

Systemic Therapy Program

Policy & Procedure

PREPARATION OF CANCER CHEMOTHERAPY

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PREAMBLE

1. *Cancer Care Nova Scotia (CCNS)* is the provincial cancer program, with a mandate to develop standards of cancer care across Nova Scotia.(Refer to [Guiding Principles # 4](#) for further information.)
2. Cytotoxic chemotherapy for cancer patients is a high-risk area of pharmacotherapy. These drugs are also used for non-cancer treatment and should be handled and administered with the same criteria as used for cancer treatment.
3. Handling cytotoxic chemotherapy agents is an area of occupational risk for hospital staff. Chemotherapy agents include cytotoxic (cell-killing) agents, which are known to be occupationally hazardous. Non-cytotoxic agents are not proven to have occupational hazards, but should be handled with the same degree of precaution.
4. Specific policies and procedures are needed to ensure quality patient care and optimal occupational safety during the administration of chemotherapy drugs. Oral chemotherapy agents are usually self-administered but reasonable occupational safety precautions should be taken to protect health care staff.
5. Policies and procedures, common to all health districts in Nova Scotia, will enhance clarity and relationships between health care professionals providing chemotherapy care, and thus further improve patient safety and quality care.

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POLICY

1. Best practice procedures to ensure safety are followed for the receipt, transportation, secure delivery, handling and storage of cancer chemotherapy drugs in the institution. Interdepartmental policies and procedures on safe handling of cancer chemotherapy products will include issues around the receiving, transportation and storage of these products.
2. The Oncology Pharmacy Service prepares all cytotoxic chemotherapy doses for the hospital.
3. Chemotherapy is prepared in the Chemotherapy Preparation Area. Cytotoxic chemotherapy drugs are not prepared on patient care wards or other areas outside the central chemotherapy preparation area.
4. The Oncology Pharmacy Service prepares only chemotherapy drugs that have been approved for the Level of Care designation assigned to the local hospital.
5. Each chemotherapy drug will be prepared with the proper diluent(s) for reconstitution and/or admixture, and given the appropriate expiry date and time, as indicated in the Chemotherapy Preparation and Stability Chart (see Systemic Therapy Manual).
6. All cancer chemotherapy drugs used for treatment of cancer patients are prepared by Pharmacy Personnel with Chemotherapy Preparation Training and dispensed by the Oncology Pharmacy Service, optimizing safety, efficiency and economical use of chemotherapeutic agents.
7. Pharmacy Personnel with Chemotherapy Preparation Training satisfactorily demonstrate their knowledge of and adherence to all required procedures through a "Cancer Chemotherapy Preparation" training program. Personnel are reassessed regularly.
8. All staff involved with handling cancer chemotherapy drugs regularly review local procedures for the safe handling of these agents.
9. All cancer chemotherapy are ordered on approved pre-printed orders (PPOs). See Policies and Procedures on Ordering Cancer Chemotherapy.
10. The Hospital Pharmacist with Oncology Training (or designate pharmacist) verifies the medication order against the treatment protocol, the patient's medication profile and the patient's health record prior to dispensing cancer chemotherapy drugs. See Policies and Procedures on Ordering Cancer Chemotherapy.
11. The Hospital Pharmacist with Oncology Training or designate prepares computer-generated labels, using a standardized format, terminology and generic

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nomenclature. The labels are verified by the Hospital Pharmacist with Oncology Training or designate pharmacist prior to dispensing cancer chemotherapy drugs.

12. The Hospital Pharmacist with Oncology Training (or designate pharmacist, pharmacy technician or other health professional) performs an independent check of the final product against the product label and a copy of the verified physician's order. The product check is performed at the time the product is prepared or using a system that ensures correct product selection and dosage volume.

SAFE HANDLING OF CANCER CHEMOTHERAPY DRUGS

13. The Oncology Pharmacy Service has a practice site, which ensures the safe handling and distribution of cytotoxic drugs. The List of Hazardous Agents identifies those drugs which require safe handling precautions, and those for which precautions are not required, but may still be practiced. Cytotoxic agents are handled in a manner to ensure:

- The safety of personnel
- The accuracy and appropriateness of the drug and dose
- Protection of the patient regarding sterility of the parenteral agent
- Protection of the environment
- Minimization of exposure and undue hazards to others including pharmacy personnel, nursing staff, allied health staff and patients.

14. Parenteral cancer chemotherapy drug admixtures are prepared in a Class II Biological Safety Cabinet (BSC) located in the Chemotherapy Preparation Area. The BSC meets current technical standards. Class II Type A cabinets are a minimum requirement and Class II Type B cabinets which are exhausted to the outside are used whenever feasible. The BSC should be equipped with a continuous monitoring device to allow confirmation of adequate airflow and cabinet performance.

- a. A horizontal laminar flow cabinet is **not** used to prepare cytotoxic chemotherapy.
- b. Due to the possibility of cross contamination, biologicals (e.g. BCG) and cytotoxic drugs should **not** be prepared in the same BSC. If a biological agent is prepared in the same BSC used for cytotoxic drugs, there will be procedures for disinfection and decontamination of the BSC after each session where biologic agents are prepared in the BSC.

15. Parenteral cancer chemotherapy drugs are prepared using appropriate equipment to ensure product sterility and optimal protection for the health care worker.

- a. Sterile disposable equipment is used for all cancer chemotherapy drugs and doses.
- b. Luer-Lock devices are used, where available.
- c. If possible, closed system devices should be used for preparation and administration of cancer chemotherapy and other occupationally hazardous drugs.

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16. Pharmacy personnel follow best practice procedures, to ensure safety in the preparation and handling of cytotoxic agents.
 - a. Protective equipment is used and protective clothing will be worn to prevent personnel exposure and to maintain product sterility.
 - b. An eye wash station is immediately accessible to the chemotherapy preparation area.
 - c. A safety shower or equivalent (e.g. hand held spray device) should be readily accessible to chemotherapy preparation personnel.
 - d. Properly trained personnel dispose of cancer chemotherapy drugs and contaminated equipment.
 - e. Employees who are pregnant, attempting to conceive or father a child, or are breast feeding may opt to be transferred to comparable duties, that do not involve handling cytotoxic drugs. There is a departmental policy to provide direction with this issue.
17. Cytotoxic preparation involves specific techniques to ensure the integrity of the product and personnel safety.
18. Personnel follow best practice procedures for the identification, containment, collection, segregated storage, and disposal or removal of cytotoxic waste materials.
 - a. Cytotoxic drug waste is disposed of in accordance with all applicable provincial guidelines (national guidelines of the Canadian Council of Ministers of the Environment) for the handling of hazardous and toxic waste.
19. Properly trained personnel follow established policies and procedures immediately for spill management and clean up procedures.
 - a. Spill kits, containing all materials and equipment necessary to clean a spill, are available and readily accessible at each area where hazardous drugs are handled.
 - b. All individuals who routinely handle cytotoxic drugs are trained in proper spill management and cleanup procedures.
 - c. The circumstances and handling of spills are documented and reported according to institutional policies and procedures.

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GUIDING PRINCIPLES

1. Preparation of cancer chemotherapy drugs is more complex than many other drugs given in the hospital due to risk and safety concerns. Educational programs for health professionals involved in the care of cancer patients are under development, including the Chemotherapy Preparation Course for pharmacy technicians (and others). These education programs are important to developing the competencies needed to comply with the *Levels of Care for Cancer Chemotherapy* and the related policies and procedures. As programs become available, personnel involved in chemotherapy preparation should complete a standard training and certification program.
2. Three basic principles must be considered at all times when handling, transporting or administering cancer chemotherapy drugs:
 - a. Protection of the patient (i.e. using good aseptic technique, prevention of extravasation events,)
 - b. Protection of personnel (i.e. using personal protective equipment and specialized techniques, and education of all personnel involved at each step that cancer chemotherapy is handled, such as nurses, housekeeping staff, and porters)
 - c. Protection of the environment (i.e. drug administration techniques to avoid leakage, aerosolization or spillage, management of waste materials to minimize environmental contamination)
3. *Cancer Care Nova Scotia (CCNS)* is the provincial cancer program, with a mandate to develop standards of cancer care across Nova Scotia. CCNS has developed a “Systemic Therapy Manual for Cancer Patients”, cataloging the drugs and regimens used for the systemic therapy of cancer (including cytotoxic chemotherapy drugs). Safe handling information is included in the Systemic Therapy Manual. This Manual is intended to provide information support to all health care professionals involved with cancer patients.
4. A list of hazardous (cytotoxic) drugs requiring special handling is included in the Systemic Therapy Manual and posted on the *Cancer Care Nova Scotia* website at www.cancercare.ns.ca. Each institution that prepares cytotoxic drugs will maintain a current list of cytotoxic drugs available at their site. Likewise, a “Chemotherapy Preparation and Stability Chart”, and other supporting information for these policies, are included in the Systemic Therapy Manual and posted on the *Cancer Care Nova Scotia* website. Current versions of the List of Hazardous Drugs and Chemotherapy Preparation and Stability Chart are included as appendices to this document, but the most up-to-date versions are available on the website.

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DEFINITIONS

<i>Administration of Cancer Chemotherapy</i>	Provincial policies and procedures for administration of cancer chemotherapy have been approved by <i>Cancer Care Nova Scotia</i> , and are standards for development of district health authority policies and procedures. The <i>Administration of Cancer Chemotherapy</i> policies and procedures integrate with the <i>Preparation of Cancer Chemotherapy</i> policies and procedures.
<i>Asepsis</i>	The absence of infection or infectious material or agents; prevention of contact with microorganisms.
<i>Aseptic Technique</i>	Includes the use of sterile gown and sterile gloves, surgical hand scrub; items used within the sterile field should be sterile. All items introduced into a sterile field should be opened, dispensed and transferred by methods to maintain sterility.
<i>Cancer Chemotherapy</i>	A single drug or combination of drugs used for the treatment of cancer. The cancer chemotherapy drugs may or may not be cytotoxic (see Systemic Therapy Manual). Supportive treatments, used to help ameliorate adverse effects of the cancer treatment or the disease, and hormone agents are not included in this definition.
<i>Cancer Chemotherapy Regimen</i>	A drug or combination of chemotherapy drugs, with predetermined relative or absolute doses, schedule of administration, and often with recommended supportive therapy (e.g. antiemetic, hydration).
<i>Chemotherapy Administration Unit</i>	A facility (usually hospital) unit dedicated for the local preparation and delivery of chemotherapy. A Chemotherapy Administration Unit requires a Chemotherapy Administration Area, a dedicated drug preparation area (which may be located in the hospital pharmacy department), dedicated Registered Nurses with Chemotherapy Certification, and on-site medical supervision. It is desirable that a Chemotherapy Administration Unit has access to a Hospital Pharmacist with Oncology Training.
<i>Chemotherapy Preparation and Stability Chart</i>	A list of all chemotherapy drugs, with information on reconstitution, vial stability and expiry dating, final product stability and expiry dating and other information for each drug/drug product. This Chart is located in the Systemic Therapy Manual and updated as necessary.
<i>Chemotherapy Preparation Area</i>	A designated area in the hospital designed for safe preparation of cancer chemotherapy drugs. This area may be located in the hospital pharmacy area, or adjacent to the chemotherapy administration unit. The Chemotherapy Preparation Area will include a designated room with the

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	Biological Safety Cabinet and associated facilities (e.g. drug storage, refrigeration unit, drug preparation staging area). There will be sufficient space and environmental controls to ensure occupational safety in this area. If possible, the Chemotherapy Preparation Area will be a proper Cleanroom ¹ .
<i>Cleaning</i>	The removal of all visible dust, soil, and other foreign material, usually done using water and soaps, detergents, or enzymatic products along with physical action such as brushing
<i>Closed System Device</i>	A drug transfer device which mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapour concentrations outside the system.
<i>Cytotoxic</i>	A drug possessing a specific destructive action on certain cells. Used commonly in referring to antineoplastic drugs that selectively kill dividing cells. Cytotoxic drugs are associated with specific occupational risk concerns.
<i>Disinfection</i>	A process that kills or destroys nearly all disease-producing microorganisms.
<i>Decontamination</i>	The process of the removal of all visible dust, soil, and other foreign material, usually done using water and detergents, or enzymatic products along with physical action such as brushing, in order to render an object safe for handling.
<i>Hospital Pharmacist with Oncology Training</i>	A hospital pharmacist, with oncology-specific training, competency assessment and practice privileges in the local treatment facility, designated to verify cancer chemotherapy treatment orders within a scope of practice, defined by the District Health Authority in consultation with <i>Cancer Care Nova Scotia</i> .
<i>Levels of Care for Cancer Chemotherapy</i>	A program to determine the resources [health professionals, services and facilities] and criteria needed to safely administer each chemotherapeutic agent or combination of agents. The Levels of Care plan and designations for systemic chemotherapy are under development by <i>Cancer Care Nova Scotia (CCNS)</i> , and, <i>for pediatric oncology, CCNS in collaboration with the Atlantic Provinces Pediatric Hematology Oncology</i>

¹ A cleanroom is a compounding environment that is supplied with high-efficiency particulate air (HEPA), or HEPA-filtered air, that meets ISO Class 7 (*No more than 352,000 particles 0.5 µm and larger per cubic meter- International Organization of Standardization (ISO) Classification of Particulate Matter in Room Air- formerly Federal Standard No. 209E Class 10,000*), the access to which is limited to personnel trained and authorized to perform sterile compounding and facility cleaning. A buffer zone is an area that provides at least ISO Class 7 air quality. An anteroom or ante-area provides at least ISO Class 8 (*No more than 3,520,000 particles 0.5 µm and larger per cubic meter*) air quality. USP 797- Pharmaceutical Compounding- Sterile Preparations (Draft Revisions Aug 2006)

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	<p><i>Network (APPHON).</i> The service components will include the required degree of expertise for all health care professionals involved in delivery of care to adults <i>or children</i> with cancer, availability of other hospital services and other factors related to patient safety during chemotherapy administration. Chemotherapy regimens will also be categorized [as Basic, Intermediate, Advanced, or Sub-specialty] to determine the health care facility in which the regimen may safely be administered. For some protocols, portions of the entire protocol may be categorized with different levels, allowing for transfer of some of the chemotherapy treatments. Chemotherapy care will not be transferred to a health care facility without the resources in place to deliver that regimen.</p>
<i>List of Hazardous Agents</i>	<p>A list of drugs used for the systemic therapy of cancer, identifying which agents must be handled as hazardous drugs, and which do not necessarily require the precautions of handling hazardous agents. This Chart is located in the Systemic Therapy Manual and updated as necessary.</p>
<i>Oncology Pharmacist</i>	<p>A pharmacist trained and assigned to a clinical practice in the Cancer Care Program by the Pharmacy Department. An oncology pharmacist is certified through an educational program offered in consultation with <i>Cancer Care Nova Scotia</i> or <i>an equivalent pediatric program</i>. An oncology pharmacist will also meet the full criteria for a Hospital Pharmacist with Oncology Training.</p>
<i>Oncology Pharmacy Service</i>	<p>A component of the hospital pharmacy department that supports the local cancer care program/services. The oncology pharmacy service is responsible for chemotherapy preparation and other related services. Personnel included in the oncology pharmacy service may include: Pharmacy Personnel with Chemotherapy Preparation Training; Hospital Pharmacist(s) with Oncology Training; and Oncology Pharmacist(s) - as appropriate for the Level of Care designation. The Oncology Pharmacy Service meets the criteria established by these policies and procedures, and by the Systemic Therapy Levels of Care.</p>
<i>Ordering Cancer Chemotherapy Policies</i>	<p>Provincial policies and procedures for ordering cancer chemotherapy have been approved by <i>Cancer Care Nova Scotia</i>, and are standards for development of district health authority policies and procedures. The <i>Ordering Cancer Chemotherapy</i> policies and procedures integrate with the <i>Preparation of Cancer Chemotherapy</i> policies and procedures.</p>

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<i>Parenteral</i>	A drug administered to a patient by a route other than enteral (via the gut). This may include intravenous, subcutaneous, intramuscular, intradermal, intrathecal, intravesicular, or intrahepatic. Since the integumental barrier will be breached in administration, precaution is required to ensure the product is aseptic.
<i>Personal Protective Equipment (PPE)</i>	Equipment designated for personnel to wear during administration of cancer chemotherapy, and other activities where physical exposure to cytotoxic agents and/or waste is a risk. PPE may include a gown, gloves, goggles and/or a mask. Gloves that meet ASTM testing standards are designated as 'chemotherapy gloves' and are defined as "sterile disposable, powder-free non-latex gloves designed and validated for chemotherapy preparation.
<i>Pharmacy Personnel with Chemotherapy Preparation Training</i>	A pharmacist, pharmacy technician (or, in selected circumstances, a nurse) who has completed training and (when available) certification to prepare cancer chemotherapy.
<i>Pre-Printed Order (PPO) Form</i>	A preprinted order sheet approved by the appropriate Cancer Site Team and the local DHA Forms Committee (for format). For pediatric oncology, the chemotherapy order forms approved by IWK will be considered as PPO for this document.
<i>Provincial Cancer Drug Formulary</i>	A listing of drugs used in cancer care, with the formulary status of each drug according to the Levels of Care Systemic Therapy Criteria. Drugs are listed as available or restricted appropriate to each facility level. This formulary will be used by all DHAs and managed by the Cancer Systemic Therapy Advisory Committee, of the Department of Health.
<i>Systemic Therapy</i>	The use of drugs for the treatment or support of cancer patients. Systemic therapy includes cancer chemotherapy, hormone therapy, immunotherapy and supportive care drugs, and includes drugs given by any route, including oral. These drugs are also used for non-cancer treatment.
<i>Systemic Therapy Manual for Cancer Treatment</i>	A manual listing all drugs and treatment regimens typically used within Nova Scotia. The <i>Systemic Therapy Manual</i> is published and updated by the Systemic Therapy Program of <i>Cancer Care Nova Scotia</i> .

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BEST PRACTICE PROCEDURES

Receiving and Storage of Cancer Chemotherapy Drugs

1. Any person who opens a container to unpack or handle chemotherapy drug products wears personal protective equipment (Procedure 5) including gloves and protective clothing (e.g. gown) while handling the products (e.g. vials outside of the box or shrink-wrap). If there is evidence or suspicion that the package is damaged, it is handled as a potential spill (see Procedure 61); the damaged package is opened in a isolated area and the personnel wear protective clothing appropriate for spill management (see Procedure 59).
2. All cancer chemotherapy products are stored in closed containers (e.g. zip-lock bags), on shelves that are not above eye level and have a ledge to prevent potential slip and breakage. This area is separate from other drug products and has sufficient external air ventilation (minimum 12 air exchanges per hour).

Personnel Responsibilities and Training

3. All personnel involved in any aspect of the handling of cytotoxic drugs are informed about the risks of occupational exposure to hazardous drugs.
4. Personnel with upper respiratory infections or cutaneous infections are excluded from preparing cytotoxics whenever possible.
5. Recommended protective clothing for the preparation of cytotoxic chemotherapy doses includes:
 - a. Sterile disposable powder-free latex or non-latex gloves designed and validated for chemotherapy preparation (chemotherapy gloves).
 - b. Personnel may double-glove, with a sterile or non-sterile non-latex glove against the skin and a latex or non-latex chemotherapy overglove. This procedure is used if the person is latex-sensitive.
 - c. Gloves are changed regularly; every 30 minutes is preferable or immediately if they are torn, punctured or contaminated. Gloves must be changed whenever it is necessary to exit and re-enter the BSC.
 - d. The inner glove is worn under the gown cuff and the outer glove over the cuff.
 - e. Thicker gloves are better than thinner gloves for personnel protection. For single gloving, extra thickness gloves should be used. If thinner or single gloves are used, they will be replaced more frequently.
 - f. A long sleeve, back closure, water repellent, disposable protective garment with solid front and tight fitting cuffs and neck which is changed daily or if soiled during preparation/handling and which is not worn outside the chemotherapy preparation area
 - g. Properly fitted masks must be used when performing BSC decontamination or cleaning a spill
 - h. Disposable hair covers, including facial hair covers and shoe covers at all times during preparation of cytotoxics or when cleaning the BSC. Disposable hair covers/boot covers must be changed whenever it is necessary to exit and re-enter the BSC area.

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- i. Protective eyewear (i.e., safety glasses with side shields) are not necessary during drug preparation but must be used during cleaning and decontamination procedures, and during the clean up of any spills, or when there is a risk for splashes or sprays. Eye glasses are not considered adequate protection.
 - j. If there is any risk of splashing, masks with face shields should be worn
 - k. Wash hands thoroughly with antiseptic soap and water before donning gloves, and immediately after removing gloves.
6. Consideration is given to surveillance of personnel who handle cytotoxic chemotherapy agents. There are no direct measurements to indicate total exposure to cytotoxic drugs, nor health outcomes related to cytotoxic exposure. Non-specific measurements have been used. Individual staff members may opt to follow selected surveillance components by their own means, which may include:
- a. Reproductive and general health questionnaires by the individual's family physician completed at the time of hire and annually
 - b. Blood work, including complete blood count, liver function tests and urinalysis completed by the individual's family physician at the time of hire and annually
 - c. Physical examination by the individual's family physician at the time of hire and then annually or as medically appropriate.
 - d. Follow up by the individual's family physician for those workers who have shown health changes/medical problems and/or have been exposed to hazardous drugs (e.g., through spills or during routine handling).
7. Documentation is maintained (as per institutional policies) on personnel working in cytotoxic chemotherapy preparation activities, which may include:
- a. Records of the work shifts or time spent by the employee preparing chemotherapy doses; other records to determine/count the number of doses prepared by each staff member
 - b. Any personal contamination from a spill
 - c. Results from any visits to occupational health related to chemotherapy preparation activities

Chemotherapy Preparation Area

8. The Chemotherapy Preparation Area for chemotherapy preparation should be in a dedicated clean room. The clean room should include the following features:
- a. An ante room or area, that is a clean area that precedes the buffer zone (where the BSC is located), for donning of personal protective equipment
 - b. In the ante room/area, supplies and equipment are removed from shipping cartons and wiped with a hospital-approved disinfectant (see Procedure 16). If supplies are received in sealed pouches, the pouches can be removed as the supplies are introduced into the clean room without the need to disinfect the individual supply items. No shipping or other external cartons may be taken into the clean room
 - c. A buffer zone or room that is the area in which the cleanest work surface (i.e., Biological Safety Cabinet- BSC) is located. This zone or room should be ventilated into the ante room/area to maintain a negative air pressure gradient

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- difference (isolating biological and chemical contaminants within the clean room and buffer zone/room)
- d. The buffer zone/room is used for storage of bulk drug and diluent supplies, assembly of materials for chemotherapy drug preparation and admixture, packaging of finished doses for transportation within the facility and other activities associated with chemotherapy preparation. This area contains hard, cleanable surfaces throughout (e.g. no porous flooring or ceilings, furniture), adequate storage shelving and dedicated refrigerated storage,
 - e. The Biologic Safety Cabinet (BSC) provides the critical area for preparing cytotoxic chemotherapy products.
9. Strict hygiene procedures are developed and followed in the chemotherapy preparation area. There will be no eating, drinking, chewing gum, applying cosmetics or storing food in or near the chemotherapy preparation area.
10. Cleaning the clean room is crucial to maintain a work environment that protects the sterility of the product. Custodial personnel will be trained and supervised to perform cleaning and disinfection of the ante area/room at least once weekly, in accordance with written procedures.
- a. Safety glasses with side shields and protective chemotherapy gloves (double gloves) are worn during the decontamination procedure. Face shields should be worn if splashing is possible. PPE should be worn in accordance to the MSDS sheets of the decontamination, disinfection, or cleaning agent used. Personnel must wash hands thoroughly with antimicrobial soap and water immediately after removing gloves.
 - b. Cleaning will proceed from the cleanest area to the dirtiest area of the room(s)/area(s). This would involve a ceiling to floor cleaning flow and a buffer zone to ante room/area sequence.
 - c. All work surfaces in the clean room (e.g., counter tops and supply carts) are cleaned and disinfected daily.
 - d. Floors are cleaned and disinfected, always proceeding from the buffer zone/room to the ante area/room. When no aseptic operations are in progress, floors in the clean room are cleaned by mopping at least once daily. Floor mops may be used in both the buffer zone/room and the ante area/room, but only in that order.
 - e. Cleaning materials (for example, wipers, mops, and disinfectants) for use in the clean room are made of materials that generate a low amount of particles. Disposable cleaning materials are recommended and after use these are disposed of along with other cytotoxic waste.
 - f. Storage shelving is emptied of all supplies and cleaned and disinfected at least once weekly in the buffer zone/room and at least once monthly in the ante room/area.
 - g. Refrigerators, freezers, shelves, and other areas where pharmacy-prepared sterile products are stored are kept clean. A regular cleaning schedule is established and maintained.
11. Chemotherapy preparation facilities maintain documentation of all quality monitoring processes and records. Routine environmental microbiological culturing is not
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recommended but may be helpful as part of an epidemiological investigation, during an assessment of hazardous environmental conditions to detect contamination, or to verify abatement of a hazard. Quality monitoring processes may include:

- a. Microbiological monitoring (e.g. settle plates, finger dabs, broth inoculations, end product testing) of BSC and preparation room
- b. If chemotherapy is prepared in a Clean room, monitoring is performed, including air particle counts, air pressure differential logs, and other monitoring parameters as defined by clean room specifications (see USP 797).
- c. Maintenance logs for all equipment
- d. Refrigerator temperature logs
- e. Certification status of all staff involved in chemotherapy preparation

Biological Safety Cabinet

12. The BSC is located in the Chemotherapy Preparation Area where air turbulence is minimal.
13. An NSF accredited biohazard cabinet field certifier (certification technician) certifies the BSC when the cabinet is installed, at least every six months thereafter, or at any time the cabinet is physically moved.
 - a. A log is maintained in which all servicing and certification records for each BSC will be filed
14. Operation of the biological safety cabinet will include:
 - a. Operating the cabinet with the blower in the turned on position, 24 hours per day, 7 days a week
 - b. Keeping the viewing window at the recommended operating position when preparing drugs
 - c. Care not to block intake or exhaust grills with paper or other materials
 - d. Daily documented checking of the magnetic gauge to ensure the BSC pressure is operating properly (if not automatically alarmed); and for externally vented BSC, the exhaust flow gauge should be operating in the normal range
 - e. Regular documentation of all routine gauge readings
15. The BSC is cleaned, disinfected and decontaminated according to the manufacturer's recommendations. Cleaning and disinfection (the operation of wiping with a non-shedding absorbent material soaked with an alcohol solution) will occur **at least once daily** or at any time that a break in sterile procedure occurs. Decontamination (cleaning with a special detergent to eliminate cytotoxic wastes) will occur **at least weekly** or any time a cytotoxic spill occurs.
16. Detergents are selected and used to clean a device and disinfectants are selected and used to render a device free from disease-producing microorganisms. Careful consideration is given to compatibilities, effectiveness, and inappropriate or toxic residues. Always use a hospital grade disinfectant /cleaner and follow the manufacturer's guidelines for reconstitution and storage of solutions. It is the responsibility of the infectious disease management processes in each District to determine the most appropriate disinfectants and detergents for local use. Careful

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consideration is given to compatibilities, effectiveness, and inappropriate or toxic residues.

- a. Diluted solutions should be kept in previously cleaned containers. They should not be stored for long periods unless sterilized and chemical stability has been established.
- b. Partly emptied containers should not be topped up.
- c. Apply the cleaning solution to the wiper, in order to avoid soiling the cleaning solution.
- d. Cleaning solutions are applied to the wiper and never sprayed in the BSC to avoid damage to the HEPA filter.

17. The following procedures describe a method, which is used for **daily** cleaning (decontaminating and disinfecting) the BSC:

- a. Protective clothing as outlined in departmental policy (gown, gloves, mask, safety goggles, disposable hair covers and shoe covers- see Procedure 5) should be worn when cleaning and disinfecting the biological safety cabinet.
- b. The BSC should be cleaned and disinfected at least once daily and prior to the mixing of any chemotherapy drugs.
- c. To disinfect the BSC, wipe with decontaminating agent, then gently spread 70% alcohol on all work surfaces of the cabinet and allow to fully air dry. The major work surfaces should be allowed several minutes' exposure to the disinfectant, for optimal disinfection
- d. Using disposable lint-free wipes, wipe the surface of the cabinet including front, sides and bottom in the direction of the groove of the surface. Clean from upstream, closest to the HEPA filter, to downstream. Start with the rear wall of the BSC and move down. Wipe in a continuous motion working parallel to the HEPA filter. When a corner is met, 'S' curve and return back to the opposite side while overlapping the previous stroke. Continue with fixtures (for example, gas or vacuum valves, bar and hooks, if present), the sides, and then the work surface. Do not use the hood until the alcohol is completely evaporated.
- e. Do not remove the sharps container from inside the BSC until full and ready for disposal.
- f. Place wipes in cytotoxic waste container.
- g. Following the disinfection procedure, allow the hood to purge for 15 minutes
- h. If the BSC is turned off between aseptic processes for routine maintenance or any other reason, it should be operated long enough to allow complete purging of room air from the critical area (for at least 30 minutes), then cleaned and disinfected before use. Note that the actual time required for purging will depend on the design of the BSC and has to be determined during the performance qualification or validation.
- i. The BSC is completely cleaned and disinfected after certification, voluntary interruption, or if the BSC is moved.
- j. Regular documentation of all cleaning and decontamination records for each BSC.

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18. The BSC work surfaces are decontaminated at least **once a week**, using the following procedures:
- a. Protective clothing as outlined in departmental policy (gown, gloves, mask, safety goggles, and disposable hair covers- see Procedure 5) should be worn when decontaminating the biological safety cabinet. This includes all personnel in the room during the decontamination procedure.
 - b. Detergent, sterile water for irrigation and disinfectant bottles will be placed on a plastic backed disposable liner outside of the BSC when not in use.
 - c. With the blower still operating, wipe the BSC with an approved or recommended detergent solution from top to bottom starting with the top grill and following airflow. An aqueous high pH detergent solution or commercial product, such as SurfaceSafe or equivalent (see Systemic Therapy Manual) is recommended.
 - d. Repeat using sterile water for irrigation on tray, wipe down with disposable towel, all scrubbed surfaces until residue is removed
 - e. Finish by disinfecting with 70% alcohol and wipe down surfaces top to bottom. An alcohol dampened cloth may be used to wipe top and front grills.
 - f. Pull the viewing window down and decontaminate both sides with detergent solution, rinse with sterile water for irrigation then disinfect.
 - g. Discard outer pair of gloves and used wipers in the sealable bag.
 - h. Decontaminate the perimeter of the opening into the BSC with detergent solution then rinse with sterile water for irrigation.
 - i. Thoroughly wash protective eye wear with detergent.
 - j. After decontamination, the BSC is allowed to purge for 30 minutes.
 - k. Regular documentation of all cleaning and decontamination records for each BSC.
19. Additional decontamination of the BSC is performed at least **once a month** or in other circumstances, using the following procedures:
- a. Clean the lower part of the hood. The fan motor (blower) may be turned off only while cleaning the lower part of the hood (sump) so that nothing will be sucked up into the fan. Some hoods have a screen on the fan to prevent anything from being sucked up.
 - b. Remove the work trays and stand on end outside of hood or raise the tray and lean on back surface of hood, if possible. Wipe the work trays with alcohol before replacing.
 - c. Record on cleaning log when the monthly sump cleaning is done.
 - d. The BSC is completely decontaminated after a cytotoxic spill has occurred using the above procedures (See Procedures 17, 18 and 19 a-c).
 - e. Regular documentation of all cleaning and decontamination records for each BSC.
20. The use of a BSC to prepare both cytotoxics and BCG vaccine is NOT recommended. BCG should be prepared on a counter-top using a closed-system device specific to this procedure.
- a. If a biological product (e.g., BCG vaccine for bladder instillation) must be prepared in the BSC, the BSC is thoroughly cleaned, and disinfected (see Procedure 17) following preparation.

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21. Waste generated throughout the cleaning or decontamination procedures is collected in suitable plastic bags, sealed and wiped with detergent and sterile water inside the BSC, and removed with minimal agitation.

Labels

22. Chemotherapy dose product labels include, but are not limited to:
- a. Name of patient, identification number, area or unit
 - b. Generic drug name, unique product identifier (e.g. DIN, bar code)
 - c. Date of preparation
 - d. Dose, total final volume, infusion solution
 - e. Route of administration
 - f. (Follow separate policy for intrathecal doses)
 - g. Drug concentration (if applicable)
 - h. If sequential, Bag 1 of 2, Bag 2 of 2 etc
 - i. If pumps, residual volume and rate and route of administration
 - j. Special delivery devices (e.g., tubing, cassette, container, etc)
 - k. Expiry date, time of expiry and initials of pharmacy personnel who checked the dose
 - l. Date of planned treatment (if different than preparation date)
 - m. Appropriate auxiliary labels, including warning labels for vesicant and irritant agents (see Systemic Therapy Manual for a List of Vesicants & Irritants)
 - n. Storage requirements
23. Each cytotoxic dose is also labeled with a clearly visible standard auxiliary label that identifies the dose as a cytotoxic agent. This label is affixed to the outer wrap and also the dose container (e.g. syringe, LVP bag, etc.) if possible. Vesicant and irritant drugs will also have auxiliary labels affixed that state “Vesicant” or “Irritant” as appropriate. Additional auxiliary labels will be affixed as indicated for specific drugs in the Chemotherapy Preparation and Stability Chart.
24. Labels are affixed to each dose in a manner that allows physical inspection of the dose by pharmacy and nursing personnel.

Checking Medication Preparation and Labeling

25. Every dose of cancer chemotherapy is checked before dispensing for patient administration.
26. The Hospital Pharmacist with Oncology Training (or designate pharmacist, pharmacy technician or other health professional) checks all chemotherapy admixtures and solutions prepared by a Pharmacy Personnel with Chemotherapy Preparation Training (who is a second person) to ensure the correct medication and quantity has been prepared and labeled properly. Checking will include verification of source products and diluents before drug preparation and checking of final product prepared. In some circumstances (e.g. during periods of high-volume drug preparation), doses are checked during preparation to verify correct source products and diluents. Checking may be done in person or by way of virtual/telecommunication techniques.

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27. Any solution to be admixed into an intravenous parenteral bag is visually checked for correct medication, quantity and quality before admixture into the bag.
28. Any IV bag is spiked with an administration set, which is flushed with non-cytotoxic drug-containing solution, before any chemotherapy agent is admixed into the bag.
29. The Hospital Pharmacist with Oncology Training (or designate pharmacist, pharmacy technician or other health professional) inspects all completed chemotherapy admixtures for particulate matter, signs of incompatibility, degradation or contamination before dispensing.
30. The Hospital Pharmacist with Oncology Training (or designate pharmacist, pharmacy technician or other health professional) checks the label against the original order for accuracy and completeness.
31. The Hospital Pharmacist with Oncology Training (or designate pharmacist, pharmacy technician or other health professional) and/or Pharmacy Personnel with Chemotherapy Preparation Training affixes the correct labels to the completed chemotherapy dose using care not to cover solution levels. Labels on syringes will not completely cover the syringe calibrations, so that the chemotherapy nurse can check the fluid volume. Labels on IV bags will not cover the bag imprint identifying the diluent solution and initial volume.
32. All finished and checked doses are properly sealed (e.g. heat-sealed or in zip-lock bags) before leaving the Chemotherapy Preparation Area room to prevent contamination.

Equipment for Drug Preparation

33. Certain cancer chemotherapy drugs are not administered in equipment that contains PVC. For these drugs (e.g. paclitaxel, docetaxel, etoposide), non-PVC equipment is used for drug administration and, if possible, drug preparation according to manufacturers' guidelines.
34. All devices for transfer and parenteral delivery of cancer chemotherapy drugs are equipped with Luer-Lock connections, to reduce the potential for spillage subsequent to accidental disconnection.
35. A closed-system may offer additional protection benefits to workers for both preparation and administration of cancer chemotherapy drugs. A closed-system may be used in conjunction with a BSC, but is not be used as a substitute for a BSC.
 - a. Closed-systems should be used whenever possible for transfer of cancer chemotherapy drugs from primary packaging (e.g. vials) to dosing equipment (e.g. infusion bags, bottles, pumps or syringes). Closed-system devices have been demonstrated to limit potential aerosol generation and reduce potential worker exposure to sharps. Closed-system devices may not be used as a substitute for a BSC.

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Preparation of Cytotoxic Drugs

36. The principle of aseptic drug preparation will be followed, along with the techniques specific for chemotherapy drugs. The following procedures describe a method for the preparation of injectable cytotoxic drugs.

General Procedures

37. Clean and disinfect the interior surface of the BSC daily, as described in Procedure 17. Disinfection will be done prior to start of shift or before a new dose is prepared (in pharmacies that prepare few doses)
- a. Assemble source products and diluents for each dose or batch and check prior to dose preparation
 - b. If multiple dose vials are used, then leftover solution should then be kept in a dedicated, visually marked location in the chemotherapy preparation area, for later use.
 - c. Whenever possible, prepare doses for a single patient at a time; alternately, prepare all doses of the same medication at one time (if the Chemotherapy Preparation Area is set up with a quality program for batch production).
 - d. Take care to avoid puncturing of gloves and possible self-inoculation.
 - e. Use only Luer-Lock syringes at all times.
 - f. Place all the necessary items for manipulation in the hood to minimize moving in and out of the BSC
 - g. Do not overload the working area.
 - h. Work 6 inches away from the grill and sides of the BSC.
 - i. No needle should be used to make more than 3 punctures during preparation of a drug dosage (the needle becomes dull with each use and coring can occur). No needle will be used for more than a single drug.
 - j. Use syringes large enough so that they are never more than 75% full (or 50 ml in 60 mL syringe), but are small enough to measure the contents with acceptable accuracy, as follows:
 - a. 1 mL syringe no more than 0.75 mL
 - b. 3 mL syringe no more than 2.3 mL
 - c. 5 mL syringe no more than 3.8 mL
 - d. 10 mL syringe no more than 7.5 mL
 - e. 20 mL syringe no more than 15 mL
 - f. 30 mL syringe no more than 22.5 mL
 - g. 60 mL syringe no more than 50 mL
 - k. Adjust volume and/or eliminate any air bubbles in the syringe before taking the needle out of the vial.
 - l. Use great care when replacing the needle cap or attaching a Luer tip. The plunger is drawn back to remove any drug from hub of needle. A fresh needle is attached if there is evident spillage inside the needle cap. Syringes contain no excess drug solution.
 - m. Attached intravenous sets are closed and secure from any cytotoxic drug leakage.
 - n. Reconstituted solutions are checked to ensure complete dissolution before withdrawal from the vial or ampoule.
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- o. The final product is visually inspected for particulate matter or physical incompatibility.
- p. Check source product, diluent, equipment/supplies and dosage for each dose during preparation or immediately after each dose is prepared (i.e. 'real-time' check). Any solution to be admixed into a large volume parenteral (LVP) is visually checked for correct medication, quantity and quality before admixture into the LVP.
- q. Collect all of the completed doses for each patient and place them together on a tray or plastic tub(s). The tray(s) or tub(s) are removed from the BSC to an adjacent counter for final check and preparation for dispensing.
- r. Remove source products and diluents from work area to permanent or temporary storage area, to reduce clutter inside work area.
- s. All waste materials are placed in a hard cytotoxic waste container within the BSC
- t. Separate institutional procedures are employed for preparation of any intrathecal doses.

38. Reconstitution of Drug in Vials

- a. Expose rubber stopper and wipe with a fresh sterile alcohol swab; allow to fully air dry.
 - b. Use a chemotherapy dispensing pin or hydrophobic filter vent device that eliminate pressure gradients or a negative pressure technique to admix and/or withdraw drug solutions from the vial.
 - c. Chemotherapy Dispensing Pin Technique
 - a. Use a chemotherapy dispensing pin with hydrophobic filter to maintain equal pressure inside and outside the vial, and to minimize the risk of aerosol spray or leakage at the needle-vial juncture that can be caused by overpressure in the vial.
 - b. Disinfect the rubber stoppers of the vials of drug and diluent; handling only the swab surface that does not contact the stopper surface, gently wipe the surface back and forth several times and allow the alcohol to air dry.
 - c. Withdraw into a syringe a volume of air equivalent the diluent volume required.
 - d. Insert the needle into the diluent vial, puncturing the centre of the rubber stopper by the needle held at a 45° angle, then bring the needle upright to a 90° angle once the point and heel of the needle are through the rubber to complete insertion. This technique causes a straight slit cut, whereas pushing the needle in at a 90° angle from the start can cause a circular hole cut and can core the rubber stopper. It is important to avoid contamination with rubber particles from coring the stopper.
 - e. Withdraw the diluent using positive pressure: inject some of the air into the diluent vial then withdraw an equivalent volume of diluent solution; repeat this process until all of the air is transferred to the vial, and the syringe is filled with the required volume of diluent.
 - f. Unwrap the dispensing pin, taking care not to touch any critical surface of the device and to maintain laminar airflow over the critical areas.
 - g. Push the pin directly into and through the rubber stopper of the drug vial. Do not twist the pin during insertion, to avoid creation of rubber particles. Make
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- sure the pin is fully inserted. Loosen the drug powder if necessary.
- h. Pinch together a sterile alcohol swab and place it at the back of the work area.
 - i. Unscrew the dispensing pin cap and place it on its side on the pinched swab. Be careful not to touch contaminate the inside of the cap.
 - j. Remove the needle from the syringe with diluent solution. Do not draw back any air into the syringe during this procedure.
 - k. Attach the syringe to the dispensing pin, with a snug tightening of the luer lock fitting. Align the vial and syringe so that the syringe graduations are visible. Do not disrupt the laminar air flow.
 - l. Slowly inject the diluent into the drug vial. Keep the vial on the work surface to maintain stability. Take care to keep the filter facing upward and avoid wetting the filter. Air cannot escape if the filter is wet.
 - m. Unscrew the empty diluent syringe and discard in the chemotherapy waste container. Replace the cap, taking care not to contaminate it. Agitate the vial in a circular motion to aid drug reconstitution.
- d. Hydrophobic Filter Vent Technique
- a. In place of a chemotherapy dispensing pin, a venting needle with hydrophobic filter may be used to maintain equal pressure inside and outside the vial.
 - b. Attach a small gauge needle to a 0.2 micron hydrophobic filter, using aseptic technique and avoiding any touch contamination. Keep the needle cap in place.
 - c. Disinfect the rubber stoppers of the vials of drug and diluent.
 - d. Withdraw into a syringe a volume of air equivalent the diluent volume required. Then withdraw the diluent solution, using Procedures 38 c (iv, v)
 - e. Remove the needle cap and insert the filter needle into the drug vial at a point off-center. Insert this needle at a 45° angle from the stopper. Ensure that the open tip of the needle does not touch any drug powder, and that it remains in an open air space within the vial (not in fluid when transferring fluids).
 - f. Insert the syringe filled with diluent into the drug vial, at the centre of the rubber stopper.
 - g. Slowly inject the diluent into the drug vial. Use a careful rotating motion to dislodge any powder from the inside surfaces of the vial. Keep the vial on the work surface to maintain stability. Take care to keep the filter facing upward and the open tip of the filter needle above the fluid level, to avoid wetting the filter.
 - h. Once the diluent fluid is fully injected, remove the diluent syringe, slowly pulling back on the barrel as the needle is pulled out of the vial.
 - i. Discard the diluent syringe without recapping it.
 - j. Withdraw the filter needle and discard without replacing the needle cap.
 - k. Shake or rotate the drug vial, as appropriate for each drug, until the drug is fully dissolved.
- e. Negative Pressure Technique:
- a. Avoid pressurizing the contents of the vial. Pressurization may cause the drug to spray out around the needle or through a needle hole or a loose seal aerosolizing the drug into the work zone.

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- b. Disinfect the rubber stoppers and withdraw the diluent as above.
- c. Once the diluent is drawn up, the needle is inserted into the vial, with the bevel facing the back of the hood. The plunger is pulled back (to create a slight negative pressure inside the vial), so that air is drawn into the syringe.
- d. Small amounts of diluent are transferred slowly as equal volumes of air are removed.
- e. The needle is kept in the vial, and the contents swirled carefully until dissolved.
- f. Alternatively, if the contents are slow to dissolve, the syringe is drawn back to create a negative pressure then the needle removed (using a sterile alcohol swab to wrap the needle and vial cap as the needle is withdrawn). When the product is dissolved, the syringe is filled with clean air (equivalent to the volume of the dose aliquot to be removed) and re-inserted into the vial to transfer the dosage aliquot, as described below.
- g. With the vial inverted, the proper amount of drug solution is gradually withdrawn while equal volumes of air are exchanged for solution.
- h. The exact volume needed must be measured while the needle is in the vial, and any excess drug remains in the vial.
- i. With the vial in the upright position, the plunger is withdrawn past the original starting point to again induce a slight negative pressure before removing the needle. The needle hub is clear of solution before the needle is withdrawn.
- f. Closed Dispensing System Technique (PhaSeal®- if used)
 - a. Use of the closed dispensing system will maintain equal pressure inside and outside the vial, and eliminate the risk of aerosol spray or leakage at the needle-vial juncture.
 - b. Disinfect the rubber stoppers of the vials of drug and diluent; handling only the swab surface that does not contact the stopper surface, gently wipe the surface back and forth several times and allow the alcohol to air dry.
 - c. Withdraw into the syringe(s) a volume of air equivalent the diluent volume required.
 - d. Insert the needle into the diluent vial, as described in Procedure 38c iv).
 - e. Withdraw the diluent using positive pressure, as described in Procedure 38c v).
 - f. Unwrap the Protector device, taking care not to touch any critical surface of the device and to maintain laminar airflow over the critical areas. Push the Protector directly into and through the rubber stopper of the drug vial, snapping the device firmly over the vial lid. Make sure the pin is fully inserted. Loosen the drug powder if necessary.
 - g. Remove the needle from the syringe with diluent solution. Replace the needle with an Injector device, firmly affixing to the Luer Lok connection of the syringe. Do not draw back any air into the syringe during this procedure.
 - h. Attach the Injector device to the Protector device. Unlock the Injector needle and slide the encased needle through the devices into the vial. Align the vial and syringe so that the syringe graduations are visible.
 - i. Slowly inject the diluent into the drug vial. Keep the vial on the work surface to maintain stability. Take care to keep the Protector device facing upward

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and avoid wetting the filter. Air cannot escape if the filter is wet. The Protector device will inflate to capture any air displaced during the reconstitution procedure.

- j. Withdraw the needle from the vial back into the Injector sheath. Unscrew and detach the empty diluent syringe, snapping the sheath lock back into place. If this syringe will be reused for dispensing, hold in a clear area of the BSC, otherwise discard it in the chemotherapy waste container. Do not remove the Injector device.
- k. Agitate the vial in a circular motion to aid drug reconstitution.
- g. Keep the number of needle punctures to the lowest possible number with each vial stopper.
- h. After removal of the solution aliquot, always wipe the top of the vial with an alcohol swab to remove any droplets of drug and discard the swab into the cytotoxic waste container within the BSC.

39. Handling Ampoules

- a. Ensure contents of ampoule are below neck of ampoule before opening. Tap ampoule with finger to remove fluid from upper section.
- b. File around neck if necessary.
- c. Wipe neck of ampoule with sterile alcohol swab. Use ampoule breaking device or wrap swab around neck, grasp with thumb and index finger and snap open using a motion away from you.
- d. For dry ampoule, slowly add diluent down inside ampoule wall. Tilt and rotate the ampoule to ensure wetting of all powder, then agitate slowly to dissolve.
- e. Withdraw solution from ampoule using a 5-micron particulate filter (filter needle or filter straw). Adjust to volume after removal of filter. Do not use this filter for drugs which exclude filtration in their monograph.
- f. To remove trapped air in syringe or to adjust volume, cap needle, tap syringe, draw back on plunger, then advance until solution appears in needle hub. Adjust to correct volume by returning excess solution to ampoule.
- g. Dispose of solution in ampoule by drawing into a syringe, cap syringe and dispose in Cytotoxic Waste (Sharp) Container. If the cytotoxic drug is stable for >24 hours, and will likely be used, transfer remaining cytotoxic drug into a sterile pyrogen free vial and label and date appropriately.

40. Preparation of Cancer Chemotherapy Admixtures in Syringes

- a. Dose aliquots are removed from vials using either a chemotherapy dispensing pin (see Systemic Therapy Manual) or a negative pressure technique. The negative pressure technique limits the number of punctures to the vial stopper, and causes inflow of air if there is a poor seal (rather than having fluid expelled from the leakage site)
- b. To withdraw a dose aliquot using a dispensing pin:
 - a. Insert a chemotherapy dispensing pin if one is not already in the vial (e.g. liquid stock solutions). Push the pin directly into and through the disinfected rubber stopper of the drug vial. Do not twist the pin during insertion. Make sure the pin is fully inserted.
 - b. Unscrew the dispensing pin cap and place it on its side on a pinched alcohol

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- swab at the back of the work area. Be careful not to touch contaminate the inside of the cap.
- c. Attach the syringe to the dispensing pin, with a snug tightening of the luer lock fitting. Align the vial and syringe so that the syringe graduations are visible. Do not disrupt the laminar air flow.
 - d. Invert the vial-syringe assembly and hold with all fingers. Hold the assembly at a 70° angle with the filter facing upward to avoid wetting or blockage of the filter.
 - e. Draw out the desired amount of drug solution from the vial, allowing air bubbles to flow in through the filter to displace the dose aliquot.
 - f. If too much fluid is withdrawn into the syringe, return the assembly to an upright position and return fluid to vial. Do not push fluid back into vial while the assembly is inverted (upside-down) or the filter will get wet.
 - g. When the correct volume of drug solution is in the syringe, unscrew the syringe from the dispensing pin. Hold the vial at a 45° angle when unscrewing the syringe, then tilt the syringe tip upward when free, to avoid spraying or spillage.
 - h. Draw the drug solution from the syringe tip into the syringe barrel. Attach the needle or needle-less device. Tap the syringe gently to dislodge any air bubbles from the syringe walls. Carefully expel the air until the drug solution just reaches the needle tip (or equivalent).
 - i. Replace the cap on the dispensing pin, taking care not to contaminate it. The vial may be discarded or stored for future dose aliquot(s), as appropriate.
- c. To withdraw a dose aliquot using a hydrophobic filter vent:
- a. Re-use the venting needle with hydrophobic filter used for drug reconstitution, or prepare a new venting needle using Procedure 38 d (ii).
 - b. Disinfect the surface of the rubber stopper on the drug vial (Procedure c (ii)), and insert the venting needle (Procedure 38 d (v)) at a site on the stopper not previously punctured. Ensure that the tip of filter needle is close to the bottom of the vial, so that it will be above the fluid level when the vial is inverted.
 - c. Attach a needle to a syringe appropriate in size for the dose to be withdrawn. Uncap the needle and insert it into the drug vial at a site on the stopper not previously punctured.
 - d. Invert the entire needle-vial assembly, ensuring that the open tip of the filter needle is above the fluid level.
 - e. Slowly withdraw the dose aliquot into the syringe, tapping out any bubbles from the syringe and expelling them while adjusting the final volume in the syringe.
 - f. Return the assembly to the upright position and carefully withdraw the dose syringe. Recap the needle.
 - g. Leave the venting needle in place. The vial may be discarded or saved for future dose aliquots.
 - h. If the venting needle becomes wet, insert a new venting needle (to equalize vial pressure then remove the old venting needle and discard it).
- d. To withdraw a dose aliquot using the negative pressure technique, follow Procedures 38 e (vii-ix)

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- e. Whenever possible, cancer chemotherapy agents are drawn into syringes using closed-system devices with locking connections.
 - f. To withdraw a dose using the closed dispensing System technique
 - a. Place an Injector device on a syringe, firmly affixing to the Luer Lok connection of the syringe (or, use the syringe from the reconstitution of the drug). Do not draw back any air into the syringe during this procedure.
 - b. Attach the Injector device to the Protector device. Unlock the Injector needle and slide the encased needle through the devices into the vial. Align the vial and syringe so that the syringe graduations are visible.
 - c. Slowly withdraw the drug solution aliquot into the syringe. Take care to keep the Protector device facing upward and avoid wetting the filter. Air cannot escape if the filter is wet. The Protector device will deflate back to normal as the aliquot is removed and the volume is replaced by air originally displaced during the reconstitution procedure.
 - d. Withdraw the needle from the vial back into the Injector sheath. Unscrew and detach the empty diluent syringe, snapping the sheath lock back into place.
 - g. If a closed system device cannot be used, Luer-Lock syringes will be used.
 - h. For very small volumes (i.e. if the dose volume is < 0.4 mL): Use a 1 mL or 3 mL Luer Lock syringe for doses given direct push through central lines or Port-a-caths (central venous access devices- CVADs).
 - a. Syringes used for CVAD procedures (i.e. direct infusions, flushes, withdrawals) are 10 mL or larger, to prevent rupture of CVAD catheter due to excess pressure in line.
 - b. A syringe smaller than 10 mL is only used for IV medication when the volume of medication in a 10 mL syringe creates a risk of incorrect medication dosage.
 - c. When using a smaller size syringe for the administration of the IV medication, the syringe containing the pre and post flush is 10 mL or larger. This ensures that the CVAD is functioning properly before using the smaller syringe.
 - i. If there is fluid in the needle cap, replace the cap before dispensing syringe.
41. Preparation of Cancer Chemotherapy Admixtures in Intravenous Parenteral Solutions
- a. Cancer chemotherapy agents are mixed into intravenous parenteral solutions inside the BSC, rather than by nursing staff in patient care areas
 - b. IV tubing, or other chemo tubing connection device, is attached and primed before placement of the bag and IV set into the BSC. Alternately, the administration set is attached in the pharmacy but primed by the nurse using backflow from a primary non-hazardous IV solution. These procedures reduce potential spillage and drug exposure to nurses administering the dose.
 - c. To attach an IV tubing to the IV bag:
 - a. Obtain the proper IV tubing set(s)
 - b. If possible, hang the IV bag in the BSC, in an area with unobstructed airflow (alternately, it is possible to hang the bag on a pole adjacent to the SC in the Chemotherapy Preparation Area, taking care to avoid any contamination)
 - c. Firmly grasp the bag at the tubing insertion port with one hand and grasp the plastic protective covering with the other hand. Firmly pull the protective

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- covering off.
- d. Holding the spike below the capped end, remove the cap. Immediately push the spike deeply into the tubing insertion port, taking care that the spike tip does not lodge or puncture the port walls and exit the bag. This procedure is best done in the BSC, since critical surfaces will be open until the spike is firmly sealed into the insertion port.
 - e. If a closed system will be used, use the Infusion Adaptor device to spike the bag, then attach the infusion line to this device.
 - f. Move the clamp to a position about 18" below the flow chamber. And clamp it in the closed position.
 - g. Pinch and release the flow chamber until it is about ½ full.
 - h. The tubing is primed with non-hazardous IV solution by pharmacy: place a needle over the end of the tubing, leaving the cap in place. Open the clamp and allow fluid to fill the tubing to the end, then clamp in the off position.
 - i. Check the tubing for any air bubbles. Bubbles may be tapped to dislodge them and move them upstream to the flow chamber. Alternately, some fluid may be run through the tubing to move the bubbles downstream and out the needle end. Excess fluid may be run into an appropriate receptacle (e.g. sterile empty IV bag, syringe).
 - j. The bag is now ready for admixture of the cytotoxic chemotherapy drug(s).
 - d. The chemotherapy agent is admixed into the bag after the tubing is attached and the tubing is flushed with non-hazardous solution.
 - a. Disinfect the injection port with a sterile alcohol swab. Allow sufficient time for the alcohol to fully air dry.
 - b. The chemotherapy drug is initially measured into a syringe. This syringe is double-checked by a second technician or a pharmacist for the drug and volume prior to admixture.
 - c. Remove the needle cap carefully to avoid any spillage. Insert the needle straight into the injection port until the needle is fully inserted.
 - d. Place the IV bag on a work surface and inject the contents of the syringe into the bag according to the treatment orders.
 - e. When the syringe contents are entirely injected, carefully remove the syringe from the injection port. If there is any concern about solution spraying upon withdrawal, wrap a sterile alcohol swab around the needle and injection port as the needle is withdrawn. Be very careful not to prick your fingers as the needle is pulled out!
 - f. Discard the syringe without recapping the needle.
 - g. Wipe the injection site with a fresh alcohol swab. Discard the swab as contaminated waste.
 - h. Carefully rock the bag to facilitate dissolution of the drug into the IV solution. Inspect the bag for any particles, discoloration, or other visible imperfections before removal from the BSC. Wipe the entire bag with sterile alcohol swab(s), especially attending to the injection port.
 - i. Label the bag and place the bag and tubing on a tray or plastic tub, then remove from the BSC to prepare for dispensing.
 - e. If a closed system is used:
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- a. Attach the Injector device on the syringe containing the drug aliquot to the Infusion Adaptor device. Unlock the Injector needle and slide the encased needle through the devices into lumen of the bag.
 - b. Slowly inject the contents of the syringe into the bag.
 - c. Withdraw the needle from the Infusion Adaptor back into the Injector sheath. Unscrew and detach the empty diluent syringe, snapping the sheath lock back into place.
 - f. When adding an admixture to an IV bag, excess overfillage should be avoided. Total final volume does not exceed the stated base solution volume for each bag size, as listed below. Remove enough solution from the bag before addition of the chemotherapy agent to ensure that the final volume does not exceed the maximum overfill amount. Fluid volume may be removed by syringe(s) via the injection port, but it is preferable to remove the excess fluid through the attached IV tubing into a measuring receptacle at the injection needle end of the tubing.
 - g. Maximum overfillage amounts are as follows:
 - a. 50 mL bag no more than 90 mL Total Volume
 - b. 100 mL bag no more than 150 mL Total Volume
 - c. 250 mL bag no more than 310 mL Total Volume
 - d. 500 mL bag no more than 580 mL Total Volume
 - e. 1000 mL bag no more than 1100 mL Total Volume
 - h. Transfer from the drug vial to the IV bag (via syringe(s)) should be carried out using closed-system devices whenever possible.
42. Preparation of Cancer Chemotherapy Admixtures in Ambulatory Infusion Device
- a. Cancer chemotherapy agents are admixed and transferred into the reservoir of an ambulatory infusion device (e.g. Infusor, CADD, etc.) inside the BSC, rather than by nursing staff in patient care areas.
 - b. To prepare a drug dose in an Infusor® device:
 - a. Draw the drug dose and diluent in syringes using aseptic technique
 - b. Double check volumes for each syringe before transfer.
 - c. Select the correct Infusor device for the protocol orders (Infusors run at fixed rates, so different rates will determine the time for complete drug infusion. See the table of Infusor rates matched to specific chemotherapy protocols- rates can be determined by the colour of the Infusor top cap.)
 - d. Ensure the winged luer cap is tightly fastened on the distal end of the Infusor tubing (this stops the device from pumping fluid into the tubing)
 - e. Remove the fill port cap from the top of the device, and retain the cap for later.
 - f. Expel all air bubbles from each syringe.
 - g. Beginning with a syringe filled with diluent, remove the needle and attach the syringe to the luer lock connection of the Infusor fill port. Make sure the connection is tight.
 - h. Invert the Infusor-syringe apparatus and place the syringe plunger on a flat surface; use a slow steady downward pressure on the syringe barrel (not the Infusor device) to fill the Infusor balloon until the entire syringe contents are transferred to the Infusor. Alternate fluid transfer methods may be used, as long as there is no pressure applied to the Infusor.
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- i. In the upright position, gently unscrew the syringe and discard the used syringe.
- j. Tap loose all bubbles from the inside of the Infusor then prime the line with non-hazardous IV fluid (from the first syringe) by removing the winged luer cap and allowing the fluid to flow freely until the leading edge of fluid reaches the luer tip then replacing the winged luer cap.
- k. Repeat steps vi – viii with the syringe(s) of drug solution next, then the remaining syringes with diluent solution until the Infusor is filled with the entire prescribed volume. Replace the fill port cap.
- l. Visually inspect the tubing to ensure that the tubing is flushed and there are no air bubbles.
- m. If the luer tip cap is contaminated, attach a new sterile luer tip cap.
- n. If the line will not flow freely, or if there are bubbles in the line, force-prime the unit by attaching a syringe tip connector and a 10 mL syringe to the distal end of the Infusor tubing and pulling back on the syringe plunger to create suction in the line until the line is flushed and/or the bubbles are removed. Remove and attach a new sterile luer cap.
- o. Wipe the Infusor with sterile alcohol swab(s).
- p. Label the Infusor and place it on a tray or plastic tub, then remove from the BSC to prepare for dispensing.
- c. To prepare a drug dose in a Pharmacia CADD pump:
 - a. All doses are prepared in 50 mL or 100 mL cassettes which are attached to a portable computerized pump to deliver programmed volumes of solution of specific time periods. Separate competencies must be achieved by personnel who program the CADD pump.
 - b. Draw up the total volume of drug (and diluent, as appropriate) into syringe(s) using aseptic technique.
 - c. Double check volumes for each syringe before transfer.
 - d. Remove the luer lock cap from the end of the reservoir tubing and attach the syringe containing drug solution to the luer lock connection tightly.
 - e. Inject the contents of the syringe through the tubing and into the cassette.
 - f. If a second syringe of diluent is required, detach the first syringe and discard it, then attach the second syringe and inject the contents of diluent solution.
 - g. The cassette may have excess air volume that causes pressurization. Before removing the final syringe, possibly before injecting the entire fluid contents, draw back on the syringe to draw out the air and any bubbles in the tubing. The cassette and tubing may require gentle tapping to dislodge any air bubbles.
 - h. Adjust the final syringe volume so that all fluid is transferred and the leading edge of the fluid is at the distal luer fitting. Clamp the tubing to prevent further fluid movement.
 - i. Disconnect the final syringe and attach an anti-siphon valve extension set.
 - j. Wipe the cassette with sterile alcohol swab(s).
 - k. Label the Infusor and place it on a tray or plastic tub, then remove from the BSC to prepare for dispensing.
- d. Other infusion devices should be prepared according to manufacturer's

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instructions with precautions to maintain aseptic technique and to minimize any potential leakage of chemotherapy-containing fluids.

- e. Transfer from the vial should be carried out using closed-system devices, whenever possible.
- f. If a closed system device cannot be used, Luer-Lock syringes will be used.
- g. If possible, IV tubing is attached and primed before removal of the device from the BSC.

43. Preparation of BCG and Cancer Chemotherapy for Bladder Instillation

- a. Intravesicular bladder instillations may be ordered with solutions containing either BCG (Bacille Calmette Guerin- live attenuated mycobacteria) or other chemotherapy agents (e.g. mitomycin [cytotoxic] or interferon alfa [biologic response modifier]).
 - a. BCG must be handled as infectious material.
 - b. It is strongly preferred that BCG be prepared on a counter-top or designated area away from the Chemotherapy Preparation Area, using a closed-system device specific to this procedure.
 - c. If BCG is prepared in the same BSC used for chemotherapy agents, the BSC must be fully decontaminated before any subsequent dose of chemotherapy is prepared.
 - d. Mitomycin is a cytotoxic agent and must be handled with the same precautions used for any other parenteral cytotoxic agent.
- b. Most intravesicular doses will be prepared using a closed-system reconstitution device, with the total dose diluted to a volume between 50-60 mL (the volume needed for complete circulation and surface contact within the bladder). Individual patient prescriptions may vary.
- c. To prepare a BCG intravesicular dose using the closed-system reconstitution device:
 - a. Personnel must wear personal protective clothing, including gown, gloves, dust respirator mask and protective eyewear during preparation and administration of this agent; if the dose is prepared in a BSC, the mask and protective eyewear is optional.
 - b. A 60 mL syringe is filled with 50 mL of normal saline and attached to the luer lock end of the reconstitution device.
 - c. The reconstitution device is in the "Off" position
 - d. Remove the cap from the BCG vial and swab the rubber stopper with sterile alcohol; allow to air dry.
 - e. Remove the spike cover from the reconstitution device and puncture the BCG vial. Ensure the vial is securely fastened.
 - f. Inject about 1 mL of normal saline into the BCG vial and gently swirl until a homogenous suspension is obtained- do not shake or swirl vigorously. The BCG will suspend in about 1 minute (OncoTICE®) to 3 minutes (Pacis®).
 - g. Gently withdraw the contents into the 60 mL syringe, and rinse the vial with about 1 mL solution 2 or 3 times to distribute the suspension. (NB. the BCG vial may have a slight negative pressure).
 - h. The suspension is stable for about 2 hours. Place the entire apparatus into a sealed zip lock bag for dispensing to the patient care site.

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- i. Remove and discard gloves as infection hazard materials. Disinfect and decontaminate the work area.
 - d. Other drugs (e.g. mitomycin, interferon alfa-2B) may be prepared in a syringe then transferred to a 60 mL syringe (with enough normal saline to reach a final volume of 50 mL) using a syringe tip connector transfer device. The contents of the drug syringe can be transferred into the larger 60 mL syringe, with careful back-rinsing to extract the entire drug dose from the initial syringe
 - a. The connection transfer device is removed from the 60 mL syringe, with care to avoid any spillage.
 - b. The initial drug dose syringe is discarded with connector device attached.
 - c. A luer tip cap or catheter syringe tip adaptor is attached to the 60 mL syringe, which is sealed in a zip lock bag for dispensing to the patient care site.
44. Preparation of Non-Sterile Cancer Chemotherapy Products
- a. Non-sterile preparations may include oral cytotoxic drugs (tablet, capsules or syrup) or the topical application of a cytotoxic drug for topical application.
 - b. Personal protective equipment, including eye protection and masks is worn during preparation and discarded at the end of the procedures as contaminated equipment.
 - c. All equipment used for extemporaneous preparation is either non-porous or disposable.
 - d. The crushing of tablets or the opening of capsules in an open mortar and the mixing of powders is avoided if possible.
 - e. If tablets must be crushed outside the pharmacy, techniques are used to minimize exposure.
 - a. Choose area near sink away from drafts and high traffic. Alternately, the procedure could be done inside the BSC, with the blower turned OFF. The BSC blower can cause drug powder to be suspended in the air and inhaled by workers. The BSC may be turned back on once the procedure and subsequent clean up is completed.
 - b. Protect work area with absorbent plastic backed pad.
 - c. Wear gloves, gown, mask, goggles/face shield.
 - d. Remove cap and plunger from oral syringe. Place required tablet(s) in oral syringe.
 - e. Replace plunger and remove excess air from syringe.
 - f. Cap syringe and place in re-sealable zipper bag.
 - g. Pull plunger back and forth to crush tablets (place thumb on syringe cap, fingers around barrel and hit plunger on counter while holding cap on with thumb).
 - h. Gently knock powder away from syringe cap.
 - i. Remove from re-sealable zipper bag. Remove syringe cap.
 - j. Draw up diluting liquid into syringe from med cup. (Note: hold syringe at angle to avoid powder from spilling into med cup)
 - k. Re-cap syringe. Place back in re-sealable zipper bag, then shake until dissolved.
 - l. Clean area with detergent and water and wipe dry.
 - m. Dispose of waste in a chemotherapy waste container.
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- n. Remove gloves and dispose in a chemotherapy waste container.
 - o. Wash hands thoroughly.
 - p. Wear new gloves to deliver and administer agent to patient.
 - q. Wear gown/face shield if risk of spitting or spraying.
 - r. Remove personal protective equipment and dispose in a chemotherapy waste container.
 - s. Note: Some antineoplastic drugs will dissolve in diluting liquid (water) in syringe without being crushed (i.e. mercaptopurine, methotrexate, and thioguanine).
- f. If capsules must be opened outside the pharmacy, techniques should be used to minimize exposure.
- a. Choose area near sink away from drafts and high traffic.
 - b. Protect work area with absorbent plastic backed pad.
 - c. Wear gloves, gown, mask, goggles/face shield.
 - d. Slowly twist the two ends of the capsule apart and squeeze the powder into a med cup containing liquid, applesauce or ice cream.
 - e. To minimize risk of spilling, draw up liquid into a syringe.
 - f. Clean area with detergent and water and wipe dry.
 - g. Dispose of waste in a chemotherapy waste container.
 - h. Remove gloves and dispose in a chemotherapy waste container.
 - i. Wash hands thoroughly.
 - j. Wear new gloves to deliver and administer agent to patient.
 - k. Wear gown/face shield if risk of spitting or spraying.
 - l. Remove personal protective equipment and dispose in a chemotherapy waste container.
- g. The extemporaneous preparation of cytotoxic drugs is performed under the same conditions and facilities as for parenteral cytotoxic drugs. All activities likely to result in particle generation, for example weighing, crushing, mixing or filling capsules, are performed in a Class I or II BSC. If this preparation is performed in the same BSC used for parenteral dose preparation, parenteral doses are not prepared in the BSC until it has been cleaned and decontaminated (see Procedure 18).
- h. All materials and equipment used (such as mortar, pestle, glass plate, spatulas, mixing devices, tube fillers) for the preparation of oral/ external use cytotoxic drugs are identified for that use and reserved solely for these activities. This equipment is not used for non cytotoxic preparations. This equipment is cleaned separately from all non cytotoxic equipment.
- i. The BSC is cleaned and decontaminated immediately after each extemporaneous preparation. Procedures are the same as would be used for a cytotoxic chemotherapy spill (see Procedure 61).
- j. Unless there is specific stability data for the medication, extemporaneous preparations should be done as soon as possible to the administration time.
45. Tablets and capsules are handled in a manner that avoids skin contact, spread of drug into the air and chemical cross contamination with other drugs. All equipment used in the dispensing of cytotoxic solid dosage forms are dedicated to this purpose and clearly labeled as such. Cytotoxic tablets or capsules are not counted using a
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counting machine. Cytotoxic tablets or capsules are not loaded into a Pyxis or similar dispensing machine. Containers with damaged contents are discarded in an appropriate cytotoxic waste container.

Transport of Cytotoxic Agents

46. Special precautions will be followed to prevent breakage, minimize exposure and contain spills when transporting cytotoxic drugs within the health care facility. Cytotoxic drugs are placed in a sealable plastic bag. The bagged contents are then transported inside a closed container that will minimize the possibility of drug products falling during delivery. Closed containers have a disposable absorbent pad to contain any spillage and to cushion the contents if dropped. Luer-Lock syringe caps are used when transporting syringes containing cytotoxic solutions.
47. All individuals involved in the transportation of cytotoxic agents have quick and reasonable access to a spill kit (Procedure 59) and are trained in methods to handle cytotoxic spills.
48. Pneumatic tubes or other mechanical transport systems should not be used to transport cytotoxic products.
 - a. If these systems are used, the institution has procedures to promptly identify and decontaminate any chemo spill within the system.
49. The above procedures apply to all cytotoxic agents transported outside the Health Care Facility. Appropriate packaging materials are used to provide cushioning. Packaged cytotoxic drugs are properly labeled for transportation to alert the handler to hazards of the package contents (see Transportation of Dangerous Goods section of Systemic Therapy Manual for more detail).
50. All involved staff are trained and comply with all applicable transportation of dangerous goods acts or regulations (see Systemic Therapy Manual).

Cytotoxic Waste

51. Cytotoxic waste includes all materials that have come into contact with cytotoxic drugs during the process of reconstitution and administration. This includes syringes, needles, empty or partially used vials, gloves, single use personal protective equipment, disposable respirator masks, and materials from the clean up of cytotoxic spills. The packaging in direct contact with received chemotherapy products is also cytotoxic waste. Air filters from BSCs are included. In addition, hazardous drugs that have expired, or for any other reason must be destroyed, are also treated as cytotoxic waste.
52. Breakable contaminated needles, syringes, ampoules, broken glass, vials, intravenous sets and tubing, intravenous and intravesical catheters etc. are placed into designated leak-proof, puncture proof sharps containers that clearly and visibly display the cytotoxic hazard symbol.
 - a. Sharps containers for chemotherapy waste are placed in the BSC as needed and full sharps containers are transferred to the oncology waste container.

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53. Non-breakable contaminated materials including disposable gowns gloves, gauzes, masks, intravenous bags etc. are placed in thick, sealed plastic bags, hard plastic or cytotoxic containers that clearly and visibly display the cytotoxic hazard symbol. When full, the bags and containers are placed in the oncology waste container.
54. Clearly marked chemotherapy waste receptacles are kept in all areas where cytotoxic drugs are prepared or administered.
55. All cytotoxic drug waste is separated from general waste.
56. Cytotoxic waste is **not** mechanically or manually compacted.
57. Cytotoxic waste is destroyed in an incinerator approved for the destruction of cytotoxic drugs. If access to an appropriately licensed incinerator is not available, transport to and burial in a licensed hazardous waste dump is an acceptable alternative.

Cytotoxic Spills

58. Personnel involved in preparation and administration of cytotoxic chemotherapy drugs, and in transportation of cytotoxic products and cytotoxic waste are instructed on procedures for managing cytotoxic spills
59. Spill kits are either assembled or purchased. Components of a spill kit include (but may not be limited to):
 - a. 2 pairs disposable gloves- large size (one pair should be non-latex for use as the inner glove)
 - b. Low permeability gown and shoe covers
 - c. Safety glasses, splash goggles or face shield
 - d. Respirator mask (unless included in face shield)
 - e. Absorbent plastic backed sheets or spill pads (sufficient to absorb a spill of up to 1000mL)
 - f. Disposable towels or swabs for absorbing and cleaning liquid spills
 - g. At least 2 sealable plastic waste bags "Cytotoxic Waste"
 - h. Disposable scoop for collecting glass fragments
 - i. Puncture-resistant container for glass fragments, clearly labeled as cytotoxic waste container
 - j. Cleaning solution for cleaning and decontamination of area
 - k. Instructions on the management of a cytotoxic chemotherapy spill, including institutional report forms for recording the incident.
 - l. Warning signs to alert other staff to the hazard and isolate the area of the spill.
60. In the event of a cytotoxic spill in any area other than the safety cabinet, the following clean up procedure is followed:
 - a. Alert other staff in the area of the potential hazard; limit access to the area by placing the warning sign in a prominent position.
 - b. Obtain a spill kit and remove the contents. Don personal protective equipment in this order: the mask/face shield, the safety glasses, one pair of gloves (PVC-under the gown cuff), gown, boots, and the second pair of gloves (Latex – over

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- the gown cuff).
- c. For a liquid spill, carefully place an absorbent pad over the spilled liquid. Absorb as much liquid as possible into the pad.
 - d. If the spill involves a powder, carefully place a damp disposable pad over the powder and then carefully pat the spill area to adsorb as much powder as possible.
 - e. If there is broken glass in the spill, carefully pick up the glass pieces using the disposable scoop and place all glass in the puncture-proof container.
 - f. Gather up the contaminated pads. Discard all of this waste into the cytotoxic waste container.
 - g. Repeat steps until the entire spill has been cleared.
 - h. Use the cleaning solution to wash the area of the spill thoroughly, discarding all waste generated into the waste container.
 - i. Rinse the area well with clean water.
 - j. Dry the area completely to prevent accidental slippage on wet floor.
 - k. Discard all used items into the cytotoxic waste container.
 - l. Remove gloves, mask and gown and dispose in the cytotoxic waste container.
 - m. Arrange for collection of waste according to institution policy.
 - n. Wash hands thoroughly with soap and water.
 - o. Arrange for hospital cleaning staff to reclean the area.
 - p. Arrange for a replacement spill kit to be obtained.
 - q. Health care personnel exposed during spill management should complete an incident report as per institutional policy.
61. In the event of a cytotoxic spill inside the safety cabinet, the following clean up procedure is followed:
- a. Obtain a spill kit if the volume of the spill exceeds 30 mL or the contents of a full vial or ampoule. Spills less than 30 mL inside the BSC may be managed using a spill kit or as a more routine BSC decontamination clean up.
 - b. If there is broken glass in the spill, carefully pick up the glass pieces using the disposable scoop and place all glass in the puncture-proof container.
 - c. For a liquid spill, carefully place an absorbent pad over the spilled liquid. Absorb as much liquid as possible into the pad.
 - d. If the spill involves a powder, carefully place a damp disposable pad over the powder and then carefully pat the spill area to adsorb as much powder as possible.
 - e. Gather up the contaminated pads. Discard all of this waste into the cytotoxic waste container.
 - f. Repeat steps until the entire spill has been cleared.
 - g. Thoroughly clean and decontaminate the BSC, including the drain trough/sump (See Procedures 18 and 19).
 - h. If the spill contaminated the HEPA filter with either liquid or powder, the BSC should not be used until a complete decontamination and HEPA filter replacement is completed.
62. Health care personnel exposed during spill management document the incident using an incident report (as per institutional policy) as soon as possible.
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63. In the event that a staff member or patient/family member is contaminated with a cytotoxic agent, the following procedure is followed:
- a. All overtly contaminated protective clothing is removed and placed in the cytotoxic waste container.
 - b. All contaminated clothing is removed and, if heavily contaminated, the clothing is discarded into the cytotoxic waste container. Clothing with a minimal amount of contamination is laundered separately and rinsed well.
 - c. An emergency shower or equivalent (e.g. hand-held spray device) is used if appropriate. If this is not available, then the contaminated area of skin is washed with soap and rinsed with large amounts of water.
 - d. Eyes that have been exposed to a cytotoxic agent are thoroughly irrigated with water or an isotonic eyewash for as long as possible (e.g. up to 15 minutes). Contact lenses, if not flushed from the eye, are removed as soon as possible and discarded. An eyewash station is used, if available (including eyewash stations attached to a faucet), or water splashed by hand into the eye from a faucet. It is not recommended to irrigate the eye directly with running water from a faucet because of the potential for water pressure damage to the eye. In all cases where the eye is contaminated by a cytotoxic agent, ophthalmologic advice should be sought.
 - e. If the skin is broken or there is a needle-stick injury, the affected area is irrigated with plenty of water and blood expressed from the wound (until the bleeding is controlled).
 - f. Seek medical attention as soon as practical.
 - g. Health care personnel exposed during spill management will complete an incident report as per institutional policy as soon as possible.

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APPENDIX 1

**Medical Surveillance of Health Care Worker Handling Cytotoxic
Drugs and Waste**

According to Occupational Safety and Health Administration (OSHA, USA), safe levels of occupational exposure to cytotoxic agents can not be determined. No reliable method of monitoring exposure exists. It is imperative that those who work with cytotoxic agents adhere to practices, as outlined above, to eliminate or reduce occupational exposure.

While there are no direct measurements to indicate total exposure to cytotoxic drugs, individual staff members may opt to follow selected surveillance components by their own means, which may include:

- Reproductive and general health questionnaires by the individual's family physician completed at the time of hire and annually
- Blood work, including complete blood count, liver function tests and urinalysis completed by the individual's family physician at the time of hire and annually
- Physical examination by the individual's family physician at the time of hire and then annually as needed
- Follow up by the individual's family physician for those workers who have shown health changes and/or have been exposed to hazardous drugs (e.g., through spills or during routine handling).

Documentation is maintained by the Occupational Health and Safety department on:

- Any personal contamination from a spill
- Results from any visits to occupational health related to chemotherapy administration activities

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APPENDIX 2

LIST OF HAZARDOUS AGENTS

List of Drugs Which Must Be Handled as Hazardous Agents¹

Parenteral Agents

Amsacrine	Fludarabine	Oxaliplatin
Arsenic Trioxide	Fluorouracil	Paclitaxel
Azacytidine	Ganciclovir	Paclitaxel NAB
Azathioprine	Gemcitabine	Pemetrexed
Bleomycin	Ibritumomab tiuxetan with	Pentostatin
Bortezomib	Y-90	Raltitrexed
Busulfan	Idarubicin	Streptozocin
Carboplatin	Ifosfamide	Strontium-89
Carmustine	Irinotecan HCl	Temsirolimus
Cisplatin	Liposomal Cytarabine	Teniposide
Cladribine	Liposomal Daunorubicin	Thiotepa
Cyclophosphamide	Liposomal Doxorubicin	Topotecan
Cytarabine	Liposomal Doxorubicin	Tositumomab with I-131
Daunorubicin HCl	(Pegylated)	Valrubicin
Diethylstilbestrol	Mechlorethamine	Vinblastine sulfate
Docetaxel	Melphalan	Vincristine sulfate
Doxorubicin	Methotrexate	Vinorelbine tartrate
Epirubicin	Mitomycin	Zoledronic Acid
Etoposide	Mitotane	
Floxuridine	Mitoxantrone HCl	

Oral and Non-Parenteral/Commercial Products²

Alitretinoin	Fludarabine	Mercaptopurine
Altretamine	Fulvestrant	Methotrexate
Bexarotene	Goserelin	Procarbazine
Bicalutamide	Histrelin	Raloxifene
Buserelin	Hydroxyurea	Sorafenib
Busulfan	Imatinib mesylate	Sunitinib
Capecitabine	Lapatinib	Tamoxifen
Chlorambucil	Lenalidomide	Temozolomide
Cyclophosphamide	Letrozole	Thalidomide
Dasatinib	Leuprolide acetate	Thioguanine
Erlotinib	Lomustine	Thyrotropin
Estramustine	Medroxyprogesterone	Toremifene
Etoposide	Megestrol	Tretinoin
Exemestane	Melphalan	Triptorelin

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List of Drugs Which Are Not Necessary To Be Handled as Hazardous Agents³

<u>Parenteral Agents</u>		
Aldesleukin	Dacarbazine	Palifermin
Alemtuzumab	Dactinomycin	Pamidronate
Amifostine	Dexamethasone	Panitumumab
Ancestim	Dexrazoxane	Pegaspargase
Asparaginase	Gemtuzumab ozogamicin	Porfimer
Asparaginase erwinia	Infliximab	Rituximab
Bacillus Calmette-Guerin	Interferon alfa	Trastuzumab
Bevacizumab	Leucovorin	
Cetuximab	Mycophenolate mofetil	
<u>Oral and Non-Parenteral/Commercial Products²</u>		
Aprepitant	Filgrastim	Nilutamide
Anastrozole	Flutamide	Palifermin
Cyproterone	Gefitinib	Pamidronate
Darbepoietin	Interferon alfa	Pegfilgrastim
Dexamethasone	Leucovorin	Pilocarpine
Dronabinol	Levamisole	Prochlorperazine
Epoietin	Mitotane	
Estramustine	Nabilone	

1. Hazardous agents: All Carcinogens as listed by IARC Group 1, 2A or 2B (See Appendix 3-C); and/or listed as Category X or D FDA Pregnancy Risk Factors (See Appendix 3-C)
2. Some hazardous agents in sealed product for dispensing (e.g. LHRH antagonist products ready for physician office administration, vials for patient self-administration) may be handled without precaution by dispensary staff; open tablets, capsules, etc. should be handled as hazardous agents
3. Where there is a Chemotherapy Preparation Area, these should be prepared as cancer chemotherapy agents. Where there is no Chemotherapy Preparation Area, these drugs should be handled using appropriate Best Practice Procedures.

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APPENDIX 3 **CHEMOTHERAPY PREPARATION AND STABILITY CHART- *Cancer Care Nova Scotia***

DRUG & STRENGTH (Storage Prior to Use, Manufacturer, Preservative Status)	Reconstitute With:	Vial Stability	Product	Product Stability	Special Precautions/Notes
	To Give:	Vial Expiry [⌘]		Product Expiry	Auxiliary Labels
Aldesleukin 22 million IU (1.3 mg) (Chiron) (F)(PFL) no preservative‡	1.2 mL <u>SWI only</u> do not shake; roll to reconstitute	48 h FT, RT‡	30–70 mcg/mL‡ 50 mL <u>D5W only</u>	48 h FT, RT‡	- non-cytotoxic§ - do not filter - nonvesicant - latex** content not determined
	18 million IU/mL (1.1 mg/mL)	48 h FT, RT‡	< 30 mcg/mL: dilute only in D5W that contains human albumin 0.1%		
Alemtuzumab 30 mg/3 mL (Schering/Ilex) (F)(PFL) do not shake no preservative‡	N/A- Solution source product - low protein binding filters use 5 micron filter to withdraw drug from ampoule	discard unused portion†	SC syringe 100 mL NS or D5W†	8 h FT or RT†	- non-cytotoxic§ - nonvesicant - latex-free - non-formulary drug
	10 mg/mL	Single use vial†			Do not shake Protect from light Refrigerate
Amifostine 500 mg (MedImmune) (RT) no preservative‡	9.7 mL <u>NS only</u>	24 h FT, 5 h RT†	25–50 mL* <u>NS only</u> †	5–40 mg/mL: 24 h FT†, 5 h RT	- non-cytotoxic - discard cloudy solution - nonvesicant - latex** content not determined - non-formulary drug
	50 mg/mL	24 h FT, 5 h RT†			
Amsacrine 75 mg/1.5 mL (Pfizer) (RT) no preservative	13.5 mL supplied diluent - transfer 1.5mL from ampoule into the diluent vial	48 h RT	500 mL <u>D5W only</u> ‡ glass container	7 d FT	- do NOT dilute in chloride-containing solutions; do NOT flush line with NS - contains latex - non-formulary drug
	5 mg/mL - glass syringes preferred during reconstitution - max time in plastic syringe: 15 min	24 h RT‡	NOT compatible with NS solutions	72 h FT, 24 h RT‡ PVC Syringe: 15 min RT	Cytotoxic Vesicant Protect from light

Codes: ‡ Data from CPS † § Data from Manufacturer's Product Monograph RT = room temperature
 ⌘ Expiry date limited to 14 d FT for unpreserved low-risk level compounded sterile product per USP 797
 water for injection

FT = refrigerated SWI = sterile water for injection
 NS = normal saline D5W = dextrose 5%
 PFL = protect from light BWI = bacteriostatic

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DRUG & STRENGTH (Storage Prior to Use, Manufacturer, Presevative Status)	Reconstitute With:	Vial Stability	Product	Product Stability	Special Precautions/Notes
	To Give:	Vial Expiry [*]		Product Expiry	Auxiliary Labels
Arsenic Trioxide 10mg/10mL ampoule Through SAP (RT) no preservative§	N/A- Solution source product	Single use ampoule	100 to 250mL D5W, NS	48 h FT , 24 h RT	- non-vesicant - non-formulary drug - do NOT save unused portion
	1 mg/mL	Single use ampoule			Cytotoxic
Asparaginase (asparaginase E. coli) 10,000 units (OPi) (F) no preservative†	4 mL SWI (IV doses) 0.5 to 4 mL NS (IM doses) - do not shake; roll to reconstitute Rotate gently. Discard if turbid. Use 5 µm filter to remove gelatinous fibres. Withdraw reconstituted sol within 15 min to minimize protein denaturization. Maximum IM vol/site = 2 mL. Not given SC	14 d FT , 7 d FT	syringe† 100 mL* NS or D5W†	Syringe: 14 d FT † IV: 14 d FT , 2 d RT †	- non-cytotoxic§ - nonvesicant - latex-free - Use for high dose only - 25,000 IU/m² or if vol of 12,500 IU/m² is >2 mL make 20,000 IU/mL rather than split syringes
		48 h FT , RT †			Do not shake
		4 mL- 2500 units/mL 2 mL- 5000 units/mL 1 mL- 10000 units/mL 0.5 mL- 20000 units/mL (high dose protocol only)	Intradermal test: ♦ Reconstitute with 5 mL SWI to give 2000 units/mL ♦ Transfer 0.1 mL to 10 mL vial (or 12 mL syringe) ♦ Add 9.9 mL SWI roll to dissolve to give 20 units/mL ♦ 2 unit test dose = 0.1 mL (Note: the rest of the reconstituted vial has a concentration of 2000 units/mL)		
Erwinia asparaginase (asparaginase Erwinia chrysanthemi) 10,000 units (OPi) (F) no preservative†	1-2 mL NS - do not shake; roll to reconstitute	15 minutes in the original container;	glass or polypropylene syringe	8 h in a glass or polypropylene syringe†	- non-cytotoxic§ - nonvesicant - latex** content not determined
	10,000-5,000 units/mL	8 h in glass or polypropylene syringe†			

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DRUG & STRENGTH (Storage Prior to Use, Manufacturer, Preservative Status)	Reconstitute With:	Vial Stability	Product	Product Stability	Special Precautions/Notes
	To Give:	Vial Expiry [✱]		Product Expiry	Auxiliary Labels
Asparaginase Pegylated- see Pegaspargase					
Azacytidine 100 mg (RT) No preservative§	4 mL SWI (SC dose)	1 h RT, 8 h FT after reconstitution†	Syringe for SC use†	Use within 1 h of reconstitution; or warm to RT for 30 min†	- non-vesicant - best freshly prepared. Increased stability in glass. Concentration <2 mg/mL not recommended. - non-formulary drug
	19.9 mL SWI (IV dose)		Lactated ringers (or D5W, NS)		Cytotoxic
BCG 81 mg (Aventis Pasteur) (F)(PFL) preservative‡	3 mL supplied diluent - do not shake; roll to reconstitute - record time of reconstitution	2 h FT, RT‡	50 mL NS‡	2 h FT or RT after reconstitution‡	- non-cytotoxic§ - nonvesicant - latex** content not determined
	10.5 ± 8.7×10 ⁸ CFU/vial (Connaught strain)	2 h FT, RT‡			Protect from light
BCG (Organon) (F)(PFL) no preservative†	1 mL NS - do not shake; roll to reconstitute - record time of reconstitution	2 h FT†	transfer from vial to 50 mL syringe, rinse vial with another 1 mL NS. Add rinse to 50 mL syngie. QS syringe to 50 mL with NS†	2 h FT after reconstitution†	-non-cytotoxic§ - do not filter - nonvesicant - latex-free**
	1-8×10 ⁸ CFU/vial (TICE strain)	2 h FT†			Protect from light
Bevacizumab 100 mg/4 mL 400 mg/16 mL (Roche) (F)(PFL) no preservative†	N/A- Solution source product	discard unused portion†	100 mL NS only†	48 h FT, RT†	- non-cytotoxic§ - nonvesicant - latex** content not determined - non-formulary drug
	25 mg/mL	Single use vial†			Do not shake

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	To Give:	Vial Expiry [Ⓜ]		Product Expiry	Auxiliary Labels
Bleomycin 15 IU (NB: dose in units only) (BMS) (F) no preservative† (Mayne) (F)(PFL) no preservative†	7.5 mL* NS (Bristol) 7.5 mL* NS or SWI (Mayne) - Can be filtered through a 5 micron filter.	14 d RT, 28 d FT (or 48 h FT† [BMS]; 48 h FT, 24 h RT [Mayne]†)	50-100 mL* NS‡ (Bristol) 50 mL* NS , SWI† (Mayne) Max Conc: 3U/mL Do NOT dilute further in D5W or 2/5-1/5	NS: 24 h RT‡ (Bristol) 24 h RT (Mayne)	- nonvesicant - latex-free (Mayne); latex** content not determined (BMS) - Test dose = 1 IU in 50 mL NS, wait 2h & monitor q30min. - 1 IU = 1mg reference standard
	2 IU/mL	14 d RT, 14 d FT [Ⓜ]		24 h RT	Cytotoxic Refrigerate
Bortezomib 3.5 mg (Millennium) (RT)(PFL) no preservative	3.5 mL NS	30 d FT, 2d RT	syringe†	5 d FT (or 8 h RT†)	- latex** content not determined - Provincial funding for specific indication
	1 mg/mL	14 d FT [Ⓜ]			Cytotoxic Irritant
Busulfan 60 mg/10 mL (Orphan Medical) (F) no preservative	N/A- Solution source product	discard unused portion†	NS or D5W (dilute in volume 10 times the busulfan volume to ~0.5 mg/mL)†	Complete administration within 12 h FT, 8 h RT: NS†, D5W	- latex** content not determined - non-formulary drug
	6 mg/mL use 5-micron nylon filter provided with ampoule to withdraw drug	Single use vial†			Cytotoxic Vesicant
Carboplatin 50 mg/5 mL 150 mg/15 mL 450 mg/45 mL (Mayne, Novopharm) (RT)(PFL) no preservative	N/A- Solution source product	7 d RT (or: discard unused portion† (Mayne); 8 h RT † (Novopharm)	D5W (IV): 250-500 mL Conc Range (0.5-4 mg/mL) (NS not recommended as diluent) <125 mg -100mL D5W 125-750 mg –250mL D5W >750 mg -500mL D5W	21 d FT, 7 d RT (or 24 h RT, 48 h FT† [Mayne]; 8 h RT † [Novopharm])	- nonvesicant - latex** content not determined (Mayne) - do not use aluminum needles - latex-free** (Novopharm)
	10 mg/mL	7 d RT		14 d FT [Ⓜ] , 7 d RT	Cytotoxic Protect from light

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	To Give:	Vial Expiry [✕]		Product Expiry	Auxiliary Labels
Carmustine 100 mg (Bristol Labs) (F) no preservative	3 mL diluent (supplied) - diluent to reach RT, then dissolve drug with 3 mL diluent; add 27 mL SWI - discard if oily film in vial	24 h FT, 8 h RT†	glass†, or polyolefin container 500 mL D5W	24 h FT: in glass† or polyolefin container use within 6 hours of reconstitution: RT	- do not use if product has oily droplets - latex** in diluent stopper ⁹ - no latex** in product stopper or drug product - best fresh prepared - administer through polyethylene-lined (non-PVC) nitro tubing set.
	3.3 mg/mL in 10% ethanol†	24 h FT, 8 h RT†			Cytotoxic Vesicant Protect from light
Cetuximab 100 mg/50 mL (BMS) (F) do not dilute no preservative†	N/A- Solution source product	discard unused portion†	syringe† sterile evacuated container (e.g., glass bottle, polyolefin bag, ethylene vinyl acetate bag, DEHP plasticized PVC bag, or PVC bag)†	12 h FT, 8 h RT†	- non-cytotoxic§ - use 0.22 micron in-line filter to administer - nonvesicant - latex** content not determined - non-formulary drug
	2 mg/mL†	Single use vial†			Do not shake
Cisplatin 10 mg/10 mL 50 mg/50 mL 100 mg/100mL (Mayne) (RT)(PFL) no preservative† continued...	N/A- Solution source product	28 d RT (or 48 h RT‡)	NS, (IV): 250 mL or 500 mL (1000 mL for BMT- Max Conc: 1 mg/mL) (DHAP protocol- divide dose in 3L NS with mannitol 20g/L [total volume]): 2/3-1/3, 3% NaCl, D5-NS, D5-1/2S; D5-NS with mannitol; D5-1/2S with mannitol†; D5W-1/3S with mannitol†	14 d RT, 14 d FT (if concentration < 0.5 mg/mL)	- must be diluted in chloride-containing solutions - latex stoppers - do not use aluminum needles - IV sol must contain ≥0.2% NaCl.
	1 mg/mL	48 h RT‡		48 h RT‡ Cisplatin + Mannitol: 48 h RT Cisplatin + KCl: 24 h RT	- do not refrigerate. - may be filtered from viaflex bag into a bottle using 5 µm filter - advance mixing with mannitol increases risk of complex forming. Cytotoxic Irritant

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	To Give:	Vial Expiry [⌘]		Product Expiry	Auxiliary Labels
Cladribine 10 mg/10 mL (Janssen-Ortho) (F)(PFL) no preservative	N/A- Solution source product	30 d FT, 7 d RT (or- discard unused portion†)	500 mL NS only † Maximum concentration 0.1 mg/mL For Pharmacia cassette or Aim pump, dilute with BSI and filter with 0.22µ hydrophilic filter	7 d RT 14 d RT (BSI diluent, conc. 0.15-0.3 mg/mL using Infusor) (or- 24 h RT†)	- shake vigorously to dissolve any precipitates from refrigeration - use 0.22µ hydrophilic filter for drug and diluent when preparing cassette - nonvesicant - latex-free** - formulary: Restricted drug
	1 mg/mL	14 d FT [⌘] after vial punctured			Cytotoxic Protect from light
Cyclophosphamide non-lyophilized 1000 mg, 2000 mg (BMS) (RT) 200 mg, 500 mg, 1000 mg, 2000 mg (Baxter) (RT)(PFL) no preservative	SWI (BMS) 1000 mg: 50 mL 2000 mg: 100 mL NS (Baxter) 200 mg: 10 mL 500 mg: 25 mL 1000 mg: 50 mL 2000 mg: 100 mL	28 d FT, 4 d RT	< 1 g: 100 NS* > 1 g: 250 NS* high dose in BMT: may need 500 NS* NS , D5W, 2/3-1/3, D5NS, D5, Ringer's, Lactated Ringer's, Sodium Chloride 0.45%, Sodium Lactate† (BMS)	30 h RT, 30 d FT in NS, 6 d FT in D5W (or- 6 d FT, 24 h RT [BMS]†; 72 h FT, 24 h RT [Baxter] †)	- nonvesicant - latex-free** (BMS); latex** content not determined (Baxter) - best if administered in a.m. with proper hydration - if present, remove small black particles from reconstituted solution with 5 µm filter - may be used to prepare oral liquids.
	20 mg/mL	6 d FT, 24 h RT (or- 48 h FT†)		30 h RT, 14 d FT [⌘]	Cytotoxic
Cytarabine 100 mg/1 mL 500 mg/5mL 1000 mg/10mL 2000 mg/20mL (Mayne) (RT) no preservative†	N/A- Solution source product record time of puncture - can be filtered through a 5 µm filter	7 d RT	0.1-0.8 mg/mL 100-1000 mL* NS , Water for Injection, D5W, Lactated Ringer's <150mg in 250mL ≥150mg in 500mL	14 d FT, 14 d RT	- nonvesicant - latex stopper** - discard if solution is hazy
	100 mg/mL	72 h FT, 24 h RT from initial vial puncture†			Cytotoxic

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	To Give:	Vial Expiry [✱]		Product Expiry	Auxiliary Labels
Cytarabine IT injection: 100 mg/1 mL 500 mg/5 mL (Mayne) (RT) no preservative†	N/A- Solution source product	24 h RT†	diluent containing preservatives should NOT be used for Intrathecal administration† qs to 6 mL with preservative free NS	use within 4 hours of initial puncture	- auxiliary label to include route in full (i.e., INTRATHECAL injection) attached to both syringe and outer ziplock bag - nonvesicant - latex stopper**
	100 mg/mL	24 h RT†			Cytotoxic INTRATHECAL injection
Cytarabine SC injection: 100 mg, 1000 mg vial (Pfizer) (RT)(PFL) 100 mg, 500 mg, 1000 mg, 2000 mg vial (Novopharm) (RT)(PFL) no preservative‡	BWI 100 mg: 5 mL 500 mg: 10 mL 1000 mg: 10 mL 2000 mg: 20 mL	30 d FT, 7 d RT (or 14 d FT [✱]) (or- 48 h RT†)	syringe	14 d FT, 48 h RT	- for high dose use, do not use diluent containing benzyl alcohol - nonvesicant - latex-free**(Pfizer); latex** content not determined (Novopharm)
	100 mg: 20 mg/mL 500 mg: 50 mg/mL 1000 mg: 100 mg/mL 2000 mg: 100 mg/mL	14 d FT [✱]			Cytotoxic
Dacarbazine 200 mg 600 mg (Mayne) (F)(PFL) no preservatives†	200 mg: 19.7 mL SWI 600 mg: 59.1 mL SWI (may use reconstitution device)	96 h FT, 8-24 h RT	0.19–3.0 mg/mL 250-500 mL* NS or D5W ≤750mg in 250mL >750ml in 500mL	24 h FT, 8 h RT	- latex stopper** - discard if solution turns pink-orange color, indicating drug decomposition
	10 mg/mL	48 h FT†, 8 h RT†			Cytotoxic Irritant Protect from light
Dactinomycin 0.5 mg (Merck Frost) (RT)(PFL) no preservative†	1.1 mL SWI	48 h FT , 24 h RT	syringe infusion: 50 mL* D5W, NS	Syringe: 48 h FT IV: 24 h FT , RT	- do not filter - latex-free
	0.5 mg/mL (500 mcg/mL)	48 h FT , 24 h RT			Cytotoxic Vesicant Protect from light

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	To Give:	Vial Expiry [*]		Product Expiry	Auxiliary Labels
Daunorubicin 20 mg (Novopharm) (RT)(PFL) no preservative†	4 mL SWI - can be filtered through a 5 µm filter	7 d RT	50-250 mL NS or D5W† Max concentration 5 mg/mL	Syringe: 43 d RT IV: 4 wk RT	- latex-free - discard if reconstituted solution changes color from red to blue - may cause red discoloration of urine for 1-2 days
	5 mg/mL	24 h RT, 48 h FT†		24 h RT, 48 h FT†	Cytotoxic Vesicant Protect from light
Daunorubicin Liposomal- see Liposomal Daunorubicin					
Dexrazoxane 250 mg 500 mg (Pfizer) (RT) no preservative†	supplied diluent : 250 mg: 25 mL 500 mg: 50 mL (may use Reconstitution device)	6 h FT, RT†	empty viaflex bag†	6 h FT, RT†	- non-cytotoxic § - nonvesicant - latex-free** - do not filter - use chemo precautions - administer in a window 30 mins prior to and 15 mins post doxorubicin. - formulary: Restricted drug
	10 mg/mL†	6 h FT, RT†			
Docetaxel 20 mg/0.5 mL 80 mg/2 mL (Aventis) (PFL) no preservative†	supplied diluent (13% ethanol): - if vials were refrigerated, allow to warm for 5 min at RT. Withdraw entire contents of the diluent and mix by repeated inversions for 45 sec – DO NOT SHAKE. - Let sit for 5 minutes.		NS or D5W 250 mL (concentration should be between 0.3-0.74 mg/mL) † - use Excel bags - max dose in 250 mL is 185 mg; for larger doses use larger bag - add to IV bag and manually rotate	28 d RT	- non-PVC bag and tubing only - latex-free** syringe - use nitroglycerin tubing. - do not use in-line filter. DO NOT FILTER - formulary: Restricted drug
	10 mg/mL	8 h FT, RT†		complete administration within 4 h FT, RT†	Cytotoxic Irritant Protect from light

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	To Give:	Vial Expiry [✱]		Product Expiry	Auxiliary Labels
Doxorubicin 10 mg, 50 mg, 150 mg (Mayne) (RT)(PFL) 10 mg/5 mL, 20 mg/10 mL, 50 mg/25 mL 200 mg/100 mL (Novopharm) (F)(PFL) no preservative†	NS, SWI, D5W (NS reconstitution takes longer) 10 mg: 5 mL 50 mg: 25 mL 150 mg: 75 mL	30 d FT, 7 d RT (or- 48 h FT, 24 h RT [Mayne]; 8 h RT [Novopharm])	syringe† (Mayne, Novopharm) IV: Conc 0.2–2 mg/mL 100 mL* NS (Mayne) Max Conc 5 mg/mL	24 d RT, 43 d FT Syringe: 30 d FT, 7 d RT IV: 30 d FT, 7 d RT	- latex stopper** (Mayne); latex** content not determined (Novopharm) - may cause red discoloration of urine for 1-2 days
	2 mg/mL	7 d RT, 14 d FT [✱]		Syringe: 48 h FT, 24 h RT† IV: 48 h FT, 24 h RT	Cytotoxic Vesicant Protect from light
	Doxorubicin Liposomal- see Liposomal Doxorubicin Doxorubicin Pegylated Liposomal- see Liposomal Doxorubicin (Pegylated)				
Epirubicin 10 mg/5 mL 50 mg/25 mL 200 mg/100 mL (Pfizer) (F)(PFL) no preservative†	N/A- Solution source product - record time of puncture	150 d FT,RT (or- 30 d FT, 24 h RT) (or- 8 h FT , RT†)	syringe† 50-100 mL * NS or D5W	Syringe: 150 d FT,RT (or- 30 d FT, 24 h RT) IV: 20 d RT, 43 d FT	- latex-free** - may cause red discoloration of urine for 1-2 days
	2 mg/mL	14 d FT [✱] , 24 h RT		Syringe: 48 h FT, 24 h RT† IV: 2 d FT , RT: NS or D5W	Cytotoxic Vesicant Protect from light
Etoposide 100 mg/5 mL 200 mg/10 mL 500 mg/25 mL 1000 mg/50 mL (BMS) (RT) (Novopharm) (RT)(PFL) preservative†	N/A- Solution source product	30 d RT (or- 14 h RT [BMS]; discard unused portion [Novopharm]†)	NS , D5W, 2/3-1/3 (IV): Excel bag ≤200 mg in 500 mL 201-235 mg in 600 mL Max Conc 0.4 mg/mL [larger doses may be prepared in an appropriate volume to maintain a concentration ≤0.4 mg/mL]	4 h RT† [Novopharm]	- use non-PVC bag and tubing only - latex** content not determined - Discard cloudy solution. Check sol periodically for precipitate. Use 22 micron filter if needed. - Do not refrigerate - USE EXCEL BAGS
	20 mg/mL	14 d FT [✱] , 14 h RT		0.2 mg/mL: 96 h 0.4 mg/mL: 24 h 0.6 mg/mL: 8 h 1.0 mg/mL: 2 h RT† (BMS)	Cytotoxic Irritant

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	To Give:	Vial Expiry [✕]		Product Expiry	Auxiliary Labels
Fludarabine 50 mg (Berlex) (F) no preservative†	2 mL SWI	16 d FT , RT (or- 48 h FT or RT†)	may be further diluted to 1 mg/mL† 50-100 mL* NS or D5W	16 d FT , RT	- nonvesicant - latex-free** - do not filter
	25 mg/mL	14 d FT [✕] , 24 h RT		48 h FT or RT†	Cytotoxic
Fluorouracil 5000 mg/100 mL (Mayne) (RT)(PFL) no preservative†	N/A- Solution source product	7 d RT	Syringe May be further diluted to 2 mg/mL in D5W† NS, D5W, ⅓-1/3 (IV): 50-1000mL CIVI Infusors - 1.5 mL/h TV 275 mL 5 mL/h-TV 240 mL and 10 mL/h- TV 240 mL or 275 mL. Use D5W only for Infusors.	Syringe: 7 d RT IV: 123 d FT , 38 d RT (Conc. Range 0.1 to 50 mg/mL)	- latex-free** - heat or shake gently if precipitate forms - slight discoloration does not alter potency - may be filtered - do not refrigerate/freeze - stable in cassettes, Infusors (latex free)
	50 mg/mL	8 h RT†		Syringe: 48 h RT 24 h RT† IV: 14 d RT CIVI: complete within 8 d RT	Cytotoxic Irritant Protect From Light
Gemcitabine 200 mg 1000 mg (Eli-Lilly) (RT) no preservative†	200 mg: 5 mL NS 1000 mg: 25 mL NS (may use Reconstitution device)	35 d RT, 7 d FT (or-48 h RT†)	syringe† 0.1–10 mg/mL† 250 mL NS	35 d RT, 7 d FT IV: 30d FT , 7 d RT	- non-vesicant - latex-free** - formulary: Restricted drug
	38 mg/mL	7 d RT		Syringe: 48 h RT IV: 48 h FT , RT†	Cytotoxic
Gemtuzumab ozogamicin 5 mg (F) no preservative§	5 mL SWI - Reconstitute with fluorescent lights turned off	8 h FT	100 mL NS	Administer over 2 h immediately after dilution	- dispense and administer inside UV protection overwrap bag - use 1.2 micron terminal filter/low protein binding - non-formulary drug
	1 mg/mL				Cytotoxic Protect from light

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	To Give:	Vial Expiry [⌘]		Product Expiry	Auxiliary Labels
Ibritumomab tiuxetan - Kit with: 3.2 mg Ibritumomab tiuxetan in 2 mL NS vial; sodium acetate vial; buffer vial; empty reaction vial (Berlex) (F) no preservative§	Prepare according to mfg instructions; use radionuclide protection	Use immediately after reconstitution and radioisotope labelling		N/A	- radiation hazard - prepared and handled by nuclear medicine dep't. - non-formulary drug
	---				Vesicant
Idarubicin 5 mg 10 mg (Pfizer) (RT)(PFL) no preservative†	vial under negative pressure 5 mg: 5 mL SWI 10 mg: 10 mL SWI	7 d FT (or- 48 h FT, 24 h RT†)	Syringe 50 mL NS, D5W	Syringe: 48 h FT, 24 h RT†	- latex-free** - do not use bacteriostatic diluent - do not filter - may cause red discoloration of the urine for 1-2 days.
	1 mg/mL	72 h FT , RT		Syringe: 24h RT IV: 72h RT	Cytotoxic Vesicant Protect From Light
Ifosfamide 1000 m g 3000 mg (Baxter) (RT) no preservative†	1000 mg: 20 mL SWI 3000 mg: 60 mL SWI shake well (may use reconstitution device)	42 d FT, 7 d RT (or- 72 h FT †)	NS, D5W (IV): ≤2000 mg in 250 mL >2000 mg in 500 mL Conc. Range 0.6–20 mg/mL†	30 d FT, 7 d RT (or- 24 h FT , RT when mixed with mesna)	- nonvesicant - latex-free* - solution strength should not exceed 4% - administration of mesna is mandatory for all patients receiving ifosfamide
	50 mg/mL	14 d FT [⌘] , 24 h RT		72 h FT † Mixed with mesna in same IV solution- Give 30h expiry.	Cytotoxic

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PREPARATION OF CANCER CHEMOTHERAPY

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	To Give:	Vial Expiry [⌘]		Product Expiry	Auxiliary Labels
Interferon Alfa -2b 18 million IU/3 mL 25 million IU/2.5 mL (Schering) (F)(or up to 7 days at RT before use) no preservative†	N/A- Solution source product	48 h FT†	syringe† IV: ≥ 0.3 million IU/mL† 50 mL NS† (Note: different volume of diluent than powder, due to different stabilizers in each product formulation)	Syringe: 14 d RT, 42 d FT IV: 24 h FT , RT	- non-cytotoxic§ - nonvesicant - latex-free** - formulary: Restricted drug
	6 million IU/mL 10 million IU/mL	48 h FT†		Syringe: 2 d FT IV: 24 h FT , RT	
Interferon Alfa -2b 10 million IU 18 million IU (Schering) (F) no preservative†	1 mL supplied diluent (SWI) or 1 mL BWI do not shake; roll to reconstitute	SWI Diluent: 24 h FT , RT† BWI Diluent: 30 d FT, 14 d RT (or- 48 h FT , RT†)	SWI Diluent: syringe†, > 0.1 million IU/mL 100 mL NS (preferred for IV doses) BWI Diluent: syringe, (100 mL NS- not recommended for IV doses)	SWI Diluent: 24 h FT , RT- syringe, IV BWI Diluent: 7 d FT- syringes (or- 14 d F, 48 h RT†)	- non-cytotoxic§ - formulary: Restricted drug
	10 million IU/mL 18 million IU/mL				
Interferon Alfa -2b for Bladder Instillation 10 million IU/3 mL (Schering) (F)(or up to 7 days at RT before use) no preservative†	1 mL supplied diluent (SWI) or 1 mL BWI do not shake; roll to reconstitute	14 d RT, 30 d FT	5 or 10 vials drawn into 60 mL syringe, qs to 50 mL with NS	24 h FT	- non-cytotoxic§ - formulary: Restricted drug
	10 million IU/mL	48 h FT			Bladder Instillation only- Do NOT use IV
Irinotecan 40 mg/2 mL 100 mg/5 mL 500 mg/25 mL (Mayne) (RT)(PFL) (Pfizer) (RT)(PFL) no preservative†	N/A- Solution source product	30 d FT,RT after puncture (or- 2 days RT [Mayne]; discard unused portion [Pfizer]†)	500 mL D5W (preferred), NS† Conc range= 0.12– 2.8 mg/mL†	24 h RT: D5W, NS† 48 h FT: D5W†	- do NOT refrigerate if in NS - nonvesicant - latex** content not determined (Mayne); latex-free (Pfizer) - formulary: Restricted drug
	20 mg/mL	14 d FT [⌘] , 7 d RT			Cytotoxic Protect From Light

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 water for injection

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Cancer Care Nova Scotia- Systemic Therapy Program
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	To Give:	Vial Expiry [✱]		Product Expiry	Auxiliary Labels
Leucovorin 50 mg/5 mL 500 mg/50 mL (Mayne) (F)(PFL) no preservative†	N/A- Solution source product	5 mL vial: discard unused portion† 50 mL vial: 8 h FT , RT	syringe may be further diluted to 0.05 mg/mL† 50-250 mL* NS, D5W, Lactated Ringer's, Ringer's, D10W, D5-NS	Syringe: 48 h FT 24 h RT†: NS , D5W, Lactated Ringer's, Ringer's 8 h RT†: D10W, D5-NS	- non-cytotoxic - non-vesicant - latex-free**
	10 mg/mL	8 h FT , RT			
Liposomal Cytarabine 50 mg/5 mL (F) no preservative§	N/A- Solution source product Warm to RT, then gently agitate to re-suspend liposomes	Single use vial		4 h RT	- do not filter - for intrathecal administration - label to include route in full (i.e., INTRATHECAL injection) attached to both syringe and outer ziplock bag - non-vesicant - non-formulary drug
	10 mg/mL			Use immediately after withdrawal from vial	Cytotoxic INTRATHECAL injection
Liposomal Daunorubicin 20 mg/10 mL (F) no preservative§	N/A- Solution source product Warm to RT, then gently agitate to re-suspend liposomes	Single use vial	D5W 1 to 1 with liposomal daunorubicin dose	6 h RT	- do not filter - non-formulary drug
	2 mg/mL				Cytotoxic Protect from light
Liposomal Doxorubicin 50 mg; 2 mL liposomes vial; 3.1 mL buffer vial (Sopherion) (F) no preservative§	20 mL NS Shake well and heat in water bath (55-60°C) for 10-15 min; admix 1.9 mL liposomes into buffer vial, shake well and withdraw contents to admix into warm doxorubicin solution; shake vigorously then wait 10 minutes	Single use vial	250 mL (doses < 90 mg) or 500 mL (doses ≥ 90 mg) D5W	8 h RT; 72 h FT	- do not filter - non-formulary drug
	2 mg/mL				Cytotoxic Irritant

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	To Give:	Vial Expiry [⌘]		Product Expiry	Auxiliary Labels
Liposomal Doxorubicin (Pegylated) 20 mg/10 mL 50 mg/25 mL (Schering) (F) no preservative†	N/A- Solution source product	Single use vial discard unused portion†	Doses up to 90 mg: 250 mL D5W only † Doses over 90 mg: 500mL D5W only	24 h F†	- do not filter - latex-free** syringe - formulary: Restricted drug
	2 mg/mL				Cytotoxic Vesicant
Mechlorethamine 10 mg (Merck) no preservative†	10 mL SWI or NS - do NOT use if discoloured or water droplets form in vial before reconstitution	1 h RT, 6 h FT	syringe† (100 mL NS- not recommended)	1 h RT, 6 h FT	- latex** content not determined - do not refrigerate - prepare immediately before use - neutralize all excess solution with sodium thiosulfate solution
	1 mg/mL	use immediately, or within 4 hours of reconstitution		complete administration within 4 hours of reconstitution†	Cytotoxic Vesicant
Melphalan 50 mg (GSK) (RT)(PFL) no preservative†	10mL supplied diluent - immediately after adding diluent, shake vigorously†, or use centrifuge to mix	2 h RT† do NOT refrigerate	IV: NS 100 mL Conc range= 0.1– 0.45 mg/mL (e.g., >45 mg and <110 mg in 250 mL NS)*	90 min RT from time of initial reconstitution	- latex-free** - reduced stability and increased degradation with rise in temperature - do not dilute with dextrose solutions - do not refrigerate - can be filtered through a 5 µm filter.
	5 mg/mL				Cytotoxic Vesicant Protect From Light
Mesna 400 mg/4 mL 1000 mg/10 mL (PPC) (RT) preservative†	N/A- Solution source product	14 d FT, RT†	> 1mg/mL† NS or D5W	48 h FT, 24 h RT†	- non-cytotoxic - nonvesicant (diluted) - irritant (undiluted) - latex** content not determined
	100 mg/mL	14 d FT, RT†			

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	To Give:	Vial Expiry [⌘]		Product Expiry	Auxiliary Labels
Methotrexate 50 mg/2mL 500 mg/20mL 1 g/40mL 5 g/200mL (Mayne) (RT)(PFL) no preservative†	N/A- Solution source product	PFL vials: discard unused portion† 500mg, 1 g mL, 5 g mL: 8 h FT , RT†	syringe IV: NS , D5W 1-20 mg/mL ≤100 mg in 50 mL 101-200 mg in 100 mL 201-500 mg in 250 mL 501-1000 mg in 500 mL continuous infusion in 1000 mL x 3 doses high dose (e.g., 1-8 g/m ²): 500–1000 mL	Syringe: 2 d FT , RT IV: 24 h RT† Methotrexate high dose (3.5g/m ²) + NAHCO ₃ 50 mEq/L in D5W 500 mL or 1L. Stable 24h at RT	- for high-dose regimens (e.g., 1-8 g/m ² as a single dose) use preservative-free methotrexate - nonvesicant - latex-free** - do not refrigerate - can be filtered through a 5 µm filter.
	25 mg/mL				Cytotoxic Protect From Light
Methotrexate 50 mg/2mL 500 mg/20mL (Mayne) (RT)(PFL) preservative†	N/A- Solution source product	30 d RT (preserved vials), 24 h FT	syringe 0.4–2 mg/mL† e.g., 100 mL* NS , D5W†	Syringe: 30 d RT (or- 7 d FT †) IV: 5 d RT, 14 d FT (or- 24 h RT†)	- non-vesicant - latex-free** - do not refrigerate - can be filtered through a 5 µm filter
	25 mg/mL			Syringe: 7 d FT † IV: 24 h RT†	Cytotoxic Protect From Light
Methotrexate IT Injection: Only preservative free methotrexate may be administered by the intrathecal route 20 mg/2mL (Mayne) (RT)(PFL) no preservative†	N/A- Solution source product	Single use vial discard unused portion†	preservative free NS, SWI or CSF (volume as per protocol)	use within 4 hours of initial puncture	- auxiliary label: "IT" - label to include route in full (i.e., INTRATHECAL injection) attached to both syringe and outer ziplock bag - nonvesicant - latex-free**
	10 mg/mL				Cytotoxic INTRATHECAL injection

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	To Give:	Vial Expiry [✱]		Product Expiry	Auxiliary Labels
Mitomycin 5 mg, 20 mg (Novopharm) (RT)(PFL) 5 mg, 20 mg (BMS) (RT)(PFL) no preservative†	SWI 5 mg: 10 mL 20 mg: 40 mL Mild agitation to dissolve (may use reconstitution device) (BMS)	14 d FT, 7 d RT (or- 48 h FT, RT†)	syringe 50-100 mL* NS , D5W, sodium lactate† Conc range= 0.02-0.04 mg/mL; Max conc 0.6 mg/mL	4 d RT, 14 d FT	- can be filtered through a 5 µm filter - latex-free** (stopper or product) (Novopharm); latex stopper**(BMS)
	0.5 mg/ mL†	14 d FT, 7 d RT		Syringe: 12 h RT IV: 3 h RT: D5W 12 h RT: NS 24 h RT: sodium lactate†	Cytotoxic Vesicant Protect From Light
Mitomycin for Bladder Instillation 20 mg (Novopharm, BMS) (RT)(PFL)	20 mL SWI Mild agitation to dissolve	12 h RT (1 mg/mL solution)	Dose drawn into 60 mL syringe, qs to 50 mL with NS	Syringe: 12 h RT	- intravesicular use: mix at 1 mg/mL concentration; NOT to be used IV or refrigerated - can be filtered through a 5 µm filter
	1 mg/mL				Cytotoxic Bladder Instillation only- Do NOT use IV Protect From Light
Mitoxantrone 20 mg/10mL (Mayne) (RT)(PFL) 20 mg/10 mL 25 mg/12.5 mL (Wyeth) (RT)(PFL) no preservative†	N/A- Solution source product	30 d FT, 7 d RT in glass container (or- discard unused portion†)	Syringe IV: 50 mL NS , D5W† Max conc 0.4 mg/mL	Syringe: 30 d FT, 7 d RT IV: 7 d FT , RT (or- NS: 24 h FT , RT; D5W: 72 h FT, 24 h RT† [Mayne]; 24 h RT†[Wyeth])	- latex-free**(Mayne); latex** content not determined (Wyeth) - may cause a blue-green discoloration to the urine for 1-2 days - can be filtered through a 5 µm filter
	2 mg/mL	14 d FT [✱] , 7 d RT		Syringe: 7 d FT IV: 7 d FT , RT	Cytotoxic Irritant Protect from light

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	To Give:	Vial Expiry ^{JK}		Product Expiry	Auxiliary Labels
Oxaliplatin 50 mg, 100 mg (Sanofi-Aventis) (RT)† 50 mg, 100 mg (Mayne) (RT) no preservative† 50 mg, 100 mg (Sigmacon) (RT) no preservative†	SWI, D5W: 50 mg: 10 mL 100 mg: 20 mL do NOT use NS or other chloride-containing solutions (degrades) (may use reconstitution device) (Sanofi-Aventis)	24 h FT discard unused portion (Mayne)†	≥ 0.2 mg/mL 250–500 mL D5W Do NOT use NS or other chloride- containing solutions (degrades) †	24 h FT†, 6 h RT† 24 h FT (Mayne)†	- latex-free (Sanofi-Aventis); latex** content not determined (Mayne, Sigmacon) - non-formulary drug
	5 mg/mL	24 h FT			Cytotoxic Irritant
Oxaliplatin 50 mg/10 mL 100 mg/20 mL (Sanofi-Aventis) (RT) no preservative†	N/A- Solution source product	Single use vial	250–500 mL D5W† 0.2-2 mg/mL† Do NOT use NS or other chloride- containing solutions (degrades) †	24 h FT†, 6 h RT† Stable 6 more hours at RT once removed from fridge	- latex-free
	5 mg/mL	discard unused portion†			- non-formulary drug
Paclitaxel 30 mg/5 mL 100 mg/16.7 mL 300 mg/50 mL (BMS) (RT)(PFL) † 30 mg/5 mL 100 mg/16.7 mL 300 mg/50 mL (Biolyse) (F) (may store at RT for 2 months) † no preservative	N/A- Solution source product Warm vial to RT if stored at FT; discard if precipitate present after warming. Do NOT use filter disk or filter needle to withdraw dose from vial	30 mg: 48 h RT† 100 mg: 48 h RT† 300 mg: 24 h RT† (BMS) 8 h RT (Biolyse)†	NS , D5W (IV): 500 mL Conc Range 0.3-1.2 mg/mL in NS , D5W, D5-NS, D5 in Ringer's (BMS)† (e.g., 100–1000 mL)* 0.3–1.2 mg/mL in NS , D5W (Biolyse)† (e.g., 100–1000 mL)* • <75 mg in 100 mL NS • 75-300 mg in 250 mL NS • >300-500 mg in 500mL NS	Glass bottle 27h RT. Polyolefin bag (McGaw Excel Bags) 72h at RT (or- 24 h RT†)	- administer in a glass bottle (or polyolefin bag), through polyethylene- lined nitro tubing/Taxol infusion set and use a 0.22µm inline filter - solution may have a slight haze - contains Cremophor EL - do not use with patients with previous hypersensitivity to cyclosporin IV - latex-free** (BMS); latex** content not determined (Biolyse) - formulary: Restricted drug
	6 mg/mL	48 h RT†			Cytotoxic Irritant Protect from light

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	To Give:	Vial Expiry [⌘]		Product Expiry	Auxiliary Labels
Paclitaxel NAB (Nanoparticle Albumin-Bound) 100 mg (Abraxis) no preservative§	20 mL NS Slowly inject diluent down inside wall of vial, let sit for 5 min, then swirl gently for 2 minutes	8 h RT, FT	Empty sterile PVC infusion bag	8 h RT, FT	- do NOT use in-line filter - protect from blue light - non-formulary drug
	5 mg/mL	8 h RT, FT			Cytotoxic Irritant
Pamidronate 30 mg/10 mL 60 mg/10 mL 90 mg/10 mL (Mayne) (RT) no preservative†	N/A- Solution source product		0.06–0.36 mg/mL NS , D5W† Do NOT mix with calcium containing solution (e.g., Ringer's) † e.g., 250 mL NS	24 h FT followed by 24 h RT (total 48 h) †	- non-cytotoxic - non-vesicant - latex-free** - formulary: Restricted drug
	3 mg/mL 6 mg/mL 9 mg/mL				Protect from light
Pegaspargase PEG-asparaginase (pegasparagase) (pegylated asparaginase E. coli) 750 units/mL (Enzon) (F) no preservative†	N/A- Solution source product	Single use vial discard unused portion†	IM : maximum volume 2 mL; if >2 mL use multiple sites† IV: 100 mL NS or D5W (given over 1-2 h) †	syringe: 4 h† bag: 4 h†	- non-cytotoxic§ - nonvesicant - latex** content not determined - discard cloudy solution - do not use if stored out of refrigerator for >48 h - do not use if previously frozen - non-formulary drug
	750 units/mL				Do not shake
Pemetrexed 500 mg (Eli Lilly) (RT) no preservative†	20 mL NS	24 h FT, RT†	Dilute with NS to total volume 100 mL Do NOT mix with calcium containing solution (e.g., Ringer's) †	24 h FT, RT	- non-vesicant - latex** content not determined - non-formulary drug
	25 mg/mL	24 h FT, RT†			Cytotoxic

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	To Give:	Vial Expiry [✱]		Product Expiry	Auxiliary Labels
Porfimer 15 mg 75 mg (Axcant) (RT)(PFL) no preservative†	6.6 mL D5W 31.8 mL D5W†	24 h FT (PFL) †	syringe†	use within 4 h of initial reconstitution	- non-cytotoxic - latex-free - non-formulary drug
	2.5 mg/mL†				Irritant
Raltitrexed 2 mg (AstraZeneca) (F, RT)(PFL) no preservative†	4 mL SWI	24 h FT, RT†	50–250 mL NS, D5W†	24 h FT, RT†	- nonvesicant - latex-free** - formulary: Restricted drug
	0.5 mg/mL	24 h FT, RT†			Cytotoxic
Rituximab 100 mg/10 mL 500 mg/50 mL (Roche) (F)(PFL) no preservative†	N/A- Solution source product	Single use vial discard unused portion†	1–4 mg/mL in NS, D5W† (e.g., 500 mg/250 mL, 1000 mg/500 mL) Gently invert to mix	24 h FT + additional 12 h RT†	- non-cytotoxic - non-vesicant - latex-free** - can be filtered through a 5 µm filter - Provincial funding for specific indications - formulary: Restricted drug (other indication)
	10 mg/mL				Protect from light Do not shake
Streptozocin 1g (Pfizer) (F)(PFL) no preservative†	9.5mL NS, SWI, D5W	96 h FT, 48 h RT	syringe†	96 h FT, 48 h RT	- latex-free**
	100 mg/mL	48 h FT, 24 h RT†	100 ml (50-500 mL) NS, D5W†, 2/3- 1/3	48 h FT, 24 h RT†	Cytotoxic Vesicant

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Teniposide 15 mg/1.5 mL amp (Bristol) Preservative‡	N/A- Solution source product Do NOT filter ampoule contents	Single use vial discard unused portion‡	0.1, 0.2, 0.4, or 1 mg/mL in NS or D5W‡	0.1, 0.2, 0.4 mg/mL: 24 h RT 0.5-1 mg/mL: complete administration within 4 h‡	- administer in a glass bottle (or polyolefin bag), through polyethylene- lined nitro tubing/Taxol infusion set - contains Cremophor EL - do not use with patients with previous hypersensitivity to cyclosporin IV - do NOT refrigerate - do not filter - do not administer through port-a- catheter - latex-free
	10 mg/mL				Cytotoxic Irritant Protect from light
Thiotepa 15 mg (Bedford) (F)(PFL) no preservative†	1.5 mL SWI†	28 d FT, 7 d RT (or 14 d FT [⌘]) (or- 8 h FT†)	IV: 50 mL NS, D5W, 2/3- 1/3:	24h RT: 1, 3 and 5 mg/mL in NS 0.5 mg/mL in NS unstable. Use immediately. 14d FT: 5 mg/mL in D5W 3d RT: 5 mg/mL in D5W	- solution is slightly opaque - filter through 0.22 micron filter before administration - non-vesicant - latex** content not determined
	10 mg/mL†	14 d FT [⌘] , 7 d RT			Cytotoxic
Thiotepa IT injection: 15 mg (Bedford) (F)(PFL) no preservative†	diluents containing preservatives should NOT be used for intrathecal administration 7.5 mL NS	Use immediately†	qs to 6 mL with preservative free NS	use within 4 h of initial reconstitution†	- auxiliary label to include route in full (i.e., INTRATHECAL injection) attached to both syringe and outer ziplock bag - filter through 0.22 micron filter before administration - non-vesicant - latex** content not determined
	2 mg/mL solution				Cytotoxic INTRATHECAL injection

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Thyrotropin alfa 1.1 mg (Genzyme) (F)(PFL) no preservative†	1.2 mL SWI† swirl contents†; do not shake	24 h FT†		24 h FT†	- noncytotoxic - nonvesicant - latex-free
	0.9 mg/mL†	24 h FT†			
Topotecan 4 mg (GSK) (RT)(PFL) no preservative†	4 mL SWI	28 d FT, 7 d RT (or 14 d FT [⌘]) (or- 24 h FT, RT†)	IV: 50–100 mL NS, D5W† Conc range= 0.02–0.5 mg/mL	28 d FT, 7 d RT	- nonvesicant - latex-free** - formulary: Restricted drug
	1 mg/mL	14 d FT [⌘] , 7 d RT		24 h FT, RT†	Cytotoxic Protect from light
Tositumomab (with Iodine¹³¹) Kit for radiolabelling with I ¹³¹ (GSK) no preservative§	Prepare according to mfr instructions; use radionuclide protection	Use immediately after reconstitution and radioisotope labelling		N/A	- radiation hazard - prepared and handled by nuclear medicine dep't. - non-formulary drug
	---				Vesicant
Trastuzumab 440 mg (Roche) (F) preservative†	20 mL BWI supplied Or 20 mL SWI swirl vial gently; allow to stand undisturbed for 5 minutes†	28 d FT	250mL NS† Do NOT use dextrose containing solutions†	24 h FT, RT†	- non-cytotoxic - non-vesicant - if patient sensitive to Benzyl Alcohol, reconstitute: SWI (in this case discard unused portion) - latex** in drug vial but not diluent vial - Provincial funding for specific indication - formulary: Restricted drug (other indication)
	21 mg/mL	14 d FT [⌘]			Do NOT shake

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	To Give:	Vial Expiry [⌘]		Product Expiry	Auxiliary Labels
Valrubicin for Bladder Instillation 200 mg/5 mL (F) preservative§	Warm 4 vials, Dilute all 4 vials with a total of 55 mL NS	Single use vial discard unused portion (or- 12 h RT)	Syringe for intravesicular (bladder) administration	12 h RT	- intravesical use only - drug must come to RT slowly before adding to NS. DO NOT SHAKE - rotate bag gently - non-PVC NS 100 mL bags supplied to make total volume 75 mL (55 mL NS + 20 mL drug) - may also use empty non-PVC bags + add NS + drug - special administration sets <u>must also</u> be ordered with drug - non-formulary drug
	40 mg/mL 800 mg/75 mL				Cytotoxic Bladder Instillation only- Do NOT use IV
Vinblastine 10 mg/10 mL (Mayne) (F)(PFL) no preservative†	N/A- Solution source product	30 d FT (or- 24 h FT, RT†)	syringe† 50 mL (up to 100–250 mL) NS , D5W Max Conc 0.4 mg/mL	syringe: 30 d FT IV: 7 d FT, 24 h RT (or- 14 d FT: NS)	- auxiliary label (for syringe only): “Warning: FATAL if Given intrathecally” - avoid dilution in large volumes to decrease the chance of extravasation - latex-free** - can be filtered through a 5 µm filter
	1 mg/mL	14 d FT [⌘]		Syringe: 48 h FT† IV: 7 d FT, 24 h RT	Cytotoxic Warning: FATAL if Given intrathecally Vesicant Protect from light

Codes: ‡ Data from CPS † § Data from Manufacturer's Product Monograph RT = room temperature
 ⌘ Expiry date limited to 14 d FT for unpreserved low-risk level compounded sterile product per USP 797
 water for injection

FT = refrigerated SWI = sterile water for injection
 NS = normal saline D5W = dextrose 5% BWI = bacteriostatic
 PFL = protect from light

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DRUG & STRENGTH (Storage Prior to Use, Manufacturer, Preservative Status)	Reconstitute With:	Vial Stability	Product	Product Stability	Special Precautions/Notes
	To Give:	Vial Expiry [✱]		Product Expiry	Auxiliary Labels
Vincristine 1 mg/1 mL 2 mg/2 mL 5 mg/5 mL (Mayne) (F)(PFL) (Novopharm) (F)(PFL) no preservative†	N/A- Solution source product	30 d FT (or- 8 h FT, RT†)	syringe: qs to 20 mL with NS in 30 mL syringe* IV: 50 mL * NS , D5W† Max conc 0.6 mg/mL	IV: 21 d FT, RT (or- 24 h FT, 6 h RT [Mayne]; 72 h FT, 24 h RT [Novopharm])	- auxiliary label (for syringe only): “Warning: FATAL if given intrathecally” - peripheral administration of a continuous infusion is not recommended - refrigerate - do not filter- latex-free**
	1 mg/mL	14 d FT [✱]		syringe: 48 h RT, 7 d FT IV: 24 h FT , RT VAD Infusor = 7d at 4°C followed by 4 days at 35°C	Cytotoxic Warning: FATAL if given intrathecally Vesicant Protect from light
Vinorelbine 10 mg/1 mL 50 mg/5 mL (GSK) (F)(PFL) 10 mg/1 mL 50 mg/5 mL (Mayne) (F)(PFL) no preservative†	N/A- Solution source product	7 d FT (or- discard unused portion†)	syringe: 1.5 – 3.0 mg/mL in NS or D5W† IV: 50 mL * NS , D5W, ½NS, D5½NS, Ringer’s, Ringer’s Lactate† Max Conc: 0.5 – 2.0 mg/mL (Mayne)† Infusion Bag: 0.5-2 mg/mL	syringe: 24 h FT , RT† 24 h FT , RT†	- auxiliary label (for syringe only): “Warning: FATAL if given intrathecally” - solution clear to pale yellow; darker yellow solutions may be used - refrigerate - latex-free** (GSK); latex** content not determined (Mayne) - formulary: Restricted drug
	10 mg/mL	7 d FT			Cytotoxic Warning: FATAL if given intrathecally Vesicant Protect From Light

Adapted from Stability and Reconstitution Chart (27 Feb 2007)- Capital District Health Authority, ACB Cytotoxic Drug Chemical Stability Chart (May 2006)-
Alberta Cancer Board, and BCCA Cancer Drug Manual (2 Feb 2007)- British Columbia Cancer Agency

Codes: ‡ Data from CPS † § Data from Manufacturer’s Product Monograph RT = room temperature
✱ Expiry date limited to 14 d FT for unpreserved low-risk level compounded sterile product per USP 797
water for injection

FT = refrigerated SWI = sterile water for injection
NS = normal saline D5W = dextrose 5% BWI = bacteriostatic
PFL = protect from light

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LEGEND

- ⌘ Expiry time in a vial is either the time provided in the product monograph, or 14 d F (maximum time to store a low-risk level compounded sterile product with no preservative per USP 797 to minimize risk from potential microbial contamination)
- ** Latex free means the product does not contain natural rubber latex in its packaging or is packaged as plastic (e.g., Polyamps) and glass ampoules
- ‡ Data from Compendium of Pharmaceuticals and Specialties (CPS), as abstracted by the BCCA Cancer Drug Manual (2 February 2007)
- † Data from Manufacturer's Product Monograph, as abstracted by the BCCA Cancer Drug Manual (2 February 2007)
- § Data from Manufacturer's Product Monograph, as abstracted by the CCNS Chemo Preparation Policy Working Group

Explanatory Notes

Stability: Physicochemical stability noted as first option, where information is available.

Expiry: If the expiry time is different than stability data, this will be noted in a separate cell. Shorter expiry times may be noted from the Manufacturer's Product Monograph or limited by USP 797 regulations due to product sterility concerns. It is the responsibility of each institution to determine the level of acceptable risk for assurance of product sterility in the local Chemotherapy Preparation Area, and to support this level through appropriate process validation data.

Vial stability: Stability of solution after first puncture or reconstituted solution

Storage temperature: If information states same stability with refrigerator and room temperature storage, then bold refrigerated as preferred

Cytotoxic: hazardous.

Discard unused portion: Unused portion from single use vials are assumed to be discarded at the end of the day.

If information states same stability with refrigerator and room temperature storage, then bold refrigerated as preferred (ie, to minimize growth of micro-organisms).

PFL = protect from light

RT = room temperature

FT = refrigerated

SWI = sterile water for injection

NS = normal saline

D5W = dextrose 5%

BWI = bacteriostatic water for injection

BSI = bacteriostatic normal saline for injection

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These Policies and Best Practice Procedures are adapted from the “Standards of Practice for Oncology Pharmacy in Canada”, published in October 2004 by the Canadian Association for Pharmacy in Oncology, and the “Guidelines on Handling Hazardous Drugs”, published in July 2006 by the American Society of Health Systems Pharmacists. It is the responsibility of each District to develop Policies and Procedures tailored to individual sites and practices, while adhering to these provincial standards.