POLICY TITLE

COMPOUNDED STERILE PREPARATIONS – ASEPTIC TECHNIQUE

Policy #

POLICY MANUAL

Pharmacy Services

AUTHORIZATION	DATE APPROVED	DATE REVISED
Regional Director Pharmacy Services	14 June 2007	

POLICY

1.1 All sterile preparations dispensed by Pharmacy Services shall be prepared by certified staff in a laminar flow hood located within a designated sterile preparation area, using aseptic technique.

1.1.1 Stat or single doses may be prepared in the laminar flow hood by certified or non-certified staff deviating from approved procedures for compounded sterile preparations, as necessary.

1.1.1.1 Doses prepared by non-certified staff and/or staff deviating from approved procedures shall be assigned beyond use dating of 24 hours or less.

1.2 Only one technician is permitted to work in a laminar flow hood at any given time, even during the training process.

PROCEDURE

Assembly

2.1 Assemble all ingredients and supplies and inspect for defects, expiry dates, damage, discolouration and other quality problems

2.2 Prepare any necessary labels

2.3 Verify the names, strengths and quantities of all ingredients against the order or worksheet, and complete the documentation as outlined in Pharmacy Services policies and procedures

2.4 Remove all items from cardboard cartons and outer containers before transfer to the compounded sterile preparation area

2.5 Gown, handwash, and glove as per policy “Compounded Sterile Preparations – Handwashing and Apparel”

2.6 Clean the laminar flow hood as per policy “Laminar Flow Hood – Cleaning”

Placement of Materials and Supplies in Laminar Flow Hood

2.7 Ensure that the door to the sterile preparation area is closed at all times

2.8 Place only those items essential for preparation in the hood

2.8.1 Use only designated pens, worksheets and labels in the sterile room

2.9 Decontaminate sharps and waste containers with isopropyl alcohol 70% and place within the laminar flow hood to one side of the work area

2.10 Decontaminate all objects by **wiping** with isopropyl alcohol 70% prior to placement in the hood

2.10.1 Items that are directly removed from sterile packaging at time of set-up do not need to be wiped

2.11 Ensure that the outer packaging of sterile items with protected critical sites are removed within the outer six inches of the laminar flow hood and the contents expelled onto the inner work surface of the hood

2.12 Remove syringes in hard plastic overwrap by twisting the cap counter-clockwise

2.12.1 The cap should offer some resistance to twisting which is an indication of the integrity of the package

2.12.2 If there is no resistance to twisting the cap, discard the syringe

2.13 Sterile packaged items with unprotected critical sites (e.g. needles, tip caps) remain within their overwraps and are placed within the outer six inches of the laminar flow hood.

2.13.1 Overwraps of items with unprotected critical sites are removed immediately before use

2.13.2 Items with paper overwraps should not be wiped with alcohol, as it compromises the integrity of the paper

2.14 After placing supplies in the laminar flow hood, allow the laminar flow hood to purge for five minutes before beginning the procedure

Aseptic Technique During Sterile Preparation

2.15 Don a clean pair of gloves immediately prior to beginning a sterile preparation

2.15.1 See Policy “Compounded Sterile Preparations – Handwashing and Apparel” for requirements for re-gloving during the preparation process

2.16 Keep movement within the laminar flow hood to a minimum

2.16.1 Actions such as talking or coughing shall be directed away from the laminar flow hood working area

2.16.2 If the worker sneezes or coughs, the mask must be changed

2.17 Keep the head and body outside the work area

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2.18 Avoid leaning or resting arms or elbows on the work surface of hood while working
2.18.1 Arms may rest on the exterior edge of the hood to avoid arm fatigue

2.19 Organize the work area so that work flows in one direction; exclude all unnecessary items from the work area

2.20 Minimize transfers in and out of the hood (e.g. equipment, hands)

2.21 Perform all aseptic manipulations at least six inches within the hood and at least three inches from the sides.

2.22 Ensure that the airflow between the HEPA filter and any exposed critical sites is not obstructed by hands or other objects.
2.22.1 Place items to the sides of the working area to maintain a clean air space
2.22.2 Maximize exposure to HEPA filtered air during:
- Needle insertion into a vial
- Withdrawal of contents from an ampoule
- Needle insertion into an IV bag
- Attaching a transfer set to an IV bag
- Puncturing the seal of a bottle
- Attachment of needle to syringe

2.23 Do not allow hands or any non-sterile products or surfaces to come into contact with the critical sites of sterile preparations

2.24 Prior to insertion of a needle or transfer set into a critical site, wipe the site (in one direction) with an alcohol swab
2.24.1 Allow the alcohol to dry before inserting the needle or set
2.24.2 Discard alcohol swabs after 30 seconds of use and do not reuse if placed on the work bench

2.25 Do not break ampoules or discharge syringes directly toward the HEPA filter
2.25.1 Nothing is permitted to come in contact with the HEPA filter including cleaning solution, aspirate from syringes, and glass from ampoules

2.26 Use appropriate techniques to prevent core formation when entering vials

2.27 Carefully mix reconstituted powders to ensure complete dissolution of drug

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2.28 Syringes with unprotected critical sites (tips) should be protected as quickly as possible by covering with a needle

2.29 When opening ampoules and withdrawing contents, use techniques to minimize particulate contamination
2.29.1 Solutions removed from ampoules are filtered unless contraindicated

2.30 Dispose all used needles and sharps safely in the designated container kept inside the hood

2.31 Perform a visual inspection of all final preparations to identify particulate matter, inappropriate discoloration, leakage or other problems

2.32 Upon completion of sterile preparation wipe all ports of mini-bags with an alcohol swab, to remove residue

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.