



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. Required updates are written by the Oncology Certification Program.

A special thanks to those who contributed their time and expertise on the preparation of the original version of the manual.

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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}

BC Cancer's 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. BC Cancer pharmacy staff who are required to handle hazardous drugs will complete the Oncology Certification Program initially and repeat certification annually. CON pharmacy staff will be offered participation in the Oncology Certification Program on an ad hoc basis.

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.

On-Line Tests

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

Two different tests consisting of questions based on BC Cancer's Pharmacy Practice Standards for Hazardous Drugs© Manual. One test is designed for technicians and assistants that mix parenteral hazardous drugs and the other test is designed for pharmacy staff 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.

Pharmacists certified in Oncology Medication Order Checking, Hazardous Drug Final Product Checking, and/or Hazardous Drug Safe Handling Awareness

Two different tests consisting of questions based on BC Cancer's Clinical Pharmacy Guide: Chemotherapy Assessment and Review and/or the Pharmacy Practice Standards for Hazardous Drugs© Manual. One test is designed for pharmacists who complete the clinical medication order review and the other test is designed for pharmacy staff who handle hazardous drugs outside of the biological safety cabinet. Each pharmacist will complete **one** test. The tests are open book and should take approximately one hour to complete.

On-Site Performance Assessments

Pharmacy Technicians and Assistants:

Pharmacy technicians and assistants 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 perform the order entry (manufacturing label) check or the final product check will perform these checks while being assessed by an observer using checklists comprised of the standards found in Module 2 of BC Cancer's Pharmacy Practice Standards for Hazardous Drugs© Manual.

Pharmacists:

Pharmacists that perform the clinical medication order review, the order entry (manufacturing label) check and/or the final product check will perform these checks 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.

Certification Results

A passing score of 80% 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 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 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. Pharmacy staff members that fall into the 'Alert' category for their Final Product Check must be re-trained before continuing to perform duties they performed unsuccessfully during certification.

Pharmacy staff members that fall into the 'Action Required' category must be re-trained before continuing to perform tasks they performed unsuccessfully during certification.

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

Gloved Fingertip Sampling and Media Fill Test

The Personnel Sampling component of the Overall Quality Management Program for sterile compounding is designed to ensure that personnel work practices reflect relevant regulatory requirements and current pharmacy practice standards.

Pharmacy compounding personnel must pass initial Gloved Fingertip Sampling (GFS) and Media Fill Tests (MFT) before working in the compounding area. On-going Media Fill Test as well as Gloved Fingertip Sampling post-hand hygiene and garbing and post-MFT is performed to ensure staff can continue to consistently and successfully perform these psychomotor skills.

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 compounding staff must also pass Gloved Fingertip Sampling and Media Fill Testing in order to compound sterile preparations for patients.

****** 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