.

Spill kits 6.53 An employer must ensure that clearly labelled spill kits

(a) are kept in or near any area in which a hazardous drug is manufactured, received, prepared, administered, stored or transported, and

(b) are readily available to workers.

Storing and labelling hazardous drugs 6.54 (1) An employer must ensure that a hazardous drug is stored as follows:

(a) if practicable, in a designated area that meets the requirements set out in subsection (2);

(b) in accordance with the exposure control plan and the manufacturer's instructions, if any.

(2) For the purposes of subsection (1)(a), the requirements for the designated area are as follows:

(a) the area must be designed and constructed to provide for the safe containment of hazardous drugs;

(b) clearly visible signs warning that hazardous drugs are stored in the area must be prominently posted;

(c) the area must not be located within any other area designated or regularly used for eating, changing clothes or storing personal items;

(d) access to the area must be restricted to authorized workers.

(3) An employer must ensure that any container, bin or shelf, in or on which a hazardous drug is stored, is correctly and clearly labelled.

Transporting hazardous drugs 6.55 (1) In this section, "transport" includes transport within a workplace.

(2) An employer must ensure that, during transport, a hazardous drug is

(a) in a sealed container, labelled with a unique and recognizable identifier to distinguish the hazardous drug from other drugs, and

(b) packaged in a manner that minimizes the risk of environmental contamination if there is a spill, leak or uncontrolled release of the hazardous drug.

Handling and disposing of waste **6.56** (1) For the purposes of this section, the following things are considered to be waste related to a hazardous drug:

(a) during the precautionary period applicable to the hazardous drug, excreta, vomit or bodily fluids from a patient treated with the hazardous drug;

(b) anything disposable that is contaminated by the hazardous drug or by waste referred to in paragraph (a).

(2) Subject to subsection (3), an employer must ensure that all waste related to a hazardous drug is handled and disposed of in accordance with the manufacturer's instructions, if any.

(3) An employer must ensure that all waste that is related to a hazardous drug and handled by a worker is disposed of by placing the waste in a container or bag referred to in subsection (4).

(4) An employer must ensure that every area in which a hazardous drug is manufactured, prepared, administered or stored is supplied with

(a) clearly labelled, leak-proof and sealable waste disposal containers, including puncture- and fluid-resistant sharps containers and solids containers, and

(b) if appropriate, distinctive sealable plastic waste bags.

Controlling cross-contamination **6.57** An employer must ensure that equipment and products used for housekeeping and emergency decontamination are

(a) designated for use only in relation to hazardous drugs, and

(b) readily available for use.

Records **6.58** (1) An employer must keep a record of all instruction and training provided under section 6.51 for a period of 3 years after the date the instruction or training is provided.

(2) An employer must, for each worker who prepares a hazardous drug, keep a record that includes the following:

(a) the name of each hazardous drug prepared by the worker;

(b) if practicable, the number of preparations per week;

(c) each risk assessment prepared, and each exposure control plan developed, including any updates, that

(i) is relevant to the worker's employment, and

(ii) applied to the worker at any time during the period of the worker's employment.

(3) An employer must, for each worker who administers a hazardous

drug, keep a record that includes the following:

(a) the name of each hazardous drug administered by the worker

(i) parenterally,

(ii) orally, in the case of a hazardous drug in powder or liquid form or contained in a capsule that was opened, or

(iii) by topical application;

(b) if practicable, the number of administrations per week;

(c) each risk assessment prepared, and each exposure control plan developed, including any updates, that

(i) is relevant to the worker's employment, and

(ii) applied to the worker at any time during the period of the worker's employment.

(4) An employer must keep a record referred to in subsection (2) or (3) for the period of employment of the worker to whom the record relates and for the 10-year period after the end of that worker's employment.

EXPLANATORY NOTES:

The purpose of the proposed amendments is to provide clearer instructions to employers on their obligations to eliminate or minimize worker exposure to hazardous drugs. In 2015 WorkSafeBC published a booklet on Best Practices for the Safe Handling of Hazardous Drugs[1]. The proposed amendments are expected to reflect these best practices, be evidence based, and improve worker health and safety.

The current provisions on cytotoxic drugs are 20 years old and outdated. The number, types and use of these drugs have evolved into treatment types and care settings or locations not envisioned 20 years ago when these types of drugs were more likely to be administered in acute hospitals and specialized care settings.

Cytotoxic drugs, as well as other potent drugs with toxicity profiles of concern, are increasingly used to treat other diseases besides cancer (e.g., Methotrexate and Tamoxifen, are now used to treat arthritis and non-cancer related conditions). An ageing population and the expansion of community and long term health care means hazardous drugs are increasingly used in these non-traditional workplaces. Exposure occurs in hospitals and institutional settings, as well as in other workplaces including community pharmacies, veterinary care clinics, and community and home care settings. Workers who may be at risk of exposure include: pharmacy workers, laboratory workers, nurses, health care assistants, cleaners, housekeeping staff and laundry staff, physicians and physician assistants, veterinary and animal attendant workers, community health workers, as well as workers involved in hazardous drug manufacturing, shipping, receiving and transport, and hazardous waste handling and waste disposal services.

Carex Canada[2] estimates approximately 75,000 Canadians are occupationally exposed to antineoplastic drugs; and over 75% of exposed workers are female. Fifty-one percent (51%) of all exposed workers are located in non-hospital settings and forty-nine percent (49%) are based in hospitals. Pharmacy workers

[1] WorkSafeBC (2015). Best Practices for the Safe Handling of Hazardous Drugs.

[2] Hall AL, Demers PA, Astrakianakis G, Ge C, Peters CE (2017). Estimating national-level exposure to antineoplastic agents in the workplace: Carex Canada findings and future research needs. Annals of Work Exposures and Health. Vol 61, No 6, 656-668.

(pharmacists, technicians, and assistants) are the largest occupational group exposed to antineoplastic agents with 42,900 workers exposed, and 30,200 of these workers are based in community settings. Carex Canada's estimates are likely much higher when the definition of hazardous drugs is broadened beyond antineoplastic drugs.

A report by ASSTAS/IRRST[3] indicates the number of cancer cases is increasing in all provinces and territories in Canada. In British Columbia the number of individuals receiving chemotherapy increased by 43% from 1996-1997 to 2001-2002. A survey of workers in Quebec's local community centers responsible for home care and other primary care services (70% response rate), indicated 35.6% had been involved in the delivery of intravenous (IV) chemotherapy[4]. Hazardous drug use is increasing in home care and in community and long term care settings[5].

Exposure to hazardous drugs is associated with acute and chronic health effects. Acute effects include skin irritation, hair loss, nausea, liver and kidney damage, hearing loss, cardiac toxicities and decreases in blood cell counts[6]. Chronic health effects of exposure include increased cancer risk[7], adverse reproductive outcomes[8], allergic and genotoxic effects[9]. These health risks of occupational exposure to hazardous drugs are likely to persist given cancer cases are projected to increase, and the usage of hazardous drugs is becoming more prevalent.

Workers in healthcare may be exposed to hazardous drugs when they handle excreta, vomit or excreta of treated patients, when vials or ampules containing hazardous drugs are contaminated or accidentally broken or when workers incur needlestick injuries[10]. Based on metabolites in the urine of healthcare workers, several studies suggest hazardous drug exposure may be a widespread problem, and exposure may extend beyond those workers who directly handle these drugs[11].

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3 Association paritaire pour la santé du travail du secteur affairs sociales (ASSTSAS). Prevention Guide: Safe Handling of Hazardous Drugs. Montreal Quebec 2008. Available at www.asstsas.qc.ca; www.irsst.qc.ca.

4 Agence d'evaluation des technologies et des modes d'intervention en santé (AETMIS). Health Care Technology at Home: Issues in Organization and Delivery in Quebec. Report prepared by Pascale Lehoux and Susan Law with the collaboration of Lucy Boothroyd. (AETMIS 04-06). Montreal: AETMIS. 2004. Xiv-102 p.

5 Canadian Institute for Health Information (CIHI). (2016) Regulated Nurses, (2014). Ottawa, Canada: Canadian Institute for Health Information.
Meijster T, Fransman W, Veldhof R et al. (2006) Exposure to antineoplastic drugs outside the hospital environment. Ann Occup Hyg; 50: 657-664.
Canadian Home Care Association. (2013) Portraits of Home Care in Canada. Mississauga, Canada: Canadian Home Care Association.

6 K Kusnetz E, Condon M. Acute effects from occupational exposure to anti- neoplastic drugs in a para-professional health care worker. *Am J Ind Med.* 2003; 44(1):107-109.
NIOSH. Hazardous drug exposures in healthcare: effects of occupational exposure. CDC website. cdc.gov/niosh/topics/hazdrug/effects.html. Updated January, 2019.(accessed August 12, 2020)

7 Dimich-Ward L , Lorenzi M, Teschke K et al.(2007) Mortality and cancer incidence in a cohort of registered nurses from British Columbia, Canada. Am J Ind Med; 50: 892- 900.

8 Connor TH, Lawson CC, Polovich M et al. (2014) Reproductive health risks associated with occupational exposures to antineoplastic drugs in health care settings: a review of the evidence. J Occup Environ Med; 56: 901-910.

9 Fransman W, Huizer D, Tuerk J et al (2007) Inhalation and dermal exposure to eight antineoplastic drugs in an industrial laundry facility. Int Arch Occup Environ Health; 80: 396-403.
National Institute for Occupational Safety and Health. (2015) Workplace Safety and Health Topic: Occupational exposure to Antineoplastic Agents.
Connor TH, Celano P, Frame JN, Zon RT (2017). Summary of the Workshop on the Safe Handling of Hazardous Drugs cohosted by the National Institute for Occupational Safety and Health and the American Society of Clinical Oncology. J Oncol Pract. 2017; 13(3):199-205. doi: 10.1200/JOP.2016.017384.

10 Jeffrey Lombardo (2018) Current and Future Considerations for the Safe Handling of Hazardous Drug, Special report: safe handing/part 1 of a three-part series. (https://www.pharmacytimes.com/publications/specialty-pharmacy-times/2018/may-2018/current-and-future-considerations-for-the-safe-handling-of-hazardous-drugs - accessed August 2020).

11 Hon C-Y, Teschke K, Shen H, Demers PA, Venners S (2015). Antineoplastic drug contamination in the urine of Canadian healthcare workers. Int Arch Occup Environ Health, Oct; 88(7): 933-941.

The work activities posing the greatest risk of exposure are preparing and administering antineoplastic drugs, cleaning up chemotherapy spill, and handling patient excreta[12]. Workers who handle, compound, administer, dispose of hazardous drugs, handle drug waste, or clean equipment used with hazardous drugs are also at risk of adverse health outcomes[13].

Proposed section 6.42 Definitions

The following new terms to the definitions section are proposed:

"decontamination" refers to the removal of a hazardous drug from a surface, material or other thing, or the inactivation or destruction of a hazardous drug that may be located on a surface, material or other thing;

"emergency decontamination" refers to decontamination activities following a spill or an emergency in relation to hazardous drugs, outside of tasks performed as part of housekeeping;

"*hazardous drugs"* refers to the three ways an organization may develop a list of hazardous drugs:

(a) it is known to have one or more of the following characteristics: carcinogenicity (cancer causing), teratogenicity (malformation of an embryo), genotoxicity (damages genetic information in cells causing mutations), reproductive toxicity (adverse effects on sexual function and fertility in adult males and females, as well as development of the offspring), organ toxicity at low doses;
(b) it is a new drug and not yet known to have one or more of the listed characteristics referenced in (a) but it is similar in structure or toxicity to one or more of those characteristics, or
(c) it is identified in the NIOSH list as a hazardous drug;

"housekeeping" refers to routine cleaning, routine decontamination and changing, handling, laundering or other cleaning, and disposing of things contaminated with the excreta, vomit or bodily fluids of patients;

"NIOSH list" means the *NIOSH List of Hazardous Drugs in Healthcare Settings,* prepared by the United States National Institute for Occupational Health and Safety and as amended from time to time;

"*precautionary period*" refers to 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 hazardous metabolite of the hazardous drug, as determined in accordance with any of the following information:

(a) information provided by the manufacturer or a supplier of the hazardous drug;
(b) information provided by a pharmacist or physician; or
(c) information in a scientific publication.

The term and definition of "*cytotoxic drug*" was removed.

Proposed section 6.43 Application

This provision sets out sections 6.44 to 6.58 apply to a workplace where a worker is or may be exposed to a hazardous drug.

Sessink PJM, Bos RP (1999). Drugs hazardous to healthcare workers: evaluation of methods for monitoring occupational exposure to cytostatic drugs. Drug Saf. 1999; 20(4):347-359.
Sessink PMJ (2011). Environmental contamination with cytostatic drugs: past, present and future. Safety Considerations in Oncology Pharmalogy, Special Edition, Fall 2011, p. 1-3.

[12] Martin, Susan (2005). The adverse health effects of occupational exposure to hazardous drugs. Community Oncology. September/October 2005, 397-400.

[13] NTP (2019). National Toxicology Program Monograph on the Systematic Review of Occupational Exposure to Cancer Chemotherapy Agents and Adverse Health Outcomes. NTP Monograph 5. Research Triangle Park, NC: National Toxicology Program (5) 1-200.

Proposed section 6.44 Identifying hazardous drugs

This section sets out the requirements for an employer to:

(a) develop and maintain a written list of hazardous drugs
(b) review and update the list at least annually, and
(c) make the list referred in (a) readily available for reference by workers.

Proposed section 6.45 Risk assessment

The intent of the risk assessment is to enable employers to make decisions about the control measures to prevent or minimize worker exposure to hazardous drugs. Exposure may occur through the skin or mucous membranes, ingestion or inhalation[14].

This section requires employers to 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. The risk to workers is usually assessed by considering the hazards, the likelihood or the probability of worker injury or harm, and the severity of the injury or harm. The risk assessment is to be used to identify areas, processes and work activities of concern, and to create a workplace-specific exposure control plan to prevent or minimize worker exposure to hazardous drugs.

The use of the singular in referencing "a" hazardous drug in this section includes the plural "hazardous drugs".

The proposed wording will allow employers the flexibility to perform a risk assessment on a group of drugs provided the employer can demonstrate the toxicological profile of the drugs in the group are similar.

The factors to be considered in the risk assessment, if this information is available, include at minimum:

(a) the toxicity of the hazardous drug based on information provided by manufacturers, suppliers or pharmacists or available in scientific publications[15];
(b) the scope, circumstances and nature of the worker's work activities;
(c) the effectiveness of existing or planned control measures to prevent or minimize the worker's exposure to hazardous drugs; and
(d) any additional information needed to complete the risk assessment.

Paragraph (c) above refers to a review of any available information in relation to spills or accidental exposure as well as environmental or exposure monitoring data to evaluate the effectiveness of existing or planned control measures. WorkSafeBC does not recognize an environmental or exposure monitoring standard for hazardous drugs[16]. However, an employer may have such data, if it implements these monitoring activities following a spill or accidental exposure, or after a worker consults a physician following a spill or accidental exposure[17]. Environmental monitoring data may also be required by another regulatory agency. For

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[14] Association paritaire pour la santé du travail du secteur affairs sociales (ASSTSAS). Prevention Guide: Safe Handling of Hazardous Drugs. Montreal Quebec 2008. Available at www.asstsas.qc.ca; www.irsst.qc.ca.

[15] Drugs are exempt from labelling requirements of the *Hazardous Products Act and Regulations*.

[16] Some pharmaceutical manufacturers have developed risk-based OELs to be used in their own manufacturing settings, and this information may be available on safety data sheets (SDSs) or from the manufacturer. See Weideman, P. Alison, M, Pecquet, M, Maier, A. (2016). Harmonization efforts for deriving health-based exposure limits in the pharmaceutical industry – Advancing the current science and practice, Regulatory Toxicology and Pharmacology: 79, S1-S2.

[17] For example to comply with USP 800 guidelines. USP General Chapter 800 *Hazardous Drugs Handling in Healthcare Settings,* United States Pharmacopeia, 2019. (https://www.aha.org/system/files/media/file/2020/02/usp-chapters-797-and-800-new-and-revised-compounding-standards-3_1.pdf – (accessed August, 2020).

example, the National Association of Pharmacy Regulatory Authorities (NAPRA) requires environmental monitoring to protect workers and patients by preventing cross-contamination[18].

Subsection (3) requires an employer to ensure the risk assessment is reviewed and updated by a qualified person when

(a) a new hazardous drug is introduced into the workplace;
(b) drug handling practices, or other work activities that may cause a worker to be at risk of exposure, are changed, or
(c) available information indicates that controls are not effective.

Subsection (4) requires the joint committee or worker health and safety representative to be consulted during the preparation of the risk assessment.

Propose section 6.46 Exposure control plan

Subsection (1) requires employers to ensure a qualified person develops an exposure control plan that (a) meets the requirements of sections 5.54(2) and (b) addresses the hazards identified in the risk assessment. An employer is also required to implement the exposure control plan.

If a risk assessment is updated, subsection (2) requires an employer to ensure the exposure control plan addresses those changes to the risk assessment and the updated exposure control plan is implemented.

Subsection (3) requires the joint committee or worker health and safety representative are consulted during the development, review and update of the exposure control plan. Where an exposure control plan applies to more than one workplace, the employer must consult with the applicable joint committees or worker health and safety representatives to which the exposure control plan applies.

Propose section 6.46.1 Work procedures

Subsection (1) requires an employer to ensure a qualified person develops written work procedures.

Subsection (2) requires written work procedures for at least the items listed in (a) through (h).

Subsection (3) requires the work procedures to be readily available for reference by workers.

Proposed section 6.47 Reproductive toxins

If a worker is or may be exposed to a hazardous drug that is a reproductive toxin or has adverse health effects, this section requires an employer to develop written policy about the availability of protective reassignment and a procedure for determining if protective reassignment is appropriate for workers who advise the employer of a pregnancy or an intent to conceive a child.

Proposed section 6.48 Eliminating or controlling exposure

This section makes explicit the hierarchy of controls for an employer making decisions to control or minimize worker exposure to hazardous drugs.

Elimination is at the top of the hierarchy of controls. In subsection (1) an employer must, if practicable, consider whether it is possible to eliminate the risk.

Subsections (2) and (3) relate to the requirements regarding substitution.

[18] https://napra.ca/general-practice-resources/model-standards-pharmacy-compounding-hazardous-sterile-preparations, (section 7), (accessed August, 2020).

Subsection (4) establishes if it is not practicable to eliminate or substitute, an employer must control the risk, keeping it as low as reasonably achievable by

- applying engineering and administrative controls, and
- ensuring that a worker who is or may be exposed to a hazardous drug is provided and uses personal protective equipment.

Engineering controls are used when elimination is not possible either through substitution or another process which would eliminate the risk. Administrative controls include measures such work procedures, scheduling, and other standard operating procedures.

If elimination or substitution are not practicable, workers must be provided with, and must wear personal protective equipment (PPE) even when engineering and administrative controls are put in place. The rationale is there is no standard to determine what would meet the as low as reasonably achievable principle; therefore, personal protective equipment provides workers with additional protection.

Proposed section 6.49 Contaminated personal protective equipment

The section addresses where personal protective equipment, including gowns and gloves, should not be worn, and the cleaning and decontamination, after use, of non-disposable personal protective equipment in accordance with the written work procedures.

Proposed section 6.50 Preparation and administration of certain hazardous drugs

This section addresses selected work activities with certain hazardous drugs which may pose a greater risk to workers. Due to the greater risk these drugs pose, selected work activities, such as preparation and administration with these hazardous drugs are to be performed in a ventilated enclosure.

Subsection (2) identifies the hazardous drugs to which this section applies:

(a) a hazardous drug that is identified as antineoplastic;
(b) a drug for which the manufacturer, in instructions, guidance or other materials respecting safe-handling recommends ventilated engineering controls[19];
(c) a hazardous drug that is classified by the IARC[20] Monographs as a Group 1 or Group 2A carcinogen.

Subsection (3) requires employers to ensure the following activities in relation to the hazardous drugs identified in subsection (2) are performed in a ventilated enclosure:

(a) mixing;
(b) preparing;
(c) priming intravenous sets for a hazardous drug.

Subsection (4) specifies the ventilated cabinet referred to in (2) must

(a) meet or exceed the requirements for a Class II Type B2 biological safety cabinet that conforms to NSF/ANSI 49-2018 Standard *Biosafety Cabinetry: Design, Construction, Performance and Field Certification*, as amended from time to time,
(b) have exhaust and ventilation systems that operate for a sufficient period of time to ensure that no contaminants escape into the workplace,
(c) exhaust to the outside atmosphere in a manner that prevents re-circulation into the workplace, and

[19] In addition to the NIOSH list, this information is usually located in section 16 of the drug "package insert" and accompanied by prescribing information that includes a manufacturer's special handling information (see p. 6 & 54 NIOSH (2020). Managing Hazardous Drug Exposures: Information for Healthcare Settings, Cincinnati, OH: US Department of Health & Human Services, Centres for Disease Control and Prevention).

[20] IARC is the International Agency for Research on Cancer.

(d) be equipped with a continuous monitoring device to permit confirmation of adequate airflow and cabinet performance.

The intent of this provision is to ensure employers do not use the risk assessment to avoid requirements for these specific tasks involving drugs identified in subsection (1) which represent high risk for workers.

Subsection (5) requires these certain hazardous drugs to be administered in accordance with the applicable work procedures.

Proposed section 6.51 Instruction and training

Subsection (1) requires employers to provide instruction and training on the safe handling of the hazardous drugs.

Subsection (2) sets out that the instruction and training required under subsection (1) must include all of the following:

(a) known health effects, including any reproductive health effects caused by exposure to the hazardous drug;
(b) the written work procedures for work activities;
(c) the selection, correct use, care and maintenance and disposal of personal protective equipment and clothing.

Subsection (3) requires a review of the adequacy of the instruction and training and further instruction and training provided, if necessary.

Subsection (4) requires the joint committee or worker health and safety representative to be consulted in relation to the instruction and training provided.

Proposed section 6.52 Supervision

The employer must ensure a worker who is or may be at risk of occupational exposure is

(a) effectively supervised, and
(b) required to follow all applicable written work procedures referred to in the exposure control plan.

Broader requirements regarding supervisor duties and training are found in sections 23 and 21 of the *Workers Compensation Act*, respectively.

Proposed section 6.53 Spill kits

This section requires employers to keep clearly labelled spill kits in or near any area in which hazardous drugs are manufactured, received, prepared, administered, stored or transported. Additionally, the kits must be readily available to workers.

Proposed section 6.54 Storing and labelling of hazardous drugs

Subsection (1) requires employers to ensure hazardous drugs are stored in a designated area, if practicable and in accordance with the exposure control plan and the manufacturer's instructions, if any.

Subsection (2) sets out the criteria for the designated area used for storage of hazardous drugs.

Subsection (3) addresses labelling for a container, bin or shelf used to store a hazardous drug.

Proposed section 6.55 Transporting hazardous drugs

In this section "transport" includes transport within a workplace.

This section sets out an employer's responsibility for packaging hazardous drugs during transport outside a workplace and within a workplace.

Proposed section 6.56 Handling and disposing of waste

Subsection (1) sets out the criteria for what is deemed to be "waste" related to a hazardous drug.

Subsection (2) requires an employer to ensure all waste related to a hazardous drug is handled and disposed of in accordance with the instructions, if any, of the manufacturer.

Subsection (3) requires all waste handled by a worker is disposed in a container or bag referred to in subsection (4).

Subsection (4) requires an employer to ensure every area in which hazardous drugs are manufactured, stored, prepared or administered is supplied with clearly labelled, leak-proof and sealable waste disposal containers, and if appropriate, distinctive sealable plastic waste bags.

Proposed section 6.57 Controlling cross-contamination

This section is to ensure equipment and products used for housekeeping and emergency decontamination are designated for use only in relation to hazardous drugs and are readily available for use.

Proposed section 6.58 Records

This section clarifies record keeping requirements.

Subsection (1) requires an employer to maintain a record of all instruction and training of workers who are or may be exposed to hazardous drugs for a period of 3 years from the date that the instruction and training was provided.

Subsections (2) and (3) separate the records required for workers who prepare drugs and who administer drugs, respectively. The rationale is that these tasks are performed by separate groups of workers. Workers who prepare drugs are usually in pharmacy and workers who administer drugs tend to work in care settings where caring and administering to patients is prevalent.

Subsection (2) requires an employer to maintain a record for each for worker who prepares a hazardous drug, which include the following:

(a) the names of the hazardous drug prepared;
(b) if practicable, the number of preparations per week;
(c) all risk assessments and the exposure control plan, including any updates, relevant to the worker's employment and for the duration of the worker's employment.

Subsection (3) contains the same requirements as (2) for a worker who administers a hazardous drug. However, for (3) the record keeping requirement for the names of the hazardous drugs only applies to those drugs that are administered (i) parenterally, (ii) orally, if capsules were opened of the hazardous drugs was in powdered or in liquid form, or (iii) by topical application.

Subsections (2)(c) and (3)(c) add a requirement for the risk assessment and the exposure control plan to be kept so that a worker's exposure and risk can be assessed in the event of a claim.

Subsection (4) requires the employer to maintain the records from subsection (2) or (3) for the duration of a worker's employment plus 10 years.