NVBOP – High Risk Sterile Compounding Sterility, Potency, and Endotoxin Requirements

- Sterility, potency, and endotoxin testing is required for all high risk products that are assigned a BUD in excess of USP 797 published guidelines.
- Sterility and endotoxin testing is required for all high risk sterile products for injection that are either:
    - Compounded in groups of more than 25 identical individual single dose packages.
    - Compounded in multiple-dose vials for administration to multiple patients.
    - Exposed >12 hours prior to sterilization at temperatures between 2-8 C.
    - Exposed >6 hours prior to sterilization at temperatures > 8 C.
- Sterility testing is required for all high risk products for inhalation or ophthalmic use that meet the same requirements listed above.
- If any high-risk sterile compounded drug product tested pursuant to this section tests positive for antimicrobial growth or endotoxin production, the high-risk sterile compounded drug product must not be administered or dispensed to a patient.

Sterilization Methods:

- **Bubble Point Testing – see specific reference related to bubble point testing procedure**
- **Autoclave (Steam)**
- **Dry Heat**

Autoclave

- Each high risk sterile compounded drug product shall be subjected to steam at 121 degrees celcius under a pressure of 15 pounds per square inch for the duration of the sterilization process.
- Before starting the sterilization process, ensure that plastic, glass and metal devices are wrapped in low particle shedding paper or fabric or sealed in envelopes that prevent microbial penetration after the sterilization of the high-risk sterile compounded drug products is completed.
- Ensure that the solutions that will be used to fill the vials which will be steam sterilized are passed through a filter having a porosity of not more than 1.2 microns to remove particulate matter immediately before filling those vials.
- The effectiveness of steam sterilization shall be verified using appropriate biological indicators. The results of the biological indicators shall be documented.
- Temperature mapping should be completed to identify hot/cold spots.

Dry Heat

- The heated air is filtered and evenly distributed by a blower throughout the chamber or oven used for the sterilization process.
- The chamber or oven used for the sterilization process is equipped with accurate temperature controls and a timer.
- A pharmacy may only use dry heat as a method of sterilization for a high-risk sterile compounded drug product if the final high-risk sterile compounded drug product would be damaged by moisture or is impermeable to moisture. Normally used for oils.
- The effectiveness of dry heat sterilization shall be verified using appropriate biological indicators. The results of the biological indicators shall be documented.

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.