CONNECTICUT DEPARTMENT OF CONSUMER PROTECTION

DRUG CONTROL DIVISION

Sterile Compounding Pharmacy Inspection

Please provide the following documents for inspection:

- ☐ 1. List of Pharmacists and Technicians that compound/enter clean room
- ☐ 2. Provide documentation for competency for the Pharmacist/technicians
- ☐ 3. List of all areas of sterile compounding within the hospital (i.e. cancer centers) or off site
- ☐ 4. Provide a copy of one year's worth of Certification Reports for each compounding area in the facility
  - ☐ a. Including certification of the Primary engineering controls (PEC)
  - ☐ b. Provide documentation of pre-filter changes for the PEC's
- ☐ 5. Provide documentation of last two Media Fill tests
  - ☐ a. Provide information on the kits used to administer Media fill tests
  - ☐ b. Incubation temperatures and length of incubation
- ☐ 6. Provide documentation of last two Gloved Fingertip tests
  - ☐ a. Provide information on the plates used to administer gloved fingertip tests
  - ☐ b. Certificates of Analysis, incubation temperatures and length of incubation
- ☐ 7. Provide Standard operating procedures (SOP) pertaining to the compounding rooms such as cleaning, gowning procedures and environmental testing
- ☐ 8. Provide the documentation for cleaning of PEC, buffer areas, and ante room—daily and monthly for the last year
  - ☐ a. If the cleaning is being done by Environmental services (ES), please provide the training documentation for the cleaners.
- ☐ 9. Please have a representative from ES available (in person or by phone) to provide information that may be needed
  - ☐ a. Provide a list of cleaning products used on the buffer/ante/PEC's/walls/ceilings including coverage of organisms and kill time

- ☐ 10. Provide the documentation for all the environmental monitoring done by the hospital for the compounding rooms
  - ☐ a. Provide information related to media utilized in the test
  - ☐ b. Provide information on air sampling device utilized by the facility
- ☐ 11. Provide Temperature log (all compounding areas)
  - ☐ a. Provide the range for max/min set up
- ☐ 12. Provide Humidity log (when monitored)
- ☐ 13. Provide Pressure log for Ante/Chemo/Buffer room (all compounding areas)
- ☐ 14. Provide documentation showing that the products used (for garbing and cleaning such as mops and wipes) are non-shedding or non-linting.
- ☐ 15. Information will be needed regarding HVAC systems specific to the compounding areas. Therefore a representative from facilities/building services available for information (in person or by phone)
  - ☐ a. Identify all the areas surrounding the compounding rooms including above and below.
  - ☐ b. Have knowledge of how the HVAC systems are set up i.e fully ducted, partial ducted, plenum based
  - ☐ c. Provide documentation of pre-filter changes to the HVAC system
- ☐ 16. Provide a list of the name and address of the facilities/outsource pharmacies the hospital purchases compounded product (i.e. chemotherapy, TPN)
- ☐ 17. Provide all work orders related to the compounding rooms for the past year
- ☐ 18. Provide a list of the standard beyond use dates (BUD) for LOW, MEDIUM and HIGH risk compounded products
- ☐ 19. If compounding high risk products, please provide all information on ACTIVE PHARMACEUTICAL INGREDIENTS (API), BUD used with supporting data, methods of sterilization, and other supporting documentation as required
- ☐ 20. If compounding high risk products, please prepare the documentation for the most recent lot of the two most compounded HIGH RISK products from API to distribution