State of Utah
Department of Commerce

Division of Occupational and Professional Licensing
160 E 300 S
P.O. Box 146741
Salt Lake City, Utah 84114-6741
Email: *DOPLInvestigations@utah.gov*
Telephone: (801) 530-6628
Toll Free in Utah: (866) 275-3675
Investigation Fax: (801) 530-6301
Website: *www.dopl.utah.gov*

STERILE COMPOUNDING

INSPECTION

☐ New Opening ☐ Regular

INFORMATION

Pharmacy Name: _____ Date: _____

Pharmacy License Number: _____ Expiration Date: _____

Controlled Substance License Number: _____ Expiration Date: _____

DEA Registration Number: _____ Expiration Date: _____

Pharmacy FEIN #: _____

Pharmacist-in-Charge (PIC): _____

Pharmacist-in-Charge License Number: _____ Expiration Date: _____

Compounding Facilities engaged in simple, moderate or complex non-sterile or any level of sterile compounding activities shall be required to maintain proper records and procedure manuals and establish quality control measures to ensure stability, equivalency where applicable and sterility. The following requirements shall be met:(a)Shall follow USP-NF Chapter 795, compounding of non-sterile preparations, and USP-NF Chapter 797 if compounding sterile preparations [UAC R156-17b-614a (3)]

	Yes	No	GENERAL OPERATIONS AND INFORMATION
			Which categories of compounding does the facility perform?
1.	☐	☐	The pharmacy does perform compounding identified as **low-risk** [USP-NF Chapter 797- *USP Microbial Contamination Risk Levels- Low-Risk Level CSPs]* ☐ The CSPs are compounded with aseptic manipulations entirely within ISO Class 5 or better air quality using only sterile ingredients, products, components, and devices. ☐ The compounding involves only transfer, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile products and not more than two entries into any one sterile container or package (e.g., bag, vial) of sterile product or administration container/ device to prepare the CSP. ☐ Manipulations are limited to aseptically opening ampules, 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. ☐ For a low-risk level preparation, in the absence of passing a sterility teste (see Sterility Tests <71>) the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and are exposed for not more than 48 hours at controlled room temperature (see General Notices and Requirements), and for 45 days in solid frozen state between -25°and -10°.
	☐	☐	The pharmacy does perform compounding identified as **medium-risk.** When CSPs are compounded aseptically under Low-Risk Conditions and one or more of the following conditions exist, such CSPs are at a medium risk of contamination. [USP-NF Chapter 797- *USP Microbial Contamination Risk Levels- Medium-Risk Levels CSPs]* ☐ Multiple individual or small doses of sterile products are combined or pooled to prepare a CSP that will be administered to either multiple patients or to one patient on multiple occasions. ☐ The compounding process includes complex aseptic manipulations other than the single-volume transfer. ☐ The compounding process requires unusually long duration, such as that required to compete dissolution or homogenous mixing. ☐ For a medium-risk preparation, in the absence of passing a sterility test (see Sterility Tests <71>0, the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and are exposed for not more than 30 hours at controlled room temperature (see Generals Notices and Requirements), and for 45 days in solid frozen state between 25°and -10°.

☐ ☐ The pharmacy does perform compounding identified as **high-risk** [USP-NF Chapter 797- *USP Microbial Contamination Risk Levels- High-Risk Levels CSPs]*

☐ Non sterile ingredients, including manufactured products not intended for sterile routes of administration (e.g. oral), are incorporated or a non-sterile device is employed before terminal sterilization.

☐ Any of the following are exposed to air quality worse than ISO 5 for more than 1 hour (see *Immediate-Use CSPs*):

- ☐ Sterile contents of commercially manufactured products,
- ☐ CSPs that lack effective antimicrobial preservative, and
- ☐ Sterile surfaces of devices and containers for the preparation, transfer, sterilization, and packaging of CSPs

☐ Compounding personnel are improperly garbed and gloved (see *Personnel Cleansing and Use of Barrier Protective Equipment).*

☐ Nonsterile water-containing preparations are stored for more than 6 hours before being sterilized.

☐ It is assumed, and not verified by examination of labeling and documentation from suppliers or by direct determination, that the chemical purity and content strength of ingredients meet their original or compendia specifications in unopened or in opened packages of bulk ingredients (see *Ingredient Selection under Pharmaceutical Compounding- Non-Sterile Preparations <795>).*

☐ In the absence of passing a sterility test, the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and are exposed for not more than 24 hours at controlled room temperature (see *General Notices and Requirements),* for not more than 3 days at a cold temperature (*see General Notices and Requirements),* and for 45 days in a solid frozen state between 25°and -10°.

☐ ☐ **Immediate-use provision in intended only for those situation where there is a need for emergency or immediate patient administration of a CSP**. Such situations may include cardiopulmonary resuscitation, emergency room treatment, preparation of diagnostic agents, or critical therapy where the preparation of the CSP under conditions described for Low-Risk Level CSPs subjects the patient to additional risk due to delays in therapy. Immediate-use CSPs are not intended for storage for anticipated needs or batch compounding. Preparations that are medium-risk level and high-risk level CSPs shall not be prepared as immediate-use CSPs. [USP-NF Chapter 797- *Immediate-use CSPs*]

☐ ☐ **Immediate-use CSPs** are exempt from the requirements described for Low-Risk Label CSPs only when all of the following are met: [USP-NF Chapter 797- *Immediate-use CSPs]*

☐ The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturer's' original containers and not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device. For example, anti-neoplastics shall not be prepared as immediate-use CSPs because they are hazardous drugs.

☐ Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour.

☐ During preparation, aseptic technique is followed and, if not immediately administered, the finished CSP is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mixups with other CSPs, and direct contact of outside surfaces.

☐ Administration begins not later than 1 hour following the start of the preparation of the CSP.

☐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 identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour BUD and time.

☐ If administration has not begun within 1 hour following the start of preparing the CSP, the CSP shall be promptly, properly, and safely discarded.

2. ☐ ☐ Does the facility dispense sterile compounded preparations pursuant to a prescription?

3. ☐ ☐ Does the facility make sterile compounded preparations that are delivered to a practitioner for administration to a patient in an office, clinic, or facility?

4. ☐ ☐ A pharmacy licensed under this chapter may, subject to rules established by the Division, repackage or compound a prescription drug for sale to a practitioner if: the prescription drug: does not include a compounded drug; or includes a compounded drug; and is not a controlled substance; the pharmacy labels the prescription drug "for

office use only"; the practitioner administers the drug to a patient in the practitioner's office or facility; and except in accordance with Title 58, Chapter 17b, Part 8, Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy, the practitioner does not dispense the drug to the patient. [UCA 58-17b-624(1)(a)(i)(ii)(A)(B)(b)(c)(d)] Pursuant to Section 58-17b-624, a pharmacy may repackage or compound a prescription drug for sale to a practitioner for office use provided that it is in compliance with all applicable federal and state laws and regulations regarding the practice of pharmacy, including, but not limited to the Food, Drug, and Cosmetic Act, 21 U.S.C A § 301 et seq. [R156-17b-624]

5. ☐ ☐ Does the facility distribute sterile compounded preparations to hospitals, clinics, or surgery centers?

6. ☐ ☐ Does the facility have a sales force that distributes samples containing active ingredients? List samples.

7. ☐ ☐ Does the facility compound sterile preparations for veterinary use?

8. ☐ ☐ Is the facility registered with the FDA as an "Outsourcing Facility"?

9. ☐ ☐ The facility does compound:

☐ allergen extracts
☐ parental solutions
☐ parenteral suspensions
☐ preservative free parenterals
☐ baths and soaks for live organs and tissues
☐ oral or nasal inhalation preparations
☐ irrigations for wounds and body cavities
☐ ophthalmic preparations

10. ☐ ☐ Does the facility compound investigational drugs? List.

11. ☐ ☐ The facility does not prepare a prescription drug in a dosage form which is regularly and commonly available from a manufacturer in quantities and strengths prescribed by a practitioner. [UAC 58-17b-102(18)(b)(ii)]

12. ☐ ☐ The facility does not prepare a prescription drug for sale to another pharmacist or pharmaceutical facility. [UAC 58-17b-102 (18)(b)(i)]

13. ☐ ☐ The facility does not prepare a prescription drug, sterile product, or device which has been withdrawn from the market for safety reasons. [UAC 58-17b-102 (18)(b)(iii)

14. ☐ ☐ Does the pharmacy makes sterile compounded preparations using bulk powder Active Pharmaceutical Ingredients?

15. ☐ ☐ Bulk active ingredients must be procured from a facility registered with the federal Food and Drug Administration and must not be listed on the federal Food and Drug Administration list of drug products withdrawn or removed from the market for reasons of safety or effectiveness. [UAC R156-17b-614a (3)(c)(i)(ii)]

16. ☐ ☐ Does the facility have a lyophilizer?

17. ☐ ☐ **The compounding facility shall have written, properly approved SOPs** designed to ensure the quality of the environment in which a CSP is prepared. [USP-NF Chapter 797-*Responsibility of Compounding Personnel-Suggested Standard Operating Procedures (SOPs)]*

a. ☐ Procedures for **measuring, mixing, dilution, purification, sterilization, packaging, and labeling** conform to the correct sequence and quality established for the specified CSP. [USP-NF Chapter 797- *Responsibility of Compounding Personnel*]

b. ☐ All **cleaning and disinfecting** practices and policies for the compounding of CSPs shall be included in written SOPs and shall be followed by all compounding personnel. [USP-NF Chapter 797- *Environmental Quality and Control and Disinfecting the Compounding Area*]

☐ ISO Class 5 PEC (e.g. LAFW, BSC, CAI, CACI)
☐ Counters and easily cleanable work surfaces
☐ Floors
☐ Walls
☐ Ceiling
☐ Storage Shelving

c. ☐ It is necessary that **equipment, apparatus, and devices** used to compound a CSP be consistently capable of operating properly and within acceptable tolerance limits. [USP-NF Chapter 797- *Element of Quality Control, Equipment]*

- ☐ Equipment calibration
- ☐ Annual maintenance
- ☐ Monitoring for proper function and controlled procedures for use of the equipment and specified time frames for these activities
- ☐ Routine maintenance and frequencies

d. ☐ The principles of HEPA-filtered unidirectional airflow in the work environment shall be understood and practiced in the compounding process in order to achieve the desired environmental conditions. Policies and procedures for **maintaining and working within the PEC** area shall be written and followed. The policies and procedure will be determined by the scope and risk levels of the aseptic compounding activities utilized during the preparation of the CSPs. [USP-NF Chapter 797- *Environmental Quality and Control, Facility Design and Environmental Control]*

e. ☐ When compounding activities require **the manipulation of a patient's blood-derived or other biological material (e.g., radiolabeling a patient's or donor's white blood cells), the manipulations shall be clearly separated from routine material-handling** procedures and equipment used in CSP preparation activities, and they shall be controlled by specific SOPs in order to avoid any cross contamination. [USP-NF Chapter 797- *Environmental Quality and Control- Additional Personnel Requirements*]

f. ☐ **Double-checking compounding** accuracy shall be followed for every CSP during preparation and immediately prior to release. [USP-NF Chapter 797- *Preparation Release Checks and Tests, Compounding Accuracy Checks*]

g. ☐ When **high-risk level CSPs are dispensed before receiving the results of their sterility tests**, there shall be a written procedure requiring daily observations of the incubating test specimens and immediate recall of the dispensed CSPs when there is any evidence of microbial growth in the test specimens. [USP-NF Chapter 797- *Finished Preparation Release Checks and Tests, Sterility Testing*]

h. ☐ **Verifying the correct identity and quality** of CSPs before they are dispensed and administered: [USP-NF Chapter 797- *Finished Preparation Release Checks and Tests, Identify and Strength Verification of Ingredients*]

- ☐ Labels of CSPs bear correct names and amounts or concentrations of ingredients, the total volume, the BUD, the appropriate route(s) of administration, the storage conditions, and other information for safe use.
- ☐ That there are correct identities, purities, and amounts of ingredients by comparing the original written order with the written compounding record for the CSP.
- ☐ That correct fill volumes in CSPs and correct quantities of filled units of the CSPs were obtained. When the strength of finished CSPs cannot be confirmed to be accurate, based on the above three inspections, the CSPs shall be assayed by methods that are specific for the active ingredients.

i. ☐ To ensure consistent practices in determining and assigning BUDs, the compounding facility should have written policies and procedures governing the **determination of the BUDs** for all compounded products. The SOP manual of the compounding facility and each specific CSP formula record shall describe the general basis used to assign the BUD and storage conditions. [USP-NF Chapter 797- *Storage and Beyond-Use Dating*]

j. ☐ The **compounding procedures and sterilization methods** for CSPs correspond to correctly designed and verified written documentation in the compounding facility. Verification requires planned testing, monitoring, and documentation to demonstrate adherence to environmental quality requirements, personnel practices, and procedures critical to achieving and maintaining sterility, accuracy, and purity of finished CSPs. [USP-NF Chapter 797- *Verification of Compounding Accuracy and Stability*]

k. ☐ Commercially available sterile drug products, sterile ready-to-use containers, and devices are examples of sterile components. A written procedure for **unit-by-unit physical inspection preparatory to use** is followed to ensure that these components are sterile, free from defects, and otherwise suitable for their intended use. [USP-NF Chapter 797- *Elements of Quality Control- Ingredients and Devices- Sterile Ingredients and Devices*]

l. ☐ Compounding personnel shall ensure proper storage and security of CSPs prepared by or dispensed from the compounding facility until either their BUDs are reached or they are administered to patients. In fulfilling this general responsibility, the compounding facility is responsible for the proper **packaging, handling, transport, and storage of CSPs prepared by or dispensed from it, including the appropriate education, training, and supervision of compounding personnel assigned to these functions**. The compounding facility should assist in the education and training of noncompounding personnel responsible for carrying out any aspect of these functions. Establishing, maintaining, and ensuring compliance with comprehensive written policies and procedures encompassing these responsibilities is a further responsibility of the compounding facility. Where noncompounding personnel are assigned tasks involving any of these responsibilities, the policies and procedures

encompassing those tasks should be developed by compounding supervisors. [USP-NF Chapter 797- *Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs*]

m. ☐ Inappropriate processes or techniques involved with packaging, handling, and transport can adversely affect quality and package integrity of CSPs. Although compounding personnel routinely perform many of the tasks associated with these functions, some tasks, such as **transport, handling, and placement into storage, may be fulfilled by noncompounding personnel** who are not under the direct administrative control of the compounding facility. Under these circumstances, appropriate SOPs shall be established by the compounding facility with the involvement of other departments or services whose personnel are responsible for carrying out those CSP-related functions for which the compounding facility has a direct interest. The performance of the noncompounding personnel is monitored for compliance to established policies and procedures. [USP- NF Chapter 797- *Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs- Packaging, Handling, and Transport*]

n. ☐ **When CSPs are distributed to locations outside the premises** in which they are compounded, compounding personnel select packing containers and materials that are **expected to maintain physical integrity, sterility, and stability of CSPs during transit**. Packing is selected that simultaneously protects CSPs from damage, leakage, contamination, and degradation, and protects personnel who transport packed CSPs from harm. The SOP manual of the compounding facility specifically describes appropriate packing containers and insulating and stuffing materials, based on information from product specifications, vendors, and experience of compounding personnel. Written instructions that clearly explain how to safely open containers of packed CSPs are provided to patients and other recipients. [USP-NF Chapter 797- *Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs- Packing and Transporting CSPs- Packing CSPs for Transit*]

o. ☐ SOPs must exist to ensure that **storage conditions in the patient-care setting** are suitable for the CSP-specific storage requirements. [USP-NF Chapter 797- *Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs- Packing and Transporting CSPs, Use and Storage*]

☐ Procedures include daily monitoring and documentation of drug storage refrigerators to ensure temperatures between 2° and 8°

☐ and the monthly inspection of all drug storage locations by compounding personnel.

p. ☐ The SOP manuals of compounding facilities shall describe **specific instructions for receiving, acknowledging, and dating receipts, and for recording, or filing, and evaluating reports of adverse events and of the quality of preparation** claimed to be associated with CSPs. Reports of adverse events with CSPs shall be reviewed promptly and thoroughly by compounding supervisors to correct and prevent future occurrences. Compounding personnel are encouraged to participate in adverse event reporting and product defects programs of the FDA and USP. [USP-NF Chapter 797- *Patient Monitoring and Adverse Events Reporting*]

Personnel Training and Requirements

18. ☐ ☐ A written description of specific training and performance evaluation program for individuals involved in the use of aseptic techniques for the preparation of sterile products shall be developed for each site. This program equips personnel with the appropriate knowledge and trains them in the required skills necessary to perform the assigned tasks. **Each person assigned to the aseptic area in the preparation of sterile products shall successfully complete specialized training in aseptic techniques and aseptic area practices prior to preparing CSPs** (see Personnel Training and Evaluation in Aseptic Manipulation Skills and Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures). [USP-NF Chapter 797 - *Elements of Quality Control*]

19. ☐ ☐ **Personnel who prepare CSPs shall be trained** conscientiously and skillfully **by expert personnel, multi-media instructional sources, and professional publications** in the theoretical principles and practical skills of **garbing procedures, aseptic work practices, achieving and maintaining ISO Class 5 environmental conditions, and cleaning and disinfection procedures**. [USP-NF Chapter 797- *Appendix I-Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures*]

20. ☐ ☐ Compounding personnel shall complete: [USP-NF Chapter 797- *Appendices- Appendix I-Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures*]

☐ didactic training,
☐ undergo skill assessment using observational audit tools,
☐ pass written competence assessments,
☐ and media-fill testing.

21. ☐ ☐ **Compounding personnel shall be visually observed during the process of performing hand hygiene and garbing procedures** (see *Personnel Cleansing* and *Garbing* under *Personnel Training and Evaluation in Aseptic Manipulation Skills* above). **The visual observation shall be documented** on a form such as the Sample Form for

Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel (see Appendix III) and maintained to provide a permanent record and long-term assessment of personnel competency. [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures- Competency Evaluation of Garbing and Aseptic Work Practice*]

22. ☐ ☐ **Sampling of compounding personnel glove fingertips shall be performed for all CSP risk level compounding** because direct touch contamination is the most likely source of introducing microorganisms into CSPs prepared by humans. Glove fingertip sampling **shall be used to evaluate the competency of personnel in performing hand hygiene and garbing procedures in addition to educating compounding personnel on proper work practices, which include frequent and repeated glove disinfection using sterile 70% IPA during actual compounding of CSPs**. All personnel shall demonstrate competency in proper hand hygiene and garbing procedures and in aseptic work practices (e.g., disinfection of component surfaces, routine disinfection of gloved hands). [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures- Competency Evaluation of Garbing and Aseptic Work Practice*]

23. ☐ ☐ **Sterile contact agar plates shall be used to sample the gloved fingertips** of compounding personnel **after garbing** in order to assess garbing competency and **after completing the media-fill preparation** (without applying sterile 70% IPA) in order to assess the adequacy of aseptic work practices prior to being initially allowed to prepare CSPs for human use and for more experienced personnel to maintain their qualifications to prepare CSPs for human use. [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures- Competency Evaluation of Garbing and Aseptic Work Practice*]

24. ☐ ☐ **All compounding personnel shall successfully complete an initial competency evaluation and gloved fingertip/thumb sampling procedure (zero cfu) no less than three times before initially being allowed to compound CSPs for human use.** Immediately after the compounding employee completes the hand hygiene and garbing procedure (e.g., donning of sterile gloves prior to any disinfection with sterile 70% IPA), the evaluator will collect a gloved fingertip and thumb sample from both hands of the compounding employee onto appropriate agar plates by lightly pressing each fingertip into the agar. The plates will be incubated for the appropriate incubation period and at the appropriate temperature (see Incubation Period). **After completing the initial gowning and gloving competency evaluation, re-evaluation of all compounding personnel for this competency shall occur at least annually for personnel who compound low- and medium-risk level CSPs and semi-annually for personnel who compound high-risk level CSPs** using one or more sample collections during any media-fill test procedure before they are allowed to continue compounding CSPs for human use. [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures- Competency Evaluation of Garbing and Aseptic Work Practice*]

25. ☐ ☐ **After successful completion of an initial Hand Hygiene and Garbing Competency Evaluation, all compounding personnel shall have their aseptic technique and related practice competency evaluated initially during the Media-Fill Test Procedure and subsequent annual or semi-annual Media-Fill Test Procedures.** Records of these evaluations will be maintained using a form such as the Sample Form for Assessing Aseptic Technique and Related Practices of Compounding Personnel (see Appendix IV) and maintained to provide a permanent record of and long-term assessment of personnel competency. [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures- Competency Evaluation of Garbing and Aseptic Work Practice*]

26. ☐ ☐ **Compounding personnel shall perform didactic review and pass written and media-fill testing of aseptic manipulative skills initially, at least annually thereafter for low- and medium-risk level compounding, and semiannually for high-risk level compounding.** Compounding personnel who fail written tests or whose media-fill test vials result in gross microbial colonization shall be immediately re-instructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic practice deficiencies. [USP-NF Chapter 797- *Personnel Training and Evaluation in Aseptic Manipulation Skills*]

27. ☐ ☐ **Compounding personnel and other personnel responsible for cleaning shall be visually observed during** the process of performing **cleaning and disinfecting procedures**, during **initial personnel training** on cleaning procedures, during **changes in cleaning staff**, and at the **completion of any media-fill test procedure** (see

Cleaning and Disinfecting of Compounding Areas). [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/ Disinfection-Procedures, Surface Cleaning and Disinfection Sampling and Assessment*]

28. ☐ ☐ **In the event that cleaning and disinfecting procedures are also performed by other support personnel** (e.g., institutional environmental services, housekeeping), thorough training of proper hand hygiene, garbing, and cleaning and disinfection procedures shall be done by a qualified aseptic compounding expert. After completion of training, support **personnel shall routinely undergo performance evaluation of proper hand hygiene, garbing, and all applicable cleaning and disinfecting procedures conducted by a qualified aseptic compounding expert**. [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures*]

29. ☐ ☐ **Compounding personnel of reproductive capability shall confirm in writing that they understand the risks of handling hazardous drugs.** The **training shall include** at least the following: [USP- NF Chapter 797- *Hazardous Drugs as CSPs*]
- ☐ safe aseptic manipulation practices;
- ☐ negative pressure techniques when utilizing a BSC or CACI;
- ☐ correct use of CSTD devices;
- ☐ containment, cleanup, and disposal procedures for breakages and spills; and
- ☐ treatment of personnel contact and inhalation exposure.

Handwashing and Garbing

30. ☐ ☐ **When individuals are experiencing rashes, sunburn, weeping sores, conjunctivitis, active respiratory infection, as well as when they wear cosmetics, they shed these particles at even higher rates.** Particles shed from compounding personnel pose an increased risk of microbial contamination of critical sites of CSPs. **Therefore, compounding personnel with such conditions as mentioned above shall be excluded from working in ISO Class 5 (see Table 1) and ISO Class 7 (see Table 1) compounding areas until their conditions are remedied.** [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Cleansing and Garbing*]

31. ☐ ☐ **Before entering the buffer area or segregated compounding area** (see Low-Risk Level CSPs with 12-Hour or Less BUD), **compounding personnel shall remove personal outer garments** (e.g., bandannas, coats, hats, jackets, scarves, sweaters, vests); **all cosmetics, because they shed flakes and particles; and all hand, wrist, and other visible jewelry or piercings** (e.g., earrings, lip or eyebrow piercings) that can interfere with the effectiveness of PPE (e.g., fit of gloves and cuffs of sleeves). **The wearing of artificial nails or extenders is prohibited** while working in the sterile compounding environment. **Natural nails shall be kept neat and trimmed.** [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Cleansing and Garbing*]

32. ☐ ☐ **Personnel shall don the following PPE in an order that proceeds from those activities considered the dirtiest to those considered the cleanest**. Garbing activities considered the dirtiest include donning of ☐ dedicated shoes or shoe covers, ☐ head and facial hair covers (e.g., beard covers in addition to face masks), and ☐ face masks/eye shields. Eye shields are optional unless working with irritants such as germicidal disinfecting agents or when preparing hazardous drugs. [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Cleansing and Garbing*]

33. ☐ ☐ **After donning dedicated shoes or shoe covers, head and facial hair covers, and face masks, a hand cleansing procedure shall be performed by removing debris from underneath fingernails using a nail cleaner under running warm water followed by vigorous hand washing. Hands and forearms shall be washed to the elbows for at least 30 seconds with soap (either nonantimicrobial or antimicrobial) and water while in the ante-area.** The use of antimicrobial scrub brushes is not recommended because they can cause skin irritation and skin damage. Hands and forearms to the elbows will be completely dried using either lintfree disposable towels or an electronic hand dryer. ☐ **After completion of hand washing, a nonshedding gown with sleeves that fit snugly around the wrists and enclosed at the neck is donned.** Gowns designated for buffer area use shall be worn, and **preferably they should be disposable. If reusable gowns are worn, they should be laundered appropriately for buffer area use.** [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Cleansing and Garbing*]

34. ☐ ☐ **Once inside the buffer area or segregated compounding area** (see Low-Risk Level CSPs with 12-Hour or Less BUD), and **prior to donning sterile powder-free gloves, antiseptic hand cleansing shall be performed**

using a waterless alcohol-based surgical hand scrub with persistent activity following manufacturers' recommendations. Hands are allowed to dry thoroughly before donning sterile gloves. [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Cleansing and Garbing*]

35. ☐ ☐ **Sterile gloves shall be the last item donned before compounding begins**. Gloves become contaminated when they contact nonsterile surfaces during compounding activities. Disinfection of contaminated gloved hands may be accomplished by wiping or rubbing sterile 70% IPA to all contact surface areas of the gloves and letting the gloved hands dry thoroughly. Only use gloves that have been tested for compatibility with alcohol disinfection by the manufacturer. **Routine application of sterile 70% IPA shall occur throughout the compounding process** and whenever nonsterile surfaces (e.g. vials, counter tops, chairs, carts) are touched. **Gloves on hands shall also be routinely inspected for holes, punctures, or tears and replaced immediately if such are detected**. Antiseptic hand cleansing shall be performed as indicated above. Compounding personnel. [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Cleansing and Garbing*]

36. ☐ ☐ **When compounding personnel exit the compounding area** during a work shift, the exterior gown may be removed and retained in the compounding area if not visibly soiled, to be re-donned during that same work shift only. However, **shoe covers, hair and facial hair covers, face masks/eye shields, and gloves shall be replaced with new ones before re-entering the compounding area, and proper hand hygiene shall be performed.** [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Cleansing and Garbing*]

37. ☐ ☐ **During high-risk compounding activities that precede terminal sterilization, such as weighing and mixing of nonsterile ingredients, compounding personnel shall be garbed and gloved the same as when performing compounding in an ISO Class 5** (see Table 1) environment. Properly garbed and gloved **compounding personnel who are exposed to air quality that is either known or suspected to be worse than ISO Class 7 (see Table 1) shall re-garb PPE along with washing their hands properly, performing antiseptic hand cleansing with a waterless alcohol-based surgical hand scrub, and donning sterile gloves upon reentering the ISO Class 7 (see Table 1) buffer area. When CAIs and CACIs are the source of the ISO Class 5 (see Table 1) environment, the garbing and gloving requirements for compounding personnel should be as described above, unless the isolator manufacturer can provide written documentation based on validated environmental testing that any component(s) of PPE or personnel cleansing are not required.** [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Cleansing and Garbing*]

38. ☐ ☐ **Cleaning and disinfecting shall occur before compounding is performed**. Items shall be removed from all areas to be cleaned, and surfaces shall be cleaned by removing loose material and residue from spills; for example, water soluble solid residues are removed with sterile water (for injection or irrigation) and lowshedding wipes. This shall be followed by wiping with a residue-free disinfecting agent such as sterile 70% IPA, which is allowed to dry before compounding begins. [USP-NF Chapter 797- *Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area*]

<u>Cleaning Requirements</u>

39. ☐ ☐ Cleaning and disinfecting surfaces in the **LAFWs, BSCs, CAIs, and CACIs** are the most critical practices before the preparation of CSPs. Consequently, such **surfaces shall be 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 of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches.** [USP-NF Chapter 797- *Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area*]

40. ☐ ☐ **Work surfaces in the ISO Class 7 (see Table 1) buffer areas and ISO Class 8 (see Table 1) ante-areas as well as segregated compounding areas shall be cleaned and disinfected at least daily**, and dust and debris shall be removed when necessary from storage sites for compounding ingredients and supplies using a method that does not degrade the ISO Class 7 or 8 (see Table 1) air quality (see Disinfectants and Antiseptics <1072>). [USP-NF Chapter 797- *Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area*]

41. ☐ ☐ **Floors in the buffer or clean area, ante-area, and segregated compounding area are cleaned by mopping with a cleaning and disinfecting agent once daily at a time when no aseptic operations are in progress.** Mopping shall be performed by trained personnel using approved agents and procedures described in the

written SOPs. It is incumbent on compounding personnel to ensure that such cleaning is performed properly. [USP-NF Chapter 797- *Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area*]

42. ☐ ☐ In the buffer or clean area, ante-area, and segregated compounding area, walls, ceilings, and shelving shall be cleaned and disinfected monthly. [USP-NF Chapter 797- *Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area*]

43. ☐ ☐ **Cleaning and disinfecting agents** are to be used with careful consideration of compatibilities, effectiveness, and inappropriate or toxic residues (see Appendix II). Their **schedules of use and methods of application shall be in accordance with written SOPs and followed by custodial or compounding personnel.** [USP-NF Chapter 797- *Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area*]

44. ☐ ☐ All **cleaning materials, such as wipers, sponges, and mops, shall be nonshedding**, preferably composed of synthetic micro fibers, and **dedicated to use in the buffer or clean area, ante-area, and segregated compounding areas and shall not be removed from these areas except for disposal.** Floor mops may be used in both the buffer or clean area and ante-area, but only in that order. Ideally, all cleaning tools are discarded after one use by collection in suitable plastic bags and removed with minimal agitation. If cleaning materials (e.g., mops) are reused, procedures shall be developed (based on manufacturers' recommendations) that ensure that the effectiveness of the cleaning device is maintained and that repeated use does not add to the bioburden of the area being cleaned. [USP-NF Chapter 797- *Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area*]

45. ☐ ☐ **Supplies and equipment removed from shipping cartons shall be wiped with a suitable disinfecting agent** (e.g., sterile 70% IPA) delivered from a spray bottle or other suitable delivery method. After the disinfectant is sprayed or wiped on a surface to be disinfected, the disinfectant **shall be allowed to dry, during which time the item shall not be used for compounding purposes.** [USP-NF Chapter 797- *Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area*]

Facilities and Environmental Monitoring

46. ☐ ☐ Surface sampling is an important component of the maintenance of a suitable microbially controlled environment for compounding CSPs, especially since transfer of microbial contamination from improperly disinfected work surfaces via inadvertent touch contact by compounding personnel can be a potential source of contamination into CSPs. It is useful for evaluating facility and work surface cleaning and disinfecting procedures and employee competency in work practices such as disinfection of component/vial surface cleaning. **Surface sampling shall be performed in all ISO classified areas on a periodic basis.** Sampling can be accomplished using contact plates or swabs, and it **shall be done at the conclusion of compounding. Locations to be sampled shall be defined in a sample plan or on a form.** The size of the plate to be used for each sampled location usually ranges from 24 to 30 cm2. Contact plates are filled with general solid agar growth medium and neutralizing agents above the rim of the plate, and they are used for sampling regular or flat surfaces. Swabs may be used for sampling irregular surfaces, especially for equipment (see Microbiological Control and Monitoring of Aseptic Processing Environments <1116>). [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures- Surface Cleaning and Disinfection Sampling and Assessment*]

47. ☐ ☐ The value of viable microbial monitoring of gloved fingertips and surfaces of components and the compounding environment are realized when the data are used to identify and correct an unacceptable work practice. **Sampling data shall be collected and reviewed on a routine basis as a means of evaluating the overall control of the compounding environment. If an activity consistently shows elevated levels of microbial growth, competent microbiology personnel shall be consulted.** [USP-NF Chapter 797- *Environmental Quality and Control - Action Levels, Documentation, and Data Evaluation*]

48. ☐ ☐ Food, drinks, and materials exposed in patient care and treatment areas shall not enter ante-areas, buffer areas, or segregated compounding areas where components and ingredients of CSPs are present. [USP-NF Chapter 797-Environmental Quality and Control- Additional Personnel Requirements]

49. ☐ ☐ **Compounding facilities shall have an adequate space that is specifically designated for compounding of prescriptions. This space shall provide for the orderly placement of equipment and materials to prevent mixups** among ingredients, containers, labels, in-process materials, and finished preparations and is designed,

arranged, and used to prevent adventitious cross-contamination. **Areas used for sterile preparations shall be separated and distinct from the nonsterile compounding area** (see Pharmaceutical Compounding—Sterile Preparations <797>, Environmental Quality and Control). [USP-NF Chapter 795- *Compounding Facilities*]

50. ☐ ☐ 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 nonshedding, thereby promoting cleanability, and minimizing spaces in which microorganisms and other contaminants may accumulate. The surfaces shall be resistant to damage by disinfectant agents. [USP-NF Chapter 797- *Environmental Quality and Control- Facility Design and Environmental Controls]*

51. ☐ ☐ Junctures of ceilings to walls shall be coved or caulked to avoid cracks and crevices where dirt can accumulate. If ceilings consist of inlaid panels, the panels shall be impregnated with a polymer to render them impervious and hydrophobic, and they shall be caulked around each perimeter to seal them to the support frame. [USP-NF Chapter 797- *Environmental Quality and Control- Facility Design and Environmental Controls*]

52. ☐ ☐ Any other penetrations through the ceiling or walls shall be sealed. [USP-NF Chapter 797- *Environmental Quality and Control- Facility Design and Environmental Controls*]

53. ☐ ☐ The buffer area shall not contain sources of water (sinks) or floor drains. [USP-NF Chapter 797- *Environmental Quality and Control- Facility Design and Environmental Controls*]

54. ☐ ☐ Work surfaces shall be constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected. [USP-NF Chapter 797- *Environmental Quality and Control- Facility Design and Environmental Controls*]

55. ☐ ☐ Storage shelving, counters, and cabinets shall be smooth, impervious, free from cracks and crevices, nonshedding, cleanable, and disinfectable; their number, design, and manner of installation shall promote effective cleaning and disinfection. [USP-NF Chapter 797- *Environmental Quality and Control- Facility Design and Environmental Controls*]

56. ☐ ☐ There shall be some demarcation designation that separates the ante-area from the buffer area. [USP-NF Chapter 797-Environmental Quality and Control- Additional Personnel Requirements]

57. ☐ ☐ **To ensure that product potency is retained through the manufacturer's labeled expiration date, compounding personnel shall monitor the drug storage areas within the compounding facility.** Controlled temperature areas in compounding facilities include controlled room temperature, 20° to 25° with mean kinetic temperature 25°; controlled cold temperature, 2° to 8° with mean kinetic temperature 8°; cold temperature, 2° to 8°; freezing temperature, −25° and −10° (see General Notices and Requirements) if needed to achieve freezing, and the media-specific temperature range for microbial culture media. **A controlled temperature area shall be monitored at least once daily and the results documented on a temperature log. Additionally, compounding personnel shall note the storage temperature when placing the product into or removing the product from the storage unit in order to monitor any temperature aberrations.** Suitable temperature recording devices may include a calibrated continuous recording device or a National Institute of Standards and Technology (NIST) calibrated thermometer that has adequate accuracy and sensitivity for the intended purpose, and it shall be properly calibrated at suitable intervals. **If the compounding facility uses a continuous temperature recording device, compounding personnel shall verify at least once daily that the recording device itself is functioning properly.** [USP-NF Chapter 797- *Storage and Beyond Use Dating- Monitoring Controlled Storage Areas*]

58. ☐ ☐ **Certification that each ISO classified area, for example, ISO Class 5, 7, and 8 (see Table 1), is within established guidelines shall be performed no less than every 6 months and whenever the LAFW, BSC, CAI, or CACI is relocated or the physical structure of the buffer area or ante-area has been altered.** Testing shall be performed by qualified operators using current, state-of-the-art electronic equipment with results of the following: [USP-NF Chapter 797- *Environmental Quality and Control- Viable and Nonviable Environmental Sampling (ES) Testing- Total Particle Counts*]

☐ ISO Class 5: not more than 3520 particles 0.5 mm and larger size per cubic meter of air for any LAFW, BSC, CAI, and CACI;

☐ ISO Class 7: not more than 352,000 particles of 0.5 mm size and larger per cubic meter of air for any buffer

area;
☐ ISO Class 8: not more than 3,520,000 particles or 0.5 mm size and larger per cubic meter of air for any ante-area.

59. ☐ ☐ **All certification records shall be maintained and reviewed by supervising personnel or other designated employees** to ensure that the controlled environments comply with the proper air cleanliness, room pressures, and ACPHs. [USP-NF Chapter 797- *Environmental Quality and Control- Viable and Nonviable Environmental Sampling (ES) Testing- Total Particle Counts*]

60. ☐ ☐ **A pressure gauge or velocity meter shall be installed to monitor the pressure** differential or airflow between the buffer area and the ante-area and between the ante-area and the general environment outside the compounding area. [USP-NF Chapter 797- *Environmental Quality and Control- Viable and Nonviable Environmental Sampling (ES) Testing- Pressure Differential Monitoring*]

61. ☐ ☐ **The results shall be reviewed and documented on a log at least every work shift** (minimum frequency shall be at least daily) or by a continuous recording device. [USP-NF Chapter 797- *Environmental Quality and Control- Viable and Nonviable Environmental Sampling (ES) Testing- Pressure Differential Monitoring*]

62. ☐ ☐ **The pressure between the ISO Class 7 (see Table 1) and the general pharmacy area shall not be less than 5 Pa (0.02 inch water column). In facilities where low- and medium-risk level CSPs are prepared, differential airflow shall maintain a minimum velocity of 0.2 meters per second (40 feet per minute) between buffer area and ante-area.** [USP-NF Chapter 797- *Environmental Quality and Control- Viable and Nonviable Environmental Sampling (ES) Testing- Pressure Differential Monitoring*]

63. ☐ ☐ **The buffer area shall maintain at least ISO Class 7 (see Table 1) conditions for 0.5-mm and larger particles under dynamic operating conditions**. The room shall be segregated from surrounding, unclassified spaces to reduce the risk of contaminants being blown, dragged, or otherwise introduced into the filtered unidirectional airflow environment, and this segregation shall be continuously monitored. [USP-NF Chapter 797 - *Environmental Quality and Control- Facility Design and Environmental Controls*]

64. ☐ ☐ For rooms providing a physical separation through the use of walls, doors, and pass-throughs, a minimum differential positive pressure of 0.02- to 0.05- inch water column is required. [USP-NF Chapter 797 - *Environmental Quality and Control- Facility Design and Environmental Controls*]

65. ☐ ☐ For buffer areas not physically separated from the ante-areas, the principle of displacement airflow shall be employed. This concept utilizes a low pressure differential, high airflow principle. Using displacement airflow typically requires an air velocity of 40 ft per minute or more from the buffer area across the line of demarcation into the ante-area. [USP-NF Chapter 797 - *Environmental Quality and Control- Facility Design and Environmental Controls*]

66. ☐ ☐ **An ISO Class 7 (see Table 1) buffer area and ante-area supplied with HEPA-filtered air shall receive an ACPH of not less than 30**. The PEC is a good augmentation to generating air changes in the air supply of an area but cannot be the sole source of HEPA-filtered air. If the area has an ISO Class 5 (see Table 1) recirculating device, a minimum of 15 ACPHs through the area supply HEPA filters is adequate, providing the combined ACPH is not less than 30. [USP-NF Chapter 797- *Environmental Quality and Control- Facility Design and Environmental Controls*]

67. ☐ ☐ **HEPA-filtered supply air shall be introduced at the ceiling, and returns should be mounted low on the wall,** creating a general top-down dilution of area air with HEPA-filtered make-up air. Ceiling-mounted returns are not recommended. [USP-NF Chapter 797- *Environmental Quality and Control- Facility Design and Environmental Controls*]

68. ☐ ☐ **Activities and tasks carried out within the buffer area shall be limited to only those necessary when working within a controlled environment**. Only the **furniture, equipment, supplies, and other material required for the compounding activities to be performed shall be brought into the area, and they shall be nonpermeable, nonshedding, cleanable, and resistant to disinfectants.** Whenever such items are **brought into the area, they shall first be cleaned and disinfected**. Whenever possible, **equipment and other items used in the buffer area shall not be taken out of the area except for calibration, servicing, or other**

activities associated with the proper maintenance of the item. [USP-NF Chapter 797- *Environmental Quality and Control- Facility Design and Environmental Controls*]

69. ☐ ☐ Secondary engineering controls such as buffer areas and ante-areas generally serve as a core for the location of the PEC. **Buffer areas are designed to maintain at least ISO Class 7 (see Table 1) conditions for 0.5-mm particles under dynamic conditions and ISO Class 8 (see Table 1) conditions for 0.5-mm and larger particles under dynamic conditions for the ante-areas.** [USP-NF Chapter 797 *Environmental Quality and Control, Facility Design and Environmental Controls*]

70. ☐ ☐ **PECs (LAFWs, BSCs, CAIs, and CACIs) and secondary engineering controls (buffer and ante-areas)** are essential components of the overall contamination control strategy for aseptic compounding. As such, it is imperative that they perform as designed and that the resulting levels of contamination be within acceptable limits. **Certification procedures such as those outlined in Certification Guide for Sterile Compounding Facilities (CAG-003-2006) shall be performed by a qualified individual no less than every 6 months and whenever the device or room is relocated or altered or major service to the facility is performed.** [USP-NF Chapter 797 - *Environmental Quality and Control, Viable and Nonviable Environmental Sampling (ES) Testing, Environmental Nonviable Particle Testing Program*]

71. ☐ ☐ PECs typically include, but are not limited to, LAFWs, BSCs, CAIs, and CACIs, which provide an ISO Class 5 (see Table 1) environment for the exposure of critical sites. **PECs shall maintain ISO Class 5 (see Table 1) or better conditions for 0.5-mm particles (dynamic operating conditions) while compounding CSPs.** [USP-NF Chapter 797 -*Environmental Quality and Control, Facility Design and Environmental Controls*]

72. ☐ ☐ **The PEC shall be placed within a buffer area in such a manner as to avoid conditions that could adversely affect their operation.** For example, strong air currents from opened doors, personnel traffic, or air streams from the HVAC systems can disrupt the unidirectional airflow in open-faced workbenches. [USP-NF Chapter 797 - *Environmental Quality and Control, Facility Design and Environmental Controls*]

73. ☐ ☐ **PECs (LAFWs, BSCs, CAIs, and CACIs) shall be located within a restricted access ISO Class 7 (see Table 1) buffer area (see Figure 1),** with the following CAI/CACI exceptions below: [USP-NF Chapter 797 - *Environmental Quality and Control, Facility Design and Environmental Controls*]
☐ Only authorized personnel and materials required for compounding and cleaning shall be permitted in the buffer area.
☐ Presterilization procedures for high-risk level CSPs, such as weighing and mixing, shall be completed in no worse than an ISO Class 8 (see Table 1) environment.
☐ PECs shall be located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns.

74. ☐ ☐ **CAIs and CACIs shall be placed in an ISO Class 7 (see Table 1) buffer area <u>unless they meet all of the following conditions</u>:** [USP-NF Chapter 797 - *Environmental Quality and Control, Facility Design and Environmental Controls*]
☐ The isolator shall provide isolation from the room and maintain ISO Class 5 (see Table 1) during dynamic operating conditions, including transferring ingredients, components, and devices into and out of the isolator and during preparation of CSPs.
☐ Particle counts sampled approximately 6 to 12 inches upstream of the critical exposure site shall maintain ISO Class 5 (see Table 1) levels during compounding operations.
☐ Not more than 3520 particles (0.5 mm and larger) per m3 shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing the transfer.

75. ☐ ☐ **If the PEC is a CAI or CACI that does not meet the requirements above or is a LAFW or BSC that cannot be located within an ISO Class 7 (see Table 1) buffer area,** then only low-risk level nonhazardous and radiopharmaceutical CSPs pursuant to a physician order for a specific patient may be prepared, and administration of the CSP shall commence within 12 hours of preparation or as recommended in the manufacturer's package insert, whichever is less. [USP-NF Chapter 797 - *Environmental Quality and Control, Facility Design and Environmental Controls*]

76. ☐ ☐ When isolators are used for sterile compounding, the recovery time to achieve ISO Class 5 (see Table 1) air quality shall be documented and internal procedures developed to ensure that adequate recovery time is

allowed after material transfer before and during compounding operations. [USP-NF Chapter 797 - *Environmental Quality and Control, Facility Design and Environmental Controls*]

77. ☐ ☐ Airborne contamination control is achieved in the PEC through the use of HEPA filters. **The airflow in the PEC shall be unidirectional (laminar flow),** and because of the particle collection efficiency of the filter, the "first air" at the face of the filter is, for the purposes of aseptic compounding, **free from airborne particulate contamination. HEPA-filtered air shall be supplied in critical areas (ISO Class 5, see Table 1) at a velocity sufficient to sweep particles away from the compounding area and maintain unidirectional airflow during operations.** Proper design and control prevents turbulence and stagnant air in the critical area. [USP-NF Chapter 797- *Environmental Quality and Control, Facility Design and Environmental Controls*]

78. ☐ ☐ **In situ air pattern analysis via smoke studies shall be conducted** at the critical area to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions. [USP-NF Chapter 797- *Environmental Quality and Control, Facility Design and Environmental Controls*]

79. ☐ ☐ **Environmental sampling shall occur as part a comprehensive quality management program** and shall occur minimally under any of the following conditions: [USP-NF Chapter 797 - *Environmental Quality and Control, Viable and Nonviable Environmental Sampling (ES) Testing*]
☐ as part of the commissioning and certification of new facilities and equipment;
☐ following any servicing of facilities and equipment;
☐ as part of the re-certification of facilities and equipment (i.e., every 6 months);
☐ in response to identified problems with end products or staff technique; or
☐ in response to issues with CSPs, observed compounding personnel work practices, or patient-related infections (where the CSP is being considered as a potential source of the infection).

80. ☐ ☐ Sampling Plan—**An appropriate environmental sampling plan shall be developed for airborne viable particles based on a risk assessment of compounding activities performed. Selected sampling sites shall include locations within each ISO Class 5 (see Table 1) environment and in the ISO Class 7 and 8 (see Table 1) areas and in the segregated compounding areas at greatest risk of contamination** (e.g., work areas near the ISO Class 5 [see Table 1] environment, counters near doors, pass-through boxes). **The plan shall include sample location, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels.** [USP-NF Chapter 797 - *Environmental Quality and Control, Viable and Nonviable Environmental Sampling (ES) Testing, Environmental Viable Airborne Particle Testing Program, Sampling Plan*]

81. ☐ ☐ Growth Medium—**A general microbiological growth medium such as Soybean–Casein Digest Medium shall be used to support the growth of bacteria. Malt extract agar or some other media that supports the growth of fungi shall be used in highrisk level compounding environments.** Media used for surface sampling must be supplemented with additives to neutralize the effects of disinfecting agents (e.g., TSA with lecithin and polysorbate 80). [USP-NF Chapter 797 - *Environmental Quality and Control, Viable and Nonviable Environmental Sampling (ES) Testing, Environmental Viable Airborne Particle Testing Program, Sampling Plan*]

82. ☐ ☐ Viable Air Sampling—**Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments** (LAFWs, CAIs, clean room or buffer areas, and ante-areas) **shall be performed by properly trained individuals for all compounding risk levels. Impaction shall be the preferred method of volumetric air sampling.** Use of settling plates for qualitative air sampling may not be able to determine adequately the quality of air in the controlled environment. [USP-NF Chapter 797 - *Environmental Quality and Control, Viable and Nonviable Environmental Sampling (ES) Testing, Environmental Viable Airborne Particle Testing Program*]

83. ☐ ☐ **For low-, medium-, and high-risk level compounding, air sampling shall be performed at locations that are prone to contamination during compounding activities and during other activities such as staging, labeling, gowning, and cleaning.** Locations shall include zones of air backwash turbulence within LAFW and other areas where air backwash turbulence may enter the compounding area (doorways, in and around ISO Class 5 [see Table 1] PEC and environments). [USP-NF Chapter 797 - *Environmental Quality and Control, Viable and Nonviable Environmental Sampling (ES) Testing, Environmental Viable Airborne Particle Testing Program*]

84. ☐ ☐ **For low-risk level CSPs with 12-hour or less BUD prepared in a PEC** (LAFWs, BSCs, CAIs) **that maintains an**

ISO Class 5 (see Table 1), **air sampling shall be performed at locations inside the ISO Class 5** (see Table 1) **environment and other areas that are in close proximity to the ISO Class 5** (see Table 1) **environment during the certification of the PEC.** [USP-NF Chapter 797 - *Environmental Quality and Control, Viable and Nonviable Environmental Sampling (ES) Testing, Environmental Viable Airborne Particle Testing Program*]

85. ☐ ☐ Air Sampling Devices—There are a number of manufacturers of electronic air sampling equipment. It is important that personnel refer to the manufacturer's recommended procedures when using the equipment to perform volumetric air sampling procedures. The instructions in the manufacturer's user's manual for verification and use of electric air samplers that actively collect volumes of air for evaluation must be followed. **A sufficient volume of air (400 to 1000 liters) shall be tested at each location in order to maximize sensitivity. The volumetric air sampling devices need to be serviced and calibrated as recommended by the manufacturer.** [USP-NF Chapter 797 - *Environmental Quality and Control, Viable and Nonviable Environmental Sampling (ES) Testing, Environmental Viable Airborne Particle Testing Program*]

86. ☐ ☐ Air Sampling Frequency and Process—**Air sampling shall be performed at least semiannually (i.e., every 6 months) as part of the re-certification of facilities and equipment**. If compounding occurs in multiple locations within an institution (e.g., main pharmacy, satellites), environmental sampling is required for each individual compounding area. A sufficient volume of air shall be sampled and the manufacturer's guidelines for use of the electronic air sampling equipment followed. Any facility construction or equipment servicing may require that air sampling be performed during these events. [USP-NF Chapter 797 - *Environmental Quality and Control, Viable and Nonviable Environmental Sampling (ES) Testing, Environmental Viable Airborne Particle Testing Program*]

87. ☐ ☐ Action Levels, Documentation, and Data Evaluation—The value of viable microbial sampling of the air in the compounding environment is realized when the data are used to identify and correct an unacceptable situation. **Sampling data shall be collected and reviewed on a periodic basis as a means of evaluating the overall control of the compounding environment. If an activity consistently shows elevated levels of microbial growth, competent microbiology personnel shall be consulted.** [USP-NF Chapter 797 - *Environmental Quality and Control, Viable and Nonviable Environmental Sampling (ES) Testing, Environmental Viable Airborne Particle Testing Program*]

88. ☐ ☐ **Any cfu count that exceeds its respective action level (see Table 2) should prompt a re-evaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location. An investigation into the source of the contamination shall be conducted.** Sources could include HVAC systems, damaged HEPA filters, and changes in personnel garbing or work practices. **The source of the problem shall be eliminated, the affected area cleaned, and resampling performed.** [USP-NF Chapter 797 - *Environmental Quality and Control, Viable and Nonviable Environmental Sampling (ES) Testing, Environmental Viable Airborne Particle Testing Program*]

89. ☐ ☐ The intermediate precision of the **ACD** can be determined on the basis of the day-to-day variations in performance of the accuracy measures. Thus, **compounding personnel shall keep a daily record of the above-described accuracy assessments and review the results over time. This review shall occur at least at weekly intervals to avoid potentially clinically significant cumulative errors over time.** [USP-NF Chapter 797 - *Elements of Quality Control- Verification of Automated Compounding Devices (ACDs) for Parenteral Nutrition Compounding- Precision*]

90. ☐ ☐ **Compounding personnel shall ensure proper storage and security of CSPs prepared by or dispensed from the compounding facility until either their BUDs are reached or they are administered to patients.** In fulfilling this general responsibility, the compounding facility is responsible for the proper packaging, handling, transport, and storage of CSPs prepared by or dispensed from it, including the appropriate education, training, and supervision of compounding personnel assigned to these functions. The compounding facility should assist in the education and training of noncompounding personnel responsible for carrying out any aspect of these functions. [USP-NF Chapter 797- *Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs*]

91. ☐ ☐ CSPs, as well as all other drug products, shall be stored in the patient-care area in such a way as to secure them from unauthorized personnel, visitors, and patients. [USP-NF Chapter 797- *Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs- Use and Storage*]

Documentation

All facilities that dispense prescriptions must comply with the record keeping requirements of their State Boards of Pharmacy. When a facility compounds a preparation according to the manufacturer's labeling instructions, then further documentation is not required. All other compounded preparations require further documentation as described in this section. [UAC R 156-17b-614a (3)(d)]

92. ☐ ☐ A master formulation record shall be approved by a pharmacist or DMP for each batch of sterile or non-sterile pharmaceuticals to be prepared. Once approved, a duplicate of the master formulation record shall be used as the compounding record from which each batch is prepared and on which all documentation for that batch occurs. The master worksheet sheet may be stored electronically and shall contain at a minimum: [UAC R156-17b-614a(3)(e)(i-xiii)]

☐ official or assigned name
☐ strength
☐ dosage form of the preparation
☐ calculations needed to determine and verify quantities of components and doses of active pharmaceutical ingredients dosage form of the preparation
☐ description of ingredients and their quantities
☐ compatibility and stability information, including references when available
☐ equipment needed to prepare the preparation
☐ container used in dispensing
☐ packaging and storage requirements
☐ description of final preparation
☐ quality control procedures and expected results;
☐ mixing instructions, which shall include: ☐order of mixing ☐ mixing temperatures or other environmental controls ☐ duration of mixing ☐ other factors pertinent to the replication of the preparation as compounded
☐ sample labeling information, which shall contain, in addition to legally required information: ☐ generic name and quantity or concentration of each active ingredient ☐ assigned beyond use date ☐ storage conditions ☐ prescription or control number, whichever is applicable

93. ☐ ☐ A compounding record for each batch of sterile or non-sterile pharmaceuticals shall document the following: [UAC R156-17b-614a(3)(f) (i-xix)]

☐ official or assigned name;
☐ strength and dosage of the preparation;
☐ Master Formulation Record reference for the preparation;
☐ names and quantities of all components
☐ sources, lot numbers, and expiration dates of components;
☐ total quantity compounded;
☐ name of the person who prepared the preparation
☐ name of the compounder who approved the preparation
☐ name of the person who performed the quality control procedures
☐ date of preparation
☐ assigned control, if for anticipation of use or prescription number, if patient specific, whichever is applicable
☐ duplicate label as described in the Master Formulation Record means the sample labeling information that is dispensed on the final product given to the patient and shall at minimum contain: ☐ active ingredients ☐ beyond use date ☐ storage conditions and ☐ lot number;
☐ proof of the duplicate labeling information, which proof shall: ☐ be kept at the pharmacy ☐ be immediately retrievable ☐ include an audit trail for any altered form; and ☐ be reproduced in: the original format that was dispensed, an electronic format, or a scanned electronic version
☐ description of final preparation
☐ results of quality control procedures (e.g. weight range of filled capsules, pH of aqueous liquids); and
☐ documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver.

94. ☐ ☐ Compounding records including the master worksheet, preparation worksheet, and MSDS files shall be kept for a minimum of five years and should be immediately retrievable in written or electronic format. [UAC R156-17b-612 (4)]

95. ☐ ☐ The facility maintains documentation regarding an ongoing quality control program that monitors and evaluates personnel performance, equipment and facility's compliance with following the USP-NF Chapters 795 and 797 standards. [UAC R156-17b-614a(3)(h)]

96. ☐ ☐ Results from the equipment calibration, annual maintenance reports, and routine maintenance are kept on file for the lifetime of the equipment. [USP-NF Chapter 797- *Elements of Quality Control- Equipment*]

Compounding Procedures

97. ☐ ☐ **Opened or needle-punctured single-dose containers**, such as bags, bottles, syringes, and vials of sterile products and CSPs **shall be used within 1 hour if opened in worse than ISO Class 5** (see Table 1) air quality (see Immediate-Use CSPs), **and any remaining contents must be discarded.** [USP-NF Chapter 797- *Single-Dose and Multiple-Dose Containers]*

98. ☐ ☐ ☐**Single-dose vials exposed to ISO Class 5** (see Table 1) **or cleaner air may be used up to 6 hours after initial needle puncture.** ☐**Opened single-dose ampuls shall not be stored for any time period.** ☐**Multiple-dose containers** (e.g., vials) **are formulated for removal of portions on multiple occasions because they usually contain antimicrobial preservatives.** The ☐**BUD after initially entering or opening (e.g., needle-punctured) multiple-dose containers is 28 days** (see Antimicrobial Effectiveness Testing <51>) unless otherwise specified by the manufacturer. [USP-NF Chapter 797- *Single-Dose and Multiple-Dose Containers]*

99. ☐ ☐ Wiping with small sterile 70% IPA swabs that are commercially available in individual foil-sealed packages (or a comparable method) is preferred for disinfecting entry points on bags and vials, allowing the IPA to dry before piercing stoppers with sterile needles and breaking necks of ampuls. **The surface of the sterile 70% IPA swabs used for disinfecting entry points of sterile packages and devices shall not contact any other object before contacting the surface of the entry point. 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.** [USP-NF Chapter 797- *Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area*]

100. ☐ ☐ Pharmacy Bulk Package (see Containers for Injections under Injections <1>)—A container of a sterile preparation for parenteral use that contains many single doses. The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for infusion or, through a sterile transfer device, for the filling of empty sterile syringes. **The closure shall be penetrated only one time after constitution with a suitable sterile transfer device or dispensing set, which allows measured dispensing of the contents.** The pharmacy bulk package is to be used only in a suitable work area such as a laminar flow hood (or an equivalent clean air compounding area). **Where a container is offered as a pharmacy bulk package, the label shall (a) state prominently "Pharmacy Bulk Package—Not for Direct Infusion," (b) contain or refer to information on proper techniques to help ensure safe use of the product, and (c) bear a statement limiting the time frame in which the container may be used once it has been entered, provided it is held under the labeled storage conditions.** [USP-NF Chapter 797- *Definitions*]

101. ☐ ☐ **The licensed healthcare professionals who supervise compounding shall be responsible for determining that the selected sterilization method** (see Methods of Sterilization under Sterilization and Sterility Assurance of Compendial Articles <1211>) both sterilizes and maintains the strength, purity, quality, and packaging integrity of CSPs. [USP-NF Chapter 797 - *Verification of Compounding Accuracy and Sterility, Sterilization Methods*]

102. ☐ ☐ Critical sites are locations that include any component or fluid pathway surfaces (e.g., vial septa, injection ports, beakers) or openings (e.g., opened ampuls, needle hubs) exposed and at risk of direct contact with air (e.g., ambient room or HEPA filtered), moisture (e.g., oral and mucosal secretions), or touch contamination. Protection of critical sites by precluding physical contact and airborne contamination shall be given the highest priority in sterile compounding practice. [USP-NF Chapter 797 - Exposure of Critical Sites]

103. ☐ ☐ All **high-risk level CSPs that are prepared in groups of more than 25 identical individual single-dose packages** (e.g., ampuls, bags, syringes, vials) **or in multiple-dose vials (MDVs) for administration to multiple patients or that are exposed longer than 12 hours at 2° to 8° and longer than 6 hours at warmer than 8° before they are sterilized shall meet the sterility test** (see Sterility Tests <71>) **before they are dispensed or administered.** [USP-NF Chapter 797- *Finished Preparation Release Checks and Tests- Sterility Testing*]

104. ☐ ☐ **All high-risk level CSPs, except those for inhalation and ophthalmic administration, that are prepared in groups of more than 25 identical individual single-dose packages (e.g., ampuls, bags, syringes, vials) or in MDVs for administration to multiple patients or that are exposed longer than 12 hours at 2° to 8° and longer than 6 hours at warmer than 8° before they are sterilized shall be tested to ensure that they do not contain excessive bacterial endotoxins** (see Bacterial Endotoxins Test <85> and Pyrogen Test <151>). In the absence of a bacterial endotoxins limit in the official monograph or other CSP formula source, the CSP shall not exceed the amount of USP Endotoxin Units (per hour per kilogram of body weight or square meters of body surface area) specified in Bacterial Endotoxins Test <85> referenced above for the appropriate route of administration. [USP-NF Chapter 797- *Finished Preparation Release Checks and Tests- Bacterial Endotoxin (Pyrogen) Testing*]

105. ☐ ☐ **Does the facility participate in the following:**
☐ Hazardous Drugs ☐ Radiopharmaceuticals ☐ Allergen Extracts as CSPs

Hazardous Drugs

106. ☐ ☐ **All personnel who compound hazardous drugs shall be fully trained** in the **storage, handling, and disposal** of these drugs. This training **shall occur prior to preparing or handling hazardous CSPs**, and **its effectiveness shall be verified by testing specific hazardous drugs preparation techniques**. Such verification **shall be documented for each person at least annually**. This **training shall include didactic overview** of hazardous drugs, including mutagenic, teratogenic, and carcinogenic properties, and it **shall include ongoing training for each new hazardous drug that enters the marketplace.** [USP- NF Chapter 797- *Hazardous Drugs as CSPs*]

107. ☐ ☐ **Compounding personnel of reproductive capability shall confirm in writing that they understand the risks of handling hazardous drugs.** The training **shall include** at least the following: [USP- NF Chapter 797- *Hazardous Drugs as CSPs*]

- ☐ safe aseptic manipulation practices;
- ☐ negative pressure techniques when utilizing a BSC or CACI;
- ☐ correct use of CSTD devices;
- ☐ containment, cleanup, and disposal procedures for breakages and spills; and
- ☐ treatment of personnel contact and inhalation exposure.

108. ☐ ☐ Hazardous drugs shall be prepared for administration only under conditions that protect the healthcare workers and other personnel in the preparation and storage areas. [USP-NF Chapter 797- *Hazardous Drugs as CSPs*]

109. ☐ ☐ Hazardous drugs shall be stored separately from other inventory in a manner to prevent contamination and personnel exposure. [USP-NF Chapter 797- *Hazardous Drugs as CSPs*]

110. ☐ ☐ Hazardous drugs shall be handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparation for administration, and disposal. [USP-NF Chapter 797- *Hazardous Drugs as CSPs*]

111. ☐ ☐ Hazardous drugs shall be prepared in an ISO Class 5 (see Table 1) environment with protective engineering controls in place and following aseptic practices specified for the appropriate contamination risk levels defined in this chapter. [USP-NF Chapter 797- *Hazardous Drugs as CSPs*]

112. ☐ ☐ Access shall be limited to areas where drugs are stored and prepared to protect persons not involved in drug preparation. [USP-NF Chapter 797- *Hazardous Drugs as CSPs*]

113. ☐ ☐ **All hazardous drugs shall be prepared in a BSC5 or a CACI that meets or exceeds the standards for CACI in this chapter. The ISO Class 5** (see Table 1) **BSC or CACI shall be placed in an ISO Class 7** (see Table 1) **area that is physically separated** (i.e., a different area from other preparation areas) **and optimally has not less than 0.01-inch water column negative pressure to adjacent positive pressure ISO Class 7** (see Table 1) **or better ante-areas, thus providing inward airflow to contain any airborne drug. A pressure indicator shall be installed that can be readily monitored for correct room pressurization.** [USP-NF Chapter 797- *Hazardous Drugs as CSPs*]

114. ☐ ☐ If a CACI that meets the requirements of this chapter is used outside of a buffer area, the compounding area shall maintain a minimum negative pressure of 0.01-inch water column and have a minimum of 12 ACPHs. [USP-NF Chapter 797- *Hazardous Drugs as CSPs*]

115. ☐ ☐ **When closed-system vial-transfer devices** (CSTDs) (i.e., vial-transfer systems that allow no venting or exposure of hazardous substance to the environment) **are used, they shall be used within the ISO Class 5 (see Table 1) environment of a BSC or CACI.** The use of a CSTD is preferred because of their inherent closed system process. In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable. [USP-NF Chapter 797- *Hazardous Drugs as CSPs*]

116. ☐ ☐ **Appropriate personnel protective equipment (PPE) shall be worn when compounding in a BSC or CACI and when using CSTD devices.** PPE should include gowns, face masks, eye protection, hair covers, shoe covers or dedicated shoes, double gloving with sterile chemo-type gloves, and compliance with manufacturers' recommendations when using a CACI. [USP-NF Chapter 797- *Hazardous Drugs as CSPs*]

117. ☐ ☐ Compounding personnel of reproductive capability shall confirm in writing that they understand the risks of handling hazardous drugs. [USP-NF Chapter 797- *Hazardous Drugs as CSPs*]

118. ☐ ☐ All personnel who compound hazardous drugs shall be fully trained in the storage, handling, and disposal of these drugs. This training shall occur prior to preparing or handling hazardous CSPs, and its effectiveness shall be verified by testing specific hazardous drugs preparation techniques. Such verification shall be documented for each person at least annually. This training shall include didactic overview of hazardous drugs, including mutagenic, teratogenic, and carcinogenic properties, and it shall include ongoing training for each new hazardous drug that enters the marketplace. [USP-NF Chapter 797- *Hazardous Drugs as CSPs*]

119. ☐ ☐ **Disposal of all hazardous drug wastes shall comply with all applicable federal and state regulations.** All **personnel** who perform routine custodial waste removal and cleaning activities in storage and preparation areas for hazardous drugs **shall be trained** in appropriate procedures to protect themselves and prevent contamination. [USP-NF Chapter 797- *Hazardous Drugs as CSPs*]

<u>Radiopharmaceuticals</u>

120. ☐ ☐ For the purposes of this chapter, **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 (see Injections <1>) shall be designated as, and conform to, the standards for Low-Risk Level CSPs.** These radiopharmaceuticals

121. ☐ ☐ **shall be compounded using appropriately shielded vials and syringes in a properly functioning and certified ISO Class 5 (see Table 1) PEC located in an ISO Class 8 (see Table 1) or cleaner air environment to permit compliance with special handling, shielding, and negative air flow requirements.** [USP-NF Chapter 797- *Radiopharmaceuticals as CSPs*]

Radiopharmaceuticals prepared as Low-Risk Level CSPs with 12-Hour or Less BUD shall be prepared in a segregated compounding area. A line of demarcation defining the segregated compounding area shall be established. Materials and garb exposed in a patient care and treatment area shall not cross a line of

122. ☐ ☐ demarcation into the segregated compounding area. [USP-NF Chapter 797- *Radiopharmaceuticals as CSPs*]

<u>Allergen Extracts as CSPs</u>

123. ☐ ☐ Allergen extracts as CSPs are single-dose and multiple-dose intradermal or subcutaneous injections that are prepared by specially trained physicians and personnel under their direct supervision. **Allergen extracts as CSPs are not subject to the personnel, environmental, and storage requirements for all CSP Microbial Contamination Risk Levels in this chapter only when all of the following criteria are met:** [USP-NF Chapter

797- *Allergen Extracts as CSPs*]

☐ The compounding process involves simple transfer via sterile needles and syringes of commercial sterile allergen products and appropriate sterile added substances (e.g., glycerin, phenol in sodium chloride injection).

☐ All allergen extracts as CSPs shall contain appropriate substances in effective concentrations to prevent the growth of microorganisms. Nonpreserved allergen extracts shall comply with the appropriate CSP risk level requirements in the chapter.

☐ Before beginning compounding activities, personnel perform a thorough hand-cleansing procedure by removing debris from under fingernails using a nail cleaner under running warm water followed by vigorous hand and arm washing to the elbows for at least 30 seconds with either nonantimicrobial or antimicrobial soap and water.

☐ Compounding personnel don hair covers, facial hair covers, gowns, and face masks.

☐ Compounding personnel perform antiseptic hand cleansing with an alcohol-based surgical hand scrub with persistent activity.

☐ Compounding personnel don powder-free sterile gloves that are compatible with sterile 70% isopropyl alcohol (IPA) before beginning compounding manipulations.

☐ Compounding personnel disinfect their gloves intermittently with sterile 70% IPA when preparing multiple allergen extracts as CSPs.

☐ Ampul necks and vial stoppers on packages of manufactured sterile ingredients are disinfected by careful wiping with sterile 70% IPA swabs to ensure that the critical sites are wet for at least 10 seconds and allowed to dry before they are used to compound allergen extracts as CSPs.

☐ The aseptic compounding manipulations minimize direct contact contamination (e.g., from glove fingertips, blood, nasal and oral secretions, shed skin and cosmetics, other nonsterile materials) of critical sites (e.g., needles, opened ampuls, vial stoppers).

☐ The label of each multiple-dose vial (MDV) of allergen extracts as CSPs lists the name of one specific patient and a BUD and storage temperature range that is assigned based on manufacturers' recommendations or peer-reviewed publications.

124. ☐ ☐ ☐ Single-dose allergen extracts as CSPs shall not be stored for subsequent additional use.

Sterilization

Does the facility participate in the following:

☐ Filter Sterilization in an ISO class 5 ☐ Steam Sterilization ☐ Dry Heat Sterilization

125. ☐ ☐ **(Filter Sterilization in an ISO class 5)**
Commercially available sterile filters shall be approved for human-use applications in sterilizing pharmaceutical fluids. **Sterile filters used to sterilize CSPs shall be pyrogen free and have a nominal pore size of 0.2 or 0.22 mm.** They shall be certified by the manufacturer to retain at least 107 microorganisms of a strain of Brevundimonas (Pseudomonas) diminuta on each square centimeter of upstream filter surface area under conditions similar to those in which the CSPs will be sterilized (see High-Risk Conditions in High-Risk Level CSPs). [USP-NF Chapter 797 - *Verification of Compounding Accuracy and Sterility- Sterilization Methods- Sterilization of High-Risk Level CSPs by Filtration*]

126. ☐ ☐ **The compounding supervisor shall ensure**, directly or from appropriate documentation, 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, including strength of ingredients of the specific CSP. [USP-NF Chapter 797 - *Verification of Compounding Accuracy and Sterility- Sterilization Methods- Sterilization of High-Risk Level CSPs by Filtration*]

127. ☐ ☐ The filter dimensions and liquid material to be sterile-filtered shall permit the sterilization process to be completed rapidly, without the replacement of the filter during the process. [USP-NF Chapter 797 - *Verification of Compounding Accuracy and Sterility- Sterilization Methods- Sterilization of High-Risk Level CSPs by Filtration*]

128. ☐ ☐ Filter units used to sterilize CSPs shall also be subjected to manufacturers' recommended integrity test, such as the bubble point test. [USP-NF Chapter 797 - *Verification of Compounding Accuracy and Sterility- Sterilization Methods- Sterilization of High-Risk Level CSPs by Filtration*]

129. ☐ ☐ Compounding personnel shall ascertain that selected filters will achieve sterilization of the particular CSPs being sterilized. [USP-NF Chapter 797 - *Verification of Compounding Accuracy and Sterility- Sterilization Methods- Sterilization of High-Risk Level CSPs by Filtration*]

130. ☐ ☐ **(Steam Sterilization)**
The process of thermal sterilization employing saturated steam under pressure, or autoclaving, is the preferred method to terminally sterilize aqueous preparations that have been verified to maintain their full chemical and physical stability under the conditions employed (see Steam Sterilization under Sterilization and Sterility Assurance of Compendial Articles <1211>).**To achieve sterility, all materials are to be exposed to steam at 121° under a pressure of about 1 atmosphere or 15 psi for the duration verified by testing to achieve sterility of the items, which is usually 20 to 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. [USP-NF Chapter 797- *Verification of Compounding Accuracy and Sterility- Sterilization Methods- Sterilization of High-Risk Level CSPs by Steam*]

131. ☐ ☐ Not directly exposing items to pressurized steam may result in survival of microbial organisms and spores. Before their sterilization, plastic, glass, and metal devices are tightly wrapped in low-particle-shedding paper or fabrics or sealed in envelopes that prevent poststerilization microbial penetration**. Immediately before filling ampuls and vials that will be steam sterilized, solutions are passed through a filter having a nominal pore size not larger than 1.2 mm for removal of particulate matter. Sealed containers shall be able to generate steam internally; thus, stoppered and crimped empty vials shall contain a small amount of moisture to generate steam.** [USP-NF Chapter 797- *Verification of Compounding Accuracy and Sterility- Sterilization Methods- Sterilization of High-Risk Level CSPs by Steam*]

132. ☐ ☐ The description of steam sterilization conditions and duration for specific CSPs shall be included in written documentation in the compounding facility. The effectiveness of steam sterilization shall be verified using appropriate BIs of Bacillus stearothermophilus (see Biological Indicators <1035>) and other confirmation methods such as temperature-sensing devices (see Sterilization and Sterility Assurance of Compendial Articles <1211> and Sterility Tests <71>). [USP-NF Chapter 797- *Verification of Compounding Accuracy and Sterility- Sterilization Methods- Sterilization of High-Risk Level CSPs by Steam*]

133. ☐ ☐ **(Dry Heat Sterilization)**
Dry heat sterilization is usually done as a batch process in an oven designed for sterilization. **Heated filtered air shall be evenly distributed throughout the chamber by a blower device.** [USP-NF Chapters 797- *Verification of Compounding Accuracy and Sterility- Sterilization Method- Sterilization of High-Risk Level CSPs by Dry Heat*]

134. ☐ ☐ **Dry heat shall be used only for those materials that cannot be sterilized by steam,** when either the moisture would damage the material or the material is impermeable. [USP-NF Chapters 797- *Verification of Compounding Accuracy and Sterility-, Sterilization Method- Sterilization of High-Risk Level CSPs by Dry Heat*]

135. ☐ ☐ During sterilization, sufficient space shall be left between materials to allow for good circulation of the hot air. [USP-NF Chapters 797- *Verification of Compounding Accuracy and Sterility- Sterilization Method- Sterilization of High-Risk Level CSPs by Dry Heat*]

136. ☐ ☐ The description of dry heat sterilization conditions and duration for specific CSPs shall be included in written documentation in the compounding facility. [USP-NF Chapters 797- *Verification of Compounding Accuracy and Sterility- Sterilization Method- Sterilization of High-Risk Level CSPs by Dry Heat*]

137. ☐ ☐ The effectiveness of dry heat sterilization shall be verified using appropriate BIs of Bacillus subtilis (see Biological Indicators <1035>) and other confirmation methods such as temperature- sensing devices (see Sterilization and Sterility Assurance of Compendial Articles <1211> and Sterility Tests <71>). [USP-NF Chapters 797- *Verification of Compounding Accuracy and Sterility- Sterilization Method- Sterilization of High-Risk Level CSPs by Dry Heat*]

Finished Preparation Release Checks and Tests

138. ☐ ☐ **All CSPs that are intended to be solutions shall be visually examined for the presence of particulate matter and not administered or dispensed when such matter is observed.** The prescription orders, written compounding procedure, preparation records, and expended materials used to make CSPs at all contamination risk levels are inspected for accuracy of correct identities and amounts of ingredients, aseptic mixing and sterilization, packaging, labeling, and expected physical appearance before they are administered or dispensed. [USP- NF Chapter 797- *Finished Preparation Release Checks and Tests- Inspection of Solution Dosage Forms and*

Review of Compounding Procedures

139. ☐ ☐ **The accuracy of identities, concentrations, amounts, and purities of ingredients in CSPs shall be confirmed by reviewing labels on packages, observing and documenting correct measurements with approved and correctly standardized devices, and reviewing information in labeling and certificates of analysis provided by suppliers.** When the correct identity, purity, strength, and sterility of ingredients and components of CSPs cannot be confirmed (in cases of, for example, unlabeled syringes, opened ampuls, punctured stoppers of vials and bags, containers of ingredients with incomplete labeling), such ingredients and components shall be discarded immediately. [USP-NF Chapter 797- *Verification of Compounding Accuracy and Sterility*]

140. ☐ ☐ The label of each batch prepared of sterile or non-sterile pharmaceuticals shall bear at a minimum: [UAC R156-17b-614a (3)(g)(i-vi)
☐ the unique lot number assigned to the batch;
☐ all active solution and ingredient names, amounts strengths and concentrations, where applicable
☐ quantity
☐ beyond use date and time, when applicable
☐ appropriate ancillary instructions, such as storage instructions or cautionary statements, including cytotoxic warning labels where appropriate; and
☐ device-specific instructions, where appropriate.

141. ☐ ☐ All prescription labels for compounded sterile and non-sterile medications when dispensed to the ultimate user or agent shall bear at a minimum in addition to what is required in Section 58-17b-602 the following: [R156-17b-614a (3)(h)(i)(ii)(iii)
☐ generic name a quantity or concentration of each active ingredient. In the instance of a sterile preparation for parenteral use, labeling shall include the name and base solution for infusion preparation;
☐ assigned compounding record or lot number; and
☐ "this is a compounded preparation" or similar language

Packaging and Storage

142. ☐ ☐ Compounding facilities that ship CSPs to locations outside their own premises shall select modes of transport that are expected to deliver properly packed CSPs in undamaged, sterile, and stable condition to recipients. [USP-NF Chapter 797- *Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs- Packing and Transporting CSPs- Transit of CSPs*]

143. ☐ ☐ Compounding personnel should ascertain that temperatures of CSPs during transit by the selected mode will not exceed the warmest temperature specified on the storage temperature range on CSP labels. It is recommended that compounding personnel communicate directly with the couriers to learn shipping durations and exposure conditions that CSPs may encounter. [USP-NF Chapter 797- *Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs- Packing and Transporting CSPs- Transit of CSPs*]

144. ☐ ☐ Compounding facilities that ship CSPs to patients and other recipients outside their own premises shall ascertain or provide, whichever is appropriate, the following assurances: [USP-NF Chapter 797- *Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSP- Storage in Locations Outside Compounding Facilities*]
☐ Labels and accessory labeling for CSPs include clearly readable BUDs, storage instructions, and disposal instructions for out-of-date units.
☐ Each patient or other recipient is able to store the CSPs properly, including the use of a properly functioning refrigerator and freezer if CSPs are labeled for such storage.

145. ☐ ☐ **Inspections shall confirm compliance with appropriate storage conditions, separation of drugs and food, proper use of MDVs, and the avoidance of using single-dose products as MDVs.** CSPs, as well as all other drug products, shall be stored in the patient-care area in such a way as to secure them from unauthorized personnel, visitors, and patients. [USP- NF Chapter 797- *Finished Preparation Release Checks and Tests- Monitoring Controlled Storage Areas*]

146. ☐ ☐ Personnel who prepare, dispense, and administer CSPs shall store them strictly in accordance with the

conditions stated on the label of ingredient products and finished CSPs. [USP-NF Chapter 797- *Storage and Beyond-use Dating*]

Quality Assurance Program

147. ☐ ☐ The assurance of CSPs' quality and packaging integrity is highly dependent on the proper adherence of all personnel to the pertinent SOPs. **Compounding personnel shall design, implement, and maintain a formal education, training, and competency assessment program that encompasses all the functions and tasks addressed in the foregoing sections and all personnel to whom such functions and tasks are assigned.** This program includes the assessment and documentation of procedural breaches, administration mishaps, side effects, allergic reactions, and complications associated with dosage or administration, such as extravasation. This program should be coordinated with the institution's adverse-events and incident reporting programs. [USP-NF Chapter 797- *Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs- Education and Training*]

148. ☐ ☐ **A provider of CSPs shall have in place a formal QA program intended to provide a mechanism for monitoring, evaluating, correcting, and improving the activities and processes described in this chapter.** Emphasis in the QA program is placed on maintaining and improving the quality of systems and the provision of patient care. In addition, the QA program ensures that any plan aimed at correcting identified problems also includes appropriate follow-up to make certain that effective corrective actions were performed. Characteristics of a QA program include the following: [USP-NF Chapter 797- *Quality Assurance (QA) Program*]

☐ Formalization in writing;
☐ Consideration of all aspects of the preparations and dispensing of products as described in this chapter, including environmental testing and verification results;
☐ Description of specific monitoring and evaluation activities;
☐ Specification of how results are to be reported and evaluated;
☐ Identification of appropriate follow-up mechanisms when action limits or thresholds are exceeded; and
☐ Delineation of the individuals responsible for each aspect of the QA program.

149. ☐ ☐ A written quality assurance procedure includes the following in-process checks that are applied, as appropriate, to specific CSPs: [USP-NF Chapter 797- *Responsibilities of Compounding Personnel*]

☐ accuracy and precision of measuring and weighing;
☐ the requirement for sterility;
☐ methods of sterilization and purification;
☐ safe limits and ranges for strength of ingredients, bacterial endotoxins, and particulate matter;
☐ pH;
☐ labeling accuracy and completeness;
☐ BUD assignment;
☐ and packaging and storage requirements.

150. ☐ ☐ Compounding facilities shall clinically monitor patients treated with CSPs according to the regulations and guidelines of their respective state healthcare practitioner licensure boards or of accepted standards of practice. **Compounding facilities shall provide patients and other recipients of CSPs with a way to address their questions and report any concerns that they may have with CSPs and their administration devices.** [USP-NF Chapter 797- *Patient Monitoring and Adverse Events Reporting*]

COMMENTS

(Use an additional sheet if necessary.)

☐ **By checking this box it is indicated that the undersigned Division Investigator has reviewed the above inspection report and comments made with the undersigned "Responsible Party."**

Signature of Responsible Party: _____ **Date of Signature:** __ / __ / ____

Signature of Division Investigator: _____ **Date of Signature:** __ / __ / ____

Revised 9/2015