



Provincial Health Services Authority

BC Cancer

Pharmacy

Practice Standards

For

Hazardous

Drugs©

****** NOTICE ******

These standards and recommendations were prepared exclusively for use by the pharmacies of BC Cancer and the Communities Oncology Network (CON).

BC Cancer's safe handling aseptic techniques for parenteral hazardous drug preparation are presented assuming prior training in aseptic work practices.

BC Cancer's Systemic Therapy Policies are located at:
<http://shop.healthcarebc.ca/phsa/BCcancer/Systemic%20Therapy/70005.pdf>

BC Cancer's Chemotherapy Preparation and Stability Chart is located at:
<http://www.bccancer.bc.ca/health-professionals/clinical-resources/cancer-drug-manual>

Introduction

Aseptic and safe handling practice standards and recommendations for hazardous drugs as well as standards for pharmacy oncology medication checking were compiled in BC Cancer's Pharmacy Practice Standards for Hazardous Drugs© Manual as part of the Pharmacy Oncology Certification Program of BC Cancer, Division of Pharmacy and the Communities Oncology Network (CON) Pharmacies. BC Cancer's Pharmacy Practice Standards for Hazardous Drugs© Manual was reviewed by pharmacists, pharmacy technicians, pharmacy assistants and pharmacy professional practice leaders.

BC Cancer's standards and recommendations for safe handling and safe and accurate delivery of chemotherapy meet best practice standards set forth by the College of Pharmacists of BC, WorkSafe BC, Accreditation Canada, the National Association of Pharmacy Regulatory Authorities (NAPRA), the United States Pharmacopeia (USP) Chapters <797> and <800>, the Canadian Society of Hospital Pharmacists (CSHP), the Canadian Association of Pharmacy in Oncology (CAPHO), the Institute for Safe Medication Practices (ISMP) Canada, and the National Institute of Occupational Safety and Health (NIOSH). These standards and recommendations are comparable with those found in other jurisdictions with similar characteristics, and with other healthcare disciplines within the cancer care spectrum. **The standards included in BC Cancer's Pharmacy Practice Standards for Hazardous Drugs© Manual are prefaced with the word 'Standard' and are written in bold purple coloured lettering in a different size and style of font.** The best practice recommendations and other information are written in black font.

BC Cancer's standards and recommendations are used as the basis to certify new and existing staff and to document that safe and acceptable checking procedures and hazardous medication preparation techniques are being adhered to. In addition to providing protection for workers and the environment, these preparation techniques and checking procedures protect the patient by providing guidelines for hazardous drug preparation with meticulous technique to yield a final product that is an accurate and aseptic preparation. Particular emphasis is placed on the safe and aseptic preparation of parenteral hazardous drugs.

BC Cancer's Pharmacy Oncology Certification Program is based on the information found in Module 1 and Module 2 of BC Cancer's Pharmacy Practice Standards for Hazardous Drugs© Manual. The content of Module 3 is included in the manual to supplement the hazardous drug safe handling material included in Module 1 and the checking standards in Module 2 and are by no means intended to be regarded as all inclusive information on Improving Patient's Safety and Compliance. A summary of BC Cancer's Pharmacy Practice **Standards** for Hazardous Drugs without the recommendations, techniques or explanations is included as a quick reference.

The BC Cancer safe handling aseptic techniques and checklists for parenteral hazardous drug preparation are presented assuming prior knowledge of basic aseptic work practices. Using the techniques described without proper training may lead to increased risk of hazardous drug exposure.

This manual was compiled and written by Joan Fabbro and Michelle Koberinski.

A special thanks to those who contributed their time and expertise on the preparation of this document.

Rhonda Kalyn
Josie Penas
Nadine Badry
Rowena Lee
Carolyn Bornstein
Yvonne Dresen
Stacey Hogg
Liz Cousineau
Krista Clement

Susan Walisser
Sanna Pellatt
Lynne Nakashima
Kimberly Kuik
Paul Koke
Dennis Jang
Roxana Ho
Tanya Leduc
Ruth Hartnup

Pharmacy Oncology Certification

Standard:

All pharmacy staff involved in the preparation and delivery of hazardous drugs must demonstrate knowledge and competency for the duties that they are required to undertake. Re-evaluation of competency and knowledge must take place on a regular basis with documentation of results.^{1,2}

The assurance of a compounded sterile product's quality and packaging integrity is highly dependent on the proper adherence of all personnel to procedures and techniques, and to safe and aseptic handling standards and recommendations.^{1,3}

A BC Cancer Pharmacy Oncology Certification Program is necessary for staff to maintain consistent, standardized practice for handling and checking of hazardous drugs within BC Cancer's Regional Centres and Communities Oncology Network pharmacies in British Columbia that check, prepare, and dispense chemotherapy. Pharmacy staff who are required to handle hazardous drugs will complete the oncology certification program initially and repeat certification annually (BC Cancer pharmacy staff) or every 3-5 years (CON pharmacy staff) thereafter. Repeat certification demonstrates that compliance with standards for the safe handling of hazardous drugs and procedures for aseptic preparation of hazardous drugs are maintained.¹ Oncology certification results will be documented.

Pharmacy Technicians and Assistants certified in Hazardous Drug Preparation, Safe Handling Awareness, and/or Hazardous Drug Final Product Checking

On-Line Tests – Two different tests consisting of questions based on BC Cancer's Pharmacy Practice Standards for Hazardous Drugs© Manual. One test is designed for technicians that mix parenteral hazardous drugs and the other test is designed for technicians and assistants that handle hazardous drugs outside of the biological safety cabinet. Each technician and assistant will complete **one** test. The tests are open book and should take approximately one hour to complete.

On-Site Performance Assessment – Pharmacy technicians that mix parenteral hazardous drugs will prepare hazardous drug doses while being assessed by an observer using checklists modeled on the descriptions of standard safe handling aseptic techniques for the preparation of parenteral hazardous drugs outlined in Module 1 of BC Cancer's Pharmacy Practice Standards for Hazardous Drugs© Manual.

Pharmacy technicians that check final products will perform final product checks while being assessed by an observer using checklists comprised of the steps required in the Final Product and Computer Order Entry Check and the Documentation of Pharmacy Medication Checks sections found in Module 2 of BC Cancer's Pharmacy Practice Standards for Hazardous Drugs© Manual.

Pharmacists certified in Oncology Medication Order Checking and Hazardous Drug Safe Handling Awareness

On-Line Test – One on-line test consisting of questions based on BC Cancer's Pharmacy Practice Standards for Hazardous Drugs© Manual and the Clinical Pharmacy Guide: Chemotherapy Assessment and Review. The test is open book and should take approximately one hour to complete.

On-Site Performance Assessment – Pharmacists will review and check chemotherapy medication orders, check and verify computer order entries (patient labels) and check final products while being assessed by an observer using checklists comprised of the steps required in Module 2 of the Clinical Pharmacy Guide: Chemotherapy Assessment and Review and the standards found in Module 2 of BC Cancer's Pharmacy Practice Standards for Hazardous Drugs© Manual.

Note:

- Pharmacists requiring certification in hazardous drug preparation as well as chemotherapy medication order checking and hazardous drug safe handling awareness due to working circumstances will be assessed using the Hazardous Drug Preparation On-Site Performance Assessment checklist in addition to completing the On-Line Test and Pharmacists On-Site Performance Assessment.

Certification Results

A passing score of 85% or higher on the **on-line test** must be obtained by the pharmacy staff member to be eligible for participation in the on-site performance assessment.

The assessment results will be disseminated to staff members by the Pharmacy Professional Practice Leader or delegate.

The individual on-site performance assessment scores will be expressed as a % score as well as 'Compliant', 'Alert', or 'Action Required' category.

- **Compliant** (80% or higher) - no action required; minimum compliance of best practice standards have been attained
- **Alert** (66%-79%) - tendency toward non-compliance; increased vigilance is required to prevent non-compliance of best practice standards
- **Action Required** (65% or less) - non-compliance; more in-depth investigation, immediate corrective action and/or preventive action are needed to avoid return to non-compliance of best practice standards

Pharmacy staff must achieve a passing score on the on-line test and a compliant score on the on-site performance assessment(s) in order to obtain successful BC Cancer Pharmacy Oncology Certification.

Pharmacy staff members that fall into the 'Alert' category will take part in remedial activities, as determined by their Pharmacy Professional Practice Leader (or delegate). Staff members will be eligible for certification during the next Oncology Certification round. Staff members that fall into the 'Action Required' category must be re-trained before continuing to perform tasks they performed unsuccessfully during certification.

**** NOTICE ****

BC Cancer's Pharmacy Oncology Certification Program content is based on the **standards, recommendations and checklists** found in BC Cancer's Pharmacy Practice Standards for Hazardous Drugs[©] Manual, and on the information found in the Clinical Pharmacy Guide: Chemotherapy Assessment and Review Manual.

References

1. National Association of Pharmacy Regulatory Authorities, (NAPRA). Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations. 2016. Available at: https://napra.ca/sites/default/files/2017-09/Mdl_Stnds_Pharmacy_Compounding_Hazardous_Sterile_Preparations_Nov2016_Revised_b.pdf. Accessed January 20, 2020
2. United States Pharmacopeia. Hazardous Drugs - Handling in Healthcare Settings. USP Compounding Compendium. USP 39 - NF 34 ed. Rockville, MD: The United States Pharmacopeial Convention; 2016. p. 85-103
3. Canadian Society of Hospital Pharmacists. Compounding: Guidelines for Pharmacies. 1st ed. : CSHP; 2014