VHA PBM Assessment Guide for Compounded Sterile Preparations (CSPs) within VAMCs and Outsourced Compounding Pharmacies

Regulatory Requirements					
Outsourced Compounding Pharmacy/Facility	**Yes**	**No**	**VAMC Pharmacy**	**Yes**	**No**
The pharmacy complies with HIPAA standards	☐	☐	Also required for VAMCs	☐	☐
The pharmacy complies with federal and state EPA regulations related to disposal and handling of pharmaceutical and hazardous wastes per the RCRA provisions	☐	☐	Also required of VAMCs	☐	☐
The pharmacy preparing patient-specific CSPs or batched CSPs is accredited an accrediting organization for pharmacy compounding (e.g. PCAB accredited).	☐	☐	*Also required of VAMCs if preparing High Risk Level CSPs per VHA PBM CSP Guidance.	☐	☐
The pharmacy has documented through a Certificate of Analysis (CoA) or purchase orders of obtaining active pharmaceutical ingredients (APIs) from an FDA-and/or DEA-registered pharmaceutical supplier with a Standard Operating Procedures to verify supplier registration status.	☐	☐	*Also required of VAMCs if purchasing APIs for compounding purposes.	☐	☐
The pharmacy has a current active pharmacy license in good standing from their Board of Pharmacy and licensed to ship to my state.	☐	☐	In cases where the outsourced compounding pharmacy has a record(s), finding(s) (i.e. FDA 483 observations), or violation(s) issued by a regulatory body, the VAMC must evaluate the pharmacy's compliance with corrective action(s) and has satisfactorily addressed violation(s) or finding(s).	N/A	
The outsourcer meets or exceeds state required pharmacist-to-pharmacy technician ratios for the state in which the compounding center is located	☐	☐		N/A	
The pharmacy has a current Drug Enforcement (DEA) registration if compounding controlled substances products to VAMCs.	☐	☐		N/A	
All pharmacy staff (pharmacists, technicians) at the pharmacy are licensed and/or certified by their respective Boards of Pharmacy.	☐	☐		N/A	
All CSPs prepared are documented to meet USP <797> standards of practice.	☐	☐	Also required for VAMCs	☐	☐
The pharmacy has documented having a policy on a contingency plan in case of an emergency need or request from the VAMC.	☐	☐		N/A	

If the outsourcer prepares a significant number of non-patient-specific preparations (> 5% of the outsourcer's volume), the outsourcer is registered as a drug manufacturer with the FDA, if required.	☐	☐		N/A
The outsourcer compounds the same drug formulation as a commercially available FDA-approved product using non-sterile powders or other components	☐	☐		N/A
When no commercial source exists to prepare admixtures, the outsourcer uses USP grade bulk ingredients obtained from a cGMP compliant supplier and can provide a certificate of analysis and potency testing of all bulk ingredients used	☐	☐		N/A
The outsourcer has the required minimum amount of product liability insurance as recommended	☐	☐		N/A
Institution is covered by insurance in the event that there is no written contract with the outsourcer	☐	☐		N/A

CSP Pharmaceutical Quality Standards					
Outsourced Compounding Pharmacy/Facility	**Yes**	**No**	**VAMC Pharmacy**	**Yes**	**No**
The pharmacy provided to the VAMC upon request at each site visit all documentation related to site visits for its accreditation and licensure, adverse reaction reports, medication error reports, recalls and patient incident reports, if feasible, in an un-redacted form.	☐	☐	The VAMC must maintain a record of such records and site visits for reference and for any follow up.	☐	☐
The pharmacy has documentation describing how CSPs will be prepared, including whether CSPs are prepared from sterile or non-sterile components.	☐	☐	The VAMC must maintain these records on site.	☐	☐
The pharmacy documents established policies and procedures to manage reporting of adverse reactions and end user problems to ensure tracking and trending of issues and resolution.	☐	☐	The VAMC documents tracking and visual inspection by pharmacist, upon receipt of outsourced CSPs, for clarity of sterile solution(s) prior to dispensing to monitor CSP for particles that may result in physical, chemical, or microbiological deterioration of CSP (ref: USP <1191> "Stability Considerations in Dispensing Practice).	☐	☐

The pharmacy has provided necessary sterility and stability documentation to the VAMC upon delivery of the compounded product. The sterility documentation for CSPs shows that testing by a qualified laboratory (laboratory must be identified), and testing for method suitability or validation, was performed for each type of CSP (or formulation) tested. Documentation reflects the USP requirement on number of test samples based on the size of each specific lot prepared by the contractor. (USP <71> "Sterility Tests".)	☐	☐		N/A	
VAMC Specific Quality and Safety Measures					
	N/A		Only one (1) Product should be prepared at a time under the hood. Complete preparation of that product to include removal of all supplies, including medication vials, should occur before beginning another product.	☐	☐
	N/A		When feasible, a pharmacist should physically select the pharmaceutical ingredients for CSPs and provide them directly to the assigned compounding personnel for: High Risk medications (e.g. products with demonstrable difficulty such as epidurals, implantable pumps, preservative free products, narcotics, cardioplegia, etc.) CSPs prepared under High Risk levels are as defined by USP <797> and include products listed in the current hazardous NIOSH drug list	☐	☐
CSP Microbial Contamination Risk Levels: Compliance with USP <797> Standards					
Low-risk Level CSPs					
Outsourced Compounding Pharmacy/Facility	**Yes**	**No**	**VAMC Pharmacy**	**Yes**	**No**
The CSPs are compounded with aseptic manipulations entirely within ISO Class 5 or better quality air using only sterile ingredients, products, components and devices	☐	☐	Applies to VAMCs	☐	☐
Compounding involves only transfer, measuring and mixing manipulations using not more than 3 commercially manufactured sterile products and not more than 2 entries into any container	☐	☐	Applies to VAMCs	☐	☐

Manipulations are limited to aseptically opening ampoules, penetrating disinfected stoppers on vials with sterile needles and syringes and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and containers for storage and dispensing	☐	☐	Applies to VAMCs	☐	☐
In the absence of sterility tests, storage is not more than 48 hours at controlled room temperature, 14 days at cold temperature (2 – 8 degrees C), and 45 days in a solid frozen state of -25° to -10° C	☐	☐	Applies to VAMCs	☐	☐
If compounding personnel are improperly garbed and gloved, CSP treated as a high-risk compound	☐	☐	Applies to VAMCs	☐	☐
Low-risk Level CSPs with 12-Hour or Less Beyond Use Date (BUD)					
Outsourced Compounding Pharmacy/Facility	**Yes**	**No**	**VAMC Pharmacy**	**Yes**	**No**
PECs are certified, maintained ISO Class 5 and located in a segregated compounding area restricted to sterile compounding activities	☐	☐	Applies to VAMCs	☐	☐
The segregated compounding area is not in a location that has unsealed windows or doors that connect to the outdoors or high traffic flow, or in a location that is adjacent to construction sites, warehouse or food preparation	☐	☐	Applies to VAMCs	☐	☐
Sinks are not located adjacent to the ISO Class 5 PEC; sinks are separated from the immediate area of the ISO Class 5 PEC device	☐	☐	Applies to VAMCs	☐	☐
Quality assurance practices include routine disinfection and air quality testing, visual confirmation that personnel are appropriately garbing, review of all orders for correct identity and strength, and visual inspection of CSPs	☐	☐	Applies to VAMCs	☐	☐
Media-fill test procedure or equivalent test is performed at least annually by personnel	☐	☐	Applies to VAMCs	☐	☐
Medium-risk Level CSPs					
Outsourced Compounding Pharmacy/Facility	**Yes**	**No**	**VAMC Pharmacy**	**Yes**	**No**
Product considered medium risk if multiple individual or small doses of sterile products are combined or pooled to prepare a CSP that will be administered either to multiple patients or to one patient on multiple occasions	☐	☐	Applies to VAMCs	☐	☐
Products considered medium-risk if the compounding process includes complex aseptic manipulations or unusually long duration	☐	☐	Applies to VAMCs	☐	☐
In the absence of sterility tests, storage is not more than 30 hours at controlled room temperature, 9 days at cold temperature (2 – 8 degrees C), and 45 days in a frozen state of -25° to -10° C	☐	☐	Applies to VAMCs	☐	☐
Products considered medium-risk if aseptic	☐	☐	Applies to VAMCs	☐	☐

manipulations within an ISO Class 5 environment use prolonged and complex mixing and transfer, more than 3 sterile products and two entries into any container, and pooling ingredients from multiple sterile products to prepare multiple CSPs					
Quality assurance practices include routine disinfection and air quality testing, visual confirmation that personnel are appropriately garbed, review of all orders for correct identity and strength, visual inspection of CSPs, as well as a more challenging media-fill test performed annually	☐	☐	Applies to VAMCs	☐	☐
If compounding personnel are improperly garbed and gloved, this makes CSP high-risk	☐	☐	Applies to VAMCs	☐	☐
High-risk Level CSPs					
Outsourced Compounding Pharmacy/Facility	**Yes**	**No**	**VAMC Pharmacy**	**Yes**	**No**
Product considered high-risk if any nonsterile ingredients or devices are used	☐	☐	Applies to VAMCs	☐	☐
Product considered high-risk if CSP is exposed to air quality worse than ISO Class 5 for > 1 hour	☐	☐	Applies to VAMCs	☐	☐
Product considered high-risk if nonsterile water-containing preparations are stored for more than 6 hours before being sterilized	☐	☐	Applies to VAMCs	☐	☐
Sterilization methods are verified to achieve sterility for the quantity and type of containers	☐	☐	Applies to VAMCs	☐	☐
Allowable limits for bacterial endotoxins are met	☐	☐	Applies to VAMCs	☐	☐
All high-risk CSP solutions subjected to terminal sterilization by filtration are appropriately prefiltered and terminally filtered in ISO Class 5 air	☐	☐	Applies to VAMCs	☐	☐
CSP maintains acceptable strength, purity and integrity of containers after sterilization	☐	☐	Applies to VAMCs	☐	☐
In the absence of sterility tests, storage is not more than 24 hours at controlled room temperature (20 – 25 degrees C), 3 days at cold temperature (2 – 8 degrees C), and 45 days in a solid frozen state of -25° to -10° C	☐	☐	Applies to VAMCs	☐	☐
Media-fill test procedure or equivalent test is performed at least semi-annually by personnel	☐	☐	Applies to VAMCs	☐	☐
Quality assurance practices include routine disinfection, air quality testing, visual confirmation of appropriate personnel garbing, review of all orders for correct identity and strength, and visual inspection of CSPs	☐	☐	Applies to VAMCs	☐	☐
Sterility tests are performed for autoclaved CSPs if they are prepared in batches > 25 units	☐	☐	Applies to VAMCs	☐	☐

Personnel Training and Evaluation in Aseptic Manipulation Skills					
Outsourced Compounding Pharmacy/Facility	**Yes**	**No**	**VAMC Pharmacy**	**Yes**	**No**
Before beginning to prepare CSPs, personnel are trained by expert personnel, audio-video instructional sources, professional publications in the theoretical principles, practical skills of aseptic manipulations and in achieving and maintaining ISO Class 5 environmental conditions	☐	☐	Applies to VAMCs	☐	☐
All personnel perform didactic review and pass written and media-fill testing of aseptic manipulative skills initially, then at least annually thereafter for low- and medium-risk level compounding	☐	☐	Applies to VAMCs	☐	☐
Personnel perform didactic review and pass written and media-fill testing of aseptic manipulative skills initially, and at least semi-annually for high-risk compounding	☐	☐	Applies to VAMCs	☐	☐
Personnel who fail written tests or whose media-fill test vials result in cross microbial colonization are immediately re-instructed and re-evaluated prior to resuming compounding	☐	☐	Applies to VAMCs	☐	☐
Immediate Use CSPs					
Outsourced Compounding Pharmacy/Facility	**Yes**	**No**	**VAMC Pharmacy**	**Yes**	**No**
Immediate-use CSPs are used only when there is a need for emergency or immediate patient administration of a CSP, where administration can begin with 1 hour of compounding	☐	☐	Applies to VAMCs	☐	☐
Product considered immediate-use only if the compounding process involves simple transfer of not more than 3 commercially manufactured packages of sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers and not more than 2 entries into any one container or package of sterile infusion solution or administration container/device	☐	☐	Applies to VAMCs	☐	☐
Unless required for preparation, compounding is a continuous process not to exceed 1 hour	☐	☐	Applies to VAMCs	☐	☐
Aseptic technique is followed and if not immediately administered, CSP is continually supervised	☐	☐	Applies to VAMCs	☐	☐
Administration begins not later than 1 hour following the start of the preparation of the CSP	☐	☐	Applies to VAMCs	☐	☐
If administration has not begun within 1 hour of being compounded, CSP is discarded	☐	☐	Applies to VAMCs	☐	☐
Single Dose and Multiple Dose Containers					
Outsourced Compounding Pharmacy/Facility	**Yes**	**No**	**VAMC Pharmacy**	**Yes**	**No**
Single-dose containers entered in worse than ISO Class 5 air quality are used within 1 hour of entry	☐	☐	Applies to VAMCs	☐	☐
Single-dose containers entered in ISO Class 5 or	☐	☐	Applies to VAMCs	☐	☐

cleaner air are used within 6 hours of entry					
Opened single-dose ampoules are not stored	☐	☐	Applies to VAMCs	☐	☐
Closure sealed multiple-dose containers are used within 28 days after initial opening or entry, unless specified otherwise by the manufacturer	☐	☐	Applies to VAMCs	☐	☐
Hazardous Drugs as CSPs					
Outsourced Compounding Pharmacy/Facility	**Yes**	**No**	**VAMC Pharmacy**	**Yes**	**No**
Hazardous drugs are prepared for administration only under conditions that protect the healthcare workers and other personnel in the preparation and storage areas	☐	☐	Applies to VAMCs	☐	☐
Hazardous drugs are stored separately from other inventory	☐	☐	Applies to VAMCs	☐	☐
Hazardous drugs are handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparation for administration and disposal	☐	☐	Applies to VAMCs	☐	☐
Hazardous drugs are prepared in an ISO Class 5 environment with protective engineering controls in place and follows aseptic practices specified for the appropriate contamination risk levels	☐	☐	Applies to VAMCs	☐	☐
Access is limited to areas where hazardous drugs are stored and prepared	☐	☐	Applies to VAMCs	☐	☐
All hazardous drugs are prepared in a BSC or a CACI that meets or exceeds standards	☐	☐	Applies to VAMCs	☐	☐
The ISO Class 5 BSC or CACI is placed in an ISO Class 7 area, physically separated and optimally has not less than 0.01-inch water column negative pressure to adjacent positive pressure ISO Class 7 or better ante-areas. Certain exceptions allowed if CACI meets 797 requirements (pages 14, 23).	☐	☐	Applies to VAMCs	☐	☐
If closed-system vial-transfer devices are used, they are used within the ISO Class 5 environment of a BSC or CACI	☐	☐	Applies to VAMCs	☐	☐
Personnel protective equipment is worn when compounding	☐	☐	Applies to VAMCs	☐	☐
Personnel who compound hazardous drugs are trained in storage, handling and disposal of drugs prior to preparing or handling hazardous CSPs	☐	☐	Applies to VAMCs	☐	☐
Effectiveness of training is verified by testing specific hazardous drug preparations techniques and is documented for each person at least annually	☐	☐	Applies to VAMCs	☐	☐
Compounding personnel of reproductive capability confirm in writing that they understand the risks of hazardous drug handling	☐	☐	Applies to VAMCs	☐	☐
Disposal of hazardous waste complies with all applicable federal and state regulations	☐	☐	Applies to VAMCs	☐	☐
Personnel who perform routine custodial waste	☐	☐	Applies to VAMCs	☐	☐

removal and cleaning activities for hazardous drugs are trained in appropriate procedures to protect themselves and prevent contamination					
Radiopharmaceuticals as CPSs					
Outsourced Compounding Pharmacy/Facility	**Yes**	**No**	**VAMC Pharmacy**	**Yes**	**No**
Radiopharmaceuticals are compounded using appropriately shielded vials and syringes in a properly functioning and certified ISO Class 5 PEC located in the ISO Class 8 or cleaner air environment	☐	☐	Applies to VAMCs	☐	☐
Radiopharmaceutical vials designed for multi-use, compounded with technetium-99m, exposed to ISO Class 5 environment, and punctured by needles with no direct contact contamination are used by the time indicated by the manufacturers' recommendations	☐	☐	Applies to VAMCs	☐	☐
Technetium-99m/molybdenum-99 generator systems are stored and operated under conditions recommended by manufacturers and applicable state and federal regulations; such generator systems are operated in an ISO Class 8 or cleaner air environment	☐	☐	Applies to VAMCs	☐	☐
Direct visual inspection of radiopharmaceutical CSPs containing high concentrations of doses of radioactivity are conducted in accordance with ALARA	☐	☐	Applies to VAMCs	☐	☐
Radiopharmaceuticals prepared as low-risk level CSPs with 12-hour or less BUD are prepared in a segregated compounding area; a line of demarcation is established	☐	☐	Applies to VAMCs	☐	☐
Materials and garb exposed in patient care and treatment do not cross the line of demarcation	☐	☐	Applies to VAMCs	☐	☐
Allergen Extracts as CSPs					
Outsourced Compounding Pharmacy/Facility	**Yes**	**No**	**VAMC Pharmacy**	**Yes**	**No**
Compounding is performed only with simple transfers using sterile ingredients and supplies	☐	☐	Applies to VAMCs	☐	☐
Allergen extracts contain appropriate concentrations of preservatives	☐	☐	Applies to VAMCs	☐	☐
Before compounding, personnel appropriately wash hands with soap and water, apply alcohol-based scrub with persistent activity, don hair covers, facial hair covers, gowns, face masks and gloves	☐	☐	Applies to VAMCs	☐	☐
Sterile gloves are intermittently disinfected with sterile 70% IPA	☐	☐	Applies to VAMCs	☐	☐
Vial/ampule critical sites are wet with 70% IPA for 10 seconds and allowed to dry before use	☐	☐	Applies to VAMCs	☐	☐
Compounding manipulations are performed to minimize contact contamination of critical sites	☐	☐	Applies to VAMCs	☐	☐

Vials are labeled with patient's name, BUD and storage information based on manufacturers' recommendations or peer-reviewed literature	☐	☐	Applies to VAMCs	☐	☐
Verification of Compounding Accuracy and Sterility (High-risk Compounding)					
Outsourced Compounding Pharmacy/Facility	**Yes**	**No**	**VAMC Pharmacy**	**Yes**	**No**
Packaged and labeled CSPs are visually inspected for physical integrity and expected appearance	☐	☐	Applies to VAMCs	☐	☐
The accuracy of identities, concentrations, amounts and purities of ingredients in CSPs are confirmed by reviewing labels on packages, observing and documenting correct measurements with approved and correctly standardized devices, and reviewing information in labeling with certificates of analysis provided by suppliers	☐	☐	Applies to VAMCs	☐	☐
The licensed healthcare professional is responsible for determining that the selected sterilization method both sterilizes and maintains the strength, purity, quality and packaging integrity of CSPs.	☐	☐	Applies to VAMCs	☐	☐
Commercially available sterile filters are approved for human-use applications in sterilizing pharmaceutical fluids	☐	☐	Applies to VAMCs	☐	☐
Sterile filters used to sterilize CSPs are pyrogen free with a nominal porosity of 0.2 or 0.22 micrometers	☐	☐	Applies to VAMCs	☐	☐
Sterile filters used are certified by the manufacturer to retain at least 10^7 microorganisms of a strain of Brevundimonas diminuta on each square centimeter of upstream filter surface area	☐	☐	Applies to VAMCs	☐	☐
The compounding supervisor ensures that the filters are chemically and physically stable at the pressure and temperature conditions to be used, that they have enough capacity to filter the required volumes, and that they will achieve sterility and maintain prefiltration pharmaceutical quality	☐	☐	Applies to VAMCs	☐	☐
The filter dimensions and liquid material to be sterile-filtered permit the sterilization process to be completed rapidly, without replacement of the filter during the process	☐	☐	Applies to VAMCs	☐	☐
When CSPs are known to contain excessive particulate matter, a prefilter of larger-porosity membrane is placed upstream from the sterilizing filter to remove gross particulate contaminants.	☐	☐	Applies to VAMCs	☐	☐
Filter units used are subjected to manufacturers' recommended integrity test	☐	☐	Applies to VAMCs	☐	☐
Personnel must know that filters will achieve sterilization of the particular CSPs being sterilized	☐	☐	Applies to VAMCs	☐	☐
The description of steam sterilization conditions and duration for specific CSPs are included in written documentation in the compounding facility	☐	☐	Applies to VAMCs	☐	☐
The effectiveness of steam sterilization is verified	☐	☐	Applies to VAMCs	☐	☐

using appropriate Bis of Bacillus stearothermophilus and other confirmation methods					
Heated filtered air is evenly distributed throughout the chamber by a blower device; the oven is equipped with a system for controlling temperature and exposure period	☐	☐	Applies to VAMCs	☐	☐
Dry heat is used only for those materials that cannot be sterilized by steam	☐	☐	Applies to VAMCs	☐	☐
During sterilization, sufficient space is left between materials to allow for good air circulation	☐	☐	Applies to VAMCs	☐	☐
The description of dry heat sterilization conditions and duration for specific CSPs are included in written documentation in the compounding facility	☐	☐	Applies to VAMCs	☐	☐
The effectiveness of dry heat sterilization is verified using appropriate BIs of Bacillus subtilis and other confirmation methods	☐	☐	Applies to VAMCs	☐	☐
The description of dry heat depyrogenation cycle conditions and duration for specific CSPs are included in written documentation in the compounding facility	☐	☐	Applies to VAMCs	☐	☐
The effectiveness of the dry heat depyrogenation cycle is verified using endotoxin challenge vials (ECVs); the bacterial endotoxin test is performed on the ECVs to verify that the cycle is capable of achieving a 3-log reduction in endotoxin	☐	☐	Applies to VAMCs	☐	☐
Environmental Quality and Control					
Facility Design and Environmental Controls					
Outsourced Compounding Pharmacy/Facility	**Yes**	**No**	**VAMC Pharmacy**	**Yes**	**No**
Critical sites are only exposed to ISO Class 5 or cleaner air	☐	☐	Applies to VAMCs	☐	☐
Compounding facility provides a comfortable and well-lighted working environment	☐	☐	Applies to VAMCs	☐	☐
PECs maintain ISO Class 5 and meet airflow requirements	☐	☐	Applies to VAMCs	☐	☐
Policies and procedures for PEC area are written and followed; determined by the scope and risk levels of aseptic compounding activities utilized during the preparation of the CSPs	☐	☐	Applies to VAMCs	☐	☐
The buffer area maintains ISO Class 7 conditions	☐	☐	Applies to VAMCs	☐	☐
A minimum differential positive pressure of 0.02- to 0.05-inch water column is used for rooms providing a physical separation through the use of walls, doors and pass-through	☐	☐	Applies to VAMCs	☐	☐
Displacement airflow is employed for buffer areas not physically separated from the ante-areas	☐	☐	Applies to VAMCs	☐	☐
Adequate HEPA-filtered airflow is supplied to the buffer area and ante-area	☐	☐	Applies to VAMCs	☐	☐

ISO Class 7 buffer and ante-area supplied with HEPA-filtered air receive an ACPH of not less than 30	☐	☐	Applies to VAMCs	☐	☐
If the area has an ISO Class 5 recirculating device, a minimum of 15 ACPHs through the area supply HEPA filters is adequate, providing the combined ACPH not less than 30	☐	☐	Applies to VAMCs	☐	☐
Only the furniture, equipment, supplies and other material required for the compounding activities are brought into the area and they are non-permeable, nonshedding, cleanable, and resistant to disinfectants; before such items are brought into the area, they are cleaned and disinfected	☐	☐	Applies to VAMCs	☐	☐
The surfaces of ceilings, walls, floors, fixtures, shelving, counters and cabinets in the buffer area are smooth, impervious, free from cracks and crevices and nonshedding; the surfaces are resistant to damage by disinfectant agents	☐	☐	Applies to VAMCs	☐	☐
Junctures of ceilings to walls are coved or caulked	☐	☐	Applies to VAMCs	☐	☐
If ceilings consist of inlaid panels, the panels are impregnated with a polymer to render them impervious and hydrophobic; they are caulked around each perimeter	☐	☐	Applies to VAMCs	☐	☐
The exterior lens surface of the ceiling lighting fixtures are smooth, mounted flush and sealed; any other penetrations through the ceiling or walls are sealed	☐	☐	Applies to VAMCs	☐	☐
The buffer area does not contain sources of water (sinks) or floor drains	☐	☐	Applies to VAMCs	☐	☐
Works surfaces are constructed of smooth, impervious materials	☐	☐	Applies to VAMCs	☐	☐
Carts are stainless steel wire, nonporous plastic or sheet metal with cleanable casters	☐	☐	Applies to VAMCs	☐	☐
Storage shelving, counters and cabinets are smooth, impervious, free from cracks and crevices, nonshedding, cleanable and disinfectable; their number, design and manner of installation promotes effective cleaning and disinfection	☐	☐	Applies to VAMCs	☐	☐
Placement of Primary Engineering Controls					
Outsourced Compounding Pharmacy/Facility	**Yes**	**No**	**VAMC Pharmacy**	**Yes**	**No**
PECs are located within a restricted access ISO Class 7 buffer area unless an exception met	☐	☐	Applies to VAMCs	☐	☐
When isolators are used for sterile compounding, the recovery time to achieve ISO Class 5 air quality is documented and internal procedures are developed	☐	☐	Applies to VAMCs	☐	☐
Certification that each ISO classified area is within established guidelines is performed no less than every 6 months and each time the LAFW, BSC, CAI or CACI is relocated or the physical structure of the	☐	☐	Applies to VAMCs	☐	☐

buffer area or anti-area has been altered					
A pressure gauge or velocity meter is installed to monitor the pressure differential or air-flow between the buffer area and the ante-area and between the ante-area and the general environment outside the compounding area; results are reviewed and documented in a log at least every work shift (minimum daily) or by a continuous recording device	☐	☐	Applies to VAMCs	☐	☐
The pressure between the ISO Class 7 and the general pharmacy area is not less than 5 Pa (0.02 inch water column)	☐	☐	Applies to VAMCs	☐	☐
In facilities where low- and medium-risk level CSPs are prepared, differential airflow is maintained at a minimum velocity of 0.2 meters/second (40 feet per minute) between buffer area and ante-area	☐	☐	Applies to VAMCs	☐	☐
Media that supports the growth of fungi is used in high-risk level environments	☐	☐	Applies to VAMCs	☐	☐
For low-risk level CSPs with 12-hour or less BUD prepared in a PEC that maintains an ISO Class 5 sampling, air sampling is performed at locations inside the ISO Class 5 environment and other areas that are in close proximity to the ISO Class 5 during the certification of the PEC	☐	☐	Applies to VAMCs	☐	☐
A sufficient volume of air (400 to 1000 liters) is tested at each location where compounding takes place, performed at least semi-annually	☐	☐	Applies to VAMCs	☐	☐
Additional Personnel Requirements					
Outsourced Compounding Pharmacy/Facility	**Yes**	**No**	**VAMC Pharmacy**	**Yes**	**No**
Foods, drinks and materials exposed in patient care and treatment areas do not enter ante-areas, buffer areas or segregated compounding areas	☐	☐	Applies to VAMCs	☐	☐
Cleaning and Disinfecting the Compounding Area					
Outsourced Compounding Pharmacy/Facility	**Yes**	**No**	**VAMC Pharmacy**	**Yes**	**No**
When compounding activities require the manipulation of blood-derived or other biological material, the manipulations are clearly separated from routine material-handling procedures and equipment used in CSP preparation and are controlled by specific SOPs to avoid any cross-contamination	☐	☐	Applies to VAMCs	☐	☐
When possible, packaged compounding supplies and components are removed from the carton and wiped down with a disinfectant that does not leave a residue in an ante-area ISO Class 8 air quality, before being passed into buffer areas; Supplies are allowed to dry before compounding	☐	☐	Applies to VAMCs	☐	☐
Personnel Cleansing and Garbing					
Outsourced Compounding Pharmacy/Facility	**Yes**	**No**	**VAMC Pharmacy**	**Yes**	**No**

Personal hand hygiene and garb procedures are performed in ante-areas	☐	☐	Applies to VAMCs	☐	☐
For ISO Class 5, all cleaning and disinfecting practices and policies for the compounding of CSPs are included in written SOPs and are followed by all compounding personnel	☐	☐	Applies to VAMCs	☐	☐
LAFWs, BSCs, CAIs, and/or CACIs are cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods, when spills occur and when surface contamination is known or suspected	☐	☐	Applies to VAMCs	☐	☐
Work surfaces in ISO Class 7 buffer areas, ISO Class 8 ante-areas and segregated compounding areas are cleaned and disinfected at least daily, and dust and debris are removed when necessary from storage sites	☐	☐	Applies to VAMCs	☐	☐
Floors in ISO Class 7 and 8 areas are cleaned daily when no compounding occurs; mopping is performed by trained personnel using approved agents and written procedures	☐	☐	Applies to VAMCs	☐	☐
In the buffer or clean area, ante-area and segregated compounding area, walls, ceilings, and shelving are cleaned and disinfected monthly	☐	☐	Applies to VAMCs	☐	☐
All cleaning materials are nonshedding and dedicated to use in the buffer or clean area, ante-area, and segregated areas and are not removed from these areas except for disposal	☐	☐	Applies to VAMCs	☐	☐
If cleaning materials are reused, SOPs ensure that the effectiveness of the cleaning device is maintained and repeated use does not add to the bioburden of the area being cleaned	☐	☐	Applies to VAMCs	☐	☐
Sterile 70% IPA swabs do not contact any object before contacting the site to be cleaned	☐	☐	Applies to VAMCs	☐	☐
No particle-generating material is used to disinfect the sterile entry points of packages and devices	☐	☐	Applies to VAMCs	☐	☐
No shipping cartons are taken into the buffer area, clean area or segregated compounding area	☐	☐	Applies to VAMCs	☐	☐
Personnel with rashes, sunburn, weeping sores, conjunctivitis, active respiratory infection or cosmetics are prohibited from preparing CSPs	☐	☐	Applies to VAMCs	☐	☐
Personnel remove personal outer garments, cosmetics, artificial nails, hand- wrist- or body-jewelry that can interfere with the fit of gowns and gloves, and visible body piercing above the neck; natural nails are kept neat and trimmed	☐	☐	Applies to VAMCs	☐	☐
Garb and cleansing in ante-area as follows: shoes or shoe covers, head and facial hair covers, face mask, fingernail cleansing, hand and forearm washing and drying, nonshedding gown	☐	☐	Applies to VAMCs	☐	☐

Cleansing and gloving in buffer room or area as follows: hand cleansing with an alcohol-based product with persistent activity, allow hands to dry, don sterile gloves	☐	☐	Applies to VAMCs	☐	☐
Gloves are routinely disinfected with sterile 70% IPA after contacting nonsterile objects	☐	☐	Applies to VAMCs	☐	☐
Gloves are inspected for holes and replaced when breaches are detected	☐	☐	Applies to VAMCs	☐	☐
Personnel Training and Competency					
Outsourced Compounding Pharmacy/Facility	**Yes**	**No**	**VAMC Pharmacy**	**Yes**	**No**
Prior to compounding, personnel are trained in garbing procedures, aseptic work practices, achieving and maintaining ISO Class 5 conditions and cleaning and disinfections procedures	☐	☐	Applies to VAMCs	☐	☐
Media-fill testing of aseptic work skills are performed initially before beginning to prepare CSPs and at least annually thereafter for low- and medium-risk level; and semi-annually for high-risk level	☐	☐	Applies to VAMCs	☐	☐
Personnel who fail written tests, observational audits, or whose media-fill test vials have one or more units showing contamination are re-instructed and re-evaluated to ensure correction of all aseptic work practice deficiencies; personnel pass all evaluations prior to resuming compounding	☐	☐	Applies to VAMCs	☐	☐
Personnel demonstrate proficiency of proper hand hygiene, garbing and consistent cleaning procedures in addition to didactic evaluation of aseptic media fill and glove tip testing	☐	☐	Applies to VAMCs	☐	☐
Personnel are visually observed during the process of performing hand hygiene and garbing procedures and appropriately documented and maintained to provide a permanent record	☐	☐	Applies to VAMCs	☐	☐
Personnel successfully complete an initial competency evaluation and gloved fingertip/thumb sampling procedure no less than 3 times before initially being allowed to compound CSPs; which must be repeated at least annually for low- and medium-risk, and twice annually for high-risk compounding	☐	☐	Applies to VAMCs	☐	☐
All compounding personnel have technique and competency evaluated initially during the Media-Fill Test Procedure and subsequent annual or semi-annual Media-Fill Test Procedures.	☐	☐	Applies to VAMCs	☐	☐
Action Levels, Documentation and Data Evaluation					
Outsourced Compounding Pharmacy/Facility	**Yes**	**No**	**VAMC Pharmacy**	**Yes**	**No**
Surface sampling is performed in all ISO classified areas on a periodic basis	☐	☐	Applies to VAMCs	☐	☐
Microbial sampling data is collected and reviewed routinely	☐	☐	Applies to VAMCs	☐	☐

Elements of Quality Control					
Outsourced Compounding Pharmacy/Facility	**Yes**	**No**	**VAMC Pharmacy**	**Yes**	**No**
A written description of specific training, competency and performance evaluations for compounding personnel is developed for each site	☐	☐	Applies to VAMCs	☐	☐
Facility follows procedures for physical inspection of all sterile drugs and devices	☐	☐	Applies to VAMCs	☐	☐
If any nonsterile components, including containers and ingredients, are used to make a CSP, such CSPs must be high risk	☐	☐	Applies to VAMCs	☐	☐
Bulk of unformulated drug substances and added substances or excipients are stored in tightly closed containers under temperature, humidity and lighting conditions that are either indicated in the official monographs or approved by suppliers	☐	☐	Applies to VAMCs	☐	☐
The date of receipt of nonsterile components is clearly and indelibly marked on each package	☐	☐	Applies to VAMCs	☐	☐
All devices used to compound a CSP operate properly within acceptable tolerance limits, as determined by the device's manufacturer or any regulations that govern the use of that device	☐	☐	Applies to VAMCs	☐	☐
For all equipment, SOPs exist and are followed that state routine maintenance required and frequency of calibration, annual maintenance, monitoring for proper function, and procedures for use	☐	☐	Applies to VAMCs	☐	☐
Personnel are appropriately trained to operate any equipment they use while compounding and are trained to determine if the device is operating properly or is malfunctioning.	☐	☐	Applies to VAMCs	☐	☐
Results from equipment maintenance and calibration are kept for the lifetime of the equipment	☐	☐	Applies to VAMCs	☐	☐
Verification of Automatic Compounding Devices for Parenteral Nutrition					
Outsourced Compounding Pharmacy/Facility	**Yes**	**No**	**VAMC Pharmacy**	**Yes**	**No**
Testing procedures for accuracy are verified to meet the USP requirements stated in the individual monograph for the component being tested	☐	☐	Applies to VAMCs	☐	☐
Compounding personnel keep a daily record of the accuracy assessments and the results are reviewed at least in weekly intervals	☐	☐	Applies to VAMCs	☐	☐
Finished Preparation Release Checks and Tests					
Outsourced Compounding Pharmacy/Facility	**Yes**	**No**	**VAMC Pharmacy**	**Yes**	**No**
All CSPs are visually inspected for being intact with no abnormal particulate matter, and prescriptions and written compounding procedures are reviewed to verify accuracy of correct ingredients and amounts, aseptic mixing, high-risk sterilization, packaging, labeling, and expected physical appearance before they are administered or dispensed.	☐	☐	Applies to VAMCs	☐	☐

A double-check system is in place that meets state regulations that includes label accuracy and accuracy of the addition of all ingredients used	☐	☐	VAMCs must assure compliance with VHA requirements, to include an end product double check by a Pharmacist.	☐	☐
High-risk level CSPs must be sterility tested if they are prepared in batches of > 25 identical containers, or exposed longer than 12 hours at 2 to 8 degrees C and 6 hours at warmer than 8 degrees C before being sterilized	☐	☐	Applies to VAMCs	☐	☐
If high-risk level CSPs are dispensed before receiving the results of their sterility tests, there is a written procedure requiring daily observation of incubating test specimens	☐	☐	Applies to VAMCs	☐	☐
High-risk level CSPs, excluding those for inhalation or ophthalmic administration, must be tested for bacterial endotoxins if prepared in batches of > 25 identical containers, or exposed longer than 12 hours at 2 to 8 degrees C (36 – 46 F) and 6 hours at warmer than 8 degrees C (46 C) before being sterilized	☐	☐	Applies to VAMCs	☐	☐
Storage and Beyond Use Dating					
Outsourced Compounding Pharmacy/Facility	**Yes**	**No**	**VAMC Pharmacy**	**Yes**	**No**
Personnel who prepare, dispense and administer CSPs store them strictly in accordance with the conditions stated on the label of ingredient products and finished CSPs	☐	☐	Applies to VAMCs	☐	☐
If CSPs are distributed to and administered in other than healthcare facilities, the effect of potentially uncontrolled and unmonitored temperature conditions is considered when assigning BUDs	☐	☐	Applies to VAMCs	☐	☐
The controlled temperature areas are monitored at least once daily and results are documented	☐	☐	Applies to VAMCs	☐	☐
Facilities have policies and procedures governing the determination of BUDs	☐	☐	Applies to VAMCs	☐	☐
Compounding personnel verify the storage temperature when placing a product into or removing a product from the storage unit	☐	☐	Applies to VAMCs	☐	☐
Temperature-sensitive mechanisms are placed to reflect true temperature in the controlled space and are not subject to significantly prolonged temperature fluctuations	☐	☐	Applies to VAMCs	☐	☐
Maintaining Sterility, Purity and Stability of Dispensed and Distributed CSPs					
Outsourced Compounding Pharmacy/Facility	**Yes**	**No**	**VAMC Pharmacy**	**Yes**	**No**
The facilities have written procedures for proper packaging, storage, and transportation conditions to maintain sterility, quality, purity and strength of CSPs	☐	☐	Applies to VAMCs	☐	☐
Chemotoxic and other hazardous CSPs have safeguards to maintain the integrity of the CSP and minimize the exposure potential of these products to	☐	☐	Applies to VAMCs	☐	☐

the environment and personnel					
Delivery and patient-care-setting personnel are properly trained to deliver the CSP to the appropriate storage location	☐	☐	Applies to VAMCs	☐	☐
Outdated and unused CSPs are returned to the compounding facility for disposition as appropriate	☐	☐	Applies to VAMCs	☐	☐
SOPs exist to ensure that the storage conditions in the patient-care setting are suitable for the CSP-specific storage requirements	☐	☐	Applies to VAMCs	☐	☐
Returned CSPs are only redispensed if sterility, acceptable purity, strength and quality can be assured	☐	☐	Applies to VAMCs	☐	☐
If redispensed CSPs are given a later BUD, sterility testing and quantitative assay of ingredients occur to support the extended BUD	☐	☐	Applies to VAMCs	☐	☐
CSPs requiring refrigeration must be supplied (shipped) in a manner that assures the CSP temperature is maintained at 2-8C (36-46F) or as indicated by the manufacturer.	☐	☐	Applies to VAMCs	☐	☐
Patient or Caregiver Training					
Outsourced Compounding Pharmacy/Facility	**Yes**	**No**	**VAMC Pharmacy**	**Yes**	**No**
A multiple component formal training program is in place to ensure that patients and caregivers understand proper storage, handling, use and disposal of CSPs	☐	☐	Applies to VAMCs	☐	☐
Patient Monitoring and Adverse Events Reporting					
Outsourced Compounding Pharmacy/Facility	**Yes**	**No**	**VAMC Pharmacy**	**Yes**	**No**
SOPs are available that describe the means for patients to ask questions, report concerns and adverse events with CSPs, and for compounding supervisors to correct and prevent future problems	☐	☐	Applies to VAMCs	☐	☐
Reports of CSP adverse events are reviewed promptly and thoroughly by compounding supervisors	☐	☐	Applies to VAMCs	☐	☐
Quality Assurance Program					
Outsourced Compounding Pharmacy/Facility	**Yes**	**No**	**VAMC Pharmacy**	**Yes**	**No**
A formal quality assurance program is in place that monitors, evaluates, corrects and improves activities and processes	☐	☐	Applies to VAMCs	☐	☐

VENDOR INFORMATION

Vendor (Facility) Name	
Vendor Point of Contact (Representative name)	
Vendor Point of Contact (Representative name)	

Vendor (Facility) Address	
Vendor (Facility) Phone	
Vendor (Facility) FAX	
Vendor (Facility) Representative Signature	
	DATE
Vendor (Facility) Representative Signature	
	DATE