Division of Professional Licensing
UTAH DEPARTMENT OF COMMERCE

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STERILE COMPOUNDING

INSPECTION

☐ Opening ☐ Random

INFORMATION

Pharmacy Name: _____ Date: _____

Pharmacy License Number: _____ Expiration Date: _____

Designated Person(s): _____

_____

_____

_____

A person engaging in sterile or non-sterile compounding shall practice in accordance with all applicable federal and state laws and rules, and in accordance with the USP-NF, including USP General Chapter <797> Pharmaceutical Compounding- Sterile Preparations.
These operating standards shall apply to any person licensed under Title 58, Chapter 17b, Pharmacy Practice Act, that engages in compounding.
R156-17b-614e(1)(b)(2)(a)

YES NO

General Operations and Information

1. Which categories of compounding does the facility perform?

☐ Category 1 ☐ Category 2 ☐ Category 3 ☐ Immediate Use ☐ Allergenic Extracts

2. The facility compounds :

☐ Injections, including infusions ☐ Irrigations for internal body cavities ☐ Implants ☐ Parenteral suspensions
☐ Ophthalmic preparations ☐ Parenteral solutions ☐ Baths and soaks for live organs and tissues
☐ Preservative-free parenteral ☐ Aqueous preparations for pulmonary inhalations ☐ Other:

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

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

5. ☐ ☐ 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 "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. [UAC R156-17b-624]

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

7. ☐ ☐ Does the facility have a sales force that distributes samples containing active ingredients? If so, list samples on separate sheet.

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

9. ☐ ☐ Does the facility compound investigational drugs? If so, list on separate sheet.

10. ☐ ☐ Does the facility have a lyophilizer?

YES NO

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 drugs, sterile products, or devices which have been withdrawn from the market for safety reasons. [UAC 58-17b-102(18)(b)(iii)]

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

The facility utilizes the following types of PECs:

☐ LAFW ☐ IVLFZ ☐ BSC ☐ CAI ☐ CACI ☐ Pharmaceutical Isolator

Personnel Training and Evaluation

15. ☐ ☐ The compounding facility must designate one or more individuals to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CSPs and for performing other functions as described in USP-NF Chapter 797. [USP-NF Chapter 797- *Introduction & Scope: Personnel and Settings Affected*]

16. ☐ ☐ All personnel who compound or have direct oversight of compounding personnel must be initially trained and qualified by demonstrating knowledge and competency in compounding CSPs according to the requirements in this section before being allowed to perform their job functions independently. [USP-NF Chapter 797- *Personnel Training and Evaluation*]

17. ☐ ☐ Designated person(s) are responsible for creating and implementing a training program for personnel and for ensuring that compounders, personnel who have direct oversight of compounders, and personnel who perform restocking or cleaning and disinfection duties are initially trained and qualified by demonstrating knowledge and competency in maintaining the quality of the sterile compounding environment before being allowed to perform their job functions independently. [USP-NF Chapter 797- *Personnel Training and Evaluation*]

18. ☐ ☐ Personnel who compound or have direct oversight of compounding personnel must complete training initially and at least every 12 months in appropriate sterile compounding principles and practices. [USP-NF Chapter 797- *Personnel Training and Evaluation*]

19. ☐ ☐ Personnel who only perform restocking or cleaning and disinfecting duties outside of the primary engineering control (PEC) must complete ongoing training as required by the facility's SOPs. Personnel compounding only immediate-use CSPs must complete training as required by the facility's SOPs. [USP-NF Chapter 797- *Personnel Training and Evaluation*]
N/A ☐

20. ☐ ☐ Each compounding facility must develop a written training program that describes the required training, the frequency of training, and the process for evaluating the performance of individuals who compound, have direct oversight of compounding personnel, perform in-process checks, final verification, and dispensing of CSPs. This program must equip personnel with the appropriate knowledge and train them in the required skills necessary to perform their assigned tasks, and SOPs should specify the training required for such tasks. [USP-NF Chapter 797- *Personnel Training and Evaluation*]

21. ☐ ☐ Training and evaluations of personnel must be documented. [USP-NF Chapter 797- *Personnel Training and Evaluation*]

22. ☐ ☐ Before beginning to compound CSPs independently or have direct oversight of compounding personnel, personnel must complete training and be able to demonstrate knowledge of principles and competency of skills for performing sterile manipulations and achieving and maintaining appropriate environmental conditions as applicable job functions. This must be completed initially and at least every 12 months in at least the following: [USP-NF Chapter 797- *Personnel Training and Evaluation- Demonstrating Knowledge & Competency of Core Skills*]

☐ Hand Hygiene ☐ Garbing ☐ Cleaning and Disinfection ☐ Aseptic Technique ☐ Use of equipment
☐ Calculations, measuring, and mixing ☐ Achieving and/or maintaining sterility ☐ Proper use of PECs
☐ Documentation of compounding process ☐ Principles of movement of materials and personnel in the compounding area
☐ Principles of high-efficiency particulate air (HEPA)- filtered unidirectional airflow withing the ISO Class 5 area

23. ☐ ☐ If the facility has only one person in the compounding operation, that person must document that they have obtained training and demonstrated competency, and they must comply with the other requirements of USP-NF Chapter 797. [USP-NF Chapter 797- *Personnel Training and Evaluation- Demonstrating Knowledge & Competency of Core Skills*]
N/A ☐

YES NO

24. ☐ ☐ Before beginning to compound Category 1, Category 2, or Category 3 CSPs or have direct oversight of compounding personnel, personnel must successfully complete an initial garbing competency evaluation no fewer than 3 separate times. The 3 successful completions must be in succession- failure of any of the 3 initial garbing competency evaluations requires repeat testing until personnel successfully complete 3 evaluations in a row. [USP-NF Chapter 797- *Personnel Training and Evaluation- Demonstrating Competency in Garbing and Hand Hygiene*]

25. ☐ ☐ The garbing competency evaluation consists of a visual observation and gloved fingertip and thumb sampling of both hands. Each of the 3 initial competency evaluations must occur after performing a separate and complete hand hygiene and full garbing procedure. All garbing competencies must be completed with gloved fingertip and thumb sampling after garbing and a documented visual audit while performing hand hygiene and garbing procedures. Gloved fingertip and thumb sampling after garbing, but before applying sterile 70% IPA to gloves, must be performed on donned sterile gloves on both hands in a classified area or segregated compounding area (SCA). [USP-NF Chapter 797- *Personnel Training and Evaluation- Demonstrating Competency in Garbing and Hand Hygiene*]

26. ☐ ☐ Results of the evaluation and corrective actions, in the event of failure, must be documented and the documentation maintained to provide a record and long-term assessment of personnel competency. Documentation must at a minimum include:[USP-NF Chapter 797- *Personnel Training and Evaluation- Demonstrating Competency in Garbing and Hand Hygiene*]

- ☐ Name of person evaluated
- ☐ Evaluation date & time Media & components used
- ☐ Media manufacturer- expiration date/lot number
- ☐ Starting temperature for each interval of incubation
- ☐ Dates of incubation
- ☐ Results and identification of the observer/personnel reading & documenting results

27. ☐ ☐ After the initial garbing competency evaluations, compounding personnel must successfully complete the garbing competency at least one time every 6 months for personnel compounding Category 1 and Category 2 CSPs, and at least one time every 3 months for personnel compounding Category 3 CSPs. Personnel who have direct oversight of compounding personnel, but do not compound, must complete a garbing competency evaluation every 12 months. [USP-NF Chapter 797- *Personnel Training and Evaluation- Demonstrating Competency in Garbing and Hand Hygiene*]

28. ☐ ☐ Personnel who have direct oversight of compounding personnel must not compound unless they successfully complete the garbing competency evaluation at the same intervals required for compounding personnel. [USP-NF Chapter 797- *Personnel Training and Evaluation- Demonstrating Competency in Garbing and Hand Hygiene*]

29. ☐ ☐ Before beginning to compound Category 1, Category 2, or Category 3 CSPs independently or have direct oversight of compounding personnel, personnel must successfully complete an aseptic manipulation competency evaluation. The aseptic manipulation competency evaluation consists of a visual observation, media-fill testing, followed by a gloved fingertip and thumb sampling on both hands, and surface sampling of the direct compounding area to assess aseptic technique and related practices. [USP-NF Chapter 797- *Personnel Training and Evaluation- Competency Testing in Aseptic Manipulation*]

30. ☐ ☐ For personnel compounding Category 1 and Category 2 CSPs, the aseptic manipulation competency must occur initially and at least every 6 months thereafter. For personnel compounding Category 3 CSPs, the aseptic manipulation competency must occur initially and at least every 3 months thereafter. Personnel who have direct oversight of compounding personnel must complete an aseptic manipulation competency evaluation annually. [USP-NF Chapter 797- *Personnel Training and Evaluation- Competency Testing in Aseptic Manipulation*]

31. ☐ ☐ Personnel who have direct oversight of compounding personnel must not compound unless they successfully complete the aseptic manipulation competency evaluation that simulates the most difficult and challenging aseptic compounding procedures encountered by the person at the same intervals required for compounding personnel. [USP-NF Chapter 797- *Personnel Training and Evaluation- Competency Testing in Aseptic Manipulation*]

32. ☐ ☐ If using commercial sterile microbial growth media, a certificate of analysis (COA) must be obtained from the supplier stating that the lot of the growth media will support the growth of microorganisms. [USP-NF Chapter 797- *Personnel Training and Evaluation- Competency Testing in Aseptic Manipulation*] ☐ N/A

33. ☐ ☐ If preparing sterile microbial growth media in-house for sterile-to-sterile media-fill testing, the growth promotion capability of the media must be demonstrated for each batch and documented. [USP-NF Chapter 797- *Personnel Training and Evaluation- Competency Testing in Aseptic Manipulation*] ☐ N/A

34. ☐ ☐ Immediately following the media-fill test, gloved fingertip and thumb sampling must be performed on both hands and inside of an ISO Class 5 PEC. If conducting gloved fingertip and thumb sampling in a compounding aseptic isolator (CAI), compounding aseptic containment isolator (CACI), or a pharmaceutical isolator, samples must be taken from the sterile gloves placed over the gloves attached to the restricted access barrier system (RABS) or pharmaceutical isolator sleeves. [USP-NF Chapter 797- *Personnel Training and Evaluation-Competency Testing in Aseptic Manipulation*]

35. ☐ ☐ Successful completion of the gloved fingertip and thumb sampling after media-fill testing is defined as ≤3 cfu as a total from both hands. Microbial identification of the cfu is not required for gloved fingertip and thumb sampling. A failure in the media fill, gloved fingertip and thumb sampling, or surface sample constitutes an overall failure of the aseptic manipulation competency. [USP-NF Chapter 797- *Personnel Training and Evaluation-Competency Testing in Aseptic Manipulation*]

- Gloved Fingertip and Thumb Sampling- After garbing: Action Level- >0
- Gloved Fingertip and Thumb Sampling- After media fill testing: Action Level >3

YES NO

36. ☐ ☐ Results of the evaluation and corrective actions must be documented and the documentation maintained to provide a record and long term assessment of personnel competency. Documentation must at a minimum include: [USP-NF Chapter 797- *Personnel Training and Evaluation- Competency Testing in Aseptic Manipulation*]

- ☐ Name of the person evaluated
- ☐ Evaluation date/time
- ☐ Media & components used
- ☐ Dates of incubation
- ☐ Media expiration dates/lot numbers
- ☐ Starting temperature for each interval of incubation
- ☐ Results
- ☐ Names or other identification of the observer/person who reads & documents results

Personal Hygiene and Garbing

37. ☐ ☐ Individuals entering a compounding area must be properly garbed and must maintain proper personal hygiene to minimize the risk of containment to the environment and/or CSPs. [USP-NF Chapter 797-*Personal Hygiene and Garbing*]

38. ☐ ☐ Individuals that may have a higher risk of contamination the CSP and the environment must report these conditions to the designated person(s). The designated person(S) is responsible for evaluating whether these individuals should be excluded from working in compounding areas before their conditions have resolved because of the risk of contaminating the CSPs and the environment. [USP-NF Chapter 797- *Personal Hygiene and Garbing*]

39. ☐ ☐ All personnel entering a compounding area where Category 1, Category 2, or Category 3 CSPs are prepared must take appropriate steps to minimize microbial contamination of the environment and of the CSPs, including hand hygiene, garbing and consideration of needed materials to be brought into the compounding area. [USP-NF Chapter 797- *Personal Hygiene and Garbing-Personnel Preparations*]

40. ☐ ☐ Food and drinks must not enter anterooms, buffer rooms, or segregated compounding areas. [USP-NF Chapter 797- *Personal Hygiene and Garbing-Personnel Preparations*]

41. ☐ ☐ Before entering a compounding area, individuals must remove any items that are not easily cleanable or are not necessary for compounding. At a minimum, individuals must: 1)Remove personal outer garments, 2)Remove all cosmetics because they shed flakes and particles, 3)Remove all hand, wrist, and other exposed jewelry, including piercings that could interfere with effectiveness of garbing or otherwise increase the risk of contamination of the CSP- cover all jewelry that cannot be removed, 4)Not wear earbuds or headphones 5)Not bring electronic devices that are not necessary for compounding or other required tasks into the compounding area, 6)Keep nails clean and neatly trimmed to minimize particle shedding and avoid glove punctures. Nail products must not be worn, 7)Wipe eyeglasses, if worn. [USP-NF Chapter 797- *Personal Hygiene and Garbing-Personnel Preparations*]

42. ☐ ☐ The designated person(s) may permit accommodations to personnel preparation as long as the quality of the CSP and environment will not be affected. Accommodations must be documented. [USP-NF Chapter 797- *Personal Hygiene and Garbing-Personnel Preparations*]

43. ☐ ☐ Any person entering a compounding area where Category 1, Category 2, or Category 3 CSPs are prepared must wash hands and forearms up to the elbows with soap and water before initiating compounding activities. Brushes must not be used for hand hygiene. Hand dryers must not be used. To minimize the risk of extrinsic contamination, disposable soap containers must not be refilled or topped off. [USP-NF Chapter 797- *Personal Hygiene and Garbing- Hand Hygiene*]

44. ☐ ☐ Proper hand washing procedures include; 1)Clean underneath fingernails under warm running water using a disposable nail cleaner, 2)Wash hands and forearms up to the elbows with soap and water for at least 30 seconds, 3)Dry hands and forearms up to the elbows completely with low-lint disposable towels or wipers. [USP-NF Chapter 797- *Personal Hygiene and Garbing-Hand Hygiene*]

45. ☐ ☐ The order of hand washing and garbing depends on the placement of the sink. The order of garbing must be determined by the facility and documented in the facility's SOPs. Hands must be sanitized with alcohol-based hand rub before donning sterile gloves. Sterile gloves must be donned in a classified room or SCA. [USP-NF Chapter 797- *Personal Hygiene and Garbing-Hand Hygiene*]

46. ☐ ☐ Proper hand sanitizing procedures include; 1) Apply an alcohol-based hand rub to dry skin 2)Apply product to one hand and rub hands together, covering all surfaces of hands and fingers, until hands are dry 3)Allow hands to dry thoroughly before donning sterile gloves. [USP-NF Chapter 797- *Personal Hygiene and Garbing-Hand Hygiene*]

47. ☐ ☐ Any person entering a compounding area where Category 1, Category 2, or Category 3 CSPs are prepared must be properly garbed. Garb must be donned and doffed in an order that reduces the risk of contamination. The required garb, manner of storage, and order of garbing must be determined by the facility and documented in the facility's SOPs. [USP-NF Chapter 797- *Personal Hygiene and Garbing-Garbing Requirements*]

48. ☐ ☐ If hand hygiene is completed outside of a classified area, alcohol based hand rub must be used prior to donning garb. [USP-NF Chapter 797- *Personal Hygiene and Garbing-Garbing Requirements*]

49. ☐ ☐ Skin must not be exposed inside the ISO Class 5 PEC. [USP-NF Chapter 797- *Personal Hygiene and Garbing-Garbing Requirements*]

50. ☐ ☐ The minimum garbing requirements for preparing Category 1, and Category 2 CSPs include the following; 1)Low-lint garment with sleeves that fit snugly around the wrists and an enclosed neck, 2)Low-lint covers for shoes, 3)Low-lint cover for head that covers the hair and ears, and if applicable, cover for facial hair, 4) Low-lint face mask, 5)Sterile powder-free gloves, and 6)If using a RABS, disposable gloves should be worn inside the gloves attached to the RABS sleeves. Sterile gloves must be worn over the gloves attached to the RABS sleeves.[USP-NF Chapter 797- *Personal Hygiene and Garbing-Garbing Requirements*]

51. ☐ ☐ Garb must be replaced immediately if it becomes visibly soiled or if its integrity is compromised. [USP-NF Chapter 797- *Personal Hygiene and Garbing-Garbing Requirements*]

52. ☐ ☐ Gowns and other garb must be stored in a manner that minimizes contamination. [USP-NF Chapter 797- *Personal Hygiene and Garbing-Garbing Requirements*]

53. ☐ ☐ If compounding Category 1 and Category 2 CSPs, gowns may be reused within the same shift by the same person if the gown is maintained in a classified in a classified area or adjacent to, or within, the SCA in a manner that prevents contamination. When personnel exit the compounding area, garb, except for gowns, cannot be reused and must be discarded or laundered before reuse. [USP-NF Chapter 797- *Personal Hygiene and Garbing-Garbing Requirements*]

54. ☐ ☐ The facility's SOPs must describe disinfection procedures for reusing goggles, respirators, and other reusable equipment. [USP-NF Chapter 797- *Personal Hygiene and Garbing-Garbing Requirements*]

55. ☐ ☐ If the facility compounds Category 3 CSPs, additional garbing requirements must be continuously met in the buffer room in which Category 3 CSPs are prepared. [USP-NF Chapter 797- *Personal Hygiene and Garbing-Garbing Requirements*]
N/A ☐

56. ☐ ☐ The following additional garbing requirements must be followed in the buffer room where Category 3 CSPs are prepared for all personnel regardless of whether Category 3 CSPs are compounded on a given day; 1)Do not allow any exposed skin in the buffer room, 2)All low-lint outer garb must be sterile, including the use of sterile sleeves over gauntlet sleeves when a RABS is used, 3) Disposable garbing items must not be reused, and laundered garb must not be reused without being laundered and re-sterilized with a validated cycle. [USP-NF Chapter 797- *Personal Hygiene and Garbing- Garbing Requirements*]

57. ☐ ☐ The facility's SOPs must describe disinfection procedures for reusing goggles, respirators, and other reusable equipment. [USP-NF Chapter 797- *Personal Hygiene and Garbing-Garbing Requirements*] ☐ N/A

58. ☐ ☐ If compounding an HD, appropriate personal protective equipment (PPE) must be worn and disposed of in accordance with USP-NF Chapter 800. [USP-NF Chapter 797- *Personal Hygiene and Garbing-Garbing Requirements*] ☐ N/A

59. ☐ ☐ Gloves must be sterile and powder free. Application of sterile 70% IPA to gloves must occur immediately before compounding and regularly throughout the compounding process.[USP-NF Chapter 797- *Personal Hygiene and Garbing-Garbing Requirements*]

60. ☐ ☐ All gloves must be inspected for holes, punctures, or tears and must be replaced immediately if such defects are detected. [USP-NF Chapter 797- *Personal Hygiene and Garbing-Garbing Requirements*]

Facilities and Engineering Controls

61. ☐ ☐ Sterile compounding facilities must be designated, outfitted, and maintained properly to minimize the risk of contamination of CSPs. The required air quality must be achieved and maintained through PECs and secondary engineering controls (SECs). The anteroom, buffer room, and SCA must be separated from areas not directly related to compounding. The anteroom and buffer room must be appropriately controlled to achieve and maintain the required air quality classifications. [USP-NF Chapter 797-*Facilities and Engineering Controls*]

62. ☐ ☐ Sterile compounding facilities must be designated to minimize the risk of airborne contamination of the area in which sterile compounding occurs. [USP-NF Chapter 797- *Facilities and Engineering Controls-Protection from Airborne Contaminants*]

63. ☐ ☐ Facilities used for compounding CSPs must be designated so that air quality improves with movement through separate operational areas to the PEC. Classified areas in which the air quality is controlled include anterooms, buffer rooms, and PECs. [USP-NF Chapter 797- *Facilities and Engineering Controls-Design requirements to maintain air quality*]

64. ☐ ☐ Anterooms providing access only to positive-pressure buffer rooms must meet at least ISO Class 8classification. [USP-NF Chapter 797- *Facilities and Engineering Controls-Design requirements to maintain air quality*] ☐ N/A

65. ☐ ☐ Anterooms providing access to negative-pressure buffer rooms must meet at least ISO Class 7 classification. [USP-NF Chapter 797-*Facilities and Engineering Controls-Design requirements to maintain air quality*] ☐ N/A

66. ☐ ☐ A buffer room must meet at least ISO Class 7 air quality. Activities in the buffer room must be controlled to minimize any effects on air quality in the area where CSPs are prepared. [USP-NF Chapter 797- *Facilities and Engineering Controls-Design requirements to maintain air quality*]

67. ☐ ☐ Category 1, Category 2, and Category 3 CSPs must be compounded in an ISO Class 5 or better PEC. If compounding only Category 1 CSPs, the PEC may be placed in an unclassified SCA. [USP-NF Chapter 797-*Facilities and Engineering Controls-Design requirements to maintain air quality*]

68. ☐ ☐ The temperature and humidity must be monitored in each room of the clean-room suite each day that compounding is performed, either manually or by a continuous recording device. The results of the temperature and humidity readings must be documented at least once daily or stored in the continuous recording device and must be retrievable. [USP-NF Chapter 797-*Facilities and Engineering Controls-Facility Design and Environmental Controls*]

69. ☐ ☐ The temperature and humidity readings must be reviewed as described in the facility's SOPs. [USP-NF Chapter 797- *Facilities and Engineering Controls-Facility Design and Environmental Controls*]

70. ☐ ☐ Temperature and humidity in the clean-room suite must be controlled through a heating, ventilation, and air conditioning (HVAC) system. Free-standing air conditioners, humidifiers, and dehumidifiers must not be used within the classified area or the SCA. [USP-NF Chapter 797- *Facilities and Engineering Controls- Facility Design and Environmental Controls*]

71. ☐ ☐ Temperature and humidity monitoring devices must be verified for accuracy at least every 12 months or as required by the manufacturer. [USP-NF Chapter 797- *Facilities and Engineering Controls- Facility Design and Environmental Controls*]

YES NO

72. ☐ ☐ The designated person(s) is responsible for ensuring that each area related to CSP preparation meets the classified air quality standard appropriate for the activities to be conducted in that area. The designated person(s) must also ensure that the ISO Class 5 areas are located, operated, maintained, monitored, and certified to have appropriate air quality. [USP-NF Chapter 797- *Facilities and Engineering Controls- Facility Design and Environmental Controls*]

73. ☐ ☐ The PEC must be located in the buffer room of the clean-room suite or the SCA in a manner that minimizes conditions that could increase the risk of microbial contamination. Access to the SEC must be restricted to authorized personnel and required materials. [USP-NF Chapter 797-*Facilities and Engineering Controls- Types of SEC's and design*]

74. ☐ ☐ The ISO-classified anteroom and buffer room must be separated from the surrounding unclassified areas of the facility by fixed walls and doors, and controls must be in place to minimize the flow of lower quality air into the more controlled areas. The classified rooms must be equipped with a pressure-differential monitoring system. Air supplied to the clean-room suite must be introduced through HEPA filters that are located in the ceiling of the buffer room and anteroom. [USP-NF Chapter 797-*Facilities and Engineering Controls- Types of SEC's and design*]

75. ☐ ☐ Air returns in the clean-room suite must be low on the wall unless a visual smoke study demonstrates an absence of stagnant airflow. This smoke study along with environmental monitoring must be repeated whenever a change is made to the placement of equipment within the room or any other alteration is performed within the clean-room suite that affects the quality of the air. [USP-NF Chapter 797-*Facilities and Engineering Controls- Types of SEC's and design*]

76. ☐ ☐ The anteroom must have a line of demarcation to separate the clean side from the dirty side. The anteroom is entered through the dirty side, and the clean side is the area closest to the buffer room. Alternatively, facilities may be designed with two separate anterooms- a dirty anteroom and a clean anteroom. The anteroom is entered through the dirty anteroom, and the clean anteroom is the area closest to the buffer room. [USP-NF Chapter 797-*Facilities and Engineering Controls-Types of SEC's and design*]

77. ☐ ☐ If a pass-through chamber is used, both doors must never be opened at the same time, and doors should be interlocking. [USP-NF Chapter 797-*Facilities and Engineering Controls-Types of SEC's and design*] ☐ N/A

78. ☐ ☐ Tacky mats must not be placed within ISO-classified areas. [USP-NF Chapter 797-*Facilities and Engineering Controls-Types of SEC's and design*]

79. ☐ ☐ If compounding both sterile and non-sterile preparations, the respective PECs must be placed in separate rooms unless those PECs are sufficiently effective that the room can continuously maintain ISO Class 7 classifications. If the PECs used for sterile and non-sterile compounding are placed in the same room, they must be placed at least 1 m apart, and particle-generating activity must not be performed when sterile compounding is in process. [USP-NF Chapter 797-*Facilities and Engineering Controls- Types of SEC's and design*]

80. ☐ ☐ A PEC may be located within an unclassified area without an anteroom or buffer room. This type of design is called an SCA. Only Category 1 CSPs may be compounded in an SCA. The SCA must be located away from unsealed windows, doors that connect to the outdoors, and traffic flow, all of which may adversely affect the air quality in the PEC. An SCA must not be located where environmental control challenges could negatively affect the air quality of the PEC within the SCA. The impact of activities that will be conducted around or adjacent to the SCA must be considered carefully when designing such an area. The area within 1 m of the PEC should be dedicated only for sterile compounding not storage, hand hygiene, donning and doffing garb, or other highly particle-generating activities such as patient care. [USP-NF Chapter 797-*Facilities and Engineering Controls- Types of SECs and design*]
N/A ☐

81. ☐ ☐ The PEC must be certified to meet ISO Class 5 or better conditions during dynamic operating conditions and must be designed to minimize the risk of contamination during compounding of CSPs. Unidirectional airflow must me maintained in the PEC. HEPA-filtered air must be supplied by the PEC at a velocity sufficient to sweep particles away from critical sites and maintain unidirectional airflow during operations. Proper design, control, and use minimizes turbulence and creation of eddies or stagnant air in the PEC.[USP-NF Chapter 797-*Facilities and Engineering Controls- The CSP compounding environment*]

82. ☐ ☐ Proper placement of the PEC is critical to ensuring an ISO Class 5 environment for preparing CSPs. Placement of the PEC must allow for cleaning around the PEC. [USP-NF Chapter 797-*Facilities and Engineering Controls-Types of PECs and placement*]

83. ☐ ☐ The LAFS must be located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns inside the PEC. If used to prepare only Category 1 CSPs, the ISO Class 5 PEC may be located in an unclassified SCA. If used to prepare Category 2 or Category 3 CSPs, the LAFS must be located within a clean-room suite with an ISO Class 7 or better buffer room with an ISO Class 8 or better anteroom. [USP-NF Chapter 797-*Facilities and Engineering Controls- Types of PECs and placement*]

84. ☐ ☐ A dynamic airflow smoke pattern test must be performed in the PEC initially to ensure that 1)the LAFS is properly placed into the facility and 2)compounder's understand how to utilize the unidirectional airflow to maintain first air in the DCA.[USP-NF Chapter 797-*Facilities and Engineering Controls-Types of PECs and placement*]

85. ☐ ☐ If used to prepare only Category 1 CSPs, the ISO Class 5 environment may be achieved by placing the RABS in an unclassified SCA. If used to prepare Category 2 or Category 3 CSPs, the RABS must be located within a clean-room suite within an ISO Class 7 or better buffer room within an ISO Class 8 or better anteroom. [USP-NF Chapter 797- *Facilities and Engineering Controls- Types of PECs and Placement*]

86. ☐ ☐ When a RABS is used, the recovery time after opening the transfer chamber to achieve ISO Class 5 air quality must be documented, and internal procedures must be developed to ensure that adequate recovery time is allowed after opening and closing the RABS, both before and during compounding operations. [USP-NF Chapter 797- *Facilities and Engineering Controls- Types of PECs and Placement*]
N/A ☐

YES NO

87. ☐ ☐ N/A ☐ A dynamic airflow smoke pattern test must be performed in the PEC under dynamic operating conditions initially to ensure that 1) the RABS is properly integrated into the facility and 2) compounders understand how to utilize the unidirectional airflow to maintain first air in the DCA. [USP-NF Chapter 797- *Facilities and Engineering Controls- Types of PECs and Placement*]

88. ☐ ☐ N/A ☐ A pharmaceutical isolator used to prepare only Category 1 CSPs can be placed in an unclassified SCA. If the pharmaceutical isolator is used to prepare Category 2 or Category 3 CSPs, the pharmaceutical isolator must be placed in an ISO Class 8 or better room- Note: An anteroom is not required when using a pharmaceutical isolator. [USP-NF Chapter 797- *Facilities and Engineering Controls-Types of PECs and Placement*]

89. ☐ ☐ A dynamic airflow smoke pattern test must be performed in the PEC initially to ensure that 1) the pharmaceutical isolator is properly placed in the facility and 2)compounders understand how to utilize the unidirectional airflow to maintain first air in the work zone. [USP-NF Chapter 797- *Facilities and Engineering Controls-Types of PECs and Placement*] ☐ N/A

90. ☐ ☐ N/A ☐ If a robotic enclosure is used as the PEC, or placed within the PEC, a dynamic airflow smoke pattern test must be performed initially to ensure 1) it is properly integrated into the facility, 2) there is no turbulence or refluxing at any critical site(s), 3) room air does not enter the PEC where sterile products and/or preparations may be exposed, and 4)all processes can be performed without introducing contamination to the DCA(s). [USP-NF Chapter 797- *Facilities and Engineering Controls- Types of PECs and Placement*]

91. ☐ ☐ A minimum of 30 total HEPA-filtered ACPH must be supplied to ISO Class 7 rooms: 1) The total HEPA-filtered air change rate must be adequate to maintain ISO Class 7 during dynamic operating conditions, 2) At least 15 ACPH of the total air change rate in a room must come from the HVAC through HEPA filters located in the ceiling, 3) The HEPA-filtered air from the PEC, when added to HVAC supplied HEPA-filtered air, must increase the total HEPA-filtered ACPH to at least 30 ACHP, 4) If the PEC is used to meet minimum total ACHP requirements, the PEC must not be turned off except for maintenance, 5) Rooms where activity levels are high may require more HEPA-filtered ACPH to maintain ISO Class 7 air quality under dynamic operating conditions, and 6) The ACPH from HVAC, ACPH contributed from the PEC, and the total ACPH must be documented on the certificate report. [USP-NF Chapter 797- *Facilities and Engineering Controls-Air exchange requirements*]

92. ☐ ☐ A minimum of 20 total HEPA-filtered ACPH must be supplied to ISO Class 8 rooms: 1) The total HEPA-filtered air change rate must be adequate to maintain ISO Class 8 under dynamic operating conditions, 2) At least 15 ACPH of the total air change rate in a room must come from the HVAC through HEPA filters located in the ceiling, 3) Rooms where activity levels are high may require more HEPA-filtered ACPH to maintain ISO Class 8 air quality under dynamic operating conditions, and 4) The total ACPH must be documented on the certification report. [USP-NF Chapter 797- *Facilities and Engineering Controls- Air exchange requirements*]

93. ☐ ☐ In a clean-room suite, a minimum differential positive pressure of 0.020-inch water column is required between adjacent ISO-classified areas. The pressure differential between anteroom and the unclassified are must not be less than 0.020-inch water column. No pressure differential is required between the SCA and the surrounding area. [USP-NF Chapter 797- *Facilities and Engineering Controls-Establishing and maintaining pressure differentials*]

94. ☐ ☐ When pressure differentials are required, a pressure differential monitoring device must be used to continuously monitor the pressure differentials. The quantitative results from the pressure monitoring device must be reviewed and documented at least daily on the days when compounding is occurring.[USP-NF Chapter 797- *Facilities and Engineering Controls-Establishing and maintaining pressure differentials*]

95. ☐ ☐ N/A ☐ If preparing Category 2 or Category 3 CSP from non-sterile component(s), presterilization procedures, such as weighing and mixing, must be completed in an ISO Class 8 or better environment. Presterilization procedures must be performed in single-use containment glove bags, containment ventilated enclosures (CVEs), BSCs, or CACIs to minimize the risk of airborne contamination. CVEs, BSCs, or CACIs used for presterilization procedures must be certified at least every 6 months. [USP-NF Chapter 797- *Facilities and Engineering Controls- Facilities preparing Category 2 or Category 3 CSPs from non-sterile starting components*]

96. ☐ ☐ Presterilization procedures must not adversely affect the required air quality of the SEC as demonstrated during certification under dynamic operating conditions. Personnel must follow the hygiene and garbing requirements during presterilization procedures. [USP-NF Chapter 797- *Facilities and Engineering Controls-Facilities preparing Category 2 or Category 3 CSPs from non-sterile starting components*] ☐ N/A

97. ☐ ☐ The surfaces of the ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets in the classified area must be smooth, impervious, free from cracks and crevices, and non-shedding so they can be cleaned and disinfected and to minimize spaces in which microorganisms and other contaminants can accumulate. [USP-NF Chapter 797- *Facilities and Engineering Controls-Creating Areas to Achieve Easily Cleanable Conditions -Cleanroom Suite*]

98. ☐ ☐ Junctures between the ceiling and the walls and between the walls and the floor must be sealed to eliminate cracks and crevices where dirt can accumulate. If ceilings consist of inlaid panels, the panels must be caulked around each panel to seal them to the support frame. [USP-NF Chapter 797- *Facilities and Engineering Controls-Creating Areas to Achieve Easily Cleanable Conditions-Cleanroom Suite*]

99. ☐ ☐ Walls must be constructed of, or may be covered with, durable material and the integrity of the surface must be maintained. Panels must be joined together and sealed to each other and the support structure. [USP-NF Chapter 797- *Facilities and Engineering Controls-Creating Areas to Achieve Easily Cleanable Conditions-Cleanroom Suite*]

100. ☐ ☐ Floors must include coving to the sidewalls, or the junctures between the floor and the wall must be caulked. [USP-NF Chapter 797- *Facilities and Engineering Controls-Creating Areas to Achieve Easily Cleanable Conditions-Cleanroom Suite*]

101. ☐ ☐ If overhangs or ledges are present, they must be easily cleanable. The exterior lens surface of ceiling light fixtures must be smooth, mounted flush, and sealed. Any other penetrations through the ceiling or walls must be sealed. [USP-NF Chapter 797- *Facilities and Engineering Controls-Creating Areas to Achieve Easily Cleanable Conditions-Cleanroom Suite*]

102. ☐ ☐ The SCA and all surfaces in the SCA must be clean, uncluttered, and dedicated to compounding. If overhangs or ledges are present, they must be easily cleanable. [USP-NF Chapter 797- *Facilities and Engineering Controls-Creating Areas to Achieve Easily Cleanable Conditions- SCA*] ☐ N/A

103. ☐ ☐ The facility where CSPs are prepared must be designated so that activities such as hand hygiene and garbing will not adversely affect the ability of the PEC to function as designed. Surfaces of the sink(s) must be cleaned and disinfected each day of use, and a sporicidal disinfectant must be applied at least monthly. [USP-NF Chapter 797- *Facilities and Engineering Controls- Water Sources*]

104. ☐ ☐ In facilities with a clean-room suite, the sink used for hand hygiene may be placed either inside or outside of the anteroom. If the sink is located outside of the anteroom, if must be located in a clean space to minimize the risk of bringing contaminants into the anteroom. [USP-NF Chapter 797- *Facilities and Engineering Controls- Water Sources*]
N/A ☐

105. ☐ ☐ The buffer room must not contain plumbed water sources. The anteroom must not contain floor drain(s). [USP-NF Chapter 797- *Facilities and Engineering Controls-Water Sources*]

106. ☐ ☐ In a facility with an SCA design, a hand-washing sink must be placed not closer than 1 m to the PEC and may be either inside the SCA or in the close proximity to the SCA. [USP-NF Chapter 797- *Facilities and Engineering Controls-Water Sources*] ☐ N/A

107. ☐ ☐ Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in a classified area or SCA. Their number, design, location, and manner of installation must not impact environmental air quality and must promote effective cleaning and disinfecting. [USP-NF Chapter 797- *Facilities and Engineering Controls-Placement and Movement of Materials*]

108. ☐ ☐ No shipping carton(s) or other corrugated or uncoated cardboard are allowed in a classified area or SCA. [USP-NF Chapter 797-*Placement and Movement of Materials*]

109. ☐ ☐ Carts used to transport components or equipment into classified areas must be constructed from non-porous materials with cleanable casters and wheels to promote mobility and ensure ease of cleaning and disinfection. In a clean-room suite, carts must not be moved from the dirty side to the clean side of the anteroom unless the entire cart, including casters, is cleaned and disinfected. [USP-NF Chapter 797-*Placement and Movement of Materials*]

110. ☐ ☐ Only equipment necessary for performing compounding activities is permitted in the PEC. Proper placement of equipment in a PEC must be initially verified by a dynamic airflow smoke pattern test to demonstrate minimal disruption in airflow. The dynamic airflow smoke pattern test must be repeated if equipment is placed in a different location. If removed, these items must be cleaned and wiped with sterile 70% IPA or a suitable disinfectant before they are returned to the classified area or the SCA. [USP-NF Chapter 797- *Placement and Movement of Materials*]

111. ☐ ☐ Materials necessary for performing compounding activities that have been exposed in patient care and treatment areas must not enter anterooms, buffer rooms, or segregated compounding areas unless thoroughly cleaned and disinfected. [USP-NF Chapter 797-*Placement and Movement of Materials*]

112. ☐ ☐ The designated person(s) is responsible for addressing other areas of risk in the facility's SOPs. The designated person(s) may permit accommodations as long as the quality of the CSP and environment will not be affected. Accommodations must be documented. [USP-NF Chapter 797- *Placement and Movement of Materials*]

Certification and Recertification

113. ☐ ☐ Before a compounding area is used to compound either Category 1, Category 2 or Category 3 CSPs, it must be independently certified using the requirements in USP-NF Chapter 797 and when applicable, manufacturers specifications. [USP-NF Chapter 797- *Certification and Recertification*]

114. ☐ ☐ Certification of the classified areas including the PEC must be performed initially, and recertification must be performed at least every 6 months and must include; 1)Airflow testing, 2) HEPA filter integrity testing, 3)Total particle count testing. [USP-NF Chapter 797- *Certification and Recertification*]

115. ☐ ☐ Classified areas additionally must be re-certified if there are changes to the area such as redesign, construction, replacement or relocation of any PEC, or alteration in the configuration of the room that could affect airflow or air quality. [USP-NF Chapter 797- *Certification and Recertification*]

116. ☐ ☐ All certification and recertification records must be reviewed by the designated person(s) to ensure that classified environments meet the minimum requirements in USP-NF Chapter 797. The number of personnel present in each PEC and SEC during total particle-count tests and dynamic airflow smoke-pattern tests must be documented. Records must be maintained in accordance with requirements in USP-NF Chapter 797.[USP-NF Chapter 797- *Certification and Recertification*]

117. ☐ ☐ A corrective action plan must be implemented and documented in response to any out-of-range results. Data collected in response to corrective actions must be reviewed to confirm that the actions taken have been effective. [USP-NF Chapter 797- *Certification and Recertification*]

118. ☐ ☐ The engineering control equipment must function as designed to ensure that the levels of total airborne particles remain within acceptable limits during compounding. Total airborne particle count testing must be conducted in all classified areas during dynamic operating conditions at least every 6 months to measure the performance of the engineering controls that are being used to provide the specified levels of air cleanliness. [USP-NF Chapter 797- *Total Airborne Particle Sampling*]

	YES	NO	
119.	☐	☐	Total airborne particle sampling sites must be selected in all classified areas. Measurements of total airborne particles must be taken in each PEC at locations where there is greatest risk to the exposed CSPs, containers and closures. All sampling sites and procedures must be described in the facility's SOPs. [USP-NF Chapter 797- *Total Airborne Particle Sampling*]
120.	☐	☐	If levels measured during the total air sampling program exceeds the criteria for the ISO classification of the area sampled, the cause must be investigated and corrective action taken and documented. Data collected in response to corrective actions must be reviewed to confirm that the actions taken have been effective. [USP-NF Chapter 797- *Total Airborne Particle Sampling*]

Microbiological Air and Surface Monitoring

121.	☐	☐	Sterile compounding facilities must develop and implement written procedures for microbiological air surface monitoring. All microbiological air and surface monitoring procedures, the test results, and the corrective actions must be documented, and the records must be maintained in accordance with requirements in USP-NF Chapter 797. Data collected in response to corrective actions must be reviewed to confirm that the actions taken have been effective. [USP-NF Chapter 797- *Microbiological Air and Surface Monitoring*]
122.	☐	☐	The microbiological air and surface monitoring program must include 1)viable impact volumetric airborne particulate sampling, and 2) surface sampling. [USP-NF Chapter 797- *Microbiological Air and Surface Monitoring-General Monitoring Requirements*]
123.	☐	☐	Regular review of the sampling data must be performed to detect trends and the results of the review must be documented. [USP-NF Chapter 797- *Microbiological Air and Surface Monitoring-General Monitoring Requirements*]
124.	☐	☐	Results from microbiological air and surface sampling must be reviewed in conjunction with personnel data to assess the state of control and to identify potential risks of contamination. Corrective action in response to any adverse findings is required to maintain the necessary environmental quality for preparation of CSPs. Data must also be reviewed following corrective actions to confirm that the actions taken have been effective in achieving the required microbiological air and surface quality levels. [USP-NF Chapter 797- *Microbiological Air and Surface Monitoring- General Monitoring Requirements*]
125.	☐	☐	Microbiological air and surface monitoring must be performed initially for sterile compounding facilities to establish a baseline level for environmental quality. After initial sampling, the environment in which sterile compounding activities are performed must be monitored according to the minimum frequencies to ensure that the environment remains suitable for sterile compounding. [USP-NF Chapter 797- *Microbiological Air and Surface Monitoring -General Monitoring Requirements*]
126.	☐	☐	Microbiological air and/or surface monitoring must be conducted in all classified areas during dynamic operating conditions to confirm that the required environmental quality is maintained. In addition to the specific sampling frequencies described in USP-NF Chapter 797, sampling must be performed in the following circumstances; 1) In conjunction with the certification of new facilities and equipment, 2) After any servicing of facilities or equipment, 3) In response to identified problems, 4)In response to identified trends, and 5) In response to changes that could impact the sterile compounding environment. [USP-NF Chapter 797- *Microbiological Air and Surface Monitoring -General Monitoring Requirements*]
127.	☐	☐	The microbiological air and surface monitoring program must be clearly described in the facility's SOPs, which must include a diagram of the sampling locations, procedures for collecting samples, frequency of sampling, size of samples, time of day of sampling in relation to activities in the compounding area, and action levels that will trigger corrective action. [USP-NF Chapter 797- *Microbiological Air and Surface Monitoring-General Monitoring Requirements*]
128.	☐	☐	To obtain air and surface samples that are representative of the typical compounding conditions at the facility, in all PECs and classified rooms, air sampling must be conducted during dynamic operating conditions and surface sampling should be performed at the end of a compounding activity or shift but before the area has been cleaned and disinfected. The monitoring program must be designated and conducted in a manner that minimizes the chance that the sampling itself will contribute to contamination of the CSP or the environment. [USP-NF Chapter 797- *Microbiological Air and Surface Monitoring-General Monitoring Requirements*]
129.	☐	☐	Personnel need to be trained and competent in air and surface sampling procedures to ensure accurate and reproducible sampling. All impaction air samplers must be serviced and calibrated as recommended by the manufacturer. [USP-NF Chapter 797- *Microbiological Air and Surface Monitoring-General Monitoring Requirements*]
130.	☐	☐	A monitoring program for viable airborne particles must be developed and implemented to assess microbiological air quality in all classified areas. [USP-NF Chapter 797- *Microbiological Air and Surface Monitoring -Monitoring Air Quality for Viable Airborne Particles*]
131.	☐	☐	Volumetric active air sampling of all classified areas using an impaction air sampler must be conducted in each classified area during dynamic operating conditions. For entities compounding Category 1 and Category 2 CSPs, this must be completed at least every 6 months. For entities compounding any Category 3 CSPs, this must be completed within 30 days prior to the commencement of any Category 3 compounding and at least monthly thereafter regardless of the frequency of compounding Category 3 CSPs. Air sampling sites must be selected in all classified areas. [USP-NF Chapter 797- *Microbiological Air and Surface Monitoring-Viable air sampling-timing and locations*]
132.	☐	☐	COAs from the manufacturer must verify that the sampling media devices meet the expected growth promotion, pH, and sterilization requirements. Samples must be incubated in an incubator at the temperatures specified in USP-NF Chapter 797- 6.2.2 Viable air sampling procedures. The incubator temperature must be monitored during incubation, either manually or by a continuous recording device, and the results must be reviewed and documented as described in the facility's SOPs. The incubator must be placed in a location outside of the sterile compounding area. [USP-NF Chapter 797- *Microbiological Air and Surface Monitoring -Viable air sampling-timing and locations*]

YES NO

133. ☐ ☐ If two sampling media devices are collected at a single location, all recovered growth on each must be documented and action levels applied to each sampling media device separately. If levels measured during the viable air monitoring program exceed the levels (ISO Class 5 >1, ISO Class 7 >10 and ISO Class 8 >100 for the ISO classification levels of the area sampled, the cause must be investigated and corrective action must be taken. Data collected in response to corrective actions must be reviewed to confirm that the action taken have been effective. The corrective action plan must be dependent of the cfu count and the microorganisms recovered. [USP-NF Chapter 797- *Microbiological Air and Surface Monitoring-Viable air sampling data evaluation and action levels*]

134. ☐ ☐ The corrective action plan must be documented and should include re-sampling of failed areas to confirm corrective action was successful. If levels measured during viable air sampling exceed the levels provided above, an attempt must be made to identify any microorganisms recovered to the genus level with the assistance of a microbiologist. [USP-NF Chapter 797- *Microbiological Air and Surface Monitoring-Viable air sampling data evaluation and action levels*]

135. ☐ ☐ All sampling sites and procedures must be described in the facility's SOP. [USP-NF Chapter 797- *Microbiological Air and Surface Monitoring-Monitoring surfaces for Viable Particles*]

136. ☐ ☐ Each classified area, including each room and the interior of each ISO Class 5 PEC and through chambers connecting to classified areas, must be sampled for microbial contamination using a risk-based approach. [USP-NF Chapter 797- *Microbiological Air and Surface Monitoring-Surface sampling-timing and locations*]

137. ☐ ☐ Surface sampling in the DCA must also be conducted in conjunction with media-fill testing to assess aseptic manipulation competency. [USP-NF Chapter 797- *Microbiological Air and Surface Monitoring-Surface sampling-timing and locations*]

138. ☐ ☐ Facilities compounding Category 1 and Category 2 CSPs, surface sampling of all classified areas, and pass-through chambers connecting to classified areas, must be conducted at least monthly. [USP-NF Chapter 797- *Microbiological Air and Surface Monitoring-Surface sampling-timing and locations*] ☐ N/A

139. ☐ ☐ Facilities compounding Category 3 CSPs, surface sampling of all classified areas, and pass-through chambers connecting to classified areas, must be completed prior to assigning a BUD longer than the limits established in USP-NF Chapter 797- Table 13, and at least weekly on a regularly scheduled basis regardless of the frequency of compounding Category 3 CSPs. Surface sampling must be conducted within the PEC used to prepare Category 3 CSPs, at the end of each batch before cleaning and disinfection occurs, unless a self-enclosed robotic device is used. [USP-NF Chapter 797- *Microbiological Air and Surface Monitoring-Surface sampling-timing and locations*]
N/A ☐

140. ☐ ☐ When a self-enclosed robotic device is used as a PEC to prepare Category 3 CSPs, surface sampling must be conducted at least once daily at the end of compounding operations, before cleaning and disinfection occurs. [USP-NF Chapter 797- *Microbiological Air and Surface Monitoring-Surface sampling-timing and locations*] ☐ N/A

141. ☐ ☐ Surface sampling media devices containing microbial growth media must be used for sampling flat surfaces. COAs from the manufacturer must verify that the sampling media devices meet the expected growth promotion, pH, and sterilization requirements. Surface sampling media devices must contain general microbial growth media supplemented with neutralizing additives to neutralize the effects of any residual disinfecting agents. Surface sampling media devices must have a raised convex surface. [USP-NF Chapter 797- *Microbiological Air and Surface Monitoring -Surface sampling procedures*]

142. ☐ ☐ Sterile swabs wetted with sterile water or a sterile neutralizing buffer may be used when sampling irregular surfaces and difficult-to-reach locations such as crevices, corners and spaces between surfaces. [USP-NF Chapter 797- *Microbiological Air and Surface Monitoring-Surface sampling procedures*]

143. ☐ ☐ After sampling, the sampled area must be thoroughly cleaned and disinfected. [USP-NF Chapter 797- *Microbiological Air and Surface Monitoring-Surface sampling procedures*]

144. ☐ ☐ Samples must be incubated in an incubator at the temperatures required in USP-NF Chapter 797- Box 6. The incubator temperature must be monitored during incubation, either manually or by a continuous recording device, and the results must be reviewed and documented. The incubator must be placed in a location outside of the sterile compounding area. [USP-NF Chapter 797-*Microbiological Air and Surface Monitoring-Surface sampling procedures*]

145. ☐ ☐ If two sampling media devices are collected at a single location, all recovered growth on each must be documented and action levels applied to each sampling media device separately If levels measured during surface sampling exceeds the levels (ISO Class 5 >3, ISO Class 7 >5 and ISO Class 8 >50) for the ISO classification levels of the area sampled, the cause must be investigated and corrective action must be taken. Data collected in response to corrective actions must be reviewed to confirm that the actions taken have been effective. The correction action plan must be dependent on the cfu count and the microorganisms recovered. [USP-NF Chapter 797-*Microbiological Air and Surface Monitoring-Surface sampling data evaluation and action levels*]

146. ☐ ☐ The corrective action plan must be documented. If levels measured during surface sampling exceed the levels provided above, an attempt must be made to identify any microorganism recovered to the genus level with the assistance of a microbiologist.[USP-NF Chapter 797-*Microbiological Air and Surface Monitoring-Surface sampling data evaluation and action levels*]

Cleaning, Disinfecting, and Applying Sporicidal Disinfectants and Sterile 70% IPA

147. ☐ ☐ Surfaces in classified areas used to prepare Category 1, Category 2 and Category 3 CSPs must be: 1)Cleaned ,2) Disinfected,and 3) Sporicidal disinfectants applied. [USP-NF Chapter 797-*Cleaning, Disinfecting, and Applying Sporicidal Disinfectants and Sterile 70% IPA*]

148. ☐ ☐ In a PEC, sterile 70% IPA must be applied after cleaning and disinfecting, or after the application of a one-step disinfectant cleaner or sporicidal disinfectant, to remove any residue. Sterile 70% IPA must also be applied immediately before initiating compounding. During the compounding process sterile 70% IPA must be applied to the horizontal work surface, including any removable work trays, of the PEC at least every 30 min if the compounding process takes 30 min or less. If the compounding takes more than 30 min, compounding must not be disrupted, and the work surface of the PEC must be disinfected immediately after compounding. [USP-NF Chapter 797- *Cleaning, Disinfecting, and Applying Sporicidal Disinfectants and Sterile 70% IPA*]

YES NO

149. ☐ ☐ Surfaces must be cleaned prior to being disinfected with an EPA-registered disinfectant or an EPA-registered one-step disinfectant cleaner is used to accomplish both cleaning and disinfection in one step. A sporicidal disinfectant must also be applied. [USP-NF Chapter 797- *Cleaning, Disinfecting, and Applying Sporicidal Disinfectants and Sterile 70% IPA*]

150. ☐ ☐ All cleaning and disinfecting activities must be performed by trained and appropriately garbed personnel using facility- approved agents and procedures, which must be described in written SOPs. Personnel must be trained if there are any changes in the cleaning and disinfecting procedures.[USP-NF Chapter 797- *Cleaning, Disinfecting, and Applying Sporicidal Disinfectants and Sterile 70% IPA*]

151. ☐ ☐ Cleaning must be performed in the direction of clean to dirty areas.[USP-NF Chapter 797- *Cleaning, Disinfecting, and Applying Sporicidal Disinfectants and Sterile 70% IPA*]

152. ☐ ☐ The same floor mop may be used in both the buffer and anteroom, but only in that order, Mops used in areas where HDs are compounded must be dedicated for use only in those areas.[USP-NF Chapter 797- *Cleaning, Disinfecting, and Applying Sporicidal Disinfectants and Sterile 70% IPA*]

153. ☐ ☐ The frequency, method(s), and location(s) of cleaning, disinfecting, and applying sporicidal disinfectants must be established in written SOPs, in accordance with the manufacturers instructions and must be followed by all cleaning personnel. The manufacturers directions or published data for the minimum contact time must be followed for each of the cleaning, disinfecting, and sporicidal disinfectants used. When sterile 70% IPA is used, it must be allowed to dry. All cleaning, disinfecting, and application of sporicidal disinfectants must be documented according to the facility's SOPs. [USP-NF Chapter 797- *Cleaning, Disinfecting, and Applying Sporicidal Disinfectants and Sterile 70% IPA*]

154. ☐ ☐ The minimum frequency for cleaning, disinfecting and applying sporicidal disinfectants for PEC(s) and equipment inside the PEC(s) is as follows:[USP-NF Chapter 797- *Cleaning, Disinfecting, and Applying Sporicidal Disinfectants and Sterile 70% IPA*]

- Cleaning and Disinfecting: Equipment and all interior surfaces of the PEC daily on days when compounding occurs and when surface contamination is known or suspected
- Applying Sporicidal Disinfectant: Monthly for facilities compounding Category 1 and/or Category 2 CSPs. Weekly for facilities compounding Category 3 CSPs.

155. ☐ ☐ The minimum frequency for cleaning, disinfecting and applying sporicidal disinfectants if a removable work tray is used in a PEC is as follows:[USP-NF Chapter 797- Cleaning, Disinfecting, and Applying Sporicidal Disinfectants and Sterile 70% IPA]

N/A ☐

- Cleaning and Disinfecting: Work surfaces of the tray daily on days when compounding occurs. All surfaces and the area underneath the work tray monthly
- Applying Sporicidal Disinfectant: Work surfaces of the tray monthly. All surfaces and the area underneath the work tray monthly

156. ☐ ☐ The minimum frequency for cleaning, disinfecting and applying sporicidal disinfectant to pass-through chambers, work surface(s) outside the PEC and floor(s) is as follows: [USP-NF Chapter 797- *Cleaning, Disinfecting, and Applying Sporicidal Disinfectants and Sterile 70% IPA*]

- Cleaning and Disinfecting: Daily on days when compounding occurs
- Applying Sporicidal Disinfectant: Monthly for facilities compounding Category 1 and/or Category 2 CSPs. Weekly for facilities compounding Category 3 CSPs.

157. ☐ ☐ The minimum frequency for cleaning, disinfecting and applying sporicidal disinfectant to walls, door(s), door frame(s), ceilings, storage shelving and bin(s), and equipment outside the PEC(s) is as follows: [USP-NF Chapter 797- *Cleaning, Disinfecting, and Applying Sporicidal Disinfectants and Sterile 70% IPA*]

- Cleaning, Disinfecting and Applying Sporicidal Disinfectant: Monthly

158. ☐ ☐ Cleaning and disinfecting agents must be selected and used with careful consideration of compatibilities, effectiveness, and user safety. After the disinfectant or sporicidal disinfecting is applied to the surface, the agent must be allowed to dwell for the minimum contact time specified by the manufacturer.[USP-NF Chapter 797- *Agents and Supplies for Cleaning, Disinfecting, and Applying Sporicidal Disinfectants*]

159. ☐ ☐ Cleaning, disinfecting and sporicidal agents used within the PEC must be sterile. When diluting concentrated cleaning and disinfecting agents for use in the PEC, sterile water must be used. [USP-NF Chapter 797- *Agents and Supplies for Cleaning, Disinfecting, and Applying Sporicidal Disinfectants*]

160. ☐ ☐ All cleaning and disinfecting supplies with the exception of tool handles and holders must be low-lint. Cleaning and disinfecting supplies use in the PEC must be sterile with the exception of tool handles and holders, which must be cleaned and disinfected prior to use in a PEC. [USP-NF Chapter 797- *Agents and Supplies for Cleaning, Disinfecting, and Applying Sporicidal Disinfectants-Supplies*]

161. ☐ ☐ If disposable cleaning supplies are used, they must be discarded after each cleaning activity. Reusable cleaning tools must be made of cleanable materials and must be cleaned and disinfected before and after each use.[USP-NF Chapter 797- *Agents and Supplies for Cleaning, Disinfecting, and Applying Sporicidal Disinfectants-Supplies*]

162. ☐ ☐ Reusable cleaning tools must be dedicated for use in the classified areas or SCA and must not be removed from these areas except for disposal. They must be discarded as determined based on the condition of the tools. Cleaning supplies used in the classified areas and SCAs must be disposed of in a manner that minimizes the potential for dispersing contaminants into the air.[USP-NF Chapter 797- *Agents and Supplies for Cleaning, Disinfecting, and Applying Sporicidal Disinfectants-Supplies*]

Introducing Items Into the SEC and PEC

163. ☐ ☐ Before any item is introduced into the clean side of anteroom(s), placed into pass-through chamber(s), or brought into the SCA, providing that packaging integrity will not be compromised, it must be wiped with a sporicidal disinfectant, EPA-registered disinfectant ,or sterile 70% IPA using low-lint wipers by personnel wearing gloves. If and EPA-registered disinfectant or sporicidal disinfectant is used, the agent must be allowed to dwell for the minimum contact time specified by the manufacturer. If sterile 70% IPA is used, it must be allowed to dry.[USP-NF Chapter 797-*Introducing items into the SEC*]

164. ☐ ☐ Just before any item is introduced into the PEC, it must be wiped with sterile 70% IPA using sterile low-lint wipers and allowed to dry before use. The wiping procedure must not render the product label unreadable.[USP-NF Chapter 797- *Introducing items into the PEC*]

YES NO

165. ☐ ☐ Critical sites must be wiped with sterile 70% IPA in the PEC to provide both chemical and mechanical actions to remove contaminants. The sterile 70% IPA must be allowed to dry before personnel enter or puncture stoppers, and septums or break the necks of ampules. [USP-NF Chapter 797- *Use of Sterile 70% IPA on Critical Sites within the PEC*]

Equipment Supplies and Components

166. ☐ ☐ Equipment must be placed in a manner that facilitates sterile compounding operations. The equipment must be capable of operating properly and within required performance parameters. Compounding personnel must follow estabished SOPs for the calibration, maintenance, cleaning, and use of the equipment based on the manufacturers recommendations. Personnel must maintain records from equipment calibration, verification, and maintenance in accordance with the requirements in USP-NF Chapter 797. [USP-NF Chapter 797-*Equipment*]

167. ☐ ☐ Equipment that must be brought into classified areas must be wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA using low-lint wipers. [USP-NF Chapter 797- *Equipment*]

168. ☐ ☐ Before using ACDs or other similar equipment, compounding personnel must conduct an accuracy assesment before the first use and again each day the equipment is used to compound CSPs. Compounding personnel must maintain a daily record of the accuracy measurements on the days the equipment is in use. Corrective actions must be implemented if accuracy measurements are outside the manufacturers specifications. [USP-NF Chapter 797-*Equipment*]
N/A ☐

169. ☐ ☐ Weighing, measuring, or otherwise manipulating components that could generate airborne chemical particles must be evaluated to determine if these activities must be performed in a PEC or other closed system processing device to reduce potential exposure to personnel or contamination of the facility or CSPs. The process evaluation must be carried out in accordance with the facility's SOPs and the assessment must be documented. [USP-NF Chapter 797-*Equipment*]

170. ☐ ☐ Supplies in direct contact with the CSP must be sterile and depyrogenated. [USP-NF Chapter 797- *Supplies*]

171. ☐ ☐ Compounding Personnel must follow the facility's SOPs, which must address the selection, receipt, evaluation, handling, storage and documentation of all CSP components, including all ingredients and container closures. [USP-NF Chapter 797-*Components*]

172. ☐ ☐ When APIs are used the following must apply: [USP-NF Chapter 797- *Component Selection*]
N/A ☐
- Must comply with criteria in the USP-NF monograph, if one exists
- Must have a COA that includes specifications and that test results for the component shown that the API meets expected quality
- Must be manufactured by an FDA-registered facility

173. ☐ ☐ For all components other than APIs the following must apply: [USP-NF Chapter 797-*Component Selection*]
- Must comply with the criteria in the USP-NF monograph, if one exists
- Must be accompanied by documentation that includes the specifications and test results and shows that the components meet the specifications.
- Should be manufactured by an FDA-registered facility. If a component cannot be obtained from an FDA-registered facility, the designated person(s) must select an acceptable and reliable source. The compounding facility must establish the identity, strength, purity and quality of the ingredients obtained from that supplier by reasonable means. Reasonable means may include but are not limited to visual inspection,evaluation of COA supplied by the manufacturer, and/or verification by analytically testing a sample to determine conformance with the COA or other specifications.

174. ☐ ☐ All APIs and other components used must be evaluated for suitability for use in sterile drug preparation. Components labeled with "not for pharmaceutical use","not for injectable use"," not for human use",or an equivalent statement must not be used to compound for these purposes. [USP-NF Chapter 797-*Component Selection*]

175. ☐ ☐ Each lot of commercially available sterile, depyrogenated containers and container closure systems must be accompanied by a COA or other documentation showing conformance with established specifications. If sterilization and depyrogenation of supplies and closure systems are performed on site, the efficacy of each process must be established and documented. [USP-NF Chapter 797-*Component Selection*]

176. ☐ ☐ Upon receipt of each lot of a component, the external packaging must be examined for evidence of deterioration and other aspects of unacceptable quality. Facility personnel must verify the labeling and condition of the component packaging is damaged and whether temperature-sensing indicators show that the component has been exposed to excessive temperature(s). Any component found to be of unacceptable quality must be promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal. Any other lots of that component from that vendor must be examined to determine whether other lots have the same defect. [USP-NF Chapter 797-*Component Receipt*]

177. ☐ ☐ The date of receipt by the compounding facility must be clearly marked on each API or added substance package that lacks a vendor expiration date. Packages of components that lack a vendor's expiration date must be assigned a conservative expiration date, not to exceed 1 year after the receipt by the compounding facility. [USP-NF Chapter 797- *Component Receipt*]

178. ☐ ☐ All components must be reinspected before use. All packages must be reinspected to detect container breaks, looseness of the cap or closure, and deviation from the expected appearance, aroma, and/or texture of the contents that might have occurred during storage. Sterile container closures must be visually reinspected to ensure that they are free from defects that could compromise sterility and that they are otherwise suitable for their intented use. Any component found to be unacceptable quality must be promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal. Any other lots of that component from that vendor must be examined to determine whether other lots have the same defect. [USP-NF Chapter 797-*Component Evaluation Before Use*]

179. ☐ ☐ Compounding personnel must ascertain before use that components for CSPs are of the correct identity, appropriate quality, within expiry date and have been stored under appropriate conditions. [USP-NF Chapter 797-*Component Evaluation Before Use*]

180. ☐ ☐ All components must be handled and stored in a manner that prevents contamination, mix-ups, and deterioration. [USP-NF Chapter 797- *Component Handling and Storage*]

181. ☐ ☐ Components must be stored in closed containers under temperature, humidity, and lighting conditions consistent with those indicated in official monographs or specified by the supplier and/or manufacturers. [USP-NF Chapter 797-*Component Handling and Storage*]

182. ☐ ☐ Personnel must monitor temperature in the area(s) where components are stored either manually at least once daily on days that the facility is open or by a continuous temperature recording device to determine whether the temperature remains within the appropriate range. The results of the temperature readings must be documented on a temperature log or stored in the continuous recording device and must be retrievable. All monitoring equipment must be calibrated or verified for accuracy as recommended by the manufacturer or every 12 months if not specified by the manufacturer. [USP-NF Chapter 797-*Component Handling and Storage*]

Sterilization and Depyrogenation

183. ☐ ☐ N/A ☐ When selecting the sterilization method for CSPs prepared from one or more non-sterile starting components or using non-sterile supplies or devices, personnel must take in consideration the nature of the component(s), their physical and chemical properties, and the intended container closure system. [USP-NF Chapter 797- *Sterilization and Depyrogenation*]

184. ☐ ☐ The sterilization method used must sterilize the CSP without degrading its physical and chemical stability or the package integrity. [USP-NF Chapter 797- *Sterilization and Depyrogenation*] ☐ N/A

185. ☐ ☐ N/A ☐ Injectable compounded preparations that contain non-sterile components or that come into contact with non-sterile devices during any phase of the compounding procedure must be sterilized within 6 hours after completing the preparation to minimize the generation of bacterial endotoxins in CSPs. [USP-NF Chapter 797-*Sterilization and Depyrogenation*]

186. ☐ ☐ N/A ☐ A description of the terminal sterilization and depyrogenation process, including the temperature, pressure (if applicable), duration, permissible load conditions for each cycle, and the use of biological indicators and endotoxins challenge vials (ECVs) must be included in the facility's SOPs. [USP-NF Chapter 797-*Sterilization and Depyrogenation*]

187. ☐ ☐ N/A ☐ SOPs must include training and competency of personnel on all sterilization methods and equipment used by the facility. The SOPs must include a schedule and method for establishing and verifying the effectiveness of the terminal sterilization and depyrogenation methods selected, as well as the methods for maintaining and cleaning the sterilizing and depyrogenation equipment. [USP-NF Chapter 797-*Sterilization and Depyrogenation*]

188. ☐ ☐ N/A ☐ Dry heat depyrogenation must be used to render glassware, metal, and other thermostable containers and components pyrogen free. The duration of the exposure period must include sufficient time for the items to reach the depyrogenation temperature. The items must remain at the depyrogenation temperature for the duration of the depyrogenation period. [USP-NF Chapter 797- *Depyrogenation*]

189. ☐ ☐ N/A ☐ The effectiveness of the dry heat depyrogenation cycle must be established initially and verified annually using ECVs to demonstrate that the cycle is capable of achieving a ≥3-log reduction in endotoxins. The effectiveness of the depyrogenation cycle must be re-established if there are changes to the depyrogenation cycle described in SOPs. This verification must be documented. [USP-NF Chapter 797- *Depyrogenation*]

190. ☐ ☐ Items that are not thermostable must be depyrogenated by multiple rinses with sterile, non-pyrogenic water and then throughly drained and dried immediately before use in compounding.[USP-NF Chapter 797- *Depyrogenation*] ☐ N/A

191. ☐ ☐ N/A ☐ Sterilizing filiters must be sterile, depyrogenated, have a nominal pore size of 0.22 µm or smaller, and be appropriate for pharmaceutical use. Sterilizing filiters with labeling that states 'for laboratory use only' or similar statement must not be used for compounding CSPs. Sterilizing filters must be certified by the manufacturer to retain at least 107 microorganisms of a strain of Brevundimonas diminuta per square centimeter of upstream filter surface area under conditions similar to those in which the CSPs will be filtered. [USP-NF Chapter 797-*Sterilization by Filtration*]

192. ☐ ☐ N/A ☐ The designated person(s) must ensure from available published information, from supplier documentation, or through direct challenge that the filters 1) are chemically and physically compatible with all ingredients in the CSP, 2) are chemically stable at the pressure and temperature condition that will be used; and 3) have enough capacity to filter the required volumes. Filter units used to sterilize CSPs must be subjected to the manufacturers recommended integrity testing, such as post-use bubble point test. If multiple filters are required for the compounding process, each of the filters must pass a filter-integrity test. [USP-NF Chapter 797-*Sterilization by Filtration*]

193. ☐ ☐ N/A ☐ When CSPs are known to contain excessive particulate matter, a prefiltration step must be performed using a filter of larger nominal pore size or a seperate filter of larger nominal pore size should be placed upstream of the sterilizing filter to remove gross particulate contaminats before the CSP is passed through the sterilizing-grade filter. [USP-NF Chapter 797-*Sterilization by Filtration*]

194. ☐ ☐ N/A ☐ CSPs that were prepared using a filter that failed integrity tests must be discarded or, after investigating the cause of the failure and selection of an appropriate filter, re-filtered for sterilization not more than one additional time. [USP-NF Chapter 797- *Sterilization by Filtration*]

195. ☐ ☐ N/A ☐ To achieve sterility when steam sterilization is used, all materials must be directly exposed to steam under adequate pressure for the length of time necessary, as determined by use of appropriate biological indicators, to render the items sterile. The duration of the exposure period must include sufficient time for the entire contents of the CSP and other items to reach the sterilization temperature. The CSP and other items must remain at the sterilizing temperature for the duration of the sterilization period. [USP-NF Chapter 797- *Sterilization by Steam Heat*]

196. ☐ ☐ CSPs must be placed in the autoclave to allow steam to reach the CSPs without entrapment of air.[USP-NF Chapter 797-*Sterilization by Steam Heat*] ☐ N/A

197. ☐ ☐ When preparing items that must be wrapped for steam sterilization, items need to be wrapped in low-lint protective fabric or paper or seam in envelopes that permit steam penetration and are designed to minimize the risk of post-sterilization microbial contamination.[USP-NF Chapter 797-*Sterilization by Steam Heat*] ☐ N/A

198. ☐ ☐ Immediately before filling containers that will be steam sterilized, CSP solutions must be passed though a filter with nominal pore size of not larger than 1.2 µm for removal of particulate matter. [USP-NF Chapter 797-*Sterilization by Steam Heat*] ☐ N/A

199. ☐ ☐ Sealed containers must be able to generate steam internally. Stoppered and crimped empty vials must contain a small amount of sterile water to generate steam.[USP-NF Chapter 797-*Sterilization by Steam Heat*] ☐ N/A

200. ☐ ☐ The effectiveness of steam sterilization must be verified and documented with each sterilization run or load by using appropriate biological indicators and other confirmation methods such as physicochemical indicators.[USP-NF Chapter 797-*Sterilization by Steam Heat*] ☐ N/A

201. ☐ ☐ The steam supplied must be generated using water per the manufacturer's recommendation. A calibrated data recorder or chart must be used to monitor each cycle and to examine for cycle irregularities, The date, run, and load numbers of the steam sterilizer used to sterilize a CSP must be documented in the CR.[USP-NF Chapter 797-*Sterilization by Steam Heat*] ☐ N/A

202. ☐ ☐ Sterilization by dry heat- The duration of the exposure period must include sufficient time for the entire contents of the CSPs and other items to reach the sterilizing temperature. The CSP and other items must remain at the sterilizing temperature for the duration of the sterilization period. Immediately before filling ampules and vials that will be sterilized by dry heat, CSP solutions must be passed through a filter with a nominal pore size of not larger than 1.2 µm for removal of particulate matter. [USP-NF Chapter 797-*Sterilization by Dry Heat*] ☐ N/A

203. ☐ ☐ Dry heat sterilization is usually performed in an oven designed for sterilization at 160° or higher. If lower temperatures are used, they must be shown to achieve effective sterilization.[USP-NF Chapter 797-*Sterilization by Dry Heat*]

204. ☐ ☐ Heated air must be evenly distributed throughout the chamber, which is typically accomplished by an air blower. The calibrated oven must be equipped with temperature controls and a timer. During sterilization, sufficient space must be left between materials to allow for circulation of the hot air. A calibrated data recorder or chart must be used to monitor each cycle and the data must be reviewed to identify cycle irregularities.[USP-NF Chapter 797-*Sterilization by Dry Heat*] ☐ N/A

205. ☐ ☐ N/A ☐ The effectiveness of the dry heat sterilization method must be verified and documented with each sterilization run or load using appropriate biological indicators and other confirmation methods. The date, run, and load numbers of the dry heat oven used to sterilize a CSP must be documented in the CR.[USP-NF Chapter 797-*Sterilization by Dry Heat*]

Mater Formulation and Compounding Records

206. ☐ ☐ An MFR must be created for all CSPs prepared from non-sterile ingredient(s) or CSPs prepared for more than one patient. Any changes or alterations to the MFR must be approved and documented according to the facility's SOPs. [USP-NF Chapter 797-*Creating Master Formulation Records*]

207. ☐ ☐ An MFR must include at least the following information:[USP-NF Chapter 797-*Creating Master Formulation Records*]

- ☐ Name, strength or activity, and dosage form of the CSP ☐ Type and size of container closure system(s) ☐ Quality control procedures
- ☐ Identities and amounts of all ingredients; if applicable, relevant characteristics of components
- ☐ Complete instructions for preparing the CSP, including equipment, supplies, compounding steps and any special precautions
- ☐ Physical description of the final CSP ☐ BUD and storage requirements ☐ Reference source supporting the stability of CSP
- ☐ Other information as needed to describe the compounding process and ensure repeatability

208. ☐ ☐ A CR must be created for all Category 1, Category 2, and Category 3 CSPs. A CR must also be created for immediate-use CSPs prepared for more than one patient. The CR must be created to document the compounding process. A prescription or medication order or label may serve as the CR. If an ACD, workflow management system, or other similar equipment is used, the required information in the CR may be stored electronically as long as it is retrievable and contains the required information. [USP-NF Chapter 797-Creating Compounding Records]

209. ☐ ☐ CRs must include at least the following information:[USP-NF Chapter 797-Creating Compounding Records]

- ☐ Name, strength or activity, and dosage form of the CSP ☐ Identity of compounder(s) and verifier of final CSP ☐ Name of each component
- ☐ Assigned internal identification number ☐ Date and time of preparation ☐ Final yield ☐ Weight or volume of each component
- ☐ Vendor, lot number, and expiration date for each component ☐ Results of QC procedures ☐ Strength or activity of each component
- ☐ Assigned BUD and storage requirements ☐ Total quantity compounded ☐ If applicable: MFR reference & Calculations

YES NO

Release Inspections and Testing

210. ☐ ☐ All release testing procedures must be included in the facility's documentation. Any out-of-specification results must be investigated, and a corrective action plan must be implemented and documented as part of the quality assurance and QC program. [USP-NF Chapter 797-*Release Inspections and Testing*]

211. ☐ ☐ At the completion of compounding, before release and dispensing, the CSP must be visually inspected to determine whether the physical appearance of the CSP is as expected. The CSP label must be visually inspected to confirm that the CSP and its labeling match the prescription or medication order. The inspection must include a visual inspection of the container closure integrity. [USP-NF Chapter 797-*Visual Inspection*]

212. ☐ ☐ Any CSPs found to be of unacceptable quality must be promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal. [USP-NF Chapter 797-*Visual Inspection*]

213. ☐ ☐ When a CSP will not be released or dispensed on the day of preparation, a visual inspection must be conducted immediatley before it is released or dispensed to make sure that the CSP does not exhibit any defects such as precipitation, cloudiness, or leakage, which could develop during storage. Any CSP found to be of unacceptable quality must be promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal. Defects that indicate sterility or stability problems must be investigated to determine the cause according to the facility's SOPs. [USP-NF Chapter 797-*Visual Inspection*]

Sterility Testing

214. ☐ ☐ Sterility testing is not required for Category 1 CSPs. For Category 2 CSPs assigned a BUD that requires sterility testing and all Category 3 CSPs, the testing must be performed according to USP-NF Chapter 71 or a validated alternative method that is non-inferior to USP-NF Chapter 71. [USP-NF Chapter 797-*Sterility Testing*]
N/A ☐

215. ☐ ☐ If the number of CSPs to be compounded in a single batch is less than the number of CSPs needed for testing as specified in USP-NF Chapter 71, additional units must be compounded to perform sterility testing as follows: [USP-NF Chapter 797- Sterility Testing]
N/A ☐

- If 1-39 CSPs are compounded in a single batch, the sterility testing must be performed on a number of units equal to 10% of the number of CSPs prepared, rounded to the next whole number.
- If more than 40 CSPs are prepared in a single batch, the sample sizes specified in USP-NF Chapter 71 must be used.

216. ☐ ☐ If sterility testing is performed according to USP-NF Chapter 71, the Method Suitability Test from that chapter must be performed to ensure that contamination can be recovered. If performing sterility testing according to USP-NF Chapter 71, the Membrane Filtration method from that chapter is the method of choice when CSP formulation permits. The preferred alternative method is used for sterility testing, the method must be validated and demonstrated to be suitable for that CSP formulation. [USP-NF Chapter 797-*Sterility Testing*]
N/A ☐

217. ☐ ☐ Sterility tests resulting in failures must prompt an investigation into the possible causes and must include identification of the microorganism, as well as an evaluation of the sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. The source(s) of the contamination, if identified, must be corrected, and the facility must determine whether the conditions causing the sterility failure affect other CSPs. The investigation and resulting corrective actions must be documented. [USP-NF Chapter 797-*Sterility Testing*]
N/A ☐

218. ☐ ☐ Category 1 injectable CSPs do not require testing for bacterial endotoxins. Category 2 injectable CSPs compounded from one or more non-sterile component(s) and assigned a BUD that requires sterility testing and Category 3 injectable CSPs compounded from one or more non-sterile component(s) must be tested to ensure that they do not contain excessive bacterial endotoxins. [USP-NF Chapter 797- *Bacterial Endotoxins Testing*]
N/A ☐

219. ☐ ☐ In the absence of a bacterial endotoxin limit in an official USP-NF monograph or other CSP formula source, the CSP must not exceed the endotoxin limit calculated for the appropriate route of administration in humans. CSPs for non-human species must not exceed the endotoxins limit calculated- based on the largest recommended dose and weight of the target animal species unless a different limit is scientifically supported. CSPs administered epidurally should have the same endotoxin limit as that of intrathecally administered CSPs. [USP-NF Chapter 797- *Bacterial Endotoxins Testing*]
N/A ☐

Labeling

220. ☐ ☐ The label on each immediate container of the CSP must, at a minimum, display prominently and legibly the following information:[USP-NF Chapter 797-*Labeling*]

- ☐ Assigned internal identification number
- ☐ Storage conditions if other than controlled room temperature
- ☐ Active ingredient(s),their amount(s), activities(s)or concentration(s)
- ☐ Total amount/volume if it is not obvious from the container
- ☐ Statement whether CSP is single/multi dose
- ☐ Dosage Form
- ☐ BUD
- ☐ As applicable: Route of administration, special handling instructions, warning statements, compounding facility name & contact information if the CSP is to be sent outside of the facility or healthcare system in which it was compounded.

221. ☐ ☐ Prescription labels for compounded sterile medications, when dispensed to the patient or patient's agent shall include; [R156-17b-614a(2)(a)(ii-iv)(A-C)]

- ☐ Generic Name
- ☐ Quantity or concentration of each active ingredient
- ☐ Labeling for sterile preparations for parenteral use shall include: name of the diluent, assigned compounding record or lot number; and the phrase "compounded preparation"

222. ☐ ☐ N/A ☐ The labeling requirements described in Subsections R156-17b-(2)(a)(i) and (2)(a)(iv) shall not apply to a label on the container of a drug that a health care provider administers to a patient at: a pharmaceutical administration facility; or a hospital licensed under Title 26, Chapter 21, Health Care Facility Licensing and Inspection Act. [UAC R156-17b-614a(2)(b)(i-ii)]

223. ☐ ☐ Labeling procedures must be followed as described in the facility's SOP's. The label of the CSP must be verified to ensure that it conforms with the 1)Prescription/medication order, and 2) MFR/CR if required.[USP-NF Chapter 797-*Labeling*]

Establishing Beyond-Use-Dates

224. ☐ ☐ Each CSP label must state the date, or the hour and date, beyond which the preparation must not be used and must be discarded. The BUD is determined from the date and time that preparation of the CSP is initiated. [USP-NF Chapter 797-*Terminology*]

225. ☐ ☐ When establishing a BUD for a CSP, compounder's must consider parameters that may affect quality, including but not limited to; 1) Chemical and physical stability properties of the drug and/or its formulation, and 2) Materials of composition of the container closure system and compatibility of the container closure system with the final preparation. [USP-NF Chapter 797-*Parameters to Consider in Establishing a BUD*]

226. ☐ ☐ The maximum batch size for all CSPs requiring sterility testing must be limited to 250 final yield units. [USP-NF Chapter 797-*Sterility Testing*]

227. ☐ ☐ N/A ☐ If the CSP will be stored in a frozen state, the container closure system must be able to withstand the physical stress during storage in a freezer. The CSP must be thawed in appropriate conditions to avoid compromising the physical and chemical stability of the preparation and its components. Once the CSP is thawed, the CSP must not be refrozen. [USP-NF Chapter 797-*Storage Conditions*]

228. ☐ ☐ The storage time of a CSP must not exceed the original BUD placed on the CSP for its labeled storage conditions, and BUDs must not be additive. Once a CSP has been stored under a condition that would require a shorter BUD, the CSP must be used within the time frame for that storage condition.[USP-NF Chapter 797-*Storage Conditions*]

229. ☐ ☐ BUDs for CSPs must be established in accordance with USP-NF Chapter 797.[USP-NF Chapter 797-*Establishing a BUD for a CSP]*

- Category 1 CSPs: Controlled Room Temperature: <12 h Refrigerator :<24 h
- Category 2 CSPs:

Aseptically processed CSPs with no sterility testing & prepared from one or more non-sterile starting components:
Controlled Room Temperature: 1 day Refrigerator: 4 days Freezer: 45 days

Aseptically processed CSPs with no sterility testing & prepared from only sterile starting components:
Controlled Room Temperature: 4 days Refrigerator: 10 days Freezer: 45 days

Aseptically processed CSPs with sterility testing performed and passed:
Controlled Room Temperature: 30 days Refrigerator: 45 days Freezer: 60 days

Terminally Sterilized CSPs with no sterility testing:
Controlled Room Temperature:14 days Refrigerator: 28 days Freezer: 45 days

Terminally Sterilized CSPs with sterility testing performed and passed:
Controlled Room Temperature: 45 days Refrigerator: 60 days Freezer: 90 days

230. ☐ ☐ Category 3 CSPs: A shorter BUD must be assigned when the physical and chemical stability of the CSP is less than the BUD limit stated below.[USP-NF Chapter 797-*Establishing a BUD for a CSP*]

Aseptically processed, sterility tested and passing all applicable tests for Category 3 CSPs:
Controlled Room Temperature: 60 days Refrigerator: 90 days Freezer: 120 days

Terminally sterilized, sterility tested and passing all applicable test for Category 3 CSPs:
Controlled Room Temperature: 90 days Refrigerator: 120 days Freezer: 180 days

231. ☐ ☐ The CSP formulation must remain chemically and physically stable, and its packaging must maintain its integrity for the duration of the BUD. A shorter BUD must be assigned when the stability of the CSP or its components is less than the hours or days stated above. [USP-NF Chapter 797- *Establishing a BUD for a CSP*]

232. ☐ ☐ The BUD must not exceed the shortest remaining expiration date of any of the commercially available starting components. For CSPs prepared from one or more compounded components, the BUD should generally not exceed the shortest BUD of any of the individual compounded components. However, there may be acceptable instances when the BUD of the final CSP exceeds the BUD of the assigned to compounded components. If the assigned BUD of the final CSP exceeds the BUD of the compounded components, the physical, chemical, and microbiological quality of the final CSP must not be negatively impacted.[USP-NF Chapter 797- *Establishing a BUD for a CSP*]

233. ☐ ☐ Increasing the storage time of a CSP introduces additional risk for chemical degradation, physical incompatibilities, the compromising of the container closure system, and microbial proliferation. To address these risks and maintain a higher state of environmental control, additional requirements must be met when assigning BUDs for Category 3 CSPs. Category 3 CSPs must not be assigned a BUD longer than the limits stated above. [USP-NF Chapter 797-*Assigning Category 3 BUDs*]

234. ☐ ☐ Category 3 garbing requirements apply to all personnel entering the buffer room where Category CSPs are compounded and apply at all times regardless of whether Category 3 CSPs are being compounded on a given day. [USP-NF Chapter 797-*Facility and Personnel Requirements for Category 3 CSPs*] ☐ N/A

YES NO

235. ☐ ☐ Increased environmental monitoring requirements apply to all classified areas where Category 3 CSPs are compounded and apply at all times whether Category 3 CSPs are being compounded on a given day.[USP-NF Chapter 797-*Facility and Personnel Requirements for Category 3 CSPs*] ☐ N/A

236. ☐ ☐ The frequency of application of sporicidal disinfectants applies to all classified areas where Category 3 CSPs are compounded and applies at all times regardless of whether Category 3 CSPs are being compounded on a given day.[USP-NF Chapter 797-*Facility and Personnel Requirements for Category 3 CSPs*] ☐ N/A

237. ☐ ☐ The BUD assigned to a Category 3 CSP must be supported by stability data obtained using a stability-indicating analytical method that is able to distinguish the active ingredient from its degradants and impurities and quantify the amount of the active ingredient. [USP-NF Chapter 797-*Stability Requirements for Category 3 CSPs*] ☐ N/A

238. ☐ ☐ N/A ☐ The Category 3 CSP must be prepared according to the exact formulation from which the stability data are derived. The Category 3 CSP must be packaged and stored in a container closure of the same materials of composition as that used in the study. The analytical method must be validated. The compounding facility must have documentation of the stability study, including a description of the methodology, validation of the method, the stability- indicating analytical method, and all of the results of the study.[USP-NF Chapter 797-*Stability Requirements for Category 3 CSPs*]

239. ☐ ☐ If the Category 3 CSP is an injection or if it is an ophthalmic solution, particulate-matter testing is conducted once per formulation with acceptable results.[USP-NF Chapter 797-*Stability Requirements for Category 3 CSPs*] ☐ N/A

240. ☐ ☐ Once for each formulation and for each container closure system in which it will be packaged, the container closure system used is evaluated for and conforms to container closure integrity to the end of the BUD.[USP-NF Chapter 797-*Stability Requirements for Category 3 CSPs*]

241. ☐ ☐ N/A ☐ Each time the Category 3 CSP is prepared, it is sterility tested and meets the requirements {71} or a validated alternative method that is non-inferior to {71} testing. Each time the Category 3 CSP is prepared, it is tested for endotoxins for acceptable results, if endotoxin testing is required. USP-NF Chapter 797- Table 14 establishes the longest permitted BUDs for Category 3 CSPs. If all of the conditions for Category 3 CSPs in the chapter are not met, the applicable BUD provided must not be exceeded. [USP-NF Chapter 797-*Release Testing for Category 3 CSPs*]

242. ☐ ☐ The use of preservatives must be appropriate for the CSP formulation and the route of administration. The use of preservatives, however, must not be considered a substitute for aseptic technique. [USP-NF Chapter 797-*Multiple-Dose CSPs*]

243. ☐ ☐ A multi-dose CSP must be prepared as a Category 2 or Category 3 CSP. [USP-NF Chapter 797-*Multiple-Dose CSPs*]

244. ☐ ☐ An aqueous multi-dose CSP must additionally pass antimicrobial effectiveness testing. The compounder may rely on antimicrobial effectiveness testing 1)conducted (or contracted for) once for each formulation in the particular container closure system in which it will be packaged, 2) results from and FDA-registered facility or published in peer-reviewed literature sources, provided that the CSP formulation (including and preservatives) and container closure system are exactly the same as those tested, unless a bracketing study is performed. Antimicrobial effectiveness testing may be performed on a low concentration and a high concentration of the active ingredient in the formulation to establish preservative effectiveness across various strengths of the same formulation. The concentration of all other ingredients (including preservatives) must be the same throughout the bracketing study.[USP-NF Chapter 797-*Multiple-Dose CSPs*]

245. ☐ ☐ After a multi-dose CSP container is initially entered or punctured, the multi-dose container must not be used for longer than the assigned BUD or 28 days if supported by antimicrobial effectiveness testing results on the CSP, whichever is shorter.[USP-NF Chapter 797-*Multiple-Dose CSPs*]

246. ☐ ☐ The container closure system used to package the multi-dose CSP must be evaluated for and conform to container closure integrity. The container closure integrity test needs to be conducted only once on each formulation and on fill volume in the part container closure system in which the multi-dose CSP will be packaged. [USP-NF Chapter 797-*Multiple-Dose CSPs*]

247. ☐ ☐ The beyond-use-date of a multi-dose, aqueous non-preserved CSP intended for topical, including topical ophthalmic, administration may be assigned in accordance with USP-Chapter 797-14.5 Multiple-Dose CSPs. However, unpreserved aqueous, topical, including topical ophthalmic formulations are at high risk for microbial proliferation if contaminated during preparation or use. To minimize the risk of patient harm, the requirement for passing antimicrobial effectiveness testing is not required only if the preparation is 1)Prepared as a Category 2 or Category 3 CSP, 2)For use by a single patient, and 3) Labeled to indicate that once opened, it must be discarded after 24 hours when stored at controlled room temperature and/or that once opened, it must be discarded after 72 hours when stored under refrigeration. [USP-NF Chapter 797-*Multiple-Dose CSPs*]

Use of Conventionally Manufactured Products and Components

248. ☐ ☐ If a single-dose vial is entered or punctured only in an ISO Class 5 or cleaner air, it may be used up to 12 hours after initial entry or puncture as long as the labeled store requirements during that 12-hour period are maintained. Opened single-dose ampules must not be stored for any time period. [USP-NF Chapter 797-*Use of Conventionally Manufactured Single-Dose Containers*]

249. ☐ ☐ Once initially entering or puncturing the multi-dose container,must not be used for more than 28 days unless otherwise specified by the manufacturer on the labeling. [USP-NF Chapter 797-*Use of Conventionally Manufactured Multi-Dose Containers*]

250. ☐ ☐ The pharmacy bulk package must be used according to the manufacturer's labeling. The pharmacy bulk package must be entered or punctured only in an ISO Class 5 PEC.[USP-NF Chapter 797-*Use of Conventionally Manufactured Pharmacy Bulk Packages*]

Use of CSPs as Components

251. ☐ ☐ When a CSP is used as a component, care must be taken to minimize the risk of contamination of both the starting component CSP and the final CSP(s). Component CSP: The component CSP must be assigned a BUD consistent with *USP-NF Chapter 797-14 Establishing Beyond-Use-Dates* and must be stored under conditions for its assigned BUD when not in use. Final CSP: The final CSP must be assigned a BUD consistent with *USP-NF Chapter 797- 14 Establishing Beyond-Use-Dates.*[USP-NF Chapter 797-*Use of CSPs as Components*]

252. ☐ ☐ Multi-dose CSPs must be stored under the conditions upon which its BUD is based. After a multi-dose CSP is initially entered or punctured, the multi-dose CSP must not be used for longer than the assigned BUD or 28 days, which ever is shorter. [USP-NF Chapter 797-*Use of Compounded Multiple-Dose CSPs*]

253. ☐ ☐ When a compounded single-dose CSP or CSP stock solution is used as a component to compound additional CSPs, the original compounded single-dose CSP or CSP stock solution must be entered or punctured is ISO Class 5 or cleaner air and must be stored under the conditions upon which its BUD is based. [USP-NF Chapter 797-*Use of Compounded Single-Dose CSPs and CSP Stock Solutions*]

SOPs

254. ☐ ☐ Facilities that prepare CSPs must develop SOPs for the compounding process and other support activities. SOPs must include the types of CSPs that are prepared. A designated person(s) must ensure that SOPs are appropriate and are implemented, which includes that personnel demonstrate competency in performing every procedure that relates to their job function. A designated person(s) must follow up to ensure that corrective actions are taken if problems, deviations, failures, or errors are identified. The corrective action must be documented. [USP-NF Chapter 797-*SOPs*]

255. ☐ ☐ All personnel who perform or oversee compounding or support activities must be trained in the SOPs. All compounding personnel must be trained to 1)Recognize potential problems, deviations, failures, or errors associated with preparing a CSP that could potentially result in contamination or other adverse impact on CSP quality, and 2) Report any problems, deviations, failures, or errors to the designated person(s).[USP-NF Chapter 797-*SOPs*]

256. ☐ ☐ SOPs must be reviewed initially and at least every 12 months by the designated person(s) to ensure that they reflect current practices, and the review must be documented. Any changes or alterations to an SOP must be made only by a designated person(s) and must be documented. Revisions to SOPs must be communicated to all personnel involved in these processes and procedures, and personnel should document acknowledgment of the communication.[USP-NF Chapter 797-*SOPs*]

Quality Assurance and Quality Control

257. ☐ ☐ A facility's QA and QC programs must be formally established and documented in the facility's SOPs that ensure that all the aspects of the preparation of CSPs are conducted in accordance with the requirements in USP-NF Chapter 797 and the laws and regulations of the applicable regulatory jurisdiction. [USP-NF Chapter 797-*Quality Assurance and Quality Control*]

258. ☐ ☐ Designated person(s) must ensure that the facility has formal, written QA and QC programs that establish a system of: 1) Adherence to procedures, 2) Prevention and detection of errors and other quality problems, 3) Evaluation of complaints and adverse events, 4) Appropriate investigations and corrective actions.[USP-NF Chapter 797-*Quality Assurance and Quality Control*]

259. ☐ ☐ The facility's SOPs must describe the roles, duties, and training of the personnel responsible for each aspect of the QA program.[USP-NF Chapter 797-*Quality Assurance and Quality Control*]

260. ☐ ☐ Designated person(s) responsible for the QA program must have the training, experience, responsibility, and authority to perform these duties. The overall QA and QC program must be reviewed at least once every 12 months by the designated person(s). The results of the review must be documented, and appropriate action must be taken if needed.[USP-NF Chapter 797-*Quality Assurance and Quality Control*]

261. ☐ ☐ If a CSP is dispensed or administered before the results of release testing are known, the facility must have procedures in place to: 1) Immediately notify the prescriber of a failure of specifications with the potential to cause patient harm, 2) Recall any unused dispensed CSPs and quarantine any stock remaining in the pharmacy, and 3) Investigate if other lots are affected and recall if necessary. [USP-NF Chapter 797-*Notification About and Recall of Out-of-Specification Dispensed CSPs*]

262. ☐ ☐ An SOP for recall of out-of-specification dispensed CSPs must contain: 1) Procedures to determine the severity of the problem and the urgency for implementation and completion of the recall, 2) Procedures to determine the distribution of any affected CSP, including the date and quantity of distribution, 3) Procedures to identify patients who have received the CSP, 4)Procedures for disposal and documentation of the recalled CSP, and 5) Procedures to investigate and document the reason for failure.[USP-NF Chapter 797-*Notification About and Recall of Out-of-Specification Dispensed CSPs*]

263. ☐ ☐ The sterile compounding facility must document the implementation of the recall procedures. The recall must be reported to appropriate regulatory bodies as required by laws and regulations of the applicable regulatory jurisdiction. [USP-NF Chapter 797-*Notification About and Recall of Out-of-Specification Dispensed CSPs*]

YES NO

264. ☐ ☐ Compounding facilities must develop and implement SOPs for handling complaints. [USP-NF Chapter 797-*Complaint Handling*]

265. ☐ ☐ A designated person(s) must review all complaints to determine whether the complaint indicates a potential quality problem with the CSP. If it does, a thorough investigation into the cause of the problem must be initiated and completed. The investigation must consider whether the quality problem extends to other CSPs. Corrective action, if necessary, must be implemented for all potentially affected CSPs. [USP-NF Chapter 797-*Complaint Handling*]

266. ☐ ☐ A readily retrievable written or electronic record of each complaint must be kept by the facility, regardless of the source of the complaint. The record must contain the name of the complainant or other unique identifier, the date the complaint was received, the nature of the complaint, and the response to the complaint. In addition, to the extent that the information is known, the following should be recorded: the name and strength of CSP and the assigned internal identification number. The record must also include the findings of any investigation and any follow-up.[USP-NF Chapter 797-*Complaint Handling*]

267. ☐ ☐ Records of complaints must be easily retrievable for review and evaluation for possible trends and must be retained in accordance with the record keeping requirements in USP-NF Chapter 797- 20 Documentation. A CSP that is returned in connection with a complaint must be quarantined until it is destroyed after completion of the investigation and in accordance with laws and regulations of the applicable regulatory jurisdiction. [USP-NF Chapter 797-*Complaint Handling*]

268. ☐ ☐ Adverse events potentially associated with the quality of CSPs must be reported in accordance with the facility's SOPs and all laws and regulations of the applicable regulatory jurisdiction. If the investigation into an adverse event reveals a quality problem with a CSP that is likely to affect other patients, those patients and prescribers affected must be informed. [USP-NF Chapter 797-*Complaint Handling*]

CSP Handling, Storage, Packaging, Shipping and Transport

269. ☐ ☐ Adverse events potentially associated with the quality of CSPs must be reported in accordance with the facility's SOPs. Personnel who will be handling, storing, packaging, and transporting CSPs within the facility must be trained in accordance with the relevant SOPs, and the training must be documented. [USP-NF Chapter 797-*CSP Handling, Storing, Packaging, Shipping and Transport*]

270. ☐ ☐ The compounding facility must detect and minimize temperature excursions that are outside the temperature limits within the controlled temperature areas. When it is known that a CSP has been exposed to temperatures either below or above the store temperature limits for the CSP, a designated person(s) must determine whether the CSP is expected to retain its integrity or quality. If this cannot be determined, it must be discarded. [USP-NF Chapter 797- *Handling and Storing CSPs*]

271. ☐ ☐ The facility must select appropriate shipping containers and packaging materials based on the product specifications, information from vendors, and the mode of transport. In some cases, the CSP must be packaged in a special container to protect it from temperature fluctuations. [USP-NF Chapter 797- *Packaging of CSPs*] ☐ N/A

272. ☐ ☐ Compounding personnel must select modes of transport that are expected to deliver properly packed CSPs in an undamaged, sterile, and stable condition. When shipping or transporting CSPs that require special handling, personnel must include specific handling instructions on the exterior of the container. [USP-NF Chapter 797- Shipping and Transporting CSPs] ☐ N/A

Documentation

273. ☐ ☐ In facilities where CSPs are prepared must have and maintain written or electronic documentation to demonstrate compliance with the requirements in USP-NF Chapter 797. This documentation must include, but is not limited to the following: [USP-NF Chapter 797-*Documentation*]

- ☐ Personnel training, competency assessments, & qualification records including corrective actions
- ☐ Equipment records
- ☐ Environmental air & surface monitoring procedures & results
- ☐ Certification reports, including corrective actions
- ☐ Release inspection and testing records
- ☐ Results of investigations and corrective actions
- ☐ SOPs, MFRs and CRs
- ☐ Receipts of Components
- ☐ Information related to complaints and adverse events including corrective actions taken

274. ☐ ☐ Records must be legible and stored in a manner that prevents their deterioration and/or loss. All required documentation for a particular CSP must be readily retrievable for at least 2 years after preparation or as required by laws and regulations of the applicable regulatory jurisdiction or accrediting organization(s), whichever is longer. [USP-NF Chapter 797-*Documentation*]

Compounding Allergenic Extracts

275. ☐ ☐ A designated person(s) with training and expertise in allergen immunotherapy is responsible for ensuring that personnel who will be preparing allergenic extract prescription sets are trained, evaluated, and supervised. [USP-NF Chapter 797-*Personnel Qualifications for Compounding Allergenic Extract Prescription Sets*] ☐ N/A

276. ☐ ☐ Before beginning to independently prepare allergenic extracts, all compounding personnel must complete training and be able to demonstrate knowledge of principles and skills for sterile compounding.[USP-NF Chapter 797-*Personnel Qualifications for Compounding Allergenic Extract Prescription Sets*] ☐ N/A

277. ☐ ☐ Annual personnel training and competency must be documented. Personnel must demonstrate knowledge and competency in these procedures by passing written or electronic testing before they can be allowed to compound allergenic extract prescription sets.[USP-NF Chapter 797-*Personnel Qualifications for Compounding Allergenic Extract Prescription Sets*] N/A ☐

YES NO

278. ☐ ☐ Before being allowed to independently compound, all compounders must successfully complete gloved fingertip and thumb sampling on both hands no fewer than 3 separate times. Each fingertip and thumb evaluation must occur after performing separate and complete hand hygiene and garbing procedures. After the initial competency evaluation, compounding personnel must successfully complete gloved fingertip and thumb sampling on both hands at least every 12 months thereafter. [USP-NF Chapter 797-*Personnel Qualifications for Compounding Allergenic Extract Prescription Sets*] N/A ☐

279. ☐ ☐ Compounding personnel must have their sterile technique and related practices evaluated at least every 12 months as demonstrated by successful completion of a media-fill test. If compounding outside of a PEC, the post-media-fill surface sample is not required.[USP-NF Chapter 797-*Personnel Qualifications for Compounding Allergenic Extract Prescription Sets*] ☐ N/A

280. ☐ ☐ Personnel who fail competency evaluations must successfully pass reevaluations in the deficient area(s) before they can resume compounding of allergenic extract prescription sets. The designated person(s) must identify the cause of failure and determine appropriate retraining requirements.[USP-NF Chapter 797-*Personnel Qualifications for Compounding Allergenic Extract Prescription Sets*] ☐ N/A

281. ☐ ☐ Personnel who have not compounded an allergenic extract prescription set in more than 6 months must be evaluated in all core competencies before resuming compounding duties.[USP-NF Chapter 797-*Personnel Qualifications for Compounding Allergenic Extract Prescription Sets*] ☐ N/A

282. ☐ ☐ Before beginning compounding of allergenic extract prescription sets, personnel must perform hand hygiene and garbing procedures according to the facility's SOPs. [USP-NF Chapter 797- *Personnel Hygiene and Garbing for Compounding Allergenic Extract Prescription Sets*] ☐ N/A

283. ☐ ☐ The minimum garb requirements include: 1) A low-lint garment with sleeves that fit snugly around the wrists and enclosed neck, 2) A low-lint, disposable head cover that covers the hair and ears and, if applicable, a disposable cover for facial hair, 3) Face mask, and 4) Sterile powder-free gloves.[USP-NF Chapter 797- *Personnel Hygiene and Garbing for Compounding Allergenic Extract Prescription Sets*] ☐ N/A

284. ☐ ☐ Throughout the compounding process, personnel must apply sterile 70% IPA onto all surfaces of the gloves and allow then to dry thoroughly.[USP-NF Chapter 797- *Personnel Hygiene and Garbing for Compounding Allergenic Extract Prescription Sets*] ☐ N/A

285. ☐ ☐ The compounding process must occur in an ISO Class 5 PEC or in a dedicated allergenic extract compounding area(AECA). The PEC or AECA used to compound allergenic extract prescription sets must be located away from unsealed windows, doors that connect to the outdoors, and traffic flow, all of which may adversely affect the air quality. Neither a PEC nor an AECA may be located where environmental control challenges could negatively affect the air quality. The PEC or the work surfaces in the AECA must be located at least 1 m away from a sink. The impact of activities that will be conducted around or adjacent to the PEC or AECA must be considered carefully when designing such an area. [USP-NF Chapter 797- *Facilities for Compounding Allergenic Extract Prescription Sets*] N/A ☐

286. ☐ ☐ If used, the PEC must be certified at least every 6 months. [USP-NF Chapter 797- *Facilities for Compounding Allergenic Extract Prescription Sets*] ☐ N/A

287. ☐ ☐ If used, a visible perimeter must define the AECA. Access to the AECA during compounding must be restricted to authorized personnel. During compounding activities, no other activity is permitted in the AECA. The surfaces of walls, floors, fixtures, shelving, counters, and cabinets in the AECA must be cleanable. Carpet is not allowed in the AECA. Surfaces should be resistant to damage by cleaning and disinfecting agents. The surfaces in the AECA upon which the allergenic extract prescription sets are prepared must be smooth, impervious, free from cracks and crevice, and non-shedding to allow for easy cleaning and disinfecting. Dust-collecting overhangs such as utility pipes, ledges, and windowsills should be minimized. If overhangs or ledges are present, they must be easily cleanable. The AECA must be designated and controlled to provide a well-lighted working environment, with temperature and humidity controls for the comfort of compounding personnel wearing the required garb.[USP-NF Chapter 797- *Facilities for Compounding Allergenic Extract Prescription Sets*] N/A ☐

288. ☐ ☐ In the PEC, all interior surfaces of the PEC must be cleaned and disinfected each day of use before compounding begins and when surface contamination is known or suspected. Apply sterile 70% IPA to the horizontal work surface between each prescription set. [USP-NF Chapter 797- *Cleaning and Disinfecting for Compounding Allergenic Extract Prescription Sets*] ☐ N/A

289. ☐ ☐ In an AECA, all work surfaces in the AECA where direct compounding is occuring must be cleaned and disinfected each day of use before compounding begins and when surface contamination is known or suspected. Apply 70% IPA to the horizontal work surface between each prescription set. If present, walls, doors, and door frames within the perimeter of the AECA must be cleaned and disinfected monthly and when surface contamination is known or suspected. Ceilings within the perimeter of the AECA must be cleaned and disinfected when visibly soiled and when surface contamination is known or suspected.[USP-NF Chapter 797- *Cleaning and Disinfecting for Compounding Allergenic Extract Prescription Sets*] N/A ☐

290. ☐ ☐ Vial stoppers on packages of conventionally manufactured sterile ingredients must be wiped with sterile 70% IPA to ensure that the critical sites are wet and allowed to dry before they are used to compound allergenic extract prescription sets.[USP-NF Chapter 797- *Cleaning and Disinfecting for Compounding Allergenic Extract Prescription Sets*] ☐ N/A

291. ☐ ☐ The BUD for the prescription set must be no later than the earliest expiration date of any allergenic extract or any diluent that is part of the prescription set, and the BUD must not exceed 1 year from the date the prescription set is mixed or diluted. [USP-NF Chapter 797- *Establishing BUDs for Allergenic Extract Prescription Sets*] N/A ☐

YES NO

292. ☐ ☐ The label of each vial of an allergenic extract prescription set must display the following prominently and understandably: 1) Patient name, 2) Type and fractional dilution of each vial, with a corresponding vial number, 3) BUD and, 4)Storage conditions. [USP-NF Chapter 797- *Labeling for Allergenic Extract Prescription Sets*] ☐ N/A

293. ☐ ☐ If shipping or transporting allergenic extract prescription sets, compounding personnel must select modes of transport that are expected to deliver properly packed prescription sets in an undamaged, sterile, and stable condition. Inappropriate transport can adversely affect the quality of allergenic extract prescription sets. When shipping or transporting allergenic extract prescription sets that require special handling, personnel must include specific handling instructions on the exterior of the container. [USP-NF Chapter 797- *Shipping and Transporting Allergenic Extract Prescription Sets*]
N/A ☐

294. ☐ ☐ All facilities where allergenic extract prescription sets are prepared must have and maintain written or electronic documentation to include, but not limited to, the following: 1) SOPs describing all aspects of the compounding process, 2) Personnel training records, competency assessments, and qualification records include corrective actions for any failures, 3) Certification reports of the PEC, if used, including corrective actions for any failures, 4)Temperature logs for refrigerator(s), 5) CRs for individual allergenic extract prescription sets, 6)Information related to complaints and adverse events including corrective actions taken and 6) Investigations and corrective actions. [USP-NF Chapter 797- *Documentation for Compounding Allergenic Extract Prescription Sets*]
N/A ☐

295. ☐ ☐ When compounding activities required the manipulation of a patient's blood-derived or other biological material, the manipulations must be clearly separated from other compounding activities and equipment used in CSP preparation activities, and they must be controlled by specific SOPs to avoid any cross-contamination. Handling of blood components and other biological materials must additionally apply with the laws and regulations of the applicable regulatory jurisdiction. [USP-NF Chapter 797- I*ntroduction and Scope- Specific Practices*]
N/A ☐

Immediate-Use CSPs

296. ☐ ☐ When all of the following conditions are met, compounding of CSPs for direct and immediate administration is not subject to the requirements for Category 1, Category 2, or Category 3 CSPs:[USP-NF Chapter 797- *Immediate-Use CSPs*
N/A ☐

- ☐ Aseptic techniques, processes, and procedures are followed, and written SOPs are in place to minimize the potential for contact with non-sterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other conventionally manufactured products or CSPs.
- ☐ Personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the facility's SOPs.
- ☐ The preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs.
- ☐ The preparation involves not more than 3 different sterile products.
- ☐ Any unused starting components from a single-dose container must be discarded after preparation is complete. Single-dose containers must not be used for more than one patient.
- ☐ Administration begins within 4 hours following the start of preparation. If administration has not begun within 4 hours following the start of preparation, it must be promptly, appropriately, and safely discarded.
- ☐ Unless directly administered by the person who prepared it or administration is witnessed by the preparer, the CSP must be labeled with the names and amounts of all active ingredients, the name or initials of the person who prepared the preparation, and the 4-h time period within which administration must begin.

297. ☐ ☐ Handling of sterile hazardous drugs must additionally comply with USP-NF Chapter 800. [USP-NF Chapter 797-*Immediate-Use CSPs*]

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: _____

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