Purpose
This document describes the proper method for preparation, storage and delivery of intrathecal chemotherapy doses in the VICC Oncology Pharmacies and areas of administration.

References
VUMC Policies: Hazardous Drug Handling (AS 201420-50.12)
VUMC Policies: Cytotoxic Drug (Chemotherapy/Biotherapy) Administration and Management (CL 30-06.09)
VUMC Policies: Sterile Product Compounding (AS 201420-50.07)
CDC NIOSH Alert: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings, September 2004
TN BOP Chapter 1140-7 Sterile Product Preparation in Pharmacy Practice

Allowable Exceptions
This SOP is meant to be followed without deviation.

Procedures
A. Preparation of chemotherapy intrathecal doses
Intrathecal medication is not prepared during the preparation of any other agents. Intrathecal chemotherapy agents are prepared on the day of use and are given an expiration of 0000(midnight). The workspace in the Biologic Safety Cabinet (BSC) is cleaned per protocol prior to preparation of all intrathecal doses.
1. **Reconstitution Directions:**
   
a. **Methotrexate for Adults:**
   Methotrexate diluted to a concentration of 10mg/ml using a ratio of 1ml 25mg/ml PF Methotrexate to 1.5ml of PF 0.9% NaCl.

   b. **Methotrexate for Pediatrics:**
   Methotrexate diluted to a concentration of 2.5mg/ml using a ratio of 1ml of 25mg/ml PF Methotrexate with 9ml of PF 0.9% NaCl.

   c. **Cytarabine for Adults:**
   Cytarabine diluted to a concentration of 50mg/ml by diluting a 100mg PF Cytarabine vial with 2ml of PF 0.9% NaCl.

   d. **Cytarabine for Pediatrics:**
   Cytarabine 100mg PFL vial diluted to a concentration of 10mg/ml using a ratio of 1ml of 20mg/ml PFL Cytarabine with 1ml of PF 0.9% NaCl.

   e. **Hydrocortisone for Adults and Pediatrics**
   Hydrocortisone diluted to a concentration of 50mg/ml using 2ml of PF 0.9% NaCl.

**NOTE:** Dilutions not listed require VUMC P&T Committee approval before patient administration.

2. **Filtering:**

   All dilutions intended for intrathecal use are filtered through a 0.22 micron filter that has been approved by the manufacturer for that use before doses are prepared.
3. Double Check

All intrathecal dilutions are checked by a pharmacist and the reconstituted vial labeled before the Pharmacy begins preparation of patient-specific doses. The labeling is consistent with any Tennessee State Board of Pharmacy rules and regulations. The dilution label indicates:

a. Drug name
b. Concentration
c. Instruction to filtering
d. Date and time of preparation
e. Date and time of expiration
f. Name of manufacturer
g. Lot number of vial used to prepare dilution
h. Expiration of vial used to prepare dilution
i. VUMC database-assigned lot number
j. Initials of preparer and verifying pharmacist

4. Patient-specific doses

Once a pharmacist verifies the intrathecal dilution, patient specific doses can then be prepared from the dilution. All patient-specific doses must also be verified by a pharmacist.

B. Storage of chemotherapy intrathecal doses

1. Labeling

All patient-specific doses are labeled immediately after pharmacist verification with HMM labels that contain:

a. Patient name
b. Patient medical record number
c. Drug name
d. Drug strength
e. Instructions for intrathecal administration
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f. Due date of administration

g. Date and time of preparation

h. Date and time of expiration

i. Initials of dose preparer and verifier

j. Hazardous chemotherapy warning

k. VUMC database-assigned lot number

l. Unique Rx number to each prep

m. Location

n. Date of Birth/(age)

o. Weight

p. Storage condition

2. Storage

Once intrathecal doses are labeled, they are stored in isolated container bins that are uniquely identifiable for intrathecal medication only and located according to temperature requirements as specified by the medication's manufacturer and specified. There are separate bins located in the refrigerator and on shelving at room temperature to accommodate storage at the appropriate temperature specified by the USP. Any unused product or returned preparations are destroyed at close of business day.

C. Dispensing of chemotherapy intrathecal doses

1. Only the Intrathecal dose is dispensed and delivered to the treatment/procedure room for Pediatrics or interventional radiology for adult inpatient. Intrathecal for ommaya injection will be delivered directly to the provider that will administer the dose.

2. Intrathecal doses are never packaged with non-intrathecal doses in bags, pneumatic tubes or any other type of transportation or storage.