# Sterile Compounding Inspection Form

| Section | Topic/Question | Y/N | Inspector Observations or Notes |
|---|---|---|---|
| 1.0 | **Background information about licensee** | | |
| 1.1 | **Risk level of CSPs (Compounded Sterile Products) reported by licensee** (circle)<br>*Low with 12 hour BUD (Beyond Use Date) only  Low  Medium  High*<br>*NOTE: If details needed, can answer question in Sections 3.2-3.6* | | |
| 1.2 | **Volume of CSPs** | | |
| 1.3 | **Types of CSPs** (circle all that apply)<br>*IV Fluids  Antibiotics  TPN  Epidurals  Inhalation  Nuclear*<br>*Controlled substances  Hazardous/Chemo  Veterinary*<br>*Non-sterile to sterile prep  Repackaged sterile FDA approved* | | |
| 1.4 | **Types & Quantity of Primary Engineering Control (PEC) Devices**<br>*LAFW _____  BSC _____  CAI _____  CACI _____*<br>*ISO-5 clean zone/open architecture  Robotic devices _____* | | Date of most recent PEC inspection: |
| 1.5 | **Does the licensee have appropriate compounding references including USP Chapter 797, injectable drug compatibility, veterinary, and hazardous material references?** | | |
| 1.6 | **Is the pharmacy registered with FDA as a repackager or 503B outsourcer?**<br>**Are they licensed as a wholesaler/outsourcing classification by the OSBP?** | | |
| 1.7 | **Are all CSPs dispensed pursuant to a patient specific prescription?** | | |
| 1.8 | **Does the pharmacy distribute CSPs to other licensee's non-patient specific?**<br>Is this in compliance with OAC 4729-9-25 and FDA's 503A | | |
| 1.9 | **Has the cleanroom and/or PEC devices been certified within the past six months?** | | |

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| 2.0 | **Responsibility of Compounding Personnel** | | |
| 2.1 | **Does the licensee have adequate measures in place so the staff understands that CSPs must be prepared, stored, and transported in a manner to keep the CSP sterile?** | | |
| 2.2 | **Does the licensee have systems in place to ensure oversight by a licensed healthcare professional for CSPs?** | | |
| 2.3 | **Do the supervisors of the licensee have the knowledge to maintain high standards for the quality and control of processes, components and environments, and for the skill and knowledge of staff who prepare CSPs?** | | |
| 2.4 | **Are there any other concerns identified by the inspector related to this chapter?** | | |
| 3.0 | **CSP Microbial Contamination Risk Levels** | | |
| 3.1 | **Does the licensee correctly identify the risk levels for CSPs?** | | |
| 3.2 | **Does the licensee compound Low-Risk level CSPs?**<br><br>Low-Risk level CSPs are defined as:<br>- Aseptic manipulations within an ISO Class 5 environment using three or fewer sterile products and 2 entries into any container<br>- In absence of passing sterility test, store not more than 48 hours at controlled room temperature, 14 days at cold temperature, and 45 days in solid frozen state at -25° to -10° or colder<br>- Media-fill test at least annually by staff | | |
| 3.3 | **Does the licensee compound Low-Risk level (with 12-hour or less BUD) CSPs?**<br><br>Low-Risk level CSPs with 12-hour or less BUD are defined as:<br>- Fully comply with Low-risk Level CSP<br>- PEC is not required to be in ISO Class 7 air<br>- Only patient specific medications | | |
| 3.4 | **Does the licensee compound Medium-Risk level CSPs?**<br><br>Medium-Risk level CSPs are defined as:<br>- Aseptic manipulations within an ISO Class 5 environment using prolonged and complex mixing and transfer, more than three sterile products and entries into any container, and pooling ingredients from multiple sterile products to prepare multiple CSPs<br>- In absence of passing sterility test, store not more than 30 hours at controlled room temperature, 9 days at cold temperature, and 45 days in solid frozen state at -25° to -10° or colder<br>- Media-fill test at least annually by staff | | |

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| 3.5 | **Does the licensee compound High-Risk level CSPs?**<br><br>High-Risk level CSPs are defined as:<br>- Confirmed presence of non-sterile ingredients or devices, or confirmed or suspected exposure of sterile ingredients for more than one hour to air quality inferior to ISO Class 5 before final sterilization<br>- Sterilization method verified to achieve sterility for the quantity and type of containers<br>- Meet allowable limits for bacterial endotoxins<br>- Maintain acceptable strength and purity of ingredients and integrity of containers after sterilization<br>- In absence of passing sterility test, store not more than 24 hours at controlled room temperature, 3 days at cold temperature, and 45 days in solid frozen state at -25° to -10° or colder<br>- Media-fill test at least semiannually by staff<br>- Compounding personnel are properly garbed and gloved<br>- Non-sterile water-containing preparations are stored for more than 6 hours before being sterilized | | |
| 3.6 | **If licensee compounds High-Risk level CSPs, are all the following conditions met:**<br>- Are all non-sterile measuring, mixing, and purifying devices rinsed thoroughly with sterile, pyrogen-free water, then thoroughly drained or dried immediately before use for high-risk compounding?<br>- Are all high-risk level CSP solutions subjected to terminal sterilization pre-filtered by passing through a filter with a nominal pore size not larger than 1.2 microns preceding or during filling into their final containers to remove particulate matter?<br>- If sterilization of high-risk level CSPs is done by filtration, it shall be performed with a sterile 0.2 micron or 0.22 micron nominal pore size filter entirely within an ISO Class 5 or superior air quality environment | | |
| 3.7 | **Are there any other concerns identified by the inspector related to this chapter?** | | |
| 4.0 | **Personnel Training and Evaluation in Aseptic Manipulation Skills** | | |
| 4.1 | **Does the licensee have a SPP (standard policy and procedure) on initial training of staff? Is the licensee following its SPP?** | | |
| 4.2 | **Does the licensee have a SPP on maintaining the ongoing competency of staff? Is the licensee following its SPP?** | | |
| 4.3 | ***Pull a personnel file of a RPh and a QPT.*** **Does the personnel file contain the following information *(if at a prescriber office, pull the file of the staff who compounds)* :**<br>Initial training with:<br>- Completion of didactic training?<br>- Successful passage of written examination?<br>- Initial Skills Assessment?<br>Annual assessment of (or semi-annual if high risk):<br>- Risk appropriate media fills<br>- Gloved fingertip (using sterile contact agar plates)<br>- Surface sampling<br>- Proficiency of proper hand hygiene, garbing, and consistent cleaning procedures (USP 797- Personal Cleansing and Garbing, and Section 11 of this document)<br>o Form used should be similar to USP 797 Appendix III<br>NOTE: For competency training and assessment of hazardous drugs, see section 7 | | |

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| 4.4 | **Were the assessment forms filled out completely and at the correct frequency for ongoing competency?** | | |
| 4.5 | **Does the training program include the following essential elements to safely compound sterile products?**<br>- Appropriate hand washing?<br>- Disinfection of non-sterile compounding surfaces and equipment?<br>- Don appropriate protective garb?<br>- Maintain or achieve sterility of CSPs in ISO Class 5 PEC devices<br>- Correctly identify, weigh/measure ingredients<br>- BUD of opened SDV/MDV<br>- BUD of CSPs<br>- Sterilization methods<br>- Cleaning and verification of compounding devices<br>- Procedures for measuring, mixing, dilution, purification, sterilization, packaging, and labeling of CSPs<br>- QA program | | |
| 4.6 | **Were the competency assessments (performed in question 4.3) for media fills done correctly?** (USP 797- Competency Evaluation of Garbing and Aseptic Work Practice)<br>Key components of assessing media fills:<br>- Form used should be similar to Appendix IV, USP 797<br>- Using Soybean-Casein Digest Medium (aka trypticase soy broth or trypticase soy agar) or equivalent<br>- For high-risk level CSPs, licensee can use non-sterile commercially available Soybean-Casein Digest Medium to make a 3% solution. Normal processing steps including filtration shall be mimicked.<br>- Sample incubated at 20° to 35° for at least 14 days<br>- Inspected for microbial growth during/after incubation (failure is indicated by turbidity on or before 14 days)<br><br>Other methods may be used if recommended by a microbiologist. | | |

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| 4.7 | **Were the competency assessments (performed in question 4.3) for gloved fingertip done correctly?** (USP 797-Competency Evaluation of Garbing and Aseptic Work Practice)<br>Key components of assessing gloved fingertip:<br>- After hand washing & garbing but before gloved disinfection with sterile 70% IPA<br>- Using sterile contact agar plates with neutralizing agents; slight impression into agar plate<br>- Gloved fingertip and thumb; both hands<br>- Rest of glove discarded and hand hygiene be performed after sample obtained<br>- Plates are secured, covered, inverted, then incubated at 30-35° for 2-3 days<br>- Results reported on form; Colony-forming units (cfu) action level for gloved hands shall be based on total number of cfu on both gloves and not per hand<br>- Tested a minimum of 3 times prior to initially being allowed to compound and annually thereafter (semi-annually if high-risk level CSPs)<br>- No cfu's are permitted | | |
| 4.8 | **Were the competency assessments (performed in question 4.3) for surface sampling done correctly**? (USP 797- Competency Evaluation of Garbing and Aseptic Work Practice)<br>Key components of assessing surface sampling of personnel:<br>- Can use contact plates or swabs, at the conclusion of compounding.<br>- Sample plate is normally 24-30 $cm^2$. | | |
| 4.9 | **Were the competency assessments (performed in question 4.3) for garbing, gowning, and hand hygiene done correctly**? (USP 797- Competency Evaluation of Garbing and Aseptic Work Practice)<br><br>Done by visual observation and documented on form similar USP 797, Appendix III | | |
| 4.10 | **Were the competency assessments (performed in question 4.3) for cleaning and disinfecting done correctly?** (USP 797-Surface Cleaning and Disinfection Sampling and Assessment)<br>Key components of assessing cleaning and disinfecting competency:<br>- Gently touch the sample area with the agar surface and roll the plate across the surface. Immediately clean surface (as a growth media residue is present) by wiping with a non-shedding wipe soaked in sterile 70% IPA.<br>- Visual observation shall be documented on form similar to USP 797. Appendix V<br>- If using a swab, place in an appropriate diluent, an aliquot is planted on agar. Results should be reported as cfu per unit of surface area. | | |
| 4.11 | **If any staff failed any of the competencies, was there a documented re-instruction and re-evaluation performed by an expert? Compounding personnel shall pass all evaluations prior to resuming compounding of sterile preparations** (USP 797-Action Levels, Documentation and Data Evaluation)? | | |
| 4.12 | ***Observe staff.*** **Does the personnel:**<br>- Use proper aseptic technique?<br>- Have no excessive, non-essentials objects with them in the buffer area?<br>- Garb properly?<br>- Wash their hands properly?<br>- Have no make-up, no jewelry, no visible piercings, and no artificial nails, nail polish or gel nails?<br>- Have no food, gum, candy, or drinks with them in the compounding area? | | |

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| 4.13 | **If non-pharmacy personnel are performing monthly cleaning (i.e. housekeeping), is their training documented adequately for cleaning procedures required by USP 797?** This shall be evaluated by an aseptic compounding expert (USP 797-Personnel Training and Competency Evaluation)<br><br>Are they routinely evaluated for proper hand hygiene, garbing, and all applicable cleaning and disinfecting procedures conducted by an aseptic compounding expert? | | |
| 4.14 | **Are there any other concerns identified by the inspector related to this chapter?** | | |
| 5.0 | **Immediate Use CSPs** | | |
| 5.1 | **Does the licensee have situations where CSPs need to be compounded for immediate use (in worse than ISO Class 5 environment)?** | | |
| 5.2 | **Are these circumstances appropriate (where immediate use CSPs are permitted to be compounded outside USP 797 standards)?** Examples:<br>- Cardiopulmonary resuscitation<br>- Emergency room treatment<br>- Preparation of diagnostic agents<br>- Critical therapy where delay in therapy puts patients at additional risk | | |
| 5.3 | **Are only low risk CSPs made for immediate use?** | | |
| 5.4 | **Does the licensee follow the six criteria for immediate use CSPs (in order to be exempt from other USP 797 requirements)?**<br>1. Compounding involves only simple transfer of not more than three commercially manufactured packages of sterile nonhazardous products or diagnostic radiopharmaceuticals (note: does not include antineoplastics since they are hazardous).<br>2. Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour.<br>3. Aseptic technique is followed and if not immediately administered, the finished CSP is under continuous supervision by compounder.<br>4. Administration begins no later than 1 hour following start of the preparation of the CSP.<br>5. Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient name, name and amount of all ingredients, and the name or initials of the person who prepared the CSP, and the exact 1 hour BUD and time.<br>6. If administration has not begun within 1 hour following the start of preparing the CSP, the CSP shall be promptly, properly, and safely discarded. | | |
| 5.5 | **Do you observe any immediate use CSPs being stored?** | | |
| 5.6 | **Are there any other concerns identified by the inspector related to this chapter?** | | |
| 6.0 | **Single-Dose and Multiple-Dose Containers** | | |
| 6.1 | **Does the licensee use single-dose vials (SDV) more than once after initial puncture?** | | |
| 6.2 | **If used more than once, does the SDV usage follow USP 797 criteria?**<br>- If initial puncture is in worse than ISO Class 5 conditions, SDV is discarded after 1 hour.<br>- If initial puncture is in ISO Class 5 conditions, SDV is discarded after 6 hours. | | |
| 6.3 | **Do you observe any open ampules in the ISO Class 5 environment?** (not permitted per USP 797) | | |

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| 6.4 | **Does the licensee have a policy to discard multiple-dose vials (MDV) 28 days after initial puncture?** | | |
| 6.5 | **Did the inspector observe any opened, multiple dose vials (MDV) unlabeled without a BUD, observe any opened MDVs in active stock beyond 28 days, or find any open MDV with contaminants in active stock?** (USP 51,USP 797- Single Dose and Multiple-Dose Containers, Section 16 of this Document) | | |
| 6.6 | **If MDV are kept longer than 28 days, does the licensee have documentation from the manufacturer that antimicrobial effectiveness testing can allow that specific container to be kept for > 28 days?** (USP 51)<br><br>Is there an evaluation by the staff for cloudiness, coring, or other signs of contamination? | | |
| 6.7 | **Are there any other concerns identified by the inspector related to this chapter?** | | |
| 7.0 | **Hazardous Drugs as CSPs** | | |
| 7.1 | **Does the licensee prepare CSPs which are considered hazardous?** | | |
| 7.2 | **Does the licensee have a negative pressure room?** | | |
| 7.3 | **Is this licensee considered a "low-volume" facility?** (NOTE: USP 797 currently does not require a low-volume facility to have a negative pressure room)<br><br>*Document in observations what volume of hazardous drug CSPs this licensee compounds.* | | |
| 7.4 | **Does this "low volume" hazardous drug licensee meet the criteria to be exempt from a negative pressure room?**<br>- Uses BSC or CACI, and<br>- Uses CSTD for all hazardous drug preparation | | |
| 7.5 | **Does the licensee have an appropriate area for storage of hazardous drugs**? (stored separately from other inventory)<br><br>Is this drug storage in a negative pressure room (not required but recommended)? | | |
| 7.6 | **Does the storage area for hazardous drugs have at least 12 air changes per hour (ACPH)?**<br><br>What was the last documented ACPH for the hazardous drug storage area (include date)? | | |
| 7.7 | **Are chemotherapy gloves used during all aspects of handling hazardous drugs?**<br>- Receiving<br>- Distributing<br>- Stocking<br>- Inventorying<br>- Preparation for administration<br>- Disposal | | |
| 7.8 | **Are all hazardous drug CSPs prepared in an ISO Class 5 environment with an appropriate PEC?** (BSC or CACI) | | |
| 7.9 | **Is the hazardous drug PEC located in an ISO Class 7 environment?** | | |
| 7.10 | **Is the hazardous drug PEC located in a physically separate space from other preparation areas?** | | |
| 7.11 | **Does the negative pressure room have a pressure indicator?** | | |
| 7.12 | **Does the pressure indicator document not less than -0.01 inch water column negative pressure to the adjacent positive pressure ISO Class 7 or better environment?** | | |

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| 7.13 | **Is the pressure indicator reading documented daily by the licensee?**<br><br>*Document in observations what the current pressure indicator reading is.* | | |
| 7.14 | **Is the hazardous drug PEC vented to the outside through HEPA filtration?** (not required but recommended) | | |
| 7.15 | **Is the licensee using closed-system vial-transfer devices (CSTDs) in an ISO Class 5 environment?** | | |
| 7.16 | **Does the licensee staff don the appropriate personnel protective equipment (PPE) when compounding in a BSC or CACI?**<br>- Gowns<br>- Face masks<br>- Eye protection<br>- Hair covers<br>- Shoe covers or dedicated shoes<br>- Double gloving with sterile chemo-style gloves<br>- (For CACI) Compliance with manufacturers' recommendations | | |
| 7.17 | **Is the compounding staff appropriately trained in the storage, handling, and disposal of hazardous drugs?**<br>- Training occurred prior to preparing<br>- Effectiveness of training shall be verified<br>- Annual verification<br>- Didactic overview of hazardous drugs<br>- Compounding personnel of reproductive capability shall confirm in writing that they understand the risks of handling hazardous drugs | | |
| 7.18 | ***Pull a personnel file of a RPh and a QPT.*** **Does the personnel file contain the following information?** *(If at a prescriber office, pull the file of staff that compounds)*<br>- Safe aseptic manipulation for hazardous drugs<br>- Negative pressure techniques when using a BSC or CACI<br>- Correct use of CSTD devices<br>- Containment, cleanup, and disposal procedures for breakages and spills<br>- Treatment of personnel contact and inhalation exposure | | |
| 7.19 | **If licensee compounds a high volume of hazardous drug CSP, do they have a QA program to evaluate contamination risk?** (recommended only) Examples:<br>- Surface wipe sampling of the work area inside the BSC or CACI, the floor under the PEC device, areas adjacent to the PEC device, and the patient administration areas (every six months is recommendation)<br>- Common marker drugs include: cyclophosphamide, ifosfamide, methotrexate, and fluorouracil<br>- If measurable amounts of contamination have been found (which causes human uptake), the QA program includes an evaluation to:<br>  o Re-train staff<br>  o Thorough cleaning (utilizing high pH soap plus water)<br>  o Venting BSC or CACI 100% to the outside<br>  o Re-assessing types of BSC or CACI used | | |

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| 7.20 | **Does the licensee comply with all state/federal regulations regarding hazardous waste?** | | |
| 7.21 | **Are the licensee's personnel who perform routine custodial waste removal and cleaning activities trained to protect themselves and prevent contamination?** | | |
| 7.22 | **Are there any other concerns identified by the inspector related to this chapter?** | | |
| 8.0 | **Radiopharmaceuticals as CSPs** | | |
| 8.1 | **Does licensee prepare CSPs which are considered radiopharmaceuticals?**<br>- Positron Emission Tomography (PET) handling, manipulation, or use after it's in the finished drug product (following USP 823) is considered compounding, and USP 797 applies.<br>- Radiopharmaceuticals compounded from sterile components in closed sterile containers and with a volume of 100 mL or less for a single-dose injection or not more than 30 mL taken from a multiple-dose container shall be designated a low-risk level CSP | | |
| 8.2 | **Are the CSP radiopharmaceuticals compounded in an appropriate environment?**<br>- Appropriate shielded vials and syringes<br>- ISO Class 5, certified PEC<br>- PEC located in a ISO Class 8 environment<br>- Negative air flow | | |
| 8.3 | **Are sterile radiopharmaceutical vials for multiple-use compounded with technetium-99m (99mTc) handled appropriately?**<br>- Compounded in an ISO Class 5 environment and stored according to manufacturers' recommendations.<br>- Storage and transport of properly shielded vials of radiopharmaceutical CSPs may occur without a specific ISO Class designation.<br>- 99mTc/molybdenum-99 generator systems shall be stored and eluted (operated) under conditions recommended by manufacturers and applicable state/federal regulations. Such generator systems shall be eluted in an ISO Class 8 or cleaner air environment. | | |

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| 8.4 | **Are the radiopharmaceuticals prepared as a low-risk level CSP with 12-hour or less BUD prepared in a segregated compounding area?** (with appropriate lines of demarcation) | | |
| 8.5 | **Are there any other concerns identified by the inspector related to this chapter?** | | |
| 9.0 | **Allergen Extracts as CSPs** | | |
| 9.1 | **Does the licensee prepare CSPs which are considered allergen extracts?** | | |
| 9.2 | **Does the licensee follow the eleven (11) requirements of allergen extracts to be exempt from the personnel, environmental, and storage requirements of USP 797?**<br>1. Simple transfer via sterile syringes/needles of commercially available allergen extracts.<br>2. All allergen extracts shall contain appropriate substances in effective concentrations to prevent growth of microorganisms. Non-preserved allergen extracts shall comply with the appropriate CSP risk level requirements of USP 797.<br>3. Staff shall perform appropriate hand washing.<br>4. Staff shall don hair covers, facial hair covers, gowns, and face masks.<br>5. Staff shall perform antiseptic hand cleansing with alcohol-based surgical hand scrub.<br>6. Staff shall don powder-free sterile gloves that are compatible with sterile 70% IPA (isopropyl alcohol) before compounding manipulation.<br>7. Staff shall disinfect their gloves intermittently.<br>8. Ampule necks and vial stoppers on packages of sterile ingredients are disinfected with sterile IPA to ensure that all critical sites are wet for at least 10 seconds and allowed to dry before use.<br>9. Aseptic compounding manipulations minimize direct contact contamination of critical sites.<br>10. The labels of each MDV of allergen extracts as CSPs list the name of one specific patient and a BUD and storage temperature range.<br>11. Single dose allergen extracts as a CSPs only used once and not stored for subsequent additional use. | | |
| 9.3 | **Are there any other concerns identified by the inspector related to this chapter?** | | |
| 10.0 | **Verification of Compounding Accuracy and Sterility** | | |
| 10.1 | **Does the licensee have policies and/or a QA program which periodically reviews accuracy of:**<br>- Labels for identity/purity of ingredients<br>  o Including certificates of analysis provided by suppliers where appropriate<br>- Measurement of ingredients<br>- Aseptic manipulation procedures<br>- Sterilization procedures | | |
| 10.2 | **Are any unlabeled drug products disposed of immediately?** | | |
| 10.3 | **Are chemicals without expiration dates and/or BUD appropriately evaluated?**<br>- Recent certificate of analysis from supplier<br>- Making changes to formulation (USP 1160) based on moisture content (USP 731) to determine correct amount to weigh for accurate content of chemical moieties in CSPs. | | |

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| 10.4 | **Does the licensee use a third party to conduct a quantitative stability-indicating chemical assay on completed sterile CSPs? (recommended) Sterility?**<br><br>If yes, describe percentage and/or frequency in observations. | | |
| 10.5 | **Does the licensee evaluate sterilization methods which will maintain the CSPs strength, purity, quality, and packaging integrity?** (USP 1211)<br>- CSPs have been ascertained to remain physically and chemically stable when subjected to sterilization method (ex. HCl drips and water miscible alcohols).<br>- Personnel ascertain this information from appropriate sources. | | |
| 10.6 | **Does the licensee appropriately sterilize high-risk level CSPs by filtration?**<br>- 0.2 micron pore size sterile membranes that are chemically and physically compatible with the CSP.<br>- Filter size is appropriate for volume of solution to be filtered.<br>- When CSPs are known to have excessive particulate matter, a prefilter is used to remove gross contaminates.<br>- Complete rapidly without filter replacement.<br>- Filter has been subjected to manufacturer's recommended integrity test (e.g. bubble point test) after filtering CSP. | | |
| 10.7 | **Does the licensee appropriately sterilize high-risk level CSPs by steam? (autoclave)**<br>- To achieve sterility, all materials are to be exposed to steam at 121° under a pressure of 1 atmosphere or 15 psi for the duration verified by testing to achieve sterility, usually 20-60 minutes for CSPs. An allowance shall be made for the time required for the material to reach 121° before the sterilization exposure duration is timed.<br>- Written procedure with sterilization conditions including duration.<br>- Pass solutions through a 1.2 micron or smaller pore size filter into final containers to remove particulates before sterilization.<br>- Test with a BI (biological indicator – usually Bacillus stearothermophilus- USP 1035).<br>- Test to verify the mass of containers to be sterilized will be sterile after the selected exposure duration in the particular autoclave.<br>- Ensure live steam contacts all ingredients and surfaces to be sterilized. | | |
| 10.8 | **Does the licensee appropriately sterilize high-risk level CSPs by dry heat?**<br>- Dry heat shall only be used for those materials that cannot be sterilized by steam, when the moisture would either damage or be impermeable to the materials.<br>- Heated filtered air shall be evenly distributed throughout the chamber by a blower device.<br>- Sufficient space shall be left between materials to allow for good circulation of the hot air.<br>- Written procedure with sterilization conditions including duration.<br>- Effectiveness of dry heat sterilization shall be verified by using an appropriate BI and other confirmation. | | |
| 10.9 | **Does the licensee appropriately depyrogenate CSPs?**<br>- Glass and metal devices may be covered tightly with aluminum foil, then exposed to dry heat in an oven at a mean temperature for 250° for 30 minutes to achieve sterilization and depyrogenation (USP 1211 and 85).<br>- Written procedure should include description of cycle and duration<br>- Effectiveness of the endotoxin test should be performed using endotoxin challenge vials (ECVs) which verify cycle is capable of achieving a 3-log reduction in endotoxins. | | |
| 10.10 | **Are there any other concerns identified by the inspector related to this chapter?** | | |

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| 11.0 | **Environmental Quality and Control** | | |
| 11.1 | **Are there any concerns with how the licensee's staff handles the exposure of the critical sites?**<br>- Should be handled in ISO Class 5 air or better<br>- Preclude direct contact (touch or secretion contamination)<br>- Sterile 70% IPA swabs (individual foil packs) are preferred method for disinfecting critical site areas (bags, vials) prior to needle puncture or for necks of ampules<br>- Sterile 70% IPA wetted gauze pads or other particle-generating material shall not be used to disinfect the sterile entry points of packages and devices | | |
| 11.2 | ***Describe facility/room design***. *Include:*<br>- Type of space/rooms, e.g. cleanroom/buffer area with ante-area<br>- PEC placement<br>- Is RPh able to supervise technician staff?<br><br>The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area shall be smooth, impervious, free from cracks and crevices, and non-shedding, thereby promoting clean-ability and minimizing spaces in which microorganisms and other contaminants may accumulate. | | |
| 11.3 | **Are there any concerns with the room design?**<br>- Are surfaces (e.g. counters, shelves, & carts) non-porous/cleanable?<br>- Flooring (cleanable surfaces, prefer vinyl with heat-welded seams and coving to the side wall, no matts)<br>- Walls (cleanable surfaces, sealed)<br>- Ceiling (cleanable surfaces, if inlaid panels (recommend) sealed with a polymer to render them impervious and hydrophobic, caulked around perimeter, junctures to walls shall be coved or caulked to avoid cracks and crevices)<br>- Light fixtures should be smooth, mounted flush, and sealed<br>- Dust-collecting overhangs, e.g. pipes should (recommend) be avoided<br>- Any other penetrations (ex. cameras) through the ceiling or walls shall be sealed<br>- Equipment (cleanable surfaces/disinfectant resistant, only essential equipment in cleanroom, free of cardboard & other particle generators, chairs are stainless steel or non-porous)<br>- Hood placement *(can a mop get beside/behind hood without moving hood?)*<br>- Area free of clutter?<br>- Are labels placed inside or near hood?<br>- Are there any windows into cleanroom? Are there flat edges (dust collectors) or are they beveled?<br>- Buffer area shall not have a water source (sink) or floor drains | | |

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| 11.4 | ***If licensee has a low-risk/12 hour BUD area, ensure:***<br>- No unsealed windows or doors nearby<br>- Staff must be gowned/garbed<br>- Not adjacent to construction/high traffic areas or food prep<br>- Sinks should not be located adjacent to the ISO Class 5 PEC | | |
| 11.5 | **Does the PEC provide ISO Class 5 conditions or better for 0.5 micron particles under dynamic conditions?** | | |
| 11.6 | **Any issues with how licensee's staff is handling PEC first air?**<br>Any clutter observed inside PEC or other concerns? | | |
| 11.7 | **What is the name of the company providing the certification for the PEC?**<br>*Is the technician CETA certified?* | | |
| 11.8 | ***Review most recent PEC certification report.*** **Are there any issues?**<br>- *Did certification report include documentation that testing was performed in dynamic conditions?*<br>- *Was smoke test performed to ensure unidirectional airflow and sweeping action over and away from the product under dynamic conditions?*<br>- *Were air velocities consistent with, no major outliers?*<br>- *Was an edge test performed?*<br><br>If there is a current problem with certification, document description of problem and planned timeframe for correction and re-inspection. | | |
| 11.9 | **Are there any concerns with the frequency of the licensee's environmental sampling program? Does the frequency of the sampling occur in a manner that provides information to licensee leadership that the engineering controls are maintaining an environment within the compounding area that consistently maintains acceptably low viable and nonviable particle levels?**<br><br>Environmental sampling of PEC (and Secondary Environmental Controls – i.e. rooms) shall occur:<br>- At any new facility or equipment<br>- After servicing of facility or equipment (including moving of PEC)<br>- Re-certification program (every six months)<br>- In response to identified problems with end products or staff technique<br>- In response to issues with CSPs, observed personnel work practices, or patient-related infections (where CSPs are potential source of infection) | | |

| Section | Topic/Question | Y/N | Inspector Observations or Notes |
|---|---|---|---|
| 11.10 | ***If the licensee compounds high-risk CSPs and/or they have a separate ante-area from buffer area (by use of walls, doors, and/or pass-through), review the most recent inspection certification report.*** **Are there any issues?**<br>- Does the Buffer area provide at least ISO Class 7 or better air?<br>- Does the Ante-area provide at least ISO Class 8 or better air?<br>- Is there a minimum differential positive pressure of 0.02- to 0.05-inch water column?<br>- Is this monitored and recorded daily by staff? (recommend per shift) This can be documented on a continuous recording device.<br>- Buffer area has at least 30 ACPH (15 ACPH may come from the PEC-LAFW) but may need to be higher if more personnel are in the Buffer Area<br>- HEPA-filtered air introduced in ceiling (required) and returns should (recommended) be low on the wall<br>- HEPA-filters should be leak tested after install<br>- Does the pharmacy do any smoke tests to visualize air flow in buffer area? | | |
| 11.11 | **If licensee does not have a physically separated buffer area from the ante-area, is the principle of displacement airflow in use?**<br>- Low pressure, high airflow principle<br>- Air velocity of 40 feet per minute or more from the buffer area across the line of demarcation into the ante-area.<br>- This may not be used if high-risk compounding is occurring<br><br>Is there a line of demarcation on the floor physically separating space? | | |

| Section | Topic/Question | Y/N | Inspector Observations or Notes |
|---|---|---|---|
| 11.12 | **If the licensee is using a CAI or CACI, are the following criteria met?**<br>- PECs shall be located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns.<br>- Pre-sterilization procedures for high-risk level CSPs, such as weighing and mixing, shall be completed in no worse than an ISO Class 8 environment.<br>- The isolator shall provide isolation from the room and maintain ISO Class 5 during dynamic operating conditions, including transferring ingredients, components, and devices into and out of the isolator and during preparation of CSPs.<br>- Particle counts samples approximately 6-12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding.<br>- Not more than 3520 particles (0.5 microns and larger) per $m^3$ shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing the transfer.<br>- Licensee has documentation from the manufacturer that the CAI/CACI will meet this standard when placed in areas exceeding ISO Class 8 air.<br>- Internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations.<br><br>NOTE: This is only required when CAI/CACI is placed in worse than ISO Class 7 air. | | |
| 11.13 | ***If the licensee has any robotic device CSPs, are there any concerns?***<br><br>(I.e. Intellifill®, Repeater® Pump, etc.) | | |
| 11.14 | **How is the licensee using surface and air sampling to identify viable particles? Is this documented in the SPP?**<br><br>Documentation – the plan shall include: sample location, method of collection, frequency of sampling, volume of air sampled, time of day related to activity in compounding area, and action levels. | | |

| Section | Topic/Question | Y/N | Inspector Observations or Notes |
|---|---|---|---|
| 11.15 | **Is there any concern with the way the licensee uses growth media for surface sampling to identify viable particles?**<br>Types of plates used:<br>- Bacteria, for all risk levels, Soybean Casein Digest Medium (aka trypticase soy broth-TSB or agar-TSA)<br>- Fungus, for high-risk compounding, Malt Extract Agar (there are other acceptable alternatives but are not explicitly mentioned in USP 797)<br>- All medium for surface sampling shall be supplemented with additives to neutralize the effects of disinfecting agents (e.g. TSA with lecithin and polysorbate 80)<br>Methodology/Use:<br>- Settling plates (gravity) is not adequate enough due to air flow<br>- Impaction is the preferred method<br>- Can use contact plates or swabs, at the conclusion of compounding.<br>Locations to sample:<br>- For low, medium, and high risk levels: areas prone to contamination such as staging, labeling, gowning, and cleaning; areas where air backwash can occur such as doorways, in & around PEC; counters near doors & pass-through boxes<br>- Swabs usually used for unusual surfaces such as equipment (USP 1116)<br>- On all ISO classified areas<br>- For low risk level/12 hour BUD: PEC and around the PEC<br>Frequency:<br>- Every six months for low & medium risk levels in each compounding area<br>- After construction before compounding occurs (recommend)<br>Incubation period:<br>- Tape shut the covers, invert plates and incubate<br>- Soybean-Casein Digest should be incubated 30° to 35° for 48-72 hours<br>- Malt extract agar (MEA) should be incubated 26° to 30° for 5-7 days | | |
| 11.16 | **Is there any concern with the way the licensee uses air sampling to identify viable particles? (usually done at time of recertification)**<br>Volumetric air sampling (electronic air sampling equipment)- USP 1116<br>- Follow manufacturer's instruction for use and calibration<br>- Collect sufficient volume of air (400 to 1000 Liters)<br>Frequency:<br>- Every six months for low & medium risk levels in each compounding area<br>- After construction before compounding occurs (recommend)<br>Incubation period:<br>- Tape shut the covers, invert plates and incubate<br>- Soybean-Casein Digest should be incubated 30° to 35° for 48-72 hours<br>- Malt extract agar (MEA) should be incubated 26° to 30° for 5-7 days | | |

| Section | Topic/Question | Y/N | Inspector Observations or Notes |
|---|---|---|---|
| 11.17 | **If the result from air and surface sampling performed in 11.15 and 11.16 identified viable particles is there an action plan in place that appropriately address all areas of concern?**<br>- Number of colonies (colony forming units - cfu) shall be counted<br>- Evaluate for adverse trends and identify the genus of the cfu<br>- If above action level: re-evaluate personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency<br>o Recommend action if cfu on surface plate:<br>▪ ISO 5 > 3 cfu, ISO 7 > 5 cu, ISO 8 > 100 cfu<br>o Recommend action if cfu per 1000 Liters of air per plate:<br>▪ ISO 5 > 1 cfu, ISO 7 > 10 cfu, ISO 8 - > 100 cfu<br>o Recommend action if highly pathogenic regardless of count (ex. gram negative rods, coag-neg staph, molds/yeasts)<br><br>If an activity consistently shows elevated levels of microbial growth, competent microbiology personnel shall be consulted. | | |
| 11.18 | **Is there any food, drinks, or other inappropriate materials in ante-area, buffer areas, or segregated compounding areas?** | | |
| 11.19 | **Is the licensee performing any compounding activities with patient's blood-derived or other biological material?** (e.g. radiolabeling a patient's or donor's white blood cells)<br><br>If yes, manipulations should be clearly separated from other routine material-handling and equipment. There must be a policy and procedure in order to avoid any cross-contamination. | | |
| 11.20 | **Are packaged compounding supplies and components wiped down with a disinfectant when possible in an ante-area of ISO Class 8 air or better?** (recommend)<br>Disinfectant should not leave a residue such as sterile 70% IPA-isopropyl alcohol<br><br>Sterile supplies received in sealed pouches (designed to keep them sterile until opening) may be opened as they are introduced into ISO Class 5 PEC without the need to disinfect the individual sterile supply item. | | |
| 11.21 | **Are personnel hand hygiene and garbing done in the ante-area?** | | |
| 11.22 | **Is the sink hands-free?** (recommend) **Is it in the ante-area** (required)? | | |
| 11.23 | **Is the soap dispenser a closed system to minimize risk of extrinsic contamination?** | | |
| 11.24 | **After personnel hand hygiene, does the staff perform antiseptic hand cleansing using an alcohol-based surgical hand scrub with persistent activity *(i.e. not Purell®)* in the buffer area?** | | |
| 11.25 | **After the alcohol-based surgical hand scrub with persistent activity is placed, does the staff don sterile gloves after entering the buffer area?** | | |

| Section | Topic/Question | Y/N | Inspector Observations or Notes |
|---|---|---|---|
| 11.26 | **Is the licensee cleaning and disinfecting the compounding area appropriately?**<br><br>Cleaning & Disinfecting – Area (frequency):<br>- ISO Class 5 PEC (at beginning of shift, before each batch, not longer than 30 minutes following previous surface disinfection when ongoing compounding activities are occurring, after spills, and when surface contamination is known/suspected)<br>- Counters and easily cleanable work surfaces (daily)<br>- Floors (daily)<br>- Walls (monthly)<br>- Ceilings (monthly)<br>- Storage shelving (monthly)<br><br>If heavy soiling, recommend a cleaning step prior to disinfection. | | |
| 11.27 | **What disinfectant is the licensee using for routine, daily cleaning?**<br>**Is there a different disinfectant being used for monthly cleaning?** | | |
| 11.28 | **Are the wipes low-shedding (not gauze)?** | | |
| 11.29 | **Are wipes, sponges, and mops non-shedding, and dedicated to use only in the buffer or clean area, ante-area, and segregated compounding areas?** *(not removed from area unless being disposed of)*<br><br>Floor mops may be used in both the buffer and ante-area, but must be used in the buffer area first, then the ante-area.<br><br>Wipes, sponges or mops may be used more than once [based on manufacturers' recommendations] that ensure the effectiveness of the cleaning device is maintained and repeated use does not add to the bioburden of the area being cleaned. | | |
| 11.30 | **Are there any concerns identified by the inspector on methodologies used for cleaning the compounding areas?**<br><br>Are all items removed from area to be cleaned when possible, are surfaces cleaned by removing loose material and residue from spills (such as with sterile water), are areas wiped with a residue-free disinfectant (such as sterile 70% IPA), and are surfaces allowed to dry before compounding resumes. | | |

| Section | Topic/Question | Y/N | Inspector Observations or Notes |
|---|---|---|---|
| 11.31 | **Are there any concerns regarding the compounding personnel?** (clothing, appearance, general health)<br>- They are not ill: exposed rashes, sunburn, weeping sores, conjunctivitis, active respiratory illness<br>- They are not permitted to makeup/cosmetics<br>- They are not permitted to wear excessive outerwear such as bandanas, coats, hats, jackets, scarves, sweaters, or vests<br>- They are not permitted to wear jewelry on hands, wrists, or other visible piercings (ear, lip, or eyebrow) which may interfere with the effectiveness of PPE (fit of gloves and/or cuffs of sleeves)<br>- They may not wear nail polish, artificial nails or extenders (natural nails should be clean, neat, and trimmed) | | |
| 11.32 | **If the licensee is using a CAI or CACI, the gowning/gloving is the same as a clean room unless the isolator manufacturer can provide written documentation based on validated environmental testing that any component of PPE or personal cleansing is not required.**<br><br>(Note: garbing procedures are also exempt for immediate use CSP) | | |

| Section | Topic/Question | Y/N | Inspector Observations or Notes |
|---|---|---|---|
| 11.33 | **Do the compounding personnel don all required PPE, in the correct order, and replace PPE when appropriate?**<br>- Dedicated shoes or shoe coverings<br>- Head and facial hair covers (beard covers in addition to face masks)<br>- Face masks and shields (eye shields are optional as long as not performing hazardous drug CSP or cleaning with irritants such as germicidal disinfectants)<br>- Clean hands by removing debris under fingernails then hand and forearm to elbows cleaning for at least 30 seconds with soap and water. *(clock/timer?)* NOTE: antimicrobial scrub brushes are not recommended. Hands and forearms to be dried with lint-free disposable towels or electric hand dryer.<br>- Non-shedding gown with sleeves which fit snuggly around wrists and enclosed at the neck. Disposable gowns are preferred but not required.<br>- Once in the buffer area or segregated compounding area, compounding personnel use a waterless alcohol surgical hand scrub with persistent activity. Hands are thoroughly dried before donning powder-free sterile gloves.<br>- Prior to and during compounding activities, compounding personnel spray gloves with sterile 70% IPA to disinfect during compounding activities and when non-sterile surfaces are touched. Sterile gloves should be continuously monitored and inspected for holes, punctures, or tears and replaced immediately if detected.<br>- During the work shift, the exterior gown may be removed and retained in the compounding area if not visibly soiled, and may be re-donned during the same work shift only. Shoe covers, hair/facial hair covers, face masks/shield, and gloves shall be replaced with each re-entry into the compounding area.<br>- In worse than ISO Class 7 air, personnel shall re-garb PPE and complete proper hand washing, antiseptic hand cleansing with a waterless alcohol-based surgical hand scrub, and don sterile gloves upon re-entering the ISO Class 7 environment. | | |
| 11.34 | **If the licensee is performing high-risk compounding, is the mixing and weighing of non-sterile ingredients done with the proper Garb/PPE?**<br><br>In ISO Class 7 air or better, garb as you would for compounding in an ISO Class 5 environment | | |
| 11.35 | **Are there any other concerns identified by the inspector related to this chapter?** | | |
| 12.0 | **Suggested Standard Operating Procedures (SOPs)** | | |
| 12.1 | **Does the licensee have a policy and procedure (SPP) manual?**<br>*Is it updated? How often?*<br><br>*Is it purchased or proprietary? If purchased, from whom, and is it modified for the specific location being inspected?* | | |
| 12.2 | **Is the licensee's SPP manual adequate?**<br>**If not, what significant items are missing?** | | |

| Section | Topic/Question | Y/N | Inspector Observations or Notes |
|---|---|---|---|
| 12.3 | **Are there any other concerns identified by the inspector related to this chapter?** | | |
| 13.0 | **Elements of Quality Control** | | |
| 13.1 | **Are commercially available sterile drug products, sterile ready-to-use containers, and devices, inspected prior to use to ensure they are sterile, free from defects, and otherwise suitable for use?** *(this should be in written SPP)* | | |
| 13.2 | **Are the non-sterile active ingredients used (and added substances or excipients) official USP or NF articles?** *(not required)* | | |
| 13.3 | **If a non USP/NF non-sterile ingredient is used, did the licensee obtain and evaluate the certificate of analysis from the supplier?** | | |
| 13.4 | **Is the storage of these non-sterile active ingredients appropriate?**<br>- Stored in tightly closed containers under temperature, humidity, and lighting conditions indicated in official monographs or approved by suppliers.<br>- Date of receipt by the licensee shall be clearly and indelibly marked on each package or ingredient.<br>- After receipt by the licensee, packages of ingredients that lack a supplier's expiration date cannot be used after 1 year unless either appropriate inspection or testing indicates that the ingredient has retained its purity and quality for use in CSPs.<br>- Visual inspection shall occur for bulk drug substances or excipients for evidence of deterioration, unacceptable quality, and wrong identification. | | |
| 13.5 | **Does the licensee have written procedures for how equipment, apparatus, or devices used to compound a CSP are calibrated?**<br>-Routine maintenance and frequency must be outlined in the facilities SPPs.<br>-Staff must be trained to determine if equipment is malfunctioning. | | |
| 13.6 | **Does the licensee maintain documentation of calibration and maintenance of equipment/compounding devices?**<br><br>Results from calibration, annual maintenance and routine maintenance must be kept on file for the lifetime of the equipment. | | |
| 13.7 | **Are there any other concerns identified by the inspector related to this chapter?** | | |
| 14.0 | **Verification of Automated Compounding Devices (ACDs) for Parenteral Nutrition Compounding** | | |
| 14.1 | **Does the licensee have an ACD?** Name and version (if applicable) | | |
| 14.2 | **How does the licensee test the ACD for volume and weight accuracy on a daily basis? Are trends reviewed at least weekly?** | | |
| 14.3 | **Is the volume accuracy test done appropriately?** (USP 31)<br>- Similar volume delivered to a volumetric device | | |
| 14.4 | **Is the weight accuracy test done appropriately? (USP 41)**<br>- If sterile water (assuming relative density of water is 1.0), 40 ml of sterile water should weigh ~ 40 grams. | | |
| 14.5 | **Are there any concerns with how the licensee is using the ACD?**<br>Such as:<br>- First air compromises<br>- Clutter in ISO Class 5 space<br>- Overriding barcodes<br>- If a barcode system is used, is this approved by a RPh daily? *(I.e. Baxa Compounder®/barcode set-up)*<br>- Are the lines changed according to the manufacturer? *(usually daily)* | | |

| Section | Topic/Question | Y/N | Inspector Observations or Notes |
|---|---|---|---|
| 14.6 | **Are there any other concerns identified by the inspector related to this chapter?** | | |
| 15.0 | **Finished Preparation Release Checks and Tests** | | |
| 15.1 | **Does the licensee have an appropriate procedure where the compounding personnel perform a pre-release inspection?**<br>Including:<br>- Physical inspection of each CSP solution for the presence of particulate matter, cloudiness, precipitation, etc…<br>- Container-closure integrity, i.e. leaking<br>- Any other defects of the CSP | | |
| 15.2 | **Does the licensee have a white and/or black background area where CSP solutions can be (better) visualized for visible particulates or other foreign matter?** (not required) | | |
| 15.3 | **If the pre-release inspection fails, such as a core is found, is the CSP destroyed? If no, why not?** | | |
| 15.4 | **Is there an appropriate double check system for the CSP to be verified for accuracy? Does the inspector have any concerns?**<br><br>Example: If a partial container was added to the LVP (Large Volume Parenteral), a syringe with the plunger pulled back to the volume added should be available for the RPh to check that the correct volume of drug was added to the LVP. | | |
| 15.5 | **Does the licensee have high-risk level CSPs that are either:**<br>a. Prepared in batches of more than 25 identical containers, or<br>b. Exposed for > 12 hours to temperatures 2-8° before sterilization<br>c. Exposed for > 6 hours to temperatures > 8° before sterilization | | |
| 15.6 | **If yes to question 15.5, does the licensee perform an appropriate sterility test per USP 71 before they are dispensed/ administered? Which sterility test is used?**<br><br>Methods not described in USP 797 may be used if validated. | | |
| 15.7 | **If any high-risk level CSP is dispensed prior to receiving results of the sterility test, is there:**<br>a. A written procedure for daily documentation of observations of incubation test specimens<br>b. Is the written procedure followed?<br>c. There is an immediate recall of all dispensed CSPs when there is evidence of microbial growth | | |
| 15.8 | **If yes to question 15.5, does the licensee perform an appropriate endotoxin test per USP 85 (Bacterial Endotoxins Test)/151 (Pyrogen Test) before CSPs are dispensed/ administered**?<br>(note: not required for inhalation or ophthalmic drugs) | | |
| 15.9 | **Has the licensee had to recall any high-risk level CSPs due to contamination?** | | |
| 15.10 | **Were the patients and physicians notified of the recall and the potential risk? If not, why?** | | |

<table>
<tr><th>Section</th><th>Topic/Question</th><th>Y/N</th><th>Inspector Observations or Notes</th></tr>
<tr><td>15.11</td><td>Was an investigation conducted to determine why the high-risk level CSP was contaminated? If yes,<br><br>Document the result of the investigation, and what corrective action was taken?</td><td></td><td></td></tr>
<tr><td>15.12</td><td>Are CSPs labeled correctly? If no, document observations.</td><td></td><td></td></tr>
<tr><td>15.13</td><td>Are there any other concerns identified by the inspector related to this chapter?</td><td></td><td></td></tr>
<tr><td>16.0</td><td>Storage and Beyond-Use Dating</td><td></td><td></td></tr>
<tr><td>16.1</td><td>In the absence of compound specific stability/sterility testing, does the licensee assign the appropriate beyond use date (BUD) based on product storage conditions?<br><br>
<table>
<tr><th>Risk Level</th><th>**Room Temp-<br>(20 to 25°C)<br>(68 to 77° F)</th><th>Cold Temp-<br>(2 to 8° C)<br>(36 to 46° F)</th><th>Frozen-<br>(-25° to -10°C)<br>(-13 to 14° F)</th></tr>
<tr><td>Low</td><td>48 hours</td><td>14 days</td><td>45 days</td></tr>
<tr><td>Medium</td><td>30 hours</td><td>9 days</td><td>45 days</td></tr>
<tr><td>High</td><td>24 hours</td><td>3 days</td><td>45 days</td></tr>
</table>
** Room temperature can be colder (per experts) for compounding personnel to be comfortable in garb (66°F +/- 2°); Room temperature excursions are permitted between 15-30°C (59 to 86°F). USP 797, Appendix I</td><td></td><td></td></tr>
<tr><td>16.2</td><td>Does the licensee perform any additional testing to justify extending the BUD? Such as thin-layer chromatography (TLC) or high-performance liquid chromatography (HPLC)</td><td></td><td></td></tr>
<tr><td>16.3</td><td>Are product specific assays done for any BUD exceeding 30 days? (recommended)</td><td></td><td></td></tr>
<tr><td>16.4</td><td>Does the licensee use appropriate references to use physical and/or chemical stability parameters, compatibility, and/or degradation information when a shorter BUD is required?</td><td></td><td></td></tr>
<tr><td>16.5</td><td>Does the licensee have a SPP outlining how BUD is assigned for all CSPs? (USP 1150)</td><td></td><td></td></tr>
<tr><td>16.6</td><td>Did the inspector observe any CSPs stored beyond their BUD? (i.e. adulterated)</td><td></td><td></td></tr>
<tr><td>16.7</td><td>Does the licensee use any proprietary bag and vial systems? (such as ADD-Vantage®, Mini Bag Plus®)</td><td></td><td></td></tr>
</table>

| Section | Topic/Question | Y/N | Inspector Observations or Notes |
|---|---|---|---|
| 16.8 | **If the licensee uses a proprietary bag and vial system, are they following the manufacturer's recommendations for assigning a BUD?** | | |
| 16.9 | **Is the temperature monitored at least daily for all drug storage areas?** Document how temperatures are measured and recorded. Document if the system provides 24 hour notification of temperature deviation.<br><br>*Record the temperature for the following drug storage areas?*<br><br>*Compounding room _____ Drug storage area outside compounding _____*<br><br>*Refrigerator # 1 _____ Refrigerator # 2 _____ Refrigerator # 3 _____*<br><br>*Freezer # 1 _____ Freezer # 2 _____ Freezer # 3 _____ Other _____* | | |
| 16.10 | **Does the licensee have any CSPs stored in an environment > 40° (104˚F)?**<br><br>Unless direct assay data available for continued stability, these CSPs should be discarded after > 4 hours (USP 797 General Notices and Requirements). | | |
| 16.11 | **Are there any concerns with how the licensee is monitoring the temperature of all drug storage areas?**<br><br>Paper log or continuous monitoring recording device may be used to record temperatures. (Must be checked at least daily to verify system is functioning properly)<br><br>Thermometer or temperature-sensing mechanisms shall be suitably placed to accurately reflect the true temperature of the storage area. | | |
| 16.12 | ***Is the refrigerator/freezer for drug storage free of food?*** | | |
| 16.13 | **Is the humidity monitored at least daily for all drug storage areas?** (not required)<br><br>What was the humidity of the room? _____% | | |
| 16.14 | **Are there any other concerns identified by the inspector related to this chapter?** | | |
| 17.0 | **Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs** | | |
| 17.1 | **Does the licensee have a SPP regarding the packaging, handling, transporting, and storing of CSPs?** | | |
| 17.2 | **Is the SPP specific for packaging, handling, transporting, and storing of CSPs?**<br><br>Example: techniques should be described in the SPP for tips to prevent a syringe's plunger from being dislodge during transport and include what the non-compounding personnel should do if this occurs. | | |
| 17.3 | **Does the licensee provide training to non-compounding personnel who package, handle, transport, and/or store CSPs?** | | |
| 17.4 | **If the licensee transports CSPs through the pneumatic tube system, are foam padding and/or inserts used to cushion certain CSPs?** (recommended)<br><br>Does the licensee have a list or otherwise address what CSPs should not be transported via the pneumatic tube system? Hazardous drugs are discouraged from being transported via the pneumatic tube system but not prohibited per USP 797. | | |

| Section | Topic/Question | Y/N | Inspector Observations or Notes |
|---|---|---|---|
| 17.5 | **Does the licensee attach tubing sets to CSPs?** If yes, describe what methods are used to safely transport these CSPs so the tubing does not become dislodged. | | |
| 17.6 | **Does the licensee add a tamper-evident closure or seal to the CSP port?** (recommended) | | |
| 17.7 | **Does the licensee have specific SPP regarding the transport and handling of hazardous drugs?** | | |
| 17.8 | **Does the licensee have special labeling on the CSP of a hazardous drug to alert personnel that this CSP is a hazardous drug?** | | |
| 17.9 | **Does the licensee's staff have access to a hazardous drug spill kit?**<br><br>Can they find it?<br>Do they know how to use it?<br>Is it available during transport and on dispensing units? | | |
| 17.10 | **Does the pharmacy redispense any CSPs?**<br><br>Are there any concerns identified by the inspector? | | |
| 17.11 | **Does the licensee ship any CSPs outside the facility?**<br><br>Is there an SPP?<br>Is it being followed?<br>How are the CSPs transported/shipped? | | |
| 17.12 | **Is the licensee able to ship CSPs in a manner which delivers the medication undamaged, sterile, and at an appropriate temperature?** | | |
| 17.13 | **Are there any other concerns identified by the inspector related to this chapter?** | | |
| 18.0 | **Patient or Caregiver Training** | | |
| 18.1 | **Does the licensee provide patient education regarding CSPs?** | | |
| 18.2 | **Does the licensee provide initial and ongoing training for home care patients?**<br><br>Does this include a formal written assessment program completed by or in conjunction with medical and/or nursing personnel? (Printed patient materials are recommended) | | |
| 18.3 | ***Does the pharmacy have a positive ID compliant record of counseling?*** | | |
| 18.4 | **Are there any other concerns identified by the inspector related to this chapter?** | | |
| 19.0 | **Quality Assurance (QA) Program** | | |
| 19.1 | **Does the licensee have a formal QA program for monitoring, evaluating, correcting, and improving the activities and processes for CSPs?**<br><br>Specific plan should focus on objective, measurable indicators for monitoring activities and processes that are deemed high risk, high volume, or problem prone. | | |

| Section | Topic/Question | Y/N | Inspector Observations or Notes |
|---|---|---|---|
| 19.2 | **Does the licensee have a quality assurance program that assesses and documents procedural breaches, administration mishaps, side effects, allergic reactions, and complications associated with dosage or administration?** (such as extravasation)<br><br>Is this reported via the licensee's incident reporting system?<br>Are severe cases reported to the FDA's Med Watch program? (see also Section 17) | | |
| 19.3 | **Are there any other concerns identified by the inspector related to this chapter?** | | |
| 20.0 | **USP Related Chapters** | | |
| | **Are there any other concerns identified by the inspector related to other USP chapters?** | | |
| 21.0 | **Miscellaneous** | | |
| | **Are there any other concerns identified by the inspector?** | | |

| ISO Classification of Particulate Matter in Room Air | | | |
|---|---|---|---|
| ISO Class | USP FS 209E | ISO, $m^3$ | FS 209E, $ft^3$ |
| **3** | Class 1 | 35.2 | 1 |
| **4** | Class 10 | 352 | 10 |
| **5** | Class 100 | 3,520 | 100 |
| **6** | Class 1,000 | 35,200 | 1,000 |
| **7** | Class 10,000 | 352,000 | 10,000 |
| **8** | Class 100,000 | 3,520,000 | 100,000 |

**Abbreviations:**

| | | | |
|---|---|---|---|
| **ACD** | Automated Compounding Device | **IPA** | Isopropyl Alcohol |
| **ACPH** | Air Changes Per Hour | **LAFW** | Laminar Air Flow Workbench |
| **BI** | Biological Indicator | **LVP** | Large Volume Parenteral |
| **BSC** | Biological Safety Cabinet | **MDV** | Multiple Dose Vial |
| **BUD** | Beyond-Use Date | **PEC** | Primary Engineering Control |
| **CACI** | Compounding Aseptic Containment Isolator | **PET** | Positron Emission Tomography |
| **CAI** | Compounding Aseptic Isolator | **PPE** | Personal Protective Equipment |
| **CETA** | Controlled Environment Testing Association | **QA** | Quality Assurance |
| **CFU** | Colony Forming Unit | **QPT** | Qualified Pharmacy Technician |
| **CSP** | Compounded Sterile Product | **RPH** | Registered Pharmacist |
| **CSTD** | Closed System Transfer Device | **SDV** | Single Dose Vial |
| **DCA** | Direct Compounding Area | **SOP** | Standard Operating Procedure |
| **ECV** | Endotoxin Challenge Vial | **SPP** | Standard Policy and Procedures |
| **HEPA** | High Efficiency Particulate Air | **SVI** | Sterile Vial for Injection |
| **HPLC** | High Performance Liquid Chromatography | **TLC** | Thin Layer Chromatography |
| **HVAC** | Heating, Ventilation and Air Conditioning | **TSA** | Trypticase Soy Agar |

| Signature of Person In Charge | Date | Signature of Inspector | Date |
|---|---|---|---|
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