MM.26.10 The laminar airflow hood is tested at least every six months and in accordance with the manufacturer's requirements, the Saudi Food and Drug Authority guidelines and the professional organizations' standards (e.g., American Society of Health-System Pharmacists, United States Pharmacopoeia USP).

MM.26.11 The hospital implements the written and approved guidelines on intravenous drug stability and compatibility.

MM.26.12 Any sterile preparation compounded outside the clean room (e.g., in the patient care area during emergency or urgency situation) is done in an appropriate environment (location, space, cleanliness, traffic, etc.) to prevent contamination.

MM.26.13 The pharmaceutical care regularly (at least once a month) inspects all areas where sterile preparations are compounded outside the pharmaceutical care clean room.

MM.26.14 The pharmaceutical care monitors the performance and qualifications of non-pharmacists permitted to prepare sterile compounded medications outside the pharmaceutical care department.

MM.26.15 There are written guidelines for safe recycling of returned (un-used) sterile preparations.

Standard Intent:

Parenteral medications account for >40% of all medications administered in institutional practice. The intravenous route is the most dangerous route of administration since all natural barriers are bypassed when the drug is given directly into the vein, so the administration of a contaminated solution can have very serious consequences. Contamination occurs when proper control over manipulation is not maintained. Contaminations may be introduced from the environment, equipment, supplies, and personnel, it is essential to control all these different sources at the time aseptic technique is carried out. Giving a patient a contaminated product can cause serious adverse effects including death.

The compounding of medications is a fundamental part of pharmacy practice. Qualified pharmacists and pharmacy technicians are responsible for compounding and dispensing sterile preparations of correct ingredient identity, purity, strength, stability and compatibility, and sterility and for dispensing them in appropriate containers that are labeled accurately and appropriately for the end user. The safety of intravenous admixture product depends on the skills of the operator, compliance with aseptic techniques, and IV room cleanliness. The pharmacy should have updated and reliable information resources for drug stability and compatibilities and establish guidelines for recycling of returned (un-used) sterile drugs.

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