Subject: Cytotoxic Agents

Purpose: To establish guidelines for ordering, storage, preparation, administration, documentation, and disposal of cytotoxic agents by nursing personnel.

Policy: Cytotoxic agents are considered to be potentially hazardous materials and require unique handling and documentation. Parenteral cytotoxic agents will be reconstituted by the pharmacy department. Protective garments/gloves will be utilized for preparing and administering cytotoxic agents. Disposal of cytotoxic contaminated material will be accomplished according to established procedure. Documentation records of personnel preparing and administering cytotoxic agents will be maintained.

1.0 Identification of Cytotoxic Agents
1.1 Cytotoxic agents are listed in the MMSC formulary under section 10:00 as “Antineoplastic Agents”. The agents are also STORED in a special area of the pharmacy designated for “chemotherapy” drugs.
1.1.1 Stock bottles or unit dose medications will be placed in red bins to indicate special handling precautions to staff when dispensing.

2.0 Physician Orders for Cytotoxic Agents
2.1 Nursing staff forwards a physician’s order sheet to pharmacy prior to preparation for use in double-checking during labeling and preparation procedures.
2.2 Pharmacy is to be notified of the date & time the agents will be needed in the patient care area (Oncology Clinic or Medical Unit).
2.3 Nursing personnel responsible for administering the agents should check the orders again for correctness of drug and dose once the agents have been delivered but before actual administration to the patient.

3.0 Labeling and Documentation
3.1 Pharmacy will enter the patient and drug information into the CPSI system.
3.2 A double label is generated.
3.2.1 The first label is to be used for IDENTIFICATION of the drugs by attaching to the final product prepared for administration.
3.2.2 The second label is to be used for DOCUMENTATION of preparation and administration of chemotherapy drugs. At the time of preparation and double-checking, the pharmacy notes on this part of the label the Lot #, Expiration, and Initials of the persons involved in the preparation process. This part of the label also accompanies the drugs to the patient care area where the nurse administering the drug attaches the label to the back side of the Drug Administration Record (same document that is used to record the information necessary for chemotherapy drug administration). Thus a complete trail of involved personnel is
generated for compliance with OSHA requirements for a cytotoxic “registry” process, and this activity documentation is saved with the patient’s Medical Record for future retrieval if necessary (regulations require 5 year storage of this documentation).

4.0 Preparation of Cytotoxic Agents

4.1 The pharmacy department will reconstitute and prepare cytotoxic admixtures utilizing the vertical laminar air flow hood.

4.2 Personnel involved in the preparation procedure will wear protective gear sufficient for personal protection, depending on the drugs being handled (gown and gloves designed for chemotoxic protection).

4.3 Preparations containing cytotoxic agents will be identified with a special label (see above) and placed in a special protective zip-lock bag for distribution and eventual disposal.

4.4 The labeled cytotoxic drugs and/or admixtures will be delivered to the unit utilizing exiting delivery procedures and by the most direct route to the patient care area where administration of the drug will occur.

4.5 All materials that may have come into contact with cytotoxic drugs during the preparation, transport, administration, or waste removal of chemotoxic agents should be considered contaminated with cytotoxic drugs. These may be disposed of in the special covered and labeled containers in the IV preparation area designated as “Chemotherapy Waste” (Note: these containers are different from the “paper” or “recyclables” waste containers). When the Chemotherapy Waste containers are full, they should be sealed for transport by the Environmental Service personnel, who will complete the waste disposal by appropriate methods as stated by their policy & procedures (eg. EPA regulated acceptable temperatures).

5.0 Administration of Cytotoxic Agents

5.1 Wash hands with soap and water before and after handling the agent.

5.2 Wear a chemo-proof gown when administering or discontinuing the drug.

5.3 Wear unpowdered latex gloves during procedures where leakage may occur.

5.4 Place a sterile alcohol swab over the tips of needles or IV tubing to collect any of the cytotoxic drugs that may be accidentally discharged when removing air bubbles from a syringe or tubing.

5.5 Direct fecal and urinary excreta from patients receiving chemotherapy agents may contain significant levels of cytotoxic residues. Using standard “universal precautions” should be sufficient to provide protection for caregivers.

6.0 Disposal of Contaminated Waste

6.1 Place contaminated/used needles and syringes in a leak proof puncture resistant container. DO NOT CLIP THE NEEDLE FROM THE SYRINGE. This will prevent aerosol generation of the cytotoxic agent.

6.2 Place gloves and other material used to administer the cytotoxic agents in a labeled plastic bag. Seal the container for transfer to the Iowa Medical Waste Reduction Center by the environmental services department.
6.3 Environmental Services will dispose of the cytotoxic material in accordance with procedures established by their policies and procedures based on acceptable hazardous waste disposal regulations.

7.0 Procurement and Storage of Cytotoxic Agents
7.1 As with all drug agents, the pharmacy is responsible for procurement of cytotoxic drugs. The supplier’s compliance with transport requirements includes shipping in containers marked “Cytotoxic Drug”, and delivery directly to the pharmacy department.
7.2 The drugs will be inventoried and physically examined by the receiving pharmacy personnel for damage prior to placing the drugs in pharmacy storage area specifically designated by cytotoxic drugs.
7.3 Material Safety Data Sheets (MSDS) must be readily available for each cytotoxic drug (may be obtained from supplier).
7.4 In the event of a receipt of damaged packaging or handling during the procurement process, the cytotoxic spill procedure is to be followed.

8.0 Accidental Exposure to Cytotoxic Contact
8.1 Management of medical emergencies involving cytotoxics
8.1.1 Items which may be helpful for a cytotoxic exposure emergency area as follows, and are included in a chemotherapy spill kit:

- 500 ml of sterile 0.9% NaCl (Normal Saline) Irrigation Solution
- 30 ml of a sterile Eye Wash Solution
- 120 ml liquid soap
- 250 ml of 5% chloride bleach solution (eg. “Clorox”)
- 4 x 4 sterile gauze pads

8.1.2 Immediately, but calmly, notify others in the area that a spill has occurred and request assistance as appropriate for treatment of the patient or staff affected by the spill, and for cleanup of the spill as outlined elsewhere in this policy and procedure. Use applicable universal precautions, including gloves and gowns as determined by the extent of the spill.

8.1.3 In the event of skin contact, thoroughly wash the affected skin area with soap and water (do NOT use hexachlorophene or iodine based soaps). Saturate 4 x 4 gauze pads with 5% chloride bleach and wipe affected areas until all trace of the cytotoxic substance has been removed. Rinse thoroughly with water. Examine area for lacerations, take patient to the emergency room and complete a variance/incident report.

8.1.4 In the event of eye contact, flush affected eye(s) at least 15 minutes with copious amount of water (use entire 500 ml container of normal saline). Take patient to the emergency room, and seek immediate ophthalmologist consult. Complete a variance/incident report.

8.1.5 For needle sticks involving vesicant cytotoxic substances: if drug has been injected into the tissue, do NOT remove the needle, but pull back on the plunger to aspirate any injected drug; if the needle has already been removed, insert a tuberculin syringe into the site and aspirate the solution if possible; proceed
immediately to the emergency room for treatment. Complete a variance/incident report.

8.1.6 For lacerations involving glass or other sharps with cytotoxic substances: rinse the area with copious amount of water, wash involved area with soap and water (do NOT use hexachlorophene or iodine based soaps), take the patient to the emergency room, and complete a variance/incident report.

8.1.7 Replenish all used items and kits as soon as emergency is over.

8.2 See material safety data sheets on file for further treatments that may be required for specific agents.

9.0 Cytotoxic Spill Procedures

9.1 A Cytotoxic Spill Kit will be available in a well-marked tote container (which also includes those items listed above as part of the emergency exposure kit) in Pharmacy, Oncology Clinic, and Environmental Services. The spill kits are obtained through the MMSC Central Supply Department being commercially available as a package containing the following:

1 protective gown (X-Large)
2 pair latex gloves (1 large, 1 medium)
1 respirator mask (NIOSH certified)
1 pair chemical splash goggles (eye protection)
2 absorbent towels
2 spill control pillows
1 disposable scoop and brush (collect fragments)
Disposal bags
4 chemo hazard labels

9.2 Management of small spills within chemo preparation LAF hood.

9.2.1 Always leave LAF hood fan in the ON position for proper functioning of the air flow control through the HEPA filter.

9.2.2 To easily control small spills, prior to preparation of any chemotoxic agents, place a special chemo absorbent mat in the hood to catch any small droplets from needles, vials, etc. Any small spills onto this mat will be contained in the mat and will be discarded with other materials after the preparation procedure is completed.

9.2.3 If spills occur within the hoods which are not caught on the special absorbent mat, they should be covered with wetted paper sheets to absorb the spilled materials. Then the surface where the spill occurred is to be wiped three times with 70% alcohol, followed by a water wipe. All such spills must be cleaned up by the person preparing the chemotherapy while still in personal protective gear, NOT left for any other personnel who may be cleaning the hood during regularly scheduled daily cleanings.

9.3 Handling spills outside of a LAF hood, using the spill kit, which is included in a specially designated polystyrene container clearly labeled as the “CHEMOTHERAPY SPILL/EMERGENCY KIT” (which may come to be known as “apicnic” basket in order to help remember the mnemonic for its use).
Note: In order to help remember the sequence of procedures to perform in case of a cytotoxic spill, the mnemonic **APICNIC** represents the flow of action:

A = ALERT co-workers to spill location and avoid personnel traffic
P = PROTECT during cleanup by wearing protective gear from the kit
I = ISOLATE the spill location with signage & monitoring Assistance
C = CONTAIN substance & collect fragments with absorbent materials
N = NEUTRALIZE with hypochlorite (bleach) additive(s) from kit
I = IMMERSE pads to absorb liquid, dispose into zip lock bag from kit
C = CLEANSE with 3 rinses 70% alcohol, dispose into zip lock bag from Kit

While this mnemonic is useful, a thorough explanation of this process is described below:

9.3.1 ALERT co-workers to assist in avoiding foot traffic by hospital personnel, patients, or visitors from the spill area.
9.3.2 PROTECT personnel involved in the cleanup by wearing protective gear over clothing, goggles, gloves, and respirator mask.
9.3.3 ISOLATE sufficient local area required for comfortable cleanup space around the spill (using signage ad assistance from hospital personnel for traffic monitoring or additional supplies).
9.3.4 CONTAIN the spilled substance from further spread by using appropriate absorptive materials (spill “pillows”, pads, etc.); CAREFULLY collect vial fragments or other sharps, using disposable scoop and brush, gathering all waste materials into central pile.
9.3.5 NEUTRALIZE this gathering of chemotoxic drugs, collected sharps, used absorptive pads, and the inert surface on which they rest, by use of the combination neutralizing agents from the spill kit.
9.3.6 IMMERSE additional pads if necessary to soak up the remaining liquids and materials, and place ALL of it in cytotoxic waste bag.
9.3.7 CLEANSE the spill area with 3 rinsings of 70% alcohol, then water rinse and wipe; after area is completely clean and dry, and all cleaning materials and waste have been placed in the cytotoxic waste bag(s), remove protective gear, seal it into waste bag(s), place into rigid waste containers, label as chemotoxic, and remove from the area to eventual incineration.

9.4 For spills inside the pharmacy department, but not within the LAF hood, the pharmacy personnel will assume responsibility for clean-up, with assistance from Environmental Services.
9.5 For spills occurring outside the pharmacy, Environmental Services must be contacted for cleanup, with pharmacy personnel providing backup.
9.6 All spills should be recorded on appropriate quality improvement or variance/incident reports and forwarded to QA coordinator and Occupational health Coordinator for safety documentation.
10.0 Notification reporting of cytotoxic spills and accidental contacts to:
10.1 Director of Pharmacy (for ALL instances).
10.2 Employee/Occupational Health Director (for accidental contacts).
10.3 Environmental Services (for surface cleanup and disposal).
10.4 Quality assurance (for variance/incident reports).

11.0 References:
MMSC Cytotoxic Drug Safety Manual
OSHA Pub. 8-8.1 Exposure to Cytotoxic Drugs

Originated by: Pharmacy
Effective date: 02/01
Authorized by: ________________________________

Occupational Health Director Date

Environmental Services Director Date

Authorized by: ________________________________

Pharmacy Director Date

Review date: 4/1/04
Revision date: 8/98; 6/09
Distribution: Pharmacy

CONTENTS of chemo drug spill kit
Addendum to Pharmacy Policy 5.11

Top Section (paperwork storage):
- Copy of Pharmacy Policy 5.11
- “APICNIC” mnemonic reminder
- MMSC Variance Report Sheet

Middle Section (Exposure items):
1 – Eye Stream 4 oz bottle
1 – Clorox Bleach 8 oz bottle
1 – Dial Soap 2 oz bottle
6 – Sterile 4x4 Dressing Sponges

Bottom Section (Cleanup items):
1 – ChemoBloc Spill Kit (USCP)
2 – 1:2 INERT Applicators (2-step)
50 – Nonsterile 4x4 sponges
1 – Normal Saline Irrigation 500 ml
1 – Sterile Water Irrigation 1500 ml
1 – Ethyl Alcohol 70% 16 oz bottle

Note: integrity of Kit is maintained by break-locks through end latches – Must replace when kit is replenished.