PREVENTION GUIDE

SAFE HANDLING OF HAZARDOUS DRUGS

ASSTSAS *Ensemble en prévention*

ASSOCIATION PARITAIRE POUR LA SANTÉ ET LA SÉCURITÉ DU TRAVAIL DU SECTEUR AFFAIRES SOCIALES

MISSION
Promote accident prevention in occupational health and safety with a view to eliminating hazards at the source and, as part of a joint, sector-based effort, provide guidance to clients in its sector by offering consulting services and information, training, and research and development activities in order to create workplaces that are safe and healthy for all.

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The production of this guide was made possible thanks to the involvement of the following people:

OVERALL SUPERVISION
– Pascal Tanguay, Executive Director, ASSTSAS

AUTHORS
– Sylvie Bédard, Advisor, ASSTSAS
– Guy Bertrand, Advisor, ASSTSAS
– Jean-François Bussières, Head Pharmacist, URPP and CHU Sainte-Justine
– Andréanne Chevrette, Assistant Head Nurse, McGill University Health Centre, AQIO representative, CEPSI member (until December 2017)
– Audrey Chouinard, Specialized Care Advisor – Oncology, CHU de Montréal, AQIO representative (since November 2017)
– Gabrielle Ferland, Pharmacist, Estrie-CHUS CIUSSS
– Kathia Gagnon, Pharmacist, CIUSSS de l'Est-de-l'Île-de-Montréal
– Annie Langlais, Pharmacist, CHU de Québec-Université Laval, APES representative
– Geneviève Lepage, Specialized Care Advisor, CHU de Québec-Université Laval, CEPSI representative (until summer 2017)
– Martine Longtin, Advisor, Online Care Procedures, Centre d'expertise en santé de Sherbrooke (since September 2017)
– Sossy Meguerdij, Technical Pharmacy Assistant, CIUSSS du Nord-de-l'Île-de-Montréal, AQATP representative
– Caroline Plante, Nursing Care Advisor, CHU Sainte-Justine, CEPSI member (until spring 2019)
– Cynthia Tanguay, Coordinator, URPP

OBSERVERS
– Laure Chauchat, Intern, URPP (until October 2017)
– Delphine Hilliquin, Intern, URPP (October 2017 to October 2018)
– Anaëlle Soubieux, Intern, URPP (since 2018)

WITH THE COLLABORATION OF
– Marc Beauchemin, Administrative Procedures and IT Analyst, Direction du génie biomédical, de la logistique et de l'approvisionnement, MSSS
– Lyne Déry, Nursing Care Advisor, Maimonides Donald Berman Geriatric Centre
– Mélanie Drouin, Pharmacist, CISSS Chaudière-Appalaches
– Bruno Dubreuil, Technical Services Coordinator, CISSS de Laval, AHSS President
– Linda Lavigne, Hygiene and Sanitation Department Manager, Direction des services techniques, CISSS de Laval
– Dominique Rousseau, Pharmacist, CISSS Chaudière-Appalaches
– Sophie Therrien, Occupational Health Advisor, CIUSSS du Nord-de-l'Île-de-Montréal
– Maura Tomi, Communications Advisor, Direction des communications, de la veille et de la mobilisation des connaissances, IRSST

Editing: Geneviève Baker
Illustrations: Jacques Perrault, Graphic design: acapelladesign.com, Cover photos: CHUM and Jean-François Lemire, shootstudio.ca
Translation: James Cookson

This guide was translated with contributions from the Institut de recherche Robert-Sauvé en santé et en sécurité du travail (IRSST).

Association paritaire pour la santé et la sécurité du travail du secteur affaires sociales
7400, boul. des Galeries d'Anjou, Suite 600, Montréal, Quebec H1M 3M2 / 514 253-6871 / 1 800 361-4528 / asstsas.qc.ca

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ACRONYMS AND ABBREVIATIONS

ACGIH	American Conference of Governmental Industrial Hygienists
AHFS	American Hospital Formulary Service
APES	Association des pharmaciens des établissements de santé du Québec [Quebec Association of Health Care Facility Pharmacists]
AQATP	Association québécoise des assistants techniques en pharmacie [Quebec Association of Pharmacy Technicians]
AQIO	Association québécoise des infirmières en oncologie [Quebec Association of Oncology Nurses]
ASCO	American Society of Clinical Oncology
ASHP	American Society of Health-System Pharmacists
ASSTSAS	Association paritaire pour la santé et la sécurité du travail du secteur affaires sociales [Joint Sector-Based Association for Occupational Health and Safety in the Social Affairs Sector]
ASTM	American Society for Testing and Materials
ATC	Anatomique, thérapeutique et chimique (classification)
BCG	Bacillus Calmette–Guérin
BSC	Biological safety cabinet
CACI	Compounding aseptic containment isolator
CAS	Centralized admixture service
CHSLD	Centre d'hébergement et de soins de longue durée [Long-Term Care Centre]
CLSC	Centre local de services communautaires [Local Community Service Centre]
CVAD	Central venous access device
CR	Cartridge respirator
HIPEC	Hyperthermic intraperitoneal chemotherapy
HVAC	Heating, ventilation and air-conditioning
HEPA	High Efficiency Particulate Air
IAC	Intraspinal access device
IARC	International Agency for Research on Cancer
IC	Confidence interval
IM	Intramuscular
INESSS	Institut national d'excellence en santé et services sociaux [National Institute of Excellence in Health and Social Services]
INSPQ	Institut national de santé publique du Québec [Quebec National Public Health Institute]
IPC	Infection prevention and control
IRSST	Institut de recherche Robert-Sauvé en santé et en sécurité du travail [Robert Sauvé Occupational Health and Safety Research Institute]
ISO	International Organization for Standardization
IV	Intravenous
MAR	Medication administration record
MSSS	Ministère de la Santé et des Services sociaux [Quebec Department of Health and Social Services]
N95	NIOSH-approved N95 respirator
N100	NIOSH-approved N100 respirator
NIOSH	National Institute for Occupational Safety and Health
NTP	National Toxicology Program
OHS	Occupational health and safety
OPQ	Ordre des pharmaciens du Québec [Quebec College of Pharmacists]
OR	Odds Ratio
PAD	Peritoneal access device
PMSD	Programme pour une maternité sans danger [For a Safe Maternity Experience Program]
PPE	Personal protective equipment
PVAD	Peripheral venous access device
RPD	Respiratory protective device
SDS	Safety data sheet
SUBCUT	Subcutaneous
URPP	Unité de recherche en pratique pharmaceutique [Pharmacy Practice Research Unit]
USP	United States Pharmacopeia
VAD	Venous access device
VC	Ventilated cabinet
WHMIS	Workplace hazardous materials information system

Preamble

This guide presents an array of measures that health care facilities can take to prevent their workers from being exposed to hazardous drugs. The aim is to help decision makers develop and implement exposure prevention measures and safe procedures.

A first edition of this guide by the Association paritaire pour la santé et la sécurité du travail du secteur affaires sociales (ASSTSAS) was published in 1995. The guide was revised in 2008, at a time when the warning issued in 2004 by the National Institute for Occupational Safety and Health (NIOSH) in the U.S. was prompting various health care stakeholders to take action. Since then, NIOSH has classified hazardous drugs into three groups, and recommendations have had to be adapted accordingly. It is also important to note that in the meantime, new standards have been published, including by the Ordre des pharmaciens du Québec (OPQ, 2012 and 2014) and the United States Pharmacopeia (USP 800, 2017).

A new committee was formed in 2017, with a mandate to review the literature, update recommendations and take into account needs expressed by key players. It was made up of health care professionals and stakeholders. Some members served on the committee as individuals, because of their expertise; others were delegated by organizations: the Association des pharmaciens des établissements de santé du Québec (APES), the Association québécoise des assistants techniques en pharmacie (AQATP), the Association québécoise des infirmières en oncologie (AQIO), the Centre d'expertise en santé de Sherbrooke (CESS) and the Comité national de l'évolution de la pratique des soins infirmiers (CEPSI). All members were urged to consult with their peers and collaborators in their respective occupational settings.

In December 2018, the following organizations received a preliminary version of the guide for consultation purposes:

- Association des buanderies-lingeries et des associés de la santé du Québec (ABLASQ)
- Association québécoise des infirmières en oncologie (AQIO)
- Association des pharmaciens des établissements de santé du Québec (APES)
- Association hygiène et salubrité en santé (AHSS)
- Association québécoise des assistants techniques en pharmacie (AQATP)
- Collège des médecins du Québec (CMQ)
- Comité national de l'évolution de la pratique des soins infirmiers (CEPSI)
- Comité de l'évolution de la pratique des soins pharmaceutiques (CEPSP)
- Institut national de santé publique du Québec (INSPQ)
- Institut de recherche Robert-Sauvé en santé et en sécurité du travail (IRSST)
- Ministère de la Santé et des Services sociaux (MSSS) - Direction de l'expertise et de la normalisation
- MSSS - Direction de la santé des personnes et du développement organisationnel, Direction générale adjointe des ressources humaines du réseau
- MSSS - Direction du génie biomédical, de la logistique et de l'approvisionnement
- Ordre des infirmières et infirmiers du Québec (OIIQ)
- Ordre des pharmaciens du Québec (OPQ)

Over a thousand comments were received. All of them were taken into consideration, which helped to improve many of the guide's recommendations.

The guide thus contains the committee's recommendations for the safe handling of hazardous drugs. It deals with practices that could entail a risk of exposure for staff working directly or indirectly with these drugs. It is organized somewhat differently from the first edition, bringing together in a same chapter all the recommendations specific to a given area of activity and reflecting NIOSH's new hazardous drug categories.

The guide's recommendations are consistent with the general recommendations made in most of the guides recently published in North America, as well as elsewhere in the world. An effort has also been made in the guide to provide more concrete recommendations that respond to many of the questions workers raised following the publication of the first edition in 2008. The guide cannot provide answers to every possible question, however, as some questions are still being researched.

While this new version of the guide may seem quite different, a significant number of the principles and recommendations remain similar to those in the original edition. The changes made include an increased effort to cover the medication circuit in its entirety, taking into consideration the interrelationships between the various sectors, as well as:

- **More attention to patient care,** with more detailed information on drug administration procedures, more varied care activities, recommendations more suited to long-term care centres (CHSLDs), local community service centres (CLSCs) and the provision of home services; the topic of workplace design is also discussed
- **Recommendations for nonsterile preparations,** including compounding and final dosage forms
- **Recommendations tailored** to each drug group
- **Tables specifying the personal protective equipment (PPE)** recommended for the main workplace activities in which staff are exposed to hazardous drugs

The measures proposed in this guide are to be regarded as recommendations: they are not standards to be met and are not requirements. Each workplace can apply them as it sees fit, taking into account its specific local circumstances. The requirements of professional practices must also be taken into consideration, as must any exceptional situation for which different measures may be required (e.g., emergencies).

The guide is intended first and foremost for ASSTSAS clients, especially health care facility committees and officers responsible for the safe management of hazardous drugs. Nevertheless, the principles set out here may be followed by other stakeholders (e.g., community pharmacies, private infusion clinics). While the guide is intended primarily for health care workers, some of the recommendations also apply to patients and their families. The purpose of these recommendations is to prevent patients and their family members from coming into direct contact with sources of contamination and ensure smooth harmonization between institutional care and home care. If patients and their caregivers are well-informed about the risks involved in certain practices, they will be better able to contribute, in return, to worker protection.

1 Introduction

1.1 Development of the Guide

1.1.1 Review of the Literature

The committee arrived at its recommendations by examining a number of guidelines. In assessing each recommendation, it focused on determining how it could be applied within a Quebec context and on providing concrete information about its implementation.

- **American Society of Health-System Pharmacists.** *Guidelines on handling hazardous drugs,* 2018.
- **Association paritaire pour la santé et la sécurité du travail du secteur affaires sociales.** *Guide de prévention. Manipulation sécuritaire des médicaments dangereux,* 2008.
- **Ministère de la Santé et des Services sociaux.** *Aires réservées aux préparations stériles - Unité de pharmacie - Répertoire des guides de planification immobilière,* 2016.
- **Ministère de la santé et des services sociaux.** *Guide de gestion des déchets du réseau de la santé et des services sociaux,* 2017.
- **National Institute for Occupational Safety and Health.** *List of antineoplastic and other hazardous drugs in healthcare settings,* 2016.
- **Oncology Nursing Society.** *Safe handling of hazardous drugs,* Third Edition, 2018.
- **Ordre des pharmaciens du Québec.** *Préparations magistrales non stériles en pharmacie.* Norme 2012.01, 2012.
- **Ordre des pharmaciens du Québec.** *Préparation de produits stériles dangereux en pharmacie.* Norme 2014.02, 2014.
- **United States Pharmacopeia.** *General chapter <800> Hazardous drugs - Handling in healthcare settings,* 2018.

As answers to many questions cannot be found in the reference material, the committee sought to resolve these controversial issues by examining the scientific literature. Where no scientific data were available, it relied on the expertise of professionals and on common sense. New research findings will hopefully provide definitive answers to the other questions.

In its work the committee assembled numerous documents on hazardous drugs. The ASSTSAS website includes a section on hazardous drugs that lists relevant literature and tools. The available references have been classified thematically, based on the topics dealt with in this guide. The complete bibliography is publicly accessible on Zotero **(https://www.zotero.org/groups/253596/guideasstsas/items)**. Consulting the references may help decision makers arrive at informed decisions about how to apply the recommendations.

A prepublication version of the guide was sent to several interested individuals and organizations, asking them to comment: their feedback was taken into account as much as possible in the final version.

1.1.2 Review of Quebec Practices

For the purposes of profiling the situation in Quebec, a questionnaire was sent out to the heads of pharmacy departments in health care facilities with over 100 beds (with at least 50 short-term care beds) at three different times: in 2006, 2011 and 2017 (with respectively 53, 33 and 41 participating facilities) (Bussières, 2007; Merger, 2013; Hilliquin, 2018). Pharmacy department heads were asked to fill out the questionnaire in conjunction with the heads of nursing. The objective was to track changes in health care facility compliance with the recommendations regarding antineoplastics made in the first edition of the guide.

Improvement was noted with respect to areas reserved for hazardous drugs, policies and procedures and the centralization of the priming of IV tubing in pharmacies. Aspects where improvement is still needed included the establishment of an interdisciplinary hazardous drug committee, assessment of the level of staff knowledge, contamination monitoring and the establishment of dedicated nonsterile areas for the handling of solid oral formulations of drugs.

The 2017 survey questionnaire showed that the 2008 guide was still being widely used in pharmacy departments. Most health care facilities remove the packaging and clean the vials at receiving. Most pharmacy departments install the tubing and remove the air from it. Storage areas reserved for antineoplastics are used in the care units. There was a wide variation in cleaning procedures, with regard to both frequency of cleaning and products used. Workers were trained in the safe handling of hazardous products at the time of hiring, but very little systematic continuous training and testing were offered for health care staff and hygiene and sanitation workers, as opposed to pharmacy staff.

1.1.3 Guiding Principles

The committee members adopted four guiding principles to direct the decision-making process when recommendations are based on incomplete knowledge and when consensus is hard to reach. These principles are drawn from the health risk management reference framework entitled *Cadre de référence en gestion des risques pour la santé dans le réseau québécois de la santé publique*, developed by the Institut national de santé publique du Québec (INSPQ, 2003). The guiding principles underpin the committee's choice of recommendations.

1.1.3.1 Priority Is Protecting Human Health

Health is seen from a global standpoint that encompasses the concepts of maintaining and improving public health and safety and disease prevention. Our first concern was the protection of those working directly with hazardous drugs, as well as the protection of patients and their families. In accordance with this principle, the guide takes a position in favour of the protection of human health. While remaining aware that other concerns (economic ones, for example) may also have to be considered, the committee believes that it is not its role to advocate for such considerations. We have, however, taken them into account as much as possible, without jeopardizing the protection of human health.

1.1.3.2 Scientific Rigour

Recommendations must be based on the best evidence and knowledge available, including the scientific opinions of experts in all relevant fields, and be the result of a structured, systematic process.

1.1.3.3 Caution

We have applied the precautionary principle, under which prevention measures must be taken whenever reasonable evidence indicates that a situation could have significant harmful effects on health, even when the scientific demonstration has not yet been completed and uncertainty remains.

For instance, there are no known values governing the limits of safe exposure to a hazardous drug. This uncertainty requires that the precautionary principle be invoked, meaning that the recommendation of prevention measures to reduce exposure to hazardous drugs must be followed, just as Quebec's Regulation respecting Occupational Health and Safety prescribes for suspected carcinogens.

1.1.3.4 Assuming Responsibility

The committee focused on strengthening the ability of individuals and organizations to make informed decisions about managing the risks of hazardous drugs. This is the reason for the prevention guide, i.e., to provide stakeholders with all the information they need to make their own enlightened decisions.

1.1.4 Structure

1.1.4.1 Wording of Recommendations

Where an act, regulation or standard exists that supports a recommendation, we use the term "must." Where the committee members are of the opinion that a recommendation cannot be ignored, "must" is likewise used.

The recommendations are not standards to be met, nor are they legal requirements. The measures proposed here are to be understood solely as recommendations: most are expressed using "should." It is up to each health care facility to define an implementation time frame and priorities, while striving to apply the recommendations as quickly as possible.

The verb "may" is used to refer to measures that are "advised," but the implementation of which may vary depending on local circumstances or the results of a risk assessment.

> **Unless otherwise indicated, recommendations apply to all hazardous drugs. Special indications are given when the recommendations apply specifically to drugs in groups 1 (G1), 2 (G2) or 3 (G3) (see section 1.2.1).**

A health care facility can always choose to enhance its prevention measures to simplify the management of hazardous drug exposure or if it suspects an increased risk. A risk assessment should be conducted to determine the measures to be implemented. There is no gradation of hazard levels within a hazardous drug group; the measures that apply to a given group of drugs apply to all drugs in that group.

1.1.4.2 Chapters

Chapter 1 presents the guide, outlines the risks associated with hazardous drugs, provides an overview of the recent literature and sets an exposure prevention objective.

Chapter 2 describes the general prevention measures that apply at all stages in the medication circuit. These first two chapters summarize the basis of the recommendations made in the other chapters. They are essential reading for understanding the rest of the guide.

Chapter 3, Pharmacy, sets out all the recommendations that apply to a pharmacy department. **Chapter 4, Care Units,** gives the recommendations that apply to patient care, whether related to the preparation of certain hazardous drugs, the administering of drugs or the care provided.

Chapters 5 and 6 set out rules for the safe handling of hazardous drugs in **CHSLD long-term care centres (Chapter 5),** and in **CLSC community service centres or home settings (Chapter 6).** CHSLDs are different from other settings in several respects, because treatments must sometimes be given over long periods, at reduced doses, to patients who may be incontinent, have trouble swallowing (pills have to be crushed) or share living quarters with other patients who do not need such treatment.

CLSCs sometimes administer hazardous drugs, but also provide other health care and related services (e.g., removal of medical devices, specimen collection, psychological services) where the worker providing them may not know the patient's whole clinical situation. Finally, home services (e.g., care, housekeeping) are provided in private settings with widely varying characteristics, and sometimes in the presence of loved ones who may have their own vulnerabilities (e.g., children, pregnant women).

The hygiene and sanitation department (Chapter 7) plays a key role in preventing exposure to hazardous drugs. Hygiene and sanitation staff is responsible for maintaining the sanitary conditions of installations and the different areas that are an integral part of the medication circuit (cleaning of facility, collection and management of waste, and spill clean-up) and must also follow procedures to ensure their own safety, as they, too, can be at risk of exposure. The last two chapters (8 and 9) are devoted to our recommendations for **laundry service (Chapter 8)** and **spill management (Chapter 9).**

1.2 Risks of Exposure to Hazardous Drugs

1.2.1 Definitions

In Quebec, a "drug" is defined as any substance or mixture of substances that can be used for:

- the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical or psychological state, or of the symptoms thereof, in humans or animals;
- with a view to restoring, correcting or modifying organic functions in humans or animals.

There are two widely used drug classifications: the World Health Organization (WHO) Anatomical, Therapeutic and Chemical (ATC) classification, and the American Hospital Formulary Service (AHFS) classification. The Régie de l'assurance maladie du Québec (Quebec medicare board) and NIOSH both use the AHFS classification. It groups drugs according to their main pharmacological effects (e.g., class 10:00 – Antineoplastic Agents, class 68:00 – Hormones and Synthetic Substitutes).

In this guide, the term "hazardous drug" is used to refer to all the drugs included on the list drawn up by NIOSH in 2016. In 2014, NIOSH reorganized the list and divided drugs into three groups (see Table 1). No drug has been removed from the list, added to the list or put into a different category. Drugs are considered by NIOSH to be hazardous if they exhibit one or more of six characteristics. The list is updated periodically; the most recent version of the list should be used by each health care facility's hazardous drug committee. The criteria used to declare a drug as hazardous were stated in earlier versions of the list.

Hazardous drugs have at least one of the following six characteristics:

- Carcinogenicity
- Teratogenicity or other developmental toxicity
- Reproductive toxicity
- Organ toxicity at low doses
- Genotoxicity
- Structure or toxicity profile of a new drug mimics that of an existing drug determined hazardous by the above criteria

In 2020, NIOSH proposed a new classification that had not yet been officially adopted at the time of publication of this guide (Table 1). The ASSTSAS intends to subscribe to the new classification once it is officially published, and any required changes will be made to the guide at that time. The current plan is to stick with the same recommendations and transpose them to the NIOSH 2020 groups as follows: our G1 recommendations will concern the drugs in the new Table 1; our G2 recommendations will concern the drugs in the new Table 2, except that we will distinguish between groups G2A and G2B, with the latter corresponding to our current group G3.

TABLE 1

Hazardous drug groups

GROUP	NIOSH 2016 DEFINITION	PROPOSED NIOSH 2020 DEFINITION
G1	Most antineoplastic drugs according to AHFS Classification 10:00 (including those that pose a reproductive risk) **> Table 1 of NIOSH list**	Drugs that are known human carcinogens according to the NTP or the IARC and/or which contain manufacturers' special handling information (MSHI) in the package insert (including those that pose a reproductive risk) **> Table 1 of NIOSH 2020 list**
G2	Non-antineoplastic drugs that meet one or more of the NIOSH criteria for a hazardous drug (including those that pose a reproductive risk) **> Table 2 of NIOSH list**	Drugs that do not contain manufacturers' special handling information (MSHI) in the package insert but that involve other hazards (that meet one or more of the NIOSH criteria for a hazardous drug, including that of having adverse developmental or reproductive effects) **> Table 2 of NIOSH 2020 list**
G3	Drugs that primarily pose a reproductive risk to women and men who are actively trying to conceive, and women who are pregnant or breast feeding **> Table 3 of NIOSH list**	Drugs in Table 2 of the NIOSH 2020 list that only meet the NIOSH criteria as a developmental and/or reproductive hazard

AHF : American Hospital Formulary Service
IARC: International Agency for Research on Cancer
NIOSH: National Institute for Occupational Safety and Health
NTP: National Toxicology Program

Most antineoplastic drugs (10:00) are G1s (Figure 1). Also called "cancer drugs," antineoplastics are used to treat cancer by "inhibiting or preventing the growth and spread of tumors or malignant cells" (Merriam-Webster Dictionary: **https://www.merriam-webster.com/dictionary/antineoplastic)**. Chemotherapy refers to "the administration of one or more cytotoxic drugs to destroy or inhibit the growth and division of malignant cells in the treatment of cancer" **(https://www.merriam-webster.com/dictionary/chemotherapy)**. The term is used primarily in connection with G1s. The term "cytotoxin" generally refers to G1s, but encompasses all substances "(such as a toxin or antibody) having a toxic effect on cells" **(https://www.merriam-webster.com/dictionary/cytotoxin)**.

Figure 1 • **Classification of hazardous drugs**

BCG: Bacillus Calmette-Guérin

As we have noted, the purpose of this guide is to ensure the protection of workers who could potentially be exposed to hazardous drugs; the guide does not offer any opinion on the specific recommendations of professional organizations with respect to work methods (e.g., measures to be taken to ensure the sterility of a compound, care procedures for administering a drug).

Furthermore, the hazardous drug groups defined by NIOSH and used in this guide are not to be confused with, for instance, the OPQ's categories of nonsterile compounds. The OPQ's 2012 and 2014.02 standards do not use NIOSH's three-group classification published in 2014, which means there are differences in the NIOSH and OPQ definitions of hazardous drugs.

It can be seen from Table 2 that the OPQ's nonsterile categories do not correspond to NIOSH's, and that OPQ category 3 defines a type of compound comprising at least one hazardous drug, as the OPQ defines it, which includes only a part of groups 1, 2 and 3 of NIOSH's classification of hazardous drugs.

A category 3 nonsterile compound, according to the OPQ, is the only one that includes a hazardous drug-type ingredient. These hazardous drugs include the use of cytotoxic drugs, hormones, immunosuppressants, some teratogenic drugs (like retinoic acid) and abortion medications (like misoprostol), according to the OPQ.

TABLE 2

Overview of OPQ categories of nonsterile compounds

CATEGORY 1	CATEGORY 2	CATEGORY 3
Use of a hazardous chemical (except a category 3 one) Small quantity (≤ 50 times the unit dose) Preparation of liquid or solid dosage forms	Use of a hazardous chemical (except a category 3 one) Large quantity (> 50 times the unit dose) Preparation of dosage forms requiring special techniques	Use of cytotoxic drugs, hormones, immunosuppressants, some teratogenic drugs (like retinoic acid) and abortion medications (like misoprostol) Use of hazardous materials[a] that are respiratory tract irritants Any prepared quantity

Based on Table 1 in OPQ standard 2012.01.
This table is a simplified version of the standards of the Ordre des pharmaciens du Québec; a complete definition is contained in the standards. All G1s, but only some G2s and some G3s are in category 3, nonsterile compounds.

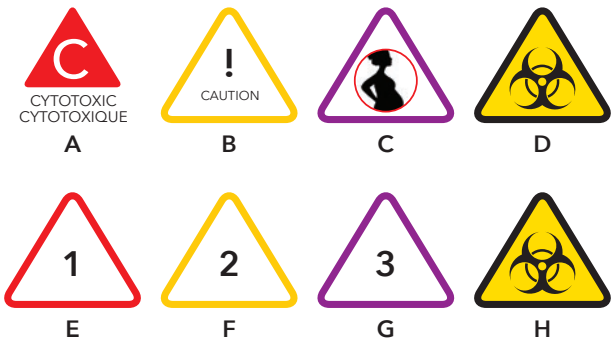
a: Hazardous material according to the WHMIS 2015 definition.

1.2.2 Symbols

Risks must be identified so that people who could potentially be exposed can take the required precautionary measures. The symbols shown for the two systems proposed below can be used to identify areas, containers and labels, as required. Usage should be standardized from one facility to the next.

- **G1s** must be identified by the "Cytotoxic" symbol and the "Cytotoxic" label.
- **BCG** must be identified by the "Biohazard" symbol.
- **G2s and G3s** must be identified by the "Caution" label. G3s should also be identified by the "Caution pregnancy" label.
- **The use of a symbol specific to G1s, G2s or G3s** may be considered, such as the group's number inside a coloured triangle, as illustrated in this guide.

Figure 2 • **Symbol examples**



A. Cytotoxic hazardous drug (Group 1)
B. Caution (Group 2)
C. Caution pregnancy (Group 3)
D. Biohazard (BCG)
E. Group 1 hazardous drug
F. Group 2 hazardous drug
G. Group 3 hazardous drug
H. Biohazard (BCG)

1.2.3 Health Effects

Despite improved safety practices, especially in pharmacy departments and drug administration areas, workers can still be exposed. "Studies have associated workplace exposures to hazardous drugs with health effects such as skin rashes and adverse reproductive outcomes (including infertility, spontaneous abortions, and congenital malformations) and possibly leukemia and other cancers," according to NIOSH (2004). However, the long-term consequences of occupational exposure are difficult to prove, and study results vary because workplaces and work methods are constantly changing.

Safety data sheets (SDS) can be obtained from manufacturers. They are an additional source of information on the health risks of hazardous drugs. Under the Hazardous Products Act, manufacturers are required to provide these sheets for their hazardous products; this obligation does not apply to hazardous drugs, however. The committee believes that this information should be made more readily available to health care professionals in Quebec.

1.2.3.1 Carcinogenic Effects

The carcinogenic effects of some drugs on animals are known, and ongoing research is tending to show that these drugs can promote the development of new cancers in people being treated. The International Agency for Research on Cancer (IARC) has drawn up lists of substances that are known carcinogens (Group 1), probable carcinogens (Group 2A) and possible carcinogens (Group 2B) for human beings, and some of these substances are drugs.

Isolating the risk of cancer due to occupational exposure from other documented risks is a difficult endeavour. Fransman et al. (2014) have developed a pharmacokinetic simulation model based on task frequency and cutaneous absorption of cyclophosphamide. They calculated that the increased risk of leukemia at age 80 for a nurse who had been exposed occupationally for 40 years was 1.04 for a million oncology nurses.

1.2.3.2 Genotoxic Effects

Genotoxic effects have been demonstrated in a number of studies. Mahmoodi (2017), for instance, found that chromosomal aberrations were significantly higher in workers exposed to antineoplastics. Chromosomal aberrations are not necessarily directly linked to a health issue, but they can lead to cancers, hereditary disorders or reproductive risks. They are also a marker indicating that a worker has been exposed to a substance.

1.2.3.3 Reproductive Risks

A review of the recent literature (Connor, 2014) underscores that health care workers who are exposed occupationally to antineoplastics face greater reproductive risks, especially with respect to malformations and miscarriages. In a meta-analysis, the increased risk of miscarriage among exposed female workers was determined to be statistically significant (OR 1.46 [CI 1.11–1.92]) (Dranitsaris, 2005). The other effects, while not statistically significant, cannot be disregarded, including an increased risk of congenital malformations (OR 1.64 [CI 0.91–2.94]) and stillbirths (OR 1.15 [CI 0.75–1.82]). Studies on this topic often involve limitations, making it difficult to draw conclusions and leading to wide confidence intervals. Infertility was another of the effects evaluated.

Measuring risk

OR (ODDS RATIO)

This is a measurement of association that provides a good estimate of the risk related to exposure. An OR of 1.46 means that the group of exposed subjects has a disease probability that is 46 percent greater than that of the group of non-exposed subjects. An OR of 1.00 means that there is no increased risk.

IC (CONFIDENCE INTERVAL)

An OR usually has a CI of 95 percent. The CI specifies the degree of statistical precision of the measurement of association. If a CI of 95 percent does not include the value of 1.0, for instance (1.11 1.92), it means that the result is statistically significant at an error threshold of 5 percent ($p < 0.05$). More precisely, the interval (1.11 1.92) should contain the real value 19 times out of 20. On the other hand, if the value 1 lies within the CI range, e.g., (0.91 2.94), the association between the effect and the factor being studied is not statistically significant.

1.3 Sources of Exposure to Hazardous Drugs

1.3.1 Increasing Use of Hazardous Drugs

Since the original list was drawn up in 2004 (NIOSH), the quantity of hazardous drugs has continued to grow. The use of hazardous drugs, especially G1s in oncology, has been rising. Not only has the number of new cases of cancer been increasing (Canadian Cancer Society, 2019), but hazardous drug use has also been growing outside of health care facilities (such as in CHSLD long-term care centres and home settings). According to an investigation conducted in Quebec CLSCs (community service centres) between 1999–2001, 35.6% of them were involved in administering antineoplastic drugs intravenously to patients in home settings (Boothroyd, 2004).

1.3.2 Places Where Hazardous Drugs Are Used

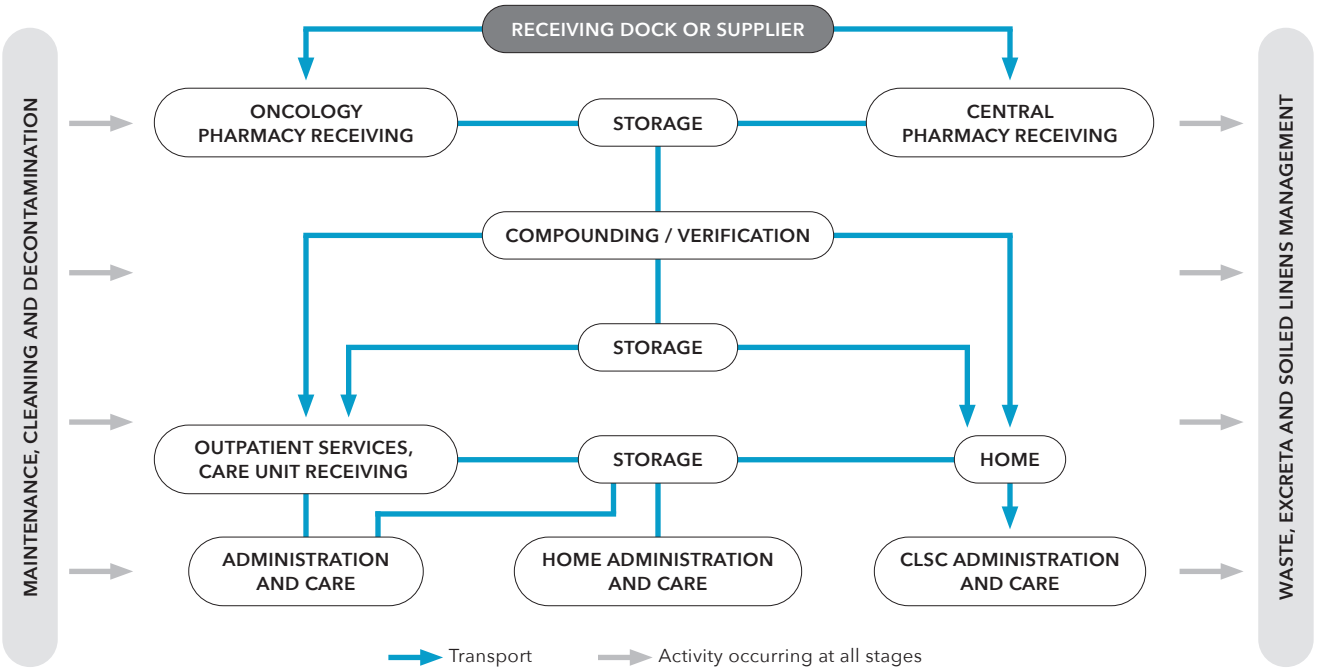
Throughout the medication circuit in a health care facility (MSSS, 2005), workers can be exposed to hazardous drugs. The medication circuit encompasses all the stages that a drug passes through, from the time it arrives at the receiving dock, to its storage, compounding, administration, and its elimination in excreta or as waste.

To keep workers informed, ensure safe handling of packages received and limit contamination, all hazardous drugs must be accurately identified right from the initial receiving stage. The pharmacy practice research unit (URPP) at the Centre hospitalier universitaire Sainte-Justine has conducted an assessment of the compliance of Canadian wholesalers' hazardous drug labelling. Only 32% (56/174) of G1 labels included an antineoplastic drug warning, a "Cytotoxic" symbol or an indication of the precautions to be taken. In the case of G2 and G3 drugs, just 11 percent (23/209) of labels included an indication of the necessary precautions to be taken (Janes, 2016).

Most G1s are stored, compounded and administered in a limited number of locations (i.e., oncology pharmacies, care units, outpatient clinics). This is not the case for G2s and G3s. Hazardous drugs are used in treating diseases other than cancer. For instance, owing to its immunosuppressant properties, methotrexate is also useful for treating arthritis and other disorders. This means that patients can be given hazardous drugs elsewhere than in hematology-oncology care units.

Patients' homes, as well as landfills and even municipal sewer systems, may also be sources of contamination.

Figure 3 • **Hazardous drugs in the medication circuit**



1.3.3 Hazardous Drugs in Body and Excreta

After being administered, a drug remains in the body for a period of time that varies with each drug. A given drug can be eliminated through a variety of routes (e.g., urine, feces, sweat, exhaled breath). The speed of elimination also varies from one drug to the next, as well as the quantity that stays intact, which in some cases can be relatively significant. Traces of a hazardous drug can be found several hours and even several days after it has been administered.

It is known, for instance, that 5 to 25 percent of a dose of cyclophosphamide can be found intact in a patient's urine (renal excretion) (Micromedex). The half-life of this drug varies between 1 and 7 hours for oral doses, and between 4 and 16 hours for IV doses (Micromedex).

There is no scientific consensus on how to define the length of time during which a hazardous drug can be found in a patient's excreta in sufficient quantity for it to still be a significant risk to an exposed worker. In 1992, Cass and Musgrave were the first to draw up a list of precautionary periods for the safe handling of excreta of 24 hazardous drugs. The period varied from 12 hours to 7 days. In cases where no information was available, a precautionary period of 48 hours was recommended. Unfortunately, Cass and Musgrave provided very few details about the methods they used to calculate these precautionary periods.

Given that only a negligible quantity remains after 5 half-lives, a precautionary period of 80 hours would appear justified for cyclophosphamide (5 half-lives times 16 hours). In 2017, Cass et al. studied the half-life of oral antineoplastics that could be administered at home; it varied from 4.5 hours to 28 days, depending on the drug.

Furthermore, drug metabolism can vary from one patient to the next and with their state of health, as well as with the doses administered (e.g., doses, frequency).

It is prudent to allow for a precautionary period long enough to reduce to a minimum any contact with hazardous drugs contained in bodily fluids. A period specific to each molecule would be difficult to apply in practice. **A minimum precautionary period of 96 hours seems reasonable, although it can be adapted depending on the situation** (e.g., administration of a drug whose life span is well-documented). On the basis of current knowledge, we recommend a precautionary period of at least this length for G1s. In other situations (excreta of G2s, G3s or beyond 96 hours for G1s), routine practices must be followed.

1.4 Worker Exposure

According to CAREX Canada (Cancer Exposure Canada), close to 75,000 Canadian workers were exposed to antineoplastics (mostly G1s) in 2017.

Many people can be exposed at the various stages of a health care facility's medication circuit, including merchandise receiving staff and transportation workers, pharmacists and pharmacy technicians, the doctors, nurses and respiratory therapists who administer the drugs, the nurses and orderlies who care for patients to whom hazardous drugs have been administered, hygiene and sanitation staff and laundry workers (Table 3). Employees in training can also be exposed. In addition, other workers may be exposed when they perform specific tasks, such as cleaning, equipment repair and spill clean-up, as well as volunteers and consultants on site. Family members and other visitors could also potentially be exposed.

TABLE 3

Potential sources of hazardous drug exposure in the medication circuit

STAGE	STAFF POTENTIALLY EXPOSED	POTENTIAL SOURCES OF EXPOSURE
Receiving and transportation	General employees (e.g., storekeepers, clerks) Hygiene and sanitation workers Pharmacy department employees	Damaged or contaminated shipping containers Broken containers
Unpacking and storage at pharmacy	Pharmacy department employees Hygiene and sanitation workers	Damaged or contaminated shipping containers Outside surfaces of vials Storage areas
Drug preparation	Pharmacy department employees Staff in outpatient clinics, care units, drop-in centres (e.g., nurses, clerks) Hygiene and sanitation workers Maintenance workers (e.g., biomedical engineering staff or preparation cabinet certification officers)	Outside surfaces of vials Handling (e.g., counting of solid oral forms of drugs, repackaging) Bins or trays for transport Contaminated equipment (syringe plungers, infusion pumps, HEPA filter maintenance) Particles or vapours in BSCs (e.g., leaks through front opening caused by quick arm movements or blockage of the front grille) Ineffectiveness of BSC Accidents (e.g., needlesticks, breakage, spills)
Transportation and storage following preparation	Pharmacy department employees Personnel in outpatient clinics, care units, drop-in centres (e.g., nurses, clerks) Transportation employees (e.g., clerks)	Broken containers Outside surfaces of vials Contaminated transportation containers

BSC: Biological safety cabinet, or biosafety cabinet **HEPA :** High Efficiency Particulate Air

Table 3 • **Potential sources of hazardous drug exposure in the medication circuit –** (cont'd)

STAGE	STAFF POTENTIALLY EXPOSED	POTENTIAL SOURCES OF EXPOSURE
Administering of drugs	Staff of care units, nursing homes, outpatient clinics, drop-in centres, and those providing home care (e.g., nurses, practical nurses, doctors, respiratory therapists) Pharmacists, hygiene and sanitation department workers Other patients Visitors/caregivers Biomedical engineering staff	Contaminated transport trays Leaks or creation of aerosols when installing or priming tubing Leaks or creation of aerosols when connecting or disconnecting syringes and tubing in injection ports Poorly cleaned drug containers or bags, tubing or syringes Contaminated surfaces (e.g., infusion pumps, chair armrests, counters) Crushing/cutting of pills Application of creams or ointments Accidents (e.g., needlesticks, damaged drug containers, spills) Splashing, aerosols and vapours when providing special kinds of treatment, such as hyperthermic intraperitoneal chemotherapy (HIPEC)
Patient care	Staff of care units, nursing homes, outpatient clinics, drop-in centres, CLSCs, medical imaging departments (e.g., nurses, doctors, respiratory therapists, clerks) Other patients Visitors/caregivers Hygiene and sanitation department workers Biomedical engineering staff	Patient's immediate surroundings (e.g., counters, sinks, toilets) Patient's excreta, basins, sheets and bathing water Supplies used in patient care
Waste management, spill clean-up	Receiving and transport employees (e.g., store-keepers, clerks) Waste collection employees Pharmacy department employees Staff of care units, outpatient clinics (e.g., nurses, doctors, respiratory therapists, clerks) Other patients Visitors/caregivers Hygiene and sanitation workers	Transfer of hazardous drugs and contaminated supplies to waste containers Waste containers (e.g., when closing up bags, transporting, improper closing of waste containers) Spills
Hygiene and sanitation	Hygiene and sanitation workers Health care employees	Contaminated surfaces, waste, excreta, soiled bedding Supplies used for cleaning and for cleaning up spills of hazardous drugs or bodily fluids
Laundry	Laundry employees	Bedding/uniforms contaminated by hazardous drugs or patient excreta

Table 3 • **Potential sources of hazardous drug exposure in the medication circuit –** (cont'd)

STAGE	STAFF POTENTIALLY EXPOSED	POTENTIAL SOURCES OF EXPOSURE
Medical device reprocessing unit (MDRU)	MDRU staff	Contaminated supplies
Equipment maintenance	Biomedical staff Technical staff (e.g., mechanics, electricians, certification officers)	Contaminated equipment or premises
Transportation outside hospital	Delivery workers Taxi drivers Patient's family and caregivers	Broken containers Outside surfaces of contaminated drug container
Home care	Health care staff visiting patients at home (nurses, health and social services auxiliary staff, home caregivers, or workers from a cooperative or an agency) Patient's family and caregivers	Broken containers Outside surfaces of contaminated container Drug storage or preparation areas Soiled clothing Excreta

1.5 Routes of Exposure

Hazardous drugs can enter the body through cutaneous absorption, ingestion, accidental injection or inhalation.

Cutaneous absorption is the main known route of entry: it occurs through direct contact with the hazardous drug or indirectly through contact with surfaces or objects contaminated with hazardous drugs or the excreta of patients who have been given hazardous drugs. Contamination of the hands, and less frequently the forearms and forehead, accounts for 87% of the contaminated areas of the body as a whole (Fransman, 2004). That is why wearing gloves, maintaining proper hand hygiene and cleaning surfaces are such important prevention measures.

Ingestion can occur by eating foods that may have been contaminated or, more often, by touching the mouth with the hands or with contaminated objects, such as pens and pencils.

The subject of accidental injection (e.g., needlesticks) is dealt with in Chapter 9.

Aside from situations where a hazardous drug is administered by inhalation, the degree to which inhaling a hazardous drug found in the ambient air (e.g., in the form of particulates or vapours) could be an exposure pathway has not been clearly established. Many studies report low levels of particulates or dust in the air. Also, it should be noted that carmustine, cisplatin, cyclophosphamide, etoposide and fluorouracil are known to generate vapours (Kiffmeyer, 2002). Dolezalova (2009) determined that evaporation is a fairly slow process for paclitaxel, doxorubicin and dacarbazine. However, the evaporation of hazardous drugs (carmustine, cyclophosphamide, cisplatin, etc.) increases if they are heated (Bhatt, 2016; Kiffmeyer, 2002; Connor, 2000). The fact that the handling of hazardous drugs in liquid form can potentially generate fine liquid particles (or aerosols) should also be taken into consideration.

1.6 Studies on Presence of Hazardous Drugs

Many studies have confirmed evidence of contamination in the medication circuit. In Quebec, eight multicentre studies conducted since 2008 in hospital pharmacies and outpatient clinics in Quebec and the rest of Canada have shown that surfaces are contaminated. While the concentrations measured on surfaces tend to decline over time, approximately half of the surfaces remain contaminated by at least one hazardous drug. In 2018, 79 Canadian hospitals were involved in a multicentre study, including 64 hospitals in Quebec (Hilliquin, 2019). The surfaces found to be most frequently contaminated were the BSC front grille, the floor in front of the cabinet and the armrests of chairs used for administering drugs.

Other studies conducted in Quebec have shown that the outer surfaces of hazardous drug vials remain contaminated (Hilliquin, 2020). In addition, traces of contamination can also be found on some surfaces in care units, mainly in the rooms of patients who have been given hazardous drugs (Hilliquin, 2019). Canadian studies carried out by another research group have corroborated the finding of contamination of the medication circuit (Hon, 2013).

So there is a wide variety of contaminated surfaces, which include work surfaces (BSCs, counting trays, shelves), equipment (infusion pumps, robotic equipment), office supplies (pencils, pens, calculators), areas accessible to patients (drug administration chairs, patient rooms, door handles, elevator buttons, washrooms). In addition to the contamination of surfaces, air contamination can also be measured (Panahi, 2016).

Traces of hazardous drugs can also be found elsewhere in a health care facility. A research team from the Institut de recherche Robert-Sauvé en santé et en sécurité du travail (IRSST) measured surface contamination with respect to sanitation (Labrèche, 2020). In another study, contamination was found on shipping containers from wholesalers (Redic, 2018). Some international studies have found contaminated surfaces in operating rooms (Schenck, 2016). Contamination has also been discovered in laundry facilities (Fransman, 2006). Patients' homes can also be contaminated (Yuki, 2012). Contamination has been found in Quebec community pharmacies (Merger, 2013), in veterinary clinics (Fung, 2016) and even in municipal sewer systems (Rabii, 2014).

Many studies have shown that staff exposed to hazardous drugs can have trace amounts of the drugs in their urine. For instance, one Canadian study (Hon, 2015) found that traces of cyclophosphamide were detected in 55 percent (111/201) of urine samples from exposed workers. Surprisingly, the workers with the highest levels of contamination were not those who had been administering the drugs, but rather the "other" types of workers, such as volunteers, nutritionists and oncologists. Conversely, two Quebec pilot studies were conducted in three hospitals, and no workers (0/101 and 0/56, respectively) were found to have any traces of cyclophosphamide, 5-fluorouracil (through its metabolite), ifosfamide or methotrexate in their urine (Poupeau, 2017; Chauchat, 2019). There are a number of reasons that could explain the differences in the findings between these studies, including differences in protocols, sampling methods, analytical methods and work methods.

2 Prevention Measures

The main objective of this guide is to propose measures that will reduce health care worker exposure to the lowest level possible, while preserving drug integrity and the health of patients and their families.

At present, there is no safe exposure level for hazardous drugs that ensures a person will not suffer any health effects. The precautionary principle must therefore be applied in seeking to achieve the lowest possible level of exposure, or preferably no exposure at all.

- **Avoid contaminating** the environment from the outset.
- **Maintain the environment** to reduce environmental contamination when it is found or suspected, insofar as it is technically possible to do so.
- **Reduce worker exposure** to hazardous drugs.

Prevention measures can be grouped into five categories, shown in Table 4. Elimination at the hazard source is the most effective preventive measure, but it is difficult to apply if it is impossible to replace the hazardous drug with a less hazardous one. The next step to consider is implementation of hazard reduction measures, such as reorganizing the workplace, defining safe work policies and procedures, ensuring safe procedures are followed and, if risks remain, wearing personal protective equipment (PPE). This chapter sets out the basic principles underlying these prevention measures. Specific recommendations regarding workplace design, equipment and work methods are detailed in the following chapters.

TABLE 4

Classification of prevention measures

PREVENTION MEASURES	EXAMPLES
Elimination at source	Replacing a drug with a less hazardous one
Engineering controls	Development of safer workplace (e.g., controlled access, non-porous materials) / Sterile compounding room / Ventilation / Drug preparation by compliant third party
Work methods	Drug preparation techniques / Drug administration techniques / PPE removal techniques / Facility cleaning – Waste collection
Organization	Identification labelling / Training / Assessment of techniques / Follow-up of measures implemented / Environmental monitoring / Policies and procedures – Waste management
Personal protection	PPE

To achieve these objectives, health care facilities where hazardous drugs are used must implement a specific exposure prevention program for them.

It is up to each health care facility to prioritize its initiatives based on its situation and to define a timetable with implementation priorities, aiming to take steps as quickly as possible. Measures that are inexpensive and easy to apply should be taken in the short term. Ones that are harder to apply and more expensive should be included in a medium-term timetable for implementation. Because contamination is invisible, the precautionary principle must be applied at all stages of the medication circuit.

The editorial committee of this guide has divided up its recommendations according to the three hazardous drug groups to facilitate implementation as much as possible.

In the United States, the USP 800 recommendations must be followed for all drugs and for all active ingredients of hazardous drugs (G1, G2 and G3), with one exception: "not all USP 800 containment requirements need to be followed if an assessment of risk is performed [G2 and G3] and if this is the final dosage form of a compounded HD preparation or a conventionally manufactured HD product [G1, G2 and G3], including antineoplastic dosage forms that do not require any further manipulation than counting or repackaging" [USP-NF (2017), Box 1, Containment Requirements].

As with the U.S. recommendations, a risk assessment can be conducted for certain drugs or dosage forms to allow other contamination risk control measures to be taken. Risk assessment is covered in section 2.5.

2.1 Hazardous Drug Committee

- **All health care facilities where hazardous drugs are handled must have a hazardous drug committee.**
  - The committee should include at least one representative of the following departments and services, as well as employee and union representation, if applicable.
    - Occupational Health and Safety (OHS)
    - Pharmacy
    - Nursing
    - Hematology-Oncology
    - Respiratory Therapy
    - Hygiene and Sanitation
    - Technical Services
    - Risk Management
- **The committee should be mandated by the facility's executive management team to develop a hazardous drug exposure prevention program and to oversee its implementation and follow-up (see section 2.2).**
- **It must have at its disposal all the information collected under the program.**

- **It must maintain an up-to-date list of all the hazardous drugs in the facility.**
  - The most recent NIOSH list is to be used.
  - The committee should have access to the safety data sheets (SDS) for all drugs used in the facility.
    - > SDSs provide information on identifying the hazard, the appropriate first aid, fire-fighting measures, spill response, handling and storage, exposure prevention and personal protection, physical, chemical and toxicological properties, environmental information, waste management and transportation.
  - Prior to first use, all drugs must be assessed to determine whether they should be treated as hazardous drugs.
- **The committee is responsible for ensuring that the list of hazardous drugs is accessible to all staff.**
- **It must be informed of any incidents or accidents involving hazardous drugs.**
- **It should meet regularly, at a frequency that allows for appropriate follow-up (i.e., at least twice a year and, in particular, following any change in procedures, any added drugs or the updating of the NIOSH list).**
- **A health care facility's hazardous drug committee must set up a hazardous drug exposure prevention program and define how the program will be monitored.**
  - A person should be put in charge of the facility's program (see section 2.2).
- **The committee must establish the policies and procedures needed to implement the recommendations set out in this guide, based on the risk assessment.**
- **The committee should supervise the assessment of compliance with the guide's recommendations and with applicable standards, including the OPQ's.**
  - It should develop an action plan, oversee its implementation and ensure compliance, at all levels of the facility (workplace design, equipment and work practices).

2.2 Hazardous Drug Exposure Prevention Program

- **The health care facility's hazardous drug committee must set up a hazardous drug exposure prevention program and define how the program will be monitored.**
- **The program must cover all potential exposure risks throughout the medication circuit.**
- **It must include policies and procedures covering, at a minimum:**
  - Procurement
  - Training of staff
  - Assessment of staff knowledge of hazards, prevention measures and procedures and their application
  - Updates to the hazardous drugs list
  - Record of staff exposure
  - Environmental monitoring program
  - Receiving of hazardous drugs

- Storage of hazardous drugs
- Identification of hazardous drugs
- Identification of locations where there is a risk of exposure
- Preparation of hazardous drugs
- Administering of hazardous drugs
- Care for patients being given hazardous drugs
- Instructions to patients and their caregivers
- In-house transport of hazardous drugs
- External transport of hazardous drugs
- Management and transport of hazardous drug waste
- Management of excreta from patients being given hazardous drugs
- Hygiene and sanitation
- Preventive maintenance of infrastructure (e.g., sterile compounding room) and equipment (e.g., preparation cabinet)
  - A maintenance log must be kept
- PPE:
  - Including respiratory protection program
  - Including proper sequence for donning and doffing PPE
- Spill management
- Accidental exposure management
- Annual self-assessment of compliance with this guide's recommendations
- Communications plan

- **The program must provide for regular updating of its policies and procedures.**

2.3 Procurement

2.3.1 Joint Procurement Group

- **Facilities must ensure that their buying takes into account the requirements specific to hazardous drugs. If purchases are made through procurement contracts, the pharmacy department heads who are members of the joint procurement group, or their representatives, should ensure that the recommendations made in this section are followed.**
- **The joint procurement group should take into account the outside surface contamination of hazardous drug containers when assessing bids.**
  - Manufacturers should be asked to provide written confirmation that the batches of drug containers they are selling are free of contamination. An obligation to clean the outside surfaces of hazardous drug containers should be added to the list of best manufacturing practices that apply throughout Canada.

- **The joint procurement group should give priority to hazardous drug formats that limit the risks of exposure and that facilitate drug preparation and administration (e.g., products already in solution form rather than powder that has to be reconstituted, pills in blister packs rather than in bottles or jars).**
- **The joint procurement group should make sure that the call for tenders for the procurement contract includes a clause stipulating that a facility may require, for one or more of its locations, that G1s be delivered directly to the oncology pharmacy by one of the distributor's employees.**
- **The joint procurement group must ensure that PPE complies with the relevant recommendations set out in this guide (see section 2.11).**

2.3.2 Purchasing of Hazardous Drugs

- **Drug procurement managers should ensure that all boxes containing G1s are clearly identified as such by manufacturers and distributors.**
- **Drug procurement managers must check that manufacturers are providing the requisite SDSs.**
  - Manufacturers should provide SDSs for all hazardous drugs, even though this is not a legal requirement.
  - SDSs should be available from a known, easily accessible source (i.e., without a password being required, to ensure quick access when needed). They may be stored on the same platform as WHMIS products.
- **Drug procurement managers should ensure that distributors package G1s separately.**
- **Drug procurement managers may order G1s, G2s and G3s on separate purchase orders, to ensure they are packaged separately from non-hazardous drugs and to make it easier to identify and sort them when they are received.**
- **Procurement managers must ensure that PPE complies with the relevant recommendations set out in this guide (see section 2.11).**

2.3.3 Manufacturers and Distributors

2.3.3.1 Hazardous Drugs

- **Manufacturers should provide the SDSs of all G1s, G2s and G3s, even though this is not a legal requirement.**
- **G1s must be packaged in a sealed plastic bag placed inside an appropriately sealed cardboard box identified with the "Cytotoxic" symbol.**
  - The cardboard box should not be placed in the same rigid shipping container as other, non-hazardous drugs, so as to reduce the possibility of cross-contamination.
- **Boxes containing G1s must be clearly identified.**
  - The labelling should indicate what segregation measures have been used by the manufacturer, as well as the precautions that should be taken when opening the containers or boxes.

- **G2s should be packaged separately.**
  - Appropriate labelling must allow them to be identified easily when received.
- **G3s may be packaged separately.**
  - Appropriate labelling must allow them to be identified easily when received.
- **Manufacturers should offer drugs in blister pack form or in already reconstituted liquid form for G1s, G2s and G3s.**
- **Manufacturers should provide written confirmation that the outside surfaces of all hazardous drug containers are free of contamination. An obligation to clean the outside surfaces of hazardous drug containers should be added to the list of best manufacturing practices that apply throughout Canada.**
- **Distributors must perform regular cleaning of all hazardous drug shipping containers, and immediate cleaning if any traces of soiling are visible.**
- **Distributors should be able, on request, to provide written confirmation of the frequency at which they clean their hazardous drug shipping containers.**

2.3.3.2 Personal Protective Equipment

- **Manufacturers of chemotherapy-resistant gloves must be able to provide certification that their products comply with the most recent version of standard ASTM D6978.**
- **They must be able, on request, to provide a list of the G1 drugs tested and the protection time afforded by their chemotherapy-resistant gloves.**
- **A permeability test for hazardous drugs should be applied when procuring gowns that must provide resistance to chemotherapy.**
  - Manufacturers must be able to provide certification of the test method used.
  - Manufacturers must meet the requirements of standard ASTM F739.

2.3.4 Destruction of Hazardous Drugs

- **Procurement managers must ensure that the incineration plants that treat hazardous drug waste comply with the Quebec requirements respecting waste management.**
  - G1 cytotoxic waste and all hazardous drug residual materials (G1, G2 and G3) must be incinerated like all other drugs.
  - G1s must be incinerated at high temperature (i.e., between 800°C and 1200°C, depending on the substance in question).
- **Procurement managers must ensure that suppliers of reusable waste containers decontaminate their containers before they are put back into use, in accordance with the standards in force.**
  - Written confirmation that the outsides of these containers are free of contamination must be provided on request.

2.4 Training

- **Each health care facility must set up a hazardous drug training program for all its workers who are or could potentially be exposed to such drugs.**
  - The training program must distinguish between worker safety issues and purely clinical aspects.
  - The content of the training program must be updated annually and reviewed whenever there is a change in hazardous drugs, employee duties or assignments (WHMIS, 2015). Worker training must reflect these updates.
- **Initial training sessions must cover the following topics, at a minimum, and must be tailored to the duties/risks specific to each job category.**
  - Definition of health risks associated with hazardous drugs
  - Safe handling of potentially contaminated containers, surfaces and equipment
  - Relevant safe practices regarding:
    - Receiving hazardous drugs
    - Storing hazardous drugs
    - Identification of hazardous drugs and of locations where exposure can potentially occur
    - Preparation of hazardous drugs
    - Administering of hazardous drugs
    - Care for patients being given hazardous drugs
    - In-house transport and external transport of hazardous drugs
    - Management and transport of hazardous drug waste
    - Management of excreta from patients being given hazardous drugs
    - Hygiene and sanitation (including knowledge of hazard symbols, risks, PPE, equipment, products, surfaces, waste management and spill clean-up)
  - Preventive maintenance of infrastructure (e.g., sterile preparation room) and equipment (e.g., preparation cabinets, infusion pumps)
  - PPE use
  - Procedures in the event of spills
  - Procedures in the event of accidental exposure
  - An accidental spill simulation drill should be conducted annually. It can be integrated into the facility's emergency response program
- **Spill response employees must be given annual training.**
  - Training must include the wearing of appropriate respiratory protection and equipment fit testing.

- **The training program for all workers should include a way to assess compliance with procedures (initial and annual).**
  - Pharmacy staff who handle hazardous drugs when compounding sterile preparations must undergo an initial assessment and then annual assessments (OPQ, 2014.02).
  - Hygiene and sanitation employees performing cleaning in controlled areas of the pharmacy must undergo an initial assessment and then annual assessments (OPQ, 2014.02).
- **A record must be kept of worker attendance at training sessions.**

2.5 Risk Assessment

- **A health care facility's hazardous drug committee must conduct a risk assessment of its workers' hazardous drug occupational exposure if certain recommendations of this guide are not complied with or should be enhanced because of local factors. The purpose of the assessment is to determine what prevention measures could be implemented to achieve the same protection objectives. The assessment must take into account the quantity to be compounded and the frequency of such compounding. An assessment must be done whenever the appropriate prevention measures for a specific work situation (e.g., reprocessing of G1-soiled medical instruments) are not covered in this guide.**
  - This assessment is specific to a given facility.
  - It is to be conducted for one single dosage form at a time. G1s and the active ingredients of G1s that are not final forms should not be covered by a risk assessment for the purpose of exempting them from this guide's recommendations.
  - The assessment must be restricted to infrequent situations and small drug quantities.
  - The assessment profiles:
    - People who could potentially be exposed and the number of them
    - Drugs used (G1s, G2s, G3s), their dosage form, their packaging, their frequency of use and the quantities involved
    - How they are handled (i.e., the risk is different for the handling of a final form) in various situations
  - The assessment must be documented in writing.
  - The assessment must be reviewed if there is any change in the facility's procedures or in the list of hazardous drugs.
- **The risk assessment is to be used by the hazardous drug committee to determine the prevention measures to be implemented. The change may require different PPE to be worn, special clean-up procedures, access restrictions, etc.**

2.6 Monitoring

Different types of monitoring are possible: detection of contaminants in the work environment, on workers (e.g., hands, bodily fluids), or health effects (medical surveillance).

2.6.1 Environmental Monitoring

Environmental monitoring involves measuring the concentration of a compound in the environment, including on surfaces. It serves to determine, at a specific time, whether a surface is contaminated. It can also be used to ascertain the degree of effectiveness of a cleaning method, for instance. This is a secondary measurement for assessing a worker's probable exposure. By comparing with past measurements, a facility can determine areas where there has been improvement and those where stricter measures need to be considered.

The hazardous drug safe exposure level, where there is no effect on health, is currently unknown. The precautionary principle must therefore be applied in seeking to ensure the lowest possible level of exposure, or preferably no exposure at all, by keeping contamination of the work environment as low as possible.

A number of authors have proposed surface contamination levels that can be useful when targeting minimum exposure. These levels, which vary from one study to the next, are based on observations and not on health effects.

- **It is the committee's opinion that the environmental contamination levels targeted by health care facilities should be specific for each drug and be updated periodically. These levels should be used to identify sectors or areas where surface contamination could be reduced by searching for causes of contamination. From this perspective, the pharmacy practice research unit (URPP) team sets annual levels corresponding to the 90th percentile of the measured concentration for a given drug in Canadian health care facilities that took part in the annual program. This enables facilities to determine quickly whether one of their surfaces is much more contaminated than corresponding surfaces in the other participating facilities (> 90th percentile for a given drug, meaning in the most contaminated 10%) and to take action accordingly. This approach is dependent, however, on the performance of the group to which a facility compares itself and on the sensitivity of the detection methods used for the sample collection and assessment.**

RECOMMENDATIONS

- **Environmental monitoring activities should be carried out periodically (at least once a year), whenever major changes (e.g., in workplace design or practices) are made or whenever practices or methods are assessed.**
  - They must be conducted at least once a year, especially in oncology pharmacy areas where there is potential for contamination (OPQ, 2014.02).
  - Each facility must document the results of these activities.
    - > Under section 43 of Quebec's Regulation respecting Occupational Health and Safety, the results must be kept for at least 5 years.
  - The results and the corrective action plan must be submitted to the facility's hazardous drug committee as soon as possible.
  - All potentially exposed workers should be informed of the results and what they mean.
  - Environmental monitoring can be conducted following a standardized method through a recognized laboratory (e.g., Institut national de santé publique du Québec's toxicology centre); if it is carried out in conjunction with the URPP, the results can be compared with those from other sites.
    - > The reference values provided can help in targeting the most contaminated surfaces.
  - Monitoring should, at a minimum, target a few areas in the oncology pharmacy and wherever hazardous drugs are administered.
  - Monitoring should also, at a minimum, target a few of the facility's representative hazardous drugs, depending on available assessment resources.
  - An action plan should be drawn up for cleaning the contaminated surfaces.
    - > Additional corrective action should be taken if a surface is repeatedly found to be contaminated or if the measured concentration of the contamination exceeds expected values (e.g., change in procedure, purchase of equipment that is easier to clean, review of procedures).

2.6.2 Biological Monitoring

Biological monitoring involves measuring the concentration of a compound or its metabolite in workers' bodily fluids, usually in urine or serum. It shows whether a worker has been exposed to a compound, taking into account the various routes of exposure or the use of effective prevention measures, in contrast with environmental monitoring, which describes the contamination of the environment. Assessing the results is more complex, however, as the exact time of exposure is generally not known, with absorption and excretion varying with the compound and the individual, and bodily fluid measurements can be performed at different times.

RECOMMENDATIONS

- **Biological monitoring is not recommended, as the current state of the art does not allow conclusions to be drawn about real health risks based on the values measured. Studies to detect contaminants in bodily fluids are nevertheless useful for exploratory purposes and to help understand the effects of hazardous drugs.**

2.6.3 Medical Surveillance

Medical surveillance is "recurrent screening of a given person for the purpose of preventive follow-up action" (INSPQ). This kind of surveillance is seldom done in Quebec, unlike in the United States, where it is common to recommend periodical medical surveillance of workers exposed to hazardous drugs (NIOSH, ASHP, USP 800).

Medical surveillance includes an assessment of a worker's health status, medical (and reproductive) history and work history (USP 800). Work history includes a record of the handling of hazardous drugs (quantities and dosage forms), time spent handling and tests to track changes in possible damage to target organs (USP 800, FAQ).

However, there is no reason to believe that a physical examination and systematic screening for symptoms will allow early detection of the effects of occupational exposure to hazardous drugs.

RECOMMENDATIONS

- **Routine medical surveillance is not recommended, as the current state of the art does not allow conclusions to be drawn about real health risks.**
- **Any significant accidental exposure to hazardous drugs must be reported to the facility's OHS department and recorded in an employee's work history.**

2.7 Preventive Withdrawal

All hazardous drugs represent a health risk.

G1 and G2 drugs are considered to be hazardous for all workers and represent reproductive risks.

G3 drugs represent a reproductive risk for women and men who are actively trying to conceive, or women who are pregnant or breast feeding. They do not represent a risk for other workers.

This guide does not take a position on the preventive withdrawal of workers who are pregnant or breast feeding. It presents ways to reduce exposure if it is decided that a person will remain at work, but these ways (e.g., PPE) still need to be recognized as adequate and applicable.

In Quebec, under the Act respecting occupational health and safety (sections 40 and following), a female worker who is pregnant or breast feeding may ask to be assigned to duties that involve no physical danger to her unborn child or to the child she is breast feeding or, by reason of her pregnancy, to herself, by providing her employer with a medical certificate. The Quebec program Pour une maternité sans danger [For a safe maternity experience] (PMSD) implements women's rights under this statute. The employer must follow the recommendations made by the attending physician in the Certificate regarding the preventive withdrawal and assignment of a worker who is pregnant or breast feeding or those included in the medical-environmental report prepared by the director of public health or the physician he or she designates. These authorities must be consulted when determining whether a reassignment or preventive withdrawal is necessary.

This guide does not take a position on preventive withdrawals for workers who are trying to conceive. In Quebec, there are guidelines for the designated physicians of workers who are pregnant or breast feeding and could potentially be exposed to hazardous drugs. However, the guidelines do not cover the three groups of drugs, the different dosage forms and the types of exposure where employees handle hazardous drugs or run the risk of exposure. It would be better if the relevant criteria were specified and disseminated.

In our view, there is no justification for prohibiting workers who have been treated for cancer from going back to work. While it may be true that the drugs used to treat cancer may increase the risk of developing a new case of cancer, the degree of occupational exposure is very low compared with the doses used in cancer treatment. Nevertheless, in this type of situation, the judgment of the clinician should be heeded.

2.8 Special Measures for G3s

G3 drugs represent a reproductive risk for women and men who are actively trying to conceive, or women who are pregnant or breast feeding. They do not represent a risk to the health of other workers.

- **A number of recommendations made in this guide are aimed at curbing contamination of the environment by G3s so as to limit the possible exposure of people at risk. They must be followed by all workers in order to prevent indirect exposure of a pregnant worker.**
- **In the event that a worker who is pregnant or breast feeding stays in her job under the PMSD program:**
  - Activities involving a higher risk of occupational exposure should not be performed by pregnant workers (e.g., cleaning up a G3 spill).
  - PPE recommended for G3s must be worn by workers who are pregnant or breast feeding if they are allowed to perform the task under the terms of their preventive withdrawal.
  - The recommendations made by the attending physician and the designated physician must be followed at all times.
- **PPE recommended for G3s may be worn by all female and male workers, including those who are trying to conceive.**
  - Out of a desire to simplify protection measures, a facility may suggest that all workers wear PPE.

2.9 Closed System Drug-Transfer Devices

A closed system drug-transfer device is a "device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of the hazardous drug or vapour concentrations outside the system" (NIOSH, 2004). A number of companies make so-called "closed system devices," but there is at present no universal protocol for determining how effective they are at protecting workers.

Several studies have shown that installing them leads to a reduction in the contamination measured on surfaces in pharmacy departments, without, however, eliminating it entirely (Sessink, 2013). These studies contain a number of biases, however, including study funding provided by the device manufacturers and observation bias. A meta-analysis concluded that the studies were not of sufficient quality to determine whether the devices had a beneficial effect on workers' health (Gurusamy, 2018).

In addition, the potential benefits of closed system devices are limited to the intravenous (IV) drug preparation and administration stages, although it is well known that there are other sources of contamination, especially the outside surfaces of vials, accidental spills, cross-contamination, drugs administered other than by IV, and patient excreta. NIOSH considers closed systems to be an additional way of protecting workers from exposure to hazardous drugs (NIOSH, 2020).

However, in light of the knowledge currently available in the literature, the committee is of the opinion that no recommendation regarding closed system drug-transfer devices can be made at present. Health care facilities can conduct their own risk assessments to determine in what situations use of these devices could possibly be beneficial.

2.10 Surface and Equipment Cleaning

There is no consensus around the cleaning of surfaces that may potentially be contaminated by hazardous drugs. A wide variety of products are available, and their effect can vary with the drugs tested. No product is able to remove all traces of every drug on a given surface, although most of them are effective at removing 95% or more of the traces. The greater the number of successive cleanings of a surface, the closer the complete cleaning of that surface (Soubieux, 2020). A cleaning method that provides for several successive cleanings is to be preferred for reducing traces of hazardous drugs on surfaces. Which cleaning product to choose depends on the suspected contamination, the need to disinfect a surface or the material to be cleaned. Measures designed to limit surface contamination are all the more important precisely because total decontamination is so difficult to achieve.

2.11 Personal Protective Equipment

- **When exposure to hazardous drugs cannot be eliminated, despite the other prevention measures implemented, PPE must be worn. A ventilated cabinet (VC) must be used for drug compounding.**
- **Workers must wear PPE that is appropriate for the handling of hazardous drugs, potentially contaminated surfaces and devices, and waste and excreta from patients who have been given hazardous drugs.**
  - All workers who could potentially be exposed to G1s must wear the PPE required in Table 5 (including women who are pregnant or breast feeding).
  - All workers who could potentially be exposed to G2s must wear the PPE required in Table 6 (including women who are pregnant or breast feeding).
  - Workers who could potentially be exposed to G3s may wear the PPE required in Table 7.
- **Women who are pregnant or breast feeding must wear the PPE required in Table 7 if the task they are performing is allowed under the terms of their preventive withdrawal (see sections 2.7, 2.8 and 2.11.4.2).**
  - The associated activities and PPE are discussed in detail in the following chapters.
- **The employer must provide the required PPE, in accordance with section 51 of the Act respecting occupational health and safety. The employer may also provide PPE that ensures a greater degree of protection than what is indicated in the tables.**
- **Workers must wash their hands with soap and water before putting on PPE and after taking it off.**
  - They may also use an alcohol-based hand sanitizer to eliminate bacterial contamination before putting on gloves. As hand sanitizers do not eliminate chemical contamination, they must not be used after gloves are removed.

- **Workers must perform a visual inspection of the PPE before putting it on to make sure it is not damaged or flawed.**
- **Workers must not move around in their PPE outside of the areas where they are supposed to wear it (e.g., sterile compounding room, anteroom, treatment room).**
- **PPE that workers wear to handle G1s must be removed before they handle G2s, G3s or other drugs.**
- **Reusable PPE must be decontaminated between uses and immediately if any contamination is suspected, in accordance with the manufacturer's instructions.**
- **Disposable PPE worn for the handling of G1s must be disposed of in cytotoxic waste containers.**
- **Disposable PPE that is potentially contaminated with G2s or G3s must be disposed of in pharmaceutical waste containers.**

TABLE 5

PPE for G1 handling, by main activity

ACTIVITIES	DOSAGE FORMS	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Receiving without opening shipping containers	All	No	No	No	No
Unpacking and decontamination of containers at pharmacy	Powders and liquids	2C	C	No	Yes[a]
	Intact solids	1C	C	No	N95
Storage, activities involving contact with containers (e.g., inventory) in pharmacy	All	1C	C	No	No
Receiving and storage in care units with handling of transport containers or outsides of sealed plastic bags	All	No[b]	No	No	No
Storage in care units with handling of potentially contaminated containers (e.g., primary container)	All	1C	No	No	No
Activities in oncology support area (e.g., preparation of trays and transport containers)	All	1C	C	No	No

1C, 2C, 3C: one, two or three pairs of chemotherapy-resistant gloves compliant with standard ASTM D6978 | **C:** gown compliant with section 2.11.2 | **1R:** one pair of regular gloves | **R:** regular gown | **CR:** cartridge respirator for vapours or gases | **N95:** particulate filter respirator, at least N95 | **VC:** ventilated cabinet | **BSC:** biological safety cabinet | **IR:** intrarectal | **IV:** intravenous | **IM:** intramuscular | **Subcut:** subcutaneous | **NA:** not applicable

Table 5 • **PPE for G1 handling, by main activity –** (cont'd)

ACTIVITIES	DOSAGE FORMS	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Activities with no contact with contaminated containers (e.g., verification)	All	No	No	No	No
Sterile compounding[c]	IV, IM, subcut, intraocular, intrapleural, intrathecal, intranasal, irrigation (e.g., heated intra-abdominal), intravesical	2C	C	No[d]	No[d]
	Intravesical irrigation with BCG	1R	R	Yes, if outside BSC[e]	Yes, if outside BSC[e]
Nonsterile compounding	All (e.g., topical, otic, ophthalmic, intranasal, IR, intravaginal, powder or solution for inhalation)	2C	C	No[d]	No[d]
Simple manipulations (e.g., repackaging of tablets and capsules for individual use, pharmaceutical verification involving contact with containers)	Intact tablets or capsules	1C	No	No	No
Complex manipulations in pharmacy (e.g., cutting tablets, repackaging batches)	Tablets, oral liquids, topical forms	2C	C	No[f]	N95 (if outside VC)
Transportation of prepared drugs	All	No[b]	No	No	No
Parenteral administration	IV, IM, subcut, intraocular, intrapleural, intrathecal	2C	C	No[f]	No
	Irrigation (e.g., heated intra-abdominal), intravesical	2C or 3C	C	Yes	Yes[g] (CR for HIPEC))
	Intravesical BCG[c]	1R	R	Yes	N95
	Powder or solution for inhalation, aerosol (nebulizer)	2C	C	No[f]	N95[h]
	Topical, otic, ophthalmic, intranasal, IR, intravaginal	2C	C	No[f]	To be determined[i]
Enteral administration	Solid single dose form	1C	No	No	No
	Oral liquids, feeding tubes (repackaging, mixing, diluting, compounding)	2C	C	No[f]	No
Hygiene care, specimen collection and other care involving contact with excreta	Bodily fluids (excreta)	1C	C	No[f]	No
	BCG	1R	R	No[f]	No

1C, 2C, 3C: one, two or three pairs of chemotherapy-resistant gloves compliant with standard ASTM D6978 | **C:** gown compliant with section 2.11.2 | **1R:** one pair of regular gloves | **R:** regular gown | **CR:** cartridge respirator for vapours or gases | **N95:** particulate filter respirator, at least N95 | **VC:** ventilated cabinet | **BSC:** biological safety cabinet | **IR:** intrarectal | **IV:** intravenous | **IM:** intramuscular | **Subcut:** subcutaneous | **NA:** not applicable

Table 5 • **PPE for G1 handling, by main activity –** (cont'd)

ACTIVITIES	DOSAGE FORMS	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Care with slight or no contact with patient (auscultation, help with walking)	All	No	No	No	No
	BCG	No	No	No	No
Handling of bedding (as well as clothing) not soiled with drugs or excreta[j]	All	1R	No	No	No
	BCG	1R	No	No	No
Handling of bedding (as well as clothing) visibly soiled with drugs or excreta	All	2C	C	No[f]	Yes[g]
	BCG	1R	R	No[f]	N95
Handling of waste containers	All	1C	No[k]	No	No
	BCG	1R	No[l]	No	No
Cleaning of areas identified by "Cytotoxic" or "G1" symbol (oncology pharmacy[c], hematology-oncology clinic, patient rooms) and BCG preparation area	All	1C	C[l]	No[f]	No
	BCG	1R	R[l]	No[f]	N95
Inside cleaning of BSC[c] and VC	All	2C	C	Yes[m]	CR[n]
	BCG	1R	R	Yes[j]	No
Spill management[o]	All	2C	C	Yes[p]	Yes[g]
	BCG	1R	R	Yes[p]	N95

1C, 2C, 3C: one, two or three pairs of chemotherapy-resistant gloves compliant with standard ASTM D6978 | **C:** gown compliant with section 2.11.2 | **1R:** one pair of regular gloves | **R:** regular gown | **CR:** cartridge respirator for vapours or gases | **N95:** particulate filter respirator, at least N95 | **VC:** ventilated cabinet | **BSC:** biological safety cabinet | **IR:** intrarectal | **IV:** intravenous | **IM:** intramuscular | **Subcut:** subcutaneous | **NA:** not applicable

a: If there is local exhaust ventilation, workers should wear an N95 fitted respirator. If there is no local ventilation, they should wear a properly fitted respirator with a particulate and organic vapour filter (mask or half-mask with chemical cartridges or filter canister for organic vapours and particulates). Respirators may be worn from the time drug shipments are first unpacked until the integrity of the containers has been confirmed, to ensure worker protection in the case of broken or damaged containers. | **b:** Except if the transport container is deemed to be contaminated. | **c:** Workers must also wear a cap, a beard covering, if applicable, a surgical mask, clean, closed shoes (which may be dedicated footwear) and a pair of shoe covers for the compounding of sterile preparations and the cleaning of the clean room and anteroom. | **d:** Not required, as drug is prepared in BSC or VC. | **e:** With a closed system drug-transfer device, respiratory protection may take the form of an N95 or a cartridge respirator. | **f:** If there is a splash risk, protection is required. | **g:** Type of respirator depends on risk assessment. | **h:** In addition to other specific prevention measures. | **i:** The necessity for and type of PPE depend on the risk assessment. | **j.** Follow routine infection prevention practices. | **k:** Compliant gown must be worn if there is a risk of contact between waste container and worker's body. | **l:** Gown must be worn if there is a risk of contact with a potentially contaminated surface. | **m:** Depending on the cleaning method, but it is likely there is a splash risk. | **n:** If the person's head is inside the cabinet or if certain parts are cleaned outside it. | **o:** Shoe covers must be worn if the spill is on the ground or if there is a risk of shoes being contaminated. | **p:** Safety goggles are recommended.

TABLE 6

PPE for G2 handling, by main activity

ACTIVITIES	DOSAGE FORMS	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Receiving without opening shipping containers	All	No	No	No	No
Unpacking and decontamination of containers at pharmacy	All	1R	R	No	No
Storage, activities involving contact with containers (e.g., inventory) in pharmacy	All	1R	R	No	No
Receiving and storage in care units where there is contact with transport containers or the outsides of sealed plastic bags	All	No[a]	No	No	No
Storage in care units with handling of potentially contaminated containers (e.g., primary container)	All	1R	No	No	No
Activities in oncology support area (e.g., preparation of tray and transport containers)	All	1R	R	No	No
Activities with no contact with contaminated containers (e.g., verification)	All	No	No	No	No
Sterile compounding[b]	IV, IM, subcut, intraocular, intrapleural, intrathecal, intranasal, irrigation (e.g., heated intra-abdominal),	1R	R	No[c]	No[c]
Nonsterile compounding	All (e.g., otic, ophthalmic, powder or solution for inhalation)	1R	R	No[c]	No[c]
Simple manipulations (e.g., repackaging of tablets and capsules for individual patient use, pharmaceutical verification involving contact with containers)	Intact tablets or capsules	1R	No	No	No
Complex manipulations in pharmacy (e.g., cutting tablets, repackaging batches)	Tablets, oral liquids, topical forms	1R	R	No[d]	N95 (if outside VC)
Transportation of prepared drugs	All	No[a]	No	No	No

1R, 2R: one or two pairs of regular gloves | **R:** regular gown | **CR:** cartridge respirator for vapours or gases | **N95:** particulate filter respirator, at least N95 | **VC:** ventilated cabinet | **BSC:** biological safety cabinet | **IR:** intrarectal | **IV:** intravenous | **IM:** intramuscular | **Subcut:** subcutaneous

Table 6 • **PPE for G2 handling, by main activity –** (cont'd)

ACTIVITIES	DOSAGE FORMS	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Parenteral administration	IV, IM, subcut, intraocular, intrapleural, intrathecal	1R	R	No[d]	No
	Irrigation (e.g., heated intra-abdominal), intravesical	1R	R	Yes	Yes[e]
	Powder or solution for inhalation, aerosol (nebulizer)	1R	R	No[d]	N95[f]
	Topical, otic, ophthalmic, intranasal, IR, intravaginal	1R	R	No[d]	To be determined[g]
Enteral administration	Solid single dose form	1R	No	No	No
	Oral liquids, feeding tubes (repackaging, mixing, diluting, compounding)	1R	R	No[d]	No
Hygiene care, specimen collection and other care involving contact with excreta[h]	Bodily fluids (excreta)	1R	R	No[d]	No
Care with slight or no contact with patient (auscultation, help with walking)	All	No	No	No	No
Handling of bedding (as well as clothing) soiled or not with excreta[h]	All	1R	No	No	No
Handling of bedding (as well as clothing) visibly soiled with drugs	All	2R	R	No[d]	Yes[e]
Handling of waste containers	All	1R	No[i]	No	No
Cleaning of areas identified with "Caution" signs[b]	All	1R	R[j]	No[d]	No
Inside cleaning of BSC[b] and VC	All	1R	R	Yes[k]	CR[l]
Spill management[m]	All	2R	R	Yes[n]	Yes[e]

1R, 2R: one or two pairs of regular gloves | **R:** regular gown | **CR:** cartridge respirator for vapours or gases | **N95:** particulate filter respirator, at least N95 | **VC:** ventilated cabinet | **BSC:** biological safety cabinet | **IR:** intrarectal | **IV:** intravenous | **IM:** intramuscular | **Subcut:** subcutaneous

a: Except if the transport container is deemed to be contaminated. | **b:** Workers must also wear a cap, a beard covering, if applicable, a surgical mask, clean, closed shoes (which may be dedicated footwear) and a pair of shoe covers for the compounding of sterile preparations and the cleaning of the clean room and anteroom. | **c:** Would be required if drug is prepared outside a BSC or VC. Risk assessment required to determine type of PPE. | **d:** If splash risk, protection required. | **e:** Type of respirator depends on risk assessment. | **f:** In addition to other specific prevention measures. | **g:** Necessity for and type of PPE depend on risk assessment. | **h:** Follow routine infection prevention practices. | **i:** Regular gown must be worn if risk of contact between waste container and body. | j: Gown must be worn if risk of contact with a potentially contaminated surface. | k: Depending on cleaning method, but likely there is a splash risk. | **l:** If person's head is inside cabinet or if certain parts are cleaned outside it. | **m:** Shoe covers must be worn if spill is on ground or if risk of shoes being contaminated. | **n:** Safety goggles are recommended.

TABLE 7

PPE for G3 handling, by main activity, for women who are pregnant or breast feeding and are allowed to perform these duties under the terms of their preventive withdrawal*

ACTIVITIES	DOSAGE FORMS	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Receiving without opening shipping containers	All	No	No	No	No
Unpacking and decontamination of containers at pharmacy	All	1R	R	No	No
Storage, activities involving contact with containers (e.g., inventory) in pharmacy	All	1R	R	No	No
Receiving and storage in care units with handling of transport containers or outside of sealed plastic bags	All	No[a]	No	No	No
Storage in care units with handling of potentially contaminated containers (e.g., primary container)	All	1R	No	No	No
Activities with no contact with contaminated containers (e.g., verification)	All	No	No	No	No
Sterile compounding[b]	IV, IM, subcut, intraocular, intrapleural, intrathecal, intranasal, irrigation (e.g., heated intra-abdominal), intravesical	1R	R	No[c]	No[c]
Nonsterile compounding	All (e.g., otic, ophthalmic, powder or solution for inhalation)	1R	R	No[c]	No[c]
Simple manipulations (e.g., repackaging of tablets and capsules for individual patient use, pharmaceutical verification involving contact with containers)	Intact tablets or capsules	1R	No	No	No
Complex manipulations in pharmacy (e.g., cutting tablets, repackaging batches)	Tablets, oral liquids, topical forms	1R	R	No[d]	N95 (if outside VC)
Transportation of prepared drugs	All	No[a]	No	No	No

* PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

1R: one pair of regular gloves | **R:** regular gown | **CR:** cartridge respirator for vapours or gases | **N95:** particulate filter respirator, at least N95 | **VC:** ventilated cabinet | **BSC:** biological safety cabinet | **IR:** intrarectal | **IV:** intravenous | **IM:** intramuscular | **Subcut:** subcutaneous | **NA:** not applicable

Table 7 • **Personal protective equipment for G3 handling, by main activity, for women who are pregnant or breast feeding and are allowed to perform these duties under the terms of their preventive withdrawal* – (cont'd)**

ACTIVITIES	DOSAGE FORMS	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Parenteral administration	IV, IM, subcut, intraocular, intrapleural, intrathecal	1R	R	No[d]	No
	Irrigation (e.g., heated intra-abdominal), intravesical[a]	1R	R	Yes	Yes[e]
	Powder or solution for inhalation, aerosol (nebulizer)	1R	R	No[d]	N95[f]
	Topical, otic, ophthalmic, intranasal, IR, intravaginal	1R	R	No[d]	To be determined[g]
Enteral administration	Solid single dose form	1R	No	No	No
	Oral liquids, feeding tubes (repackaging, mixing, diluting, compounding)	1R	R	No[d]	No
Hygiene care, specimen collection and other care involving contact with excreta[h]	Bodily fluids (excreta)	1R	R	No[d]	No
Care with slight or no contact with patient (auscultation, help with walking)	All	No	No	No	No
Handling of bedding (as well as clothing) soiled or not with excreta[h]	All	1R	No	No	No
Handling of bedding (as well as clothing) visibly soiled with drugs[i]	All	NA	NA	NA	NA
Handling of waste containers	All	1R	No[j]	No	No
Cleaning of areas identified with "Caution" signs[b]	All	1R	R[k]	No[d]	No
Inside cleaning of BSC[b] and VC	All	1R	R	Yes[l]	CR[m]
Spill management[i]	All	NA	NA	NA	NA

* PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

1R: one pair of regular gloves | **R:** regular gown | **CR:** cartridge respirator for vapours or gases | **N95:** particulate filter respirator, at least N95 | **VC:** ventilated cabinet | **BSC:** biological safety cabinet | **IR:** intrarectal | **IV:** intravenous | **IM:** intramuscular | **Subcut:** subcutaneous | **NA:** not applicable

a: Except if the transport container is deemed to be contaminated. | **b:** When performing cleaning of the clean room and the anteroom, as well as when compounding sterile preparations, staff must also wear a cap, a beard covering, if applicable, a surgical mask, clean, closed shoes (which may be dedicated footwear) and a pair of shoe covers. | **c:** Would be required if drug is prepared outside a BSC or VC. Risk assessment required to determine type of PPE. | **d:** If splash risk, protection required. | **e:** Type of respirator depends on risk assessment. | **f:** In addition to other specific prevention measures. | **g:** Necessity for and type of PPE depend on risk assessment. | **h:** Follow routine infection prevention practices. | **i:** Pregnant women should not be assigned to clean up a spill, on any kind of surface, including bedding. | **j:** Regular gown must be worn if risk of contact between waste container and worker's body. | **k:** Gown must be worn if risk of contact with a potentially contaminated surface. | **l:** Depending on cleaning method, but likely there is a splash risk. | **m:** If person's head is inside cabinet or if certain parts are cleaned outside it.

2.11.1 Gloves

- **Workers must be aware that their gloves are potentially contaminated and must avoid any contact with their environment so as not to contaminate it.**
- **Gloves used to handle hazardous drugs must be powder free and made of latex, nitrile, polyurethane or neoprene.**
  - Because of its allergenic potential, latex is often ruled out in favour of gloves made of other materials.
  - Vinyl gloves are not recommended because of their greater permeability to hazardous drugs.
  - Sterile or nonsterile gloves may be worn, depending on the requirements of the procedure in question.
- **Gloves used to handle G1s must comply with the most recent version of ASTM standard D-6978 (chemotherapy gloves designated "C" for compliant). This standard includes a specific protocol for assessing resistance to certain chemotherapy solutions.**
- **Gloves worn for handling G2s and G3s must be resistant to chemicals (designated "R" for "regular") or may be compliant with the most recent version of ASTM standard D-6978 (chemotherapy gloves).**
- **Workers should change gloves every 30 minutes or less in the case of contamination, spill, failure, end of the current task or operation, or according to the requirements of the procedure.**
  - All gloves have a certain degree of permeability to hazardous drugs. This permeability increases over time: 30 minutes is a length of time that ensures protection.
    - > Manufacturers must, on request, provide the list of drugs with which the gloves have been tested and the duration of the protection.
  - When administering drugs, workers must change their gloves between patients.
- **Gloves must be long enough to cover any skin at risk of exposure.**
  - When a gown is worn, gloves must fit over the gown sleeves.
  - Gloves must be long enough to stay in place regardless of what activity is being performed and must cover the area that could potentially come into contact with the hazardous drug (e.g., up to the elbow for the administration of hyperthermic intraperitoneal chemotherapy).
- **When compounding sterile preparations.**
  - The pair of gloves in contact with the skin must be worn under the gown and must always be kept in the clean room for performing tasks outside the cabinet, such as labelling or bagging.
  - A second pair of gloves must be put on over the gown sleeves and must be removed inside the cabinet upon completion of the sterile handling.
- **In some situations where a single pair of gloves is recommended, wearing two pairs may be preferable so that the outer pair can be removed before continuing a task, to prevent possible cross-contamination (e.g., remove outer pair after installing tubing in order to program an infusion pump).**

2.11.2 Gowns

- **Gowns worn for the handling of G1 hazardous drugs (designated "C" for "compliant") must (OPQ, 2014.02) be disposable, have low permeability, as well as long sleeves with closed cuffs that are elastic or knit and must fasten in the back.**
  - Polypropylene gowns covered with polyethylene or vinyl are recommended.
  - The supplier must be able to certify that the gown protects against hazardous drugs.
- **Gowns worn for the handling of G2 and G3 hazardous drugs (designated "R" for "regular") must be disposable, have long sleeves and have low permeability to liquids.**
- **Gowns worn for compounding in the clean room must be disposed of when removed, after 3.5 consecutive hours of compounding or immediately if soiled (or suspected of being soiled) through contamination, a spill or damage.**
- **When worn for other purposes (e.g., providing care), gowns should also be disposed of when removed or immediately if soiled (or suspected of being soiled) through contamination, a spill or damage.**
  - However, if a gown is used more than once because the risk of it being soiled is virtually non-existent:
    - It must be hung up outside of traffic areas.
    - It must be left in the work area (e.g., room, clinic, pharmacy support area).
    - Steps must be taken to reduce environmental contamination to a minimum.
      - *The gown can be folded up so that the potentially contaminated part faces inside.*
      - *The potentially contaminated side of the gown can be put facing the wall on condition that the wall is washed regularly (e.g., at the same frequency as high-touch surfaces are cleaned).*
    - When taking the gown off or putting it back on, workers must be careful not to touch the "outside".

2.11.3 Face Protection

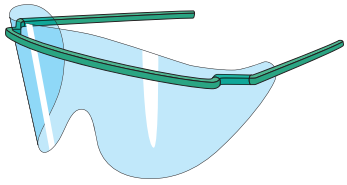
- **Face protection must be worn when there is a splash risk. Standards Z94.3.1-16 (Guideline for Selection, Use, and Care of Eye and Face Protectors) and Z94.3-2020 (Eye and Face Protectors) should be followed to be sure to choose appropriate protection.**
- **This risk is particularly acute when liquids are being handled outside a ventilated cabinet, at eye level or above, when liquid spills are being cleaned up, when tubing is being installed or removed, for instance, when providing hygiene care to an agitated patient, when administering a drug intravenously to a patient who refuses to cooperate or when there is vomiting.**
- **Face protection may be single-use (disposable) (Figure 4) or reusable.**
- **After use, face protection must be disposed of or, if it is reusable, be cleaned with water and detergent. For this task, workers must wear gloves and a protective gown.**

- **Face protection must be left in the work area (e.g., room, clinic, compounding room, anteroom).**
- **A full face shield is to be preferred to safety goggles except in some situations (e.g., liquid spill).**
  - A surgical mask that is part of the face shield provides protection against splashing, but is not to be relied on for respiratory protection.
- **Safety goggles may be used.**
  - They must meet the requirements of standard Z94.3.1-16 (*Guideline for the Selection, Use and Care of Eye and Face Protectors*).
  - When handling G1s, safety goggles must be worn along with a fluid-resistant surgical mask.
    - > A surgical mask may be worn for handling G2s and G3s.
  - Class 2B goggles are the most appropriate.
  - Goggles may be single use.
    - > They are usually models where the lens is disposable and the frame can be cleaned and used more than once (Figure 5).
  - Goggles can be washable.
    - > They must be cleaned with water and detergent after each use; gloves and a protective gown need to be worn for this task.

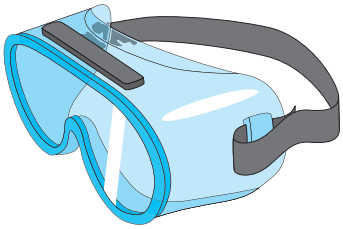
Figure 4 • **Face shield**

Disposable face shield consisting of fluid-resistant mask and attached visor

Figure 5 • **Safety goggles**



Disposable lens and reusable frame



Reusable

2.11.4 Respirators

2.11.4.1 Types of respirators

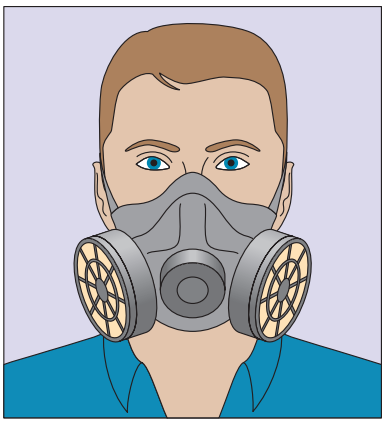
- **A respirator that meets standards must be used when there is a risk of being exposed to a hazardous drug in the air, whether in the form of solid particles, liquid particles or vapours. A surgical mask is not to be worn for the purpose of providing respiratory protection.**

- **If there is a risk of exposure to hazardous drug particles (solid or fine liquid particles), a full- or half-mask air-purifying respirator with an N95 or N100 (NIOSH approved) particulate filter must be worn.**

If there is a possibility of exposure to vapours, a respirator capable of absorbing organic vapours, combined with a particulate filter, should be worn (e.g., chemical cartridge respirator for volatile organic compounds, combined with a P100 particulate filter (P100-CC respirator) (Figure 6).

  - There are disposable models that protect against low vapour concentrations, and reusable models combined with chemical cartridges for organic vapours and a particulate filter.

Figure 6 • **Chemical cartridge respirator with particulate filter**



- **Reusable models are more expensive, but last longer. They can provide combined protection against particles, as well as organic vapours and gases. They must be inspected, cleaned after each use and stored in accordance with the manufacturer's recommendations. If there is no safe threshold level, reusable models are to be preferred.**
- **Respirator use must be covered by a facility's respiratory protection program and must include:**
  - Risk assessment
  - Choice of respirator
  - Associated training
  - Quebec's Regulation respecting Occupational Health and Safety specifies that the respiratory protection program must meet the requirements of CAN/CSA standard Z94.4-11 (sec. 45.1 of ROHS)
- **A fit test must be conducted to find the best model and size for each worker.**
  - The test must be repeated periodically in compliance with the respiratory protection program.
  - Workers who have beards are prohibited from wearing respirators.
- **Positive pressure and negative pressure seal checks must be performed by the user before each use, in accordance with the training that was given.**
- **Single-use respirators must be disposed of in accordance with the instructions given in the respiratory protection program training course.**
- **Reusable respirators must be cleaned after each use; the cleaning must be done with a wipe provided for that purpose, and gloves must be worn. Periodical cleaning with water and detergent/disinfectant is recommended. Follow the supplier's recommendations or, if there are none, follow those given in standard CSA Z94.4. Cartridges must be changed as recommended by the supplier. Replacement frequency depends on the estimated concentration of contaminants in the air and on the frequency and duration of respirator use. There is no hazardous drug exposure standard, which makes it difficult to accurately estimate cartridge service life.**

2.11.4.2 Respirator Use by Pregnant Women

Reservations have been voiced about respirator use by pregnant women. The first has to do with the need to conduct fit tests more frequently, as a woman's face changes over the course of her pregnancy. However, one recent study has concluded that it is unlikely that additional fit tests would be required during pregnancy (Roberge RJ, 2015). The second reservation concerns the additional discomfort that a pregnant woman must put up with when wearing a respirator. One study recently concluded that for pregnant women, no significant physiological change was associated with wearing an N95 respirator for one hour of effort (Roberge RJ, 2014). The decision about whether to allow a pregnant woman to perform a task while wearing a respirator is governed wholly by the terms of her preventive withdrawal and is not addressed in this guide (see section 2.7).

2.11.5 Other Equipment

- **Workers should wear a uniform when handling G1 hazardous drugs, especially liquid forms.**
  - These uniforms should be cleaned by the employer.
  - They may, however, be cleaned by the employee.
    - > They should be washed separately from regular clothing.
    - > A wash cycle with extra water and an extra rinse should be chosen, if the washing machine offers these options.
- **Personal clothing or a uniform that has been soiled significantly by G1 splashing or a G1 spill should be placed in a closed and sealed bag marked "Cytotoxic" and washed separately.**
  - Heavily soiled clothing or uniforms may be disposed of as cytotoxic waste.
- **Dedicated footwear should be worn in areas where G1s are prepared and administered in large quantities (e.g., pharmacy and oncology unit).**
- **Disposable shoe covers must be worn when required (e.g., aseptic handling, spills).**
  - They must be changed each time they are removed.
  - They should also be changed every half shift, or the equivalent of 3.5 total working hours.
  - They must be changed immediately if they are visibly soiled or if they are damaged.
  - When compounding sterile preparations in the oncology pharmacy, a pair of shoe covers could be worn in the support area and a second pair could be added on top before entering the clean room.
  - It is recommended to wear two pairs of shoe covers if, in spite of other measures taken, there is still a high splash risk.

2.11.6 Sequence for Donning and Doffing PPE

- **PPE must be put on in an order that reduces the chances of any possible microbial contamination of products.**
- **PPE must likewise be removed in a specific order that reduces the chances of any chemical contamination of the worker, prepared drug containers and the environment.**
  - Workers must be careful not to touch the outer surfaces of their gloves or gown with their bare hands.
  - Face shield, goggles and respirator must be removed by touching only the part that secures them behind the head or behind the ears, while taking care not to touch the surface and sides.
- **The general sequence for donning and doffing PPE is outlined in Table 8.**
  - Shoe covers and caps are not included, as the order depends on the situation they are worn in (e.g., one or two pairs, spill, operating room).
  - For the specific case of sterile compounding, see Chapter 3.
  - For the specific case where workers keep their gowns on but change their gloves, the procedure illustrated in Figure 7 should be followed.

TABLE 8

Correct sequence for donning and doffing personal protective equipment*

	PUTTING ON PPE
IF WEARING ONE PAIR OF GLOVES	1. Wash hands 2. Gown, if required 3. Respiratory and facial protection, if required 4. Pair of gloves (over top of gown wrist band)
IF WEARING TWO PAIRS OF GLOVES	1. Wash hands 2. Inner pair of gloves (underneath gown wrist band) 3. Gown 4. Respiratory and facial protection, if required 5. Outer pair of gloves (over top of gown wrist band)

	TAKING OFF PPE
IF WEARING ONE PAIR OF GLOVES	1. Pair of gloves 2. Face protection in room or cubicle, if wearing 3. Gown, if wearing 4. Respiratory protection outside of room or cubicle, if wearing 5. Wash hands
IF WEARING TWO PAIRS OF GLOVES	1. Outer pair of gloves 2. Face protection in room or cubicle, if wearing 3. Gown** 4. Respiratory protection outside of room or cubicle, if wearing 5. Inner pair of gloves 6. Wash hands

* Detailed instructions about the order in which to put on PPE when compounding sterile preparations in a pharmacy may be found in the Pharmacy chapter.

** After administering drugs and providing care, workers must remove their PPE in the patient's room (care unit) or cubicle (health services clinic/treatment room), except for respirators, which are to be removed outside.

Figure 7 • **Doffing gloves**

1 DOFF OUTER PAIR OF GLOVES (OVER TOP OF GOWN WRIST BAND)

Grasp hand 1's outer glove with hand 2 and remove it, touching only the outside of the glove to avoid contaminating the inner glove.

Remove hand 2's outer glove with hand 1 by touching only the inside of the glove on hand 2.

2 DOFF INNER (OR ONLY) PAIR OF GLOVES

Pull on the gloves to free them from the gown wrist bands. Touch only the outside of the gloves.

Using gloved hand 1, remove the glove from hand 2 by pulling the outside of it.

Using bare hand 2, put fingers under the wrist band of the glove on hand 1 and remove it.

2.12 Precautionary Period

- **Given that hazardous drugs may be found in patients' excreta, precautions should be taken for a minimum of 96 hours following the administration of the last dose of a drug. Based on current knowledge, we recommend following this guideline at least for G1s. In other situations (G2 or G3 excreta, or longer than 96 hours), routine practices must be followed.**
- **A risk assessment should be conducted if a health care facility wishes to modify the precautionary period (see section 1.3.3).**
  - For instance, when it is known that a drug persists in a patient's excreta for longer than 96 hours, the precautionary period can be lengthened.

3 Pharmacy

This section sets out recommendations for reducing workplace contamination and pharmacy worker exposure as much as possible. Practices must be examined locally, and measures respecting workplace organization and design, as well as safe work methods, must be implemented. This may involve updating the list of hazardous drugs, opting for safe dosage forms, moving quickly to validate the classification of a new drug, providing training to new staff, monitoring how practices have been implemented, specifying where hazardous drugs are to be received, reviewing the order in which PPE is put on and taken off and increasing the frequency at which waste is collected.

3.1 Workplace Design

3.1.1 Oncology Pharmacy (Where G1s Are Handled)

3.1.1.1 General Principles of Workplace Design

- The oncology pharmacy is the place where most G1 drugs (e.g., sterile, nonsterile, oral drugs) prepared by the health care facility for patients being treated in oncology (outpatient clinic and hematology-oncology hospitalization unit) and outside oncology (e.g., hospitalization unit, outpatient clientele) are handled. Its design must comply with strict recommendations in order to make it a safe place for all. This pharmacy may be set up as a satellite (at the hematology-oncology department) or be attached to the central pharmacy. The design requirements are the same for the two locations.
- The oncology pharmacy must include an ISO Class 7 or better clean room (sterile compounding room) and anteroom (for donning and doffing PPE and accessing the clean room), as well as other rooms and areas that can be used for drug compounding support, all in compliance with OPQ recommendations. The oncology pharmacy should be divided into several areas: receiving, unpacking and cleaning, storage area, nonsterile preparation compounding area (for hazardous and non-hazardous drugs), support area for preparation compounding and equipment required for sterile compounding, data entry area, and rooms or cupboards for storing supplies that the hygiene and sanitation team need for cleaning. One area should be set up as a changing room, with dressing cubicles when uniforms are worn, and with space where oncology pharmacy employees can store their personal effects. Note that the term "area" is being used here because, depending on the volume of activity, several different tasks may be performed inside the same room, designated as a "support area." Nevertheless, each area must be clearly delimited.

- **For nonsterile compounding in oncology, the workplace design rules proposed for the central pharmacy should be followed (see section 3.1.2.4).**
- **In situations where the oncology pharmacy is attached to the central pharmacy, the support area may be shared with non-hazardous sterile installations (e.g., centralized intravenous admixture (CIVA) services). The requirements are the same. However, premises must be organized into two areas, with a minimum of crossover in activities; one area reserved for oncology, and the other for CIVA services (separate storage cupboards, separate counters) (see section 3.1.1.7).**
- **Refer to the technical design specifications (e.g., pressure gradient values, air exchange values, materials) given in the following documents.**
  - *Aires réservées aux préparations de produits stériles - Unité de pharmacie - Répertoire des guides de planification immobilière,* Gouvernement du Québec, 2016.
  - *Préparation de produits stériles dangereux en pharmacie de l'OPQ - Norme 2014.02*.
  - *Préparations magistrales non stériles en pharmacie - Norme 2012.01, OPQ*.
- **The ventilation system must be able to manage pressure gradients between the clean room, the anteroom and the other oncology pharmacy rooms (OPQ, 2014). These gradients not only help prevent contaminants from spreading from the sterile compounding area to adjacent areas, but also curb the growth of microbial and particulate contamination in the sterile compounding area. To make it easier for pressure gradients to be maintained, the clean room and anteroom must be built to ensure an airtight seal (e.g., sealed joints, sealing of drilled holes).**
  - The support area does not have to be classified, but it should meet the air quality requirements of classification ISO 8 and have neutral pressure in relation to the rest of the pharmacy.
- **Preference should be given to workplace design features that facilitate installation cleaning, such as avoiding the creation of areas that are hard to access and the placement of furniture or equipment that has a footprint. All work surfaces where handling is performed, all ceilings, walls, floors, doors, door frames, shelves, counters and cabinets must be smooth, waterproof, free of holes, cracks and splits and be resistant to damage caused by cleaning products. All joints in the clean room and anteroom must be sealed. Joints elsewhere in the facility should also be sealed. Horizontal surfaces that serve no purpose are to be avoided.**
- **An eye-wash station must be provided. It is usually placed in the anteroom. A full emergency shower stall should also be available. It can be shared with the drug administration room by locating it close to both areas.**

3.1.1.2 Receiving, Unpacking and Cleaning Area

- **The G1 receiving, unpacking and cleaning area must be a separate area, preferably a separate room, identified by a symbol indicating that G1s are handled there.**
  - If activity volume is low, receiving, unpacking and cleaning may be performed in the support area, in a dedicated space.
    - > The facility must conduct a risk assessment to justify this workplace design.

- **The receiving, unpacking and cleaning area must be equipped with a wall-mounted extractor fan located next to the work surface.**
  - One hundred percent of the air must be exhausted to the outside, and the capture velocity must be between 50 and 100 feet per minute (ACGIH, 2007) in the handling area.
- **Where the unpacking and cleaning area is a separate room, ventilation with a negative pressure gradient and 100 percent extraction to the outside must be provided to prevent contaminants from spreading to adjacent rooms.**
- **The area must be located outside controlled areas such as the anteroom or clean room.**
- **It must provide enough space for unpacking drug shipments and placing them on a counter, and putting various supplies and equipment in storage.**
  - A waste container for G1 drugs must be available.
  - A storage space for PPE must also be available.
- **The unpacking table should not have a raised edge at the front, so as to make it easier to handle shipping containers safely.**
- **A sink, preferably a dedicated one, made of stainless steel or any other non-porous material that can withstand frequent cleaning, must be installed in the unpacking area for the cleaning of drug containers.**

3.1.1.3 Drug Storage Area

- **The storage area for G1 drugs may be located in a room separate from the rest of the oncology pharmacy.**
  - The room must have negative pressure and provide 100 percent air extraction to the outside.
  - The area can be adjacent to the support area.
  - Suitable signage must indicate that G1 drugs are found there.
- **For practical reasons, the support area may also be used for storage.**
  - Given that people work in this area, G1s must be stored in ventilated cabinets, with 100 percent of the air being exhausted to the outside.
- **Storage spaces must be clearly identified, and shelves must have raised edges to reduce the chances that drug containers could fall off and break.**
- **The refrigerators and freezers used to store G1s must be biomedical commercial appliances reserved for that purpose.**
  - The appliances must be located in a well-ventilated place in the pharmacy or, preferably, in the support area or the storage room (OPQ standard 2014.02).
  - The ceiling return air grille of the general ventilation system should be located near the appliances.
  - Suitable signage must indicate that they are being used to store G1s.
- **G2 and G3 drugs must be stored in a clearly identified area separate from non-hazardous drugs.**

3.1.1.4 Pass-Throughs

- **Pass-throughs are used to pass drugs and materials between the support area and the clean room.**
- **The pass-through dimensions must be large enough to accommodate the bins used to pass drugs and materials. Oversize doors are to be avoided because of the obstruction they create when opened (maximum size of 60 cm x 60 cm, in accordance with USP 800).**
- **Doors must be glass, must provide an airtight seal and must have a mechanism that prevents them from opening simultaneously.**
- **Pass-through ventilation is not required.**
- **Having two pass-throughs means that one can be used to bring materials in, and the other for sending them out, which helps to prevent cross-contamination.**

3.1.1.5 Anteroom

- **The anteroom is an airtight room adjacent to the clean room. It must be used to access the clean room. Positive pressure must be maintained in the anteroom, in relation to the other rooms in the oncology pharmacy.**
- **The air quality in the anteroom must be level ISO 7 or better, and 100 percent of the air must be exhausted to the outside.**
- **All of its atmospheric characteristics (temperature, humidity, pressure gradients, air movements) must be controlled.**
- **The two doors of the anteroom must be interlocked to prevent them from opening simultaneously.**
  - They must have an automatic opening mechanism, open easily, without hands being needed, and must open in the right direction.
  - The direction the doors open should help maintain airtightness with respect to the pressure gradient (opening into the anteroom for both doors).
  - The two doors should be glass.
- **The anteroom should be divided into two areas identified by a visual demarcation (line on the floor or other means).**
  - A "chemically clean" area (entrance side of the anteroom) that should be free of chemical contamination. This area is said to be "microbiologically soiled."
  - A "chemically soiled" area (clean room side of anteroom). This area is said to be "microbiologically clean."
  - The division of the two areas and the layout of supplies and equipment must be adapted to suit the order in which clothes are put on and removed, and hands are washed.

- **The anteroom must contain:**
  - Storage space for PPE
  - A wall-mounted scrub sink for washing hands and forearms, featuring a hands-free faucet
  - A soap dispenser and a paper-towel dispenser or a hands-free activated hand dryer designed to be used in a controlled area
  - A surface for putting on gloves, along with a long-acting hydroalcoholic hand sanitizer dispenser
  - An eye-wash station
  - A seat (ideally wall-mounted to facilitate floor cleaning) placed near the demarcation line between the two areas
  - A paper-towel waste container and a waste container for G1-soiled PPE
  - A mirror for people to check their PPE
  - Only supplies used for hand hygiene and donning/doffing PPE may be stored in the anteroom
- **The workplace design should allow and facilitate cleaning of all surfaces without restrictions (e.g., rounding of edges where walls, walls and ceilings, and walls and floors meet, finish that is resistant to cleaning products and alcohol, floor coverings with no joins, or else sealed joins, and that rise up where floor meets wall, no waxing, elimination of unnecessary horizontal surfaces).**

3.1.1.6 Clean Room

- **The clean room is an airtight room adjacent to the anteroom.**
  - It must be maintained in negative pressure in relation to the anteroom and the support area (confinement).
  - The air quality in the anteroom must be level ISO 7 or better, and 100 percent of the air must be exhausted to the outside.
  - All of its atmospheric characteristics (temperature, humidity, pressure gradients, air movements) must be controlled.
  - Only trained staff may have access to it, and entries and exits must be kept to a minimum.
- **Furniture in the clean room must be kept to a strict minimum:**
  - One or more BSCs
  - A hands-free camera and communication system (to allow pharmacists, for instance, to check work without having to enter and leave the compounding room)
  - Carts or mobile work surfaces
  - A station for putting on gloves
  - A section of counter near the pass-through
  - Containers reserved for G1 waste (one inside the BSC, and one outside)
- **Preparation cabinets inside clean rooms should be located far from air turbulence and high-traffic areas, especially far from doors and drafts (e.g., heating and air conditioning), while at the same time meeting manufacturers' requirements for minimum clearance. The clean room should have a minimum surface area of 8 m^2 for every 1.8 m cabinet. It is important to guarantee the required clearances around the cabinet so that the room (floor, walls, ceiling) and the outside of the cabinet can be cleaned properly.**
- **There should be a visual link (window) between the clean room and the support area.**

- **The workplace design should allow and facilitate cleaning of all surfaces without restrictions (e.g., rounding of edges where walls, walls and ceilings, and walls and floors meet, finish that is resistant to cleaning products and alcohol, floor coverings with no joins or with sealed joins and that rise up where floor meets wall, no waxing, elimination of unnecessary horizontal surfaces).**

3.1.1.7 Shared Installations

In hospitals or facilities that do not have a satellite oncology pharmacy and that do a low volume of sterile hazardous drug compounding, the support area can be shared with the sterile non-hazardous drug section (e.g., CIVA services). Regarding the concept of a shared anteroom, refer to the recommendations given in OPQ standard 2014.02.

- **Hospitals must have two separate compliant clean rooms, one for the compounding of hazardous sterile preparations, and the other for the compounding of non-hazardous sterile preparations.**
  - The anteroom and clean room specifications, set out in 3.1.1.5 and 3.1.1.6, must be applied for the compounding of hazardous sterile preparations.
  - Specifications for the compounding of non-hazardous sterile preparations must meet OPQ standard 2014.01, *Préparation de produits stériles non dangereux en pharmacie de l'OPQ*.
- **The shared support area must be divided into two separate sections, reserved for each type of preparation and set up to prevent cross-contamination (e.g., traffic areas, location of reserved areas close to clean rooms). The specifications set out in 3.1.1.1 must be applied.**

3.1.1.8 Biological Safety Cabinets (BSC)

- **Class II, Type B2 BSCs (also called vertical laminar flow hoods) equipped with protective glass must be used and preferred. This model protects the (sterile) preparation, the handler and the environment, while at the same time ensuring that 100 percent of the air is exhausted to the outside through ducts and plenums under negative pressure. A Class III isolator, sometimes called a compounding aseptic containment isolator (CACI), can also be used.**
  - The selected BSC must be adequate to keep the ISO 5 classification at all times.
  - A BSC for G1s may be used for the compounding of nonsterile preparations only on a very occasional basis or in an emergency situation (USP 800) (see section 3.2.4.2.1).
- **More than one BSC may be installed in the same clean room, provided their air flows do not interfere with each other.**
  - A BSC of another classification than B2 can, however, be installed in the clean room for non-hazardous sterile drugs intended for oncology patients.
- **BSCs must be kept running 24 hours a day, 7 days a week, in order to maintain their required sterility level, as well as negative pressure in the preparation room.**
- **The flow rate can be reduced or the glass pulled down completely outside of operating hours in the interests of energy efficiency.**
  - This mode of operation must nevertheless guarantee that air quality requirements in the cabinet and clean room are met.

3.1.1.9 Preventive Maintenance and Monitoring

- **The pharmacy department must designate a pharmacist to be in charge of the certification of the controlled areas and equipment used for sterile preparation compounding.**
- **The HEPA filters of the BSCs and the HEPA prefilters and filters of the ventilation system for the controlled areas must be replaced as soon as their efficiency drops significantly or they are contaminated by a major accidental spill. Their service life is hard to estimate. Filters should be changed by the certificating officer if the officer notices a reduction in air velocity inside the fume hood when performing the certification. Certificating officers must ensure that the filtering material, gasket and filter housing seal do not leak. The filters and prefilters must be disposed of in the cytotoxic waste.**
- **Control and alarm systems for the operating parameters of the ventilation system and the BSCs (e.g., pressure, heat and humidity monitoring) must be operational so that any necessary adjustments can be made quickly to prevent contamination of controlled areas.**
  - These parameters should be displayed on an easily accessible electronic dashboard that provides real-time and historical data.
- **Ventilated cabinets and controlled areas must be certified before they are commissioned, and subsequently every six months, or whenever ventilation work is done, the cabinet is moved, when sterility tests show lack of compliance, or when poor functioning is suspected to be the cause of the sterility noncompliance problems. For BSCs, certification must be performed by a certified technician who must conduct the required in-situ tests described in Appendix 7 to OPQ standard 2014.02. For cabinets used for nonsterile compounding, an annual inspection is required (OPQ standard 2012.01).**
- **Heating, ventilation and air-conditioning (HVAC) systems must have a high level of reliability, which requires choosing superior quality components at the design stage, ensuring redundancy of air supply and extraction systems, and implementing a robust preventive maintenance program if redundancy is not ensured, for the anteroom and the clean room.**
- **Pharmacy staff must record facility control parameter values daily (e.g., temperature, humidity, pressure gradients) obtained by means of fixed measurement instruments.**

3.1.1.10 Nonsterile Compounding Area (see section 3.1.2)

- **In a number of facilities, nonsterile preparations are made at the central pharmacy. Those compounded in oncology must meet the requirements of section 3.1.2.4.**

3.1.1.11 Hygiene and Sanitation

- **A room must be reserved, near the compounding areas, for the storage of the products, materials and equipment required for cleaning the premises.**
  - A supplementary storage space can be located in the support area.
  - Dedicated equipment is required (e.g., handle for pivoting head mop, cart).
  - Materials must be disposable (e.g., wipes, mop heads).

3.1.1.12 Initial Storage of Waste

- **At the oncology pharmacy, the storage areas for cytotoxic and pharmaceutical waste containers must be kept locked up and be identified by the appropriate symbols (see section 1.2.2).**
- **Initial storage should be done in a well-lit room that is easy to clean and that facilitates waste collection.**
- **Ventilation of the area should prevent contamination from spreading to adjacent rooms.**
  - Air should be exhausted to the outside.
- **The area should not be located near areas frequented by patients.**

3.1.2 Central Pharmacy (Areas Where G2, G3 and Certain G1 Drugs Are Handled)

Nonsterile preparations involve a wide range of handling activities, from repackaging to compounding.

The risk of environmental contamination and handler exposure varies with the complexity of the handling and the form of the drug in question. As a result, the design of work areas must be taken into consideration, and workplace design recommendations will vary depending on the type of preparation.

3.1.2.1 Receiving, Unpacking and Cleaning Area

- **All G1 drug containers must be regarded as contaminated.**
  - They should be received at the oncology pharmacy, as the containers need to be decontaminated.
    - > If certain G1s (e.g., final dosage forms for patients outside oncology) cannot be received, unpacked and cleaned at the oncology pharmacy, these operations should be performed in a dedicated area of the central pharmacy that meets the recommendations set out in section 3.1.1.2.
- **G2 and G3 containers may be received, unpacked and cleaned in a regular area of the central pharmacy.**
- **The area must provide enough space for unpacking drug shipments and placing them on a counter, and putting various supplies and equipment in storage.**
  - A waste container must be available.
  - A storage space for PPE must also be available.

3.1.2.2 Storage Area

- **Hazardous drugs (G1s, G2s, G3s) should be stored in physical locations separate from those used to store non-hazardous drugs and be clearly identified with appropriate pictograms (see section 1.2.2). They can, however, be grouped together in the same storage space, but be segregated by drug class to avoid any risks of confusion.**
- **The refrigerators and freezers used to store G1s, G2s and G3s must be biomedical commercial models and must be used solely for storing drugs.**

- Potentially volatile, non-final G1s must be stored in accordance with the conditions set out in section 3.1.1.3. They may be stored at the central pharmacy if these conditions are met. A cabinet that is ventilated, with 100 percent of the air exhausted to the outside, must be used if the storage room has workstations.
- G1 final dosage forms (e.g., oral forms that only need to be counted and repackaged, without any other handling) may be stored with the regular inventory, provided they are in a well-identified, dedicated area, following a proper risk assessment.
- Temporary storage of small quantities of G1 liquids, either in nonsterile final form, or as sterile preparations, may be tolerated at the central pharmacy. However, preparations must be segregated (e.g., placed inside the thickness of two sealed plastic bags, then put in a sealed container).
- G2s may be stored with the regular inventory, but they must be kept apart, in a dedicated, clearly identified area, following a proper risk assessment.
- G3s may be stored with the regular inventory, following a proper risk assessment. The storage area must be identified by a pictogram that clearly indicates and specifies the reproductive risk.

3.1.2.3 Sterile Compounding Installations

- Sterile G2 preparations should be compounded in installations similar to those described for sterile G1 preparations.
- Sterile G2s should be prepared in a dedicated Class II, Type B2 biological safety cabinet.
- A risk assessment must be conducted for any G2 prepared on other premises.
- The clean room and BSC reserved for the compounding of G1s may be used for G2s, provided the measures set out in section 3.2.4.1.4 are taken.
- Sterile G3s may be prepared in the regular clean room, in a standard laminar flow hood in accordance with the workplace design prescribed by the OPQ (2014.01), provided the cleaning procedures specified in section 3.2.4.1.5 for G3s are followed.
- If the stability of the preparation or the urgency of the situation makes G2 or G3 compounding impossible under the conditions set out above, it may be done outside a BSC (e.g., care unit).

3.1.2.3.1 SPECIAL CONDITIONS REGARDING BCG

- The installation requirements for preparing a solution that complies with the OPQ standard (2014.02) must be met.

3.1.2.4 Nonsterile Preparation Areas

- **The workplace design of nonsterile preparation areas must allow for a wide range of activities, from simple repackaging to compounding.**
- **The set-up must include spaces for the equipment, work surfaces and supplies used in compounding nonsterile hazardous drug preparations, which must be reserved for this handling, and a space for their cleaning and appropriate waste containers.**
- **The surfaces must be easy to clean and resistant to the cleaning products used.**

3.1.2.4.1 NONSTERILE COMPOUNDING AREA

- **When nonsterile drugs are compounded, the workplace design rules of the OPQ standard governing compounding (2012.01) must be followed. A preparation must be considered to be a category 3 compound if one of the ingredients is:**
  - A G1
  - A G2 given as an example in the category 3 compounds defined in OPQ standard 2012.01 (e.g., hormones, immunosuppressants)
  - A G3 given as an example in the category 3 compounds defined in OPQ standard 2012.01 (e.g., hormones, teratogenic drugs like retinoic acid, and abortion medications like misoprostol)
- **Compounded drugs containing another G2 hazardous drug should be handled like an OPQ category 3 preparation (see section 1.2.1).**
- **Compounded drugs containing another G3 hazardous drug should be handled like an OPQ category 1 or 2 preparation (see section 1.2.1).**
- **The workplace design of an OPQ category 3 room must in general meet the following requirements.**
  - A separate, closed, dedicated room with negative pressure in relation to adjacent rooms, and with ventilation that exhausts 100 percent of the air to the outside.
  - The room should include a sink, ideally made of stainless steel or some other non-porous material that can withstand frequent cleaning, and an eye-wash station.
  - A ventilated cabinet with a system that exhausts 100 percent of the air to the outside (chemical fume hood or Class II, Type B2 biological safety cabinet) must be available. The use of a HEPA filter does not preclude the need to exhaust 100 percent of the air to the outside. Chemical fume hoods must be inspected annually.
    - > For occasional compounding of nonsterile preparations, a VC designated for G1s or G2s may be used, provided the comprehensive cleaning operations set out in section 3.2.4.2.1 are performed.
  - A risk assessment must be conducted to decide whether the same work area reserved for G1s can be used to prepare G2s, and to determine the procedure, if necessary, like the one proposed in section 3.2.4.2.1.

- **For G3 compounding (categories 1 or 2), the workplace design must meet the following requirements:**
  - A space reserved solely for compounding (category 1)
  - In a closed, well-ventilated room that has a sink (category 2)

3.1.2.4.2 AREA FOR OTHER NONSTERILE PREPARATIONS

- **G1 or G2 preparations (such as repackaging, cutting or crushing pills) that do not involve mixing products must be done in a dedicated space (e.g., work surface), ideally close to storage areas.**
  - Simple manipulations of G1s or G2s, such as handling final dosage forms and preparations with intact forms, may also be done in the support area of the oncology pharmacy.
  - Complex manipulations (such as the repackaging of tablets into batches or large quantities) that are performed on non-intact forms or that can generate particulates, aerosols or volatile emissions (i.e., any volatile product, liquid or powder) should be done under a chemical fume hood in a closed room or an area of the pharmacy with little traffic. The room reserved for the compounding of category 3 nonsterile preparations could be used.
    - > Complex manipulations may be done in the area provided for OPQ categories 1 or 2, depending on the risk assessment.
- **G3 preparations may be done in the areas provided for the compounding of non-hazardous nonsterile preparations.**

3.1.2.5 Waste Storage

- **At the oncology pharmacy, the storage areas for cytotoxic and pharmaceutical waste containers must be kept locked up and be identified by the appropriate symbols (see section 1.2.2).**
- **Initial storage should be done in a well-lit room that is easy to clean and that facilitates waste collection.**
- **Ventilation of the area should prevent contamination from spreading to adjacent rooms.**
- **The air must be exhausted to the outside, without recirculation.**
- **The area should not be located near areas frequented by patients.**

3.2 Safe Practices

3.2.1 Receiving

3.2.1.1 Drug Selection

- **Health care facilities should make sure that their purchases reflect recommendations about hazardous drugs. If purchases are made through procurement contracts, pharmacy department heads who are members of procurement groups, or their representatives, should ensure that this advice is followed.**
- **The joint procurement group can take into account the possible outside surface contamination of hazardous drug containers when assessing bids.**
  - Manufacturers should provide written confirmation that the batches of drug containers they are selling are free of contamination. An obligation to clean the outside surfaces of hazardous drug containers should be added to the list of best manufacturing practices that apply throughout Canada.
- **The joint procurement group can prioritize hazardous drug formats that limit risks of exposure and facilitate drug preparation and administration. For this reason, priority may be given to:**
  - A product already in solution rather than a powder that must be reconstituted
  - Tablets in blister packs rather than in bottles or jars

3.2.1.2 Drug Ordering

- **Health care facilities must order G1 drugs on a separate purchase order, so as to limit contamination and facilitate drug sorting at receiving.**
  - Facilities should likewise order G2 drugs on a separate purchase order.

3.2.1.3 Taking Delivery at Receiving Dock

- **The outer shipping container for G1 drugs must be identified by the "Cytotoxic" symbol.**
- **Distributors should deliver G1 shipping containers directly to the oncology pharmacy or the central pharmacy, in accordance with the pharmacy procedure, and not leave them at the receiving dock.**
  - If the delivery is made to the receiving dock, dock employees should visually inspect the integrity of the outer shipping containers upon receipt (without opening them) and a qualified person must transport them immediately to the pharmacy department, in a cart that reduces the risks of the containers falling and breaking open and that is easy to clean.
- **The employees who take receipt of the shipping containers must be informed that they may contain a mix of G1, G2 and G3 hazardous drugs, as well as non-hazardous drugs.**

- **The shipping containers should be handled with care to avoid any chance of damage and should not be left unattended in a corridor or an unsecure space.**
- **The outside of shipping containers can be considered to be non-contaminated if the containers are not damaged.**
- **Receiving dock and supply room employees must not open shipping containers. Only pharmacy department staff are authorized to do the unpacking.**
- **When a container or its contents are damaged, the accidental spill protocol must be followed.**
  - An accidental spill kit must be kept available at the receiving dock.
  - Receiving dock employees must be given accidental spill response training.
- **Staff must not eat, drink or chew gum in a G1 receiving area.**

TABLE 9

PPE for receiving activities*

ACTIVITIES	DOSAGE FORMS	GROUP	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Receiving without opening shipping containers	All	G1 G2 G3	No No No	No No No	No No No	No No No

* PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

3.2.1.4 Receiving in Pharmacy Department

- **G1s must be delivered to the pharmacy in their shipping containers, ideally directly to the oncology pharmacy.**
- **Shipping containers must be left in the unpacking area.**
- **Storage at the pharmacy of shipping containers and cardboard from wholesalers must be kept to a minimum.**
- **Staff must not eat, drink or chew gum in an area where G1 orders are delivered to the pharmacy.**

TABLE 10

PPE for pharmacy receiving activities*

ACTIVITIES	DOSAGE FORMS	GROUP	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Receiving at the pharmacy without opening drug shipping containers	All	G1 G2 G3	No No No	No No No	No No No	No No No

* PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

3.2.2 Unpacking and Decontamination

- **Secure, easy-to-clean bins or carts should be used for in-house transportation to unpacking areas.**
- **Employees must not eat, drink or chew gum in an area where hazardous drugs are unpacked, cleaned and stored.**
- **Workers assigned to unpacking must inspect the integrity of the shipping containers and their contents at the time of unpacking.**
  - In case of damage or leaks, workers must treat the damaged containers as an accidental spill.
  - Visibly damaged containers of hazardous drugs (e.g., cardboard box containing drugs) should not be opened.
  - A damaged G1 or G2 container should never be returned to the manufacturer or distributor. The manufacturer or distributor should be notified in writing and evidence of the damage should be provided (e.g., supporting documents, photos). If the manufacturer asks for the damaged products to be returned in order to compensate the facility, it should be asked about the risks of contamination and the proper return procedure to ensure no accidental exposure occurs during shipping.
- **A fully compliant spill kit must be kept available near places where hazardous drugs are unpacked.**
- **Packaging that has no direct contact with the containers (e.g., outer cardboard, bubble packing, filler, foam) may be thrown out in the general waste if it is not soiled (e.g., no leak or damage). These materials must not be used for other purposes.**

TABLE 11

PPE for unpacking and decontamination activities*

ACTIVITIES	DOSAGE FORMS	GROUP	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Unpacking and decontamination	Powders and liquids	G1 G2 G3	2C 1R 1R	C R R	No No No	Yes[a] No No
	Intact solids	G1 G2 G3	1C 1R 1R	C R R	No No No	N95 No No

* PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

1C and 2C: one or two pairs of chemotherapy-resistant gloves compliant with standard ASTM D6978 | **C:** gown compliant with section 2.11.2 | **1R:** one pair of regular gloves | **R:** regular gown | **N95:** particulate filter respirator, at least N95.

a: If the room is equipped will local exhaust ventilation, workers should wear an N95 fitted respirator. If there is no local ventilation, they should wear a fitted respirator with a particulate and organic vapour filter (mask or half-mask with chemical cartridges or filter canister for organic vapours and particulates). A fitted respirator with a particulate and organic vapour filter (mask or half-mask with chemical cartridges or filter canister for organic vapours and particulates) may be worn for initial unpacking, until container integrity has been ascertained, to protect workers in the event of damage discovered during unpacking.

3.2.2.1 G1 Unpacking

- **G1s must be unpacked in a dedicated area of the central pharmacy or the oncology pharmacy.**
- **All containers (e.g., vials, ampoules, jars of tablets, bottles, blister packs) should be placed on a disposable, absorbent, waterproof pad on a work surface where they can be cleaned.**
- **G1 containers (e.g., vials, ampoules, jars of tablets, bottles) must be removed from their packaging or cardboard box before being put in storage.**
  - The plastic film covering some vials must not be removed; it has been added by the manufacturer to limit external contamination.
  - Cleaning may be omitted if the manufacturer guarantees the product is free of external contamination.
- **Packaging in direct contact with G1 hazardous drug containers must be regarded as hazardous drug waste and disposed of in the recommended waste container for that group of drugs (see section 3.2.9).**
- **G1 drug containers (e.g., vials, ampoules, jars of tablets, bottles, blister packs) must be cleaned before they are put in storage.**
  - If the containers cannot be cleaned for whatever reason after being unpacked (e.g., research protocol), they should be stored separately from those that have been cleaned.
    - > They must be stored in a way that limits contamination (e.g., sealed bag).
    - > In that case, they should be cleaned before they are used.
- **Cleaning should be done with a disposable cloth and a household water-and-detergent solution or with cleaning wipes.**
  - Cleaning must not damage the labelling in any way.
  - To prevent particle dispersion, it is important not to vaporize the cleaning solution.
  - A wipe used to clean a G1 should not be used again to clean another supplied item or other equipment.
    - > A wipe may be used to clean a few vials, but must be disposed of and a new wipe used to clean a new product.
- **Work surfaces must be cleaned with a water-and-detergent solution after each G1 unpacking and cleaning activity.**
  - The materials used to unpack and clean G1s and surfaces must be disposed of in cytotoxic waste containers.

3.2.2.2 G2 and G3 Unpacking

- **G2s and G3s may be unpacked at the central pharmacy, at the same place as non-hazardous drugs. No dedicated area or special set-up is required.**
- **The containers may be placed on a disposable, absorbent, waterproof pad spread out on a work surface.**
- **The containers may be left in their packaging (or cardboard box) for storage.**
- **G2 and G3 drug containers may be cleaned after they are unpacked.**

- **G2 and G3 container packaging may be disposed of in the general waste.**
- **Work surfaces must be cleaned with a water-and-detergent solution after each unpacking and cleaning activity.**

3.2.3 Storage

- **Secure, easy-to-clean bins or carts should be used for in-house transportation to storage areas.**
- **Hazardous drugs must be stored immediately after they are received, unpacked and cleaned. Note: This refers to the cleaning of containers that have not yet been used by the pharmacy.**

3.2.3.1 Storage of G1s

- **G1s must be stored in a clearly identified area separate from non-hazardous drugs, as stated in 3.1.2.1.**
  - Refrigerated storage requires a dedicated refrigeration unit.
    - > G1s may be stored in small quantities in a regular refrigerator if, after being unpacked, they are kept in a sealed plastic bag inside a sealed rigid container, in a separate, clearly identified area of the refrigerator.
- **G1s may be stored in the pharmacy's general inventory in a non-ventilated area in some situations for which a risk assessment has been conducted (e.g., commercial unit dose packaging, standard tablets for dispensing).**
  - Containers (e.g., jars, blister packs, commercial syringe packs) must have been unpacked and cleaned beforehand.
  - The storage area must be dedicated and clearly identified, and isolated from non-hazardous drugs.

3.2.3.1 Storage of G2s and G3s

- **L2s and G3s should be stored separate from non-hazardous drugs.**
  - G2s may be stored with the regular inventory, but they must be kept apart, in a dedicated, clearly identified area, following a proper risk assessment.
  - For refrigeration, they may be stored in a refrigeration unit for non-hazardous drugs, provided they are kept separate from them and placed in a clearly identified, rigid, sealed container.

3.2.4 Compounding

3.2.4.1 Compounding of Sterile Preparations

All sterile drug compounding requires the performance of support tasks before or after the actual preparation. These tasks are usually performed in the support area designated for the preparation of the products and supplies required for the compounding of sterile preparations. The set-up and work organization may vary from one facility to another. Procedures must be defined to ensure personnel and preparation safety. The PPE guidelines set out in the table may vary with local conditions.

Sterile drug compounding requires work methods that are not only free of microbial contamination, but that also ensure the protection of personnel and the work environment.

This guide does not address aseptic compounding methods that are common to both hazardous and non-hazardous drugs and focuses instead on prevention measures specific to hazardous drugs.

TABLE 12

PPE for sterile drug compounding*

ACTIVITIES	DOSAGE FORMS	GROUP	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Activities in support area	All	G1 G2 G3	1C 1R 1R	C R R	No No No	No No No
Sterile parenteral preparation[a]	All	G1 G2 G3	2C 1R 1R	C R R	No[b] No[c] No[c]	No[b] No[c] No[c]
Intravesical preparation of BCG[a]		BCG	1R	R	Yes if outside BSC[d]	Yes if outside BSC[e]
Activity with no contact with contaminated containers (e.g., inspection)	All	G1 G2 G3	No No No	No No No	No No No	No No No

*PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

1C and 2C: one or two pairs of chemotherapy-resistant gloves compliant with standard ASTM D6978 | **C:** gown compliant with section 2.11.2 | **1R:** one pair of regular gloves | **R:** regular gown | **BSC:** biological safety cabinet, or biosafety cabinet.

a: Workers must also wear a cap, a beard covering, if applicable, a surgical mask, clean, closed shoes (which may be dedicated footwear) and a pair of shoe covers for the compounding of sterile preparations and the cleaning of the clean room and anteroom. | **b:** Not required, as drug is prepared in BSC. | **c:** Required if drug is prepared outside a BSC in very exceptional circumstances. Risk assessment required to determine type of PPE. | **d:** With a closed system drug-transfer device. | **e:** With a closed system drug-transfer device. Respiratory protection may be an N95 respirator or a chemical cartridge respirator.

3.2.4.1.1 | STERILE COMPOUNDING OF G1 DRUGS

Sterile compounding procedures must meet the requirements of OPQ standard 2014.02, including those regarding employee conduct (e.g., to not chew gum, not eat or drink, and to remove jewellery). The rules set out below comply with the standard.

- **All the stages involved in compounding G1 sterile preparations must:**
  - Be performed in a clean room that meets the workplace design requirements (see section 3.1.1.6)
  - Be performed in a Class II, Type B2 BSC or in a CACI (see section 3.1.1.8)
- **The BSC must be decontaminated and deactivated in accordance with the recommendations in 3.2.11.**
- **A sterile, absorbent, waterproof pad must be spread out on the work surface to absorb any liquid contamination during handling (OPQ, 2014.02).**
  - The sterile absorbent pad must not extend onto the front and rear grilles of the BSC.
  - The pad must be changed at regular intervals not exceeding 3.5 hours of continuous work or immediately if a spill or contamination occurs.
  - It must be disposed of in a dedicated hazardous drug waste container.
- **Care must be taken to ensure return-air grilles are never blocked.**
- **Manufacturer's instructions regarding appropriate work distancing inside the cabinet must be followed.**
- **The protective glass must be lowered, in accordance with the manufacturer's recommendations.**
  - The bottom of the glass should never be higher than the handler's shoulders. In general, the height of the opening should be 20 cm.
- **The supplies required for a batch or a preparation must be grouped together to avoid creating turbulence by going in and out of the cabinet frequently.**
  - The number of G1 vials and supplies brought into the cabinet must be limited.
  - The arrangement of the supplies inside the cabinet must not block the laminar flow.
    - Accessory equipment (e.g., waste containers) must be placed on the sides of the cabinet.
    - The sterile products required for the compounding must be placed around the centre.
    - Manipulations must be performed at the centre.
  - Drugs and supplies brought into the cabinet must be free of chemical and bacterial contamination.
    - If the vials were not cleaned when they were unpacked, they should be cleaned before they are brought into the sterile compounding room, in accordance with 3.2.2.1.
    - Spraying to decontaminate or disinfect the drugs or supplies is prohibited as it will cause particle dispersion.
    - A wipe used to clean or disinfect a G1 should not be used again to clean another supplied item or other equipment.
- **Sterile preparation compounding must be performed using techniques that limit the risks of contamination or spill.**
  - The positive pressure technique is prohibited.
  - A 0.22 micron hydrophobic filter venting device must be used when transferring fluids (e.g., diluting a powder or withdrawing a solution).
  - The negative pressure technique should be used only if a venting device cannot be used.

- The volume sampled in a syringe should be corrected before the needle is removed from the vial.
- Luer-Lock syringes and other devices should be used.
- Syringes should not be filled to more than ¾ capacity.
  - > In some exceptional cases, if the method of administration requires a specific final volume, syringes may be filled to more than ¾ capacity (e.g., syringes for intravesical administration). IV bags should not be overfilled.
  - > When transferring fluid into an IV bag, employees must take care not to puncture the side of the injection port or the side of the bag.
- Ampoules and vials must be tapped gently to bring the fluid or powder down from the cap or neck.
  - > The neck of an ampoule must be disinfected with an alcohol swab before it is opened. An ampoule should be opened by holding the neck with sterile gauze to avoid any cuts.
  - > The diluent must be poured slowly over the edge of the ampoule or vial and must be shaken gently, if possible.

- **The needle should be disposed of in a rigid sharps disposal container without removing it from the syringe.**
  - The protective cap of a needle should not be put back on after a manipulation.
    - > When recapping is necessary (e.g., taking pictures to check a preparation), a protective cap holder may be used.

- **The pharmacy should prepare drugs in the administration device so that further manipulations are not required for administration.**

- **Needles should not be placed on the end of syringes when transporting them to the place where the drug will be administered.**
  - Luer-Lock protective caps should be affixed to syringes.
  - A needle may be placed in certain exceptional cases (e.g., very small volumes).
  - A closed system drug-transfer device of proven effectiveness may be used for the compounding if the dosage form permits.
    - > This is no substitute for the use of preparation cabinets or the compounding techniques recommended in the previous sections.

- **Tubing or a piercing spike for a single-tube closed-circuit connection must be installed in the pharmacy BSC, before the G1 is added to the IV solution.**
  - The use of short tubing should be preferred when possible in order to reduce the number of decontamination manipulations in the BSC.
  - The tubing may be installed after the G1 has been added to the solution if conditions make it impossible to do it beforehand (e.g., robot).

- **Air may be removed from the tubing at the pharmacy or by the nurse, depending on the risk assessment.**
  - The method chosen must limit the nurse's exposure.
  - The air must be removed from the tubing with a compatible solution.
    - > If the air cannot be removed by means of backpriming, it must be done by the pharmacy. Removing air from tubing using a G1 solution must be limited to certain exceptional cases (e.g., continuous infusions or desensitizations) and must be done by the pharmacy.

3.2.4.1.2 | BCG PREPARATION

- **The BCG solution should be prepared at the pharmacy in accordance with the organizational requirements set out in 3.1.2.3.1 and dispensed in a final dosage form.**
  - The BCG solution with a closed system drug-transfer device may be prepared outside a BSC if the worker wears an N95 respirator. A respirator with combined cartridges and P100 filter is also suitable. The strict workplace design requirements specified in 3.1.2.3.1 must be met, that is:
    - Closed room with neutral or slightly negative pressure
    - Room with very little traffic
- **No other activity may be performed simultaneously.**
- **PPE recommended for infectious risks must be worn. Compliant PPE (i.e., chemotherapy-resistant) is suitable.**

3.2.4.1.3 | ORDER FOR DONNING AND DOFFING PPE

- **The PPE procedure for the compounding of sterile preparations at the pharmacy focuses on avoiding any contact with a soiled surface before PPE is put on. The procedure must preserve PPE sterility. It may follow the order indicated here, although other similar procedures are also possible.**
  - In the first section of the anteroom (microbiologically contaminated):
    - Put on shoe covers and then place feet on the microbiologically clean side of the anteroom (adjacent to the clean room).
  - In the second section of the anteroom (microbiologically clean):
    - Sanitize hands and put on PPE in accordance with the facility's procedure.
    - Two pairs of gloves must be worn (see section 2.11.6):
      - *Lower gown sleeves over wrists of the first, inner pair of gloves.*
      - *Put on the second, outer pair of gloves over the wrists of the gown (this step may also be done in the clean room or the anteroom).*
  - In the clean room, at the end of the work session:
    - Remove the outer pair of gloves and dispose of them in the BSC's waste container.
  - In the chemically contaminated section of the anteroom:
    - Remove cap and mask by touching only the part that secures them behind the head or behind the ears, while taking care not to touch the surface and sides.
    - Remove the gown (by turning it inside out).
    - Dispose of it in a cytotoxic waste container.
    - Take off the shoe covers in the demarcated area between the microbiologically clean section and the chemically clean section, put feet one after another on the microbiologically contaminated side.
    - Take inner pair of gloves off and dispose of them in the cytotoxic waste container.
    - In the support area, wash hands with soap and water, as close as possible to the exit from the anteroom.
      - *Hand washing may be done in the anteroom, if a second sink is available there, in the microbiologically contaminated section, and if the door has an automatic opening mechanism.*

The section of the anteroom considered to be "microbiologically contaminated" is located at the entrance to the anteroom, in the part adjacent to the support area. Even if this section is "microbiologically contaminated," it is "chemically clean."

The so-called "microbiologically clean" section of the anteroom is next to the clean room. While this section is considered to be "microbiologically clean," it is regarded as "chemically contaminated."

3.2.4.1.4 | STERILE COMPOUNDING OF G2 DRUGS

- **All the stages involved in compounding G2 sterile preparations should:**
  - Be performed in a G2-dedicated Class II, Type B2 BSC or CACI (see section 3.1.2.3)
  - Be performed in a clean room that meets the workplace design requirements (see section 3.1.2.3), which can be the same room where sterile G1s are compounded
- **During compounding of G2s, employees must follow the same recommendations as for G1s (see section 3.2.4.1.1).**
- **Tubing should be installed inside the BSC at the pharmacy before the G2 is added to the IV solution; a risk assessment must be conducted before any decision about not installing the tubing at the pharmacy is made.**
  - Air may be removed from the tubing at the pharmacy or by the nurse. The method chosen must limit the nurse's exposure or the contamination of the environment.
- **G2 compounding may be done outside of a BSC under very exceptional circumstances (e.g., preparation stability constraints, urgent clinical situation). A procedure must be defined based on a risk assessment.**
- **A cabinet used for G1 compounding may be used to prepare a G2, after a risk assessment, provided complete cleaning is done in between, i.e., decontamination of all surfaces (except for the subfloor) with detergent, followed by rinsing and disinfection, before the compounding of the G2.**
  - Employees' outer gloves and the disposable waterproof absorbent pad must be changed before the compounding of the G2.
  - Any drug compounded in G1 installations may be regarded as a G1 with respect to the precautions surrounding handling (e.g., labelling, PPE).

3.2.4.1.5 | STERILE COMPOUNDING OF G3 DRUGS

- **The compounding of G3 sterile preparations may be done in a standard laminar flow hood of the centralized admixture service (CAS). If a pregnant woman uses these installations, a risk assessment must be conducted for the purposes of defining an acceptable procedure.**
  - A disposable waterproof absorbent pad must be used and then disposed of at the end of the manipulations.
  - The work surface must be thoroughly cleaned (decontamination with detergent followed by rinsing with sterile water and then disinfection) after the manipulations.
  - A dedicated cabinet may be used.
- **G3 compounding may be done outside of a BSC under very exceptional circumstances (e.g., drug stability constraints, urgent clinical situation). A risk assessment must be conducted for the purpose of defining an acceptable procedure to limit environmental contamination.**
- **Tubing may be installed inside the preparation cabinet at the pharmacy before the G3 is added to the IV solution.**

3.2.4.2 Nonsterile Preparations

Nonsterile preparations involve a wide range of manipulations, from repackaging to compounding.

- **The risk of environmental contamination and handler exposure varies with the complexity of the handling and the form of the drug in question. As a result, PPE and manipulations must be adapted to suit different situations, as specified in Tables 13 and 14.**
- **All activities other than actual drug compounding must be prohibited (e.g., food storage, eating and drinking, chewing gum, applying make-up).**

3.2.4.2.1 NONSTERILE COMPOUNDING

- **Compounding is governed by OPQ standard 2012.01, including requirements regarding employee clothing and conduct.**
  - A preparation must be considered to be a category 3 compound if one of the ingredients is:
    - A G1
    - A G2 given as an example in the category 3 compounds defined in OPQ standard 2012.01 (e.g., hormones, immunosuppressants)
    - A G3 given as an example in the category 3 compounds defined in OPQ standard 2012.01 (e.g., hormones, teratogenic drugs like retinoic acid, and abortion medications like misoprostol).
  - Compounded drugs containing another G2 hazardous drug should also be handled like an OPQ category 3 preparation (see section 1.2.1).
  - Compounded drugs containing another G3 hazardous drug should also be handled like an OPQ category 1 or 2 preparation (see section 1.2.1).

TABLE 13

PPE for nonsterile compounding activities*

ACTIVITIES	DOSAGE FORMS	GROUP	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Compounding[a]	All	G1 G2 G3	2C 1R 1R	C R R	No[b] No[c] No[c]	No[b] No[c] No[c]

* PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

1C and 2C: one or two pairs of chemotherapy-resistant gloves compliant with standard ASTM D6978. | **1R:** one pair of regular gloves. | **R:** regular gown.

a: G1s must be compounded in accordance with the conditions of OPQ category 3; G2s and G3s should also be compounded under the same conditions. | **b:** Not required, as drug is prepared in VC. | **c:** Required if drug is prepared outside a VC.

- **Compounding of G1 and G2 drugs (OPQ category 3) must be done in a closed room, in accordance with the following requirements:**
  - Inside a ventilated cabinet reserved for nonsterile G1s or G2s; certain aspects of the required design are described in 3.1.2.4.1.
  - Work methods must limit contamination of the cabinet, work surfaces, supplies and preparations, caused in particular by the use of already contaminated gloves.
  - The work surface of the cabinet must be cleaned before and after compounding.
  - Only the supplies required for a single preparation should be brought into the cabinet at a given time.
  - The preparations and the supplies must be cleaned before they are brought out of the cabinet.
  - Equipment and devices must be cleaned following compounding.
  - A disposable waterproof absorbent pad must be used.
  - Work surfaces must be decontaminated periodically, depending on the volume of compounding, as indicated in 3.2.11.
  - Waste must be disposed of in an appropriate container.
- **G3 preparations (OPQ categories 1 or 2) must be compounded to meet the following requirements:**
  - Work methods must limit contamination of work surfaces, supplies and preparations, caused in particular by the use of already contaminated gloves.
  - The supplies and equipment used must be cleaned following compounding.
  - A disposable waterproof absorbent pad must be used.
  - Waste must be disposed of in an appropriate container.
- **Nonsterile G2 preparations may be compounded in a VC used for nonsterile G1 preparations, provided the following conditions are met:**
  - All the surfaces of the cabinet must be cleaned prior to G2 compounding, i.e., decontamination with detergent and then rinsing.
  - Any drug compounded in G1 installations may be regarded as a G1 with respect to the precautions surrounding handling (e.g., labelling, PPE).
- **Compounding of nonsterile G1s may be done in the BSC for sterile G1 preparations only on a very occasional basis or in an emergency situation (USP 800), after the possibility of external compounding has been excluded. The same is true of nonsterile G2 compounding, which may occasionally be done in a BSC intended for sterile G2 preparations. The following conditions must be met:**
  - Decontamination followed by disinfection, as indicated by the monthly cleaning specifications given in 3.2.11 must be done and then, after a 30-minute waiting period, sterile production may resume.
  - If there is more than one BSC in the clean room, sterile production should be halted during occasional nonsterile production.
  - Staff must follow the sterile preparation compounding procedures, which means they must be given training on them.

3.2.4.2.2 | OTHER NONSTERILE PREPARATIONS

- **The risk of environmental contamination and handler exposure varies with the complexity of the handling and the form of the drug in question. As a result, PPE and manipulations must be adapted to suit different situations. PPE requirements are set out in Table 14.**
- **G3 preparations may be done in the areas reserved for the compounding of non-hazardous nonsterile preparations. Work methods must limit contamination of work surfaces, supplies and preparations, caused in particular by the use of already contaminated gloves. The supplies and equipment used must be cleaned after use.**

TABLE 14

PPE for preparation activities involving simple and complex manipulations*

ACTIVITIES	DOSAGE FORMS	GROUP	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Activities with no contact with contaminated containers (e.g., pharmaceutical verification)	All	G1 G2 G3	No No No	No No No	No No No	No No No
Simple manipulations (e.g., repackaging of tablets and capsules for individual use, pharmaceutical verification involving contact with containers)	Intact tablets or capsules	G1 G2 G3	1C 1R 1R	No No No	No No No	No No No
Complex manipulations (e.g., cutting tablets, repackaging in batches)	Tablets, oral liquid, topical forms	G1 G2 G3	2C 1R 1R	C R R	No[a] No[a] No[a]	N95 (if out of VC) N95 (if out of VC) N95 (if out of VC)

* PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

1C and 2C: one or two pairs of chemotherapy-resistant gloves compliant with standard ASTM D6978 | **C:** chemotherapy-resistant gown compliant with standard ASTM D6978 | **1R:** one pair of regular gloves | **R:** regular gown | **N95:** particulate filter respirator, at least N95 | **VC:** ventilated cabinet.

a: If splash risk, protection required.

Among preparations that are not the result of compounding as defined by the OPQ (2012.01), there are:

- Activities involving no contact with drugs or contaminated containers.
- Simple manipulations with intact tablets or capsules, such as the repackaging of tablets or capsules for individual patient use, pharmaceutical verification entailing contact with containers.
- Complex manipulations, including the cutting of tablets, the repackaging of tablets or capsules into batches, and the repackaging of an oral liquid or a topical form.

- **G1s must be dispensed in a final form that limits handling in care units.**
  - Tablets and capsules may be packaged in single-dose sachets manually or separately in a dedicated device (e.g., tray).
  - Half-tablets must be cut at the pharmacy.

- When a solid form is not possible, liquid forms (commercial or compounded preparations) are to be preferred, so as to avoid having to crush tablets and should be repackaged in single-dose oral syringes closed by a protective cap.
- Under very exceptional circumstances (e.g., constraints related to drug stability or urgent clinical situations), tablets may be crushed in the care unit, provided the conditions described in 4.2.3.2.1 are met.

- **G2s should be dispensed in a final form that limits the need for handling at the care unit, as described above for G1s.**

3.2.4.2.2.1 | ACTIVITIES WITH NO CONTACT WITH HAZARDOUS DRUGS OR CONTAMINATED CONTAINERS

No special personal protection measures need to be taken if there is no contact with contaminated containers. The same is true if an uncontaminated container is being handled.

3.2.4.2.2.2 | SIMPLE MANIPULATIONS OF INTACT G1 OR G2 TABLETS OR CAPSULES

No special personal protection measures need to be taken if there is no contact with contaminated containers. The same is true if an uncontaminated container is being handled.

- **Simple manipulations must be performed in a dedicated space, which can be at the central pharmacy (e.g., counter) or in the support area of the oncology pharmacy.**
- **Work methods must limit contamination of work surfaces, supplies and preparations, caused in particular by the use of already contaminated gloves.**
- **The work area must be a dedicated one, set apart from other activities.**
- **The supplies and equipment used must be dedicated for that purpose and be cleaned after use.**
- **The work area must be cleaned at the end of each manipulation.**
- **Containers must be cleaned if contamination is suspected.**

3.2.4.2.2.3 | COMPLEX MANIPULATIONS OF G1 AND G2 DRUGS

Complex manipulations include the cutting of tablets, the repackaging of tablets or capsules into batches (larger quantities) and the repackaging of an oral liquid or a topical form.

- **Complex manipulations should be performed in a ventilated cabinet (e.g., chemical fume hood) located either in an area of the pharmacy with little traffic or, ideally, in a closed room.**
  - They may be performed in another area of the pharmacy (e.g., counter), depending on the risk assessment, provided respiratory protection is used for final G1 forms and all G2 forms.
  - A ventilated cabinet reserved for nonsterile G1s may be used to compound nonsterile G2s, provided a risk assessment is conducted beforehand, in accordance with the conditions set out in 3.2.4.2.1.
  - A BSC generally used to compound sterile G1 preparations may be used to compound nonsterile G1s or G2s, provided a risk assessment is done beforehand, in accordance with the conditions set out in 3.2.4.2.1.
- **A disposable waterproof absorbent pad should be used.**

- **Work methods must limit contamination of work surfaces, supplies and preparations, caused in particular by the use of already contaminated gloves.**
- **The work surface must be cleaned before and after preparation.**
- **Only the supplies required for a single preparation should be brought into the cabinet at a given time, if applicable.**
- **The supplies and equipment used must be cleaned after each type of preparation.**
- **The preparations and the supplies must be cleaned before they are brought out of the cabinet.**

3.2.5 Automated Packaging

A variety of technological tools are used for the automated packaging of solid oral drugs. Some devices may be more sensitive than others to contamination (e.g., bagging machine as opposed to robot). The restrictions on their use for some drugs may vary, as well as the procedures for using and maintaining them. In all cases, it is important to prevent cross-contamination with hazardous drugs.

- **For G1s, automated dispensing machines must not be used for bagging.**
- **Non-intact, powdery G2 or G3 tablets or capsules must not be placed in an automated bagger, unless they have already been prepackaged (e.g., blister packs).**
  - Intact, non-powdery tablets may be bagged in automated machines if the results of the risk assessment allow it.
  - Appropriate cleaning should be performed after use.
- **A possible alternative is to use a small manual bagger that is reserved for a hazardous drug.**

3.2.6 Post-Preparation Cleaning, Packaging, Labelling and Storage

3.2.6.1 Cleaning and Packaging Following Compounding of Sterile or Nonsterile (G1 and G2) Preparations

- **Preparers working in a ventilated cabinet should clean the outer surfaces of G1 and G2 hazardous drug containers (e.g., syringes, bags of IV solution, tubing, bottles, jars) inside the cabinet.**
- **The outer pair of gloves worn for the preparation procedure must be removed inside the cabinet, if applicable, when cleaning, without contaminating the newly cleaned area.**
  - Another possible solution is to decontaminate the outer gloves using sterile water before going ahead with cleaning the preparations.
- **The primary containers must be wiped with a gauze pad that has been soaked in sterile water or a water/detergent solution.**
  - A new gauze pad should be used for each prepared dose.

- **Each hazardous drug container (e.g., syringes, bottles, bags, jars), as well as drug-administration-related materials (e.g., tubing), must be placed in a transparent, sealed plastic bag so that the nurse can easily identify them without having to take them out of the bag.**
  - Precautions must be taken to prevent contamination of the secondary container (e.g., resealable zip bag), as it will be considered to be uncontaminated and will be handled as such.
  - In the case of photosensitive drugs, a transparent bag and an opaque one should be used.
    - > A single transparent bag may be acceptable if an opaque transport container is used, provided the drug is administered quickly.
- **Hazardous and non-hazardous drugs must not be mixed together in the same plastic packaging.**
- **Plastic bags containing hazardous drugs should be placed on a work tray so that they can be moved out of the sterile compounding room via the pass-through.**
  - Transport containers used to take items to the care units must not be brought into the sterile compounding room.
- **Plastic bags containing liquid hazardous drugs should be placed in a rigid sealed transport container (e.g., tray, case), ideally opaque and properly identified.**

3.2.6.2 Labelling Following Preparation

- **The labelling of hazardous drugs must inform the people who use them about the nature of the drugs so that they can take appropriate precautionary measures (see section 1.2.2).**
  - G1s must be identified by the "Cytotoxic" symbol and the "Cytotoxic" label. BCG must be identified by the "Biohazard" symbol.
  - G2s and G3s must be identified by the "Caution" label. G3s should also be identified by the "Caution pregnancy" label.
  - The use of a symbol specific to G1s, G2s and G3s may be considered, such as the group's number inside a coloured triangle, as illustrated in this guide.
- **G2, G3 or non-hazardous drugs prepared in a G1 preparation cabinet may be labelled in the same way as G1s to indicate that PPE must be worn to handle them, because their surface may be contaminated by G1s (e.g., non-hazardous antinausea drugs prepared in a G1 cabinet for a patient being given G1s).**
- **The labelling should be done outside the cabinet while wearing the pair of gloves that is in contact with the skin.**
  - If, to reduce the chance of mistakes, the label is affixed in the preparation cabinet, it is important to make sure that cleaning and disinfection do not damage it.
- **The pharmacy department should have a warning message programmed to be displayed on the screen of the automated dispensing machines in the care units and on the medication administration records to make it easier to identify G1s, G2s and G3s.**

3.2.7 Storage of Final Dosage Forms

- **Should G1s, G2s or G3s have to be stored at the pharmacy before they are delivered, they should be stored separately from non-hazardous drugs.**
  - They may be stored with the regular inventory, but they must be kept apart, in a dedicated, clearly identified area, following a proper risk assessment.
  - They may be stored in a refrigerator for non-hazardous drugs, provided they are kept separate from the latter and placed in a rigid, sealed, clearly identified container.

3.2.8 Transport

3.2.8.1 In-house Transport

- **Anyone transporting hazardous drugs (e.g., pharmaceutical assistants, clerks, floor technicians) must be informed that the drugs are hazardous.**
- **The hazardous drugs must be placed beforehand in a closed, sealed plastic bag.**
- **Hazardous drugs bagged along with non-hazardous drugs are delivered as if they were hazardous.**
- **Separately bagged or packaged solid oral drugs may be delivered along with non-hazardous drugs.**
- **When G1s in liquid form are taken from the pharmacy to a room adjacent to the hazardous drug preparation area (e.g., care unit, outpatient clinic), they must be transported in a rigid, shock-resistant container made from a material that is easy to clean and decontaminate.**
- **When G1s in liquid form are moved from the pharmacy to a room not adjacent to the hazardous drug preparation area (e.g., care unit, outpatient clinic), they must be transported in a rigid, sealed, shock-resistant container made from a material that is easy to clean and decontaminate.**
  - The bottom of the container must be covered with an absorbent substance.
  - The container must be identified with the "Cytotoxic" hazard symbol.
  - Hazardous drug transport containers must not be used for any other purpose.
  - No detour should be made during transport.
  - Hazardous drug transport containers should be delivered to a secure location or handed to the intended recipient in person, and should not be left on a counter. A system to alert recipients that a drug has been delivered should be available or a staff member should be notified.
- **An accidental spill kit, including a written procedure, must be available.**
- **G1 and G2 transport containers must be clean, and the outsides must be free of contamination. Cleaning frequency should be tailored to how they are used. They must be cleaned immediately if traces of drugs are visible on them (e.g., leakage).**

- **G2 and G3 liquids may be transported using a non-hazardous drug delivery cart (e.g., cassettes) in a sealed bag.**
- **Mechanical transport systems that exert a force on the content (e.g., pneumatic) should not be used for the transport of G1s.**
  - Lifts may be used if the drugs are being transported in rigid containers.
  - Pneumatic transport is a possibility for non-liquid forms of G1s, provided the product is placed in a sealed container (e.g., sealed plastic bag), with the required "Cytotoxic" labelling, and delivered in a secure manner (e.g., the capsule can be retrieved by the nurse to whom the pharmacy has sent a security code granting access).
- **Pneumatic transport systems may be used for G2s and G3s, provided the required transport container is used (e.g., sealed double plastic bags for liquid forms) with proper "Caution" labelling, and is delivered in a secure manner (e.g., the capsule can be retrieved by the nurse to whom the pharmacy has sent a security code granting access).**

TABLE 15

PPE for prepared drug transport activities*

ACTIVITIES	DOSAGE FORMS	GROUP	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Transport of prepared drugs (transport container)	All	G1 G2 G3	No[a] No[a] No[a]	No No No	No No No	No No No

* PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

a: Except if the transport container is deemed to be contaminated.

3.2.8.2 External Transport

- **Anyone who transports hazardous drugs (e.g., couriers, patients or caregivers) must be informed that the drugs are hazardous. Patients must be given clear instructions for safe use (see sections 4.3, 5.3, 6.1.3 and 6.2.4).**
- **In most cases, the Transportation of Dangerous Substances Regulation does not apply to these situations.**
- **An accidental spill kit and a written procedure for handling spills should be provided if drugs are being transported in liquid form.**
- **Reusable shipping containers should be reserved for the transportation of hazardous drugs.**
  - G1 and G2 transport containers must be clean, and the outsides must be free of contamination. Cleaning frequency must be tailored to how they are used. They must be cleaned immediately if traces of drugs are visible on them (e.g., leakage).
- **Patients must not reuse hazardous drug transport containers for other household purposes, as that could expose family members to the drugs (e.g., toy boxes or sewing kits).**

- **G1s must be packed separately from other drugs.**
  - Liquid G1s must be packed in a double plastic bag and placed inside a rigid, sealed container, furnished with an absorbent substance and identified with the "Cytotoxic" hazard symbol. The drugs must be immobilized with packing material.
  - Solid G1s must be packed in a single plastic bag and placed inside a rigid container, properly identified with the "Cytotoxic" hazard symbol.
  - The "Cytotoxic" hazard symbol must be easily visible on the outside of the shipping container.

3.2.9 Waste

3.2.9.1 Waste Management – General Considerations

- **Pharmaceutical waste must be dealt with in accordance with the *Guide de gestion des déchets du réseau de la santé et des services sociaux* (2017).**
- **Production of hazardous waste must be kept to a minimum.**
- **The terms "cytotoxic waste" and "hazardous pharmaceutical waste" refer to the drug itself or any materials that come into contact with G1s (e.g., packing materials, PPE, syringes, tubing, bags, prefilters and HEPA filters, disposable wipes).**
  - The excreta of patients who have been given G1s are considered to be cytotoxic waste.
- **For G2s and G3s, the term "waste" refers to the drug itself or any materials that are visibly soiled with it. This waste must be disposed of in a pharmaceutical waste container.**
- **Cytotoxic (G1) waste must be disposed of in a compliant waste container clearly and visibly identified with the "Cytotoxic" hazard symbol or the "Chemotherapy" label.**
  - Container covers must be kept closed, except when disposing of waste.
  - Sharps waste must be placed in rigid containers with sealed covers.
  - Other waste (e.g., soft objects like tubing) and PPE may be placed in a strong red polyethylene plastic bag that is leak- and tear-resistant under expected conditions of use. For their final elimination, outside the health care facility, these bags must be placed in a rigid cardboard box, identified with the "Cytotoxic" hazard symbol, and intended for off-site transportation.
  - While the containers are awaiting pick-up, they should be closed as soon as possible by the person designated by the various departments concerned.
- **Pharmaceutical waste (G2 and G3) must be disposed of in a compliant pharmaceutical waste container clearly and visibly identified with the pharmaceutical waste symbol.**
  - Compliant containers are white, sealed and rigid or else red polyethylene plastic bags placed in a cardboard box (non-sharp, non-breakable solid waste).
  - For their final elimination, outside the health care facility, these bags must be placed in a rigid cardboard box, identified as "pharmaceutical waste," and intended for off-site transportation.
  - While the containers are awaiting pick-up, they should be closed as soon as possible by the person designated by the various departments concerned.

- **Appropriate containers must be available close to places where waste is generated, including in the unpacking/cleaning area of the oncology pharmacy, in the support area, the anteroom, the clean room (including the cabinet), the compounding area and other nonsterile preparation areas.**
- **The date the waste was generated can be indicated on the container.**
- **Any liquid hazardous drug residue must be placed in a compliant, rigid, sealed container, the bottom of which is covered with an absorbent substance.**
- **Waste should never be thrown or forced into a container.**
  - Waste containers must not be filled to more than ¾ capacity.
- **Employees must take care not to contaminate the outside of containers when putting waste in them.**
  - Also, they are not to handle containers while wearing already contaminated gloves.
- **The sewer system must never be used as a way of eliminating drugs.**

3.2.9.2 Characteristics of Waste Generated in Sterile or Nonsterile G1 and G2 Preparation Cabinets

- **When sterile and nonsterile preparations are being compounded, all waste generated in the cabinet should be disposed of in the appropriate container. The waste container must be rigid to make it easier to handle and it must be cleaned before it is removed from the preparation cabinet.**
- **Waste generated in the G1 preparation cabinet must be placed in an easy-to-clean sealed container. These containers may then be disposed of in the appropriate, properly identified waste container.**
- **A properly identified, rigid container must be used in the cabinet for liquid, sharps and breakable waste.**
  - The waste container must be closed up, sealed and decontaminated with sterile water before it is removed from the cabinet.
- **Waste generated outside the cabinet must be disposed of in the appropriate waste container placed outside the cabinet.**

3.2.9.3 Special Characteristics of BCG Waste

Non-anatomical biomedical waste includes live-strain vaccines and microorganism cultures.

- **Waste produced during BCG preparation must be managed like non-anatomical biomedical waste.**
- **It must be placed in a yellow container identified with a "Biohazard" symbol. Liquid or sharps waste must be disposed of in a puncture- and shock-resistant rigid container.**

3.2.10 Returns Management

- **The facility should agree to manage the cytotoxic waste containers that patients use at home.**
- **Returns must be destroyed, in accordance with the destruction policy in force.**

3.2.11 Cleaning

Pharmacy cleaning is performed jointly by pharmacy staff and sanitation staff. The cleaning duties of pharmacy staff are described in this section. Those of hygiene and sanitation staff are set out in Chapter 7.

Pharmacy staff can move waste from the place it is generated to the initial storage site.

TABLE 16

PPE for pharmacy staff cleaning activities*

ACTIVITIES	DOSAGE FORMS	GROUP	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Handling of waste containers	All	G1 G2 G3	1C 1R 1R	No[a] No[a] No[a]	No No No	No No No
Inside cleaning of BSC[b]	All	G1 BCG G2 G3	2C 1R 1R 1R	C R R R	Yes[c] Yes[c] Yes[c] Yes[c]	CCR[d] N95 CCR[d] CCR[d]
Inside cleaning of VC	All	G1 G2 G3	C R R	C R R	Yes[c] Yes[c] Yes[c]	CCR[d] CCR[d] CCR[d]
Work area cleaning	All	G1 G2 G3	C R R	C R R	No[e] No[e] No[e]	No No No

*PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

1C and 2C: one or two pairs of chemotherapy-resistant gloves compliant with standard ASTM D6978 | **C:** gown compliant with section 2.11.2 | **1R:** one pair of regular gloves | **R:** regular gown | **N95:** particulate filter respirator, at least N95 | **CCR:** chemical cartridge respirator for vapours or gases | **BSC:** biological safety cabinet | **VC:** ventilated cabinet (chemical).

a: A compliant (G1) or regular (BCG, G2, G3) gown must be worn if there is a risk of contact between the waste container and the body. | **b:** In addition to a cap and shoe covers for cleaning of the clean room, anteroom and BSC. | **c:** Depending on cleaning method, but likely there is a splash risk. | **d:** If person's head is inside cabinet or if certain parts are cleaned outside it. | **e:** Wear eye protection if there is a splash risk.

3.2.11.1 BSC Cleaning

3.2.11.1.1 BSC FOR COMPOUNDING OF G1 STERILE PREPARATIONS

- **The inside of BSCs in which G1s are handled must be cleaned by pharmacy staff who have been trained and certified in compliance with the requirements of OPQ standard 2014.02.**
- **Only the staff who are cleaning the cabinet should be present in the clean room while cleaning is being done. A sign may be posted outside the room to indicate that cleaning is in progress.**
- **During cleaning of the cabinet, all sterile preparation compounding activities must cease.**
- **Cleaning must be performed by trained staff from the pharmacy department.**
- **The inside of the cabinet must be cleaned using disposable low-lint wipes.**
- **The cabinet must be disinfected using disposable low-lint sterile wipes.**
- **Wipes used to clean and disinfect the cabinet must be disposed of in a cytotoxic waste container.**
- **The inside of the cabinet (i.e., work surfaces, side walls, glass screen) must be cleaned on a daily basis.**
  - At least at the start and at the end of the workday.
  - Surfaces must be decontaminated using a sterile water and detergent solution and then rinsed with sterile water (to reduce possible contamination from hazardous drugs).
  - After surfaces have been decontaminated, they must be disinfected to limit possible microbial contamination, using recommended products and following the procedures established by the facility's infection prevention and control officers.
  - Decontamination of work surfaces should be repeated if contamination is suspected or following a minor spill.
- **Complete cleaning of the cabinet, including the plenum below the work surface, must be performed on a weekly basis, by decontaminating it using sterile water and detergent, rinsing it with sterile water and then disinfecting it.**
- **A deactivation must be performed monthly or if significant contamination is suspected. It must be done following decontamination (described above). A 2.4% sodium hypochlorite solution* should be used, with a contact time of at least 10 minutes. Another chlorinated cleaning product designed for deactivating sterile preparation cabinets may be used, provided the cabinet manufacturer is contacted first to ensure the product is compatible with the surfaces to be cleaned.**
  - Afterwards, cabinet surfaces should be rinsed or neutralized with a product like sodium thiosulphate, and then disinfected.
  - Procedures must be established for using chlorine, with appropriate PPE, as chlorinated solutions are irritants and their use may require respiratory protection.
- **Equipment used inside the cabinet (e.g., filling pump, waste container holder) should be cleaned on a daily basis.**

* Recommended chlorine concentrations vary by study (e.g., 0.1%, 0.5% up to 2.4%).

- **A procedure like the one below must be followed for the removal of PPE and the cleaning and storage of respiratory protection (CR).**
  - Enter anteroom (on chemically soiled side).
  - Remove outer pair of gloves if not done in clean room.
  - Remove respirator.
  - Clean, following procedure established by respiratory protection program administrator.
  - Place dry respirator in sealed bag.
  - Remove other PPE items and sanitize hands in accordance with usual sequence.
  - Put respirator away in anteroom, support area or any other location within sterile installations.
- **In the event that ventilation of the facility stops, there must be internal procedures in place regarding requirements for infection prevention and sterile preparation compounding that can be followed. Current data are not sufficient to allow us to determine the exact procedures to put in place or the best time to implement them.**
  - In the event of an extended stoppage of the clean room ventilation or a pressure inversion, the room and equipment may have to be thoroughly cleaned, depending on the situation and the problem in question.
  - Cleaning of the inside of the preparation cabinets must also be planned.
  - If the BSC stops operating, it must be started up again and then it is important to wait 30 minutes, or the length of time recommended by the manufacturer, before proceeding with decontamination and disinfection and only then the compounding of hazardous sterile preparations.

3.2.11.1.2 BSC FOR COMPOUNDING OF BCG STERILE PREPARATIONS

- **In the case of BCG, staff must disinfect surfaces with an appropriate infection prevention and control (IPC) agent after preparation.**

3.2.11.1.3 BSC FOR COMPOUNDING OF G2 STERILE PREPARATIONS

- **Cleaning of a BSC used to compound G2s should follow the same cleaning procedures as those set out in 3.2.11.1.1.**

3.2.11.1.4 BSC FOR COMPOUNDING OF G3 STERILE PREPARATIONS

- **Cleaning of a BSC used to compound G3s must follow the cleaning procedures given in OPQ standard 2014.01.**
  - In addition, following compounding, the work surface must be cleaned with detergent and water, and then rinsed and disinfected.

3.2.11.2 Cleaning of Nonsterile Ventilated Cabinet

3.2.11.2.1 VENTILATED CABINET FOR COMPOUNDING OF NONSTERILE G1 DRUGS

- **The cleaning of the inside of ventilated cabinets in which G1s are handled must be performed by pharmacy staff.**
  - The work surface of the preparation cabinet (e.g., chemical fume hood) should be cleaned each time the type of preparation changes.
  - The equipment in the cabinet should also be cleaned with water and detergent after each work session.
  - The work surface should also be cleaned before nonsterile compounding is done.
  - Reusable equipment used for the compounding of nonsterile preparations should be wiped with disposable wipes in the cabinet before it is cleaned with detergent.
  - Reusable equipment that comes into contact with waste (e.g., waste containers, container holders) must be cleaned regularly.
- **According to the Guide de qualité de l'air (Quebec, 2011), "chemical fume hoods must be maintained periodically, in accordance with the manufacturer's recommendations. A periodical cleaning program must also be implemented, based on the conditions of use and the substances evacuated. For more information, see standard CSA Z316.5 Fume Hoods and Associated Exhaust Systems and standard ANSI/ASHRAE 110 Method of Testing Performance of Laboratory Hoods. The ANSI/ASHRAE standard sets out a procedure for testing the performance of laboratory fume hoods. The method consists of three tests: an air flow visualization test, a cross draft velocity test and, if necessary, a tracer gas leak test. Capture efficiency must be checked annually or more often if any inefficiency is noted."**

3.2.11.2.2 VENTILATED CABINET FOR COMPOUNDING OF NONSTERILE G2 DRUGS

- **Cleaning of a ventilated cabinet used to compound G2s should follow the same cleaning procedures as those set out in 3.2.11.2.1.**

3.2.11.2.3 VENTILATED CABINET FOR NONSTERILE G3 PREPARATIONS

- **For these preparations, cleaning must be done as for an area outside of the cabinet. See the following section.**

3.2.11.3 Cleaning of Work Areas Outside of the Cabinet

- **For other nonsterile preparations (e.g., nonsterile compounding of G3s, tablet counting, tablet cutting), staff must use detergent to clean the work area and equipment or instruments used for the preparation, after the G1, G2 and G3 preparation sequence.**
- **Other surfaces should be cleaned as part of regular cleaning. For example, transport trays or bins, the pass-through shelf, the clean room countertop, the oncology pharmacy support area countertop, the countertops of the compounding room for categories 1, 2 or 3 and the insides of the compartments of medication carts.**

4 Care Units
Hospitalized and Ambulatory Patients

This section presents recommendations on how to keep care unit contamination and worker exposure to a minimum. Practices must be examined locally, and organizational measures (e.g., have dedicated rooms for patients being given hazardous drugs, train new caregivers, conduct an audit of adopted practices, increase the frequency of waste collection), workplace design decisions and safe work methods (e.g., opt for oral solutions rather than crushing tablets, establish a sequence for donning and doffing PPE) must be implemented.

4.1 Workplace Design

4.1.1 Design of Workplaces Where G1s Are Administered

- **Hazardous drugs must be administered in a controlled-access setting and, ideally, in a dedicated place. Special conditions with respect to CHSLDs (long-term care centres) are set out in Chapter 5, while those regarding CLSCs (local community service centres) can be found in Chapter 6.**
- **Places where patients are treated must be identified by any method in accordance with the institution's regulations (e.g., signs placed at entrance to treatment room).**
- **Treatment rooms must have:**
  - Hand-washing stations and washrooms for staff
  - Washrooms reserved for patients
- **Treatment rooms must be divided into predetermined distinct areas so as to prevent cross-contamination. Areas may be dedicated to the following purposes:**
  - Receiving hazardous drug deliveries
  - Placing hazardous drugs near patients before administering them
  - Record-keeping activities (on paper or computerized)
  - Preparing medication
- **An area must be reserved for:**
  - Storing PPE
  - Storing hazardous and non-hazardous drugs
  - Storing replacement waste containers
  - Spill kits

- **There should be a hygiene and sanitation room nearby for storing treatment-room-dedicated cleaning supplies.**
- **The initial storage areas (in care units) for cytotoxic waste containers must be ventilated, with air exhausted to the outside, so as to prevent the spread of contamination to adjacent rooms.**
- **Materials, surfaces and furnishings must be chosen to ensure easy cleaning. Preference should be given to:**
  - Non-porous surfaces
  - No carpets and no fabric surfaces
  - Limiting the number of horizontal surfaces where dust can build up
  - Furniture with as small a footprint as possible
  - Chairs with removable parts, no seams and made of a material that stands up well to cleaning

4.1.1.1 Treatment Room Design (Ambulatory Patients)

- **The room should connect directly to the pharmacy (e.g., a pass-through may be used).**
- **Access to the treatment room should be restricted to authorized personnel, patients and a limited number of family and friends, as required.**
- **A reception desk and waiting area must be included in the workplace design.**
- **An area must be made available where staff and patients' family and friends may drink, eat, go to the washroom, rest and change into and store their work clothes.**
  - It must be located nearby, but outside of the treatment room.
- **Patients may eat and drink in the treatment room, if necessary (e.g., lengthy treatments).**
- **The treatment room should be reserved for patients being given hazardous drugs.**
  - If the room must be shared with patients who are not being given hazardous drugs, then separate areas should be reserved for them, and specific procedures should be implemented following a risk assessment (e.g., washrooms, cleaning of surfaces).
- **The treatment room must be well ventilated, with air exhausted to the outside.**
  - Neutral- or negative-pressure ventilation is required.
- **An emergency shower must be available nearby.**

4.1.1.2 Care Unit Design (Hospitalized Patients)

- **Health care facilities providing hazardous drug treatment in the care unit should set aside single rooms for patients or else group patients into cohorts.**
  - If a room must be shared with patients who are not being treated with hazardous drugs, measures to limit their exposure must be taken.
  - A risk assessment should be conducted when washrooms are shared in order to determine whether personal hygiene equipment needs to be added (e.g., a commode with a bag containing an absorbent substance for collecting and disposing of feces and urine).

- **There is currently no universal recommendation regarding air circulation in rooms used for the administration of hazardous drugs.**
  - However, a hazardous drug administered by inhalation (in aerosol form) should be administered in a room that has efficient mechanical ventilation (e.g., negative pressure, 100% of the air exhausted to the outside, adequate number of air changes per hour).

4.1.2 Design of Rooms Where G2s and G3s Are Administered

- **Rooms where G2s are administered to patients should be set up to limit contamination and risks of exposure. It is important, for instance, to provide separate spaces for G2 storage, preparation areas, easy-to-clean surfaces, space for waste containers (storage and use area) and space for PPE storage. The recommendations proposed for G1s should be considered and adapted to suit the drug administration circumstances.**
- **There are no specific requirements regarding the design of rooms where G3s are administered.**

4.2 Safe Practices

4.2.1 Receiving

TABLE 17

PPE for prepared drug transport and receiving activities*

ACTIVITIES	DOSAGE FORMS	GROUP	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Transportation of prepared drugs	All	G1 G2 G3	No[a] No[a] No[a]	No No No	No No No	No No No
Receiving in care units and handling of transport containers or outsides of sealed plastic bags	All	G1 G2 G3	No[a] No[a] No[a]	No No No	No No No	No No No

* PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

a: Except if the transport container is deemed to be contaminated.

4.2.1.1 Delivery (Reminder)

The information presented here is a reminder of some of the conditions required for transporting prepared hazardous drugs between the pharmacy and the care unit.

- **Anyone transporting hazardous drugs (e.g., pharmaceutical assistants, clerks, floor technicians) must be told the drugs are hazardous.**
- **Hazardous drugs must be in closed, sealed plastic bags.**
- **Hazardous drugs bagged along with non-hazardous drugs may be delivered as hazardous drugs.**
- **Separately bagged or packaged solid oral drugs may be delivered along with non-hazardous drugs.**
- **Liquid-form G1s taken from the pharmacy to a room adjacent to the hazardous drug preparation area (e.g., care unit, outpatient clinic) must be transported in a rigid, shock-resistant container made from a material that is easy to clean and decontaminate.**
- **Liquid-form G1s taken from the pharmacy to a room not adjacent to the hazardous drug preparation area (e.g., care unit, outpatient clinic) must be transported in a rigid, sealed, shock-resistant container made from a material that is easy to clean and decontaminate.**
  - The bottom of the container should be covered with an absorbent substance.
  - The container must be identified with the "Cytotoxic" hazard symbol.
  - Hazardous drug transport containers must not be used for any other purpose.
  - No detour should be made during transport.
  - Hazardous drug transport containers should be delivered to a secure location or handed to the intended recipient in person. They should not be left on a counter. A warning signal may be used to notify the recipient that a hazardous drug has been delivered.
- **An accidental spill kit, including a written procedure, must be available.**
- **G1 transport containers should be clean. The pharmacy should be notified if that is not the case.**
- **Liquid-form G2s and G3s placed in sealed bags may be transported using a non-hazardous drug delivery cart (e.g., cassettes).**
- **Mechanical transport systems that exert a force on the contents (e.g., pneumatic) should not be used for the transport of G1s.**
  - Lifts may be used if the drugs are being transported in rigid containers.
  - Pneumatic transport is possible for non-liquid-form G1s, provided the drug is placed in a leakproof container (e.g., plastic bag with sealed closure), with the required "Cytotoxic" labelling, and delivered in a secure manner (e.g., the capsule can be retrieved by the nurse to whom the pharmacy has sent a security code granting access).
- **Pneumatic transport systems may be used for G2s and G3s, provided the required transport container is used (e.g., double plastic bags with sealed closures for liquid forms) with proper "Caution" labelling, and is delivered in a secure manner (e.g., the capsule can be retrieved by the nurse to whom the pharmacy has sent a security code granting access).**

4.2.1.2 External Transport Overseen by Care Units

- **For transportation outside of the hospital setting, the patient, their caregivers or the courier service must be notified that they are transporting hazardous drugs.**
- **Reusable shipping containers should be reserved for the transportation of hazardous drugs.**
  - G1 and G2 transport containers must be clean, and the outsides must be free of contamination. Cleaning frequency must be tailored to how the containers are used. They must be cleaned immediately if traces of drugs are visible on them (e.g., leakage).
- **Nursing staff who hand hazardous drugs over to patients for in-home administration must make sure that the drug packaging meets the requirements for safe external transportation.**
- **Nursing staff must also educate patients and others appropriately about spill risks and management, as well as about appropriate in-home storage.**
- **An accidental spill kit and a written procedure for handling spills should be provided if drugs are being transported in liquid form.**
- **Patients must not reuse hazardous drug transport containers for other household purposes (e.g., toy boxes or sewing kits), as that could expose family members to the drugs.**
- **G1s must be packaged separately from other drugs.**
  - Liquid-form G1s must be packaged in a double plastic bag and placed inside a rigid, leakproof container, furnished with an absorbent substance and identified with the "Cytotoxic" hazard symbol. The drugs must be immobilized with packing materials.
  - Solid-form G1s must be packaged in a single plastic bag placed inside a rigid container, properly identified with the "Cytotoxic" hazard symbol.
  - The "Cytotoxic" hazard symbol must be easily visible on the outside of the shipping container.
- **Liquid-form G2s should be packaged in a double leakproof plastic bag, placed inside a sealed, rigid container, furnished with an absorbent substance, and identified with the "Caution" hazard symbol. The drugs must be immobilized with packing materials.**
- **Solid-form G2s should be packaged in a single plastic bag and placed inside a rigid container, properly identified with the "Caution" hazard symbol.**
- **The "Caution" hazard symbol should be easily visible on the outside of the shipping container.**
- **G3s may be delivered in the same way as non-hazardous drugs. They should be labelled with the "Caution pregnancy" hazard symbol.**

4.2.1.3 Packaging and Labelling (Reminder)

The information presented here is a reminder of certain conditions required for the packaging and labelling of hazardous drugs by the pharmacy. Details are given in Chapter 3.

- **Each hazardous drug container (e.g., syringes, bags) must be received in a transparent, sealed plastic bag so that the drugs can be easily identified without removing them from the bag.**
  - Photosensitive drugs must be delivered and stored in opaque bags.
  - A second sealed, transparent bag should be used.
  - Drugs in liquid form administered by needle or that will be used outside of the care unit (planned external transportation) must be packaged in a double plastic bag, as the risk of a spill is higher.
- **Hazardous and non-hazardous drugs must not be put in the same plastic packaging.**
- **The labelling of hazardous drugs must inform the people who use them about the nature of the drugs so that they can take appropriate precautionary measures.**
- **Patients and their family members must be taught how to handle their hazardous drugs safely.**
- **G1s must be identified with the "Cytotoxic" symbol and the "Cytotoxic" label.**
  - BCG must be identified with the "Biohazard" symbol.
- **G2s and G3s must be identified with the "Caution" label. G3s should also be distinctly labelled "Caution pregnancy".**
- **The use of a symbol specific to G1s, G2s and G3s may be considered, such as the group's number inside a coloured triangle, as illustrated in this guide.**

4.2.1.4 Transfer to Nursing Staff

- **If precautions have been taken to prevent contamination of the transport container (e.g., resealable zip bag, case), the transport container may be considered to be non-contaminated and handled without PPE.**
- **Only authorized staff should be allowed to receive hazardous drugs.**
- **Hazardous drugs must be delivered to a secure location or handed to the intended recipient in person.**
  - They must not simply be left on a counter.
- **A system to alert staff that a hazardous drug has been delivered should be available so that it can quickly be put in storage.**
- **When the hazardous drug is received, the drug container must be examined without removing the drug from its sealed plastic bag, and then it must be stored appropriately, if necessary.**
  - In the event of a leak, the spill response procedure must be followed.

4.2.2 Storage

- **Secure, easy-to-clean bins or carts should be used for in-house transportation to storage areas.**
- **Hazardous drugs must be stored immediately after they are received.**
- **A spill kit must be available near the storage area.**
- **G1 and G2 drugs must be stored in a clearly identified area separate from non-hazardous drugs.**
- **G3s may be stored according to the same criteria as for G2s, so that the reproductive risk can be better identified and controlled.**

TABLE 18

PPE for storage activities performed by health care staff*

ACTIVITIES	DOSAGE FORMS	GROUP	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Storage in care units with handling of potentially contaminated containers (e.g., primary container)	All	G1 G2 G3	1C 1R 1R	No No No	No No No	No No No

* PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

1C: one pair of chemotherapy-resistant gloves compliant with standard ASTM D6978 | **1R:** one pair of regular gloves.

4.2.2.1 G1 Storage

- **G1s must be stored so as to limit the possibility of cross-contamination.**
  - They should be stored in an area separate from the one where non-hazardous drugs are stored and which is clearly identified as an area reserved for hazardous drugs (e.g., dedicated fridge, shelf identified as being reserved for G1s in the storage unit).
  - Solid-form G1s (e.g., tablets, capsules) may be stored with a patient's other medications, provided the packaging is deemed to be non-contaminated (e.g., single-dose cart).
  - Small quantities of liquid-form G1s may be stored in a regular refrigerator, provided they are placed in a separate part of the fridge that is identified as being reserved for hazardous drugs. They must be kept in a sealed plastic bag, which is then placed in a closed, leakproof rigid container.
  - The other G1 dosage forms (e.g., syringes, multiple-use topical medication containers) must be stored in the same packaging they are delivered in (sealed plastic bag) and identified with the patient's name.

4.2.2.2 G2 Storage

- **G2s must be stored so as to limit the possibility of cross-contamination.**
  - They should be stored in an area separate from non-hazardous drugs and be clearly identified with the "Caution" label (e.g., dedicated refrigerator or shelf identified as being reserved for G2s in the storage unit).
  - Solid oral forms packaged with a bagging machine, whether automated or not, may be stored with a patient's other medications (e.g., drug cart) or in an automated cabinet.
  - G2s may be stored in a regular refrigerator, provided they are kept in a closed, sealed, rigid container identified as being reserved for hazardous drugs.
  - Other G2 dosage forms (e.g., syringes, multiple-use topical medication containers) must be stored in the same packaging they are delivered in (sealed plastic bag) and identified with the patient's name.

4.2.2.3 G3 Storage

- **G3s may be stored according to the same criteria as for G2s, so that the reproductive risk can be identified and controlled.**

4.2.3 Preparation by a Nurse

Note that the term "preparation" here refers to the steps that must be taken before the drug can actually be administered. This may include setting up an IV solution, preparing a syringe or opening a packet of pills. Where preparation ends and actual administration begins can be a thin line. The PPE to be worn for preparation is generally the same as for administration.

The parenteral route refers to all modes of administration in which the drug enters the body via a route other than the digestive tract (e.g., intramuscular [IM], subcutaneous [Subcut], intravenous [IV], intrathecal or intra-arterial).

The enteral route covers all modes of administration in which the drug passes through the digestive tract (e.g., oral, sublingual or nasogastric).

- **The drugs should be prepared at the pharmacy. They may be prepared in part in the room where the drug will be administered to the patient. The decision must be based on a risk assessment by the health care facility. The assessment must take a number of factors into account, including the route of administration, the dosage form of the drug (e.g., solid, liquid) and the hazardous drug group in question.**
- **Secure connection systems (e.g., Luer-Lock, ENFit) should be used for parenteral drugs to ensure a better seal at connection sites.**
- **Syringes must not be filled to more than ¾ capacity. Syringes supplied by the pharmacy must include a device that prevents accidental leakage during transport (e.g., Luer-Lock tip).**
- **Nurses must prepare drugs in an area that is not used for any other activity (e.g., food storage, eating, drinking, applying make-up).**

4.2.3.1 Preparation – Parenteral Route

TABLE 19

PPE for parenteral dosage form preparation activities*

ACTIVITIES	DOSAGE FORMS	GROUP	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Preparation	Parenteral	G1[a] BCG G2[c] G3[c]	2C 1R 1R 1R	C R R R	No Yes[b] Yes Yes	No N95[b] Yes Yes

* PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

2C: two pairs of chemotherapy-resistant gloves compliant with standard ASTM D6978 | **C:** gown compliant with section 2.11.2 | **1R:** one pair of regular gloves | **R:** regular gown | **N95:** particulate filter mask, at least N95..

a: These items of PPE are recommended for preparations that are ready to be administered or for backpriming. | **b:** With a closed system drug transfer device. | **c:** Gloves and a gown are recommended for preparations that are ready to be administered or for backpriming. If tubing has to be set up (under exceptional circumstances), respiratory and face protection is recommended.

4.2.3.1.1 PREPARATION OF G1 DRUGS – INTRAVENOUS ROUTE

- **Spiking must be done at the pharmacy.**
- **Priming should also be done at the pharmacy.**
- **Priming of tubing may be performed by a nurse, depending on the risk assessment.**
  - The nurse must backprime to remove air from the tubing that will be used to administer a G1 drug (see technique A, Figure 8).
  - Backpriming must be performed with a compatible solution.
  - If backpriming cannot be performed, the tubing must be primed by the pharmacy.
- **Using a G1 solution to prime tubing must be restricted to certain exceptional cases (e.g., continuous infusions or desensitizations) and must be done by the pharmacy.**

4.2.3.1.2 PREPARATION OF G2 AND G3 DRUGS – INTRAVENOUS ROUTE

- **G2 drugs should be prepared at the pharmacy.**
- **Spiking a G2 container should be done at the pharmacy.**
- **Under very exceptional circumstances (e.g., constraints related to drug stability or urgent clinical situations), G2s and G3s may, as a last resort, be prepared outside a BSC following a risk assessment, provided the following criteria are met:**
  - The task must be performed in a segregated area, well away from traffic, on a disposable waterproof absorbent pad.
  - Appropriate PPE must be worn.
  - The hazardous drug must be prepared as close as possible to the drug administration time.
  - A closed system drug-transfer device may be used.
  - The work area must be decontaminated with detergent at the end of each preparation.

- **Three techniques may be used for these intravenous preparations:**
  - If the tubing was inserted at the pharmacy without being primed (acceptable for a G1, a G2 or a G3), backpriming must be performed (see technique A, Figure 8).
  - If the tubing was not inserted at the pharmacy (acceptable for a G2 or a G3), priming must be done with a compatible solution, and the tubing inserted, using technique B (see Figure 9).
  - If the tubing was not inserted at the pharmacy and the drug is provided in a syringe (acceptable for a G3), the tubing must be inserted and primed with a compatible solution, and then the G3 injected into the bag using technique C (see Figure 10).

4.2.3.1.3 PREPARATION OF G1, G2 AND G3 DRUGS – SUBCUTANEOUS, INTRAMUSCULAR, INTRADERMAL OR OPHTHALMIC INJECTION

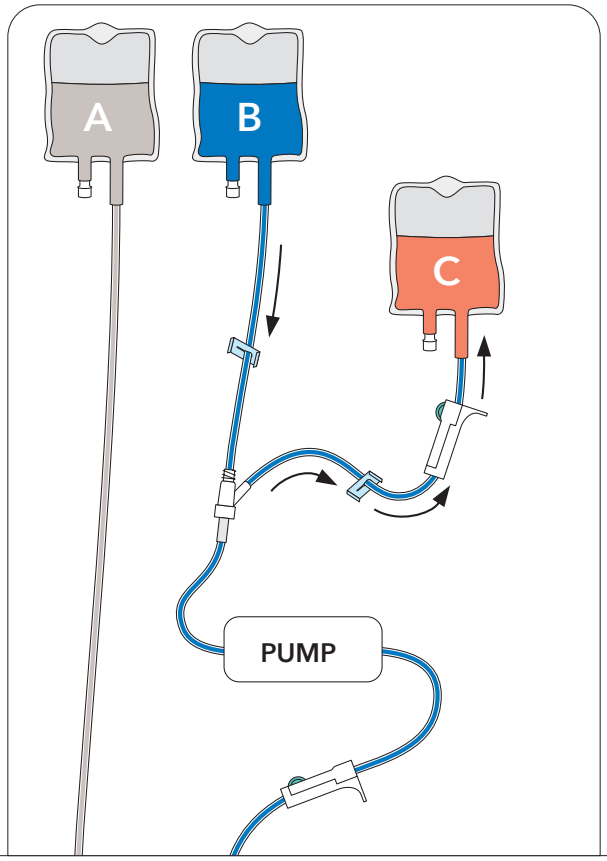
- **G1s must be prepared at the pharmacy and dispensed in their final dosage form ready to be administered, so as to limit the handling required in the administration room.**
- **G2s and G3s should be prepared at the pharmacy.**
- **G1, G2 and G3 syringes must be supplied with an appropriate protective cap (e.g., Luer-Lock) on the tip.**
  - A safety needle should be used to administer the drug.
  - Syringes used to administer small amounts (e.g., pediatric doses, cutaneous allergy tests) may be supplied with a needle.
- **A disposable waterproof absorbent pad must be placed on the work surface when connecting a needle to a G1 or G2 syringe.**
- **Air should never be expelled from a G1 or G2 syringe.**
  - Under exceptional circumstances, air can, as a last resort (e.g., ophthalmology procedure where bubbles can be harmful), be expelled, provided the following criteria are met:
    - > Appropriate PPE is worn.
    - > Air explusion is done in a segregated area, well away from traffic, on a sterile gauze pad placed on top of a disposable waterproof absorbent pad.
    - > Air expulsion is done as close as possible to the drug administration time.
    - > The work area is decontaminated with detergent at the end of the procedure.
- **Under very exceptional circumstances (e.g., constraints related to drug stability or urgent clinical situations), G2s and G3s may, as a last resort, be prepared in a care unit, following a risk assessment that takes a number of factors into account, including:**
  - A closed system drug-transfer device may be used.
  - The task must be performed in a segregated area, well away from traffic, on a disposable waterproof absorbent pad.
  - Appropriate PPE must be worn.
  - The preparation must be done as close as possible to the drug administration time.

TECHNIQUE A

BACKPRIMING (RETROGRADE TECHNIQUE) – G1, G2 OR G3 CONTAINER
FOR WHICH THE TUBING WAS INSERTED BY THE PHARMACY

- Place a disposable waterproof absorbent pad below the work area and work at waist height.
- Check that the roller clamp on the primary tubing and the one on the secondary tubing (which will be used to administer the hazardous drug) are closed.
- There must not be any anti-free-flow valves on the secondary tubing.
- Connect the secondary tubing to the Y-site of the primary tubing.
- Lower the hazardous drug container below the level of the primary infusion container to allow a sufficient amount of the primary solution to reach the hazardous drug container.
- Open the roller clamp on the secondary tubing.
- Close the roller clamp when the air has been expelled from the secondary tubing and the drip chamber is 2/3 full.
- Hang the hazardous drug container on the IV pole and proceed with administration.

Figure 8 • **Backpriming (retrograde technique)**



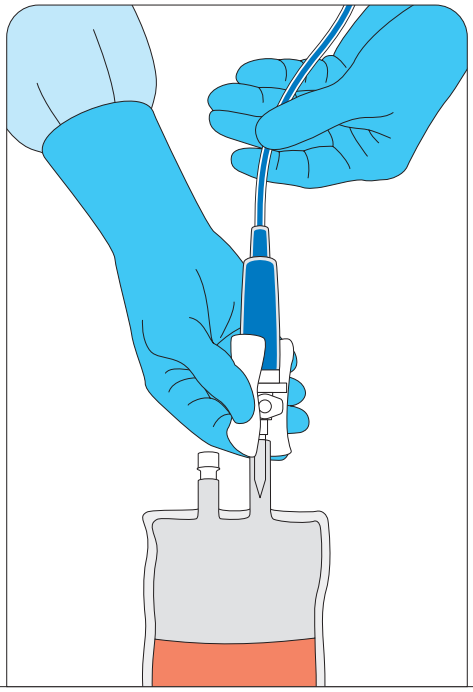
A. Main solution
B. Primary solution
C. Secondary solution (drug)

TECHNIQUE B

PRIMING USING A COMPATIBLE SOLUTION AND SETTING UP A HAZARDOUS DRUG CONTAINER (G2 AND G3)

- Place a disposable waterproof absorbent pad below the work area and work at waist height.
- Close the roller clamp of the secondary tubing (which will be used to administer the hazardous drug).
- Turn the compatible solution container upside down (insertion site pointing upwards, so an air bubble forms in the upper part of the container).
- Insert the spike of the secondary tubing into the container.
- Hang the compatible solution container on the IV pole.
- Compress the drip chamber and allow it to fill to about 2/3 full.
- Place the end of the tubing above the disposable waterproof absorbent pad.
- Slowly release the roller clamp to prime the tubing.
- Close the roller clamp as soon as a drop appears at the end of the tubing.
- Connect the secondary tubing to the Y-site of the primary tubing.
- Disconnect the compatible solution container from the secondary tubing.
- Turn the hazardous drug container upside down.
- Wrap the container insertion site in gauze pads.
- Insert the spike of the secondary tubing into the hazardous drug container (G2 or G3).
- Hang the hazardous drug container on the IV pole and proceed with administration.

Figure 9 • **Setting up tubing with compatible solution**

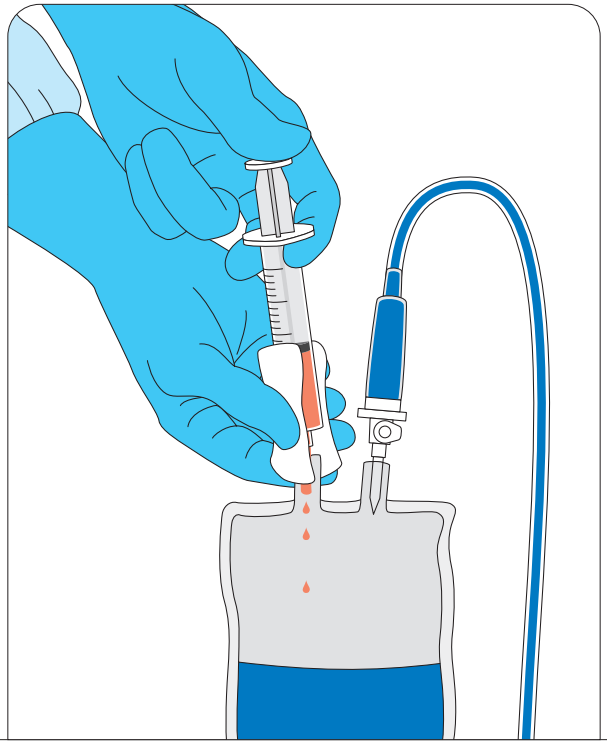


TECHNIQUE C

INERTING TUBING, PRIMING WITH COMPATIBLE SOLUTION, INJECTING G3 INTO BAG

- Place a disposable waterproof absorbent pad below the work area and work at waist height.
- Close the roller clamp on the secondary tubing.
- Turn the solution container upside down (to allow an air bubble to form in the upper part of the container).
- Insert the spike in the container insertion site.
- Hang the compatible solution container on the IV pole.
- Compress the drip chamber and allow it to fill to about 2/3 full.
- Place the end of the tubing above the disposable waterproof absorbent pad.
- Slowly release the roller clamp to prime the tubing.
- Close the roller clamp as soon as a drop appears at the end of the tubing.
- Wrap the container injection site in gauze pads.
- Inject the G3 into the container. Preferably use a needleless syringe.
- Dispose of the needleless system or the syringe and needle as a single unit in the appropriate waste container.
- Mix by turning the solution container upside down several times.
- Hang the hazardous drug container on the IV pole and proceed with administration.

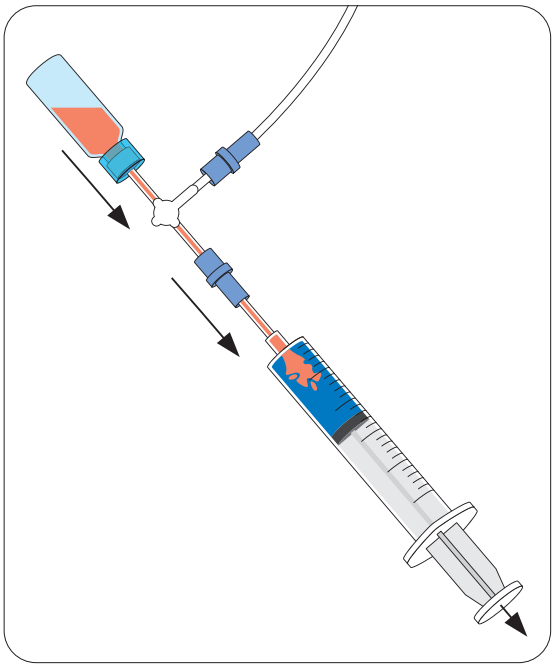
Figure 10 • **Injecting drug into bag**



4.2.3.1.4 | BCG PREPARATION

- **BCG solutions should be prepared at the pharmacy and dispensed in a final dosage form.**
  - A BCG solution in a closed system drug-transfer device may be prepared outside a BSC if the worker wears an N95 respirator (Figure 11). A respirator with combined cartridges and P100 filter is also suitable.
  - The strict workplace design requirements specified in 3.1.2.3.1 must be met, that is:
    - > Closed room with neutral or slightly negative pressure
    - > Room with very little traffic
- **No other activity may be performed simultaneously. PPE recommended for infectious risks must be worn.**
- **Compliant PPE (i.e., chemotherapy-resistant) is suitable.**
- **Clean the work surface with an IPC-approved disinfectant.**

Figure 11 • **Example of closed system**



4.2.3.2 Preparation – Enteral Route

TABLE 20

PPE for enteral dosage form preparation activities*

ACTIVITIES	DOSAGE FORMS	GROUP	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Preparation involving simple manipulations[a]	Intact tablets or capsules	G1 G2 G3	1C 1R 1R	No No No	No No No	No No No
Preparation involving complex manipulations[a]	Non-intact tablets or capsules (e.g., crushing of tablets and capsules) Repackaging of oral liquids, feeding tubes, topical forms	G1 G2 G3	2C 1R 1R	C R R	No[b] No[b] No[b]	Yes Yes Yes

* PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

1C, 2C: one or two pairs of chemotherapy-resistant gloves compliant with standard ASTM D6978 | **C:** gown compliant with section 2.11.2 | **1R:** one pair of regular gloves | **R:** regular gown | **N95:** particulate filter mask, at least N95.

a: If the preparation is not done in the pharmacy, the PPE indicated here must be worn | **b:** If splash risk, protection required. | **c:** Yes, if there's an inhalation risk, the type of PPE to be worn will depend on the risk assessment.

4.2.3.2.1 | PREPARATION OF G1 DRUGS – ENTERAL ROUTE

- **All G1s administered by the enteral route must be prepared in the pharmacy and dispensed in a final dosage form that limits the manipulations required in the administration room:**
  - Tablets or capsules
  - Pre-cut tablets
  - Liquid form or compound repackaged in a unit dose form
- **When a solid form does not suit the patient, liquid forms (commercial or compounded preparations) dispensed in oral syringes with protective caps are to be preferred in order to avoid having to crush tablets.**
  - Some tablets will dissolve in water, or other appropriate liquids, depending on the drug, which allows extemporaneous preparation in an oral syringe (or ENFit, depending on the route used) by a nurse. The compatibility of the technique with the drug to be administered (as an oral tablet) must be confirmed by the facility's pharmacy. If compatibility is confirmed, the following technique may be applied, which is to be preferred to crushing tablets:
    - > Remove the plunger from an oral syringe (or ENFit) of the appropriate volume (generally with a capacity of at least 30 ml).
    - > Put the tablet (or fraction of tablet) in the syringe.
    - > Put the plunger back into the syringe and draw water (or other liquid, as the case may be) up into it. Let a certain amount of air into the syringe to allow effective agitation.
    - > Put the protective cap on the tip of the syringe and shake vigorously for at least 5 minutes or according to the instructions from the pharmacy.
    - > Administer within 15 minutes of the tablet or fraction of tablet dissolving completely, by mouth or enteral tube (e.g., gastrostomy, jejunostomy or nasogastric feeding tube).
    - > Draw up liquid again to rinse the syringe if drug particles are still visible, to ensure that the full dose has been administered.
    - > Dispose of the syringe and any other supplies used in a cytotoxic waste container.
    - > The PPE recommended in Table 20 must be worn.
    - > A waterproof absorbent pad should be placed below the work area.
    - > Work methods must limit contamination of work surfaces, supplies and preparations, caused in particular by the use of already contaminated gloves.
    - > The work surface must be cleaned before and after preparation.
- **Under very exceptional circumstances (e.g., constraints related to drug stability or urgent clinical situations), some manipulations with G1s may, as a last resort, be performed in the drug administration room, following a conclusive risk assessment. For example, to crush tablets, the following criteria must be met:**
  - The task must be performed in a segregated area, well away from traffic, on a disposable waterproof absorbent pad.
  - Appropriate PPE must be worn, including N95 respiratory protection.
  - The G1 drug must be prepared as close as possible to the time it will be administered, or in accordance with OPQ requirements.
  - Equipment used to manipulate G1s must be reserved for G1s.
    - > The equipment may be reserved for a specific patient.

- The G1 must be crushed and then manipulated in a way that keeps particle dispersion to a minimum (e.g., transfer from container, mixing with fruit purée).
- The equipment used must be decontaminated with detergent after each use or each patient.
- The work area must be decontaminated with detergent at the end of each preparation.

4.2.3.2.2 PREPARATION OF G2S AND G3S – ENTERAL ROUTE

- **G2s administered enterally should be prepared at the pharmacy, in a final dosage form that will limit the manipulations required in the administration room.**
- **G2s and G3s may be prepared in the administration room, provided the following criteria are met:**
  - The task is performed in a segregated area, well away from traffic, on a disposable waterproof absorbent pad.
  - Appropriate PPE is worn, including N95 respiratory protection, for instance, when crushing a tablet.
  - G2s and G3s are prepared as close as possible to the drug administration time.
  - Equipment used to manipulate G2s or G3s is reserved for G2s and G3s, respectively, and then decontaminated with detergent after each use or each patient.
    - > Equipment may be reserved for a specific patient.
  - The G2 to be crushed is manipulated in a way that keeps particle dispersion of the drug to a minimum during crushing and mixing (e.g., transfer, mixing with fruit purée).
  - The work area must be cleaned at the end of each preparation.

4.2.4 Administration (G1, G2, G3)

Unless otherwise indicated, the recommendations in this section concern G1s, G2s and G3s.

- **Before handling a hazardous drug, staff must read the label on the drug container, as well as the medication administration record (MAR), to determine the hazardous drug group (G1, G2 or G3) to which the drug belongs and follow the appropriate precautions.**
- **Before going ahead with administration, the nurse must:**
  - Don the appropriate PPE, as the drug packaging must be considered to be potentially contaminated
  - Examine the integrity of the container and contents
- **The nurse must perform proper hand hygiene with soap and water before and after each manipulation and instruct the patient to do likewise.**
- **Staff must abstain from all activities other than drug administration (e.g., food storage, eating and drinking, chewing gum, applying make-up).**

4.2.4.1 Administration - Parenteral Route

TABLE 21

PPE for parenteral dosage form administration activities*

ACTIVITIES	MODES OF ADMINISTRATION	GROUP	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Parenteral administration	Parenteral solution (IV, IM, subcut, intraocular, intrapleural, intrathecal)	G1 G2 G3	2C 1R 1R	C R R	No[a] No[a] No[a]	No No No
	Irrigation (e.g., heated intra-abdominal), intravesical BCG[b]	G1 BCG G2 G3	2C or 3C 1R 1R 1R	C R R R	Yes Yes No No	Yes[c] (CR for HIPEC) N95 Yes[c] Yes[c]
	Inhalation	G1 G2 G3	2C 1R 1R	C R R	No[a] No[a] No[a]	N95[d] N95[d] N95[d]
	Topical (otic, ophthalmic, intranasal, IR, intravaginal)	G1 G2 G3	2C 1R 1R	C R R	No[a] No[a] No[a]	TBD[e] TBD[e] TBD[e]

*PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

2C, 3C: two or three pairs of chemotherapy-resistant gloves compliant with standard ASTM D6978 | **C:** gown compliant with section 2.11.2 | **1R:** one pair of regular gloves | **R:** regular gown | **N95:** particulate filter respirator, at least N95 | **CR:** chemical cartridge respirator for vapours or gases | **IR:** intrarectal | **IV:** intravenous | **IM:** intramuscular | **Subcut:** subcutaneous | **TBD:** to be determined

a: If splash risk, protection required. | **b:** Personnel must also wear a cap, a beard covering, if applicable, a surgical mask, clean, closed shoes (which may be dedicated footwear) and a pair of shoe covers. | **c:** The type of respirator depends on the risk assessment. | **d:** In addition to other specific prevention measures. | **e:** Yes, if there's an inhalation risk, with the type of PPE depending on the risk assessment.

- **Various parenteral routes are described in sections 4.2.4.1.1 to 4.2.4.1.10. For all other routes not discussed in these sections, the risk of contamination of the worker and the environment must be assessed.**
  - A risk assessment (see section 2.5) must be conducted by the facility.
    - > It should be based on information on the routes discussed in this guide so that a safe work procedure can be developed.

4.2.4.1.1 VENOUS ACCESS DEVICES (VAD) – PERIPHERAL (PVAD) AND CENTRAL (CVAD)

Depending on the type and mode of administration, VADs can be used to administer large volumes of fairly concentrated doses of hazardous drugs at high flow rates.

PVADs involve a significant risk of occupational exposure (e.g., extravasation, migration/dislodgement, leakage at the insertion site).

- **While a hazardous drug is being administered via a VAD, measures designed to reduce the risks of exposure as much as possible must be implemented at all stages that involve contact with the infusion system (including the infusion pump, tubing and hazardous drug container).**
- **For all questions concerning, more specifically, the drug administration technique, the prevention of extravasation and hazardous drug monitoring, staff should refer to the nursing care procedures recommended by the Comité national de l'évolution de la pratique des soins infirmiers (CEPSI) in cancer care and to the guide of the Institut national d'excellence en santé et services sociaux (INESSS) on extravasation.**
- **A device with a needleless connection system (e.g., syringe with Luer-Lock tip with appropriate connector) must be used.**
- **Disposable waterproof absorbent pads must be placed on the work surface and below the connection between the tubing/syringe and the VAD.**
- **Dry gauze pads must be placed around the connections before they are handled (e.g., tightening or loosening the connection between the tubing/syringe and the VAD).**
- **The primary infusion solution must be used to rinse the tubing of a G3 drug before the tubing connection is loosened temporarily (see backpriming in section 4.2.3.1.2) or before a G1, G2 or G3 syringe is unscrewed permanently.**
- **The secondary tubing or sections of tubing connected to a G1 or G2 container or syringe must remain in place after the drug has been administered.**
  - Check that the entire amount of the hazardous drug dose has been administered before removing any parts of the infusion system (i.e., tubing and container).
    - > If a closed system drug-transfer device is used, some parts of the circuit may be removed.
  - Do not inject compatible rinsing solution into the hazardous drug container, unless a closed system drug-transfer device is being used.
- **The infusion system must be disconnected and disposed of as a single unit (including the gauze pads and the disposable waterproof absorbent pad) in the appropriate waste container at the end of the procedure.**
- **G1s and G2s must be manipulated at waist height, so as to keep the risk of being splashed in the face to a minimum.**
- **There are specific verifications and actions that must be performed throughout the process of administering a hazardous drug.**

BEFORE ADMINISTRATION

- **The following verifications must be performed:**
  - Integrity of the transport container (e.g., sealed plastic bag), drug container (e.g., bag, syringe), contents, tubing/syringe and connections
  - Tubing for G1s, G2s and G3s is free of air
    - > See sections 4.2.3.1.1 and 4.2.3.1.2 for priming tubing
  - All infusion system clamps and roller clamps are closed
  - Infusion system includes a compliant protective cap
- **The transport container must be returned unopened if a problem is found.**

DURING ADMINISTRATION

- **The infusion system connections must be checked for leaks (e.g., between VAD and tubing).**

AFTER ADMINISTRATION

- **The infusion system and the connection between the VAD and the primary tubing must be rinsed with the primary infusion solution.**
- **All clamps and roller clamps must be closed before any part or all of the rinsed infusion system is removed. The connection to the primary tubing or the VAD must be secured with gauze pads and a disposable waterproof absorbent pad before the rinsed infusion system is disconnected.**

4.2.4.1.1.1 | VAD – DIRECT METHOD (PUSH)

- **The plunger must not move when the syringe is taken out of the transport bag and when the protective cap is removed.**
- **The tip of the syringe must be pointed downward during handling.**
- **Air must never be expelled from the syringe in the drug administration room.**
- **The syringe must be removed gently using gauze pads to protect the connection site.**
- **The tubing must be rinsed with the compatible solution.**
- **The syringes, gauze pads, protective caps and waterproof absorbent pad must be disposed of in an appropriate waste container.**

4.2.4.1.1.2 | VAD – ELASTOMERIC BALLOON PUMP ADMINISTRATION

An elastomeric balloon pump is used to administer a hazardous drug in continuous or intermittent mode.

- **A CVAD must be used.**
- **The elastomeric balloon pump should be connected to extension tubing having two connection sites so that rinsing and irrigating can be done without having to disconnect the pump, thereby reducing the risks of contamination.**
  - The extension tubing must be installed between the CVAD and the pump tubing.
  - The extension tubing must be primed beforehand, using a solution that is compatible with the hazardous drug.
- **The clamp of the pump tubing must be kept closed during the connection process.**

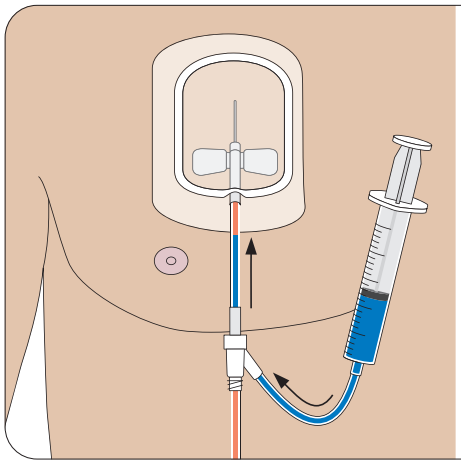


Figure 12 • **Rinsing post elastomeric balloon pump administration**

- **After administering the dose, disconnect the equipment using the following technique:**
  - Close the clamp of the pump tubing.
  - Protect the connection between the pump and the extension with gauze pads and a disposable waterproof absorbent pad.
  - Flush the CVAD using the unused connection site of the extension tubing (Figure 12).
  - Close the clamp of the extension tubing.
  - Disconnect the extension tubing from the CVAD and dispose of the system (extension, pump, etc.) as a single unit in the appropriate waste container.
- **Dispose of the irrigation supplies, gauze pads and PPE in the appropriate waste container.**

4.2.4.1.1.3 | VAD – PROGRAMMABLE INFUSION PUMP OR SYRINGE PUMP

Programmable infusion pumps and syringe pumps are used to administer hazardous drugs in continuous or intermittent mode.

- **Pumps used for hazardous drugs:**
  - Must be handled after the outer pair of gloves has been removed
  - Must be reserved for the use of cancer care units and ambulatory treatment centres that administer hazardous drugs, so as to reduce the risk of environmental contamination
  - Should be reserved for patients being given hazardous drugs
  - Must be maintained according to an established procedure
- **Pumps must be cleaned:**
  - After each patient
  - Before being removed from the unit
  - Every 24 hours, as they are considered to be high-touch surfaces
  - If they are contaminated
- **The cleaning procedure must include the precautions that biomedical engineering staff must take when handling potentially contaminated pumps (e.g., wear appropriate PPE).**
- **The administration set must be put together safely (see CEPSI cancer care procedures).**

- **To determine which G1s can be administered using a programmable infusion pump or a syringe pump, refer to the CEPSI cancer care procedures and the INESSS guide on extravasation (2019).**

4.2.4.1.1.4 | VAD – GRAVITY

- **For G1s, G2s and G3s, the general precautions given in section 4.2.4.1.1 must be followed; only PPE requirements vary.**

4.2.4.1.2 | INTRASPINAL ACCESS DEVICE (IAD)

IADs may be used to administer volumes of less than 3 ml (including flushing, if required), at a low flow rate and for low-concentration doses.

Depending on the type, however, they involve a risk of leakage at the insertion site, as well as a risk of migration/dislodgement.

- **Disposable waterproof absorbent pads must be placed on the work surface and under the connection between the tubing/syringe and the IAD.**
- **Dry gauze pads must be wrapped around the connections before they are handled.**
- **All syringes and similar devices must have Luer-Lock tips.**
- **Syringes must not be filled to more than ¾ capacity.**
- **G1s and G2s must be handled at waist height so as to reduce to a minimum the risk of being splashed in the face.**
- **The infusion system must be disconnected and disposed of as a single unit (including the gauze pads and the waterproof absorbent pad) in the appropriate waste container at the end of the procedure.**

4.2.4.1.3 | INTRAVENTRICULAR ACCESS DEVICE (CEREBRAL VENTRICLE)

An intraventricular access device (e.g., Ommaya reservoir) consists of a silicone dome, a radiopaque reservoir and a flexible catheter leading to the cerebral ventricle. The reservoir is secured to the skull and a hole is made into the skull so that a catheter can be inserted into a cerebral ventricle. The device is used to administer small volumes of a hazardous drug at a low flow rate to treat forms of cancer that affect the central nervous system. It allows repeated access to the cerebrospinal fluid.

- **Disposable waterproof absorbent pads must be placed on the work surface and under the connection between the tubing/syringe and the intraventricular access device.**
- **Dry gauze pads must be wrapped around the connections before they are handled.**
- **All syringes and devices must have Luer-Lock tips.**
- **Syringes must not be filled to more than ¾ capacity.**
- **G1s and G2s must be handled at waist height so as reduce to a minimum the risk of being splashed in the face.**
- **The infusion system must be disconnected and disposed of as a single unit (including the gauze pads and the waterproof absorbent pad) in the appropriate waste container at the end of the procedure.**

4.2.4.1.4 PERITONEAL ACCESS DEVICE (PAD)

Depending on the type, PADs may be used to administer often large volumes of generally very concentrated doses at high flow rates.

PADs do, however, depending on the type, involve a significant risk of complications (e.g., leakage at the insertion site, extravasation and migration).

- **Disposable waterproof absorbent pads must be placed on the work surface and under the connection between the tubing/syringe and the PAD.**
- **Dry gauze pads must be wrapped around the connections before they are handled.**
- **All syringes and devices must have Luer-Lock tips.**
- **Syringes must not be filled to more than ¾ capacity.**
- **The primary infusion solution must be used for rinsing before the tubing of a G3 is temporarily disconnected (see backpriming, in section 4.2.3.1) or a G1, G2 or G3 syringe is removed permanently.**
- **The secondary tubing or sections of tubing connected to a G1 or G2 container or syringe should remain in place.**
- **The infusion system must be disconnected and disposed of as a single unit (including the gauze pads and the waterproof absorbent pad) in the appropriate waste container at the end of the procedure.**
- **G1s and G2s must be handled at waist height so as to reduce to a minimum the risk of being splashed in the face.**
- **There are specific actions that must be taken throughout the process of administering a hazardous drug.**

BEFORE ADMINISTRATION

- **The following verifications must be performed:**
  - Integrity of the transport container (e.g., sealed plastic bag), drug container (e.g., bag, syringe), contents, tubing/syringe and connections
  - Tubing for G1s is free of air
    - > Priming may be done in the administration room only in an emergency.
    - > Backpriming must be used (see backpriming, in section 4.2.3.1).
  - All infusion system clamps and roller clamps are closed
  - Infusion system includes a compliant protective cap
  - Integrity of the insertion site of the drains or tubing used for drug administration
- **The transport bag must be returned unopened if a problem is found.**

DURING ADMINISTRATION

- **All connections of the infusion system must be checked for leaks (e.g., between PAD and tubing).**

AFTER ADMINISTRATION

- **The infusion system and the connection between the PAD and the primary tubing must be rinsed with the compatible solution from the primary tubing.**
  - The tubing must not be rinsed by injecting compatible solution into the hazardous drug bag.
- **All clamps and roller clamps must be closed before any part or all of the rinsed infusion system is removed.**
- **The connection to the primary tubing or the PAD must be secured with gauze pads and a disposable waterproof absorbent pad before the rinsed infusion system is disconnected.**
- **If drainage is required, the drainage bag must be attached to the most proximal connection site of the primary tubing and be lowered to collect the residual solution, which is considered to be cytotoxic waste.**

4.2.4.1.5 | HYPERTHERMIC INTRAPERITONEAL CHEMOTHERAPY (HIPEC)

The HIPEC procedure consists in administering concentrated doses of hazardous drugs heated to a temperature of approximately 42 to 45°C. Sometimes the doses are administered directly into the patient's abdomen following cytoreduction surgery. The purpose of these doses is to increase peritoneal toxicity and absorption and to keep side effects on the body as a whole to a minimum. The hazardous drug is left in the peritoneal cavity for a given length of time (e.g., 15, 30, 60 or 90 minutes) before being drained out. Vapours are released during this procedure.

- **The closed abdomen technique should be performed to reduce the risk of direct contact and inhalation of hazardous drug vapours/aerosols.**
  - If the closed abdomen technique is impossible, the surgeon's outer pair of gloves should go up to the elbow.
- **Staff in contact with the patient must wear two pairs of gloves.**
  - Gloves must be changed every 30 minutes during the drug handling and exposure phase.
  - For greater protection, staff in contact with the patient may wear three pairs of gloves.
- **HIPECs should be done in a dedicated procedure room in order to reduce the risks of exposure and cross-contamination (e.g., same room in an intensive care unit or same operating room).**
  - This room should have a system for limiting exposure to vapours and aerosols while preventing the contamination of other rooms (e.g., smoke evacuator).
- **Only strictly required staff should be admitted to the procedure room.**
- **The procedure room must be identified, using any method in accordance with the institution's regulations (e.g., sign).**
- **Clarifications regarding PPE:**
  - PPE, especially respiratory protection, may be worn just for the drug administration step.
  - The surgeon's outer pair of gloves must be long enough to cover the entire area that could come into contact with the hazardous drug (e.g., up to the elbow for an open-abdomen HIPEC procedure).
  - In addition to PPE (and a cartridge respirator to protect against potential vapours), staff must wear a double pair of shoe covers.
    - > Keep both pairs of shoe covers in the sterile area, as there is a high risk of contamination in that area.
    - > Remove the first pair of shoe covers upon leaving the sterile area.
    - > Remove the second pair of shoe covers before leaving the nonsterile area.

- **Disposable surgical drapes and sheets must be used.**
- **Sterile disposable waterproof absorbent pads must be placed on the work surface and under the connection located between the tubing and the drains/tubing entering the abdominal cavity.**
- **Disposable waterproof absorbent pads must be used on the ground between the operating table and the table with the sterile instruments.**
- **Devices with needleless connection systems (e.g., Luer-Lock tip) must be used.**
- **The infusion system must be disconnected and disposed of as a single unit (including the gauze pads and the waterproof absorbent pad) in the appropriate waste container at the end of the procedure.**
- **Anything that could have been contaminated during the surgical procedure must be decontaminated.**
  - Reusable instruments must be placed in a retreatment transport container labelled "Cytotoxic" (G1) or "Caution" (G2 or G3).
- **G1s and G2s must be handled at waist height so as to reduce to a minimum the risk of being splashed in the face.**
- **A product that solidifies liquids (e.g., bodily fluids, hazardous drugs) must be added to the waste container to reduce the risk of leakage of significant volumes evacuated during the procedure.**
- **There are specific actions that must be taken throughout the process of administering a hazardous drug.**

BEFORE ADMINISTRATION

- **The following verifications must be performed:**
  - Verify the integrity of the transport container (e.g., sealed plastic bag), drug container (e.g., bag, syringe), contents, tubing/syringe, connections and drain/tubing insertion site.
  - Verify that tubing for G1s is free of air.
    - > Priming may be done in the administration room only in an emergency.
    - > Backpriming must be used (see backpriming, in section 4.2.3.1).
  - All infusion system clamps and roller clamps must be closed.
  - Infusion system must include a compliant protective cap.
- **The transport container must be returned unopened if a problem is found.**

DURING ADMINISTRATION

- **The integrity of the drain/tubing insertion site must be checked.**
  - If a leak occurs, additional, tighter stitches should be done to reduce the drainage.
  - If a leak occurs, the fluid must be collected using sterile gauze pads.
    - > The gauze pads must be disposed of immediately in the appropriate waste container.

AFTER ADMINISTRATION

- **All clamps and roller clamps must be closed before the infusion system as a whole is removed.**
- **Hemostats must be placed at the ends of the drains/tubing that are outside the abdominal cavity. They help reduce the risk of hazardous drug drainage. Drains/tubing must be disposed of immediately in the appropriate waste container.**

4.2.4.1.6 | INTRAPLEURAL ACCESS DEVICE

The intrapleural access device (e.g., pleural drain/catheter) is inserted in the space located between the pleura of the lungs. It allows air or fluid to drain and certain hazardous drugs to be administered (e.g., pleurodesis for continuous pleural effusion caused by a cancerous tumour).

- **The administration should be performed in a dedicated procedure room to reduce the risks of exposure and cross-contamination (e.g., same radiology treatment room or same operating room).**
- **The procedure room must be identified, using any method in accordance with the institution's regulations (e.g., sign).**
- **In addition to PPE, staff must wear shoe covers.**
  - The shoe covers must be removed before leaving the procedure room.
- **Disposable surgical drapes and sheets must be used.**
- **Disposable waterproof absorbent pads must be placed on the work surface and under the connection between the tubing/syringe and the intrapleural access device.**
- **Devices with needleless connection systems (e.g., Luer-Lock tip) must be used.**
- **Dry gauze pads must be wrapped around the connections before they are handled.**
- **G1s and G2s must be handled at waist height so as to reduce to a minimum the risk of being splashed in the face.**
- **The infusion system must be disconnected and disposed of as a single unit (including the gauze pads and the disposable waterproof absorbent pad) in the appropriate waste container at the end of the procedure.**
- **Anything that could have been contaminated during the surgical procedure must be decontaminated.**
  - Reusable instruments must be placed in a retreatment transport container labelled "Cytotoxic" (G1) or "Caution" (G2 or G3).

4.2.4.1.7 | INTRAVESICAL CATHETER (G1, G2, G3 OR BCG)

As a general rule, volumes of less than 50 ml are administered through an intravesical catheter.

- **A needleless, filterless system must be used to perform an intravesical instillation.**
- **The administration should be performed in a dedicated procedure room to reduce the risks of exposure and cross-contamination.**
- **The procedure room where patients receive their treatment must be identified, using any method in accordance with the institution's regulations (e.g., sign).**
- **The protective cap must be removed from the administration device without pushing on the plunger.**
- **If a syringe is used to administer the drug, a certain volume of air (e.g., approximately 10 ml) must be added, near the plunger, to allow the urinary catheter to be drained of any hazardous drug and to reduce the splash risk (e.g., when the catheter is removed or when the drainage system is installed).**
- **G1s and G2s must be handled at waist height so as to reduce to a minimum the risk of being splashed in the face.**

- **A disposable waterproof absorbent pad must be placed under the patient's perineal area.**
  - Staff must help patients change positions safely (e.g., to prevent accidental disconnections, reposition waterproof absorbent pads).
- **For BCG, in addition to PPE against the risk of infection (gloves, N95 mask and face protection), staff must also wear shoe covers.**
  - The shoe covers must be removed before leaving the procedure room.
- **After drug instillation, either of the two following procedures must be used to remove the urinary catheter, depending on the patient's mobility and degree of continence (see box for description of the two procedures).**

4.2.4.1.8 | ARTERIAL ACCESS DEVICE (E.G., CHEMOEMBOLIZATION)

An arterial access device allows concentrated doses of a hazardous drug to be administered directly into the artery that feeds a tumour while reducing exposure of the body as a whole to the drug.

Chemoembolization is a procedure that involves injecting a hazardous drug along with an embolization agent, or injecting drug-laden beads that play the role of the embolization agent.

- **If a hazardous drug is to be administered through an arterial access device, it should be done in a dedicated procedure room so as to reduce the risks of exposure and cross-contamination (e.g., reserve a radiology treatment room for chemoembolization).**
- **The procedure room must be identified, using any method in accordance with the institution's regulations (e.g., sign).**
- **Only strictly required staff should be admitted to the procedure room during the drug administration.**
- **Staff must wear PPE and two pairs of shoe covers.**
  - The shoe covers must be removed before leaving the procedure room.
- **Disposable surgical drapes and sheets must be used.**
- **Disposable waterproof absorbent pads must be placed on the work surface and under the tubing connection.**
- **Disposable waterproof absorbent pads must be placed on the ground between the operating table and the table with the sterile instruments.**
- **Devices with needleless connection systems (e.g., Luer-Lock tips) must be used.**
- **Dry gauze pads must be wrapped around the connections before they are handled.**
- **The drug administration system must be disconnected and disposed of as a single unit (including the gauze pads and the waterproof absorbent pad) in the appropriate waste container at the end of the procedure.**
- **G1s and G2s must be handled at waist height so as to reduce to a minimum the risk of being splashed in the face.**

PROCEDURES FOR REMOVING URINARY CATHETER

REMOVE CATHETER AND ADMINISTRATION SYSTEM

- The administration system (e.g., tubing, syringe, solution container, vial) and the urinary catheter must be removed and disposed of as a single unit in the appropriate waste container at the end of the procedure.
- The urinary catheter must be kinked to prevent any backflow of urine.
- Gauze pads must be placed around the perineum before the urinary catheter is removed.
- The perineum must be cleaned with a soapy washcloth or disposable wipes.
- The patient must be told to:
  - Abstain from urinating for 1 to 2 hours after the end of the procedure
  - Only go to the toilet at home, if possible
  - Follow the instructions to prevent contamination of the environment and their family members (see section 4.3)
  - Follow these additional instructions for 6 hours after BCG treatment:
    - Pour 500 ml of bleach into the toilet bowl
    - Let it sit for 15 minutes before flushing

KEEP THE URINARY CATHETER CLOSED IF THE PATIENT STAYS IMMOBILE OR IS INCONTINENT

- A disposable waterproof absorbent pad must be placed under the connection between the administration system and the urinary catheter.
- Gauze pads must be wrapped around the connection between the administration system and the urinary catheter before any handling is done.
- The urinary catheter must be kinked to prevent any backflow of urine.
- The hazardous drug administration system must be removed and disposed of as a single unit in the appropriate waste container.
- A drainage system must be installed at the end of the urinary catheter.
- The urinary catheter must be clamped for 1 to 2 hours following the end of the procedure.
  - The clamp must be removed from the catheter after this time to allow free drainage.
- The drainage system must be removed 96 hours after the end of the instillation of the G1 hazardous drug and disposed of as a single unit in the appropriate waste container.

- **Owing to its low stability, the emulsion (hazardous drug plus Lipiodol) must be prepared in the procedure room after the artery has been located.**
  - The admixture must be prepared over a disposable waterproof absorbent pad, and a closed circuit should be used (e.g., 3-way stopcock).
- **If a leak occurs, the fluids must be soaked up with sterile gauze pads.**
- **The gauze pads must be disposed of immediately in the appropriate waste container.**
- **All clamps and roller clamps must be closed before the drug administration system as a whole is removed.**
- **The drug administration system must be disconnected and disposed of as a single unit (including the gauze pads and the disposable waterproof absorbent pad) in the appropriate waste container at the end of the procedure.**
- **Anything that could have been contaminated during administration must be decontaminated or disposed of in an appropriate waste container.**
- **Reusable instruments must be placed in a retreatment transport container labelled "Cytotoxic" (G1) or "Caution" (G2 or G3).**

4.2.4.1.9 | INTRAOCULAR ACCESS DEVICE

An intraocular access device may be used to administer a small dose of a hazardous drug directly into the eye, which helps to reduce the exposure of the body as a whole to the drug.

4.2.4.1.9.1 | INTRAOCULAR INJECTION

- **Intraocular injections must be performed in a dedicated procedure room to reduce the risks of exposure and cross-contamination.**
- **The procedure room must be identified, using any method in accordance with the institution's regulations (e.g., sign).**
- **Only strictly required staff should be admitted to the procedure room during the drug administration.**
- **Disposable surgical drapes and sheets must be used.**
- **Disposable waterproof absorbent pads must be placed on the work surface.**
- **The syringe must not be filled to more than ¾ capacity.**
- **The needle should be primed at the pharmacy.**
  - If it is not done at the pharmacy, it must be performed above a gauze pad, on top of a disposable waterproof absorbent pad.
  - Bubbles can cause deleterious effects.
- **G1s and G2s must be handled at waist height so as to reduce to a minimum the risk of being splashed in the face.**
- **If a leak occurs, the fluids must be soaked up with sterile gauze pads.**
  - The gauze pads must be disposed of immediately in the appropriate waste container.
- **The drug administration system must be disconnected and disposed of as a single unit (including the gauze pads and the disposable waterproof absorbent pad) in the appropriate waste container at the end of the procedure.**
- **Anything that could have been contaminated during administration must be decontaminated or disposed of in an appropriate waste container.**

4.2.4.1.9.2 | OPHTHALMIC DROPS

- **Disposable waterproof absorbent pads must be placed on the work surface.**
- **G1s and G2s must be handled at waist height so as to reduce to a minimum the risk of being splashed in the face.**
- **Each drop of the hazardous drug must be instilled into the conjunctival sac (between the ocular globe and the lower eyelid).**
- **If a leak occurs, the fluids must be soaked up with sterile gauze pads.**
  - The gauze pads must be disposed of immediately in the appropriate waste container.
- **Anything that could have been contaminated during administration must be decontaminated or disposed of in an appropriate waste container..**

4.2.4.1.10 | SUBCUTANEOUS, INTRAMUSCULAR OR INTRADERMAL INJECTION

- **Disposable waterproof absorbent pads must be placed on the work surface.**
- **The syringe must not be filled to more than ¾ capacity.**
- **G1s and G2s must be handled at waist height so as to reduce to a minimum the risk of being splashed in the face.**
- **The needle tip cap or the compliant protective cap must be removed over a disposable waterproof absorbent pad placed on the work surface.**
- **The safety needle must be installed without pushing on the plunger.**
- **No air should be removed from the needle unless otherwise indicated (e.g., in ophthalmology, bubbles can cause deleterious effects).**
- **A G1 drug should be inserted between two air bubbles (i.e., plunger, bubble, G1, bubble, needle: this technique is commonly referred to as an "air sandwich").**
- **The hazardous drug must be injected slowly (approximately 1 ml every 10 seconds).**
- **Then, at the end of the injection, the nurse must wait 10 seconds before taking the needle out.**
- **An intramuscular injection must be performed into a muscle with sufficient mass using the Z-track technique.**
- **The injection site must be covered with dry gauze pads or an adhesive bandage.**
- **The syringe and the needle must be disposed of as a single unit.**
  - The protective cap must never be put back onto the needle.
  - The needle must never be removed from the syringe.

4.2.4.1.11 | ADMINISTRATION BY INHALATION

If there are no exposure control measures (ventilation, extraction at source), some of the drug administered by inhalation will be dispersed into the air. There are no recognized air exposure limits for hazardous drugs.

The risk of exposure during the administration of a drug to an intubated or ventilated patient is lower. As a result, some of the control measures described below do not apply, or apply only partially, to these patients.

- **Hazardous drugs given by inhalation should be administered in a room with negative pressure that ensures at least 12 air changes per hour.**
- **Ideally, the air should be exhausted to the outside or be filtered through a HEPA filter, in the case of non-volatile particles.**
- **The door must be kept closed at all times to ensure that negative pressure is maintained.**
- **The ventilation should be kept going for 30 minutes after the end of the treatment.**
- **Hazardous drugs given by inhalation must not be administered in a room with positive pressure.**

- **A drug administration system that leaks as little drug as possible should be used. It should also have an exhaust filter and should stop automatically if patients remove it from their mouth. Alternatively, it can also be equipped with an administration interruption mechanism that can be operated by patients, provided they are able to use it.**
  - The patient must be given instructions on how to operate it and be encouraged to interrupt the administration before calling the health care staff at the end of the procedure. Patients can also interrupt it before removing their masks if they need to cough.
- **In an emergency, health care staff must stop the nebulization as soon as possible.**
- **For any intervention within the room, PPE must be worn.**
  - PPE must be changed if a worker has to leave the room and then come back in.
  - PPE must be removed and disposed of in an appropriate waste container placed in the room next to the exit.
  - Gloves must be changed every 30 minutes for G1s and G2s.
  - PPE must be worn to handle the nebulizer and for any situation where there is a high risk of exposure (e.g., accidental disconnection, patient with severe cough or who refuses to cooperate).
- **Staff should leave the room during the administration of hazardous drugs and should re-enter only if required to assist the patient, except in the case of a child.**
  - A visual (window pane in the door) or vocal means of communication should be available to allow the patient to be monitored remotely.

4.2.4.1.12 | TOPICAL ROUTE

- **A risk assessment that takes into account the nature of the hazardous drug (e.g., volatility) and the amount to be applied must be conducted to determine whether the following prevention measures are sufficient.**
  - A disposable waterproof absorbent pad must be placed under the site to be treated with the hazardous drug.
  - A disposable device that eliminates the need for contact with the hazardous drug must be used to apply the medication (e.g., disposable tongue depressor).
  - The area treated with the hazardous drug must be covered with a bandage whenever possible.

4.2.4.2 Administration – Enteral Route

TABLE 22

PPE for enteral dosage form administration activities*

ACTIVITIES	DOSAGE FORMS	GROUP	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Enteral administration	Solid single-dose form	G1 G2 G3	1C 1R 1R	No No No	No No No	No No No
	Oral liquid (e.g., syringe)	G1 G2 G3	2C 1R 1R	C R R	No[a] No[a] No[a]	No No No

* PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

1C, 2C: one or two pairs of chemotherapy-resistant gloves compliant with standard ASTM D6978 | **C:** gown compliant with section 2.11.2 | **1R:** one pair of regular gloves | **R:** regular gown.

a: If splash risk, protection required.

- **Whenever possible, preference should be given to oral self-administration of tablets, capsules and liquids.**
  - Single-dose hazardous drugs: Encourage patients to open the container themselves and take their medication.
  - Multidose hazardous drugs: Transfer the tablets or capsules into a disposable container and hand it to the patient.
- **Health care staff must wear:**
  - One pair of gloves and avoid touching the tablets or capsules
  - Two pairs of gloves to administer a G1 in liquid form
- **If the hazardous drug is administered through a feeding tube:**
  - Disposable waterproof absorbent pads must be placed on the work surface.
  - The syringe must not be filled to more than ¾ capacity.
  - G1s and G2s must be handled at waist height so as to reduce to a minimum the risk of being splashed in the face.
  - The protective cap must be removed over a disposable waterproof absorbent pad placed on the work surface.
  - The hazardous drug must be injected slowly.
  - When the syringe is removed, the connection between the tubing and the syringe must be wrapped in dry gauze pads and a disposable waterproof absorbent pad must be placed beneath the injection site.
  - The syringe, as well as the gauze pads and the waterproof absorbent pad, must be disposed of as a single unit in an appropriate waste container.
- **Proper hand hygiene with soap and water must be practised by both the staff and the patient after each manipulation.**

4.2.5 Other Care Given to Patients

Health care staff may occasionally come into contact with hazardous drugs in the course of activities other than those related to drug administration. Direct and indirect contact with bodily fluids (e.g., urine, feces, blood) is a potential source of exposure to hazardous drugs (see section 1.5).

- **No special measures are recommended regarding contact with the bodily fluids of patients being given a G2 or a G3. Routine practices must be followed.**
- **Precautions must be taken for at least 96 hours following the last G1 dose given to a patient.**
  - These precautions may be adapted depending on the situation, following a risk assessment (see section 2.5).
- **A communication system must be set up to inform staff about the potential risk of exposure to a G1 from a patient in treatment.**
  - The room occupied by this patient must be identified, using any method in accordance with the institution's regulations (e.g., signs posted at the entrance to the room), for 96 hours following the treatment.
  - In the event of a transfer, the list of hazardous drugs that the patient has been given in the last 96 hours must be provided so that appropriate precautions may be taken.
  - The patient's specimens (e.g., blood samples) and other biological materials do not need to be identified, as routine practices must be followed.
- **In the case of a G1, preference should be given to the use of disposable equipment (e.g., urinals, bedpans, diapers) in order to reduce as much as possible the need to handle bodily fluids.**
  - Any absorbent substances that are used must be treated as cytotoxic waste.
- **The use of closed-circuit bedpan washers may be considered when available.**
  - Caution must be exercised when transporting bedpans from a patient's room to the washer to make sure none of the contents spills and contaminates the surrounding environment.

HANDLING OF BODILY FLUIDS AND HYGIENE CARE FOR PATIENTS WHO HAVE BEEN GIVEN A G1 IN THE LAST 96 HOURS

- **Health care staff must:**
  - Wear compliant PPE to handle bodily fluids, excreta, bedding and soiled equipment (e.g., bedpans)
  - Deal with excreta (e.g., vomit, feces, urine) that accidentally ends up on equipment, furniture or the floor as a result of spills, for instance, and follow the appropriate clean-up procedure
  - Clean up any drops of bodily fluids found on toilet surfaces and floors
  - Dispose of incontinence briefs and diapers (for pediatric patients) in appropriate cytotoxic waste containers
  - Collect pleural, peritoneal and urinary drainage waste in a disposable closed system (e.g., closed container) and dispose of it in a cytotoxic waste container as a single unit

TABLE 23

PPE for other care activities*

ACTIVITIES	GROUP	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Hygiene care, specimen collection, other care where there is contact with excreta	G1 BCG G2[b] G3[b]	1C 1R 1R 1R	C R R R	No[a] No[a] No[a] No[a]	No No No No
Indirect care (health-care professional who talks to the patient) and slight contact with patient (auscultation, help with walking)	G1 BCG G2 G3	No No No No	No No No No	No No No No	No No No No
Handling of bedding (as well as clothing) not soiled with excreta or drugs[b]	G1 BCG G2 G3	1R 1R 1R 1R	No No No No	No No No No	No No No No
Handling of bedding (as well as clothing) visibly soiled with excreta	G1 BCG G2[b] G3[b]	2C 1R 1R 1R	C R R R	No[a] No[a] No[a] No[a]	Yes[c] N95 No No
Handling of bedding (as well as clothing) visibly soiled with drugs	G1 BCG G2[b] G3[d]	2C 2R 2R NA	C R R NA	No[a] No[a] No[a] NA	Yes[c] N95 Yes[c] NA

* PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

1C, 2C: one or two pairs of chemotherapy-resistant gloves compliant with standard ASTM D6978 | **C:** gown compliant with section 2.11.2 | **1R, 2R:** one or two pairs of regular gloves | **R:** regular gown | **N95:** particulate filter respirator, at least N95 | **NA:** not applicable.

a: If splash risk, protection required. | **b:** Follow routine infection prevention practices. | **c:** The type of respirator depends on the risk assessment. | **d:** Pregnant women should not be assigned to clean up a spill, on any kind of surface, including bedding.

- **Health care staff should:**
  - Limit, as much as possible, the measurement of volumes of bodily fluids (e.g., urine) because of the risks of splattering when pouring from one container to another
    - > Weight can be taken as a substitute measurement of fluid balance by using a sufficiently accurate scale and then converting grams (g) to millilitres (ml). Place an absorbent substance on the scale
  - Change the collection bags (e.g., pleural, peritoneal, urinary) after the 96-hour time period following the end of the administration of a G1 has elapsed
  - Check that the toilet flushes properly and that the waste water in the toilet has been flushed

INDIRECT CARE

- **Staff that provide care without physical contact (e.g., discussion with a patient) or with only slight contact (e.g., helping to walk) do not have to take any special measures. Routine practices must be followed.**

HANDLING OF BEDDING

- **An agreement must be reached with the laundry service regarding bedding and personal clothing.**
- **Bedding (as well as clothing) that is not visibly soiled with a G1 (or with excreta containing a G1), G2 or G3 hazardous drug must be treated as regular bedding.**
  - Staff must wear the appropriate PPE.
  - Bedding must not be shaken and must be placed in a single bag.
  - It may be sent to the regular laundry service; bags must be handled in accordance with routine IPC practices.
  - Closed bags may be transported in a laundry cart or put down a laundry chute.
- **Bedding (as well as clothing) that is visibly soiled with a G1 (or excreta containing a G1), G2 or G3 hazardous drug should be dealt with in a special way.**
  - A risk assessment must be done to determine the procedures to be followed. These procedures should be based on the same logic as those described for dealing with a spill (see Chapter 9).
  - Bedding (as well as clothing) should be disposed of in the appropriate waste containers to reduce as much as possible the risk of exposure of laundry staff.
  - If bedding is sent to the laundry service:
    - An agreement about the correct procedures to follow must have been reached with the laundry service to avoid exposure of employees during transport and washing. An agreement of this kind could cover the following points:
      - *Send bedding (as well as clothing) to the laundry in sealed double bags, of different colours, labelled "Cytotoxic" (for G1s) or "Caution" (for G2s, G3s).*
      - *Transport the bedding in carts rather than put it down a laundry chute.*
  - Washing personal clothing in care units is to be avoided, as it is important to limit contamination of equipment and staff exposure.
    - If laundry is done in care units, staff should do the washing, following a procedure similar to the one applied in the laundry service. Staff must wear appropriate PPE.

4.2.6 Waste Management

TABLE 24

PPE for waste container handling*

ACTIVITIES	GROUP	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Handling of waste containers	G1 G2 G3	1C 1R 1R	No[a] No[a] No[a]	No No No	No No No

* PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

1C: one pair of chemotherapy-resistant gloves compliant with standard ASTM D6978 | **1R:** one pair of regular gloves.

a: A compliant (G1) or regular (G2, G3) gown must be worn if there is a risk of contact between the waste container and the body.

4.2.6.1 Waste Management – General Considerations

- **Waste must be dealt with according to the instructions given in the *Guide de gestion des déchets du réseau de la santé et des services sociaux* (2017).**
- **The term "cytotoxic waste" refers to any material that comes into contact with a G1 (e.g., packaging materials, PPE, syringes, tubing, bags, equipment used in the cleaning of areas where G1s are handled, soiled materials used to clean up a spill). Production of cytotoxic waste must be reduced as much as possible.**
  - The excreta of patients who have been given G1s are considered to be cytotoxic waste. They must either be flushed down the toilet, or be placed in cytotoxic waste containers (e.g., incontinence briefs, disposable materials used to clean up after an incontinence episode).
  - In the case of BCG, any waste is considered to be biomedical waste. It must be disposed of in the appropriate waste container.
- **For G2s and G3s, the term "waste" refers to the drug itself or to any materials that are visibly soiled with it. This waste must be disposed of in a pharmaceutical waste container.**
  - The excreta of patients who have been given G2s and G3s are not considered to be pharmaceutical waste. They must be disposed of in the appropriate waste containers (e.g., biomedical, general).
- **Cytotoxic and pharmaceutical waste must not be disposed of in containers intended for infectious biomedical waste that can be autoclaved and landfilled.**
- **Cytotoxic (G1) waste must be placed in a compliant waste container clearly and visibly identified with the "Cytotoxic" hazard symbol.**
  - Compliant containers are red, rigid and leakproof or red bags placed in a cardboard box (non-sharp, non-breakable solid waste).
  - Containers must be kept closed, except when waste is being placed in them.
  - Any liquid hazardous drug residue must be placed in a compliant, rigid, leakproof container, the bottom of which is covered with an absorbent substance.
  - Sharps waste must be placed in rigid containers with sealable covers.
  - Other waste (e.g., soft items like tubing, PPE) can be placed in a strong red polyethylene plastic bag that is leak- and tear-resistant under expected conditions of use.
  - Containers awaiting pick-up should be sealed as soon as possible by the designated person.
- **Pharmaceutical waste (G2 and G3) must be disposed of in a compliant pharmaceutical waste container clearly and visibly identified with the pharmaceutical waste symbol.**
  - Compliant containers are white, rigid and leakproof or red polyethylene plastic bags placed in a cardboard box (non-sharp, non-breakable solid waste).
  - Any liquid hazardous drug residue must be placed in a compliant, rigid, leakproof container, the bottom of which is covered with an absorbent substance.
  - Sharps waste must be placed in rigid containers with sealable covers.
  - Other waste (e.g., soft items like tubing, PPE) can be placed in a strong red polyethylene plastic bag that is leak- and tear-resistant under expected conditions of use.
  - For their final elimination outside the health care facility, these bags must be placed in a rigid cardboard box, identified as "Pharmaceutical Waste," and intended for off-site transportation.

- **Supplies used for the cleaning of areas where G2s and G3s are handled may be placed in a general waste container.**
  - Supplies used to clean up a G2 or G3 spill should be disposed of in a pharmaceutical waste container.
- **Containers awaiting pick-up should be sealed as soon as possible by the designated person.**
- **Staff must never use force to push waste into a container.**
  - Waste containers must not be filled to more than ¾ capacity.
- **Staff must take care not to contaminate the outside of containers when putting waste in them.**
  - Also, they are not to handle containers while wearing already contaminated gloves.
- **Reusable equipment that comes into contact with waste (e.g., carts, waste container holders) must be cleaned at least once a month, as must other surfaces, or daily if high-touch surfaces.**
- **The sewer system must never be used as a way of eliminating drugs, except for excreta (urine and feces) of patients who have been given hazardous drugs.**

4.2.6.2 Waste Related to Drug Administration and Patient Care

- **All locations where G1s are handled, including patient rooms, must have cytotoxic waste containers in them. The containers must be placed as close as possible to the area where drugs are administered or care is given, so as to reduce the risks of environmental contamination as much as possible.**
  - In care units, the waste containers may be transported on the carts that are brought into patients' rooms for activities that generate cytotoxic waste (e.g., drug administration).
- **Pharmaceutical waste containers must be available near places where G2s and G3s are administered.**
- **For practical purposes, a single type of container should be used for hazardous drug (G1, G2 and G3) waste management for oncology patients, given that most of the pharmaceutical waste from that clientele comes from G1 hazardous drugs.**

4.2.6.3 BCG Waste

- **Waste produced during BCG preparation or administration must be managed like non-anatomical biomedical waste.**
- **Sharps waste must be placed in a compliant, yellow, tear-and-shock-resistant, rigid, plastic container identified with the "Biohazard" symbol.**
- **Other waste (e.g., soft items like PPE) may be put in compliant plastic bags.**

4.2.7 Returning Hazardous Drugs

- **Hazardous drugs may be returned to the pharmacy only if they are still intact (e.g., dose postponed, refused or to be changed).**
  - They must be returned to the pharmacy in the same, or equally safe, state they were delivered in.
- **In the event of a leak, a detailed hazardous drug spill management procedure must be available (in the unit or at the pharmacy).**
- **Any hazardous drug remaining after partial administration must not be returned to the pharmacy and must be treated as waste.**
  - A residual dose of a G1 must be placed in a leakproof container (e.g., sealable plastic bag) and then disposed of in a cytotoxic waste container.
    - > If the residual dose is a BCG, it must be disposed of in a biomedical waste container.
  - A residual dose of a G2 or G3 should be placed in a leakproof container (e.g., sealable plastic bag) and then disposed of in a pharmaceutical waste container.
- **The institution should agree to manage the cytotoxic waste containers that patients use at home.**

4.2.8 Cleaning

TABLE 25

PPE for workplace cleaning*

ACTIVITIES	GROUP	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Cleaning	G1	1C	C[b]	No[c]	No
	BCG[a]	1R	R[b]	No[c]	No
	G2	1R	R[b]	No[c]	No
	G3	1R	R[b]	No[c]	No

* PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

1C: one pair of chemotherapy-resistant gloves compliant with standard ASTM D6978 | **C:** gown compliant with section 2.11.2 | **1R:** one pair of regular gloves | **R:** regular gown.

a: In the case of BCG, the PPE required for exposure to a biohazard must be worn. | **b:** Gown must be worn if risk of contact with a potentially contaminated surface. | **c:** Face protection must be worn when there is a splash risk.

- **Areas where hazardous drugs are prepared and administered are maintained jointly by health care staff (e.g., orderlies, licensed practical nurses, nurses) and hygiene and sanitation staff.**
  - There must be an agreement between the parties about cleaning responsibilities. For example, hygiene and sanitation staff could take care of cleaning hazardous drug storage shelves and storage systems for each patient, provided drugs are moved out of the way beforehand by pharmacy staff.
  - The agreement must include detailed procedures (frequency, products, equipment, methods). See Chapter 7.

- **Health care staff must:**
  - Keep the work and care environment clean and free of any superfluous supplies (e.g., rolls of paper, gauze pads, alcohol swabs)
  - Clean all equipment used in administering hazardous drugs and providing care after each use (e.g., pill crushers, bedpans, urinals)
  - Clean the work surface used after preparing a hazardous drug (e.g., top of a cart)
  - Clean chairs or stretchers after each patient in clinics and ambulatory health care facilities
    - > Employees must clean in a logical order, going from the least chemically contaminated surface to the most contaminated (e.g., back, seat, armrests)
  - Clean infusion pumps and IV poles daily, or after each patient
- **For BCG, caregivers must use whatever product is recommended by IPC.**
- **PPE must be disposed of in the appropriate waste containers.**
- **If patients being given hazardous drugs share a room with patients who are not receiving them, cleaning measures must be increased (e.g., frequency, products).**

4.3 Instructions to Patients and Caregivers

Patients being given hazardous drugs contaminate their environment, which can lead to cross-contamination. Patients and family members who are helping provide care must be given personalized instructions, both verbally and in writing, about the following points:

- **Access to treatment area**
- **Storage of hazardous drugs in the home**
- **Safe handling and administration of hazardous drugs in the home and waste management**
- **Management of bodily fluids containing G1s or BCG**
- **Spill management**

ACCESS TO TREATMENT AREA

- **Access to the treatment area should be restricted to authorized staff, patients and a small number of family and friends.**
  - If the presence of family and friends is deemed essential, they must be informed of the risks involved in exposure.
  - Visitors who are pregnant and children under 12 should not be authorized to enter the area.
    - > If their presence is deemed essential, they must be informed of the risks involved in exposure and avoid all contact with potential sources of contamination (e.g., excreta).

STORAGE OF HAZARDOUS DRUGS IN THE HOME

- **All hazardous drugs must be stored out of the reach of children and pets.**
- **Solid hazardous drugs must be kept in containers that, ideally, are hard for children to open and that are labelled "Cytotoxic" (G1) or "Caution" (G2 or G3).**
  - If a pill organizer is used, it must be a disposable one.
- **Liquid hazardous drugs must be kept in a sealed double plastic bag identified with the patient's name.**
- **Hazardous drugs that must be kept in the refrigerator should be placed in a closed rigid container, and the container should be put on a high shelf.**

SAFE HANDLING AND ADMINISTRATION OF HAZARDOUS DRUGS IN THE HOME AND WASTE MANAGEMENT

- **Women who are pregnant or breast feeding should avoid handling or administering hazardous drugs for others.**
  - If they must do it, they should wear appropriate PPE.
- **Oral route**
  - Preference must be given to oral self-administration of drugs, whenever possible.
    - Single dose hazardous drugs: Encourage patients to open the container themselves and to take their medication.
    - Multidose hazardous drugs: Transfer the required number of tablets or capsules into a disposable container and give it to the patient.
  - It is important not to touch the tablets or capsules or put them down on a work surface (e.g., countertop). If they come into contact with any other surface than the container, the surface must be washed with detergent.
  - Family and other caregivers who handle hazardous drugs must follow these instructions:
    - Avoid touching the medication.
    - Use disposable gloves if direct contact with the medication is necessary.
    - After use, throw the gloves away.
  - All empty hazardous drug containers must be returned to the pharmacy in a closed disposable bag.
    - If that is impossible, the drug container must be closed and disposed of in a waste container that has a lid. The container must never be reused for other items or food.
- **Intravenous route**
  - Patients who are given infusions at home:
    - Should put their mattress in a plasticized cover to protect it from contamination (e.g., in case of accidental disconnection of the IV equipment, urinary or fecal incontinence)
    - Must keep the cytotoxic waste container out of the reach of children and pets
  - Containers must be kept closed, except when disposing of waste into them.
  - Caregivers must wear disposable gloves when handling the infusion pump or hazardous drug bags.
  - After use, disposable gloves must be disposed of in a plastic bag, which must then be closed and discarded in a cytotoxic waste container, for G1s, or in a regular waste container, for G2s and G3s.

- Patients and their caregivers must wash their hands thoroughly with soap and water before and after each time they handle the pump or a hazardous drug bag.
- Patients and their caregivers must know the:
  - Signs and symptoms of infiltration and extravasation, as well as the other possible complications
  - Ways to prevent spills (e.g., precautions to take when getting dressed)
  - Steps to take if problems or questions arise, such as how to:
    - *Check the VAD and the drug infusion control device if the infusion slows or stops*
    - *Return the hazardous drug (provide contact information)*
    - *Manage a spill*
    - *Contact the resource person (provide contact information)*

- **Intramuscular, subcutaneous or intradermal route**
  - Patients and their caregivers must wash their hands thoroughly with soap and water before and after each time they handle a hazardous drug.
  - Caregivers must wear disposable gloves when handling hazardous drugs.
  - Patients who are given injections at home must keep cytotoxic waste containers out of the reach of children and pets.
  - Containers must be kept closed, except when disposing of waste in them.
  - Patients and caregivers must:
    - Place a disposable waterproof absorbent pad or a towel on the work surface and under the hazardous drug injection site
    - Know the safe procedure for administering the hazardous drug
    - Handle the syringe and needle with care
    - Dispose of the syringe and needle as a single unit in the appropriate rigid waste container:
      - *Cytotoxic for a G1*
      - *Pharmaceutical for a G2 or a G3*

MANAGEMENT OF BODILY FLUIDS FOR THE 96 HOURS FOLLOWING G1 TREATMENT AT HOME

- **Patients and their caregivers must:**
  - Know the precautions to take during this 96-hour period in order to protect themselves as well as the patient's surrounding environment (e.g., contact with excreta)
  - Always wash their hands with soap and water after handling bodily fluids
  - Wear a pair of compliant gloves to handle excreta and soiled clothing and bedding
- **Patients and their caregivers should dispose of incontinence briefs and diapers by double bagging them in closed regular garbage bags.**
  - After 96 hours, this waste may be disposed of in a general waste container.
- **Patients should:**
  - Sit to urinate
  - Put the toilet lid down and flush twice after using the toilet
  - Wipe the toilet bowl, the toilet lid and the floor around the toilet daily using regular cleaning products
    - Cleaning rags must not be reused on other surfaces

- **If possible, family members should use a different toilet from the one used by the patient.**
- **Bedding (and clothing) that is not visibly soiled may be washed with the regular laundry.**
- **Bedding (and clothing) that is visibly soiled:**
  - Should be washed separately and as soon as possible after it is soiled (e.g., urine, vomit or profuse sweating)
    - > If bedding is heavily soiled, it can be washed twice in hot water
  - Must be placed in a plastic bag that can be closed tightly if a washing machine is not available
  - Should never be shaken, as shaking can release contaminated particles
- **Patients or their partner must wear a condom for sexual intercourse during the 96 hours following treatment with a G1. Sperm and vaginal secretions may contain hazardous drug residues.**

MANAGEMENT OF BODILY FLUIDS CONTAINING BCG AT HOME

- **Patients who have received intravesical treatment with BCG must follow these instructions for 6 hours after their treatment:**
  - Add 500 ml of bleach to the toilet bowl.
    - > Let it sit for 15 minutes before flushing.
    - > Repeat each time the patient uses the toilet over the 6-hour period.
- **Patients or their partner must wear a condom for sexual intercourse for the first 24 hours after treatment.**

MANAGEMENT OF A FLUID G1 OR G2 SPILL AT HOME

- **Patients must be given a spill kit and the instructions for using it, as well as the contact information of a resource person if health care staff do not remain on site during drug administration.**
- **Spill kit instructions must include the following information:**
  - The waste resulting from the clean-up of a G1 spill must be disposed of in a cytotoxic waste container.
  - The waste resulting from the clean-up of a G2 must be placed in a closed bag and disposed of in an outside waste container.
  - Contaminated surfaces must be cleaned with detergent.

5 Care in Long-Term Care Centres and Seniors' Residences

Living Environment

Hazardous drugs are being used more and more in long-term care centres (CHSLDs) and seniors' residences. Exposure prevention measures need to be implemented. Chapters 1 and 2 are essential reading for an understanding of this chapter. In addition, a number of recommendations are also made in chapters 4 and 7, and the relevant sections of those chapters are indicated here. This not only makes the guide easier to read, but also provides opportunities to focus on specific characteristics of the living environment, such as the predominant use of solid dosage forms of drugs and the presence of residents who are coping with a loss of autonomy and continence issues.

5.1 Workplace Design

5.1.1 Receiving and Storing Drugs

- In situations where receiving hazardous drugs involves unpacking them, a space must be set aside for this activity.
- If hazardous drugs must be stored in an area separate from non-hazardous drugs (e.g., G1 in oral liquid form), a dedicated, clearly identified space must be set aside for them, as is recommended in section 4.2.2 (storage of G1s, G2s and G3s).

5.1.2 Drug Preparation

- When a hazardous drug must be crushed as part of drug preparation, the crushing must be performed in a segregated area well away from traffic.

5.1.3 Room, Lavatory, Bathroom and Other Places Frequented by Resident

- **Residents who are given G1s should be accommodated in single rooms.**
  - If a room must be shared with residents who are not being treated with hazardous drugs, measures to limit their exposure must be implemented.
  - If lavatories are shared, a risk assessment (see section 2.5) should be conducted to determine whether consideration should be given to the addition of personal hygiene equipment (e.g., commode with a bag containing an absorbent substance that can be disposed of along with feces and urine).
- **Residents who are given G2s can be accommodated in double rooms.**
- **A hand washing station must be located close to the room.**
- **Rooms where hazardous drugs are administered can be ventilated mechanically. However, no specific ventilation requirements are set out in the standards.**
  - Nevertheless, if a hazardous drug is administered by inhalation, the room should be ventilated by an efficient mechanical system (e.g., negative pressure, 100% of air exhausted to the outside, adequate number of air changes per hour).
- **Other places frequented by residents receiving hazardous drugs do not require any particular measures to be taken (e.g., bathroom, dining room).**

5.1.4 Waste Storage

- **In care units, soiled materials utility rooms (initial holding areas) must include a section for keeping hazardous drug waste containers (e.g., incontinence briefs).**
- **Final storage must comply with the recommendations of the MSSS's *Guide de gestion des déchets* (2017).**
  - Under lock and key
  - In a cool room with ventilation that prevents the spread of contamination to adjacent rooms
  - Air should be exhausted to the outside, without recirculation
  - The room should not be located near areas frequented by residents

5.2 Safe Practices

5.2.1 Receiving

TABLE 26

PPE for receiving activities performed by health care staff*

ACTIVITIES	DOSAGE FORMS	GROUP	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Receiving in care units and handling of transport containers or of outsides of sealable plastic bags	All	G1 G2 G3	No[a] No[a] No[a]	No No No	No No No	No No No

* PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

a: Except if the transport container is deemed to be contaminated.

- **If precautions have been taken to prevent contamination of the transport container (e.g., resealable zip bag, case), the transport container may be considered to be non-contaminated and be handled without PPE.**
- **Only trained staff should be allowed to receive hazardous drugs.**
- **The labelling of hazardous drugs must inform the people who use them about the nature of the drugs so that they can take the appropriate precautions.**
  - G1s must be identified with the "Cytotoxic" symbol and the "Cytotoxic" label.
  - G2s and G3s must be identified with the "Caution" label. G3s should also be identified with the "Caution pregnancy" label.
  - The use of a symbol specific to G1s, G2s and G3s may be considered, such as the drug group's number inside a coloured triangle, as illustrated in this guide.
- **In most long-term care facilities, hazardous drugs come from outside, either through the facility's pharmacy department or through the community pharmacy. Hazardous drugs must be delivered in the conditions described in Chapter 3, more specifically in a transport container that must be:**
  - Rigid
  - Shock-resistant and sealed
  - Made of a material that is easy to clean and disinfect if it is reusable
  - Identified appropriately ("Cytotoxic" hazard symbol or "Caution" label)
- **Hazardous drug transport containers should be delivered to a secure location or handed to the intended recipient in person.**
  - They must not be left on a counter.
- **Hazardous drug transport containers must not be used for any other purpose.**

- **Hazardous drug containers (e.g., syringes, bottles, bags, jars) and the equipment required for drug administration (e.g., tubing) must be delivered in a sealed, transparent plastic bag so that the contents can be identified without having to open the bag.**
- **The health care facility should require the hazardous drug dispensing pharmacy to follow the recommendations for preparation, packaging, labelling and transport given in Chapter 3.**
  - G1s must be packaged separately from other drugs.
  - Liquid G1s must be packaged in a double plastic bag, which is then placed in a secondary sealed container that includes an absorbent substance.
  - The container must be identified properly with the "Cytotoxic" hazard symbol.
- **When the hazardous drug is received, the container must be examined without removing the drug from its sealed plastic bag, and then stored appropriately.**
- **In the event of a leak, the accidental spill procedure must be followed.**
- **A spill kit, including a written procedure, must be available.**

5.2.2 Storage

The way a hazardous drug is stored depends on the drug in question, its dosage form and the dispensing pharmacy.

TABLE 27

PPE for storage activities performed by health care staff*

ACTIVITY	DOSAGE FORMS	GROUP	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Storage in care units with handling of potentially contaminated containers (e.g., primary container)	All	G1 G2 G3	1C 1R 1R	No No No	No No No	No No No

* PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

1C: one pair of chemotherapy-resistant gloves compliant with standard ASTM D6978 | **1R:** one pair of regular gloves.

5.2.2.1 Storage of G1s

- **G1s must be stored so as to limit the possibility of cross-contamination.**
  - They should be kept in an area separate from non-hazardous drugs, and be clearly identified (e.g., in the storage unit, on a dedicated, clearly identified section of shelving).
  - Solid G1s (e.g., tablets, capsules) may be kept with a resident's other medications (e.g., medication cart), provided the packaging is deemed to be not contaminated.

- Small quantities of G1s in liquid form may be stored in a regular refrigerator, provided they are kept in a separate, dedicated, clearly identified part of the fridge. They must be kept in a sealed plastic bag, which is then placed in a closed, sealed, rigid container.
- Other G1 dosage forms (e.g., syringes, multiple-use topical medication containers) must be stored in the same packaging they are delivered in (sealed plastic bag) identified by the resident's name.

5.2.2.2 Storage of G2s

- **G2s must be stored so as to limit the possibility of cross-contamination.**
  - They should be kept in an area separate from non-hazardous drugs and be clearly identified by the label "Caution" (e.g., a dedicated section in a refrigerator or in the storage unit, on a clearly identified shelf).
  - Solid oral forms (e.g., tablets, capsules), whether or not packaged with an automated bagging machine, may be stored with a resident's other medications (e.g., medication cart).
  - G2s may be stored in a regular refrigerator, provided they are kept in a closed, sealed, rigid container identified as being reserved for hazardous drugs.
  - Other G2 dosage forms (e.g., syringes, multiple-use topical medication containers) must be stored in the same packaging they are delivered in (sealed plastic bag) identified by the resident's name.

5.2.2.3 Storage of G3s

- **G3s may be stored according to the same criteria as for G2s, so that the reproductive risk can be better identified and controlled.**

5.2.3 Preparation

Hazardous drugs can be administered by the parenteral or enteral route.

REMINDER

> The parenteral route refers to all modes of administration in which the drug enters the body via a route other than the digestive tract (e.g., intramuscular [IM], subcutaneous [Subcut] or intravenous [IV] route).

> The enteral route covers all modes of administration in which the drug passes through the digestive tract (e.g., oral, sublingual or nasogastric)

- **The drug should be prepared at the pharmacy. It may be prepared in part at the site where it is to be administered to the resident. That decision will depend on the results of a risk assessment that takes several factors into account: hazardous drug group, route of administration, dosage form (e.g., solid, liquid) and stability of the drug.**
  - If the hazardous drug is prepared by a nurse, preparation must be done as close as possible to the drug administration time.
- **Luer-Lock connection systems should be used for parenteral drugs to ensure a better seal at the connection sites.**
- **Syringes must not be filled to more than ¾ capacity, to avoid spillage.**
- **Appropriate PPE must be worn to handle hazardous drug containers and to prepare and administer hazardous drugs.**
- **The work area must be cleaned at the end of each preparation.**

5.2.3.1 Parenteral Route

For a complete description of the preparation of parenteral drugs, see section 4.2.3.1.

TABLE 28

PPE for parenteral drug preparation activities*

ACTIVITIES	DOSAGE FORMS	GROUP	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Preparation	Parenteral	G1[a] BCG G2[b] G3[b]	2C 1R 1R 1R	C R R R	No[a] Yes[c] Yes Yes	No[a] N95[c] Yes Yes

*PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

2C: two pairs of chemotherapy-resistant gloves compliant with standard ASTM D6978 | **C:** gown compliant with section 2.11.2 | **1R:** one pair of regular gloves | **R:** regular gown | **N95:** particulate filter mask, at least N95

a: G1s must be prepared at the pharmacy and be ready to be administered. For the hazardous steps (setting up tubing and priming), G1s must be prepared at the pharmacy, in accordance with the risk assessment, and be ready to be administered, which requires PPE different from what is recommended for G2s and G3s. | **b:** Under very exceptional circumstances, G2s and G3s may, as a last resort, be prepared outside a BSC after a risk assessment has been done. This assessment must specify what PPE is required. | **c:** With a closed system drug-transfer device.

5.2.3.1.1 PREPARATION OF G1, G2 AND G3 DRUGS – INTRAVENOUS ROUTE

- **For G1, G2 or G3 intravenous preparations, see sections 4.2.3.1.1 and 4.2.3.1.2.**

5.2.3.1.2 PREPARATION OF G1, G2 AND G3 DRUGS – SUBCUTANEOUS OR INTRAMUSCULAR INJECTION

- **G1s must be prepared at the pharmacy and dispensed in their final dosage form ready to be administered, so as to limit the handling required in the administration room.**
- **G2s and G3s should be prepared at the pharmacy.**
  - G2s and G3s should be prepared in the administration room only if that is required to meet drug stability constraints.
- **G1, G2 and G3 syringes must be supplied without a needle and with a compliant protective cap on the end.**
  - A safety needle should be used to administer the drug.
  - Syringes used to administer small amounts (e.g., cutaneous allergy tests) may be supplied with a needle.
- **A disposable waterproof absorbent pad must be placed on the work surface when fitting a needle on a G1 or G2 syringe.**
  - Air should never be removed from a G1 or G2 syringe.

- **Under very exceptional circumstances (e.g., stability constraints), G2s and G3s may, as a last resort, be prepared in a care unit, provided a risk assessment is done beforehand that takes a number of factors into account, including:**
  - A closed system drug-transfer device may be used.
  - The task must be performed in a segregated area, well away from traffic, on a disposable waterproof absorbent pad.
  - Appropriate PPE must be worn.
  - Preparation must be done as close as possible to the drug administration time.
- **The work area must be decontaminated with detergent at the end of each preparation.**

5.2.3.2 Enteral Route

TABLE 29

PPE for enteral drug preparation activities*

ACTIVITIES	DOSAGE FORMS	GROUP	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Preparations with simple manipulations[a]	Intact tablets or capsules	G1 G2 G3	1C 1R 1R	No No No	No No No	No No No
Preparations with complex manipulations[a]	Non-intact tablets or capsules (e.g., crushing of tablets or capsules) Repackaging of oral liquids, feeding tubes, topical forms	G1 G2 G3	2C 1R 1R	C R R	No[b] No[b] No[b]	Yes Yes Yes

* PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

1C, 2C: one or two pairs of chemotherapy-resistant gloves compliant with standard ASTM D6978 | **C:** gown compliant with section 2.11.2 | **1R:** one pair of regular gloves | **R:** regular gown | **N95:** particulate filter mask, at least N95

a: If the preparation is not done in the pharmacy, the PPE indicated here must be worn. | **b:** If splash risk, protection required. | **c:** Yes, if there's an inhalation risk, with the type of PPE depending on the risk assessment.

5.2.3.2.1 PREPARATION OF G1 DRUGS – ENTERAL ROUTE

- **All G1s administered by the enteral route must be prepared in the pharmacy and dispensed in a final dosage form that limits the handling required in the administration room:**
  - Tablets or capsules
  - Pre-cut tablets
  - Liquid form or compound repackaged in a single dose form

- **When the solid form is not suitable for the resident, liquid forms (commercial or compounded preparations) dispensed in oral syringes closed by a protective cap should preferably be used so as to avoid having to crush tablets.**
  - Some tablets will dissolve in water, or other appropriate liquids, depending on the drug, which allows extemporaneous preparation in an oral syringe (or ENFit, depending on the enteral route being used) by a nurse. The compatibility of the technique with the drug to be administered (as an oral tablet) must be confirmed by the facility's pharmacy. If that is the case, the following technique may be applied, which is to be preferred to crushing tablets.
    - Remove the plunger from an oral syringe (or ENFit) of the appropriate volume (generally with a capacity of at least 30 ml).
    - Put the tablet (or fraction of a tablet) in the syringe.
    - Put the plunger back into the syringe and draw water (or other liquid, as the case may be) up into it. Also let a certain amount of air into the syringe to allow effective agitation.
    - Put the stopper in the syringe and shake vigorously for at least 5 minutes or according to the instructions from the pharmacy.
    - Administer within 15 minutes of the tablet or fraction of tablet dissolving completely, by mouth or enteral tube (e.g., gastrostomy or jejunostomy or nasogastric feeding tube).
    - Draw liquid up into the syringe again to rinse it if drug particles are still visible to ensure that the full dose is administered to the patient.
    - Dispose of the syringe and any other supplies used in a cytotoxic waste container.
    - The PPE recommended in Table 29 must be worn.
    - A waterproof absorbent pad should be placed below the work area.
    - Work methods must limit contamination of work surfaces, equipment and preparations, caused in particular by the use of already contaminated gloves.
    - The work surface must be cleaned before and after preparation.
- **Under very exceptional circumstances (e.g., stability constraints), certain G1 manipulations may, as a last resort, be performed in the drug administration room, provided a conclusive risk assessment has been done. For example, to crush tablets, the following criteria must be met:**
  - The task must be performed in a segregated area, well away from traffic, on a disposable waterproof absorbent pad.
  - Appropriate PPE must be worn, including N95 respiratory protection.
  - The G1 must be prepared as close as possible to the drug administration time.
  - Equipment used to handle G1s must be reserved for G1s.
    - Equipment can be reserved for a specific patient.
  - The G1 must be crushed and handled so as to minimize dispersion (e.g., transfer of container, mixing with fruit purée).
  - The equipment used must be decontaminated with detergent after each use or each resident.
    - The work area must be decontaminated with detergent at the end of each preparation.

5.2.3.2.2 PREPARATION OF G2 AND G3 DRUGS – ENTERAL ROUTE

- **G2s administered enterally should be prepared at the pharmacy, in a final dosage form that will limit the handling required in the administration room.**
- **G2 and G3 preparations (e.g., cutting or crushing a tablet, measuring an enteral liquid) may be done in the drug administration room if the following criteria are met:**
  - The task must be performed over a disposable waterproof absorbent pad and in a segregated area well away from traffic.
  - Appropriate PPE must be worn, including an N95 mask when crushing a tablet, for instance.
  - G2s and G3s must be prepared as close as possible to the drug administration time.
  - Equipment used to handle G2s or G3s must be reserved for G2s and G3s, respectively, and must be cleaned after each use or each resident.
    - > Equipment can be reserved for a specific resident.
- **The G2 to be crushed must be handled in a way that keeps particle dispersion of the drug to a minimum during crushing and mixing (e.g., transfer, mixing with fruit purée).**
- **The work area must be cleaned at the end of each preparation.**

5.2.4 Administration

- **Before handling a hazardous drug, health care professionals and their patients must read the label on the drug container, as well as the MAR, to determine the hazardous drug group (G1, G2 or G3) to which the drug belongs and to know what precautions must be taken.**
- **Before going ahead with administration, the nurse must:**
  - Don the appropriate PPE, as the drug packaging could potentially be contaminated
  - Examine the integrity of the container and contents
- **Nurses must wash their hands with soap and water before and after each manipulation and ask the resident to do likewise.**
- **Drug self-administration is to be preferred whenever possible and safe.**

5.2.4.1 Parenteral Route

The various parenteral routes of drug administration are described in section 4.2.4.1.

- **Venous access devices (VADs), peripheral (PVADs) and central (CVADs) –** See section 4.2.4.1.1 and subsections.
- **Ophthalmic drops –** See section 4.2.4.1.9.
- **Subcutaneous or intramuscular injection –** See section 4.2.4.1.10.
- **Administration by inhalation –** See section 4.2.4.1.11.
- **Topical route –** See section 4.2.4.1.12.

TABLE 30

PPE for parenteral drug administration activities*

ACTIVITIES	MODES OF ADMINISTRATION	GROUP	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Parenteral administration	Parenteral solution	G1 G2 G3	2C 1R 1R	C R R	No[a] No[a] No[a]	No No No
	Inhalation	G1 G2 G3	2C 1R 1R	C R R	No[a] No[a] No[a]	N95[b] N95[b] N95[b]
	Topical (otic, ophthalmic, intranasal, IR, intravaginal)	G1 G2 G3	2C 1R 1R	C R R	No[a] No[a] No[a]	TDB[c] TDB[c] TDB[c]

* PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

2C: two pairs of chemotherapy-resistant gloves compliant with standard ASTM D6978 | **C:** gown compliant with section 2.11.2 | **1R:** one pair of regular gloves | **R:** regular gown | **IR:** intrarectal | **N95:** particulate filter mask, at least N95 | **TBD:** to be determined

a: If splash risk, protection required. | **b:** In addition to other specific prevention measures. | **c:** Yes, if there's an inhalation risk, with the type of PPE depending on the risk assessment.

5.2.4.2 Enteral Route

TABLE 31

PPE for enteral drug administration activities*

ACTIVITIES	DOSAGE FORMS	GROUP	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Enteral administration	Solid single dose form	G1 G2 G3	1C 1R 1R	No No No	No No No	No No No
	Oral liquid (e.g., syringe)	G1 G2 G3	2C 1R 1R	C R R	No[a] No[a] No[a]	No No No

* PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

1C, 2C: one or two pairs of chemotherapy-resistant gloves compliant with standard ASTM D6978 | **C:** gown compliant with section 2.11.2 | **1R:** one pair of regular gloves | R: regular gown.

a: If splash risk, protection required.

- **Oral self-administration of tablets, capsules and liquids is to be preferred whenever possible.**
  - Single dose hazardous drugs: Encourage residents to open the container themselves and take their medication without touching it.
  - Multidose hazardous drugs: Transfer the tablets or capsules to a disposable container and give it to the resident.

- **Health care staff must:**
  - Wear one pair of gloves and avoid touching the tablets or capsules
  - Wear two pairs of gloves to administer a G1 in liquid form
- **If the hazardous drug is administered through a feeding tube:**
  - Disposable waterproof absorbent pads must be placed on the work surface.
  - The syringe must not be filled to more than ¾ capacity.
  - G1s and G2s must be handled at waist height so as to reduce to a minimum the risk of being splashed in the face.
  - The protective cap must be removed over a disposable waterproof absorbent pad placed on the work surface.
  - Hazardous drugs must be injected slowly.
  - When the syringe is removed, the injection site must be covered with dry gauze and a disposable waterproof absorbent pad must be placed under the injection site.
  - The syringe (including the gauze pads and the waterproof absorbent pad) must be disposed of as a single unit in an appropriate waste container.
- **Both staff and residents must wash their hands thoroughly with soap and water after each manipulation.**

5.2.5 Other Care Provided to Residents

5.2.5.1 Hygiene Care (including residents' common bedding and clothing)

Health care staff can sometimes come into contact with hazardous drugs in the course of activities other than those related to drug administration. Direct contact or contact with excreta (e.g., urine, feces, blood) is a potential source of exposure to hazardous drugs.

- **A communication system must be set up to inform staff about the potential risk of exposure to a G1 from a resident in treatment.**
  - The room occupied by this resident must be identified, using any method in accordance with the institution's regulations (e.g., signs posted at the entrance to the room), for the first 96 hours after treatment.
  - In the event of a transfer, the list of hazardous drugs that the resident has been given in the last 96 hours must be provided so that appropriate precautions may be taken.
  - The resident's specimens (e.g., blood samples) and other biological materials do not need to be identified, as routine practices must be followed anyway.
- **Preference is to be given to disposable supplies (e.g., urinals, bedpans, diapers) in order to reduce as much as possible the need to handle bodily fluids.**
  - Any absorbent materials that are used must be treated as cytotoxic waste.
- **The use of closed-circuit bedpan washers may be considered when available.**
  - Caution must be exercised when transporting bedpans from a resident's room to the washer to make sure none of the contents spills and contaminates the surrounding environment.

TABLE 32

PPE for other care activities*

ACTIVITIES	GROUP	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Hygiene care, specimen collection, other care where there is contact with excreta	G1 BCG G2[b] G3[b]	1C 1R 1R 1R	C R R R	No[a] No[a] No[a] No[a]	No No No No
Indirect care with slight or no contact with resident (auscultation, help walking)	G1 BCG G2 G3	No No No No	No No No No	No No No No	No No No No
Handling of bedding (as well as clothing) not soiled with excreta or drugs[b]	G1 BCG G2 G3	1R 1R 1R 1R	No No No No	No No No No	No No No No
Handling of bedding (as well as clothing) visibly soiled with excreta	G1 BCG G2[b] G3[b]	2C 1R 1R 1R	C R R R	No[a] No[a] No[a] No[a]	Yes[c] N95 No No
Handling of bedding (as well as clothing) visibly soiled with drugs	G1 BCG G2[b] G3[d]	2C 2R 2R NA	C R R NA	No[a] No[a] No[a] NA	Yes[c] N95 Yes[c] NA

* PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

1C, 2C: one or two pairs of chemotherapy-resistant gloves compliant with standard ASTM D6978 | **C:** gown compliant with section 2.11.2 | **1R, 2R:** one or two pairs of regular gloves | **R:** regular gown | **N95:** particulate filter mask, at least N95 | **NA:** not applicable

a: If splash risk, protection required. | **b:** Follow routine infection prevention practices. | **c:** Type of respirator depends on risk assessment. | **d:** Pregnant women should not be assigned to clean up a spill, on any kind of surface, including bedding.

HANDLING OF BODILY FLUIDS AND HYGIENE CARE FOR RESIDENTS WHO HAVE BEEN GIVEN A G1 IN THE LAST 96 HOURS

- **Health care staff must:**
  - Wear the required PPE to handle bodily fluids, excreta, bedding and soiled equipment (e.g., bedpans)
  - Deal with excreta (e.g., vomit, feces, urine) that accidentally ends up on equipment, furniture or the floor as a result of spills, for instance, and follow the appropriate clean-up procedure
  - Make sure that any drops of bodily fluids found on toilet surfaces and floors are cleaned up
  - Dispose of incontinence briefs in a cytotoxic waste container
  - Collect urinary drainage waste in a disposable closed system and dispose of it in a cytotoxic waste container as a single unit

- **Health care staff should:**
  - Limit, as much as possible, the measurement of volumes of bodily fluids (e.g., urine) because of the risks of splattering when pouring from one container to another
    - Weight can be taken as a substitute measurement of fluid balance.
  - Change the urinary collection bag after the 96-hour period following the end of the administration of a G1 has elapsed
  - Check that the toilet flushes properly and that the waste water in the toilet has been flushed
    - Depending on toilet flush power, it may be necessary to flush twice.
- **Residents must:**
  - Use the toilet rather than a bedpan (commode) and the urinal whenever possible.
    - Toilets must be reserved for use by residents only.
    - If toilets are shared, measures must be taken to prevent contamination, such as:
      - *Increase toilet cleaning frequency.*
      - *Use a commode equipped with a disposable bag containing an absorbent substance. The absorbent material must be treated as cytotoxic waste, in the same way as incontinence briefs.*
  - Sit down to urinate in order to reduce the risk of aerosol propagation and contamination.
  - Close the lid before flushing and be sure to flush twice for a regular household toilet.
  - Wash hands regularly with soap and water, and especially after using the toilet.

HELPING RESIDENTS WITH BATHS AND SHOWERS IN THE FIRST 96 HOURS AFTER THEY HAVE BEEN GIVEN G1 DRUGS

- **Staff who provide assistance with baths and showers do not have to take any special measures. Routine practices must be followed.**
  - If bodily fluids need to be dealt with, staff must wear appropriate PPE.

5.2.5.2 Indirect Care and Slight Contact with Residents

Some activities may involve indirect care, such as talking with residents, providing meal service or conducting a group activity. Other activities may entail slight contact with a resident, such as auscultation, helping to walk and helping to eat.

- **Staff who provide care that does not involve direct contact or only slight contact do not have to take any special measures. Routine practices must be followed.**

5.2.5.3 Bedding and Personal Clothing

- **Bedding (as well as clothing) that is not visibly soiled with a hazardous drug or with excreta containing a G1 may be treated as regular bedding.**
  - Staff must wear the appropriate PPE.
  - Bedding must not be shaken and must be placed in a single bag.
  - It may be sent to the regular laundry, and bags may be handled in accordance with routine IPC practices.
  - Closed bags may be transported in a laundry cart or put down a laundry chute.

- **Bedding (as well as clothing) that is visibly soiled with a G1 (or excreta containing a G1), G2 or G3 hazardous drug must be dealt with as follows:**
  - A risk assessment must be done to determine the procedures to be followed. These procedures should be based on the same logic as those described for dealing with a spill (see Chapter 9).
  - Bedding (as well as clothing) should be disposed of in the appropriate waste containers to reduce as much as possible the risk of exposure of laundry employees.
  - If bedding is sent to the laundry service:
    - An agreement about the correct procedures to follow must have been reached with the laundry service to avoid exposure of staff during transport and washing. An agreement of this kind could cover the following points:
      - *Send bedding (as well as clothing) to the laundry in sealed double bags, of different colours, labelled "Cytotoxic" (for G1s) or "Caution" (for G2s, G3s).*
      - *Transport the bedding in carts rather than put it down a laundry chute.*
  - Washing of personal clothing in care units is to be avoided, as it is important to limit equipment contamination and staff exposure.
    - If personal clothing is washed in care units, it should be done by staff, following a procedure similar to the one applied in the laundry service. Employees must wear appropriate PPE.

5.2.6 Waste Management

TABLE 33

PPE for waste container handling*

ACTIVITIES	GROUP	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Handling of waste containers	G1 G2 G3	1C 1R 1R	No[a] No[a] No[a]	No No No	No No No

* PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

1C: one pair of chemotherapy-resistant gloves compliant with standard ASTM D6978 | **1R:** one pair of regular gloves

a: A compliant (G1) or regular (G2, G3) gown must be worn if there is a risk of contact between the waste container and the body.

See section 4.2.6 for waste management by health care staff, and Chapter 7 (7.1.2 and 7.2) for management by hygiene and sanitation staff.

5.2.7 Returning Hazardous Drugs

See section 4.2.7 for the management of hazardous drug returns.

5.2.8 Cleaning

TABLE 34

PPE for workplace cleaning*

ACTIVITY	GROUP	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Cleaning	G1	1C	C[b]	No[c]	No
	BCG[a]	1R	R[b]	No[c]	No
	G2	1R	R[b]	No[c]	No
	G3	1R	R[b]	No[c]	No

*PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

1C: one pair of chemotherapy-resistant gloves compliant with standard ASTM D6978 | **C**: gown compliant with section 2.11.2 | **1R:** one pair of regular gloves | **R:** regular gown

a: In the case of BCG, the PPE required for exposure to a biohazard must be worn. | **b:** Gown must be worn if risk of contact with a potentially contaminated surface. | **c:** Face protection must be worn when there is a splash risk.

- **Care areas where hazardous drugs are prepared and administered (e.g., nursing stations, resident rooms) are maintained jointly by health care staff (e.g., orderlies, licensed practical nurses, nurses) and hygiene and sanitation staff. There must be an agreement between the parties about cleaning responsibilities. See Chapter 7.**
  - Typical items that need cleaning include the top and other outer surfaces of medication carts, shelves used to store hazardous drugs and the handle of the drug cabinet.
- **The cleaning responsibilities of health care staff are as follows:**
  - Keep the work and care environment clean and free of any superfluous supplies (e.g., rolls of paper, gauze pads, alcohol swabs).
  - Clean all equipment used in administering hazardous drugs and providing care after each use (e.g., pill crushers, bedpans, urinals).
  - Clean the work surface used after preparing a hazardous drug (e.g., top of cart).
  - Dispose of PPE in appropriate waste containers.

5.3 Instructions to Residents and Caregivers

Residents being given hazardous drugs contaminate their environment, which can lead to cross-contamination. Residents and family members who are helping provide care must be given personalized instructions, both verbally and in writing, about the following points:

- Storage of hazardous drugs in the home (if resident spends time at home)
- Safe handling and administration of hazardous drugs (including self-administration), as well as safe waste management
- Management of bodily fluids containing G1s
- Spill management (if resident spends time at home)

STORAGE OF HAZARDOUS DRUGS IN THE HOME

- **All hazardous drugs must be stored out of the reach of children and pets.**
- **Solid hazardous drugs must be kept in containers that, ideally, are hard for children to open and that are labelled "Cytotoxic" (G1) or "Caution" (G2 or G3).**
  - If a pill organizer is used, it must be a disposable one.
- **Liquid hazardous drugs must be kept in a sealed double plastic bag identified with the resident's name.**
- **Hazardous drugs that must be kept in the refrigerator should be placed in a closed rigid container, and the container should be put on a high shelf.**

SAFE HANDLING AND ADMINISTRATION OF HAZARDOUS DRUGS

- **Women who are pregnant or breast feeding should avoid handling or administering hazardous drugs to others.**
  - If they must do it, they should wear appropriate PPE.
- **Oral route**
  - Preference must be given to oral self-administration of drugs, whenever possible.
    - Single dose hazardous drugs: Encourage residents to open the container themselves and take their medication.
    - Multidose hazardous drugs:
      - *Ask resident to transfer the required number of tablets/capsules into the lid of the hazardous drug container and to swallow them.*
      - *Transfer the tablets/capsules to a disposable container and give it to the resident.*
  - It is important not to touch the tablets or capsules or put them down on a work surface (e.g., countertop). If they come into contact with any other surface than the container, the surface must be washed with detergent.

- Caregivers who handle hazardous drugs must follow these instructions:
  - Wear disposable gloves to touch drugs.
    - *After use, disposable gloves must be put in a plastic bag, and the bag must be closed and disposed of in the appropriate waste container, cytotoxic for G1s or regular waste for G2s and G3s.*
- Residents and their caregivers must wash their hands thoroughly with soap and water before and after each time they handle a hazardous drug.
- All empty hazardous drug containers must be returned to the pharmacy in a closed disposable bag.
  - If that is impossible, the drug container must be closed and disposed of in a waste container that has a lid. The drug container must never be reused for other items or food.

- **Intramuscular or subcutaneous route**
  - Residents and their caregivers must wash their hands thoroughly with soap and water before and after each time they handle a hazardous drug.
  - Caregivers must wear disposable gloves when handling hazardous drugs.
  - Caregivers of residents who receive injections at home must keep cytotoxic waste containers out of the reach of children and pets.
  - Containers must be kept closed, except when disposing of waste into them.
  - Caregivers must:
    - Place a waterproof absorbent pad on the preparation work surface and below the site where the hazardous drug is to be injected
    - Know the safe procedure for administering the hazardous drug
    - Handle the syringe and needle with care
    - Dispose of the syringe and needle as a single unit in the appropriate rigid waste container:
      - *Cytotoxic for a G1*
      - *Pharmaceutical for a G2 or a G3*

- **Other routes of administration**

  The various parenteral routes of drug administration are described in section 4.2.4.1.
  - Infusion by way of a venous access device, whether peripheral (PVAD) or central (CVAD) – See section 4.2.4.1.1 and subsections.
  - Administration of ophthalmic drops – See section 4.2.4.1.9.
  - Administration by inhalation – See section 4.2.4.1.11.
  - Topical administration – See section 4.2.4.1.12.

MANAGEMENT OF BODILY FLUIDS FOR THE 96 HOURS FOLLOWING G1 TREATMENT

- **Residents and their caregivers must:**
  - Know the precautions to take for the 96 hours following the administration of a G1, so as to protect themselves and the resident's environment (e.g., contact with excreta)
  - Always wash their hands thoroughly with soap and water after handling bodily fluids
  - Wear a pair of compliant gloves to handle excreta and soiled clothing and bedding

- **Residents and their caregivers should dispose of a resident's incontinence briefs in a closed double plastic bag.**
  - After 96 hours, this waste may be disposed of in a general waste container.

- **Residents should:**
  - Sit to urinate
  - Put the toilet lid down and flush twice after using the toilet
    - Wipe the toilet bowl, the toilet lid and the floor around the toilet daily using regular cleaning products
      - *Cleaning rags must not be reused on other surfaces*
- **Family members should use a different toilet from the one used by the resident, if possible.**
- **Bedding (as well as clothing) that is not visibly soiled may be washed in the regular laundry.**
- **Bedding (as well as clothing) that is visibly soiled (e.g., urine, vomit or profuse sweating):**
  - Should be washed separately and as soon as possible
    - If the bedding is heavily soiled, it can be washed twice in hot water
  - Must be placed in a plastic bag that can be closed tightly if a washing machine is not available
  - Should never be shaken, as shaking can release contaminated particles
- **Residents or their partner must wear a condom for sexual intercourse for the first 96 hours after treatment with a G1. Sperm and vaginal secretions can contain hazardous drug residues.**

MANAGEMENT OF A LIQUID G1 OR G2 SPILL

- **Residents must be given a spill kit and the instructions for using it, as well as the contact information of a resource person if health care staff do not remain on site during drug administration.**
- **The spill kit should be placed in a plastic bag or a sealed plastic container to keep it intact and allow it to be disinfected. That way, if it has not been used, it can later be taken back and given to another resident.**
- **Spill kit instructions must specify the following information:**
  - The waste resulting from the clean-up of a G1 spill must be placed in a cytotoxic waste container.
  - The waste resulting from the clean-up of a G2 spill must be placed in a closed bag and disposed of in an outside waste container.
  - Contaminated surfaces must be cleaned with detergent.

6 CLSCS And Home Care

This chapter is a guide to the safe handling of hazardous drugs by CLSC community health centre staff, for both health services and home care. It is also intended for people who provide home services, such as home care service workers (social economy).

This chapter's recommendations are specific to the community sector, but build on those presented in the preceding chapters (see indicated section numbers).

Hazardous drugs are used in two different care settings at CLSCs: at the health services clinic and for home care. In both these settings, the clients are the ones who provide the medication prepared generally by their local community pharmacy. CLSCs should therefore not have to manage the receiving, storage and transport of hazardous drugs. Under exceptional circumstances, however, the recommendations given in Chapter 4 may have to be implemented.

CLSCs and any other organization responsible for client care should require that the hazardous drug dispensing pharmacy follow the recommendations for preparation, packaging, labelling and transport set out in Chapter 3.

6.1 CLSC Health Services

6.1.1 Workplace Design

- **Provide a treatment room or a reserved section of a treatment room (not necessarily exclusive) for the preparation and administration of hazardous drugs (G1, G2 and G3).**
  - Access to this room or section of room should be restricted to authorized staff, clients and, if necessary, a small number of family and friends.
  - If the room/section is not dedicated, special procedures should be implemented following a risk assessment (e.g., dedicated toilet, cleaning of surfaces).
- **The treatment room should be furnished with the customary equipment (e.g., counter, sink, medical supplies, storage for PPE, spill kit). There should also be space to accommodate hazardous drug waste containers.**

- **The room/section should be easy to clean (e.g., seamless surfaces that withstand cleaning, non-porous materials).**
- **There are no special ventilation requirements, except if treatment is administered by inhalation (in aerosol form) (see sections 4.1 and 4.2.4.1.11).**
- **A room should be made available for receiving hazardous drug waste containers from health services and home care services. This final storage area must comply with the recommendations of the MSSS's *Guide de gestion des déchets* (2017):**
  - Be kept under lock and key
  - In a cool room with ventilation that prevents the spread of contamination to adjacent rooms
  - Air should be exhausted to the outside, without recirculation
  - The room should not be located near areas frequented by clients

6.1.2 Safe Practices

- **Each hazardous drug must be identified by the appropriate symbol so that nurses can recognize to which group it belongs (see sections 1.2.1 and 1.2.2).**
  - G1s must be identified with the "Cytotoxic" symbol and the "Cytotoxic" label.
  - G2s and G3s must be identified with the "Caution" label. G3s should also be identified with the "Caution pregnancy" label.
  - The use of a symbol specific to G1s, G2s or G3s may be considered, such as the group's number inside a coloured triangle, as illustrated in this guide.

6.1.2.1 Preparation

Hazardous drugs may be administered by the parenteral or enteral route.

REMINDER
> The parenteral route refers to all modes of administration in which the drug enters the body via a route other than the digestive tract (e.g., intramuscular [IM], subcutaneous [Subcut] or intravenous [IV] route).
> The enteral route covers all modes of administration in which the drug passes through the digestive tract (e.g., oral, sublingual or nasogastric).

- **Before handling a hazardous drug, staff must read the label on the drug container in order to determine the hazardous drug group (G1, G2 or G3) to which the drug belongs and to know what precautions must be taken.**
  - If there is insufficient information on the label, some other means must be used to inform nurses about the nature of the drug.
- **Appropriate PPE must be worn to handle the container and packaging of a hazardous drug, as they are deemed to be a potential source of contamination.**
- **The drug may be prepared wholly or in part at the local community pharmacy or in the room, or section of room, where it is to be administered to the client. That decision will depend on the results of a risk assessment that takes several factors into account: route of administration, dosage form (e.g., solid, liquid), stability of drug and hazardous drug group to which it belongs.**

6.1.2.1.1 | PREPARATION - PARENTERAL ROUTE

TABLE 35

PPE for parenteral drug preparation activities*

ACTIVITY	DOSAGE FORMS	GROUP	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Preparation	Parenteral	G1 BCG G2[b] G3[b]	2C 1R 1R 1R	C R R R	No[a] Yes[c] Yes Yes	No[a] N95[c] Yes Yes

*PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

2C: two pairs of chemotherapy-resistant gloves compliant with standard ASTM D6978 | **C:** gown compliant with section 2.11.2 | **1R:** one pair of regular gloves | **R**: regular gown | **N95:** particulate filter mask, at least N95

a: This PPE is recommended for preparations that are ready to be administered or for backpriming. | **b:** Gloves and a gown are recommended for preparations that are ready to be administered or for backpriming. If tubing has to be set up (under exceptional circumstances), respiratory and face protection is recommended. | **c:** With a closed system drug-transfer device.

- **Luer-Lock systems should be used for parenteral drug delivery to ensure a better seal at connection sites.**
- **Syringes must not be filled to more than ¾ capacity, to avoid spillage.**

6.1.2.1.2 | PREPARATION OF G1S – INTRAVENOUS ROUTE

See section 4.2.3.1.1.

6.1.2.1.3 | PREPARATION OF G2S AND G3S – INTRAVENOUS ROUTE

See section 4.2.3.1.2.

6.1.2.1.4 | PREPARATION OF G1S, G2S AND G3S – SUBCUTANEOUS OR INTRAMUSCULAR INJECTION

- **G1s must be prepared at the pharmacy and dispensed in their final dosage form ready to be administered, so as to limit the handling required in the administration room.**
- **G2s and G3s should be prepared at the pharmacy.**
- **G1, G2 and G3 syringes must be supplied with the required protective cap (e.g., Luer-Lock) on the end.**
  - A safety needle should be used to administer the drug.
  - Syringes used to administer small amounts may be supplied with a needle.
- **A disposable waterproof absorbent pad must be placed on the work surface when fitting a needle onto a G1 or G2 syringe.**

- **Air should never be removed from a G1 or G2 syringe.**
  - Under exceptional circumstances, air may, as a last resort, be removed, if the following criteria are met:
    - Appropriate PPE is worn.
    - Air removal is done in a segregated area, well away from traffic, over a piece of sterile gauze placed on top of a disposable waterproof absorbent pad.
    - Air removal is done as close as possible to the drug administration time.
    - The work area is decontaminated with detergent at the end of the administration.
- **Under very exceptional circumstances (e.g., constraints related to drug stability), G2s and G3s may, as a last resort, be prepared at a CLSC, provided a risk assessment is done beforehand that takes the following points into account:**
  - A closed system drug-transfer device may be used.
  - The task must be performed in a segregated area, well away from traffic, on a disposable waterproof absorbent pad.
  - Appropriate PPE must be worn.
  - The preparation must be done as close as possible to the drug administration time.
  - The work area must be decontaminated with detergent at the end of each preparation.

6.1.2.1.5 PREPARATION - ENTERAL ROUTE

In principle, hazardous drugs are not prepared for administration by mouth or by feeding tube in CLSCs. If it must be done, see section 4.2.4.2.

6.1.2.2 Administration

Unless otherwise indicated, recommendations apply to G1s, G2s and G3s.

- **Before handling a hazardous drug, staff must read the label on the drug container to determine the drug group (G1, G2 or G3) to which the drug belongs and to know what precautions must be taken.**
  - If there is insufficient information on the label, some other means must be used to inform nurses about the nature of the drug.
- **Before going ahead with administration, nurses must:**
  - Don the appropriate PPE, as the drug packaging is considered to be potentially contaminated.
  - Examine the integrity of the container and contents.
- **Wash their hands with soap and water before and after each manipulation and ask the client to do likewise.**

6.1.2.2.1 | ADMINISTRATION – PARENTERAL ROUTE

TABLE 36

PPE for parenteral drug administration activities*

ACTIVITIES	MODES OF ADMINISTRATION	GROUP	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Parenteral administration	Parenteral solution	G1 G2 G3	2C 1R 1R	C R R	No[a] No[a] No[a]	No No No
	Inhalation	G1 G2 G3	2C 1R 1R	C R R	No[a] No[a] No[a]	N95[b] N95[b] N95[b]
	Topical (otic, ophthalmic, intranasal, IR, intravaginal)	G1 G2 G3	2C 1R 1R	C R R	No[a] No[a] No[a]	TBD[c] TBD[c] TBD[c]

* PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

2C: two pairs of chemotherapy-resistant gloves compliant with standard ASTM D6978 | ***C:*** gown compliant with section 2.11.2 | **1R:** one pair of regular gloves | **R:** regular gown | **IR:** intrarectal | **N95:** particulate filter mask, at least N95 | **TBD:** to be determined

a: If splash risk, protection required. | **b:** In addition to other specific prevention measures | **c:** Yes, if there is an inhalation risk, with the type of PPE depending on the risk assessment.

The various parenteral routes of drug administration are described in section 4.2.4.1.

- **Venous access devices (VADs), peripheral (PVADs) and central (CVADs) –** See section 4.2.4.1.1 and subsections.
- **Ophthalmic drops –** See section 4.2.4.1.9.
- **Subcutaneous or intramuscular injection –** See section 4.2.4.1.10.
- **Intravesical administration –** See section 4.2.4.1.7**.**
- **Administration by inhalation –** See section 4.2.4.1.11.
- **Topical route –** See section 4.2.4.1.12.

6.1.2.2.2 | ADMINISTRATION – ENTERAL ROUTE

In principle, hazardous drugs are not administered orally or by feeding tube in CLSCs. If it must be done, see section 4.2.4.2.

6.1.2.3 Other Care

TABLE 37

PPE for other care activities*

ACTIVITIES	GROUP	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Hygiene care, specimen collection, other care where there is contact with excreta	G1 BCG G2[b] G3[b]	1C 1R 1R 1R	C R R R	No[a] No[a] No[a] No[a]	No No No No
Indirect care with slight or no contact with client (auscultation, help walking)	G1 BCG G2 G3	No No No No	No No No No	No No No No	No No No No

* PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

1C: one pair of chemotherapy-resistant gloves compliant with standard ASTM D6978 | **C:** gown compliant with section 2.11.2 | **1R:** one pair of regular gloves | **R:** regular gown

a: If splash risk, protection required. | **b:** Follow routine infection prevention practices.

See section 4.2.5 for further details. Only recommendations specific to health services and activities are presented in this section.

Health care staff can sometimes come into contact with hazardous drugs in the course of activities other than those related to drug administration. Direct and indirect contact with bodily fluids (e.g., urine, feces, blood) is a potential source of exposure to hazardous drugs (see sections 1.2.1 and 1.2.2).

- **No special measures are recommended regarding contact with the excreta and bodily fluids of clients being given a G2 or a G3. Routine practices must be followed.**
- **Precautions regarding contact with excreta and bodily fluids must be taken for at least 96 hours following the last dose administered to clients being given a G1.**
  - Appropriate PPE must be worn.
  - These precautions may be adapted to suit the situation, following a risk assessment (see section 2.5).
  - Special instructions must be given to these clients if they use the toilets at a CLSC (e.g., avoid using them if possible, sit to urinate, always flush twice).

INDIRECT CARE

- **Staff that provide care without physical contact (e.g., discussion with a client) or with only slight contact (e.g., helping to walk) do not have to take any special measures. Routine practices must be followed.**

6.1.2.4 Waste Management

TABLE 38

PPE for waste container handling*

ACTIVITIES	GROUP	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Handling of waste containers	G1 G2 G3	1C 1R 1R	No[a] No[a] No[a]	No No No	No No No

* PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

1C: one pair of chemotherapy-resistant gloves compliant with standard ASTM D6978 | **1R:** one pair of regular gloves

a: A compliant (G1) or regular (G2, G3) gown must be worn if there is a risk of contact between the waste container and the body.

- **Hazardous waste is defined in section 4.2.6.1. A partially administered hazardous drug must be treated as waste. For details about waste management, see section 4.2.6.**

6.1.2.5 Cleaning

TABLE 39

PPE for workplace cleaning*

ACTIVITIES	GROUP	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Cleaning	G1 BCG[a] G2 G3	1C 1R 1R 1R	C[b] R[b] R[b] R[b]	No[c] No[c] No[c] No[c]	No No No No

* PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

1C: one pair of chemotherapy-resistant gloves compliant with standard ASTM D6978 | **C:** gown compliant with section 2.11.2 | **1R:** one pair of regular gloves | R: regular gown

a: In the case of BCG, the PPE required for exposure to a biohazard must be worn. | **b:** Gown must be worn if risk of contact with a potentially contaminated surface. | **c:** Face protection must be worn when there is a splash risk.

Facility cleaning is a joint responsibility of health care staff and the hygiene and sanitation department. For cleaning tasks performed by the hygiene and sanitation department, see Chapter 7. When cleaning is carried out by health care staff, the following measures must be applied:

- **Keep the work and care environment clean and free of any superfluous supplies (e.g., rolls of paper, gauze pads, alcohol swabs).**
- **Clean the work surface after preparing a hazardous drug.**

- **Clean chairs and stretchers after each use.**
  - It is important to clean in a logical order, going from the least chemically contaminated surface to the most contaminated (e.g., back, seat, armrests of a chair).
- **Dispose of PPE in the appropriate waste containers if it is soiled or in accordance with specific instructions (see section 4.2.6).**

6.1.3 Instructions to Clients and Caregivers

Clients being given hazardous drugs contaminate their environment, which can lead to cross-contamination. Clients and family members who are helping provide care must be given personalized instructions, both verbally and in writing, about the following points:

- Access to place of treatment
- Storage of hazardous drugs in the home
- Safe handling and administration of hazardous drugs in the home and waste management
- Management of bodily fluids containing G1s or BCG
- Spill management
- Housekeeping and waste management

ACCESS TO PLACE OF TREATMENT

- **Access to the place of treatment should be restricted to authorized staff, clients and a small number of caregivers.**
  - If the presence of caregivers is deemed essential, they must be informed of the risks involved in exposure.
  - Visitors who are pregnant and children under 12 should not be authorized to enter the treatment area.
  - If their presence is deemed essential, they must be informed of the risks involved in exposure and avoid all contact with potential sources of contamination (e.g., excreta).
- **The dispensing pharmacy or CLSC staff that contacts clients to give them their first appointment for health services must inform them that it is important for them to bring the hazardous drug in the same packaging they received it in.**

STORAGE OF HAZARDOUS DRUGS IN THE HOME

- **All hazardous drugs must be stored out of the reach of children and pets.**
- **Solid hazardous drugs must be kept in containers that, ideally, are hard for children to open and that are labelled "Cytotoxic" (G1) or "Caution" (G2 or G3).**
  - If a pill organizer is used, it must be a disposable one.
- **Liquid hazardous drugs must be kept in the sealed double plastic bag identified with the client's name.**
- **Hazardous drugs that must be kept in the refrigerator should be placed in a closed rigid container, and the container must be put on a high shelf.**

SAFE HANDLING AND ADMINISTRATION OF HAZARDOUS DRUGS IN THE HOME AND WASTE MANAGEMENT

- **Women who are pregnant or breast feeding should avoid handling or administering hazardous drugs for others.**
  - If they must do it, they should wear appropriate PPE.
- **Oral route**
  - Preference must be given to oral self-administration of medications, whenever possible.
    - Single dose hazardous drugs: Encourage clients to open the container themselves and take their medication.
    - Multidose hazardous drugs: Transfer the required number of tablets or capsules into a disposable container.
  - It is important not to touch the tablets or capsules or put them down on a work surface (e.g., countertop).
    - If they come into contact with any other surface than the container, the surface must be washed with detergent.
  - Caregivers who handle hazardous drugs must follow these instructions:
    - Avoid touching the medication.
    - Wear disposable gloves if direct contact with the medication is necessary.
    - After use, throw the gloves away.
    - Clients and their caregivers must wash their hands thoroughly with soap and water before and after each time they handle a hazardous drug.
  - All empty hazardous drug containers must be returned to the pharmacy in a closed disposable bag.
    - If that is impossible, the drug container must be closed and disposed of in a waste container that has a lid. The drug container must never be reused for other items or food.
- **Intravenous route**
  - Clients who are given infusions at home:
    - Clients should put their mattress in a plasticized cover to protect it from contamination (e.g., in case of accidental disconnection of the IV equipment, or urinary or fecal incontinence).
    - Caregivers must wear disposable gloves when handling the infusion pump or hazardous drug bags.
    - Clients and their caregivers must wash their hands thoroughly with soap and water before and after each time they handle the pump or a hazardous drug bag.
  - Clients and their caregivers must know the:
    - Signs and symptoms of infiltration and extravasation, as well as other possible complications
    - Ways to avoid spills (e.g., precautions to take before moving, getting dressed)
    - Measures to take when there are problems or questions, such as how to:
      - *Check the VAD and the drug administration device if the infusion slows or stops*
      - *Return the hazardous drug (provide contact information)*
      - *Manage a spill*
      - *Contact the resource person (provide contact information)*

- **Intramuscular, subcutaneous or intradermal route**
  - Clients and their caregivers must wash their hands thoroughly with soap and water before and after each time they handle a hazardous drug.
  - Caregivers must wear disposable gloves when handling hazardous drugs.
  - Clients and caregivers must:
    - Place a disposable waterproof absorbent pad or a towel on the preparation work surface and below the site where the hazardous drug is to be injected.
    - Know the safe procedure for administering the hazardous drug.
    - Handle the syringe and needle with care.
    - Dispose of the syringe and needle as a single unit in the appropriate rigid waste container:
      - *Cytotoxic for a G1*
      - *Pharmaceutical for a G2 or a G3.*

MANAGEMENT OF BODILY FLUIDS FOR THE 96 HOURS FOLLOWING G1 TREATMENT

- **Clients and their caregivers must:**
  - Know the precautions to take for the 96 hours following the administration of a G1, so as to protect themselves and the client's environment (e.g., contact with excreta).
  - Always wash their hands thoroughly with soap and water after handling bodily fluids.
  - Wear a pair of compliant gloves to handle excreta and soiled clothing and bedding.
- **For the 96 hours following a last dose, clients and their caregivers should dispose of the client's incontinence briefs and diapers in a regular double garbage bag and close it tightly before putting it out with the regular garbage.**
  - After 96 hours, incontinence briefs and diapers may be disposed of directly in the regular garbage.
- **Clients should:**
  - Sit to urinate.
  - Put the toilet lid down and flush twice after using the toilet.
    - Wipe the toilet bowl, the toilet lid and the floor around the toilet daily using regular cleaning products.
    - Cleaning rags must not be reused on other surfaces.
- **Family members should use a different toilet from the one used by the client, if possible.**
- **Bedding (as well as clothing) that is not visibly soiled may be washed in the regular laundry.**
- **Bedding (as well as clothing) that is visibly soiled (e.g., urine, vomit or profuse sweating):**
  - Should be washed separately and as soon as possible.
    - If the bedding is heavily soiled, it may be washed twice in hot water.
  - Must be placed in a plastic bag that can be closed tightly if a washing machine is not available.
  - Should never be shaken, as shaking can release contaminated particles.
- **Clients or their partner must wear a condom for sexual intercourse for the first 96 hours after treatment with a G1. Sperm and vaginal secretions can contain hazardous drug residues.**
- **A spill of bodily fluids (e.g., vomit, urine) must be treated in the same way as an accidental spill (see following section).**

MANAGEMENT OF BODILY FLUIDS CONTAINING BCG

- **Clients who have received intravesical treatment with BCG must follow these instructions for 6 hours after their treatment:**
  - Add 500 ml of bleach to the toilet bowl after using it.
  - Let the bleach sit for 15 minutes before flushing.
  - Repeat each time the client uses the toilet over the 6-hour period.
- **Clients or their partner must wear a condom for sexual intercourse for the first 24 hours after treatment.**

MANAGEMENT OF A LIQUID G1 OR G2 SPILL

- **Clients must be given a spill kit and the instructions for using it, as well as the contact information of a resource person if health care staff do not remain on site during drug administration.**
- **The spill kit should be placed in a plastic bag or a sealed plastic container to keep it intact and allow it to be disinfected. That way it can be passed on to another client if it has not been used.**

HOUSEKEEPING AND WASTE MANAGEMENT BY CLIENT OR CAREGIVER

- **Regular cleaning products may be used.**
- **The cleaning method of working from what is non-contaminated to what is potentially contaminated with hazardous drugs must be applied.**
- **In places with low potential contamination (e.g., kitchen), the person who does the cleaning:**
  - Must follow routine practices.
  - May choose not to wear gloves.
- **In places with higher potential contamination (e.g., washrooms, drug storage areas), the person who does the cleaning must:**
  - Use disposable wipes.
  - Wear disposable gloves.
  - Dispose of the soiled gloves and soiled cleaning supplies in a regular garbage bag.
- **Cleaners must wash their hands thoroughly with soap and water after removing their gloves and after completing the cleaning.**
- **Waste (e.g., gloves, empty drug containers) must be put in a plastic bag, which must then be closed up tightly.**
  - The bag may be put out with the regular garbage or wherever regular garbage is placed for pick-up.
  - A rigid, sealed container must be used for the disposal of sharps or breakable waste. The container must have a lid. It must be kept closed except for when placing waste in it.
  - All waste must be stored out of the reach of children and pets.

6.2 Home Care

6.2.1 Assistance with Administering Drugs

6.2.1.1 Storing Drugs at Home

- **The labelling of hazardous drugs must inform the people who use them about the nature of the drugs so that they can take appropriate precautions.**
  - G1s must be identified with the "Cytotoxic" symbol and the "Cytotoxic" label.
  - G2s and G3s should be identified with the "Caution" label.
  - The use of specific symbols for G1s, G2s and G3s may be considered. For instance, the number for the drug group can be placed inside a coloured triangle, as illustrated in this guide (see section 1.2.2).
- **All hazardous drugs must be stored out of the reach of children and pets.**
  - Hazardous drugs that must be kept in the refrigerator should be placed in a closed rigid container, and the container should be put on a high shelf.
  - Liquid hazardous drugs must be kept in a sealed double plastic bag.
- **An accidental spill kit, including a written procedure, must be available.**

6.2.1.2 Drug Preparation and Administration

6.2.1.2.1 PREPARATION AND ADMINISTRATION OF PARENTERAL DRUGS

See sections 4.2.3 and 4.2.4 regarding the preparation and administration of parenteral products.

6.2.1.2.2 PREPARATION OF ENTERAL DRUGS

See Table 40 below.

6.2.1.2.2.1 PREPARATION OF G1S – ENTERAL ROUTE

- **All G1s administered by the enteral route must be prepared in the pharmacy and dispensed in a final dosage form that limits the manipulations required in the administration room:**
  - Tablets or capsules
  - Pre-cut tablets
  - Liquid form or compound repackaged in a single dose form

TABLE 40

PPE for enteral drug preparation activities*

ACTIVITIES	DOSAGE FORMS	GROUP	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Preparations with simple manipulations[a]	Intact tablets or capsules	G1 G2 G3	1C 1R 1R	No No No	No No No	No No No
Preparations with complex manipulations[a]	Non-intact tablets or capsules (e.g., crushing of tablets and capsules) Repackaging of oral liquids, feeding tubes, topical forms	G1 G2 G3	2C 1R 1R	C R R	No[b] No[b] No[b]	Yes Yes Yes

* PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

1C, 2C: one or two pairs of chemotherapy-resistant gloves compliant with standard ASTM D6978 | **C:** gown compliant with section 2.11.2 | **1R:** one pair of regular gloves | **R:** regular gown | **N95:** particulate filter mask, at least N95

a: If the preparation is not done in the pharmacy, the PPE indicated here must be worn. | **b:** If splash risk, protection required. | **c:** Yes, if there is an inhalation risk, with the type of PPE depending on the risk assessment.

- **When the solid form is not suitable for the client, liquid forms (commercial or compounded preparations) dispensed in oral syringes closed by a protective cap should preferably be used so as to avoid having to crush tablets.**
  - Some tablets will dissolve in water, or other appropriate liquids, depending on the drug, which allows extemporaneous preparation in an oral syringe (or ENFit, depending on the enteral route being used) by a nurse. The compatibility of the technique with the drug to be administered (as an oral tablet) must be confirmed by the facility's pharmacy. If compatibility is confirmed, the following technique may be applied, which is to be preferred to crushing tablets:
    - Remove the plunger from an oral syringe (or ENFit) of the appropriate volume (generally with a capacity of at least 30 ml).
    - Put the tablet (or fraction of tablet) in the syringe.
    - Put the plunger back into the syringe and draw water (or other liquid, as the case may be) up into it. Let a certain amount of air into the syringe to allow effective agitation.
    - Put the stopper in the syringe and shake vigorously for at least 5 minutes or according to the instructions from the pharmacy.
    - Administer within 15 minutes of the tablet or fraction of tablet dissolving completely, by mouth or enteral tube (e.g., gastrostomy, jejunostomy or nasogastric feeding tube).
    - Draw up liquid again to rinse the syringe if drug particles are still visible in it, to ensure that the full dose is administered to the client.
    - Dispose of the syringe and any other supplies used in a cytotoxic waste container.
    - The PPE recommended in Table 40 must be worn.
    - A waterproof absorbent pad should be placed below the work area.
    - Work methods must limit contamination of work surfaces, supplies and preparations, caused in particular by the use of already contaminated gloves.
    - The work surface must be cleaned before and after preparation.

- **Under very exceptional circumstances (e.g., constraints related to drug stability), certain manipulations with G1s may, as a last resort, be performed in the drug administration room, following a conclusive risk assessment. For example, to crush tablets, the following criteria must be met:**
  - The task must be performed in a segregated area, well away from traffic, on a disposable waterproof absorbent pad.
  - Appropriate PPE must be worn, including N95 respiratory protection.
  - The G1 drug must be prepared as close as possible to the time it will be administered.
  - Equipment used to manipulate G1s must be reserved for G1s.
    - > Equipment can be reserved for a specific client.
  - The G1 must be crushed and then manipulated in a way that keeps particle dispersion to a minimum (e.g., transfer from container, mixing with fruit purée).
  - The equipment used must be decontaminated with detergent after each use or each client.
  - The work area must be decontaminated with detergent at the end of each preparation.

6.2.1.2.2.2 | PREPARATION OF G2S AND G3S – ENTERAL ROUTE

- **G2s administered enterally should be prepared at the pharmacy, in a final dosage form that will limit the manipulations required in the administration room.**
- **G2 and G3 preparations (e.g., cutting or crushing a tablet, measuring an enteral liquid) may be done in the drug administration room if the following criteria are met:**
  - The task must be performed over a disposable waterproof absorbent pad and in a segregated area well away from traffic.
  - Appropriate PPE must be worn, including N95 respiratory protection, for instance, when crushing a tablet.
  - G2s and G3s must be prepared as close as possible to the drug administration time.
  - Equipment used to manipulate G2s or G3s must be reserved for G2s and G3s, respectively, and must be cleaned after each use or each client.
    - > Equipment can be reserved for a specific client.
- **The G2 or G3 to be crushed must be manipulated in a way that keeps particle dispersion of the drug to a minimum during crushing and mixing (e.g., transfer, mixing with fruit purée).**
- **The work area must be cleaned at the end of each preparation.**

6.2.1.2.3 | ENTERAL ADMINISTRATION

- **Oral self-administration of tablets, capsules and liquids is to be preferred whenever possible.**
  - Single dose hazardous drugs: Encourage clients to open the container themselves and take their medication without touching it.
  - Multidose hazardous drugs: Transfer the tablets or capsules to a disposable container and give it to the client.
- **Health care staff must:**
  - Wear one pair of gloves and avoid touching the tablets or capsules.
  - Wear two pairs of gloves to administer a G1 in liquid form.

TABLE 41

PPE for enteral administration activities*

ACTIVITIES	DOSAGE FORMS	GROUP	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Enteral administration	Solid single dose form	G1 G2 G3	1C 1R 1R	No No No	No No No	No No No
	Oral liquid (e.g., syringe)	G1 G2 G3	2C 1R 1R	C R R	No[a] No[a] No[a]	No No No

* PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

1C, 2C: one or two pairs of chemotherapy-resistant gloves compliant with standard ASTM D6978 | **C:** gown compliant with section 2.11.2 | **1R:** one pair of regular gloves | R: regular gown

a: If splash risk, protection required.

- **If the hazardous drug is administered through a feeding tube:**
  - Disposable waterproof absorbent pads must be placed on the work surface.
  - The syringe must not be filled to more than ¾ capacity.
  - G1s and G2s must be handled at waist height so as to reduce to a minimum the risk of being splashed in the face.
  - The protective cap must be removed over a disposable waterproof absorbent pad placed on the work surface.
  - Hazardous drugs must be injected slowly.
  - When the syringe is removed, the injection site must be covered with dry gauze, and a disposable waterproof absorbent pad must be placed under the injection site.
  - The syringe (including the gauze pads and the waterproof absorbent pad) must be disposed of as a single unit in an appropriate waste container.
- **Both staff and clients must wash their hands thoroughly with soap and water after each manipulation.**

6.2.2 Other Home Care and Assistance Services

- **Special requirements for home care (for additional information, see section 5.2.5)**
  - Staff providing home care and services to clients receiving G1s must know the precautions they must take to protect themselves and the client's environment (e.g., contact with excreta or drugs).
  - Staff providing home care and services must be informed about clients receiving G1s if their duties involve a risk of contact with excreta or drugs.
  - People who handle bodily fluids (e.g., wound care, drawing blood, removing/inserting tubes), excreta, bedding or soiled equipment (e.g., bedpans) from clients who have been given G1s must wear compliant PPE for at least the first 96 hours after treatment.

TABLE 42

PPE for other care activities*

ACTIVITIES	GROUP	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Hygiene care, specimen collection, other care where there is contact with excreta	G1 BCG G2[b] G3[b]	1C 1R 1R 1R	C R R R	No[a] No[a] No[a] No[a]	No No No No
Indirect care with slight or no contact with client (auscultation, help walking)	G1 BCG G2 G3	No No No No	No No No No	No No No No	No No No No
Handling of bedding (as well as clothing) not soiled with excreta or drugs[b]	G1 BCG G2 G3	1R 1R 1R 1R	No No No No	No No No No	No No No No
Handling of bedding (as well as clothing) visibly soiled with excreta	G1 BCG G2[b] G3[b]	2C 1R 1R 1R	C R R R	No[a] No[a] No[a] No[a]	Yes[c] N95 No No
Handling of bedding (as well as clothing) visibly soiled with drugs	G1 BCG G2[b] G3[d]	2C 2R 2R NA	C R R NA	No[a] No[a] No[a] NA	Yes[c] N95 Yes[c] NA

* PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

1C, 2C: one or two pairs of chemotherapy-resistant gloves compliant with standard ASTM D6978 | **C:** gown compliant with section 2.11.2 | **1R, 2R:** one or two pairs of regular gloves | **R:** regular gown | **N95:** particulate filter mask, at least N95 | **NA:** not applicable

a: If splash risk, protection required. | **b:** Follow routine infection prevention practices. | **c:** Type of respirator depends on risk assessment. | **d:** Pregnant women should not be assigned to clean up a spill, on any kind of surface, including bedding.

- Potentially contaminated equipment and waste kept in the home must be stored out of the reach of children and pets.
- For clients who have received a G1 in the last 96 hours, staff should dispose of their incontinence briefs and diapers in a double plastic bag, which must be kept closed.
  - After 96 hours, this waste may be disposed of in a general waste container.
- Staff must always wash their hands thoroughly after such handling.
- The bedding and clothing of clients who have received a G1 in the last 96 hours that is not visibly soiled with excreta/bodily fluids may be washed with the regular laundry.
- The bedding and clothing of clients who have received a G1 in the last 96 hours that is visibly soiled:
  - Must be washed separately and as soon as possible.
    - *If the clothing or bedding is heavily soiled, it can be washed twice in hot water.*
    - *Clothing or bedding must be placed in a plastic bag that can be closed tightly if a washing machine is not available.*
  - Should not be shaken, as shaking can release contaminated particles.

6.2.3 Waste Management

TABLE 43

PPE for waste container handling*

ACTIVITIES	GROUP	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Handling of waste containers	G1 G2 G3	1C 1R 1R	No[a] No[a] No[a]	No No No	No No No

* PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

1C: one pair of chemotherapy-resistant gloves compliant with standard ASTM D6978 | **1R:** one pair of regular gloves

a: A compliant (G1) or regular (G2, G3) gown must be worn if there is a risk of contact between the waste container and the body.

See sections 4.2.6 and 4.2.7 for general information about waste management and returning hazardous drugs. Only the special requirements of home care will be covered in this section.

- **The sewer system must never be used as a way of disposing of drugs, which must be returned in an appropriate container to the pharmacy they came from.**
- **The excreta of clients who have been given hazardous drugs may be disposed of in the sewer system.**
- **Residual doses of G1s, G2s and G3s and any supplies soiled by these hazardous drugs must be disposed of in an appropriate waste container.**
  - Appropriate waste containers must be provided to clients along with their hazardous drugs.
    - > The CLSC nurse must ensure that an appropriate container is available and must bring one if that is not the case.
    - > Residual doses must be returned in the containers in which the drugs were delivered if their state still allows safe transport.
  - Waste containers must be kept closed, except when disposing of waste into them.
- **Hazardous drugs, supplies used and waste stored at home must be kept out of the reach of children and pets.**
- **The health care facility (e.g., CLSC) should agree to manage the cytotoxic waste containers used at home by clients being given G1s.**
  - In some cases, under local agreements, other locations can also serve as collection sites for cytotoxic waste from homes (e.g., specialized clinics, community pharmacies).
- **Health care staff must bring cytotoxic waste from clients being given G1s (with the exception of incontinence briefs) back to the CLSC, except in the case of self-care. For self-care, clients/caregivers are responsible for taking their waste back to the place that supplied them with the medication.**
- **Waste from G2 and G3 drugs must be treated as pharmaceutical waste. Residual doses must be returned to the local community pharmacy or disposed of in a pharmaceutical waste container, which must then be taken back to the CLSC.**
- **Cytotoxic (and possibly pharmaceutical) waste containers must be transported so as to keep the risks of contamination of the health care employee's vehicle to a minimum. Two techniques are recommended.**

TECHNIQUE NO. 1: REUSABLE SECONDARY CONTAINER FOR TRANSPORT

BEFOREHAND

- **Sharps and breakable objects must be put in a sealed, puncture-resistant, rigid container identified with the "Cytotoxic" symbol.**
- **All excess liquids (e.g., remains of medication) must be put in a sealed container (e.g., jar with lid) and placed in a rigid container with an absorbent substance covering the bottom.**
- **Solid waste that is not sharp or breakable may be disposed of in a red polyethylene (strong plastic) bag. These bags must be leak- and tear-resistant under normal conditions of use.**
  - They must be identified with the "Cytotoxic" hazard symbol.
  - The container or bag must never be filled to over ¾ capacity.
  - People must never put their hands in the bag or container or use force to compress the waste.
  - The bag or container must be sealable for transport purposes.

FOR TRANSPORT

- **Bags and containers must be put in a secondary container, which is then placed and immobilized in the vehicle's trunk. The secondary container must be sealed, rigid, washable and properly identified with the "Cytotoxic" symbol.**

TECHNIQUE NO. 2: DISPOSABLE SECONDARY CONTAINER FOR CYTOTOXIC WASTE

BEFOREHAND

- **Sharp objects must be put in a compliant, sealed, puncture-resistant, rigid container.**
- **All excess liquids (e.g., remains of medication) must be put in a compliant sealed container (e.g., jar with lid) and placed in a rigid container with an absorbent substance covering the bottom.**
- **All contaminated materials (e.g., needles, tubing, gowns, gloves) may be placed in a sufficiently large compliant disposable rigid container.**
  - The container must never be filled to over ¾ capacity.
  - People must never put their hands in the container or use force to compress the waste.
  - The container must be sealable for transport purposes and must be identified with the "Cytotoxic" hazard symbol.

FOR TRANSPORT

- **The disposable secondary container should be placed and immobilized in the vehicle's trunk.**
- **It may be placed inside a plastic bag to further limit possible contamination of the vehicle's trunk.**

6.2.4 Instructions to Clients and Caregivers

- **Clients being treated with hazardous drugs contaminate their environment and must be given instructions about what they can do to prevent cross-contamination. See section 6.1.3.**

7 Hygiene and Sanitation

This chapter deals with the activities of the hygiene and sanitation department: cleaning and waste management. These activities performed by pharmacy staff or health care staff were described in the preceding chapters. Surfaces contaminated with a hazardous drug must be cleaned to eliminate or reduce any traces of the drug. Hygiene and sanitation workers play a key role in sanitizing the facility. They must also follow best practices to protect themselves and prevent the spread of hazardous drug particles. Recommendations regarding spill management are set out in Chapter 9.

7.1 Safe Cleaning Practices

7.1.1 General Cleaning Principles – G1, G2 and G3 Drugs

TABLE 44

PPE for cleaning activities in areas labelled "G" or "Caution"*

ACTIVITIES	DOSAGE FORMS	GROUP	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Cleaning[a]	All	G1 BCG[d] G2 G3	1C 1R 1R 1R	C R[e] R[e] R[e]	No[b] No[b] No[b] No[b]	No[c] No No No

* PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

1C: one pair of chemotherapy-resistant gloves compliant with standard ASTM D6978 | **C:** gown compliant with section 2.11.2 | **1R:** one pair of regular gloves | **R:** regular gown

a: For the cleaning of sterile preparation compounding areas (clean room) and anterooms, staff must also wear a cap, a beard covering, if applicable, a surgical mask, clean, closed shoes (which may be dedicated footwear) and a pair of shoe covers. | **b:** If splash risk, protection is required (e.g., cleaning of ceilings). | **c:** Chlorinated solutions are irritants and require respiratory protection at certain concentrations in the air. A respirator with combined cartridges and prefilter (P100 CC respirator) may be worn if such a solution is chosen. | **d:** Shoe covers must be worn for cleaning the drug administration room. | **e:** Gown must be worn if there is a risk of contact with a potentially contaminated surface.

- **The facility's cleaning procedure should be specified locally by the hazardous drug committee (or the person in charge of the safe management of hazardous drugs) in conjunction with the hygiene and sanitation department.**
  - The procedure must specify the surfaces to be cleaned, the nature and frequency of the required cleaning, and the products and supplies to be used.
    - > The cleaning frequency must be tailored to the risk of contamination of a surface. It can be reviewed on the basis of the results of environmental monitoring.
    - > The frequency can be adjusted if potential contamination activities are not performed daily.
    - > So-called "high-touch" areas should be cleaned more frequently.
    - > Hard-to-reach areas with little potential for contamination should be cleaned once or twice a year.
    - > Targeted cleaning should be planned if certain areas are found to be contaminated.
  - An agreement needs to be reached with the various departments regarding each one's responsibility for the cleaning of the facility in question.
    - > In general, work surfaces should be the responsibility of the staff that uses them. However, they can be cleaned by the hygiene and sanitation department after being cleared of all equipment and supplies.
- **The staff who do the cleaning must be given training on the relevant policies and procedures, as well as on the precautions to be taken to protect themselves and the environment.**
- **Hygiene and sanitation staff must know the areas labelled G1 or "Caution" (e.g., hazardous drug receiving, storage, preparation and administration.)**
  - Workers who perform cleaning at patients' homes must be informed if G1 drugs are being administered there.
- **Places potentially contaminated with a G3 (e.g., frequency, equipment, products) can be cleaned according to the usual procedure.**
- **In a potentially contaminated area, cleaning should start with the cleaner areas and progress toward the areas known to be, or more likely to be, contaminated with hazardous drugs.**
  - Wipe or scour to apply mechanical action.
  - Use a wet method.
  - Never directly vaporize surfaces.
  - Use suitable products recognized for their effectiveness.
  - Follow recommendations about giving products time to work.
- **According to the literature, there is no product that can completely eliminate all hazardous drugs, even if sodium hypochlorite is often cited for the way it deactivates G1s on surfaces. Recent research by the URPP (Soubieux, 2020) on decontamination strategies for surfaces contaminated with cyclophosphamide seem to indicate that various cleaning methods (products, types of wipes) are relatively similar in terms of effectiveness. A second or even third cleaning – in other words mechanical action – has a significant impact on effectiveness. A range of options can be considered. The committee is of the opinion that the following approach should be favoured:**

- Cleaning areas contaminated with G1 or G2 hazardous drugs must include the decontamination of surfaces, which in some cases should be followed by deactivation, and include microbial disinfection when the cleaning protocol requires it.
  - Decontamination should be done in two stages, first with a mixture of water and detergent (with or without a germicidal agent) followed by rinsing. It can include a second pass with another product and then a rinse, especially in the case where there are residual traces of drugs.
  - Deactivation should be done after decontamination when heavier contamination of surfaces is suspected (e.g., spill) or periodically in areas known to be contaminated.
    - It can be done with a chlorinated solution (concentrations vary depending on the study, e.g., 0.1%, 0.5% or up to 2.4% sodium hypochlorite).
    - Stainless steel surfaces treated with chlorine should then be rinsed, using a neutralizing agent such as sodium thiosulphate, in order to reduce the corrosive effect of the sodium hypochlorite.
    - Chlorinated solutions are irritants and require special procedures and respiratory protection at certain concentrations in the air. A combined cartridge and prefilter respirator (P100 CC respirator) can be used.
  - Disinfection, when necessary, is performed at the end, using a product authorized by ICP.

- **Cleaning supplies (floor mop pads, wipes) should be disposable.**
  - They must be disposable for some locations (e.g., oncology pharmacy).
  - If supplies are reusable, they should be dedicated. An agreement should be reached with the laundry service, setting out the details of the required cleaning procedure.
    - Soiled items must be placed in a reserved bag, which must be kept closed until laundry time.
    - These items should be washed separately.

- **Supplies must be changed frequently, whenever cleaners move from one room or area occupied by a patient to another (e.g., anteroom, clean room, support area, compounding room, chairs in treatment room, patient room, washroom).**

- **All reusable equipment (e.g., handle for trapezoid mop, cart push bar) must be decontaminated after use.**

- **PPE must be removed and disposed of after use or upon leaving a contaminated place.**
  - Hands must be washed thoroughly after PPE has been removed.

- **A record of cleaning activities must be kept to ensure they are completed in accordance with the hygiene and sanitation program (date/time, done/not done, initials).**

7.1.2 Safe Cleaning Practices by Room

7.1.2.1 Oncology Pharmacy (Satellite or Central Pharmacy)

- **Hygiene and sanitation equipment used to clean the oncology pharmacy must be reserved for that task.**

- **A storage space for that equipment must also be reserved in a closed closet outside the clean room and anteroom.**

- **Disposable, low-lint materials must be used in controlled areas (anteroom and clean room) (e.g., wipes, floor mop pads) and must be disposed of in appropriate cytotoxic waste containers.**
  - Using a flat system with disposable pads for floors makes it easier to meet this requirement.
  - Disposable microfibre fabrics are a good option for wipes and pads.
- **The breakdown of which areas pharmacy staff are supposed to clean and which ones hygiene and sanitation staff are supposed to do should be specified in the cleaning procedures.**
  - The cleaning of certain sensitive areas or equipment (such as hazardous drug storage shelves or refrigerators) should be performed by pharmacy staff only, unless the surfaces are free of equipment and supplies.

7.1.2.1.1 | CLEAN ROOM AND ANTEROOM

- **All hygiene and sanitation staff involved in the cleaning of controlled areas of the anteroom and clean room must follow the hand hygiene, and donning and doffing procedures in effect.**
- **New PPE must be donned for the cleaning of other areas (e.g., support area).**
- **Hygiene and sanitation staff must:**
  - Disinfect all equipment and supplies that are brought into the clean room (e.g., carts, mop handles, outsides of buckets) to maintain sterility.
  - Decontaminate all equipment taken out of the clean room.
- **All work surfaces at high risk of being contaminated (e.g., countertops), all high-touch surfaces (e.g., door/closet handles, outsides of waste containers) and all floors must be decontaminated on a daily basis.**
  - These same surfaces should be deactivated on a monthly basis.
- **All other surfaces (e.g., ceilings, walls, outer surfaces of equipment, outsides of sterile preparation cabinets, shelves, chairs), except for the interior of preparation cabinets, must be decontaminated on a monthly basis.**
  - These surfaces should be deactivated once or twice a year.
- **Decontamination may be followed by disinfection, depending on the cleaning protocol in effect.**
- **Deactivation must be carried out whenever more significant contamination of surfaces by a hazardous drug is suspected (e.g., spill).**

7.1.2.1.2 | SUPPORT, UNPACKING/CLEANING AND STORAGE AREAS

- **All work surfaces at high risk of being contaminated with a G1 (e.g., preparation areas, countertops), all high-touch surfaces (e.g., door, closet, refrigerator handles, chair armrests) and all floors must be decontaminated on a daily basis.**
- **All other surfaces (e.g., ceilings, walls, outer surfaces of equipment, shelves, chairs) must be decontaminated. The frequency must be established on the basis of a contamination risk assessment and specified in the cleaning procedures. Areas used for decontaminating containers or for storage, for instance, should be decontaminated more often (e.g., monthly) whereas other areas may be done less often (e.g., annually).**
- **Given the current state of knowledge, and to simplify matters, the same cleaning procedure (frequency, stages and products) used to decontaminate surfaces should be used for G2s, too.**

7.1.2.2 BCG Preparation Room

- **Staff must wear the same PPE as for regular cleaning. They may remove it when they leave the area in question, in compliance with IPC.**
- **Hygiene and sanitation staff should clean the room by following the usual procedures, especially for surfaces and traffic areas where contamination is suspected or known to exist (e.g., floors, countertops).**

7.1.2.3 Central Pharmacy

At the central pharmacy, G1s, as well as G2s and G3s, are sometimes used for nonsterile compounding or final dosage forms requiring manipulations. As a result, in some areas of the pharmacy, G1s are unpacked, G1 containers are cleaned, tablets are cut up and hazardous drugs are put into storage.

- **Areas must be identified properly to make it easier to determine what specific cleaning measures (e.g., products, frequency) need to be applied and what PPE is required.**
- **All work surfaces at high risk of being contaminated with a G1 (e.g., preparation areas, countertops), all high-touch surfaces (e.g., door, closet handles) and all floors must be decontaminated or cleaned on a daily basis.**
- **Areas at greater risk of contamination (e.g., drug storage shelves) should be decontaminated more often (e.g., monthly) while others may be done less often.**
- **All other surfaces (e.g., ceilings, walls, outer surfaces of equipment, shelves, chairs) must be decontaminated. The frequency must be established on the basis of a contamination risk assessment and specified in the cleaning procedures.**
- **Given the current state of knowledge, and to simplify matters, the same cleaning procedure (frequency, stages and products) used to decontaminate surfaces should be used for G2s, too.**

7.1.2.3.1 CATEGORY 3 NONSTERILE COMPOUNDING AREA

- **This area must be identified with the "Cytotoxic" symbol so that hygiene and sanitation staff know what type of special cleaning is required there.**
- **As standard OPQ 2012.01 stipulates, cleaning of a facility of this kind must follow a specific procedure, and the hygiene and sanitation equipment used for it must be reserved for it alone.**
  - Accessories that come into contact with hazardous drugs should be disposable.
- **The nonsterile compounding area reserved for hazardous drugs should be cleaned regularly.**
  - High-touch surfaces (e.g., door and closet handles, light switches) and floors must be decontaminated on a daily basis. A lower frequency may be adopted if production is not a daily activity.
  - At least once a year, all surfaces, including all walls, ceilings and storage areas, must be decontaminated.
- **Disposable cleaning supplies must be discarded in a cytotoxic waste container for G1s.**
  - Supplies may be discarded in a general waste container for G2s.

7.1.2.3.2 | AREAS FOR OTHER NONSTERILE PREPARATIONS

- **Areas used for the simple preparation of G1 and G2 drugs (e.g., cutting up small quantities of tablets) do not require special cleaning by the hygiene and sanitation department.**
  - Cleaning frequencies, products and basic personal protective equipment are the same as for all regular preparation areas.
- **Areas used for the complex preparation of G1 and G2 drugs (e.g., cutting up large quantities of tablets, preparing batches) should be maintained in the same way as category 3 compounding areas.**

Proposed frequencies for pharmacy cleaning are given in Table 45.

TABLE 45

Proposals regarding specific cleaning requirements for pharmacy areas labelled "Cytotoxic" or "Caution" (G1, G2)

PLACE	AREAS / SURFACES	MINIMUM SUGGESTED FREQUENCY*
Pharmacy – Sterile preparations	**Clean room and anteroom** High-touch surfaces and other surfaces at high risk of contamination (e.g., door handles, counters, keyboards and scanner handles, floors, lids and outsides of reusable waste containers)	Daily
	Clean room and anteroom All other surfaces (e.g., ceilings, walls and outsides of equipment, outsides of BSCs, shelves, chairs) except the interior of BSCs	Monthly
	Other areas (e.g., support area, storage, decontamination room) High-touch surfaces and other surfaces at high risk of contamination (e.g., door/closet handles, light switches, counters in support and unpacking areas, floors and reusable waste containers)	Daily
	Other areas (e.g., support areas, storage, decontamination room) All other surfaces (e.g., inside of pass-through, ceilings, walls and outsides of equipment, shelves)	Varies with the surface (weekly, monthly to annually)
Central pharmacy – Nonsterile preparations	**Category 3 room** High-touch surfaces and other surfaces at high risk of contamination (e.g., door/closet handles, light switches), floors and reusable waste containers, counters)	Daily, if activities performed there during the day
	Category 3 room All other surfaces	Varies with use and risk of contamination (monthly to annually)
	Other preparation areas High-touch surfaces (e.g., door/closet handles, light switches) and other surfaces at high risk of contamination (e.g., counters, work surfaces, lids of reusable waste containers) and floors	Varies with surface (daily to weekly)
	Other preparation areas All other surfaces (e.g., drug storage, walls, ceilings)	Varies with use and risk of contamination (monthly to twice a year)

* Minimum decontamination frequencies are suggested as a guideline for the development of policies and procedures that can be applied in each health care facility. Frequency must be increased if contamination is suspected or a spill occurs. Deactivation may be performed periodically in addition to decontamination.

7.1.2.4 G1 and G2 Drug Administration Areas

7.1.2.4.1 ONCOLOGY TREATMENT ROOM

- **Treatment rooms, including patient rooms and any other treatment areas where hazardous drugs are administered to patients, must be identified, using any method in accordance with the institution's regulations (e.g., signs posted at entrance).**
- **Staff must wear the appropriate PPE (see Table 44). They should remove the PPE when they leave the treatment area, in accordance with IPC practices.**
- **Staff tasked with cleaning rooms or areas where G1s or G2s are administered to patients must be informed of the precautions to be taken in order to protect themselves and the patients' environment (e.g., contact with excreta or drugs).**
- **All work surfaces at high risk of contamination (e.g., preparation areas, countertops, wall sections near hanging gowns, patient tables), all high-touch surfaces (e.g., door, closet, refrigerator handles, treatment chair armrests, waste container lids) and all floors must be decontaminated daily or even twice daily.**
- **All other surfaces must also be decontaminated. Cleaning frequency must be established on the basis of a contamination risk assessment and specified in the cleaning procedures.**
  - Surfaces with a higher degree of contamination risk (e.g., chair legs, IV poles, nursing stations, window ledges) should be decontaminated more often (e.g., weekly or monthly).
  - Other surfaces (e.g., walls, ceilings, supply storage shelves) may be done less often (e.g., once or twice a year).
- **Special attention must be given to washrooms reserved for patient use.**
  - They should be cleaned more frequently than the washrooms in other departments.
- **Any significant soiling caused by patient excreta (e.g., profuse vomiting) must be treated as a spill.**

7.1.2.4.2 RESPIRATORY THERAPY ROOM

- **Walls and ceilings must be cleaned periodically if drugs are nebulized, owing to the risk of production of aerosolized hazardous drug particles.**
  - Cleaning frequency should be determined on the basis of a risk assessment. It will vary with the conditions of drug administration (number of cases, local or general ventilation, number of air changes per hour).
    - In certain situations, the risk of infection must also be taken into account.
      - *Only moist mops and cloths should be used.*
- **The decontamination procedure for other surfaces should be similar to that used for an oncology treatment room.**

7.1.2.4.3 ROOMS WHERE BCG IS ADMINISTERED

- **Note that in contrast to the precautions taken for other hazardous drugs, the precautions and measures implemented for BCG are aimed at controlling a biological hazard. They must comply with IPC recommendations.**
- **Staff must wear PPE for regular cleaning. They should remove the PPE when they leave the BCG area.**

- **Hygiene and sanitation staff should clean and disinfect in accordance with the usual procedures, especially surfaces and traffic areas where contamination is suspected or known to exist (e.g., floors, counters, beds).**
- **Special attention must be given to washrooms reserved for patient use.**
  - Not only must sodium hypochlorite be added to the toilet bowl, but all high-touch surfaces must be disinfected before the washroom may be used by another person.

7.1.2.4.4 | CARE UNITS AND LIVING ENVIRONMENT

- **Given the hazards associated with patient and resident excreta, precautions should be taken for at least the first 96 hours following the administration of the last dose of a G1 drug.**
  - A risk assessment should be conducted if a health care facility wishes to modify the precautionary period (see 1.3.3).
  - Places where patients receive treatment must be identified, using any method in accordance with the institution's regulations (e.g., signs placed at entrance to treatment room).
- **We are not proposing any special precautionary measures for G2 or G3 excreta.**
- **Staff must don the appropriate PPE (see Table 44) before coming into contact with the surfaces to be cleaned. They should then remove the PPE on leaving the area. Local IPC rules must be taken into account when they apply.**
- **All work surfaces at high risk of contamination (e.g., preparation areas, counters, wall sections near hanging gowns, patient tables), all high-touch surfaces (e.g., door, closet, refrigerator handles, bed rails, waste container lids) and all floors must be decontaminated daily.**
  - In patient rooms, cleaning frequency should be increased (e.g., to twice a day) if the patient is incontinent, vomiting or sweating profusely, and on the patient's treatment days. A second pass can be done with a different cleaning product.
  - For washrooms used by patients receiving G1s, the cleaning frequency should be increased.
- **All other surfaces must also be decontaminated. Cleaning frequency must be established on the basis of a contamination risk assessment and specified in the cleaning procedures.**
  - Surfaces with a higher degree of contamination risk (e.g., chair legs, IV poles, nursing stations, soiled utility rooms, window ledges) should be decontaminated more often (e.g., weekly or monthly).
  - Other surfaces (e.g., walls, ceilings, supply storage shelves) may be done less often (e.g., once or twice a year).
- **When a patient leaves (terminal cleaning), the usual cleaning procedure with detergent/disinfectant must be applied in the patient's room and washroom, except in the following case:**
  - For a G1, decontamination must be performed.
    - > If deemed necessary (e.g., if patient was incontinent or had been vomiting), a second decontamination or a deactivation (e.g., chlorine solution) may also be performed.
- **Given the current state of knowledge, and to simplify matters, the same cleaning procedure (frequency, stages and products) used to decontaminate surfaces should be used for G2s, too.**

Proposed frequencies for the cleaning of G1 and G2 hazardous drug administration areas are given in Table 46.

TABLE 46

Proposals regarding specific cleaning requirements for drug administration areas labelled "Cytotoxic" or "Caution" (G1, G2)

PLACE	AREAS	MINIMUM SUGGESTED FREQUENCY*
Oncology clinic – Treatment room	High-touch surfaces and other surfaces at high risk of contamination (e.g., door/cabinet handles, light switches, washrooms reserved for patients, counters, patient chairs, beds, tables, section of wall where gowns are hung, floors near places where treatment is given)	Once or twice a day (middle and end of day)
Oncology clinic – Treatment room	Other surfaces with risk of contamination (e.g., other furniture items, chair legs, IV poles, outsides of waste containers, nursing stations, soiled utility rooms)	Weekly to monthly
Oncology clinic – Treatment room	All other surfaces (e.g., walls, ceilings, partition panels, clean utility rooms, other rooms)	Varies with traffic and risk of contamination (monthly to annually)
Care unit – Treatment (room and washroom) and preparation areas	High-touch surfaces and other surfaces at high risk of contamination (e.g., washrooms reserved for patients, taps, call system devices, bed rails, patient chairs, bedside tables, floors near where treatment is given)	Once or twice a day depending on risk of surface contamination (e.g., dosage form, incontinence)
Care unit – Treatment (room and washroom) and preparation areas	Surfaces with some risk of contamination (e.g., other furniture items, chair legs, outsides of waste containers)	Weekly to monthly
Care unit – Treatment area (room and washroom)	All surfaces (e.g., walls, ceilings, mattress, under bed)	After departure or frequency adjusted to deal with risk of contamination, length of stay (once or twice a year)
Care unit	Drug storage areas (e.g., outsides of cart, shelves), soiled utility room	Varies with risk of surface contamination (monthly to annually)
Living environment	As in care units: high-touch surfaces representing a certain contamination risk, all surfaces (after departure)	Same as in care units or adjusted to deal with risk of surface contamination (e.g., lower if tablets administered intact; higher if patient is incontinent or if outbreak of gastroenteritis)
Respiratory therapy room	Same as for oncology clinic	Same as for a treatment room except for walls and ceilings, for which cleaning frequency must be adjusted to suit drug administration conditions (e.g., number of administrations, efficiency of mechanical ventilation)
Rooms where BCG is administered	Same as for oncology clinic	Same as for a treatment room

* Minimum frequencies are suggested as a guideline for the development of policies and procedures that can be applied in each health care facility. Frequency must be increased if contamination is suspected.

7.2 Waste Management

7.2.1 General Principles of Waste Management

TABLE 47

PPE for waste container handling*

ACTIVITIES	TYPES OF WASTE	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Handling of waste containers	Cytotoxic (G1)	1C	No[a]	No	No
	BCG	1R	No[b]	No	No
	Pharmaceutical (G2)	1R	No[b]	No	No
	Pharmaceutical (G3)	1R	No[b]	No	No

* PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

1C: one pair of chemotherapy-resistant gloves compliant with standard ASTM D6978 | **1R:** one pair of regular gloves

a: A compliant gown must be worn if there is a risk of contact between waste container and worker's body. | **b:** A regular gown must be worn if risk of contact between waste container and worker's body.

- **Waste must be dealt with according to the instructions given in the *Guide de gestion des déchets du réseau de la santé et des services sociaux* (2017).**
- **Hazardous drug waste must not be disposed of in containers intended for infectious biomedical waste that can be autoclaved and landfilled.**
- **The sewer system must not be used to dispose of hazardous drugs.**
- **Waste containers must be available wherever potentially contaminated waste is generated.**
- **Waste containers must be closed up by the designated officer, following an agreement between the departments concerned.**
- **Waste must be collected as often as possible.**
  - Collection frequency must be adjusted to handle the quantity of waste generated so that waste sits awaiting pick-up for the shortest time possible.
  - Choose container capacity to ensure containers are filled sufficiently for pick-up.
  - At the oncology pharmacy, waste must be picked up daily, at the end of the day, or more frequently if the waste generated or the risk of contamination makes it necessary.
  - In care units, waste must be collected at least once a day, at the end of the day's last treatment or before waste containers become ¾ full.

- **The carts used to transport waste must be designed to guard against the occurrence of spills and leaks.**
  - Open carts may be used to transport plastic bags, provided the bags are closed up beforehand and are properly secured to the cart.
  - Carts must be made of easy-to-clean materials.
  - Pharmaceutical waste may be transported on the same cart as biomedical waste, provided it is identified properly and kept separate.
- **The final storage areas for containers holding G1, G2 or G3 waste must comply with the recommendations of the *Guide de gestion des déchets du réseau de la santé et des services sociaux* (2017).**
  - The storage areas must be kept under lock and key.
  - They should be located in a cool room that has a ventilation system that will prevent contamination from spreading to adjacent rooms.
    - Air should be exhausted to the outside, without recirculation.
    - The area should not be located near areas frequented by patients.
- **Bags or containers must be sealed before they leave the facility to be eliminated and must not be reopened.**
- **A spill kit must be available.**

7.2.2 Waste Management by Hazardous Drug Group

7.2.2.1 Principles of G1 Waste Management

- **The term "cytotoxic waste" refers to all materials that come into contact with G1s (e.g., packaging materials, PPE, syringes, tubing, bags, disposable cleaning equipment reserved for G1s).**
  - The excreta of patients who have been given G1s are considered to be cytotoxic waste. They must either be eliminated by flushing them down the toilet, or be placed in cytotoxic waste containers (e.g., incontinence briefs, disposable supplies used to clean up after an incontinence episode).
  - G1 waste containers:
    - Must be labelled "Cytotoxic"
    - Should have a lid, preferably a sliding type
    - Must be rigid and leakproof for sharps and fluid waste
      - *May be bags held on a rigid support (e.g., box, pedal-operated container) for soft waste (e.g., gowns, gloves)*
  - In the case of BCG, all waste is considered to be biomedical waste. Waste containers must be labelled "Biohazard."
- **G1 waste container holders (e.g., pedal-operated containers) must be cleaned at least once a week (inside and out).**
- **The route taken to transport cytotoxic (G1) waste must, as much as possible, avoid passing through care units, public areas, or areas where there is food or laundry.**
- **G1 waste must be incinerated at high temperature.**

7.2.2.2 Principles of G2 and G3 Pharmaceutical Waste Management

- **For G2s and G3s, the term "waste" refers to the drug itself and to materials that are visibly soiled with it. This waste must be disposed of in a pharmaceutical waste container.**
- **The excreta of patients who have been given G2s or G3s are not considered to be pharmaceutical waste.**
- **Supplies used in the cleaning of areas where G2s or G3s are handled may be disposed of in a general waste container.**
- **Supplies used to clean up a G2 or G3 spill should be disposed of in a pharmaceutical waste container.**
- **G2 and G3 hazardous drug waste should be managed in the same way as pharmaceutical waste.**
  - G2 and G3 waste must be incinerated like other pharmaceutical waste.

8 Laundry

Dealing with the bedding of patients who have been given hazardous drugs can expose workers to hazardous drugs to varying degrees, especially through touch or by inhaling particles on patients' sheets when they are sorted or shaken before being washed. Research suggests that no contamination remains on the sheets after a prewash (Fransman, 2006).

Laundry service installations vary with the size and function of each health care facility. Many facilities now feature washing tunnels that require virtually no contact with bedding and no sorting prior to the prewash. In these cases, the risk of exposure is lower than in facilities where washing machines must be loaded manually. In some facilities, it may be necessary to sort soiled linens, including patients' personal clothing, which creates a risk for laundry workers.

TABLE 48

PPE for the handling of bedding/clothing by laundry staff*

ACTIVITIES	GROUP	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Handling of bedding (as well as clothing) not soiled with excreta or drugs[a]	G1 BCG G2 G3	1R 1R 1R 1R	No No No No	No No No No	No No No No
Handling of bedding (as well as clothing) visibly soiled with excreta	G1[b] BCG[b] G2[a] G3[a]	2C 1R 1R 1R	C R R R	No[c] No[c] No[c] No[c]	Yes[d] N95 No No
Handling of bedding (as well as clothing) visibly soiled with drugs	G1[b] BCG[b] G2[b] G3[e]	2C 2R 2R NA	C R R NA	No[c] No[c] No[c] NA	Yes[d] N95 Yes[d] NA

* PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

2C: two pairs of chemotherapy-resistant gloves compliant with standard ASTM D6978 | **C:** gown compliant with section 2.11.2 | **1R, 2R:** one or two pairs of regular gloves | **R:** regular gown | **N95:** particulate filter mask, at least N95 | **NA:** not applicable

a: Follow routine infection prevention practices. | **b:** The best practice to follow is to dispose of these items and not transfer them to the laundry, unless a risk assessment is done first. The situation should be dealt with like a spill. | **c:** If splash risk, protection required. | **d:** The type of respirator depends on the risk assessment. | **e:** Pregnant women should not be assigned to clean up a spill, on any kind of surface, including bedding.

8.1 Not Visibly Contaminated Bedding

- **Bedding and clothing that are not visibly soiled may be handled in accordance with routine practices. They do not require any special treatment, when handling laundry bags, transporting or opening them, nor when loading the contents into washing machines.**
- **All this bedding must be dealt with by the laundry service like regular bedding in a health care setting.**
  - Bedding must be put in regular laundry bags.
  - Soiled materials must not be sorted.
  - Workers must wear appropriate PPE when handling laundry bags.
  - They must avoid shaking or tossing bedding, as that can cause contaminated particles to be released into the air.

8.2 Visibly Contaminated Bedding

Any G1s (drug itself or patient excreta within 96 hours of last treatment), G2s or G3s found on patient bedding, towels or clothing are a source of exposure for the people who handle these items (e.g., patient who wets the bed).

- **Visibly soiled items should be disposed of at the place where they are used (e.g., care units) so as to reduce the exposure of laundry staff as much as possible.**
- **A policy of sending these items to the laundry service may be implemented only after an agreement about proper procedures has been reached with the departments concerned.**
- **If, on the basis of a risk assessment, the health care facility decides to have these soiled items washed, the procedure should specify:**
  - How duties are to be shared with the care team (e.g., sorting at source, double bagging, provision of labelled bags, bag deposit area)
  - How the bags containing these items are to be identified (e.g., specific colour, "Cytotoxic" [G1] or "Caution" [G2, G3] pictogram)
  - How the items are to be transported (e.g., prohibit use of laundry chute, set aside area for them on cart and vehicle)
  - How they are to be stored (e.g., set aside separate area)
  - How washing machines are to be loaded (e.g., handling of soiled items must be eliminated or reduced to a minimum; bedding must not be shaken)
  - Different laundry procedure (e.g., prewashed and washed separately, washed twice in a row) that does not entail handling soiled items
  - Cleaning of carts and bags
  - Appropriate PPE to be worn

9 Spills and Accidental Exposure

Spills can contaminate surfaces. Health care facilities must draw up policies and procedures for handling all types of spills, both minor and major. A spill's significance depends not only on the quantities involved, but also the type of contaminated surface, the concentration, the nature and volatility of the drug, the place and complexity of the spill clean-up and decontamination required, etc. Any amount that escapes accidentally must be treated as a spill. Spills of bodily fluids contaminated by a G1 hazardous drug or BCG (e.g., urine from a patient given a G1) must be treated as a hazardous drug spill.

9.1 Spills of G1 and G2 Hazardous Drugs

TABLE 49

PPE for spill management*

ACTIVITIES	DOSAGE FORMS	GROUP	GLOVES	GOWN	FACE PROTECTION	RESPIRATORY PROTECTION
Spill management, clean-up[a]	All	G1 BCG G2 G3[d]	2C 1R 2R NA	C R R NA	Yes[b] Yes[b] Yes[b] NA	Yes[c] N95 Yes[c] NA

* PPE must be worn by any worker who could potentially be exposed to G1s or G2s. It must be worn by women who are pregnant or breast feeding and who could potentially be exposed to G3s (see section 2.11); it may also be worn by any worker who wishes to wear it.

2C: two pairs of chemotherapy-resistant gloves compliant with standard ASTM D6978 | **C:** gown compliant with section 2.11.2 | **1R:** one pair of regular gloves | **R:** regular gown | **N95:** particulate filter respirator, at least N95 | **NA:** not applicable

a: Shoe covers must be worn if spill is on ground or if risk of shoes being contaminated. | **b:** Safety goggles are recommended. | **c:** Type of respirator depends on risk assessment. | **d:** Pregnant women should not be assigned to spill clean-up.

9.1.1 Implementation of Spill Management Procedures

- **The health care facility must draw up procedures to deal with spills, taking into account the various possible types of spills and the staff required to deal with them (e.g., pharmacy staff, care unit/clinical staff, hygiene and sanitation staff, security staff).**
  - These procedures should be an integral part of the facility's emergency response planning process, which is set out in the *Manuel de planification des measures d'urgence pour les établissements du réseau de la santé et des services sociaux* (MSSS, 2004).
  - The procedures must cover, among other things:
    - The steps to be taken by each person who has a role to play in managing the spill, both the trained and non-trained employees of the department where the spill occurs, as well as employees of the hygiene and sanitation, security, OHS and other departments
    - Training and skill maintenance of staff in question; practice drills should be held regularly
    - A checklist covering all the steps; a decision-making tree can help employees understand what operations they have to perform
    - Conditions that could make evacuation necessary and the steps that would need to be taken
    - Means required to contain the spill
    - Clean-up and decontamination method
    - Guidelines for assessing an event (e.g., extent and nature of contaminated surfaces) before specifying what steps need to be taken
    - List of officers in charge with their contact information (e.g., training, OHS office, contents of spill kit, pharmacy, hygiene and sanitation)
  - Procedures must ensure that all parties are able to respond quickly.
  - Procedures to follow in the event of accidental contact with skin, eyes or clothing must be provided (see section 9.2).
  - Procedures for handling a major spill may include additional security measures taken in conjunction with the emergency response team.
  - Spill management procedures for hazardous drugs must also cover:
    - Spills of bodily fluids contaminated with G1 hazardous drugs or BCG (e.g., urine from a patient given a G1)
    - Spills of contents (e.g., bag leakage)
- **Damaged hazardous drug containers (e.g., cardboard box containing drugs) must be treated like an accidental spill.**
  - A visibly damaged container should not be opened. If it does need to be opened, it should be done in an isolated, well-ventilated location, such as in the area set aside for shipment unpacking.
  - A damaged container should not be returned to the manufacturer or distributor. The manufacturer or distributor should be notified in writing and should be provided with evidence of what happened (e.g., supporting documents, photos). If the manufacturer asks for the damaged products to be returned in order to compensate the facility, the facility should discuss with the manufacturer the risks of contamination and the recommended method of returning it in order to avoid accidental exposure during shipping.

- **Women who are pregnant or breast feeding should not be assigned to spill clean-up.**
- **Each health care facility may set up its own spill management team.**
  - The criteria under which the team may be asked to intervene should be stipulated (e.g., more than one litre spilled of a drug ready to be administered, more than one or two spill kits required to manage spill, wide-spread spill with a lot of splattering or in a high-traffic area).
  - There is no universal criterion that can be used to distinguish a minor spill, which can be managed locally, from a major spill that requires a specially trained team to be called in.
  - The following criteria may be used to determine major spills that may require the involvement of a specialized internal emergency response team:
    - Concentrated spill outside a fume hood (e.g., a drug vial from a supplier breaks)
    - Spill outside a fume hood that cannot be contained using a spill kit
    - Spill that is hard to manage because of its extent or the environment
    - Spill on an absorbent surface (textile)
    - Spill involving significant spread of a very large quantity of bodily fluids or excreta from a patient who has been treated with a G1 within the last 96 hours
  - A call code may be established for the emergency response team. "Code Brown" is often used in health care facilities to indicate chemical spills.
- **If the product has an SDS, it must be available for reference in the event of a spill.**
- **All spills must be recorded in a logbook so that the causes can be analysed and repeat spills can be avoided.**
  - An accidental spill report form must be filled out if a worker is exposed. An incident may be reported using the same form. The actions required to fill in the form and ensure follow-up must comply with the facility's rules.
  - The form for reporting accidental chemical spills (see Spill Report Form in appendix) that is part of a facility's emergency response planning process can be used. The form may be reserved, or not, for reporting accidental spills.
  - Copies of the completed form must be sent to the OHS department and to the hazardous drug management committee.

9.1.2 Spill Kit

- **A spill kit must be available near all places where G1 and G2 drugs are found or handled (receiving, unpacking and cleaning, storage, preparation, transport carts, drug administration, hazardous waste).**
  - A second kit should also be available in areas where the spill risk is higher.
  - For home care, a spill kit must be available for use by nurses who administer G1 and G2 drugs.
  - Patients who are being treated with G1 or G2 drugs at home in a form (e.g., liquid) that involves a spill risk must be provided with a spill kit by their health care facility.
- **A spill kit must contain all the materials required for the entire spill management procedure, while also being suited to the specific needs of the place and drugs in question.**
  - A commercial spill kit may be used and adapted as needed.

- **The materials in the kit should be adequate for absorbing approximately 1 litre of liquid.**
- **The following materials should be included in the kit:**
  - Simplified instructions to facilitate quick execution of the spill response procedure
  - Materials for identifying and isolating the spill area (e.g., cones, yellow ribbon)
  - Absorbent materials (e.g., towels, absorbent pads, absorbent powder)
  - Materials for collecting dry substances (powder)
  - Two or more pairs of certified chemotherapy-resistant gloves of various sizes
  - One pair of thick (utility) gloves for picking up broken glass
  - A disposable small shovel and broom for sweeping up and collecting glass fragments/shards safely
  - A compliant protective gown
  - A face shield or pair of safety goggles
  - Disposable absorbent wipes
  - Two plastic bags labelled "Cytotoxic"
  - A safe, rigid container for collecting glass fragments/shards
  - A bag for storing a reusable respirator, as needed
  - Labels for cytotoxic substances
  - Instructions to follow in case of exposure
  - A report form for documenting the event
  - List of kit contents
- **The respirators required for spill clean-up may be kept in the kit or separate from it if the kit cannot hold them all.**
  - Make inventory adjustments on the basis of the results of employee respirator fit testing.
  - Respirators must be chosen as part of a respiratory protection program that assesses the relevant risks. Different models and sizes may be required, depending on the results of the fit testing.
  - Larger spills may be managed by a specially trained emergency response team equipped with respirators having chemical cartridges (against organic vapours) and P100 particulate filters (e.g., P100 chemical cartridge respirators).
  - Oncology pharmacy staff should use respirators with chemical cartridges (against organic vapours) and P100 particulate filters (e.g., P100 chemical cartridge respirators), already provided for other purposes.
- **Spill kits should be sealed to prevent the contents from being changed. When a kit is opened, the contents must be checked and replaced, and then the kit must be sealed up again.**
- **Spill kits should be checked regularly, both for their contents and their expiration dates.**

9.1.3 G1 Drug Spill

- **Anyone who discovers a spill must respond immediately if they have been trained to deal with an accidental spill.**
  - If they have not been trained, they must immediately notify the appropriate officer that an accidental spill has occurred.

- **Emergency response employees (from the department where the spill has occurred, from the hygiene and sanitation department, or any other assigned officer) must take the following steps:**
  - Restrict access to the spill area.
    - Anyone not needed for spill clean-up who can be moved safely should be directed to another room.
    - If that is impossible (e.g., patients undergoing treatment), people not needed to manage the spill should be moved as far away as possible.
  - Ascertain the extent of the spill, call a colleague in to help, contact the hygiene and sanitation department or the designated officer, in accordance with the established procedure.
  - Apply the procedure according to the type of spill (e.g., minor or major; characteristics of spill in terms of location, traffic, surface).
    - A spill of just a few drops that are easy to clean up must still be treated as a spill. The clean-up procedure can be made easier, without a spill kit being required, but all surfaces must be decontaminated. For instance, the following procedure may be followed:
    - Wear a gown and gloves.
    - Wipe up the spill with gauze pads.
    - Dispose of the gauze pads in a cytotoxic waste container.
    - Wet a gauze pad with water and wipe the spill surface with it.
    - Clean the surface a second time with a cleaning agent.
    - A small volume spill may be managed locally using a spill kit.
    - A large spill, or one that is difficult to clean up, may require contacting the emergency response teams provided for under policies and procedures in such circumstances.
  - Bring the accidental spill kit to the place where the spill has occurred.
  - Establish a safety perimeter using the materials provided in the kit (signage, cones, tape).
  - Don protective equipment: two pairs of gloves (one under the gown and one overtop), a compliant gown, the respirator for which the employee has passed the fit test, face protection and shoe covers.
    - For minor spills, an N95 or N100 respirator may be worn.
    - For major spills, a respirator having chemical cartridges (for organic vapours) and P100 particulate filters (P100 chemical cartridge respirator) or an assisted ventilation respirator should be worn.
    - In a pharmacy, the type of respirator used for certain other activities should also be worn for spill clean-up, as it is readily available.
  - Clean up the spill:
    - In the case of a liquid spill, cover it with an absorbent substance.
    - In the case of a powder spill, cover with wet materials.
    - For drug vials that have broken inside a box, put the whole box in a large bag intended for this purpose (labelled "Cytotoxic") and seal it up.
    - Use the thick gloves, shovel and broom in the kit to collect any glass shards and put them in a rigid container.
  - Remove the absorbent substance and dispose of it in a plastic bag labelled "Cytotoxic."
  - Wipe the contaminated area.
  - Clean the contaminated area by repeating the operation several times.
    - Clean the area three times in a row with detergent, rinsing afterwards each time.
  - Deactivate the affected area with a 2.4% sodium hypochlorite solution for 10 minutes.

- Neutralize with sodium thiosulphate for stainless steel surfaces or rinse with water for other types of surfaces.
  - Commercial wipes are available that contain a chlorinated derivative or sodium thiosulphate designed for deactivation.
- Dispose of all contaminated materials in a thick plastic bag labelled "Cytotoxic."
- To remove PPE, first take off the outer pair of gloves, then the face shield, gown and shoe covers, being careful not to contaminate yourself, and dispose of them in a plastic bag.
- Still wearing the inner pair of gloves, close the bag and place it in a second plastic bag. Take off the respirator.
  - If the respirator is reusable, the cartridges must be disposed of and the respirator placed in a separate bag for later cleaning. Clean PPE (gown and gloves) must be donned to clean the non-disposable PPE.
  - If the respirator is disposable, remove it, then take off the inner pair of gloves and dispose of everything in the bag and close it.
- Wash hands with soap and water.
- Ensure that cytotoxic waste containers are picked up as soon as possible.
- Fill out a spill report form.
- Allow access to the cleaned area again.

IN THE EVENT OF A SPILL IN A BSC

- **To deal with a spill in a BSC, the following actions must also be taken:**
  - If the outer pair of gloves has been contaminated, they must be removed and discarded inside the cabinet. Then a new outer pair of gloves must be donned.
  - If the spill is limited to and contained by a sterile absorbent pad, pharmacy staff must apply the following procedure:
    - Dispose of the absorbent pad in the BSC's cytotoxic waste container.
    - Clean the work surface twice with sterile water.
    - Disinfect with 70% isopropyl alcohol.
    - Dispose of the contaminated materials and wipes in the BSC's cytotoxic waste container.
    - Close and dispose of the cytotoxic waste container.
    - Change both pairs of gloves.
    - Set out a new sterile disposable waterproof absorbent pad.
  - For any other spill in the BSC, pharmacy staff must follow an adapted procedure, taking general recommendations into account.
    - The spill must be cleaned up.
    - All surfaces in the cabinet, including the subfloor if it, too, has been contaminated, must be decontaminated using detergent and then rinsed with water.
    - If the ventilation ducts or HEPA filter have been affected, a special clean-up operation must be planned with specialized resources. The operational capability of the cabinet should be maintained. The cabinet cannot be used again until an expert has been consulted.

9.1.4 G2 Drug Spill

- **To facilitate work organization, the procedures that apply in the case of a G1 spill may be followed to manage a G2 drug spill.**
- **The procedure may also be different, depending on the following factors:**
  - Criteria used to define a major or minor spill.
  - Evacuation procedures.
  - Regular PPE may be worn (gloves, gown).
  - Deactivation may be optional.
- **Waste generated by the spill and during clean-up must be disposed of in a pharmaceutical waste container that meets standards and is clearly and visibly identified with the pharmaceutical waste symbol.**
  - The waste may also be placed in a cytotoxic waste container.

9.1.5 G3 Drug Spill

- **Pregnant women should not be assigned to the management of a G3 spill, except to report that one has occurred.**
- **For people who are not particularly at risk, supplementary PPE does not need to be added to basic protection (e.g., gloves) for the management of a G3 spill.**
- **As with other types of hazardous drug spills, G3 spills must be managed and cleaned up adequately so as to prevent contamination of the environment and workers at risk.**

9.2 Accidental Exposure

- **Response measures in the event of accidental contact with a G1 or G2 hazardous drug (or a G3 for workers at risk), as well as with vesicants, must include removing the source of contamination, cleaning up the affected area and contacting the OHS department immediately for follow-up.**
- **In the event of contact with the skin or clothing, the affected person must:**
  - Immediately take off any contaminated PPE.
  - Immediately take off any contaminated clothing.
  - Rinse their skin with water.
  - Wash the affected area thoroughly with soap and water, then rinse with water.

- Take a full body shower if necessary; a full shower stall should be available nearby (e.g., in oncology units/clinics).
- Consult the OHS department immediately; if necessary, it will refer the affected person to a doctor.
- Place clothes in a bag and close it.

- **In the event of eye contact, the affected person must:**
  - Wash their eyes thoroughly using an eye-wash station installed on an accessible plumbing fitting or sink (sections 75 and 76 of the ROHS) or a portable eye-wash system (that complies with standard ANSI Z358.1):
    - Rinse their eyes with lukewarm water or an isotonic solution (e.g., sterile 0.9% NaCl) for at least 15 minutes.
    - Have at least one person assist them, which is generally the case for proper eye washing.
    - Open their eyes wide and move them around to optimize eye contact with the water.
    - Remove contact lenses immediately in the event of accidental exposure and discard them; getting splashed in the eye with a hazardous drug can be more harmful for people who wear contact lenses; they do not provide any protection, contrary to what many people believe.
    - Clean glasses if they are soiled, using water and an appropriate type of soap, then rinse them thoroughly with water and make sure that skin and eyes have not been exposed.
    - Consult the OHS department immediately; if necessary, it will refer the affected person to a doctor.

- **If someone is pricked accidentally with a needle that has been in contact with a hazardous drug, they must:**
  - Wash the affected area thoroughly with soap and water, then rinse with water for 15 minutes.
  - Consult the OHS department immediately; if necessary, it will refer the affected person to a doctor.

- **Consult an emergency physician immediately in the case of a wound, burn, redness or difficulty breathing.**

- **Any accidental exposure to a G1 or G2 hazardous drug (or a G3 drug for workers at risk), or exposure to patient bodily fluids or blood, by way of the skin, eyes or mucous membranes must be reported on the accident report form used in the health care facility, and the completed form must be submitted to the OHS department, which will take care of any medical follow-up that may be necessary and will investigate the event.**
  - The event report must be kept in the employee's file or in a logbook.
  - For prevention purposes, all accidents of this kind should be investigated.
  - It should be possible to retrace such events for a given period.
  - Affected employees may notify their family doctors of any accidental exposure.
  - The SDS of the drug in question must be available for consultation in the workplace.

REFERENCES

Act respecting occupational health and safety, CQLR c S-2.1, sec. 40–48.. https://canlii.ca/t/xcr#40

American Conference of Governmental Industrial Hygienists. (2007). *Industrial ventilation: A manual of recommended practice for design* (26th ed.). Cincinnati, OH: ACGIH.

American National Standards Institute, & American Society of Heating, Refrigerating and Air-Conditioning Engineers (2016). *Methods of testing performance of laboratory fume hoods*. Atlanta, GA: ASHRAE.

ASSTSAS. (2008). *Safe handling of hazardous drugs: Prevention guide.* Montréal: ASSTSAS.

Bhatt A., Mittal S., K. S. Gopinath. (2016). Safety considerations for health care workers involved in cytoreductive surgery and perioperative chemotherapy. *Indian Journal of Surgical Oncology*, *7*(2). 249-257. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4818614/

Boothroyd, L., & Lehoux, P. (2004). *La chimiothérapie basée au domicile : les enjeux pour les patients, les soignants et le réseau de la santé : rapport.* Montréal : Agence d'évaluation des technologies et des modes d'intervention en santé. https://numerique.banq.qc.ca/patrimoine/details/52327/49738

Boulanger, J. (2014). *Prise en charge de l'extravasation associée aux traitements antinéoplasiques: guide de pratique clinique: rapport.* Québec, Qc : INESSS. https://www.inesss.qc.ca/fileadmin/doc/INESSS/Rapports/Oncologie/INESSS_Extravasation_traitements_antineoplasiques.pdf

Bussières, J.-F., Gagnon, K., Bérard, G., Gallant, C., & Barret, P. (2007). Enquête québécoise sur la préparation et l'administration de médicaments dangereux incluant les médicaments cytotoxiques. *Pharmactuel*, *40*(1), 37-42. https://www.researchgate.net/profile/Jean-Francois_Bussieres/publication/242415227_Enquete_quebecoise_sur_la_preparation_et_l'administration_de_medicaments_dangereux_incluant_les_medicaments_cytotoxiques/links/0deec53b1d4778f171000000.pdf

CAREX (Carcinogen exposure) Canada: Informing efforts to reduce Canadians' exposures to known and suspected carcinogens in workplaces and communities: 2016-2017 Annual Report. (2018). CAREX Canada. https://www.carexcanada.ca/CAREX_Annual_Report_2017.pdf

Cass, Y., & Musgrave, C. F. (1992). Guidelines for the safe handling of excreta contaminated by cytotoxic agents. *Journal of Hospital Pharmacy*, *49*(8), 1957-1958.

Cass, Yaakov, Connor, T. H., & Tabachnik, A. (2017). Safe handling of oral antineoplastic medications: Focus on targeted therapeutics in the home setting. *Journal of Oncology Pharmacy Practice: Official Publication of the International Society of Oncology Pharmacy Practitioners, 23*(5), 350-378. https://doi.org/10.1177/1078155216637217

Chauchat, L., Tanguay, C., Therrien, R., Dufour, A., Gagné, S., Caron, N. J., & Bussières, J.-F. (2019). Biological monitoring of 4 antineoplastic drugs in health care workers from 2 adult hospitals: A pilot study. *The Canadian Journal of Hospital Pharmacy, 72*(1), 56. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6391236/

Canadian Cancer Statistics Advisory Committee. (2019). *Cancer Statistics 2019. Toronto: Canadian Cancer Society.* https://www.cancer.ca/fr-ca/cancer-information/cancer-101/canadian-cancer-statistics/?region=on

Connor, T. H., Shults, M., FRASER M. P. (2000). Determination of the vaporization of solutions of mutagenic agents at 23 and 37 degrees C using a dessicator technique. *Mutat Res, 470*, 85-92.

Connor, T. H., Lawson, C. C., Polovich, M., & McDiarmid, M. A. (2014). Reproductive health risks associated with occupational exposures to antineoplastic drugs in health care settings: A review of the evidence. *Journal of Occupational and Environmental Medicine, 56*(9), 901-910. https://doi.org/10.1097/JOM.0000000000000249

Cyclophosphamide. (2020). In *Micromedex® (electronic version)*. Greenwood Village, Colorado : IBM Watson Health. https://www.micromedexsolutions.com

Dionne, L., & Comité des immobilisations en prévention des infections nosocomiales. (2012). *Principes généraux d'aménagement en prévention et en contrôle des infections nosocomiales: répertoire des guides de planification immobilière* (2e éd). Québec : MSSS. https://numerique.banq.qc.ca/patrimoine/details/52327/2217603

Direction générale de la planification stratégique, de l'évaluation et de la gestion de l'information, & Direction générale du personnel réseau et ministériel. (2005). *Les systèmes automatisés et robotisés utilisés pour la distribution des médicaments dans les établissements de santé au Québec : rapport et recommandations.* Québec : Direction des communications du Ministère de la santé et des services sociaux. https://publications.msss.gouv.qc.ca/msss/fichiers/2005/05-719-01.pdf

Direction générale de la prévention-inspection et du partenariat, & Direction de l'indemnisation et de la réadaptation. (2018). *Programme Pour une maternité sans danger.* Montréal : CNESST. https://www.cnesst.gouv.qc.ca/fr/prevention-securite/milieu-travail-sain/programme-pour-une-maternite-sans-danger

Dolezalová L., Odráska P., Gorná L., Prudilová M., Vejpustková R., Bláha L. (2009). Evaporation of selected cytotoxic drugs and permeation of protective gloves--research into the occupational risks of health care personnel handling hazardous cytotoxic drugs (CYTO project). *Klin Onkol, 22*(5), 218-22.

Dranitsaris, G., Johnston, M., Poirier, S., Schueller, T., Milliken, D., Green, E., & Zanke, B. (2005). Are health care providers who work with cancer drugs at an increased risk for toxic events? A systematic review and meta-analysis of the literature. *Journal of Oncology Pharmacy Practice: Official Publication of the International Society of Oncology Pharmacy Practitioners, 11*(2), 69-78. **https://pubmed.ncbi.nlm.nih.gov/16465719/**

Drolet, C. (2016). *Aires réservées aux préparations stériles (Unité de pharmacie)* (Juin 2016). Québec : Direction des communications du ministère de la Santé et des Services sociaux. **https://publications.msss.gouv.qc.ca/msss/document-000363/**

Fransman, W. (2006). *Antineoplastic drugs: Occupational exposure and health risks*. PhD Thesis. Utrecht University, Utrecht, The Netherlands. (978-90-393-4331-9). **https://dspace.library.uu.nl/handle/1874/12854**

Fransman, W., Kager, H., Meijster, T., Heederik, D., Kromhout, H., Portengen, L., & Blaauboer, B. J. (2014). Leukemia from dermal exposure to cyclophosphamide among nurses in The Netherlands: Quantitative assessment of the risk. *The Annals of Occupational Hygiene, 58*(3), 271-282. **https://doi.org/10.1093/annhyg/met077**

Fransman, W., Vermeulen, R., & Kromhout, H. (2004). Occupational dermal exposure to cyclophosphamide in Dutch hospitals: A pilot study. *The Annals of Occupational Hygiene, 48*(3), 237-244. **https://doi.org/10.1093/annhyg/meh017**

Fung, V., & Seneviratne, M. (2016). Regulatory verification on safe use of cytotoxic drugs in veterinary clinics and animal hospitals. *Australian Veterinary Journal*, 94(11), 400-404. **https://doi.org/10.1111/avj.12515**

Gurusamy, K. S., Best, L. M., Tanguay, C., Lennan, E., Korva, M., & Bussières, J.-F. (2018). Closed-system drug-transfer devices plus safe handling of hazardous drugs versus safe handling alone for reducing exposure to infusional hazardous drugs in healthcare staff. *Cochrane Database of Systematic Reviews,* (3). **https://doi.org/10.1002/14651858.CD012860.pub2**

Hiliquin, D., Tanguay, C., & Bussières, J.-F. (2018). Pratiques entourant la manipulation des médicaments dangereux dans les établissements de santé du Québec | Toxicologie clinique. *Bulletin d'information toxicologique, 34*(2), 23-31. **https://www.inspq.qc.ca/toxicologie-clinique/pratiques-entourant-la-manipulation-des-medicaments-dangereux-dans-les-etablissements-de-sante-du-quebec**

Hiliquin, D., Tanguay, C., Gagné, S., Caron, N., & Bussières, J.-F. (2019, 2 février). Multicenter study of environmental contamination with ten antineoplastic drugs in 79 Canadian centers: A 2018 follow-up study [Poster]. Canadian Society of Hospital Pharmacists - Professional Practice Conference, Toronto. **http://indicible.ca/urpp/20190125_EXPOPROF40_Affiche.pdf**

Hilliquin, D., Tanguay, C., & Bussières, J.-F. (2020). External contamination of commercial containers by antineoplastic agents: A literature review. *European Journal of Hospital Pharmacy, 27*(5), 313-314. **https://doi.org/10.1136/ejhpharm-2018-001705**

Hilliquin, D., Tanguay, C., Gagné, S., Caron, N. J., & Bussières, J.-F. (2019). Cross-sectional evaluation of surface contamination with antineoplastic drugs in Canadian health care centres. *The Canadian Journal of Hospital Pharmacy, 72*(5), 377-384. **https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6799961/**

Hodson, L., Ovesen, J., Couch, J., Hirst, D., Lawson, C., Lentz, TJ., Mead, K. (2020). Managing hazardous drug exposures: Information for healthcare settings: DRAFT. Cincinnati, Ohio: *National Institute for Occupational Safety and Health*. **https://www.cdc.gov/niosh/docket/review/docket233c/pdfs/DRAFT-Managing-Hazardous-Drug-Exposures_Information-for-Healthcare-Settings.pdf**

Hon, C.-Y., Teschke, K., Chu, W., Demers, P., & Venners, S. (2013). Antineoplastic drug contamination of surfaces throughout the hospital medication system in Canadian hospitals. *Journal of Occupational and Environmental Hygiene, 10*(7), 374-383. **https://pubmed.ncbi.nlm.nih.gov/23668810/**

Hon, C.-Y., Teschke, K., Shen, H., Demers, P. A., & Venners, S. (2015). Antineoplastic drug contamination in the urine of Canadian healthcare workers. *International Archives of Occupational and Environmental Health, 88*(7), 933-941. **https://doi.org/10.1007/s00420-015-1026-1**

International Safety Equipment Association, & American National Standards Institute. (2014). *American national standard for emergency eyewash and shower equipment.* Arlington, Va.: ISEA.

INSPQ. (2003). *Cadre de référence en gestion des risques pour la santé dans le réseau québécois de la santé publique*. Montréal, Québec : Institut national de santé publique du Québec. **http://www.santecom.qc.ca/Bibliothequevirtuelle/INSPQ/2550407814.pdf**

Janes, A., Bérard, C., & Bussières, J.-F. (2016). État des lieux de l'étiquetage des médicaments dangereux sur le marché canadien. *The Canadian Journal of Hospital Pharmacy, 69*(1), 30-35. **https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4777578/**

Kiffmeyer, T. K., et al. (2002). Vapour pressure, evaporation behaviour and airborne concentrations of hazardous drugs: Implications for occupational safety, *The Pharmaceutical Journal, 268* (March), 331-337.

Lara, J., Vennes, M., Larouche, A., Gagné, M., Commission de la santé et de la sécurité du travail du Québec, & Institut de recherche Robert-Sauvé en santé et en sécurité du travail (Québec) (Éds). (2003). *Guide pratique de protection respiratoire* (2e éd). Montréal : CSST. https://www.cnesst.gouv.qc.ca/publications/200/Documents/DC200_1635web.pdf

Labrèche, F., Ouellet, C., Roberge, B., Yennek, A., Caron, N. (2020). *Antinéoplasiques en milieu hospitalier : étude pilote sur l'exposition potentielle du personnel d'hygiène et de salubrité*. Institut de recherche Robert-Sauvé en santé et en sécurité du travail (Québec) (Éds). Montréal : IRSST. https://www.irsst.qc.ca/publications-et-outils/publication/i/101072/n/antineoplasiques-milieu-hospitalier

Mahmoodi, M., Soleyman-Jahi, S., Zendehdel, K., Mozdarani, H., Azimi, C., Farzanfar, F., … Rezaei, N. (2017). Chromosomal aberrations, sister chromatid exchanges, and micronuclei in lymphocytes of oncology department personnel handling anti-neoplastic drugs. *Drug and Chemical Toxicology, 40*(2), 235-240. https://doi.org/10.1080/01480545.2016.1209678

McEvoy, G. K., & American Society of Health-System Pharmacists (Éds). (2018). *AHFS drug information 2018*. Bethesda, MD: American Society of Health System Pharmacists. https://www.ahfsdruginformation.com/

Merger, D., Tanguay, C., & Bussières, J.-F. (2013). Circuit des médicaments dangereux en établissements de santé. *Québec Pharmacie*, (Février-mars 2013), 13-18. http://indicible.ca/urpp/20130331_ASSTSAS2_Article.pdf

Merger, D., Tanguay, C., Langlois, É., Lefebvre, M., & Bussières, J.-F. (2013). Environmental contamination with methotrexate in Canadian community pharmacies. *Journal of the American Pharmacists Association, 53*(4), 423-426. https://doi.org/10.1331/JAPhA.2013.12245

MSSS. (2016). *Aires réservées aux préparations stériles - Unité de pharmacie - Répertoire des guides de planification immobilière*. Québec : Direction des communications du ministère de la Santé et des Services sociaux du Québec. https://publications.msss.gouv.qc.ca/msss/document-000363/

MSSS. (2017). *Guide de gestion des déchets du réseau de la santé et des services sociaux*. Québec : [Québec] : Direction des communications du Ministère de la santé et des services sociaux du Québec. https://numerique.banq.qc.ca/patrimoine/details/52327/4973852327/2217603

MSSS. (2004). *Manuel de planification des mesures d'urgence pour les établissements du réseau de la santé et des services sociaux*. Québec : Direction des communications du ministère de la Santé et des Services sociaux du Québec. https://publications.msss.gouv.qc.ca/msss/document-001447/

Neuss, M. N., Gilmore, T. R., Belderson, K. M., Billett, A. L., Conti-Kalchik, T., Harvey, B. E., Polovich, M. (2017). 2016 Updated American Society of Clinical Oncology/Oncology Nursing Society Chemotherapy Administration Safety Standards, Including Standards for Pediatric Oncology. *Oncology Nursing Forum, 44*(1), 31-43. https://doi.org/10.1188/17.ONF.31-43

NIOSH (Ed.). (2004). *Preventing occupational exposure to antineoplastic and other hazardous drugs in health care settings*. Cincinnati, Ohio: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH). https://www.cdc.gov/niosh/docs/2016-161/default.html

NIOSH (Ed.). (2016). *NIOSH list antineoplastic and other hazardous drugs in healthcare settings, 2016*. Cincinnati, Ohio: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH). https://www.cdc.gov/niosh/docs/2016-161/default.html

NIOSH. (2020). *DRAFT Managing Hazardous Drug Exposures: Information for Healthcare Settings*. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH). https://www.cdc.gov/niosh/docket/review/docket233c/pdfs/DRAFT-Managing-Hazardous-Drug-Exposures_Information-for-Healthcare-Settings.pdf

Norme 2012.01 *– Préparations magistrales non stériles en pharmacie et documents complémentaires*. (2012). Montréal : Ordre des pharmaciens du Québec. https://www.opq.org/documentation/norme-2012-01-preparation-magistrales-non-steriles-en-pharmacie/

Norme 2014.02 *– Préparations de produits stériles dangereux en pharmacie*. (2014). Montréal : Ordre des pharmaciens du Québec https://www.opq.org/wp-content/uploads/2020/03/1847_38_fr-ca_0_norme201402_prod_striles_dang_oct2017.pdf

Palamini, M., Hilliquin, D., Delisle, J.-F., Chouinard, A., & Bussières, J.-F. (2020). Surface Contamination by Antineoplastic Drugs in Two Oncology Inpatient Units. *Pharmaceutical Technology in Hospital Pharmacy, 5*(1). https://doi.org/10.1515/pthp-2019-0017

Panahi, D., Azari, M., Akbari, M. E., Zendehdel, R., Mirzaei, H. R., Hatami, H., & Mehrabi, Y. (2016). Development of a new method for sampling and monitoring oncology staff exposed to cyclophosphamide drug. *Environmental Monitoring and Assessment, 188*(4), 238. https://doi.org/10.1007/s10661-016-5255-x

Peters, C. E., Ge, C. B., Hall, A. L., Davies, H. W., & Demers, P. A. (2015). CAREX Canada: an enhanced model for assessing occupational carcinogen exposure. *Occupational and Environmental Medicine, 72*(1), 64-71. https://doi.org/10.1136/oemed-2014-102286

Polovich, M., Olsen, M. M., & Oncology Nursing Society. (2018). *Safe handling of hazardous drugs* (Third edition). Pittsburgh, PA: Oncology Nursing Society.

Poupeau, C., Tanguay, C., Plante, C., Gagné, S., Caron, N., & Bussières, J.-F. (2017). Pilot study of biological monitoring of four antineoplastic drugs among Canadian healthcare workers. *Journal of Oncology Pharmacy Practice: Official Publication of the International Society of Oncology Pharmacy Practitioners, 23*(5), 323-332. **https://doi.org/10.1177/1078155216643860**

Power, L. A., & Coyne, J. W. (2018). ASHP guidelines on handling hazardous drugs. *American Journal of Health-System Pharmacy, 75*(24), 1996-2031. **https://doi.org/10.2146/ajhp180564**

Programme québécois de cancérologie. (2019). *Méthode de soins infirmiers : administration d'agents antinéoplasiques par voie intraveineuse* (Mise à jour 2019). Québec : Direction des communications du Ministère de la santé et des services sociaux. **https://publications.msss.gouv.qc.ca/msss/fichiers/2019/19-902-13W.pdf**

Public Health Agency of Canada. (2016). *Biological Safety Cabinets*. In Canadian Biosafety Handbook (2nd ed., pp. xvi, 346). Ottawa, Ont.: Government of Canada. **https://publications.gc.ca/site/eng/9.894171/publication.html**

Québec (Province). Comité sur la qualité de l'air intérieur, & Québec (Province). Ministère de la santé et des services sociaux (Éds). (2011). *Guide de qualité de l'air intérieur dans les établissements du réseau de la santé et des services sociaux* (2e éd). Québec : Direction des communications du Ministère de la santé et des services sociaux. **https://publications.msss.gouv.qc.ca/msss/fichiers/2011/11-610-05W.pdf**

Rabii, F. W., Segura, P. A., Fayad, P. B., & Sauvé, S. (2014). Determination of six chemotherapeutic agents in municipal wastewater using online solid-phase extraction coupled to liquid chromatography-tandem mass spectrometry. *The Science of the Total Environment, 487*, 792-800. **https://doi.org/10.1016/j.scitotenv.2013.12.050**

Redic, K. A., Fang, K., Christen, C., & Chaffee, B. W. (2018). Surface contamination of hazardous drug pharmacy storage bins and pharmacy distributor shipping containers. *Journal of Oncology Pharmacy Practice: Official Publication of the International Society of Oncology Pharmacy Practitioners, 24*(2), 91-97. **https://doi.org/10.1177/1078155216679027**

Regulation respecting occupational health and safety, RLRQ c S-2.1, r 13, sec. 43, 51, 75 and 76. **https://canlii.ca/t/1128#43**

Roberge, R. J., Kim, J.-H., Palmiero, A., & Powell, J. B. (2015). Effect of pregnancy upon facial anthropometrics and respirator fit testing. *Journal of Occupational and Environmental Hygiene, 12*(11), 761-766. **https://doi.org/10.1080/15459624.2015.1049269**

Roberge, R. J., Kim, J.-H., & Powell, J. B. (2014). N95 respirator use during advanced pregnancy. *American Journal of Infection Control, 42*(10), 1097-1100. **https://doi.org/10.1016/j.ajic.2014.06.025**

Schenk, K. E., Schierl, R., Angele, M., Bukhart-Reichl, A., Glockzin, G., Novotny, A., Nowak, D. (2016). Cisplatin and oxaliplatin surface contamination in intensive care units (ICUs) and hospital wards during attendance of HIPEC patients. *Int Arch Occup Environ Health, 89*(6), 991-996.

Sessink, P. J. M., Trahan, J., & Coyne, J. W. (2013). Reduction in surface contamination with cyclophosphamide in 30 US hospital pharmacies following implementation of a closed-system drug transfer device. *Hospital Pharmacy, 48*(3), 204-212. **https://doi.org/10.1310/hpj4803-204**

Soubieux, A., Palimi, M., Tanguay, C., Bussières, J.-F. (2020). Evaluation of decontamination strategies for cyclophosphamide. *Journal of Oncology Pharmacy Practice, 26*(2), 413-422. DOI: **https://doi.org/10.1177/1078155219865931.**

Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs. **(2019).** (S.l.): American Society for Testing and Materials. **https://www.astm.org/Standards/D6978.htm**

USP-NF. (2017). General chapter 800. Hazardous drugs – Handling in healthcare settings. **https://www.uspnf.com/notices/gc-800- hazardous-drugs-handling-in-healthcare-settings**

Yuki, M., Sekine, S., Takase, K., Ishida, T., Sessink, P. J.-M. (2013). Exposure of family members to antineoplastic drugs via excreta of treated cancer patients. *Journal of Oncology Pharmacy Practice, 19*(3). **https://journals.sagepub.com/doi/10.1177/1078155212459667**

Z94.3.1-16 Guideline for Selection, Use and Care of Eye and Face Protectors. (2016) (3rd ed.). Toronto: CSA Group.

Z94.3-20 Eye and face protectors. (2020) (9th ed.). Toronto: CSA Group.

Z94.4-11 (R2016) Selection, Use and Care of Respirators. (2011) (4th ed.). Mississauga, Ont.: CSA Group.

Z94.4-93 (R1997) Selection, Use and Care of Respirators. (1993) (2nd ed.). Rexdale, Ont.: Canadian Standards Association.

Z316.5-04 (R2014) Fume Hoods and Associated Exhaust Systems. (2004) (2nd ed.). Mississauga, Ont.: CSA Group.

GLOSSARY

TERMS	DEFINITIONS
Antineoplastic	Drug that destroys cancer cells or prevents them from proliferating
Biological safety cabinet (BSC), or biosafety cabinet	Ventilated cabinet that protects product sterility In the guide, unless otherwise indicated, this term refers to BSCs where 100% of the air is exhausted to the outside, which serves to protect both the preparer and preparation sterility. Synonyms: Class II, Type B2 safety cabinet, Class II, Type B2 sterile biosafety cabinet A standard laminar flow hood is used in the centralized admixture service (CAS) for sterile preparation of non-hazardous drugs; it helps ensure preparation sterility
Carcinogen	Substance that may cause or promote the development of cancer
Cleaning	Activity that involves removing dirt, dust and other substances
Compounding	Combination or mixture of two or more ingredients in order to produce a final dosage form appropriate to be taken by the patient; in most cases, at least one ingredient is pharmacologically active
Container	If used without a qualifier, refers to the primary container, the one in direct contact with the hazardous drug (e.g., vial, IV bag) Secondary container: a container that contains the primary container (e.g., Ziplock)
Cytotoxic	Quality of a substance or drug of being toxic to a living cell that inhibits or prevents cells from functioning
Deactivation	Action of making a chemical (like a hazardous drug) less hazardous through treatment with another chemical, heat or another agent
Decontamination (of surface)	Action of transferring a hazardous drug contaminant from one surface (e.g., countertop, IV bag, handle) to another (e.g., wipe, towel)
Detergent	Product that can be used to eliminate soiling of the solid environment by suspending the soiling in a solution
Disinfection	Action of eliminating most pathogens on a surface by treating the surface with a chemical, heat or another agent
Final dosage form	Drug ready to be administered
Final waste storage area	Storage room for various categories of waste awaiting shipment to a processing centre or landfill
Genotoxic	Substance that can damage genetic material (DNA) and cause mutations
In-house transport	Transport of hazardous drugs from one building to another by way of a public road
Initial waste storage area	Temporary waste storage room located close to place where waste is generated

TERMS	DEFINITIONS
Outside transport	Transport of hazardous drugs within the same building by a person or by mechanical means
Preparation (of a hazardous drug) by a nurse	Stage preceding administration of a drug (e.g., crushing a G2 tablet, dissolving a drug in solution)
Repackaging	Simple drug preparation (e.g., counting tablets)
Safety needle	Needle equipped with a device that prevents contact with the contaminated section of the needle
Support area	Area reserved for sterile compounding support activities, which can include supply and drug storage areas, work areas and prescription verification, validation and follow-up areas; in general, access to the clean room anteroom and to the pass-through is located in this area
Teratogenic	Substance that can cause congenital malformations by affecting an embryo
Toxic for reproduction	Substance having an effect on fertility (e.g., miscarriage, late fetal death, infertility)
Toxic for organs at low doses	Substance having a toxic effect on an organ or on health at a low dose (e.g., liver damage, local necrosis of exposed tissue)
Validation (pharmaceutical)	Decision by a pharmacist to approve a prescription after verifying its legality, content and appropriateness for the patient and the patient's condition
Venous access device (VAD)	Any device (like a catheter) installed to provide access to a vein; the device can be peripheral (PVAD) or central (CVAD)
Ventilated cabinet (VC)	Cabinet that protects the preparer and that can also protect the preparation in question, depending on the type of cabinet; it can be a chemical fume hood with 100% of the air exhausted to the outside or a biological safety cabinet
Verification by pharmacist	Activity performed by a pharmacist to ensure the preparation corresponds to the prescription

APPENDIX

Spill Report Form (1/2)

Please fill in this form to document a hazardous drug spill

Time of spill

Date of spill	
Place	
Time assistance requested	
Team called	☐ Hygiene and sanitation
	☐ Spill management team
	☐ Code brown
	☐ Other:
Time spill management began	

Circumstances surrounding spill

People in contact with spill	
Description of spill	
Drug	
Drug group	☐ Group 1 hazardous drug
	☐ Group 2 hazardous drug
	☐ Group 3 hazardous drug
	☐ Other:
Estimated volume	

Spill Report Form (2/2)

Spill management

Spill management stages

- ☐ Isolation of potentially contaminated area
- ☐ Use of spill kit
- ☐ Clean-up of spill
- ☐ Other: _____

Comments on spill management

Time spill management ended

Assessment of event

Causes of spill

Changes or solutions proposed

Completion of report

Report submitted to

- ☐ OHS
- ☐ Head of department concerned: _____

Report completed by (name and title)

NOTES

This prevention guide proposes a set of recommendations to help health care facilities work safely with hazardous drugs. The recommendations concern practices that could entail a risk of exposure for people working directly or indirectly with these drugs. The objective is to help decision makers develop and implement exposure prevention measures and safe procedures.

ASSTSAS

Association paritaire pour la santé et la sécurité
du travail du secteur affaires sociales
7400, boul. des Galeries d'Anjou, Suite 600
Montréal, Quebec H1M 3M2
514 253-6871 / 1 800 361-4528
asstsas.qc.ca