

<u>POLICY TITLE</u>		Policy #
COMPOUNDED STERILE PREPARATIONS - GENERAL POLICIES		
<u>POLICY MANUAL</u>		
Pharmacy Services		
<u>AUTHORIZATION</u>	<u>DATE APPROVED</u>	<u>DATE REVISED</u>
Regional Director of Pharmacy	14 June 2007	

POLICY

- 1.1 Pharmacy staff shall utilize processes and equipment designed to assure the safety and quality of all compounded sterile preparations.
- 1.2 All drugs, solutions, supplies and equipment used for the preparation or administration of compounded sterile preparations shall be stored in accordance with manufacturers' requirements and professional standards.
- 1.3 Equipment and devices used for the preparation and storage of compounded sterile preparations shall be maintained, monitored, calibrated and certified in accordance with manufacturers' recommendations and professional standards of practice.
- 1.4 All Pharmacy Services personnel preparing sterile preparations shall follow appropriate processes for handwashing and gloving as per policy "Compounded Sterile Preparations – Handwashing and Apparel" and shall wear special garments designed to minimize contamination of the sterile preparation work area.
- 1.5 Pharmacy staff shall prepare sterile preparations, using aseptic technique, in a laminar flow hood within a designated, limited-access sterile preparation area.
- 1.6 All parenteral preparations prepared by pharmacy personnel shall be prepared with latex precautions. (See Policy "Compounded Sterile Preparations – Latex Precautions")
- 1.7 All pharmacy personnel who prepare sterile preparations shall be trained in aseptic technique, and in the use and monitoring of any special equipment required for preparation of sterile preparations.
- 1.8 All pharmacy technicians who prepare sterile preparations shall have established competency in all required areas through completion of a program of personnel performance validation and certification.
- 1.9 All compounded sterile preparations prepared by Pharmacy Services shall first have a contamination risk level assigned, as specified in the Policy "Compounded Sterile Preparations - Risk Level Assignment".
- 1.10 All pharmacy technicians who prepare sterile preparations shall be certified.
 - 1.10.1 Pharmacy technicians shall be re-certified on an annual basis.

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- 1.10.2 In addition to the annual recertification process, pharmacy technicians who prepare high risk sterile preparations shall perform media fill testing twice a year. (See policy "Compounded Sterile Preparations – Training and Certification")
- 1.10.3 Annual certification for site personnel shall be performed centrally at the Pharmacy Drug Distribution Centre (PDDC). **(This process is delayed pending sufficient resources at PDDC)**
- 1.11 Any open or partly-used multi-dose parenteral medication packages shall be stored under refrigeration, unless otherwise specified by the manufacturer.
- 1.11.1 For beyond use dating, see Policy "Compounded Sterile Preparations – Reconstitution, Dilution, and Stability Chart" and Policy "Cytotoxic Preparations – Reconstitution, Dilution and Stability Chart".
- 1.12 All compounded sterile preparations shall be labelled as specified in Pharmacy Services policies, including storage instructions and beyond use dates.
- 1.13 Sterile preparation areas shall be routinely cleaned and disinfected.
- 1.14 Previously dispensed sterile preparations shall only be reused if the product is within the assigned beyond use date and is known to have been stored under appropriate conditions. See policy "Compounded Sterile Preparations – Beyond Use Dating".
- 1.15 When compounded sterile preparations are shipped between sites, appropriate modes of transport, temperature control and packaging shall be utilized to maintain integrity of the preparation.

REFERENCES

CSHP Guidelines for Preparation of Sterile Products in Pharmacies, Canadian Society of Hospital Pharmacists, Ottawa, Ontario, 1996. www.cshp.ca

ASHP Guidelines on Quality Assurance for Pharmacy-prepared Sterile Products Am J Health-Syst Pharm. 2000; 57;150-69.

Cooper J. Ed. *Sterile Product Preparation-An Interactive Training Program for Pharmacists and Pharmacy Technicians* Canadian Society of Hospital Pharmacists /Canadian Pharmacists Association, Ottawa, Ontario, 1999.

United States Pharmacopeia, General Chapter 797, Official Version Published in First Supplement to USP 27-NF 22, 2004.