monitoring of compliance with national and international practice guidelines. Inclusion of in-line membrane filter of appropriate pore size is very crucial for retaining viable, non-viable particles and toxins.

When the hospital is outsourcing total parenteral nutrition formulations from an outside vendor, the pharmacy team should have copy of the valid contract. In order to ensure compliance of the vendor with CBAHI quality and safety standards, contract monitoring should be conducted at least annually with corrective actions accordingly. CBAHI contract monitoring form for total parenteral nutrition formulations must be used.

MM.28 The hospital has a system for safe preparation of sterile chemotherapy compounded preparations.

MM.28.1 There is a multidisciplinary policy and procedure on preparation and handling of sterile compounded chemotherapy preparations.

MM.28.2 The chemotherapy compounding services is operated and managed by the pharmaceutical care.

MM.28.3 The hospital permits only pharmaceutical care staff qualified in chemotherapy compounding to work in the chemotherapy compounding area.

MM.28.4 Aseptic technique is strictly followed by all staff in the chemotherapy compounding area.

MM.28.5 Visual inspection is performed for all compounded sterile chemotherapy preparations by a trained pharmacist for particulate, discoloration or evidence of loss of integrity.

MM.28.6 The chemotherapy compounding area is physically and functionally separate area to maintain product sterility and prevent cross contamination.

MM.28.7 The design of the chemotherapy compounding area is guided by the professional organizations' standards (e.g., the American Society of Health-System Pharmacists, United States Pharmacopoeia USP).

MM.28.8 The pharmaceutical care uses ISO Class 5 biological safety cabinet with 100% exhaust air outside the building (class II B vertical laminar airflow hood) for preparing chemotherapy.

MM.28.9 The biological safety cabinet is tested at least every six months and in accordance with the manufacturer requirements. the Saudi Food and Drug Authority guidelines, and the professional organizations' standards such as the American Society of Health-System Pharmacists (ASHP) and United States Pharmacopoeia (USP).

MM.28.10 The hospital implements written and approved guidelines on chemotherapy drug stability and compatibility.

MM.28.11 The hospital uses chemotherapy ziploc plastic bags to prevent accidental spills during transportation and storage of compounded chemotherapy preparations.

MM.28.12 Special chemotherapy protective materials such as gloves, gowns, and masks are adequately available and consistently used.

MM.28.13 Chemotherapy spill kits are available in all areas where chemotherapy agents are stored, prepared, dispensed, and/or administered.

MM.28.14 Relevant staff are trained on the proper handling of chemotherapy spills.

MM.28.15 Trash plastic bags for collection and disposal of contaminated materials and articles used for preparation, dispensing and/or administration of chemotherapy are as guided by the Saudi Food and Drug Authority (SFDA) and the international organizations standards such as Occupational Safety & Health Administration (OSHA).

MM.28.16 When chemotherapy products are compounded by an outside vendor, the pharmaceutical care team maintains a copy of the contract and ensures compliance of the vendor with quality and safety standards. Contract monitoring is conducted at least annually with corrective actions accordingly.

Standard Intent:

Many hazardous drugs are designed for parenteral administration, requiring aseptic reconstitution or dilution to yield a final sterile preparation. As such, the compounding of these products is regulated as pharmaceutical compounding by the United States Pharmacopeia (USP), chapter 797 which becomes chapter 800 in late 2015. The intent of the chapter is to ensure the safety of personnel involved according to OSHA guidelines and protect patients from improperly compounded sterile preparations by regulating facilities, equipment, and work practices to ensure the sterility of extemporaneously compounded sterile preparations. Due to the high-risk involved in the handling of chemotherapy, a highly qualified and trained pharmacists in addition to proper design and close monitoring of chemotherapy admixture area are required to reduces the risk of environmental contamination as well as operator risk.

When the hospital is outsourcing chemotherapy formulations from an outside vendor, the pharmacy team should have copy of the valid contract. In order to ensure compliance of the vendor with CBAHI quality and safety standards, contract monitoring should be conducted at least annually with corrective actions accordingly. CBAHI contract monitoring form for chemotherapy formulations must be used.