Clean room design, equipment and cleanliness are pre-requisite for aseptic technique. Proper selection and maintenance of equipment prevent any break-through aseptic procedure. The pharmacy regularly monitors the performance of laminar airflow hood (LAFH) and maintains updated certification. Chemotherapy admixture area is completely separated from regular IV area.

It is the responsibility of pharmacy director to closely monitor nurses' performance, dispensing environment where sterile preparations are compounded outside the clean room (e.g., in the patient care area during emergency or urgency situation), and confirm compliance with given guidelines.

MM.27 The hospital has a system for safe preparation of parenteral nutrition products.

MM.27.1 There is a multidisciplinary policy and procedure on preparation and dispensing of parenteral nutrition products.

MM.27.2 All parenteral nutrition products are compounded in the pharmaceutical care clean room under the laminar air flow hood.

MM.27.3 The hospital permits only pharmaceutical care staff qualified in aseptic technique and parenteral nutrition to prepare parenteral nutrition products.

MM.27.4 Aseptic technique is strictly followed by all staff in the parenteral nutrition compounding area.

MM.27.5 Double check policy is implemented at each stage of compounding and visual inspection of the final parenteral nutrition product.

MM.27.6 All essential macro-and micro-nutrients of parenteral nutrition are available.

MM.27.7 Appropriate membrane filters are available for the different types of parenteral nutrition and different patient-age groups.

MM.27.8 The hospital implements the written and approved guidelines on stability and compatibility of parenteral nutrition products.

MM.27.9 When parenteral nutrition products are compounded by an outside vendor, the pharmaceutical care team maintains a copy of the contract and ensures the compliance of the vendor with quality and safety standards. Contract monitoring is conducted at least annually with corrective actions accordingly.

Standard Intent:

Parenteral nutrition formulations are extremely complex admixtures containing 40 or more components including amino acids, dextrose, fat emulsions, water, electrolytes, trace elements, multivitamins, and others. Serious harm and death have been reported secondary to administration of improperly prepared, and/or contaminated parenteral nutrition formulations. Compounding of such formulation should be performed by qualified staff using aseptic technique in clean room environment with close

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.