Part 6, Hazardous Drugs (formerly Cytotoxic Drugs)

The Policy, Regulation and Research Department (PRRD) held a public hearing on the proposed amendments to Part 6 of the *Occupational Health and Safety Regulation* (*OHSR*) on March 3, 2021. All issues raised by stakeholders were analyzed by the PRRD and WorkSafeBC subject matter experts, resulting in further changes to the proposed amendments.

The following chart contains a summary of the key changes made to the proposed amendments since public hearing held in the spring of 2021. Please note editorial revisions are not included in the changes listed below.

Section(s) of the *OHSR*	What has changed since the public hearing
6.42 *Definitions*	The definition of "antineoplastic" was removed from section 6.42 as it was only referred to once. Instead the definition was integrated into section 6.50(2)(a). The definition of "decomtamination" was revised to combine two parts to avoid repetition. The definition of "emergency decontamination" was revised to exclude routine decomtamination conducted as part of housekeeping. The definition of "precautionary period" was revised to clarify only hazardous metabolites are of concern. The definition was further revised to clarify the reference to "period" relates to a time period. Additionally, "administered" was changed to "treated" to maintain consistency. A definition for "exposure control plan" and "risk assessment" was added to the definitions list for convenience to avoid cross-referencing to the section number throughout.
6.44 *Identifying hazardous drugs* and 6.45 *Risk assessment*	The phrase "if a worker is or may be exposed to a hazardous drug" was removed because it repeated section 6.43 *Application*.
6.44 *Identifying hazardous drugs*	In section 6.44(a) the term "maintain" was removed as the concept of maintaining a list is addressed in (b). Section 6.44(b) was revised to clarify the requirement in which the list of hazardous drugs only needs to be updated when necessary. Section 6.44(c) was revised to ensure workers to which the list applies have access in a readily available manner.

Section(s) of the *OHSR*	What has changed since the public hearing
6.45 *Risk assessment*	Section 6.45(1) was split into two separate subsections, consequently 6.45(1)(a) is re-numbered to section 6.45(2). The re-numbered section 6.45(2) was revised to allow employers to use other sources of data, in addition to the list provided in this subsection. Additionally, the clause "if any" was added to the re-numbered section 6.45(2)(a) to allow for situations where some of this information may not currently be available. The re-numbered section 6.45(2)(a)(iii) was revised to clarify the intent was the interaction of multiple hazardous drugs.
6.46 *Exposure control plan*	Section 6.46(1) was revised to remove the clause referring to the risk assessment. The requirement to have an exposure control plan is based on whether workers are exposed to a hazardous drug. Section 6.46(1)(a)(i) was revised to remove reference to 5.54 as a whole and instead specify section 5.54(2). The reference to section 5.57 was also removed because it does not relate to an exposure control plan, but to substitution and control measures. Section 6.46(1)(b) was revised requiring an updated exposure control plan to be implemented. Section 6.46(3) was added to require consultation with the joint committee or worker health and safety committee when reviewing and updating the exposure control plan. This section also ensures the requirement from 5.54(3) was not removed.
6.46.1 *Work procedures*	The requirements for work procedures were separated from section 6.46 and a new section was created. The re-numbered section 6.46.1(2)(a) was revised to replace the term "work procedures" with "work activities" to better reflect the true intent of this requirement and minimize confusion with "safe work procedures". The re-numbered section 6.46.1(2)(e) was split into two subparagraphs and the reference to personal hygiene was removed as many of the activities listed were not related to personal hygiene. The re-numbered section 6.46.1(2)(h) was revised to replace "any material" to "anything" to maintain consistency with the definition of housekeeping.
6.47 *Reproductive toxins*	Section 6.47 was re-configured to separate the requirements and clarify the purpose of a policy versus procedures.
6.48 *Eliminating or*	Section 6.48 was re-configured by separating the requirement to control the risk through elimination from the requirement to use

Section(s) of the *OHSR*	What has changed since the public hearing
controlling exposure	substitution. Consequently, re-numbering was required. In the re-numbered section 6.48(4)(a), the reference to section 5.55 as a whole was removed because this subparagraph is not consistent with the requirements in section 5.55. The applicable requirement from section 5.55(2) was added as section 6.48(3). In the re-numbered section 6.48(4)(a), the reference to section 5.57 was removed because it did not add any further requirements.
6.50 *Preparation and administration of certain hazardous drugs*	The re-numbered section 6.50(2)(c) was revised to include hazardous drugs classified by IARC[1] as Group 1 (Carcinogenic) and Group 2A (Probably carcinogenic). The purpose of this addition was intended to ensure any drug not identified by NIOSH as antineoplastic, but classified by IARC as carcinogenic or probably carcinogenic will be required to be handled in accordance with the requirements in this section. Consequently a definition of IARC Monograph was inserted into section 6.50(1) and re-numbering was required. Re-numbered section 6.50(3)(c) was revised to allow for priming with non-hazardous drugs. Re-numbered section 6.50(4)(a) was revised to refer to specific requirements within a standard. Re-numbered section 6.50(4)(a) was revised to remove "as amended from time to time" because automatically adopting a newer version of the standard does not enable WorkSafeBC to review the standard first and for stakeholders to be consulted.
6.51 *Instruction and training*	This section was re-named to "Instruction and training" instead of "Education and training" to maintain consistency with the language in the *Workers Compensation Act* section 21(2)(e). Section 6.51(1) was revised to remove the reference to "pre-job" and "on-the-job" as determining what is pre-job versus on-the-job obscures the intent of this section. Section 6.51(3)(a) was revised to require a review rather than an evaluation of the instruction and training. The term "review" more accurately captures the intent of this requirement.
6.53 *Spill kits*	Section 6.53(b) was revised to remove reference to spill procedures as it is a repetition of re-numbered sections 6.46.1(2)(g) and 6.46.1(3).

[1] International Agency for Research on Cancer (IARC) is the specialized cancer agency of the World Health Organization. IARC classifies agents into groups based on their known carcinogenicity.

Section(s) of the *OHSR*	What has changed since the public hearing
6.54 *Storing and labelling of hazardous drugs*	Section 6.54(2)(c) was revised to include storing of personal items.
6.55 *Transporting hazardous drugs*	Section 6.55(3) was removed to avoid repetition with section 6.51(2)(b).
6.56 *Waste handling and disposal*	A new subsection (1) was inserted with a description of what constitutes waste as it relates to this section. Consequentially, re-numbering was required. The re-numbered section 6.56(3) was revised to require only waste handled by a worker, not waste directly deposited into a toilet, is required to be handled with precautions. The re-numbered subsection 6.56(4) was revised requiring employers to have bags on hand only when applicable.
6.58 *Records*	A new section 6.58(4) was added to include the period of time with which these records must be kept so as to avoid repetition.
6.58.01 *Consultations*	Section 6.48.01 was eliminated and the requirement to consult with a joint committee or worker health and safety representative was moved into the sections to which it applies (risk assessment, exposure control plan, and instruction and training).

Online feedback

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.~~

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 criteria 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 may contain the hazardous drug or a hazardous metabolite of the hazardous drug;**
"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 information, if any, 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 the 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 sections 5.54(2), and

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

(d) 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 section 5.54 (2) (d), an employer must ensure that a qualified person includes written work procedures in an exposure control plan.**

(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, including the frequency of 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 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 the uncontrolled release, of a hazardous drug;

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

(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) written policy in relation to protective reassignment, and

(b) work procedures that include both of the following:

(i) a process to inform workers about adverse reproductive health effects;

(ii) a process to determine 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 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.

(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 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 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 work procedures, including procedures to be followed in the event of a spill 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

(a) 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 are 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 is 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 facility.

(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 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 a hazardous drug, 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~~s~~ 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 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 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, 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 (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

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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).

studies suggest hazardous drug exposure may be a widespread problem, and exposure may extend beyond those workers who directly handle these drugs[11].

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;

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[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.
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.

"*precautionary period*" refers to the period during which the excreta, vomit or bodily fluids of a patient to whom a hazardous drug has been administered may contain the hazardous drug or metabolite of the hazardous drug.

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

Proposed section 6.43 Application

Sets out that sections 6.44 to 6.58 apply to a workplace where a worker is or may be exposed to a hazardous drug.

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 drug.

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 providing 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 need to complete the risk assessment.

[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*.

Paragraph (c) above refers to a review of any available information in relation to spills or accidental exposure and 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 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.

Propose section 6.46.1 Work procedures

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

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

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

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[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).

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

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 and procedures which include:

- a process to inform workers about adverse reproductive health effects, and
- a process to determine if protective re-assignment 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 (3) and (4) relate to the requirements regarding substitution.

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 Decontamination of 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 biological safety cabinet.

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
(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.

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 from the exposure control plan;
(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.

[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.

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.

It differs from the provisions in section 23 of the *Workers Compensation Act* which outlines a supervisor's duties in broader terms.

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 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 Transport of hazardous drugs

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

This section sets out an employer's responsibility for packaging hazardous drugs during transport.

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.