

657—13.33(124,155A) Storage and delivery of sterile preparations. The pharmacy is responsible for proper packaging, handling, transport, and storage of preparations compounded and dispensed by the pharmacy and for appropriate education, training, and supervision of pharmacy and nonpharmacy personnel responsible for such functions. The pharmacy shall establish, maintain, and implement written policies and procedures to ensure product quality and packaging integrity until the preparation is administered.

13.33(1) Storage areas. Controlled temperature storage areas within the pharmacy shall be monitored at least once daily and the results documented on a temperature log. Temperature-sensing mechanisms shall be suitably placed within the storage space to accurately reflect the area's temperature.

13.33(2) Packaging, handling and transport. Appropriate policies and procedures shall be established, maintained, and implemented by the pharmacy with the involvement of other departments or services whose personnel are responsible for preparation or handling functions outside the pharmacy.

a. Policies and procedures shall include instruction in proper hand washing, aseptic techniques, site care, and change of administration sets to ensure the quality and sterility of the preparation.

b. A pharmacy that compounds or prepares products or devices or uses techniques where in-line filtration, automated infusion control devices, or replenishment of drug products into reservoirs of portable infusion pumps is required shall implement policies and procedures to address the special needs related to those products and techniques.

c. Policies and procedures shall provide for the return to the pharmacy of unused preparations for appropriate disposition. Appropriate disposition may include redispensing only if the continuing quality and sterility of the preparation can be fully ensured. The pharmacy shall be the sole authority for determining whether a preparation that was not administered as originally intended can be used for an alternate patient or under alternate conditions.

d. Policies and procedures regarding the handling of hazardous preparations shall identify safeguards intended to maintain the integrity of the preparations and to minimize the exposure potential of these products to the environment and to personnel who have contact with the products.