CUPE·SCFP | Canadian Union of Public Employees
Syndicat canadien de la fonction publique

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August 27, 2019 **Sent Via Email: policy@worksafebc.com**

Ms. Willa Duplantis
Senior Policy and Legal Advisor
Policy and Regulation Division
WorkSafeBC
P.O. Box 5350, Stn. Terminal
Vancouver BC V6B 5L5

Dear Ms. Duplantis:

Re: WorkSafeBC ("WCB") Consultation
Proposed Changes – OHS Regulations – Cytotoxic and Antineoplastic Drugs and Agents
Worker Position – Canadian Union of Public Employees (BC)("CUPE")

I. INTRODUCTION:

Thank you for requesting stakeholder feedback on the proposed amendments regarding Proposed Changes – OHS Regulations – Cytotoxic Drugs[1] (See Appendix A).[2] CUPE appreciates the opportunity to comment on the proposed changes.

CUPE is Canada's largest Union with over 680,000 members across the country and more than 70 offices.[3] CUPE represents workers in many sectors including health care, emergency services, education, early learning and child care, municipalities, social services, libraries, utilities, transportation, airlines and more. There are nearly 97,000 members in over 160 Locals in BC.[4]

[1] Antineoplastic drugs and agents are not the same as cytotoxic drugs as inferred by the WCB in the current Consultation. Any references to these in this submission are not to be construed as the two terms being synonymous. See HSE Health and Safety Executive at http://www.hse.gov.uk/healthservices/safe-use-cytotoxic-drugs.htm
[2] WorkSafeBC. Consultations. See https://www.worksafebc.com/en/resources/law-policy/discussion-papers/part-6-substance-specific-requirements-cytotoxic-drugs?lang=en
[3] See https://cupe.ca/
[4] See https://www.cupe.bc.ca/

II. OVERVIEW OF CUPE'S POSITION AND PRELIMINARY CONCERNS:

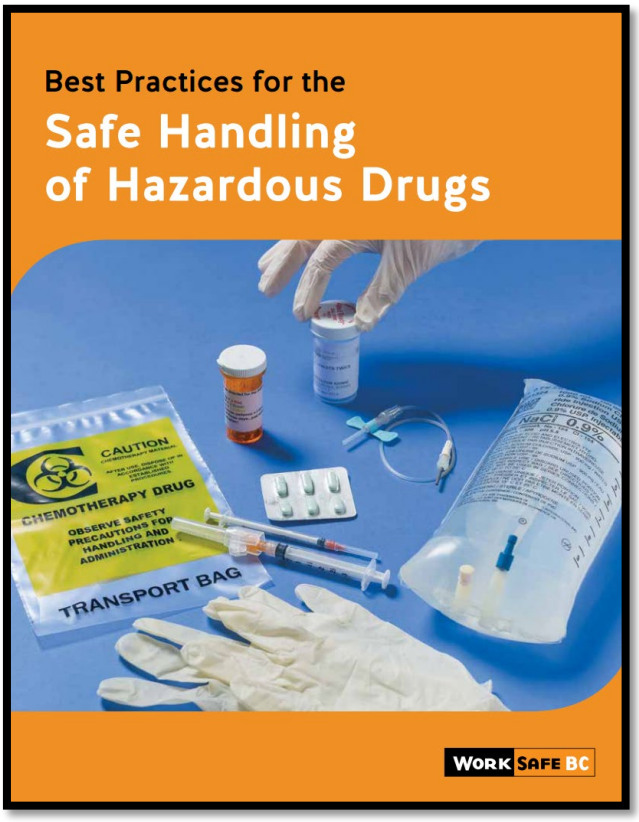
II.I. Overview of Position on Proposed Changes:

II.I.I. CUPE in Agreement with Underlying Principles for Changes:

CUPE agrees with the WCB's implementation of best practices and that the current provisions are 20 years old and require updating, however CUPE disagrees with the specific changes. As stated in the "Explanatory Notes" section of the current Consultation:

> "In 2015 WorkSafeBC published a booklet on Best Practices for the Safe Handling of Hazardous Drugs. The proposed amendments are expected to reflect these best practices, be evidence based, and improve worker health and safety."[5]

Figure 1 – Best Practices for the Safe Handling of Hazardous Drugs:



[5] WorkSafeBC. Best Practices for the Safe Handling of Hazardous Drugs. See https://www.worksafebc.com/en/resources/health-safety/books-guides/best-practices-safe-handling-hazardous-drugs?lang=en

II.I.II. Scope of Issue and Problem:

There is no safe exposure level for any carcinogen, including antineoplastic drugs or cytotoxic drugs. As stated previously, antineoplastic drugs and agents are not the same as cytotoxic drugs as inferred by the WCB in the current Consultation. Any references to these in this submission are not to be construed as the two terms being synonymous. Antineoplastic and cytotoxic drugs are increasingly used in a greater variety of workplace settings, as stated in the "Explanatory Notes" section:

> "An ageing population and the expansion of community and residential health care means that 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."[6] (Emphasis added)[7]

And,

> "Fifty-one percent (51%) of all exposed workers are located in non-hospital settings…"

This is supported by CAREX Canada. See Figures 2 and 3:[8]

Figure 2 – Prevalence of Exposure: Antineoplastic Agents (see next page):

[6] This submission does not speak on behalf of the Hospital Employees' Union or other healthcare sector and allied Unions or organizations.
[7] Also see Canadian Union of Public Employees. "Cytotoxic Drugs". See https://cupe.ca/cytotoxic-drugs
[8] CAREX Canada. See https://www.carexcanada.ca/profile/antineoplastic_agents-occupational-exposures/

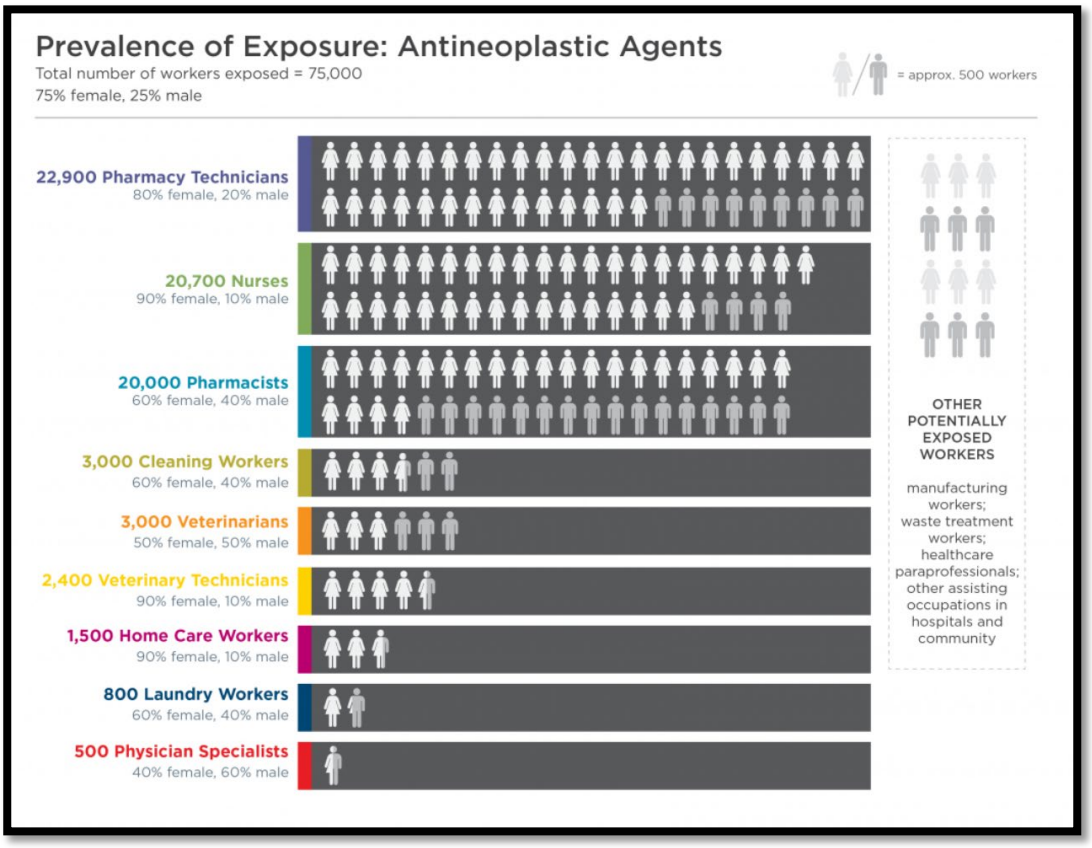
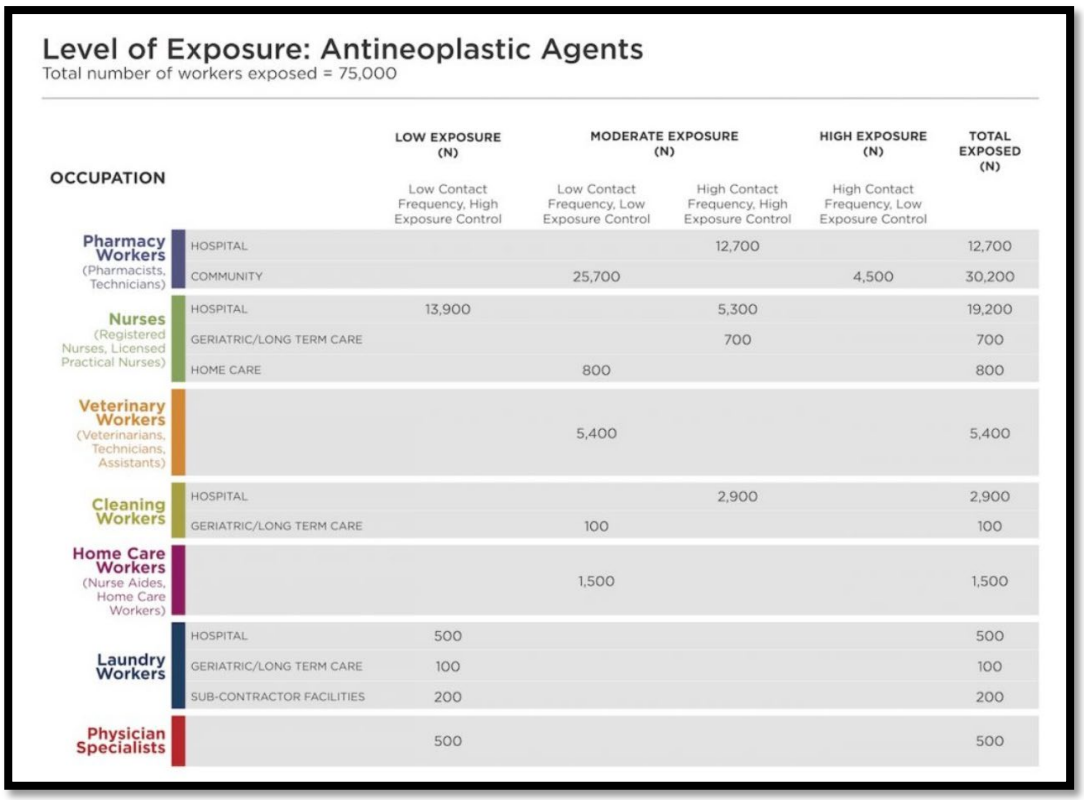


Figure 3 – Level of Exposure: Antineoplastic Agents (see next page):



Level of Exposure: Antineoplastic Agents

Total number of workers exposed = 75,000

OCCUPATION		LOW EXPOSURE (N)	MODERATE EXPOSURE (N)		HIGH EXPOSURE (N)	TOTAL EXPOSED (N)
		Low Contact Frequency, High Exposure Control	Low Contact Frequency, Low Exposure Control	High Contact Frequency, High Exposure Control	High Contact Frequency, Low Exposure Control	
Pharmacy Workers (Pharmacists, Technicians)	HOSPITAL			12,700		12,700
	COMMUNITY		25,700		4,500	30,200
Nurses (Registered Nurses, Licensed Practical Nurses)	HOSPITAL	13,900		5,300		19,200
	GERIATRIC/LONG TERM CARE			700		700
	HOME CARE		800			800
Veterinary Workers (Veterinarians, Technicians, Assistants)			5,400			5,400
Cleaning Workers	HOSPITAL			2,900		2,900
	GERIATRIC/LONG TERM CARE		100			100
Home Care Workers (Nurse Aides, Home Care Workers)			1,500			1,500
Laundry Workers	HOSPITAL	500				500
	GERIATRIC/LONG TERM CARE	100				100
	SUB-CONTRACTOR FACILITIES	200				200
Physician Specialists		500				500

II.I.III. CUPE Unable to Agree with Certain Specific Changes:

There are several questions and concerns regarding the proposed language, as per the following. Until these are addressed CUPE is not able to agree to the proposed changes for the reasons contained in this submission. For example (not an exhaustive list):

- Will the 2015 Best Practices for the Safe Handling of Hazardous Drugs be revised and updated? Is there a schedule for updating this document?

- Why were the definitions changed to exclude, for example, the term “cytotoxic drugs”? While the term used is now “antineoplastic agents” e.g. by CAREX, the definition could have been amended to refer to both for transition and clarification purposes e.g.:

  “’antineoplastic’, previously referred to as ‘cytotoxic drugs / agents’ and including cytotoxic drugs, in relation to a drug, means a drug that

  (a) interferes with the deoxyribonucleic acid of tumour cells, and

(b) meets the American Hospital Formulary Service drug classification 10.00, and

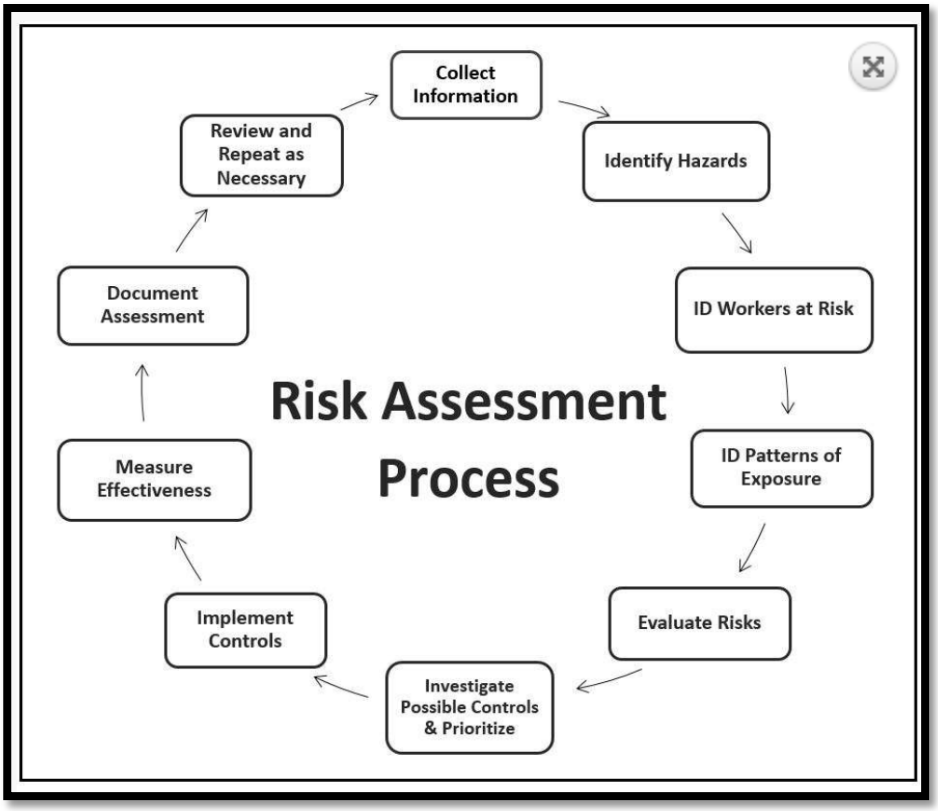
(c) is cross referenced, for example, with the CAREX Canada Substance Profile;"[9] (Emphasis added) (See Appendix B)

- The WCB appears to be limiting the applicability of the OHS Regulations and narrowing the scope by changing the terminology from cytotoxic drugs to antineoplastic drugs.

- The WCB needs to require employers to perform Risk Assessments, Hazard Assessments. Risk Identification and Hazard Identification. These terms are not synonymous as per OSHA.[10] Hazard Assessments identify a particular hazard(s). Hazard Assessments are part of a plan to address the hazard(s). Risk Identification identifies the chance of a hazard(s) occurring and the severity of the harm. Risk Assessments are part of a plan to address the risk(s). All four should be part of any workplace plan for what is generally called "Risk Assessment".[11] See Figure 4:[12]

Figure 4 – Risk Assessment Process (see next page):

[9] CAREX Canada. See https://www.carexcanada.ca/profile/antineoplastic_agents/
[10] OSHA. Hazard Identification and Assessment. See https://www.osha.gov/shpguidelines/hazard-Identification.html
[11] OSHA. Module 3. Hazard Identification and Assessment. See https://www.osha.gov/sites/default/files/2018-12/fy11_sh-22318-11_Mod_3_ParticipantManual.pdf. This is in addition to the CSA. See CSA. CSA-Z1002-12. See https://store.csagroup.org/ccrz__ProductDetails?sku=2703276
[12] See https://www.orcasafety.ca/health-safety-training/hazard-identification-assessment-and-control-4-hours/



- The WCB needs to ensure that Risk Assessments, Hazard Assessments and Exposure Control Plans apply to the most encompassing terminology rather than narrowing the scope of terminology and definitions.

- What is the process for standardized informatics systems to ensure quality management, traceability of processes and minimization of risks associated with these drugs?

This list is for illustration purposes only. As stated below, every issue and concern are not identified because CUPE disagrees with the proposed changes overall. CUPE will provide a comprehensive Table of Concordance and list of issues and concerns upon request.

II.I.IV. Related Consultations, Policies, Regulations and Guidelines (this is a preliminary issue as opposed to a reply to the specific Consultation):

As stated above, there is no safe level for carcinogenic drugs. This is supported by numerous studies. Will the related OHS Regulations be updated e.g. requirements for Risk Assessments, Exposure Control Plans, education, etc?

CUPE also questions if the current Consultation is related to or overlaps with the Consultation on TLVs (Consultation on Proposed Occupational Exposure Limits based on the New or Revised

2016, 2017, and 2018 ACGIH TLVs for Selected Chemical Substances)[13] and if any of the substances therein overlap with the current Consultation. This would include cross referencing these with the U.S. Department of Health and Human Services "14th Report on Carcinogens".[14] If so, stakeholders need to be advised of this as both the Consultations and the stakeholder replies to the respective Consultations will need to be coordinated.

III. BACKGROUND TO CONSULTATION:

In the current Consultation, the WCB states:

> "The Policy, Regulation and Research Division is requesting feedback on proposed amendments to Part 6, Substance Specific Requirements - Cytotoxic Drugs, of the Occupational Health and Safety Regulation. The consultation phase provides stakeholders an opportunity to provide feedback prior to the proposed amendments being taken to public hearing.
>
> All stakeholder feedback is carefully considered and analyzed, and provided to the Board of Directors of WorkSafeBC as part of their decision-making process.
>
> The proposed regulatory amendment package under review:
>
> Part 6, Substance Specific Requirements – sections 6.43 to 6.58.01, Cytotoxic Drugs
>
> To access the information please click on each regulatory package above. Proposed deletions are identified with a ~~strikethrough~~ and additions are highlighted in yellow." (See Appendix A)

And, under 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." (See Appendix A)

[13] WorkSafeBC. Consultations. See https://www.worksafebc.com/en/law-policy/public-hearings-consultations/current-public-hearings-and-consultations/consultation-proposed-oel-based-new-revised-2016-2017-2018-acgih-tlvs

[14] National Toxicology Program. See https://ntp.niehs.nih.gov/pubhealth/roc/index-1.html

IV. ORGANIZATION POSITION:

CUPE does not agree to the proposed changes as per the following and Section II above.

V. REASONS FOR ORGANIZATION POSITION:

Every issue and concern are not identified because CUPE disagrees with the proposed changes overall. CUPE will provide a comprehensive Table of Concordance and list of issues and concerns upon request.

V.I. Terminology and Definitions:

The terms "cytotoxic" and "antineoplastic" are both used in this submission. The primary difference between cytotoxic and antineoplastic drugs are that a cytotoxic drug is a cytotoxin while an antineoplastic drug is used for inhibiting the development of tumours. The term "cytotoxic" refers to being toxic to living cells. Cytotoxic drugs would include antineoplastic drugs. Therefore, the WCB should use the term that is the most expansive and includes all sub-categories. CUPE objects to the narrowing of the definition in the proposed changes.

As per the above, CUPE also questions why were the definitions changed to exclude, for example, the term "cytotoxic drugs"? While the term used is now "antineoplastic agents" e.g. by CAREX, the definition could have been amended to refer to both for transition and clarification purposes e.g.:

> "'antineoplastic', previously referred to as 'cytotoxic drugs / agents' and including cytotoxic drugs, in relation to a drug, means a drug that
>
> (a) interferes with the deoxyribonucleic acid of tumour cells, and
>
> (b) meets the American Hospital Formulary Service drug classification 10.00, and
>
> (c) is cross referenced, for example, with the CAREX Canada Substance Profile;"[15] (Emphasis added) (See Appendix B)

As per proposed OHS Regulation 6.52, how is "effectively supervised" defined? What are the criteria? How is it measured?

[15] CAREX Canada. See https://www.carexcanada.ca/profile/antineoplastic_agents/

As per proposed OHS Regulation 6.58.01, how is "consult" defined? Both the Risk Assessment and Hazard Assessment should be included.

V.II. Outdated Source Documents:

The source document relied upon by the WCB is from 2015. Page 4 (of 84) of "Best Practices for the Safe Handling of Hazardous Drugs" refers to the following contributing organizations:

> "WorkSafeBC thanks the many organizations who generously donated their time and knowledge to reviewing this edition of Best Practices for the Safe Handling of Hazardous Drugs, including:
>
> • BC Provincial Hazardous Drugs Working Group
> • BC Provincial Hazardous Drug List Working Group
> • College of Pharmacists of BC
> • University of British Columbia
> • BC Nurses' Union
> • College of Veterinarians of BC
> • Health Sciences Association of BC"[16]

What is the status of the BC Provincial Hazardous Drugs Working Group and the BC Provincial Hazardous Drug List Working Group? Have the other organizations been contacted to update the current Best Practices Guide? Is CAREX Canada going to be included?

CUPE also refers to the most recent definition of a hazardous drug from NIOSH / CDC:[17]

> "NIOSH Definition of a Hazardous Drug
>
> 1. Carcinogenicity
> 2. Teratogenicity or other developmental toxicity††
> 3. Reproductive toxicity††
> 4. Organ toxicity at low doses††
> 5. Genotoxicity‡‡
> 6. Structure and toxicity profiles of new drugs that mimic existing drugs determined"[18]

[16] WorkSafeBC. Best Practices for the Safe Handling of Hazardous Drugs. See https://www.worksafebc.com/en/resources/health-safety/books-guides/best-practices-safe-handling-hazardous-drugs?lang=en

[17] Recognizing that there are differences between risk, hazard, risk assessment and hazard assessment. Any OHS Regulations must include definitions of all of these.

[18] NIOSH. Healthcare settings only. See https://www.cdc.gov/niosh/review/peer/isi/hazdrug2018-pr.html

This includes screened and evaluated drugs into one of five categories:[19]

- Category 1—Special handling information
- Category 2—Insufficient toxicity information available to meet the NIOSH definition of a hazardous drug
- Category 3—Available information shows no toxic effect or shows a toxic effect that does not meet the NIOSH definition of a hazardous drug
- Category 4—Available toxicity information demonstrates or supports a determination that the drug does not meet the NIOSH definition of a hazardous drug
- Category 5—Available toxicity information demonstrates or supports a determination that the drug meets the NIOSH definition of a hazardous drug[20]

V.III. Other Sources of Scientific Data Need to be Considered:

The WCB does not appear to have considered the following sources of information and data:

- Cancer Care Ontario – Safe Handling of Cytotoxics - updated June 22, 2018[21]
- NIOSH and CDC – updated 2019[22]
- Registry of Toxic Effects of Chemical Substances ("RTECS")[23]
- CHEMINFO
- Hazardous Substances Data Bank ("HSDB")[24]
- International Agency for Research on Cancer ("IARC")

[19] Healthcare settings only. This list illustrates the need for further non-healthcare setting studies and resultant Regulations.
[20] Federal Register. NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings: Proposed Additions to the NIOSH Hazardous Drug List 2018. See https://www.federalregister.gov/documents/2018/02/14/2018-02957/niosh-list-of-antineoplastic-and-other-hazardous-drugs-in-healthcare-settings-proposed-additions-to
[21] Cancer Care Ontario. See file:///C:/Users/tmckenna/Downloads/pebc16-3s.pdf
[22] NIOSH. See https://www.cdc.gov/niosh/review/peer/isi/hazdrug2018-pr.html
[23] CDC. See https://www.cdc.gov/niosh/docs/97-119/default.html
[24] U.S. National Library of Medicine. TOXNET. See https://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB

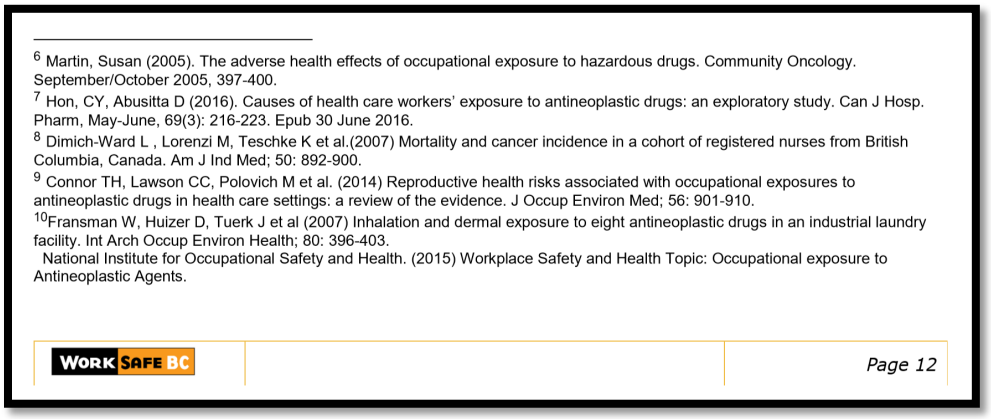
- The United States Pharmacopeia ("USP") – updated May 31, 2019[25]

- United States Department of Labor has the "Controlling Occupational Exposure to Hazardous Drugs" Guidelines.[26]

V.IV. Rationale for Specific Changes to OHS Regulations Not Clear:

CUPE questions the rationale for the changes. As per page 12 of the Consultation, Figure 5 shows that the source documents relied upon are outdated e.g. 2005, 2007, etc:

Figure 5 – References – Explanatory Notes (see next page):



[6] Martin, Susan (2005). The adverse health effects of occupational exposure to hazardous drugs. Community Oncology. September/October 2005, 397-400.
[7] Hon, CY, Abusitta D (2016). Causes of health care workers' exposure to antineoplastic drugs: an exploratory study. Can J Hosp. Pharm, May-June, 69(3): 216-223. Epub 30 June 2016.
[8] 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.
[9] 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.
[10]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.

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Upon review of several of these e.g. via the National Institutes of Health ("NIH"),[27] there are much more current studies and information. For example, reference 10 refers to "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." However, there are a number of studies on the same overall subject (but not limited to laundry facilities). For example:

- Dubray, Q., Diallo, T., Loeuillet, R., Andre, E., Fauquer, A.S., Poil, S., Thromas, N., Secretan, P.H., Cisternin, S. and Schlatter, J. (2019). Occupational risks evaluation in a centralized antineoplastic agent preparation unit.

- Boiano, J.M., Steege, A.L., Sweeney and M.H. (2016). Adherence to Safe Handling Guidelines by Health Care Workers Who Administer Antineoplastic Drugs.

[25] USP. Assessment of Risk. See https://www.usp.org/frequently-asked-questions/hazardous-drugs-handling-healthcare-settings
[26] United States Department of Labor. See https://www.osha.gov/SLTC/hazardousdrugs/controlling_occex_hazardousdrugs.html
[27] NIH. See https://www.nih.gov/

- Connor, T.H., Lawson, C.C., Polovich, M. and McDiarmid, M.A. (2014). Reproductive Health Risks Associated with Occupational Exposures to Antineoplastic Drugs in Health Care Settings: A Review of the Evidence. J Occup Environ Med.

- Hon, C.Y. and Abusitta, D. (2016). Causes of Health Care Workers' Exposure to Antineoplastic Drugs: An Exploratory Study. Can J Hosp Pharm.

- U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings. 2016.

- Occupational Safety and Health Administration. United States Department of Labor. OSHA Technical Manual. Hazardous Drug Safety and Health Topics. Controlling Occupational Exposure to Hazardous Drugs. 2016.

With respect to proposed OHS Regulation 6.45 Risk Assessment, the WCB states in the "Explanatory Notes" section that:

> "An employer must also ensure the risk assessment is reviewed and updated by a qualified person when:
>
> > (a) a new 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) exposure monitoring or health monitoring of a worker indicates that a review of the risk assessment is necessary.
>
> WorkSafeBC does not recognize any exposure monitoring or occupational exposure limit standard for hazardous drugs[13]. However, exposure monitoring or health monitoring could occur after the fact. For example, if there is an accidental spill, the cleanup may require exposure or surface sampling to measure or monitor the potential for worker exposure. Similarly, in the event of a spill or accidental exposure, workers may be sent for biomonitoring, or seek this for themselves. These are likely to generate a review or update of the risk assessment." (Emphasis added)

CUPE disagrees with the proposed wording on Risk Assessments. The WCB has proposed OHS Regulation 6.45, which states, in part, that:

> "Risk assessment

6.45 (1) If a worker is or may be exposed to a hazardous drug, an employer must ensure that a qualified person prepares a written risk assessment of the worker's work activities in accordance with subsection (2).

(2) The written risk assessment must include consideration of all of the following:

(a) information respecting the hazardous properties of both brand and generic versions of the hazardous drug, as provided by manufacturers, suppliers or pharmacists or in scientific publications, with respect to

(i) the active ingredients in the hazardous drug and the concentration of those ingredients,

(ii) any special precautions a worker is advised to take, and

(iii) the health risks of exposure to the hazardous drug, including both acute and chronic effects and potential reproductive hazards, if any;

(b) the scope, circumstances and nature of the worker's work activities, including

(i) the quantity and concentration of the hazardous drug to which the worker may be exposed,

(ii) the frequency and duration of exposure,

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

(iv) any known drug interactions, and

(v) whether another worker in the same work area may be at risk of exposure;

(c) the effectiveness of existing and planned control measures to prevent or minimize the worker's exposure to the hazardous drug;

(d) any additional information needed to complete the risk assessment.

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

(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 to a hazardous drug, are changed;

(c) exposure monitoring or health monitoring of a worker indicates that a review of the risk assessment is necessary."

There should be both risk assessments and hazard assessments.[28] CUPE has argued this issue in the past as per the following Figure 6 which is supported by the Canadian Standards Association ("CSA"):[29]

Figure 6 – Hazard versus Risk (see next page):

[28] CUPE National Health and Safety Committee Resource Kit. See https://cupe.ca/health-and-safety-committee-resource-kit

[29] CUPE National Health and Safety Committee Resource Kit. See https://cupe.ca/health-and-safety-committee-resource-kit

Hazard vs Risk

The terms 'hazard' and 'risk' mean very different things. However, due to many people not fully understanding this difference, the two terms are often used interchangeably.

It is important to note how we use these terms can affect the way health and safety practices are implemented for the jobs CUPE members perform.

In short, CUPE advocates that the question that needs to be asked is not "What is the chance someone will get hurt?" but "Have all hazards been removed or controlled so that no one will get hurt?"

> The Canadian Standards Association defines hazard and risk as follows:
> **Hazard** – a potential source of harm to a worker.
> **Risk** – the combination of the likelihood of the occurrence of a harm and the severity of that harm.

Hazard Analysis

Work related hazards can come from a wide range of sources. A hazard analysis is the process of determining and describing in detail the hazards in a workplace, job or task, then defining how each could cause harm so that the hazard(s) can be removed or adequate controls can be put in place.

It is best to perform a hazard analysis in a systematic manner. One way is to examine one task at a time, so as not to be overwhelmed by everything that a person does as part of their job. After each task in a job has been examined, the entirety of all the tasks in a job can be examined to determine if the hazards within each task could be contributory to other hazards in the cause of injury.

To do this, a detailed analysis of the materials, tools and equipment in relationship to their intended use or application must be performed. In this process, historical hazard and incident data can be useful at identifying hazards. It is important to also consider hazards that could occur over the system life cycle.

After each hazard has been identified, each should be considered in light of the hierarchy of controls;

Elimination: Can the hazard be removed, or substituted with a less hazardous product?

Engineering Controls: Can a barrier be installed that prevents the worker from coming into contact with the hazard?

Administrative Controls: Are there rules or procedures that people can be trained to follow to prevent their exposure?

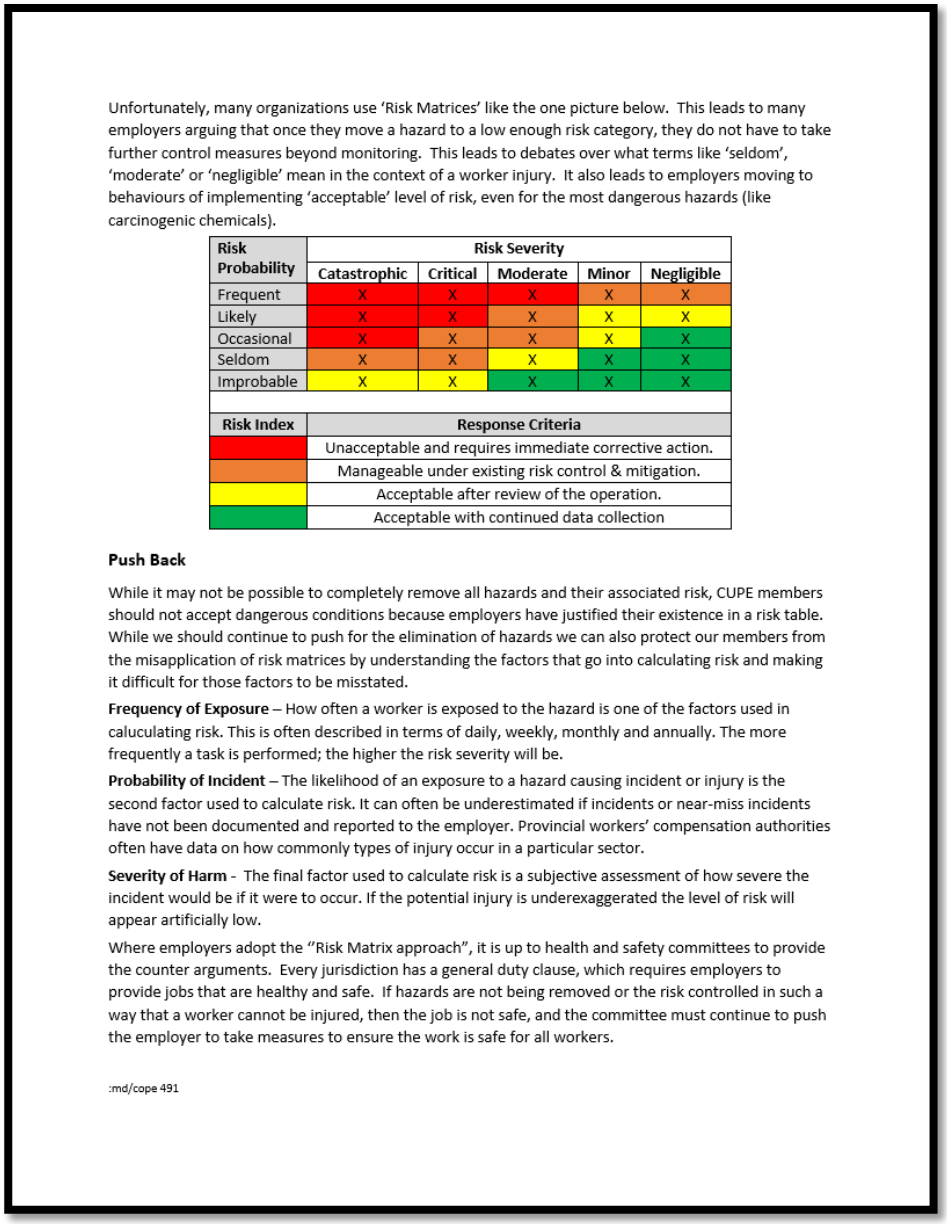
Personal Protective Equipment. As a last resort, is there protective equipment that can keep the worker from being exposed?

The hierarchy should be applied with elimination first, and other options down the hierarchy should not be considered until the higher level, more protective control has been eliminated as an option.

Risk Assessment

Risk assessment is a term used to describe the overall process or method where hazards are identified and each is examined to determine the likelihood of exposure and the level of harm that is expected if exposure takes place.

Risk assessments should form a portion of the hazard assessment. Knowing the likelihood and severity of exposure is important, as it helps to drive decisions around what should be corrected first. But it should never be used to deter a committee from seeking improvements for all hazards that are related to the jobs that CUPE members perform.



Unfortunately, many organizations use 'Risk Matrices' like the one picture below. This leads to many employers arguing that once they move a hazard to a low enough risk category, they do not have to take further control measures beyond monitoring. This leads to debates over what terms like 'seldom', 'moderate' or 'negligible' mean in the context of a worker injury. It also leads to employers moving to behaviours of implementing 'acceptable' level of risk, even for the most dangerous hazards (like carcinogenic chemicals).

Risk Probability	Risk Severity				
	Catastrophic	Critical	Moderate	Minor	Negligible
Frequent	X	X	X	X	X
Likely	X	X	X	X	X
Occasional	X	X	X	X	X
Seldom	X	X	X	X	X
Improbable	X	X	X	X	X

Risk Index	Response Criteria
	Unacceptable and requires immediate corrective action.
	Manageable under existing risk control & mitigation.
	Acceptable after review of the operation.
	Acceptable with continued data collection

Push Back

While it may not be possible to completely remove all hazards and their associated risk, CUPE members should not accept dangerous conditions because employers have justified their existence in a risk table. While we should continue to push for the elimination of hazards we can also protect our members from the misapplication of risk matrices by understanding the factors that go into calculating risk and making it difficult for those factors to be misstated.

Frequency of Exposure – How often a worker is exposed to the hazard is one of the factors used in caluculating risk. This is often described in terms of daily, weekly, monthly and annually. The more frequently a task is performed; the higher the risk severity will be.

Probability of Incident – The likelihood of an exposure to a hazard causing incident or injury is the second factor used to calculate risk. It can often be underestimated if incidents or near-miss incidents have not been documented and reported to the employer. Provincial workers' compensation authorities often have data on how commonly types of injury occur in a particular sector.

Severity of Harm - The final factor used to calculate risk is a subjective assessment of how severe the incident would be if it were to occur. If the potential injury is underexaggerated the level of risk will appear artificially low.

Where employers adopt the "Risk Matrix approach", it is up to health and safety committees to provide the counter arguments. Every jurisdiction has a general duty clause, which requires employers to provide jobs that are healthy and safe. If hazards are not being removed or the risk controlled in such a way that a worker cannot be injured, then the job is not safe, and the committee must continue to push the employer to take measures to ensure the work is safe for all workers.

:md/cope 491

Also see the CSA Standard CAN/CSA-Z1002-12 (R17) "Occupational health and safety – Hazard identification and elimination and risk assessment and control."[30] This is one example. The CSA has multiple applicable Standards e.g. Z31710-15. As stated previously, Hazard Assessments identify a particular hazard(s). Hazard Assessments are part of a plan to address the hazard(s). Risk Identification identifies the chance of a hazard(s) occurring. Risk Assessments are part of a plan to address the risk(s). All four should be part of any workplace plan.

[30] CSA. CSA-Z1002-12. See https://store.csagroup.org/ccrz__ProductDetails?sku=2703276

The current system does not adequately address all the parameters of risk as supported by Bernabeu-Martinez et al. (2018).[31] They state, in part, that:

> "Based on the above findings, we can conclude that no standardized informatics system was found to ensure quality management, traceability of processes and minimization of risks associated with these drugs. In the considered guidelines, no mention of computerized systems that guarantee the correct management of the HD process was identified.
>
> From the authors' point of view, it would be convenient to be at the disposal of ICT-based tools that allow a simple and complete configuration of management systems to tackle the prevention of risks associated with HDs. Moreover, further works and specific developments regarding the management and traceability of HDs that allow for their monitoring and evaluation must be generated." (Emphasis added)

The same applies to Exposure Control Plans and proposed OHS Regulation 6.46, where the "Explanatory Notes" section states that:

> "If the risk assessment indicates a worker is or may be exposed to a hazardous drug, subsection (1) requires employers to ensure a qualified person develops an exposure control plan meeting the requirements of sections 5.54, 5.57 and subsection (3) of this section.
>
> 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) addresses written work procedures relating to all the items listed in subsections (a) through (f).
>
> Subsection (4) requires the work procedures to be readily available for reference by workers, and where practicable, summaries are posted in the appropriate areas."

The proposed OHS Regulation 6.46 language is:

> "Exposure control plan
>
> 6.46 (1) If a risk assessment indicates that a worker is or may be exposed to a hazardous drug, an employer must

[31] Bernabeau-Martinez, M.A., Merino, M.R., Gago, J.M.S., Sabucedo, L.M.A., Wanden-Berghe, C. and Sanz-Valero, J. (2018). Guidelines for safe handling of hazardous drugs: A systemic review. *PLOS One. 2018; 13(5)*/ Retrieved August 26, 2019 from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5947890/

(a) ensure that a qualified person develops an exposure control plan that meets the requirements of sections 5.54 and 5.57 and subsection (3) of this section, and

(b) implement the exposure control plan.

(2) If a risk assessment is updated under section 6.45(3), an employer must ensure that

(a) the exposure control plan addresses any changes to the risk assessment, and

(b) the updated exposure control plan is implemented.

(3) For the purposes of section 5.54(2)(d), a qualified person must ensure that the written work procedures in an exposure control plan address at least the following:

(a) work procedures relating to:

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

(ii) housekeeping, including the frequency of housekeeping,

(iii) routine decontamination and emergency decontamination, and

(iv) any other work activity in which a worker is or may be at risk of exposure to a hazardous drug;

(b) the containment or enclosure of work activities or work processes related to reducing or minimizing worker exposure to hazardous drugs, if containment or enclosure is used as a control measure;

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

(d) personal hygiene, including

(i) the prohibition of eating, drinking, storing food and applying personal care products in areas where hazardous drugs are present, and

(ii) handwashing and related protocols;

(e) reporting procedures for incidents that involve

(i) accidental exposure to a hazardous drug, or

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

(f) the identification, removal, cleanup and disposal of a hazardous drug waste, including

(i) any material that comes into contact with a hazardous drug, and

(ii) anything contaminated by excreta, vomit or bodily fluids from a patient treated with a hazardous drug.

(4) The work procedures required under subsection (3) must be readily available for reference by workers and, where practicable, summaries must be posted in the appropriate work areas."

The proposed language is incomplete and needs significant revisions. For example:

- All aspects of both Hazard Identification, Hazard Assessments, Risk Identification and Risk Assessments should be referred to.

- CUPE disagrees with Risk Assessments, Hazard Assessments and Exposure Control Plans being done for only antineoplastic drugs. All drugs should be included e.g. cytotoxic drugs, not just a sub-set or category of cytotoxic drugs.

- Health surveillance programs and feedback loop mechanisms should be included. Section (c) of the proposed OHS Regulation 6.45 states "exposure monitoring or health monitoring of a worker indicates that a review of the risk assessment is necessary". The two OHS Regulations should overlap with specific references to key areas. For example, see United States Department of Labor has the "Controlling Occupational Exposure to Hazardous Drugs" Guidelines, Section VI. MEDICAL SCREENING AND SURVEILLANCE.[32] See Appendix C.

- There should be a standardized informatics system to ensure quality management, traceability of processes and minimization of risks and hazards.

[32] United States Department of Labor. See https://www.osha.gov/SLTC/hazardousdrugs/controlling_occex_hazardousdrugs.html

- There should be a more robust mechanism for addressing new drugs or changes in mechanisms for administration of drugs e.g. nanotechnology.

The University of British Columbia ("UBC") has a very comprehensive Exposure Control Plan for cytotoxic drugs.[33] This 2017 Plan[34] refers to antineoplastic drugs, as part of cytotoxic drugs. The Plan also refers to Risk Assessments (page 9 and 11) but does not refer to Hazard Assessments. The HSE Health and Safety Executive document "Safe handling of cytotoxic drugs in the workplace"[35] refers to health surveillance programs and feedback loop mechanisms.[36] The United States Department of Labor has the "Controlling Occupational Exposure to Hazardous Drugs" Guidelines.[37] Cancer Care Ontario – Safe Handling of Cytotoxics [38] has specific recommendations on the use of cytotoxics. In BC the BCCA has the "Summary of BCCA Pharmacy Practice Standards for Hazardous Drugs".[39]

V.V. Related Consultations, Policies, Regulations and Guidelines:

As stated previously, CUPE also questions if the current Consultation is related to or overlaps with the Consultation on TLVs (Consultation on Proposed Occupational Exposure Limits based on the New or Revised 2016, 2017, and 2018 ACGIH TLVs for Selected Chemical Substances)[40] and if any of the substances therein overlap with the current Consultation. This would include cross referencing these with the U.S. Department of Health and Human Services "14th Report on Carcinogens".[41] If so, stakeholders need to be advised of this as both the Consultations and the stakeholder replies to the respective Consultations will need to be coordinated.

[33] Reference to the UBC Plan is not an endorsement or acceptance of the Plan. CUPE disagrees with any references to the OHS Regulations that do not meet the requirements CUPE has set out in this submission, nor the mot up to date list (as per Appendix B and C etc of the UBC Plan).
[34] UBC. Exposure Control Plan. See http://riskmanagement.sites.olt.ubc.ca/files/2017/12/ECP_Cytotoxics.pdf
[35] Government of the UK. HSE. See http://www.hse.gov.uk/healthservices/safe-use-cytotoxic-drugs.htm
[36] CUPE does not endorse nor agree to the HSE Plan.
[37] United States Department of Labor. See https://www.osha.gov/SLTC/hazardousdrugs/controlling_occex_hazardousdrugs.html
[38] Cancer Care Ontario. See file:///C:/Users/tmckenna/Downloads/pebc16-3s.pdf
[39] BCCA. Summary of BCCA Pharmacy Practice Standards for Hazardous Drugs. See http://www.bccancer.bc.ca/pharmacy-site/Documents/Safe%20Handling/8%20Safe%20Handling%20Standards%20Summary_September%202016.pdf
[40] WorkSafeBC. Consultations. See https://www.worksafebc.com/en/law-policy/public-hearings-consultations/current-public-hearings-and-consultations/consultation-proposed-oel-based-new-revised-2016-2017-2018-acgih-tlvs
[41] National Toxicology Program. See https://ntp.niehs.nih.gov/pubhealth/roc/index-1.html

VI. CONCLUSION:

The proposed changes do not address the systemic and specific issues noted in this submission. CUPE reserves the right to comment on how these changes apply to the OHS Regulations, related Policies, the *Act*, Policy (RSCM), Guidelines and the Practice Directives.

Respectfully submitted,

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Appendix A – Consultation on Proposed Amendments to the Occupational Health and Safety Regulation:

PROPOSED AMENDMENTS TO PART 6: SUBSTANCE SPECIFIC REQUIREMENTS
IN THE OCCUPATIONAL HEALTH AND SAFETY REGULATION

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.

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 6.58.01:

"antineoplastic" in relation to a drug, means a drug that

(a) interferes with the deoxyribonucleic acid of tumour cells, and

(b) meets the American Hospital Formulary Service drug classification 10.00;

"decontamination" means inactivation, destruction or removal of a hazardous drug that is a contaminant;

"emergency decontamination" means cleaning and decontamination of a surface or object after a spill or an emergency involving, or that may have involved, hazardous drugs, outside of tasks performed as part of routine housekeeping;

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

"housekeeping" includes the following:

(a) routine cleaning for hygiene;

(b) changing, handling and laundering linens, and cleaning and disposing of things, contaminated with the excreta, vomit or bodily fluids of patients treated with hazardous drugs;

"routine decontamination" means decontamination carried out other than in the context of spills or emergencies.

Application 6.43 Sections 6.44 to 6.58.01 apply to a workplace where a worker is or may be exposed to a hazardous drug.

Identifying hazardous drugs 6.44 If a worker is or may be exposed to a hazardous drug, an employer must do all of the following:

(a) develop and maintain a written list of all hazardous drugs that workers may be exposed to;

(b) review and, if necessary, update the list referred to in paragraph (a) at least annually;

(c) make the list referred to in paragraph (a) readily available for reference by workers.

Risk assessment 6.45 (1) If a worker is or may be exposed to a hazardous drug, an employer must ensure that a qualified person prepares a written risk assessment of the worker's work activities in accordance with subsection (2).

(2) The written risk assessment must include consideration of all of the following:

(a) information respecting the hazardous properties of both brand and generic versions of the hazardous drug, as provided by manufacturers, suppliers or pharmacists or in scientific publications, with respect to

(i) the active ingredients in the hazardous drug and the concentration of those ingredients,

(ii) any special precautions a worker is advised to take, and

(iii) the health risks of exposure to the hazardous drug, including both acute and chronic effects and potential reproductive hazards, if any;

(b) the scope, circumstances and nature of the worker's work activities, including

(i) the quantity and concentration of the hazardous drug to which the worker may be exposed,

(ii) the frequency and duration of exposure,

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

(iv) any known drug interactions, and

(v) whether another worker in the same work area may be at risk of exposure;

(c) the effectiveness of existing and planned control measures to prevent or minimize the worker's exposure to the hazardous drug;

(d) any additional information needed to complete the risk assessment.

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

(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 to a hazardous drug, are changed;

(c) exposure monitoring or health monitoring of a worker indicates that a review of the risk assessment is necessary.

Exposure control plan **6.46** (1) If a risk assessment indicates that a worker is or may be exposed to a hazardous drug, an employer must

(a) ensure that a qualified person develops an exposure control plan that meets the requirements of sections 5.54 and 5.57 and subsection (3) of this section, and

(b) implement the exposure control plan.

(2) If a risk assessment is updated under section 6.45(3), an employer must ensure that

(a) the exposure control plan addresses any changes to the risk assessment, and

(b) the updated exposure control plan is implemented.

(3) For the purposes of section 5.54(2)(d), a qualified person must ensure that the written work procedures in an exposure control plan address at least the following:

(a) work procedures relating to:

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

(ii) housekeeping, including the frequency of housekeeping,

(iii) routine decontamination and emergency decontamination, and

(iv) any other work activity in which a worker is or may be at risk of exposure to a hazardous drug;

(b) the containment or enclosure of work activities or work processes related to reducing or minimizing worker exposure to hazardous drugs, if containment or enclosure is used as a control measure;

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

(d) personal hygiene, including

(i) the prohibition of eating, drinking, storing food and applying personal care products in areas where hazardous drugs are present, and

(ii) handwashing and related protocols;

(e) reporting procedures for incidents that involve

(i) accidental exposure to a hazardous drug, or

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

(f) the identification, removal, cleanup and disposal of a hazardous drug waste, including

(i) any material that comes into contact with a hazardous drug, and

(ii) anything contaminated by excreta, vomit or bodily fluids from a patient treated with a hazardous drug.

(4) The work procedures required under subsection (3) must be readily available for reference by workers and, where practicable, summaries must be posted in the appropriate work areas.

Reproductive toxins **6.47** If a worker is or may be exposed to a hazardous drug that is a reproductive toxin or has adverse reproductive health effects, an employer must ensure that the written work procedures referred to in section 6.46(3) include both of the following:

(a) information respecting adverse reproductive health effects;

(b) a process to determine if protective reassignment is appropriate for workers who advise the employer of a pregnancy or an intention to conceive a child.

Elimination or control of exposure **6.48** (1) An employer must, to the extent it is practicable, eliminate the risk of worker exposure to a hazardous drug by using a less hazardous form of the same drug or a process that, under normal conditions, would eliminate that risk.

(2) If it is not practicable to eliminate the risk of worker exposure to a hazardous drug, an employer must control or minimize the risk, keeping it as low as reasonably achievable by doing both of the following:

(a) applying engineering and administrative control measures that

(i) are appropriate to the work activity, and

(ii) are consistent with the risk assessment under section 6.45 and with sections 5.55 and 5.57;

(b) ensuring that a worker who is or may be exposed to a hazardous drug

(i) is provided with personal protective equipment identified in the written work procedures referred to in section 6.46 (3), and

(ii) uses the personal protective equipment in accordance with the information, instruction and training provided under section 6.51.

Decontamination of 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 of areas where hazardous drugs are manufactured, stored, prepared or administered.

(2) An employer must ensure that non-disposable personal protective equipment is cleaned and decontaminated after use in accordance with the written work procedures referred to in section 6.46 (3).

Preparation and administration of antineoplastic drugs **6.50** (1) An employer must ensure that the following work activities are performed in a designated biological safety cabinet that meets the requirements of subsection (2):

(a) mixing and preparing a hazardous drug classified as antineoplastic;

(b) priming intravenous administrative sets using antineoplastic drugs.

(2) The biological safety cabinet must

(a) be at least Class II Type B2, conforming to NSF/ANSI 49-2018 *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 recirculation into the workplace, and

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

(3) An employer must ensure that antineoplastic drugs are administered in accordance with the written work procedures referred to in section 6.46(3).

Instruction and training **6.51** (1) An employer must ensure that a worker who is or may be exposed to a hazardous drug receives pre-job and on-the-job information, instruction and training on the safe handling of the hazardous drug.

(2) The information, instruction and training provided under subsection (1) must include all of the following:

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

(b) the written work procedures referred to in section 6.46 (3);

(c) the selection, correct use and maintenance of personal protective equipment and clothing;

(d) the procedures to be followed in the event of a spill or unintended exposure to the hazardous drug.

(3) An employer must

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

(i) the hazardous drug or the information available respecting the hazardous drug, or

(ii) work procedures, and

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

Supervision and personal hygiene **6.52** An employer must ensure that a worker who is or may be exposed to a hazardous drug

(a) is effectively supervised, and

(b) follows all applicable written work procedures referred to in section 6.46(3).

Spill kits **6.53** An employer must ensure that

(a) clearly labelled spill kits are kept in or near any area in which hazardous drugs are manufactured, transported, received, stored, prepared or administered, and

(b) the kits and spill procedures are readily available to workers.

Storage of hazardous drugs **6.54** (1) An employer must ensure that a hazardous drug is stored

(a) in a designated area for the hazardous drug, unless it is not practicable to do so, and

(b) in accordance with the exposure control plan under section 6.46 and the manufacturer's instructions, if any.

(2) An employer must ensure that the area referred to in subsection (1)(a) meets all of the following criteria:

(a) the area is 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 is not located in any space designated or regularly used for eating or for changing or storing clothes;

(d) access to the area is restricted to authorized personnel.

(3) An employer must ensure that a container holding a hazardous drug, and a bin or shelf used to store a hazardous drug, is correctly and prominently labelled.

Transport of hazardous drugs **6.55** (1) 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 drug from other drugs, and

(b) packaged in a manner that minimizes environmental contamination if the hazardous drug is dropped or if there is spillage or leakage.

(2) An employer must ensure that a worker who transports a hazardous drug is trained in spill control and has a spill kit readily available.

Waste handling and disposal **6.56** (1) An employer must ensure that

(a) every area in which a hazardous drug is manufactured, stored, prepared or administered is supplied with

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

(ii) distinctive sealable plastic waste bags, and

(b) all waste related to a hazardous drug, except urine or feces, is placed in a container or bag referred to in paragraph (a).

(2) An employer must ensure that excreta are treated as hazardous drug-related waste if the excreta

(a) are from a patient treated with a hazardous drug, and

(b) are handled by a worker.

Storage and use of cleaning equipment **6.57** An employer must ensure that equipment and products used for housekeeping, routine decontamination and emergency decontamination are

(a) stored and used in accordance with the exposure control plan under section 6.46,

(b) designated for use only in the area in which the equipment and products are to be used, and

(c) stored within or in close proximity to, and used only in, the areas in which the equipment and products are to be used.

Records **6.58** (1) An employer must 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 was given or the training was provided.

(2) An employer must maintain, for the duration of a worker's employment plus 10 years, a record for each worker who prepares or administers a hazardous drug, that includes

(a) the names of the hazardous drugs prepared or administered, and

(b) if practicable, the number of preparations or administrations per week.

Consultations 6.58.01 An employer must consult with the joint committee or the worker health and safety representative, as applicable, with respect to each of the following:

(a) the risk assessment completed under section 6.45;

(b) the exposure control plan and written work procedures developed under section 6.46;

(c) the instruction and training provided under section 6.51.

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 residential health care means that 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 that 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 (pharmacists, technicians, and assistants) are the largest occupational group exposed to antineoplastic agents with 42,900 workers exposed, and 30,200 of these 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 that 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 that 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 residential care settings[5].

[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.

[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.

The work activities posing the greatest risk of exposure are preparing and administering antineoplastic drugs, cleaning up chemotherapy spill, and handling patient excreta[6]. Many of the antineoplastic drugs and their metabolites are found in the excreta of patients treated with such drugs. Unprotected handling of these drugs was most associated with symptomatology[6,7]. Occupational exposure to antineoplastic drugs has been associated with increased cancer risks[8], adverse reproductive outcomes[9], dermal, allergic and other genotoxic effects[10].

Proposed section 6.42: Definition

The following new terms are added to the definition section:

"*antineoplastic*" refers to anti-cancer drugs meeting the American Hospital Formulary Service drug classification 10.00;

"decontamination" refers to the inactivation, destruction or removal of a hazardous drug that is a contaminant;

"emergency decontamination" refers to decontamination activities following a spill or an emergency relating to hazardous drugs;

"*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 listed characteristics,
(b) it is not 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 on the *NIOSH List of Hazardous Drugs,* as amended from time to time (NIOSH updates its list every two years based on Food and Drug Administration approvals, and newly published scientific data or other governmental agency evaluations);

"housekeeping" refers to routine cleaning for hygiene and laundering, cleaning and disposing of things contaminated with the excreta, vomit or bodily fluids of patients treated with hazardous drugs;

"routine decontamination" refers to decontamination activities carried out other than in the context of spills and emergencies.

Proposed section 6.43: Application

Sections 6.44 to 6.58.01 are affected by these proposed amendments.

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 readily available for reference by workers.

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

[7] Hon, CY, Abusitta D (2016). Causes of health care workers' exposure to antineoplastic drugs: an exploratory study. Can J Hosp. Pharm, May-June, 69(3): 216-223. Epub 30 June 2016.

[8] 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.

[9] 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.

[10] 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.

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[11].

This section requires employers to ensure a qualified person prepares a written risk assessment of the worker's work activities if a worker is or may be exposed to a hazardous drug. A list of factors that must be considered in the risk assessment is provided. These factors include: the toxicity of the hazardous drug[12], the scope, circumstances and nature of the worker's work activities, and the effectiveness of existing or planned control measures to prevent or minimize the worker's exposure to hazardous drugs.

An employer must also ensure the risk assessment is reviewed and updated by a qualified person when:

(a) a new 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) exposure monitoring or health monitoring of a worker indicates that a review of the risk assessment is necessary.

WorkSafeBC does not recognize any exposure monitoring or occupational exposure limit standard for hazardous drugs[13]. However, exposure monitoring or health monitoring could occur after the fact. For example, if there is an accidental spill, the cleanup may require exposure or surface sampling to measure or monitor the potential for worker exposure. Similarly, in the event of a spill or accidental exposure, workers may be sent for biomonitoring, or seek this for themselves. These are likely to generate a review or update of the risk assessment.

Proposed section 6.46: Exposure control plan

If the risk assessment indicates a worker is or may be exposed to a hazardous drug, subsection (1) requires employers to ensure a qualified person develops an exposure control plan meeting the requirements of sections 5.54, 5.57 and subsection (3) of this section.

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) addresses written work procedures relating to all the items listed in subsections (a) through (f).

Subsection (4) requires the work procedures to be readily available for reference by workers, and where practicable, summaries are posted in the appropriate areas.

Proposed section 6.47 Reproductive toxins

When a worker is or may be exposed to a hazardous drug that is a reproductive toxin or has adverse health effects, this section requires employers to include information about the adverse reproductive health effects of the drug, and a process to determine if protective re-assignment is appropriate for workers who inform the employer of a pregnancy or an intention to conceive a child.

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[11] 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

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

[13] 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.

Proposed section 6.48: Elimination or control of 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. An employer must, to the extent practicable, consider whether it is possible to eliminate the risk by using a less hazardous form of the drug (e.g. a pellet instead of a powder), or a different process that under normal conditions eliminates the risk of occupational exposure.

Subsection (2) establishes if it is not practicable to eliminate the risk of worker exposure to hazardous drugs, an employer must control or minimize the risk, keeping it as low as reasonably achievable by doing both of the following:

(a) applying engineering and administrative controls that are appropriate to the work activity and consistent with the risk assessment, and

(b) ensuring that a worker who is or may be exposed to a hazardous drug

  (i) is provided with personal protective equipment identified in the exposure control plan, and
  (ii) uses the personal protective equipment in accordance with instruction and training.

The intent of this provision is that workers must wear personal protective equipment even when engineering and administrative controls are put in place. The rationale is that 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. Employers must do all three if the risk of worker exposure cannot be eliminated and a worker is or may be exposed to a hazardous drug.

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.

Proposed section 6.50: Preparation and administration of antineoplastic drugs

This prescriptive section requires the mixing and preparation of antineoplastic drugs and the priming of intravenous administration sets using antineoplastic drugs to be performed in a designated biological safety cabinet conforming, at minimum, to Class II Type B2 of *NSF/ANSI 49-2018 Biosafety Cabinetry: Design, Construction, Performance, and Field Certification*.

The intent of this provision is to ensure that employers do not use the risk assessment to avoid requirements for these specific tasks involving antineoplastic drugs which represent high risks for workers.

Proposed section 6.51: Instruction and training

Subsection (1) requires employers to provide pre-job and on-the-job information, instruction, and training on the safe handling of the hazardous drugs.

Subsection (2) sets out what must be included in the information, instruction and training provided to a worker who is or may be exposed to a hazardous drug. These include

- known health effects, including any adverse reproductive health effects,
- the written work procedures for work activities from the exposure control plan,

- the provision, selection, correct use and maintenance of PPE, and
- emergency procedures.

Subsection (3) addresses when further training needs to be provided.

Proposed section 6.52: Supervision and personal hygiene

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

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

Proposed section 6.53: Spill kits

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

Proposed section 6.54: Storage of hazardous drugs

This section requires employers to ensure hazardous drugs are stored in a designated area unless this is not practicable. If this is not practicable, then storage must be in accordance with the exposure control plan, and any manufacturer's instructions.

These provisions are expected to cover all workplaces, from manufacturing, hospitals, residential and community-based care, retail pharmacy, veterinary clinics through to homes where home care takes place.

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

This section sets out the employer's responsibility for packaging hazardous drugs during transport, and ensuring a worker transporting a hazardous drug is trained in spill control and has a spill kit readily available.

Proposed section 6.56: Waste handling and disposal

This section requires every area where hazardous drugs are manufactured, stored, prepared or administered to be supplied with clearly labelled, leak-proof and sealable waste disposal containers, and distinctive sealable plastic waste bags.

All waste related to hazardous drugs, except for urine or feces, must be disposed using these containers.

An employer must also ensure excreta from a patient treated with a hazardous drug, and handled by a worker is treated as a hazardous drug waste.

Proposed section 6.57: Storage of cleaning equipment

The intent of this section is to ensure equipment and products used for housekeeping, routine decontamination, and emergency decontamination are designated, and stored within or in close proximity to those areas for which their use is designated.

Proposed section 6.58: Records

This is an existing provision. The original was struck out and revised to clarify the intent.

Employers are required to maintain records of:

(a) all instruction and training of workers who are or may be exposed to hazardous drugs, from the date the instruction and training was provided plus 3 years; and
(b) the names of the hazardous drugs prepared and administered by a worker and, if practicable, the number of preparations or administrations per week for the duration of a worker's employment plus 10 years.

Proposed section 6.58.01: Consultations

Employers are required to consult with the joint committee or the worker health and safety representative, as applicable, on each of the following:

(a) the risk assessment,
(b) the exposure control plan, and
(c) the information, instruction and training.

Appendix B – CAREX Canada – Antineoplastic Agents:

Antineoplastic Agents Profile

QUICK SUMMARY

- A group of drugs that are used to treat various cancers
- **Associated cancers:** Cancers of the breast, lung, ovary, liver, and bladder; cancers of the hematopoietic system
- **Most important routes of exposure:** Inhalation, skin contact, ingestion, needle stick injury
- **Uses:** Prevent the growth and spread of tumor cells
- **Occupational exposures:** Approx. 75,000 Canadians are exposed at work, primarily pharmacy staff (pharmacists, technicians, and assistants) and nurses
- **Environmental exposures:** Via drinking water, results are inconclusive; also, from cancer treatment for patients
- **Fast fact:** Antineoplastic agents are increasingly used as treatments for cancer and other conditions.

General Information

Antineoplastic agents, also referred to as chemotherapy drugs or cytotoxic drugs, are the most common type of systemic drug therapy to treat cancer.[1] These drugs interfere with cancer cells' ability to grow and spread in a variety of ways. They are administered to treat chemo-sensitive cancers (e.g. testicular cancer), as adjuvant therapy (i.e. in conjunction with surgery or radiation), as maintenance therapy (i.e. to prevent relapse and improve survival), or as palliative treatment (i.e. to reduce symptoms and improve quality of life).[1]

Different antineoplastic agents have been classified by the International Agency for Research on Cancer (IARC) as Group 1 (*carcinogenic to humans*), Group 2A (*probably carcinogenic to humans*), or Group 2B (*possibly carcinogenic to humans*) based on varying strengths of evidence of carcinogenicity in animal and human studies, as well as mechanistic considerations.[2,3,4,5,6,7]

A number of adverse health effects are associated with exposure to antineoplastic agents in humans and animals. These include gastrointestinal problems, kidney damage, neurotoxicity, bone marrow suppression, hair loss, and reproductive problems after long-term use.[8]
In addition, patients receiving antineoplastic agents as therapeutic treatments are at increased risk of cancer and other health outcomes. CAREX Canada does not review this exposure

circumstance because these treatments are often a necessary medical intervention with tangible benefits for patients. Conversely, workers handling antineoplastic agents are at risk of adverse health outcomes with no positive impact on their well-being.

IARC Classification of antineoplastic agents[9,10]

IARC Classification Group	Antineoplastic Agent
1 (Carcinogenic to humans)	Arsenic trioxide Melphalan Thiotepa Busulfan Chlorambucil Cyclophosphamide Etoposide Tamoxifen
2A (Probably carcinogenic to humans)	Azacitidine Cisplatin Procarbazine Teniposide Carmustine Adriamycin Lomustine
2B (Possibly carcinogenic to humans)	Amsacrine Streptozotocin Daunomycin Bleomycin Mitomycin Mitoxantrone

Regulations and Guidelines

Occupational Exposure Limits (OEL)

No occupational exposure limits for Canada or any other international bodies were located.

Classifications under the Canadian Environmental Protection Act (CEPA)

Agent	Designation	Date added
Adriamycin	DSL* – high priority substance with lowest potential for exposure	2006[11]
Chlorambucil	DSL* – high priority substance	2004[11]
Cisplatin	NDSL**	1998[11]
Cyclophosphamide	DSL* – high priority substance	2004[11]
Melphalan	DSL* – high priority substance	2004[11]

*The Domestic Substances List (DSL) is an inventory of approximately 23,000 substances manufactured in, imported into, or used in Canada on a commercial scale. The DSL is the sole standard against which a substance is judged to be "new" to Canada.[12,13]

**The Non-Domestic Substances List (NDSL) is an inventory of substances included in the EPA's Toxic Substances Control Act (TSCA), but not on Canada's DSL.[13]

Adriamycin, chlorambucil, cisplatin, cyclophosphamide, and melphalan were not included in other Canadian government chemical listings reviewed.[14]

Main Uses

Antineoplastic agents are drugs used to treat cancer and other conditions such as rheumatoid arthritis and psoriasis.[15]

Canadian Production and Trade

Several companies import antineoplastic agents, including: Janssen Pharmaceutical Inc., Hoffman-La Roche Ltd., and Sanofi-Aventis Canada Inc.[16] The total value of imports is approximately 1.2 billion Canadian dollars.[16]

Occupational Exposures Overview

Occupational exposure to antineoplastic agents may occur directly via dermal contact, inhalation, ingestion, accidental injection, or indirectly via contact with contaminated surfaces and objects.[17] This can occur in hospitals, where antineoplastic agents are handled in shipping and receiving areas, prepared in pharmacies, administered in wards, and contacted through sanitary services such as laundry, cleaning, and waste handling.[18] Exposure can also occur

outside of hospitals in workplaces such as community pharmacies, veterinary care facilities, and home care settings.[19]

CAREX Canada estimates that approximately 75,000 Canadians are exposed to antineoplastic agents at work; most exposures occur in the moderate category. In addition, over 75% of exposed workers are female.

Exposure to antineoplastic agents was not estimated by industry per se, but by setting. The largest number of workers exposed were in non-hospital settings, with a substantial proportion working in hospitals.

Occupations at risk of exposure to antineoplastic agents are community pharmacy workers (including pharmacists, technicians, and assistants), hospital nurses (including nurses and licensed nurse practitioners), and hospital pharmacy workers (including pharmacists, technicians, and assistants).

For more information, see the occupational exposure estimate for antineoplastic agents.

Appendix C – VI. Medical Screening and Surveillance:

VI. MEDICAL SCREENING AND SURVEILLANCE

Like workers who are potentially exposed to other chemical hazards in healthcare, such as ethylene oxide and formaldehyde, those exposed to HDs, which include agents known to be human carcinogens, as well as those which are reproductive and developmentally toxic, should be monitored in a medical surveillance program (ASHP, 1990; ASHP, 2006; OSHA, 1995; ISOPP, 2007; Polovich, 2011; NIOSH, 2013). Medical screening and surveillance are one part of a comprehensive approach for minimizing hazardous exposures, which also includes training, engineering and work practice controls, and use of PPE. The purpose of screening is to identify the earliest reversible biologic effects so that exposure can be reduced or eliminated before the employee sustains irreversible harm. The occurrence of exposure-related disease or other adverse health effects should prompt immediate reevaluation of primary preventive measures (e.g., engineering controls, work practices, and use of PPE). Separately, OSHA views surveillance as the formal evaluation of groups of workers; in this manner, medical surveillance acts as a check on the efficiency and appropriateness of controls already in use (OSHA, 2015).

For detection and control of work-related health effects, screening is typically performed at specific intervals:

- Before job placement;
- Periodically during employment;
- Following acute exposures; and
- At the time of job termination or transfer (exit examination).

In addition to review of individual worker results obtained during a screening, the data obtained should be analyzed in a systematic fashion to allow early detection of disease patterns in groups of workers. Such surveillance requires systematic collection of information and, usually, some form of electronic data management system, ideally with exposure tracking.

A. **Pre-Placement Medical Examinations**

1. As is the case for employees who work with other known carcinogens and highly toxic agents, those handling HDs in the workplace should have an initial evaluation consisting of a medical and work history, a baseline physical exam, and laboratory studies. To assist the healthcare provider in making their assessment, information provided by the employer to the examining physician should include:
    a. A description of the employee's duties as they relate to the employee's exposure.
    b. The employee's exposure levels or anticipated exposure levels, which may include estimates of frequency and/or duration of HD handling.
    c. A description of any personal protective equipment used or to be used.

d. Information from previous medical examinations of the employee.

2. The history details the individual's medical and reproductive experience with emphasis on potential risk factors, such as past hematopoietic, malignant, or hepatic disorders. It should focus on the known target organs of commonly used HDs (skin, kidney, bladder, hematopoetic) (Polovich, 2011). A complete occupational history, with information on the extent of past exposures (including environmental sampling data, if possible) and use of protective equipment, is also obtained. Estimates of worker exposure, in the absence of environmental sampling data, may include:
    a. Records of drugs and quantities handled;
    b. Hours spent handling these drugs per week;
    c. Number of preparations/administrations per week; and
    d. Over-exposure events.
3. An initial physical examination is performed, which focuses on the targeted organ systems of commonly used drugs: the skin, mucous membranes, and lymphatic systems. Other organ systems suggested from the medical history should also be assessed.
4. The most valuable test in a laboratory assessment is a complete blood count with differential. This allows for a determination of any pre-existing blood condition that may place the worker at increased risk when handling HDs. Other laboratory testing (liver function tests, blood urea nitrogen, creatinine, and a urine dipstick for blood) may sometimes be appropriate (Polovich, 2011). However, these tests should be conducted only at the discretion of the physician, as a function of the medical history obtained, or as part of a formal surveillance program with well-defined goals.
5. Due to poor reproducibility, inter-individual variability, and difficulty in interpreting individual results, measures of genetic effects (i.e., chromosomal aberrations, micronuclei, or other markers of genotoxic exposure) are not recommended in routine surveillance.
6. Biological monitoring, i.e., the measure of a specific agent or its metabolite in a body fluid (such as a urine 5-FU level), is also not recommended for a screening protocol on a routine basis due to the large number of agents an employee handles on a given work shift.
7. An evaluation for respirator use must be performed in accordance with the RPS [29 CFR 1910.134], if the employee will wear a respirator (for example, during cleaning of the BSC, or in a larger spill response) (OSHA, 2011b).

B. **Periodic Medical Examinations**

The medical, reproductive, and exposure history should be updated on a periodic basis, everyone to three years, although many employees are reluctant to divulge details of reproductive history. Another approach is to administer the history annually but use

the health and exposure history responses to guide the interval for physical exam and laboratory studies. A primary purpose of the examinations is to explore adherence and identify obstacles to good work practices.

The interval between exams of individual workers depends on the opportunity for exposure, the duration and intensity of exposure, and (possibly) the age of the worker. The worker's health and exposure history may also influence the decision of the occupational medicine physician. Careful updating of an individual's routine drug handling history and any acute accidental exposures are made. The physical examination and laboratory studies follow the format outlined in the pre-placement examination (McDiarmid, 1990). The periodic examination may also be incorporated into an existing, broader, periodic health assessment for an organization's healthcare workers rather than function as a "stand-alone" program.

C. **Post-exposure Examinations**

Post-exposure evaluations are tailored to the type of exposure (e.g., spills or needle sticks from syringes containing HDs). An assessment of the extent of exposure is made and included in the confidential database (discussed below) and in an incident report. The physical examination focuses on the involved area of the body, as well as other organ systems commonly affected (i.e., for a spill, the skin and mucous membranes of the affected area; for aerosolized HDs, the pulmonary system). Treatment and laboratory studies follow as indicated and should be guided by emergency protocols.

The following are general suggestions for acute exposure management (Polovich, 2011):

1. Removal of contaminated clothes, stockings, etc.
2. Decontamination based on SDS for the agent of exposure.
3. Visit to employee health professional to document and assure complete decontamination.
4. Physical examination for acute findings at the site of exposure (e.g., skin or the pulmonary system for an inhalation exposure). Other aspects of the exam focus on target organs for drug(s) involved.
5. Blood for baseline counts and archiving (spin and freeze) after major exposures.
6. The employee health clinician can determine appropriate follow up intervals based on drug half-life and, for example, expected timing of blood count nadir (low point).
7. Counseling should be provided to the individual as appropriate to the situation and may include a discussion to defer attempts at conceiving for a period of time, what symptoms to report, and recommended medical follow up.

D. **Exit Examinations**

The exit examination completes the information on the employee's medical, reproductive, and exposure histories. Examination and laboratory evaluation should be guided by the individual's history of exposures and follow the outline of the periodic evaluation.

E. **Exposure-Health Outcome Linkage**

Exposure assessment of all employees who have worked with HDs is important, and the maintenance of existing records is required by 29 CFR 1910.1020 (OSHA, 2011a). The use of previously outlined exposure estimates is acceptable, although actual environmental or employee monitoring data are preferable, when available. Details of the use of personal protective equipment and engineering controls present should be included, as well as maintenance of a confidential database with information regarding the individual's medical and reproductive history, with linkage to exposure information to facilitate epidemiologic review.

F. **Reproductive Issues**

The examining physician should consider the reproductive status of employees and inform them regarding relevant reproductive issues. The reproductive toxicity of HDs should be carefully explained to all workers who will be exposed to these chemicals, and providing this explanation is required for those chemicals that are covered by the HCS. While controversy previously existed as to the degree of hazard that handling HDs presented to pregnant HCWs or those attempting to conceive, data published recently have shown excess reproductive loss in those workers, even with the use of BSCs as mentioned above (Peelen, 1999). Moreover, the most recent U.S. study of nurses working as recently as 2001 (that is, many years after OSHA and professional organizations published safe handling guidance, and presumably influenced safety procedures) documented statistically significant excesses of spontaneous abortion in nurses with first trimester HD exposure (Lawson, 2012).

Due to the reproductive and developmental toxicity profile of many HDs, professional organizations whose members handle HDs and NIOSH now have proposed providing employees who are pregnant or actively attempting to conceive with the option of alternative work assignments that do not involve HD handling (Polovich, 2011; ASHP, 2006; ISOPP, 2007, NIOSH 2015). Also, because many of these drugs are known to enter breast milk, and possess hazard warnings from FDA (FDA, 1997), breast-feeding workers should also have alternative work assignment options. Indeed, NIOSH has recently issued a publication on this topic with suggested implementation approaches (Connor, 2014). Importantly, some HDs possess male mediated reproductive toxicity and, therefore, alternative duty should also be extended to male employees, especially those with a history of inability to conceive (HSE, 2003). The American College of

Occupational and Environmental Medicine also suggests that a risk assessment be made, and alternative reassignment be considered for HD handlers during these vulnerable periods (ACOEM, 2011).

Organizations should establish a mechanism by which those workers who are actively trying to conceive, are pregnant, or are breast-feeding can request alternative duty or protective reassignment. In European countries and some Canadian provinces where these programs already exist, the working pregnant woman initiates the request (a "notification" of pregnancy) and occupational health physicians validate the occupational risk (Taskinen, 1995; Plante, 1998; Romito, 1992). Discussions with large health care systems in the U.S. have identified that many have established programs but not developed written policies. Implementing such mechanisms generally required collaboration between the employee health unit, human resources personnel, the specific service (nursing, pharmacy), and the worker. Information about reproductive risks of the job and the procedures by which alternative duty can be requested can be part of Hazard Communication training for workers. The healthcare worker's private physician may also play a role in providing "validation" of the worker's request for alternative duty assignment. This may be sought by the employer as a matter of policy or may be provided by the worker when a personal medical risk factor places them at additional risk of health harm from work exposure. It is important, however, that requests for this protective, alternative reassignment should ideally be made prior to pregnancy to avoid exposure during the vulnerable first months of pregnancy when early stages of development are occurring. Thus, a discussion of alternative duty availability and the administrative mechanisms to request it should be part of the hazard communication discussion. Ongoing review of actions taken should be performed on a regular basis.