NVBOP Sterile Compounding Inspector Checklist

All Sterile Compounding Facilities

- Equipment certified (Incubator, Dry Oven, Weights, Autoclave, etc…).
- Facility using sterile gloves for all sterile compounding.
- Review initial and ongoing glove finger-tip testing process and results. Check to make sure that plates are stored Agar side up so condensation doesn't drip and cause false positives). Results should be reported as total number of CFU's for both hands.
- Review initial and ongoing Media Fill testing process and results.
- Watch gowning process and compare to best practice and facility SOP.
- Review list of compounding personnel and risk level approved including HD compounding personnel. Review initial and annual training documents.
- Review environmental certification report. Confirm that certifier has CETA certification and NSF is performing hazardous certification. Confirm that HEPA leak testing has been performed. Review ACPH (30 in buffer area with 15 from outside air, 20 ACPH in ante-room). Review non-viable and viable results. Any items above threshold should have documentation.
- Review cleaning and disinfectant agents and documentation. Watch cleaning process and compare to best practice and facility SOP. Review cleaning vs disinfectant agent and review dwell time for sporicidal agent. Cleaning agent must have surfactant. Recommended to use sporicidal agent at a minimum of every 30 days. No need to rotate cleaning agents. 70% sterile IPA is NOT a cleaning agent. Bleach is not a cleaning agent and does not have a surfactant. Germicidal agent should be used to clean all surfaces. Sterile IPA is only needed in ISO 5 environment. Review cleaning order (top to bottom, back to front, items left on deck, deck). Daily cleaning should be done at the end of the day. Clean from cleanest to dirtiest.
- Review pressure log for buffer and ante rooms. Minimum pressure for positive pressure room should be 0.02 – 0.05. Minimum negative pressure for negative pressure room should be 0.01.
- Does facility have clock in ante/buffer room. If not how are they calculating time needed for handwashing and dwell time for cleaning agents.
- Does facility have mirror in ante room. If not how are they checking to make sure that they are garbed appropriately.
- Eye wash station located in ante room. If using eye wash solution is product in date.
- CAI/CACI sleeves should be changed every 6 months (best practice recommendation).
- CAI – BUD's – currently CAI allows for full USP 797 BUD. Proposed USP 797 guidelines will only allow for 12 hours BUD unless CAI is in ISO 7 buffer room.
- CAI – Full garb shall be worn per USP 797 guidelines.
- PEC's – No requirement to record magnahelic gauge pressures located on hoods. These are used by certification personnel during semi-annual verification.
- PEC's – Pre-filters should be changed every 12 months.
- Sink should be located on clean side of ante room.

- Segregated compounding area – low risk level CSP with 12 hour BUD with LAFW. May use full BUD with CAI.
- If facility has pass thru then surface sampling should be performed in the pass thru every 6 months.
- Review process for wiping down products coming into buffer area. Products should be wiped down prior to entering ISO 7 area and also prior to entering ISO 5 area.
- Every Isolator must have cleaning tool. If no tool available ask them to show you how they clean the back portion of the hood. Tools should be stored in the PEC.
- Sticky mats should only be stored in unclassified areas. NO sticky mats in the Ante Room.
- Immediate use products – Administration begins within 1 hour from time of compounding.
- Transfer devices are NOT considered compounding per USP 797 guidelines (i.e Advantage).
- There is no requirement for a line of demarcation in the ante room per USP 797

Hazardous Drug Compounding Facilities

- Informed consent signed by all HD compounding personnel annually
- ISO 5 HD PEC vented to outside of facility.
- Hazardous products stored separately from other inventory.
- 2 pair of sterile chemo gloves worn during HD compounding.
- Hazardous Drug compounding facilities – are they using CSTD's for compounding (best practice.)
- Hazardous Drug compounding facilities – Chemo spill kit located near compounding area.

High Risk Compounding Facilities

- Review product list for high risk compounding facilities including assigned BUD.
- Method suitability is required anytime sterility testing is required for 503A facilities.
- Sterility/Endotoxin testing must be performed if batch >25, BUD beyond 797 guidelines, or if the product is exposed >12 hours to temp of 2-8 C or > 6 hours to temp of > 8 C before they are sterilized, multiple dose containers meant to be administered to multiple patients.
- Review recall procedure for any high risk compounding facilities.
- Sterility testing must be for at least 14 days for high risk compounding facilities.
- Review sterility, endotoxin, and potency testing results for all high risk products with assigned BUD's in excess of USP 797.
- Review bubble point testing results and process for high risk compounding facilities if applicable. Actual pressure should be documented as opposed to only pass/fail.
- Review autoclave testing results and process for high risk compounding facilities if applicable including biological indicators.
- Review dry oven testing results and process for high risk compounding facilities if applicable.

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