POLICY

To establish environment guidelines to limit the risk of contamination of compounded sterile products.

PROCEDURE

1 The goal of the buffer area has to be demonstrably (ISO Class 8) better than that of ambient air to reduce the risk of contaminants being blown, dragged, or otherwise introduced into the filtered unidirectional airflow environment.

2 Only non-permeable, non-shedding, and disinfectant-resistant furniture, equipment, supplies, and other goods required for the tasks to be performed may be brought into the buffer area. The furniture, equipment, supplies, and other goods will be first cleaned and sanitized outside the buffer area.

3 The buffer area contains neither sinks nor floor drains.
- a Work surfaces are smooth, impervious materials, such as stainless steel or molded plastic, which can be readily cleaned and sanitized.
- b Carts are constructed of non-porous material with good quality, cleanable casters to promote mobility.
- c Storage shelving, counters, and cabinets are smooth, impervious, free from cracks and crevices, and non-shedding, such that cleaning and sanitizing is complete.

4 Anteroom area
- a Supplies, such as needles, syringes, ampules, bags, vials and parenteral fluids, and packages of transfer tubing sets for large volume fluids are removed from their cartons and disinfected.
- b A demarcation line or barrier separates the compounding area from the remaining Inpatient Pharmacy area.

5 Environmental Monitoring
- a Air quality of the buffer area and anteroom is evaluated by a qualified operator(s) at least every six months as well as video of smoke studies in all ISO certified spaces.
- b. Additionally, air quality testing will be evaluated by a qualified operator(s) under the following conditions:
  - i. during commissioning and certification of new facilities and equipment.
  - ii. In response to any identified problems with end products or staff techniques.
  - iii. In response to issues with CSPs, observed work practices or patient-related

infections, where the CSP is being considered as a potential source of infection.

c. In-situ air pattern analysis via smoke studies will be conducted by a qualified operator(s) during dynamic conditions and kept on file.

d. Viable Air sampling
   i. Sampling will occur in each ISO Class 5 environment and segregated compounding areas at greatest risk of contamination. Locations include zones of air backwash turbulence.
   ii. Volumetric collection of 400-1000 liters are tested at each location, preferably by impaction, and performed by properly trained individuals adhering to manufacturer instructions for the verification and use of electric air samplers.
   iii. Sampling occurs at least every 6 months during periods of activity, as part of the re-certification of facilities and equipment for areas where PECs are located.
   iv. Use of a general microbiological growth medium such as TS or TSB to support the growth of bacteria. TSA should be incubated at 35° $\pm$ 2° for 2-3 days.
   v. Discrete colonies of microorganisms are counted and reported as colony-forming units (cfu) and documented on an environmental monitoring form. Counts are transformed into cfu/cubic meter of air and evaluated for adverse trends.
   vi. A cfu count that is >100 will prompt a re-evaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location. An investigation into the source of the contamination shall be conducted. The source of the problem shall be eliminated, the affected area cleaned, and resampling performed.
   vii. If trending of the samples consistently shows elevated levels of microbial growth, competent microbiology personnel shall be consulted.
   viii. Highly pathogenic microorganisms (e.g. Gram-negative rods, coagulase positive staphylococcus, molds, and yeasts) will be immediately remedied, regardless of cfu count, with the assistance of a competent microbiologist, infection control professional, or industrial hygienist.

e. Surface Sampling
   i. Surface sampling shall be performed in all ISO classified areas on a monthly basis.
   ii. Sampling shall be accomplished using contact plates filled with general

solid agar growth medium and neutralizing agents above the rim of the plate at the conclusion of compounding.

iii. Locations sampled shall be defined in a sample plan or on a form.

iv. The contact plate should gently touch the sample area with the agar surface and rolled across the surface to be sampled.

v. Immediately after sampling, the sampled area should be thoroughly wiped with a non-shedding wipe soaked in sterile 70% isopropyl alcohol.

vi. Results will be reported as cfu per unit of surface area.