KENTUCKY BOARD OF PHARMACY
STATE OFFICE BUILDING ANNEX, STE 300
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FRANKFORT KY 40601
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Revised 2/2016

STERILE COMPOUNDING

Pharmacy:_____ **Permit:**_____ **Date of Inspection:**_____

Street Address:_____ **City**:_____ **State:**_____

COMPOUNDING PERSONNEL

NAME	PHARMACIST	TECHNICIAN
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		

COMPOUNDING AMOUNTS

TYPE	%/total per day	Hazardous %/per day	Controlled Substances %/per day	Veterinary %/per day
LOW				
MEDIUM				
HIGH				
12 HOUR				
IMMEDIATE USE				

HOODS

LOCATION	MANUFACTURER	SERIAL NUMBER
1.		
2.		
3.		
4.		
5.		

PRODUCTS INSPECTED

NAME/STRENGTH	QUANTITY	LABELED	BUD
1.			
2.			
3.			
4.			
5.			

LIST OF STATES

STATE	PERMITTED IN	SHIP TO	INSPECTED BY
1.			
2.			
3.			
4.			
5.			

Inspected by FDA, if yes, please list date and results of inspection:

Accredited by an organization, if yes, please list and date of last survey:

Inspected by another state or entity, if yes, please list state/entity and date of inspection:

Does pharmacy receive CSP from another entity, if yes, who and what:

Does the pharmacy provide CSP to another entity, if yes, who and what:

Black – Required **Red –** Best Practice

POLICIES AND PROCEDURES	COMPLIANT	NON COMPLIANT	N/A	NOT INSPECTED
Reference Material *[201 KAR 2:076 Reference Material]*				
Investigational Drug Protocol *[201 KAR 2:076 Investigation Drug Protocol]*				
Compounding Personnel Education and Assessment *[Elements of Quality Control* and *201 KAR 2:076 Duties and Qualifications for Staff]*				
Personnel Cleansing and Garbing *[Personnel Cleansing and Garbing and 201 KAR 2:076 Sanitation]*				
Cleaning and Disinfecting Compounding Area *[Cleaning and Disinfecting the Compounding Area* and *201 KAR 2:076 Sanitation]*				
Operation of Isolators *[Placement of Primary Engineering Controls* and *201 KAR 2:076 Quality Assurance to include Hood Maintenance and Certification]*				
Compounding Procedures for In-Process Checks and Final Product Verification *[Responsibility of Compounding Personnel* and *201 KAR 2:076 Drug Dispensing]*				
Ingredient Inspection and Assessment *[Sterile Ingredients and Devices* and *Nonsterile Ingredients and Devices* and *201 KAR 2:076 Drug Dispensing and Recordkeeping]*				
Checks for Compounding Accuracy and Recordkeeping of Compounding Log *[Compounding Accuracy Checks* and *201 KAR 2:076 Recordkeeping]*				
Physical Inspection of CSPs *[Physical Inspection* and *201 KAR 2:076 Drug Dispensing]*				
Final Check of CSPs Including Labeling *[Identity and Strength Verification of Ingredients* and *201 KAR 2:076 Drug Labeling and Drug Dispensing]*				
Maintenance and Assessment of Compounding Equipment *[Equipment* and *201 KAR 2:076 Equipment]*				
Assignment of BUDs *[Determining Beyond-Use Dates* and *201 KAR 2:076]*				
Monitoring of Storage Areas *[Monitoring Controlled Storage Areas* and *201 KAR 2:076]*				
Packaging, Handling, Security, Storage, Disposal, Destruction, Transport and Return of CSPs and Supplies *[Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs* and *201 KAR 2:076 Disposal of Unused Supplies and Medication and Drug Destruction and Return]*				
Quality Assurance Program *[Quality Assurance (QA) Program* and *201 KAR 2:076 Quality Assurance]*				
Adverse Events Reporting and Monitoring *[Patient Monitoring and Adverse Events Reporting* and *201 KAR 2:076 Safety]*				
Hazardous and Oncology Drug Handling and Disposal *[Hazardous Drugs as CSPs* and *201 KAR 2:076 Oncology Drugs]*				
Sterilization by Steam *[Sterilization of High-Risk Level CSPs by Steam* and *201 KAR 2:076 Quality Assurance to include Sterile Testing]*				

POLICIES AND PROCEDURES continued	**COMPLIANT**	**NON COMPLIANT**	**N/A**	**NOT INSPECTED**
Sterilization by Dry Heat *[Sterilization of High-Risk Level CSPs by Dry Heat* and *201 KAR 2:076 Quality Assurance to include Sterile Testing]*				
Depyrogenation by Dry Heat *[Depyrogenation by Dry Heat* and *201 KAR 2:076 Quality Assurance to include Sterile Testing]*				
Monitoring of CSPs Dispensed Prior to Sterility Results, including Recall Procedures *[Sterility Testing* and *201 KAR 2:076 Quality Assurance to include Recall Procedure]*				
P&P reviewed and revised annually *[201 KAR2:076 Section 1]*				
COMMENTS:				

TRAINING AND GARBING **[Review 5 employees]**	**COMPLIANT**	**NON COMPLIANT**	**N/A**	**NOT INSPECTED**
Documentation all compounding personnel passed initial and annual/semi-annual written exam for appropriate risk level for: 1. Cleaning and Disinfecting 2. Hand Hygiene and Garbing 3. Aseptic Technique *[Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures]*				
Visually observed and appropriately documented competencies of: 1. Cleaning and disinfecting, initially and at the completion of media fill test, and including environmental services, if applicable and when appropriate 2. Hand hygiene and garbing, initially and whenever aseptic media fill is performed A. Initial gloved fingertip sampling with zero growth B. Annual/semiannual gloved fingertip sampling with up to 3 total CFU, done upon completion of media fill test 3. Aseptic technique, initially and annually/semi-annually for appropriate risk level under most challenging conditions *[Cleaning and Disinfecting Competency Evaluation* and *COMPETENCY EVALUATION OF GARBING AND ASPTIC WORK PRACTICE]*				
Training of any equipment used. *[Equipment]*				
Documentation of immediate reinstruction, reevaluation and retesting of compounding personnel who fail any testing. *[Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices,* and *Cleaning/Disinfection Procedure]*				
Written policy personnel cannot compound if have sunburn, illness, open sores, etc. *[Personnel Cleansing and Garbing]*				
Personnel remove outer garments, make-up, visible jewelry (hand, wrist, ears, lips, eyebrow piercings). *[Personnel Cleansing and Garbing]*				
Personnel keep nails short and natural. *[Personnel Cleansing and Garbing]*				
COMMENTS:				

GARBING *[Personnel Cleansing and Garbing]*	**COMPLIANT**	**NON COMPLIANT**	**N/A**	**NOT INSPECTED**
Garb from dirtiest to cleanest, with appropriate hand washing.				
Use waterless, alcohol based surgical scrub with persistent activity. Has chlorhexidine/emollients: Purell Surgical Scrub; Avagard, Sterillium, Surgicept, Triseptin, Alcare				
Sterile gloves donned appropriately.				
Dispose of gown when leave compounding area or reuse for one shift (nonhazardous).				
Non-garbed personnel are not entering compounding area.				
COMMENTS:				

ENVIRONMENT: **BUFFER AND ANTE ROOMS**	**COMPLIANT**	**NON COMPLIANT**	**N/A**	**NOT INSPECTED**
Physical: floor, walls, ceiling smooth, impervious, free from cracks and crevices, seams heat sealed and non-shedding equipment. Ceiling tiles are sealed and walls are appropriate material. *[Facility Design and Environmental Controls]*				
Limited entry to necessary personnel. *[ISO Class 5 Air Sources, Buffer Areas, and Ante- Areas]*				
Accessories: shelving, chairs, stools, carts easily cleanable and non-permeable, free from cracks and crevices, low particulate generating and limited to necessary equipment in ante and buffer rooms. *[Facility Design and Environmental Controls]*				
All items cleaned and disinfected before bringing into buffer room. *[Facility Design and Environmental Controls]*				
Ante Room has a sink with hot and cold water and hands dried with lint free non-shedding, disposable paper towels or blow dryer. *[Additional Personnel Requirements]*				
Buffer Room has no sink, drain or water source. *[Facility Design and Environmental Controls]*				
Proper utilization of line of demarcation (LOD). *[Additional Personnel Requirements]*				
HEPA Filters must be on air ducts in the ceiling of ante and buffer rooms. *[Facility Design and Environmental Controls]*				
Food, drinks, gum prohibited in compounding area. *[Additional Personnel Requirements]*				
If LAFW Blower turned off, must run for 30 minutes before using. *[Suggested Standard Operating Procedures (SOPs)]*				
If no physical barrier between the buffer and ante room: 1. Can only perform low and medium risk compounding 2. Air velocity must be at least 40 feet/minute continuously from buffer area across LOD into ante area 3. Air velocity recorded every shift, a minimum of daily *[Facility Design and Environmental Controls]*				

ENVIRONMENT: **BUFFER AND ANTE ROOMS continued**	**COMPLIANT**	**NON COMPLIANT**	**N/A**	**NOT INSPECTED**
Pressure *[Pressure Differential Monitoring]* 1. Recorded each shift, a minimum of daily 2. Ante room is positive pressure of at least 0.02 inch water column to general pharmacy 3. Buffer room is positive pressure of at least 0.02 inch water column to ante room				
Temperature *[Monitoring Controlled Storage Areas]* 1. Recorded daily: A. Buffer room (68 F or below) B. Controlled storage areas for room (68 to 77 F or 20 to 25 C) C. Controlled storage areas for cold (36 to 46 F or 2 to 8 C) D. Controlled storage areas for freezer (-13 to 14 F or -25 to -10 C)				
COMMENTS:				

CLEANING *[Cleaning and Disinfecting the Compounding Area]*	**COMPLIANT**	**NON COMPLIANT**	**N/A**	**NOT INSPECTED**
Personnel appropriately garbed when cleaning. *[Personnel Training and Competency Evaluation Of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedure]*				
Cleaning and disinfecting agent (may be one step cleaning and disinfecting) appropriate for bacteria, viruses, fungi.				
Cleaning equipment is non-shedding, disposable or dedicated.				
Daily cleaning of compound area takes place when no compounding is occurring and includes easily cleanable surfaces and floor.				
Monthly cleaning of compound area takes place when no compounding is occurring and includes everything in compound area – bins, equipment, ceiling, walls and floor.				
Cleaning ISO Class 5 PEC, using non-linting towels: 1. Documented daily/shift cleaning with germicidal detergent diluted with sterile water, if necessary, followed by disinfectant 2. Disinfected between compounding activities, as needed 3. Disinfected every 30 minutes during continuous compounding 4. Cleaned with sterile water followed by disinfectant after spills or surface contamination				
70% sIPA allowed to remain in contact with surface for 30 seconds before compounding.				
PEC cleaning order: 1. Top 2. Back 3. Sides 4. Racks/poles 5. Items on the deck 6. Deck				

COMMENTS:				
ENVIRONMENTAL MONITORING: **CERTIFICATION OF COMPOUNDING AREAS AND PRIMARY ENGINEERING CONTROLS (PECs)**	**COMPLIANT**	**NON COMPLIANT**	**N/A**	**NOT INSPECTED**
All ISO Class 5 PEC and ISO Class 7 and/or ISO Class 8 rooms have been certified as required. *[Viable and Nonviable Environmental Sampling (ES) Testing]*				
Review report from outside agency: DATE: CERTIFIER:				
Certification done to CETA guidelines CAG-003-2006, or similar. *[Engineering Control Performance Verification]*				
Certifier's equipment calibrated to manufacturer standards. *[Air Sampling Devices]*				
HEPA Filtered Air *[Facility Design and Environmental Controls]* Ante room has HEPA filtered air certified to ISO Class 8 for non-hazardous compounding.				
Ante room has HEPA filtered air certified to ISO Class 7 for hazardous compounding. *[Facility Design and Environmental Controls and Hazardous Drugs as CSPs]*				
Buffer room has HEPA filtered air certified to ISO Class 7.				
Air Changes Per Hour (ACPH) *[Facility Design and Environmental Controls]* ISO Class 7 ante room, minimum of 30 ACPH. ACPH:				
ISO Class 8 ante room, recommended 20 ACPH. ACPH:				
ISO Class 7 non-hazardous buffer room, minimum of 30 ACPH with at least 15 from outside source. ACPH:				
ISO Class 7 hazardous buffer room, minimum of 30 ACPH. ACPH: *[Facility Design and Environmental Controls and Hazardous Drugs as CSPs]*				
Smoke test performed in PEC in direct compounding area to demonstrate unidirectional airflow under dynamic conditions.				
Pressure *[Pressure Differential Monitoring]* Differential pressure measured to be at least positive 0.02 inch water column from ante room to general pharmacy with door closed.				
Differential pressure measured to be at least positive 0.02 inch water column from buffer room to ante room with door closed.				
Differential pressure measured to be at least negative 0.01 inch water column from buffer room to positive pressure ISO 7 ante room with door closed. *[Hazardous Drugs as CSPs]*				
If no physical separation of ante and buffer room, displacement airflow measured requiring air velocity of 40 feet/minute or more from buffer area across LOD into ante room.				
Particle Counts *[Environmental Nonviable Particle Testing Program* and *Facility Design and Environmental Control]* ISO Class 5 areas not more than 3,520 particles per cubic meter of air, taken under dynamic conditions.				
ISO Class 7 areas not more than 352,000 particles per cubic meter of air, taken under dynamic conditions.				
ISO Class 8 areas not more than 3,520,000 particles per cubic meter of air, taken under dynamic conditions.				
HEPA Filters *[Facility Design and Environmental Controls]* Room HEPA filters leak tested and repaired if needed.				
Hood HEPA filters leaks tested and repaired if needed.				
Hood air flow velocity measured.				

ENVIRONMENTAL MONITORING: **CERTIFICATION OF COMPOUNDING AREAS AND PECs continued**	**COMPLIANT**	**NON COMPLIANT**	**N/A**	**NOT INSPECTED**
Viable Air and Surface Sampling Documentation of viable air and surface sampling shall include: 1. Date and time of sampling 2. Sample locations 3. Method of collection 4. Frequency of sampling 5. Volume of air sampled (for viable air) 6. Time of day, in relationship to compounding 7. Action levels *[Sampling Plan]*				
Viable air sampling performed using active impaction device with appropriate growth media to support bacteria and for high risk compounding fungus, at least every 6 months in all ISO classified areas using 400 – 1000 L of air per sample. *[Air Sampling Frequency and Process]*				
Viable air microbial action levels: 1. **1000 L:** ISO Class 5 > 1 Colony Forming Unit (CFU)/m3 or **400 L**: >1 CFU/m3 2. **1000 L**: ISO Class 7 > 10 CFU/m3 or **400 L** > 4 CFU/m3 3. **1000** L: ISO Class 8 > 100 CFU/m3 or **400 L:** > 40 CFU/m3 *[Action levels, Documentation, And Data Evaluation]*				
Viable surface sampling performed periodically on direct compounding areas, buffer and ante rooms, pass thru and surfaces likely to be contaminated, as applicable, using media supplemented with neutralizing effects of disinfecting agents (TSA with lecithin & Polysorbate 80) and done at the conclusion of compounding. *[Surface Cleaning And Disinfection Sampling and Assessment]*				
Surface microbial action levels: 1. ISO Class 5, less than 3 CFU/m3 2. ISO Class 7, less than 5 CFU/m3 3. ISO Class 8, less than 100 CFU/m3 *[Surface Cleaning and Disinfection Sampling and Assessment]*				
All CFUs analyzed down to the genus with mold, yeast, coagulase positive Staph, gram negative rods requiring immediate Investigation. *[Action Levels, Documentation and Data Evaluation]*				
Exceeded action levels should prompt a re-evaluation of adequacy of personnel work practices, cleaning, operational procedures and/or air efficiency and require an investigation into the source of contamination. *[Action Levels, Documentation, and Data Evaluation]*				
COMMENTS:				

COMPOUNDING PROCEDURES	**COMPLIANT**	**NON COMPLIANT**	**N/A**	**NOT INSPECTED**
Documentation of equipment maintenance and calibration logs. *[Equipment]*				
Objects that shed prohibited from buffer room or compounding area of CAI/CACI: pencils, cardboard, paper towels, cotton gauze pads. *[Facility Design and Environmental Controls]*				
Essential paper products (syringe overwrap, work records in protective plastic sleeves) are wiped down with 70% sIPA in ante room before bringing into buffer room or before placing in the ante chamber of CAI/CACI. *[Suggested Standard Operating Procedures (SOPs)]*				
Required supplies wiped down with 70% sIPA (or removing outer wrap) as item introduced into aseptic work space. *[Additional Personnel Requirements]*				
Syringes, needles, tubing opened only In ISO Class 5 PEC. *[Cleaning and Disinfecting the Compounding Area]*				
Personnel use correct aseptic technique, compounding in first air. *[Facility Design and Environmental Controls]*				
Personnel routinely inspecting sterile gloves for wear and tear and replace as necessary. *[Personnel Cleansing and Garbing]*				
Personnel routinely disinfecting sterile gloves with 70% sIPA prior to entering and when re- entering ISO Class 5 area and touching non-sterile objects. *[Personnel Cleansing and Garbing]*				
Personnel ascertain CSP ingredients are correct by looking at label and doing unit by unit inspection of product before using. [*Ingredients and Devices]*				
Rubber stoppers of vials/bottles and ampules disinfected with 70% sIPA prior to introducing needle/breaking ampule, waiting 10 seconds for 70% sIPA to dry. *[Cleaning and Disinfecting the Compounding Area]*				
Contents thoroughly mixed and inspected for particulate matter, incompatibility or other issues. *[Inspection of Solution Dosage Forms* and *Review of Compounding Procedures]*				
Before dispensing CSP, clarity is visually confirmed. Identity and amounts of ingredients, procedures to prepare, sterilize, and specific release criteria are reviewed to assure accuracy and completeness. *[Inspection of Solution Dosage Forms* and *Review of Compounding Procedures]*				
Single and Multiple Use Vials (MDV) *[Single-Dose and Multiple-Dose Containers]* Opened single dose ampules must be discarded immediately.				
Single dose containers opened in worse than ISO Class 5 used within 1 hour then discarded, with time first used/discard time documented on container.				
Single dose containers opened in ISO Class 5 used within 6 hours then discarded, with time first used/discard time documented on container.				
MDV used for 28 days, or as specified by manufacturer, once punctured, with date first used/discard date documented on MDV.				
Compound Record – Required Documentation, may be a log, may be computerized, may be retained label Compound record is required				
Procedure for in-process checks Appropriate procedures and packaging followed for each step. *[Inspection of Solution Dosage Forms* and *Review of Compounding Procedures]*				
Pharmacist verification of steps performed by technicians by visual inspection. *[Compounding Accuracy Checks]*				

COMPOUNDING PROCEDURES continued	**COMPLIANT**	**NON COMPLIANT**	**N/A**	**NOT INSPECTED**
Documentation of compounding accuracy by 2nd person in addition to compounder if more than one person is compounding, to ensure proper measurement, reconstitution, component usage. *[Compounding Accuracy Checks]*				
Batch Labels Name and quantity of each component				
Date and time preparation compounded (may be internal reference number)				
Verifying pharmacist identifier				
BUD – cannot use exp/expiration. May use Use Before/Discard After/Administer By, etc				
Auxiliary labels, ie packaging and labeling of hazardous CSP				
Patient Specific Labels Standard label requirements				
Verifying pharmacist identifier				
BUD – cannot use exp/expiration. May use Use Before/Discard After/Administer by, etc				
Flow rate, if applicable				
Auxiliary labels, ie packaging & labeling of hazardous CSP				
Beyond Use Dates (BUDs) If Not Sterility Testing Low: Room temp: 48 hours Frig: 14 days Frozen: 45 days *[Low-Risk Level CSPs]*				
Medium: Room temp: 30 hours Frig: 9 days Frozen: 45 days *[Medium-Risk Level CSPs]*				
High: Room temp: 24 hours Frig: 3 days Frozen: 45 days *[High-Risk Level CSPs]*				
Sterility test required for: 1. Extending BUD beyond USP 2. High risk CSP prepared in groups or more than 25 single-dose units or in MDV for administration to multiple people 3. High risk CSP that are exposed longer than 12 hour at 2-8 C/36-46 F and longer than 6 hours at warmer than 8 C/46 F before being sterilized *[CSP Microbial Contamination Risk Levels]*				
Redispensing CSPs: If redispense CSPs, must ensure sterility, purity and stability of CSP and BUD cannot be changed unless retested. *[Redispensed CSPs]*				
Finish Check Check for container and closure integrity, done after compounding and if stored, before dispensing. *[Physical Inspection]*				

COMPOUNDING PROCEDURES continued	**COMPLIANT**	**NON COMPLIANT**	**N/A**	**NOT INSPECTED**
Compounding accuracy documented by verification of steps. *[Compounding Accuracy Checks]*				
Verification of identity and quantity verified by reconciliation of components. *[Compounding Accuracy Checks]*				
Labels verified as being correct. *[Compounding Accuracy Checks]*				
COMMENTS:				

CONTINUOUS QUALITY IMPROVEMENT (CQI)/QUALITY ASSURANCE (QA)/QUALITY IMPROVEMENT(QI) *[Quality Assurance (QA) Program]*	**COMPLIANT**	**NON COMPLIANT**	**N/A**	**NOT INSPECTED**
Summarize Program: Share data with staff - How often? _____				
Track and trend data.				
Track complaints from patients and practitioners.				
Characteristics of Program: Formalized in writing.				
Consideration of all aspects of preparation and dispensing including environmental testing and verification of results.				
Description of specific monitoring and evaluation activities.				
Specification of how results are to be reported and evaluated.				
Identification of appropriate follow-up mechanisms when action limits or thresholds are exceeded.				
Delineation of the individuals responsible for each aspect of the program.				
COMMENTS:				

STERILE COMPOUNDING OF HAZARDOUS DRUGS (HD) AS OF 01/2016 *[Hazardous Drugs As CSPs]*	**COMPLIANT**	**NON COMPLIANT**	**N/A**	**NOT INSPECTED**
TRAINING Personnel who handle, dispose or compound HD are trained and competency is assessed prior to handling HD and annually thereafter. Training shall be a didactic overview and verified by testing specific HD preparation techniques.				
Personnel who compound HD shall be trained in: 1. Storage, handling and disposal 2. Safe aseptic manipulation practices 3. Negative pressure techniques when utilizing BSC or CACI 4. Correct use of Closed-System Transfer Device (CSTD), if applicable 5. Containment, cleanup and disposal for breakages and spills 6. Treatment of personnel contact and inhalation exposure				
Written confirmation by all compounding personnel of reproductive capability that they understand the risks of handling HD.				
GOWNING AND GLOVING WITH PERSONAL PROTECTIVE EQUIPMENT (PPE) HD are handled with caution at all times using chemo rated gloves during receiving, distributing, stocking, inventorying, preparing for administration, and disposal.				
Personnel compounding equipment (PPE) includes: 1. Gowns, low permeability like polyethylene 2. face masks, 3. eye protection, as appropriate, 4. hair covers, 5. shoe covers or dedicated shoes, and 6. Double gloving with chemo rated gloves				
ENVIRONMENT HD CSP are compounded in a BSC or CACI.				
BSC or CACI is located inside an ISO Class 7 area that is physically separate from other areas and is negative pressure of 0.01 inch water column to adjacent positive pressure ISO Class 7 ante room.				
Documentation from CACI manufacturer that the ISO Class 5 environment is maintained under dynamic conditions when not located in an ISO Class 7 environment but must be in a negative pressure room with at least 12 ACPH (exemption for low volume).				
For low volume, defined by KBOP as 5 compounds/ 2 week period, may use 2 levels of containment.				
Documentation from manufacturer of recovery time to achieve ISO Class 5 air quality of CACI when turn off /on and when transferring material from ante chamber to main chamber before and during compounding. *[Placement of Primary Engineering Controls]*				
CACI located in low traffic area. *[Placement of Primary Engineering Controls]*				
For CACI, pressures recorded each shift, minimum of daily. Main chamber is negative 0.01 inch water column to ante chamber and ante chamber is at least positive 0.02 inch water column to general pharmacy. *[Pressure Differential Monitoring]*				
Daily/each shift documented cleaning of PEC, in the following order: 1. Top of BSC/CACI 2. Back of BSC/CACI 3. Sides of BSC/CACI 4. Rack/pole in the BSC/CACI 5. Front inside of shield of BSC or front inside of CACI 6. Gauntlets in CACI 7. Items on the deck 8. Deck 9. Ante chamber in same order in CACI				

STERILE COMPOUNDING OF HAZARDOUS DRUGS (HD) AS OF 01/2016 continued *[Hazardous Drugs as CSPs]*	**COMPLIANT**	**NON COMPLIANT**	**N/A**	**NOT INSPECTED**
HD shall be stored separately from other inventory				
HD disposed of in a manner that complies with all Federal and State laws				
COMMENTS:				

12 HOUR BUD, IMMEDIATE USE, and CAI NOT IN ISO CLASS 7	**COMPLIANT**	**NON COMPLIANT**	**N/A**	**NOT INSPECTED**
12 BUD – ISO Class 5 LAFW outside ISO Class 7 Room *[Low-Risk Level CSPs with 12-Hour or Less BUD]* Compounded in an ISO Class 5 LAFW not located in ISO Class 7 room.				
Low risk, non-hazardous, patient specific CSP.				
BUD 12 hours or less, administration begins no later than 12 hours from beginning of compounding.				
Personnel gowns and garbs the same as for a clean room.				
Cleaning of ISO Class 5 LAWF is the same as for an ISO Class 5 LAWF in clean room.				
ISO Class 5 LAWF is segregated compounding area, not near garbage can, sink, window, door.				
IMMEDIATE USE – Emergency Use *[Immediate-Use CSPs]* Compounding does not take place in ISO Class 5 PEC.				
Low risk, non-hazardous CSP.				
Compounding procedure is continuous not exceeding 1 hour & administration begins no later than 1 hour from start of compounding, if not CSP is discarded.				
During compounding, aseptic technique is followed and if not immediately administered the CSP is under continuous supervision to minimize contact with non-sterile items.				
CSP is immediately and completely administered by compounder or witnessed by compounder, if not must be labeled with 1. Patient identifier 2. Names and amounts of ALL ingredients 3. Name/initials of compounder 4. Exact 1-hour BUD and time				
CAI NOT LOCATED IN ISO Class 7 ENVIRONMENT *[Placement of Primary Engineering Controls]* Documentation from CAI manufacturer the ISO Class 5 environment is maintained under dynamic conditions when not located in an ISO Class 7 environment.				
Documentation from CAI manufacturer of recovery time to achieve ISO Class 5 air quality when turn off and on and when transferring material from ante chamber to main chamber before and during compounding.				
CAI located in low traffic area.				
Documentation from CAI manufacturer compounder Is exempt from garbing.				
CAI Pressures documented each shift, minimum of daily. Main chamber at least positive 0.02 inch water column to ante chamber and ante chamber at least positive 0.02 inch water column to general pharmacy.				

12 HOUR BUD, IMMEDIATE USE, and CAI NOT IN ISO CLASS 7 continued	COMPLIANT	NON COMPLIANT	N/A	NOT INSPECTED
Daily/shift documented cleaning of CAI, in the following order: 1. Top 2. Back 3. Sides 4. Rack/pole 5. Inside front 6. Gauntlets and any gloves that are reused 7. Items on the deck 8. Deck 9. Ante chamber in same order				
COMMENTS:				

HIGH RISK	COMPLIANT	NON COMPLIANT	N/A	NOT INSPECTED
Active Pharmaceutical Ingredient (API) *[Nonsterile Ingredients and Devices]* Certificate of Analysis on file.				
Use USP or NF product and if not, safety and purity established.				
Label bears batch or lot number.				
Label bears expiration date, if not, an expiration date of no more than 1 year from date of receiving is assigned.				
Pharmacy marks API with date received.				
If pharmacy puts API in smaller container for ease of use, container bears: 1. Name 2. Date API received 3. Date API transferred 4. Batch or lot number 5. Expiration date from manufacturer or pharmacy assigned expiration date of no more than 1 year from date of receiving 6. Name, date API received,				
APIs stored in tightly closed containers under temperature, humidity and lighting conditions per official monograph or suppliers.				
STERILIZATION *[Sterilization Methods]* Pre-sterilization procedures for high risk CSP, weighing and mixing, shall be completed in no worse than ISO Class 8 environment.				
Appropriate sterilization methods used and documented.				
Terminal sterilization of non-sterile empty vials or stoppers/closures used and documented.				
FILTER STERILIZATION [*Sterilization of High-Risk Level CSPs by Filtration]* Pre-filter with 1.2 micron to remove large particles, if needed.				
Filtration performed in ISO Class 5 environment. *[High-risk Level CSPs 367]*				
Documentation 0.2/ 0.22 micron sterile, non-pyrogenic microporous membrane filter is chemically/physically compatible with CSP.				

HIGH RISK continued	**COMPLIANT**	**NON COMPLIANT**	**N/A**	**NOT INSPECTED**
Filtration is completed rapidly without filter replacement.				
Filter integrity testing is performed for each filter used with each batch sterilized by filtration.				
STEAM STERILIZATION (AUTOCLAVE) *[Sterilization of High-Risk Level CSPs by Steam]* Solutions are passed thru 1.2 micron or smaller filter into final containers to remove particulate before sterilization, if needed.				
Written documentation of description of steam sterilization includes conditions and duration for specific CSP.				
Prior to sterilizing, plastic, glass and metal devices are tightly wrapped in low particle shedding paper or fabric or sealed in envelopes that prevent post-sterilization microbial penetration.				
Autoclave allowed to reach 121 C before starting sterilization process.				
Usual expose to 121 C at 15 psi for 20 – 60 minutes. Maintains log of temperature and exposure time for each steam sterilized CSP.				
Ensures steam contacts all ingredients and surfaces to be sterilized.				
Autoclave was mapped.				
Effectiveness of steam sterilization is verified each time using biological indicators (BI) and temperature-sensing devices.				
DRY HEAT STERILIZATION (IE OIL BASED HORMONES) *[Sterilization of High-Risk Level CSPs by Dry Heat]* Heat filtered air is evenly distributed throughout chamber with a blower.				
Dry heat oven is equipped with system for controlling temperature and exposure period and has been mapped.				
Sufficient space is left between materials to allow circulation of hot air.				
Written documentation of description of dry heat includes conditions and duration for specific CSP.				
Effectiveness of dry heat sterilization is verified each time using biological indicators (BI) and temperature-sensing devices.				
DEPYROGENATION BY HEAT *[Sterilization Methods and Depyrogenation by Dry Heat]* Used to render glassware, containers, vials free from pyrogens and viable microbes. Cover tightly with aluminum foil, bake at 250 C for 30 minutes, use immediately or if stored must be ISO Class 7 environment.				
Written documentation of description of cycle and duration for specific load items.				
Effectiveness of cycle is verified using Endotoxin Challenge Vials (ECVs) with bacterial endotoxin testing performed on ECVs to verify the cycle is capable of achieving a 3 log reduction in endotoxins.				
Other methods of sterilization are used with documented procedures and validation performed.				
COMMENTS:				

EXTENDING BUD and STERILITY TESTING *[Sterility Testing]*	**COMPLIANT**	**NON COMPLIANT**	**N/A**	**NOT INSPECTED**
Sterility testing for both bacteria and fungus performed each time BUD is extended beyond USP guidelines. *[Low, Medium and High Risk Level CSPs]*				
Sterility testing performed on high risk CSP prepared in groups of more than 25 identical containers.				
Sterility testing performed on high risk CSP exposed longer than 12 hours at 2-8C (36-46F) and longer than 6 hours at warmer than 8C (46F) before sterilization.				
Sterility testing is done using membrane filtration (preferred method) or direct inoculation per USP <71>.				

EXTENDING BUD and STERILITY TESTING continued *[Sterility Testing]*	**COMPLIANT**	**NON COMPLIANT**	**N/A**	**NOT INSPECTED**
Appropriate number of CSP tested for sterility per USP <71> **Parenterals:** 1. Less than 100 units, test 10% or 4 units, whichever is greater 2. 100-500 units, test 10 units 3. Greater than 500 units, test 2% or 20 units, whichever is less **Large Volume Parenterals:** 2% or 10 containers, whichever is less **Non-parenterals (eye drops, inhalation):** 1. Less than 200 units, test 5% or 2 units, whichever is greater 2. 200 or more units, test 10 units 3. If packaged as unit dose, use parenteral testing numbers				
Bacterial endotoxin testing performed on high risk CSP if prepared in groups of more than 25 identical containers.				
Bacterial endotoxin testing performed on high risk CSP if exposed longer than 12 hours at 2-8C (36-46F) or b longer than 6 hours at warmer than 8C (46F) before sterilization.				
CSP quarantined until results of sterility and endotoxin tests received or if dispensed before receiving results, written procedure requiring daily observation of incubating CSPs and immediate recall when evidence of growth. Patient and prescriber notified of potentially contaminated CSP and potential risk.				
Positive sterility test results promptly investigated including aseptic technique, environmental control, etc. to identify source of contamination and correct the issue.				
Stability data documented to support extended BUD, either from literature or testing. *[Responsibility of Compounding Personnel]*				
If potency testing is performed, strength must be within 10% of stated potency. *[Responsibility of Compounding Personnel]*				
COMMENTS:				
TRANSPORTING CSP OUTSIDE FACILITY	**COMPLIANT**	**NON COMPLIANT**	**N/A**	**NOT INSPECTED**
Packing *[Packing CSPs for Transit]* P&P for packing containers specifying which to use.				
P&P for insulating and stuffing materials specifying which to use.				
Written instructions to patients how to safely open containers of CSP.				
Transit *[Transit of CSPs]* Ascertain temperature of CSP during transit.				
Specific handling and exposure instructions on the exteriors of containers packed with CSPs.				
Periodic review of delivery performance of couriers to ascertain CSPs are being efficiently and properly transported.				
Storage Outside Facility *[Storage in Locations Outside Compounding Facilities]* Provide CSP labeling that includes clearly readable BUDs, storage instructions, and disposal information for out of date units.				
Ascertain each patient is able to store CSP properly, including use of properly functioning refrigerator or freezer if needed.				

COMMENTS:
ADDITIONAL COMMENTS: