

## **NVBOP Sterile Compounding Facility – Items required for Inspection**

### **All Sterile Compounding Facilities**

- SOP's for all Sterile Compounding processes.
- Copy of last EM inspection report from outside vendor. If any non-viable or viable results were above threshold then documentation of what steps were taken by facility along with retesting results must be available.
- SOP's for gowning and garbing.
- SOP's for cleaning and disinfection.
- Glove finger-tip testing results for last 12 months – any results above thresholds must have documentation of action taken.
- Media fill testing results for last 12 months – any results above thresholds must have documentation of action taken.
- Inspector may request to enter ISO-7 buffer room to observe sterile compounding process – Inspector may take photographs during this process.
- Inspector may request to enter ISO-7 buffer room to observe sterile compounding cleaning/disinfecting process. Inspector may take photographs during this process.
- Inspector may request to enter ISO-8 ante room to observe gowning/garbing process. Inspector may take photographs during this process.
- Cleaning logs for last 6 months.
- Pressure logs for last 6 months.
- List of compounding personnel and associated approved list level for sterile compounding.
- Initial training documentation for sterile compounding personnel.
- Annual training/competency documentation for sterile compounding personnel.
- Prior year's regulatory inspection form.
- Temperature monitoring logs for last 6 months.
- Sample compounding sheets.

### **High Risk Compounding Facilities**

- List of products with associated BUD's.
- Sterility, Potency, and Endotoxin results for all products with BUD's extended past USP 797 guidelines.
- Sterilization methods used – documentation of results

### **Hazardous Drug Compounding Facilities**

- SOP's for decontamination for HD areas.
- List of compounding personnel approved to perform Hazardous Drug compounding.
- Signed informed consent for personnel performing Hazardous drug compounding (signed annually.)

This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.