STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV797-Sterile Compounding

File #
Insp #

NAME	PERMIT NUMBER	DATE OF INSPECTION	
DOING BUSINESS AS			
STREET ADDRESS		TELEPHONE #	EXT
CITY	COUNTY	STATE/ZIP	

Additional Information

Business Operation Hours

M-T-W-TH-F	Weekly Hours
Monday	Tuesday
Wednesday	Thursday
Friday	Saturday
Sunday	Monday Hours
Tuesday Hours	Wednesday Hours
Thursday Hours	Friday Hours
Saturday Hours	Sunday Hours

Registered Pharmacist / Intern / Tech

License #	Licensee Name
License Type	
License #	Licensee Name
License Type	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg #	

License Relations

Pharmacy Affiliate

	License #
	License #
	License #
	License #
	License #

RX DPT MGR/COR/POR

	License #

Special Sterile Compounding

	License #

INV797 - Sterile Compounding

LOW RISK

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1. Low risk CSP's are properly identified: Aseptic manipulations within an ISO Class 5 environment using three or fewer sterile products and no more than two entries into any container. [CSP MICROBIAL CONTAMINATION RISK LEVELS: Low-Risk Level CSPs]	
2. Low Risk CSP's, in absence of passing sterility test, stored not more than 48 hours at controlled room temperature, 14 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS: Low-Risk Level CSPs]	
3. Low Risk CSP's with 12-hour BUD are properly identified and comply with all four specific criteria. 1. PEC in Segregated Compounding area 2. Away from windows, doors, high traffic areas 3. Hygiene & garbing required, sinks not adjacent to PEC. 4. Cleaning & Disinfecting, Personnel training, Competency evaluation, Garbing, Aseptic work practices, Viable and non-viable environmental sampling apply. [CSP MICROBIAL CONTAMINATION RISK LEVELS: Low-Risk Level CSPs]	

MEDIUM RISK

4. Medium Risk CSP's are properly identified: Aseptic manipulations within an ISO Class 5 environment using prolonged and complex mixing and transfer, more than three sterile products and entries into any container, and pooling ingredients from multiple sterile products to prepare multiple CSPs. [CSP MICROBIAL CONTAMINATION RISK LEVELS: Medium-Risk Level CSPs]	
5. Medium Risk CSP's, in absence of passing sterility test, stored not more than 30 hours at controlled room temperature, 9 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS: Medium-Risk Level CSPs]	

HIGH RISK

6. Presterilization procedures for high-risk level CSPs, such as weighing and mixing, are completed in no worse than an ISO Class 8 environment. [ENVIRONMENTAL QUALITY AND CONTROL: Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	
7. High Risk CSP's are properly identified: Confirmed presence of nonsterile ingredients and devices, or confirmed or suspected exposure of sterile ingredients for more than one hour to air quality inferior to ISO Class 5 before final sterilization. [CSP MICROBIAL CONTAMINATION RISK LEVELS: High-Risk Level CSPs]	
8. High Risk CSP's, in absence of passing sterility test are not stored more than 24 hours at controlled room temperature, 3 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS: High-Risk Level CSPs]	
9. A 0.2-µm certified sterilizing membrane filter is used that is chemically and physically compatible with the CSP. Filtration is completed rapidly without filter replacement. Sterilization method is verified to achieve sterility for the quantity and type of containers. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY: Sterilization of High-Risk Level CSPs by Filtration]	
10. Sterilization method used has documentation that acceptable strength and purity of ingredients and integrity of containers is maintained. [CSP MICROBIAL CONTAMINATION RISK LEVELS: High-Risk Level CSPs]	
11. The manufacturer recommended filter integrity (e.g., bubble point) test is performed and documented for all sterilizing filters after filtering CSPs. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY: Sterilization of High-Risk Level CSPs by Filtration]	
12. Autoclave cycle has been verified using appropriate biological indicators. Solutions are passed through a 1.2-µm or smaller filter into final containers to remove particulates before sterilization. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY: Sterilization of High-Risk Level CSPs by Steam]	
13. Dry heat ovens used for sterilization have filtered forced air. Only those items that will be damaged by steam are sterilized by dry heat. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY: Sterilization of High-Risk Level CSPs by Dry Heat]	
14. The description of dry heat sterilization conditions and duration for specific CSPs is included in written documentation in the compounding facility. The effectiveness of dry heat sterilization is verified using appropriate biological indicators and other confirmation. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY: Sterilization of High-Risk Level CSPs by Dry Heat]	
15. Dry heat depyrogenation is used to render glassware or containers, such as vials free from pyrogens as well as viable microbes. The description of the dry heat depyrogenation cycle and duration for specific load items is included in written documentation in the compounding facility. The effectiveness of the dry heat depyrogenation cycle is verified using endotoxin challenge vials (ECVs). [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY: Depyrogenation by Dry Heat]	
16. Sterility testing is completed for all High-risk level CSPs prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8° before being sterilized. [FINISHED PREPARATION RELEASE CHECKS AND TESTS: Sterility Testing]	

USP <71> STERILITY TESTING (Outsourced)

17. Outsourced sterility testing results indicate that it is compliant with USP<71>. A method not described in the USP may be used if validation demonstrates that the alternative is at least as effective and reliable. [STERILITY TEST USP<71>]	
18. Outsourced: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71>: Number of Articles to Be Tested]	
19. Outsourced: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71>: Number of Articles to Be Tested]	
20. Outsourced: A USP<71> method suitability test has been done with appropriate inoculum, additives and rinses. [STERILITY TEST USP<71>: Method Suitability Test]	
21. Outsourced: Sterility testing reports are reviewed and appropriate actions taken and documented. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	

USP <71> STERILITY TESTING

22. On site: Membrane filtration is used if appropriate. (The technique of membrane filtration is used whenever the nature of the product permits; that is, for filterable aqueous preparations, for alcoholic or oily preparations, and for preparations miscible with, or soluble in, aqueous or oily solvents, provided these solvents do not have an antimicrobial effect in the conditions of the test.) Filters are rinsed according to USP<71>. [FINISHED PREPARATION RELEASE CHECKS AND TESTS: Sterility Testing]	
23. On site: Direct inoculation is done only when membrane filtration cannot be carried out. Volume to be inoculated does not exceed 10% of the culture media volume. [FINISHED PREPARATION RELEASE CHECKS AND TESTS: Sterility Testing]	
24. On site: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71>: Number of Articles to Be Tested]	
25. On site: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71>: Number of Articles to Be Tested]	
26. On site: A growth promotion test has been done on the media with the 5 specified organisms (not more than 100 CFU) according to USP<71>. [STERILITY TEST USP<71>: Growth Promotion Test of Aerobes, Anaerobes, and Fungi]	
27. On site: A USP<71> method suitability test has been done with appropriate inoculum, additives and rinses. [STERILITY TEST USP<71>: Method Suitability Test]	

28. On site: TSB or SCD is incubated at 20-25 C for 14 days (2 incubators present). [STERILITY TEST USP<71>: Culture Media and Incubation Temperatures]	
29. On site: FTM is incubated at 30-35 C for 14 days (2 incubators present). [STERILITY TEST USP<71>: Culture Media and Incubation Temperatures]	
30. On site: Sterility testing is documented including lot numbers and expiration dates of media. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	
31. On site: Sterility testing reports are reviewed and appropriate actions taken and documented. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	

ENDOTOXIN TESTING

32. Endotoxin testing is conducted for High-risk level CSP's that are prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8°, before being sterilized or in multidose containers for administration to multiple patients. (excluding those for inhalation and ophthalmic administration) [FINISHED PREPARATION RELEASE CHECKS AND TESTS: Bacterial Endotoxin (Pyrogen) Testing]	
33. Endotoxin testing process indicates that it is compliant with USP<85>. [BACTERIAL ENDOTOXINS TEST USP<85>]	
34. High Risk CSP's are within allowable limits for bacterial endotoxins. [FINISHED PREPARATION RELEASE CHECKS AND TESTS: Bacterial Endotoxin (Pyrogen) Testing]	

IMMEDIATE USE COMPOUNDING

35. Immediate-use compounding complies with all six specified criteria. 1. Low-risk sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers. Anti-neoplastics shall not be prepared as immediate-use CSPs because they are hazardous drugs. 2. Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour. 3. During preparation, aseptic technique is followed and, if not immediately administered, the finished CSP is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other CSPs, and direct contact of outside surfaces. 4. Administration begins not later than 1 hour following the start of the preparation of the CSP. 5. Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour BUD and time. 6. If administration has not begun within 1 hour following the start of preparing the CSP, the CSP shall be promptly, properly, and safely discarded. [IMMEDIATE-USE CSPs]	

SINGLE/MULTIPLE DOSE CONTAINER BUD

36. Beyond-use date does not exceed 28 days for multiple-dose containers after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	
37. Beyond-use time does not exceed 6 hours for closure sealed single-dose containers in ISO Class 5 or cleaner air after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	
38. Beyond-use time does not exceed 1 hour for closure sealed single-dose containers after being opened or entered in worse than ISO Class 5 air. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	
39. Single-dose ampules are discarded immediately after use. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	

HAZARDOUS DRUGS

40. A pressure indicator is installed and differential pressures are monitored and documented daily for hazardous buffer room. [HAZARDOUS DRUGS AS CSPs]	
41. Hazardous drug buffer room is at least 0.01-inch water column negative pressure with 30 ACPH of HEPA filtered air. [HAZARDOUS DRUGS AS	
42. At least 0.01-inch water column negative pressure and 12 air changes per hour in non-cleanrooms in which CACIs are located. FAC: USP Chapter 797 requires that: "When closed-system vial-transfer devices (CSTDs) (i.e., vial-transfer systems that allow no venting or exposure of hazardous substance to the environment) are used, they shall be used within an ISO Class 5 environment of a BSC or CACI. The use of the CSTD is preferred because of their inherent closed system process. In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable." For purpose of said provision, a "low volume of hazardous drugs" is defined as less than 40 doses per month. [HAZARDOUS DRUGS AS CSPs]	
43. Personnel compounding hazardous drugs wear appropriate personal protective equipment. [HAZARDOUS DRUGS AS CSPs]	
44. Hazardous drugs are handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparing for administration, and disposal. Spill kits are available. [HAZARDOUS DRUGS AS CSPs]	
45. Hazardous drugs are prepared in an ISO Class 5 environment (BSC or CACI) with protective engineering controls in place, following aseptic practices specified for the appropriate contamination risk levels. [HAZARDOUS DRUGS AS CSPs]	
46. Hazardous drugs are stored separately from other inventory in a manner to prevent contamination and personnel exposure. [HAZARDOUS DRUGS AS CSPs]	
47. Access to hazardous drug preparation areas is limited to authorized compounding personnel. [HAZARDOUS DRUGS AS CSPs]	
48. Annual documentation of hazardous drug training of personnel regarding storage, handling, containment techniques and disposal of hazardous drugs is available. [HAZARDOUS DRUGS AS CSPs]	
49. Compounding personnel of reproductive capability have confirmed in writing that they understand the risks of handling hazardous drugs. [HAZARDOUS DRUGS AS CSPs]	
50. Facility maintains appropriate disposal containers for all hazardous waste. [HAZARDOUS DRUGS AS CSPs]	

FACILITY DESIGN AND CERTIFICATION

51. Certification and testing of primary (LAFWs, BSCs, CAIs and CACIs) and secondary engineering controls (buffer and ante areas) have been performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. Corrective action for deficiencies are documented. Certification procedures such as those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006) are conducted under dynamic conditions. [ENVIRONMENTAL QUALITY AND CONTROL: Environmental Nonviable Particle Testing Program]	
52. Primary engineering controls provide unidirectional (i.e., laminar) HEPA filtered air. Air pattern analysis via smoke studies are conducted at the critical site to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions. [ENVIRONMENTAL QUALITY AND CONTROL: Facility Design and Environmental Controls]	

53. The primary engineering controls are placed within a buffer area in such a manner as to avoid conditions that could adversely affect their operation. The PEC is placed out of the traffic flow and in a manner to avoid disruption from the HVAC system and room cross drafts. [ENVIRONMENTAL QUALITY AND CONTROL: Facility Design and Environmental Controls]	
54. All HEPA filters are leak tested after installation and every six months thereafter. [ENVIRONMENTAL QUALITY AND CONTROL: Facility Design and Environmental Controls]	

ISOLATORS

55. CAIs are proven to maintain ISO Class 5 air when particle counts are sampled 6 to 12 inches upstream of critical site exposure areas during performance of normal inward and outward transfer of materials, and compounding manipulations when such CAIs are located in air quality worse than ISO Class 7. [ENVIRONMENTAL QUALITY AND CONTROL: Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	
56. Adequate recovery time for isolators to achieve ISO Class 5 air quality is allowed after material transfer before and during compounding operations. [ENVIRONMENTAL QUALITY AND CONTROL: Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	
57. Personnel garbing requirements are followed for CAIs unless manufacturer provides written documentation based on validated testing that any components of PPE are not required to maintain sterility of CSPs. [ENVIRONMENTAL QUALITY AND CONTROL: Personnel Cleansing and Garbing]	

FACILITY DESIGN AND CERTIFICATION (Secondary Engineering Controls)

58. Facility has pressure gauges or velocity meters to monitor the pressure differential or airflow between the buffer area and ante-area, and the ante-area and the general environment outside the compounding area. The results are reviewed and documented on a log at least daily or by a continuous recording device. The pressures differentials meet or exceed 5 Pa (0.02-inch water column (w.c.)). Alternatively, in facilities where low- and medium-risk level CSPs are prepared, differential airflow is maintained at a minimum velocity of 0.2 meter/second (40 fpm) across a line of demarcation between buffer area and ante-area. [ENVIRONMENTAL QUALITY AND CONTROL: Pressure Differential Monitoring]	
59. Clean rooms for nonhazardous and nonradioactive CSPs are supplied with HEPA filtered air that enters from ceilings with return vents low on walls, and that provides not less than 30 air changes per hour or qualifies for exception in 64B16-27.797(4)(c). [ENVIRONMENTAL QUALITY AND CONTROL: Facility Design and Environmental Controls]	
60. Activities and tasks carried out within the buffer area are limited to only those necessary when working within a controlled environment. [ENVIRONMENTAL QUALITY AND CONTROL: Facility Design and Environmental Controls]	
61. Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed are brought into the buffer room. [ENVIRONMENTAL QUALITY AND CONTROL: Facility Design and Environmental Controls]	
62. Surfaces and essential furniture in buffer rooms or zones and clean rooms are nonporous, smooth, non-shedding, impermeable, cleanable, and resistant to disinfectants. [ENVIRONMENTAL QUALITY AND CONTROL: Facility Design and Environmental Controls]	
63. The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area are smooth, impervious, free from cracks and crevices, and non-shedding, thereby promoting cleanability, and minimizing spaces in which microorganisms and other contaminants may accumulate. [ENVIRONMENTAL QUALITY AND CONTROL: Facility Design and Environmental Controls]	
64. Ceiling tiles are caulked around each perimeter and to walls to seal them to the support frame. The exterior lens surface of ceiling lighting fixtures is smooth, mounted flush, and sealed. All other penetrations through the ceiling or walls are sealed. [ENVIRONMENTAL QUALITY AND CONTROL: Facility Design and Environmental Controls]	
65. The buffer area does not contain sources of water (sinks) or floor drains. Work surfaces are constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected. [ENVIRONMENTAL QUALITY AND CONTROL: Facility Design and Environmental Controls]	
66. Storage shelving, counters, cabinets and carts/casters in the buffer area are smooth, impervious, free from cracks and crevices, non-shedding, non-porous, cleanable, and disinfectable. [ENVIRONMENTAL QUALITY AND CONTROL: Facility Design and Environmental Controls]	
67. When devices (e.g., computers and printers) and objects (e.g., carts and cabinets) are placed in buffer areas, air quality is verified by particle counts on certification. [ENVIRONMENTAL QUALITY AND CONTROL: ISO Class 5 Air Sources, Buffer Areas, and Ante-Areas]	

QUALITY AND CONTROL

68. An appropriate environmental sampling plan has been developed for airborne viable particles based on a risk assessment of compounding activities performed. Volumetric air sampling is conducted every six months and sites include locations within each ISO Class 5 environment and in the ISO Class 7 and 8 areas, and the areas at greatest risk of contamination (e.g., work areas near the ISO Class 5 environment, counters near doors, pass-through boxes). The plan includes sample locations, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels. [ENVIRONMENTAL QUALITY AND CONTROL: Environmental Viable Airborne Particle Testing Program—Sampling Plan]	
69. Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments is performed by properly trained individuals for all compounding risk levels. [ENVIRONMENTAL QUALITY AND CONTROL: Viable Air Sampling]	
70. Volumetric air sampling using malt extract agar (MEA) or some other media that supports the growth of fungi is used in high-risk level compounding environments. [ENVIRONMENTAL QUALITY AND CONTROL: Growth Media]	
71. For low-risk level CSPs with 12-hour or less BUD, air sampling is performed at locations inside the ISO Class 5 environment and other areas that are in close proximity to the ISO class 5 environment. [ENVIRONMENTAL QUALITY AND CONTROL: Viable Air Sampling]	
72. The number of discrete colonies of microorganisms is counted and reported as colony-forming units (cfu) and documented on an environmental monitoring form. Counts from air monitoring are transformed into cfu/cubic meter of air and evaluated for adverse trends. [ENVIRONMENTAL QUALITY AND CONTROL: Incubation Period]	
73. Surface sampling is accomplished in all ISO classified areas on a periodic basis using TSA contact plates with lecithin and polysorbate 80 and/or swabs and is done at the conclusion of compounding. [ENVIRONMENTAL QUALITY AND CONTROL: Surface Cleaning and Disinfection Sampling and Assessment]	
74. Sampling data is collected and reviewed on a periodic basis as a means of evaluating the overall state of control of the compounding environment. [ENVIRONMENTAL QUALITY AND CONTROL: Action Levels, Documentation and Data Evaluation]	
75. Competent microbiology personnel are consulted if an environmental sampling consistently shows elevated levels of microbial growth. If any mold, yeast, coagulase positive staphylococcus, or gram-negative rods are detected immediate remediation and investigation into the cause and source was conducted. [ENVIRONMENTAL QUALITY AND CONTROL: Action Levels, Documentation and Data Evaluation]	
76. Surfaces in the LAFWs, BSCs, CAIs, and CACIs are cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches. [ENVIRONMENTAL QUALITY AND CONTROL: Cleaning and Disinfecting the Sterile Compounding Areas]	

77. Cleaning and disinfecting occurs before compounding is performed. Items are removed from all areas to be cleaned, and surfaces are cleaned by removing loose material and residue from spills, e.g., water-soluble solid residues are removed with Sterile Water and low-shedding wipes. This shall be followed by wiping with a residue-free disinfecting agent, such as sterile 70% IPA, which is allowed to dry before compounding begins. [ENVIRONMENTAL QUALITY AND CONTROL: Cleaning and Disinfecting the Sterile Compounding Areas]	
78. Cleaning and disinfecting agents and methods of application are in accordance with written SOPs and followed by custodial and/or compounding personnel. [ENVIRONMENTAL QUALITY AND CONTROL: Cleaning and Disinfecting the Sterile Compounding Areas]	
79. Cleaning materials, such as wipes, sponges, and mops, are non-shedding, preferably composed of synthetic micro fibers, and dedicated to use in the buffer area, ante-area, and segregated compounding areas and are not removed from these areas except for disposal. If cleaning materials are reused (e.g., mops), there are procedures based on manufacturer recommendations that ensure that the effectiveness of the cleaning device is maintained and repeated use does not add to the bioburden of the area being cleaned. [ENVIRONMENTAL QUALITY AND CONTROL: Cleaning and Disinfecting the Sterile Compounding Areas]	
80. Supplies and equipment removed from shipping cartons are wiped with a suitable disinfecting agent (e.g., sterile 70% IPA). [ENVIRONMENTAL QUALITY AND CONTROL: Cleaning and Disinfecting the Sterile Compounding Areas]	
81. Disinfectant sprayed or wiped on a surface to be disinfected is allowed to dry, and during this time the item is not be used for compounding purposes. [ENVIRONMENTAL QUALITY AND CONTROL: Cleaning and Disinfecting the Sterile Compounding Areas]	
82. Sterile 70% IPA pads are used to disinfect the sterile entry points of packages and devices. Wetted gauze pads or other particle-generating material are not appropriate. [ENVIRONMENTAL QUALITY AND CONTROL: Cleaning and Disinfecting the Sterile Compounding Areas]	

QUALITY AND CONTROL (Secondary Engineering Controls)

83. Work surfaces in ISO Class 7 and 8 areas and segregated compounding areas are cleaned at least daily. IPA (70% isopropyl alcohol) remains on surfaces to be disinfected for at least 30 seconds before such surfaces are used to prepare CSPs. [ENVIRONMENTAL QUALITY AND CONTROL: Cleaning and Disinfecting the Sterile Compounding Areas]	
84. Floors in ISO Class 7 and 8 areas are mopped daily by trained personnel at a time when no aseptic operations are in progress using approved agents and procedures described in written SOP's. [ENVIRONMENTAL QUALITY AND CONTROL: Cleaning and Disinfecting the Sterile Compounding Areas]	
85. Shelving, walls, and ceilings in ante-areas and buffer areas are cleaned and disinfected at least monthly. [ENVIRONMENTAL QUALITY AND CONTROL: Cleaning and Disinfecting the Sterile Compounding Areas]	

PERSONNEL CLEANSING, GARBING & COMPETENCY EVALUATION

86. Personnel preparing CSP's are free from rashes, sunburn, weeping sores, conjunctivitis, and active respiratory infections. [ENVIRONMENTAL QUALITY AND CONTROL: Personnel Cleansing and Garbing]	
87. Compounding personnel remove personal outer garments; cosmetics; artificial nails; hand, wrist, and body jewelry that can interfere with the fit of gowns and gloves; and visible body piercing above the neck. [ENVIRONMENTAL QUALITY AND CONTROL: Personnel Cleansing and Garbing]	
88. Facility has adequate supplies to meet PPE requirements of USP<797>. [ENVIRONMENTAL QUALITY AND CONTROL: Personnel Cleansing and Garbing]	
89. Garbing and hand hygiene are accomplished in the ante-area in order of dirtiest to cleanest: shoes or shoe covers, head and facial hair covers, face mask, fingernail cleansing, hand and forearm washing and drying; non-shedding gown. [ENVIRONMENTAL QUALITY AND CONTROL: Personnel Cleansing and Garbing]	
90. Sterile gloves are donned in the buffer room/isolator after hand cleansing with an alcohol-based product with persistent activity and hands are allowed to dry. [ENVIRONMENTAL QUALITY AND CONTROL: Personnel Cleansing and Garbing]	
91. Gloves are routinely disinfected with sterile 70% IPA after contacting nonsterile objects. [ENVIRONMENTAL QUALITY AND CONTROL: Personnel Cleansing and Garbing]	
92. Personnel repeat garbing and hand hygiene after they are exposed to direct contact contamination or worse than ISO Class 8 air. Gowns may be hung in the anteroom and reused during the same work shift. [ENVIRONMENTAL QUALITY AND CONTROL: Personnel Cleansing and Garbing]	
93. Low/Medium Risk media-fill tests that closely simulate the most challenging or stressful conditions encountered during compounding are completed at least annually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	
94. High Risk Media-fill tests that closely simulate the most challenging or stressful conditions encountered during compounding have been completed at least semiannually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS: High-Risk Level CSPs]	
95. Documentation indicates compounding personnel have successfully completed didactic training, passed written competency assessments, undergone skill assessment using observational audit tools (hand hygiene, garbing, aseptic technique) and media-fill testing annually or semiannually (high risk) and before any compounding personnel begin to prepare CSPs. [ENVIRONMENTAL QUALITY AND CONTROL: Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	
96. Compounding personnel who fail written tests, observational audits, or whose media-fill test vials have one or more units showing visible microbial contamination, are reinstructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic work practice deficiencies. Corrective action is documented. Compounding personnel pass all evaluations prior to resuming compounding of sterile preparations. [ENVIRONMENTAL QUALITY AND CONTROL: Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	
97. Other cleaning personnel performing cleaning and disinfecting procedures (e.g. environmental) are thoroughly trained in proper hand hygiene, and garbing, cleaning, and disinfection procedures by a qualified aseptic compounding expert. [ENVIRONMENTAL QUALITY AND CONTROL: Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	
98. Compounding personnel and other personnel responsible for cleaning routinely undergo performance evaluation of proper hand hygiene, garbing, and all applicable cleaning and disinfecting procedures conducted by a qualified aseptic compounding expert. Visual observation of hand hygiene, garbing and cleaning is documented and maintained to provide a permanent record and long-term assessment of personnel competency. [ENVIRONMENTAL QUALITY AND CONTROL: Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	
99. Immediately after the compounder completes the hand hygiene and garbing procedure, the evaluator collects a gloved fingertip and thumb sample from both hands of the compounder onto appropriate agar plates. The plates are incubated at 30-35° for 2–3 days. All compounding personnel have successfully completed an initial competency evaluation and gloved fingertip/thumb sampling procedure (0 cfu) no less than three times before initially being allowed to compound CSPs for human use. [ENVIRONMENTAL QUALITY AND CONTROL: Gloved Fingertip Sampling]	
100. Re-evaluation of glove fingertip testing onto appropriate agar plates (Trypticase soy agar (TSA) with lecithin and polysorbate 80) for all compounding personnel occurs at least annually for low- and medium-risk level CSPs and semiannually for high-risk level CSPs before being allowed to continue compounding CSPs. Gloves shall not be disinfected with sterile 70% IPA prior to testing. The cfu action level is based on the total number of cfu on both gloves and not per hand. [ENVIRONMENTAL QUALITY AND CONTROL: Gloved Fingertip Sampling]	

VERIFICATION

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101. Labels of CSPs contain name and address of pharmacy, correct names and amounts or concentrations of ingredients, total volumes, beyond-use dates, storage conditions, and route(s) of administration. [FINISHED PREPARATION RELEASE CHECKS AND TESTS: Identity and Strength Verification of Ingredients]	
102. Facility has documentation that procedures have been followed to ensure sterility, purity, correct identities and amounts of ingredients, and stability. [FINISHED PREPARATION RELEASE CHECKS AND TESTS: Inspection of Solution Dosage Forms and Review of Compounding Procedures]	
103. CSP's are visually inspected for abnormal particulate matter and color, and intact containers and seals. [FINISHED PREPARATION RELEASE CHECKS AND TESTS: Inspection of Solution Dosage Forms and Review of Compounding Procedures]	
104. Beyond Use Dates are assigned using direct stability-indicating assays or authoritative literature that supports the assigned BUD. [STORAGE AND BEYOND-USE DATING: Determining Beyond-Use Dates]	
105. Storage time of assembled bag and vial systems are according to the manufacturer recommendations. (eg Minibag plus, Addvantage, Add-ease) [STORAGE AND BEYOND-USE DATING: Proprietary Bag and Vial Systems]	

DISPENSING/DISTRIBUTION

106. Facility has written procedures for proper packaging, storage, and transportation conditions to maintain sterility, quality, purity, and strength of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs:]	
107. Modes of transport are used that maintain appropriate temperatures and prevent damage to CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs: Packaging and Transporting CSPs]	
108. Facility provides a multiple component formal training program to ensure patients and caregivers understand the proper storage, handling, use, and disposal of CSPs. [PATIENT OR CAREGIVER TRAINING]	

POLICY/PROCEDURE

109. Written procedures detail cleaning and disinfecting the sterile compounding areas including cleansers, disinfectants, and non-shedding wipe and mop materials. [ENVIRONMENTAL QUALITY AND CONTROL: Cleaning and Disinfecting the Sterile Compounding Areas]	
110. A written procedure is in place for cleaning and disinfecting the Direct Compounding Areas. [ENVIRONMENTAL QUALITY AND CONTROL: Cleaning and Disinfecting the Sterile Compounding Areas]	
111. Facility has written procedures to verify correct identity, quality, amounts, and purities of ingredients used in CSPs. [FINISHED PREPARATION RELEASE CHECKS AND TESTS: Identity and Strength Verification of Ingredients]	
112. Policies address packaging to maintain physical integrity, sterility, stability, and purity of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs: Packaging and Transporting CSPs]	
113. Written standard procedures describe means for patients to ask questions and report concerns and adverse events with CSPs, and for compounding pharmacists to correct and prevent future problems. [PATIENT MONITORING AND ADVERSE EVENTS REPORTING]	

RADIOPHARMACEUTICALS

114. Facility has appropriate primary engineering controls and radioactivity containment and shielding. Location of primary engineering controls permitted in ISO Class 8 controlled environment. [RADIOPHARMACEUTICALS AS CSPs]	
115. Radiopharmaceuticals prepared as low-risk level CSPs with 12-hour or less BUD are prepared in a segregated compounding area. Segregated compounding area is designated with a line of demarcation. [RADIOPHARMACEUTICALS AS CSPs]	
116. Technetium-99m/Molybdenum-99 generators are eluted in ISO Class 8 conditions. [RADIOPHARMACEUTICALS AS CSPs]	

MISCELLANEOUS

117. Facility engaged in office use sterile compounding for human use is registered with FDA as an outsourcing facility. [FAC 64B16-27.700 (3) (g)]	
118. Compounding records are properly maintained. [FAC 64B16-28.140(4)]	
119. When compounding activities require the manipulation of a patient's blood-derived or other biological material, the manipulations are clearly separated from routine material-handling procedures and equipment used in CSP preparation activities, and they are controlled by specific standard operating procedures in order to avoid any cross-contamination. [ENVIRONMENTAL QUALITY AND CONTROL: Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	

SPECIAL PARENTERAL ENTERAL & EXTENDED SCOPE

120. Pharmacy technicians properly identified and supervised. [64B16-27.420, F.A.C.]	
121. Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]	
122. Expired medications removed from the shelves. [64B16-28.110, F.A.C.]	
123. CQI Policy and Procedures and quarterly meetings. [766.101, F.S.] [64B16-27.300, F.A.C.]	
124. Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1)(c) 6, F.S.] [64B16-28.140(3)(b), F.A.C.]	
125. Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]	
126. All controlled substance prescriptions contain information required. [893.04, F.S.]	
127. Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a Department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].	
128. Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.]	
129. DEA 222 order forms properly completed. [893.07, F.S.]	
130. Controlled substance records and Rx information in computer system is retrievable. [21CFR 1306.22] [64B16-28.140, F.A.C.]	
131. Controlled substance records maintained for 4 years. [465.022(12) (b), F.S.]	
132. Certified daily log OR printout maintained. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]	
133. Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4), F.S.]	

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134. Pharmacy maintains invoices documenting that medicinal drugs were obtained from a Florida licensed distributor. 499.005 (14)	

LYOPHILIZATION

135. Sterile products prepared for lyophilization are maintained in ISO 5 unidirectional laminar flow air throughout sterilization, filling and transport to the lyophilizer. [64B16-27.797(5) F.A.C.]	
136. A recorded smoke study is available and demonstrates that transport from the PEC to the lyophilizer is accomplished in ISO 5 laminar flow air at all times. [64B16-27.797(5) F.A.C.]	
137.The pharmacy has established and follows policies and procedures for the high-level disinfection of the lyophilizer chamber, piping, and all other areas of the unit which pose a potential risk for contamination of the product. [64B16-27.797(5) F.A.C.]	
138. The pharmacy validated the high-level disinfection procedure initially, and after changes to the cleaning process or agents. Documentation of studies is available for inspection. [64B16-27.797(5) F.A.C.]	
139. Validation studies for high level disinfection are performed with the 5-aerobic bacterial and fungal ATCC organisms referenced in USP<71> are conducted by an external vendor unless the firm has an internal laboratory capable of performing the studies. An internal laboratory is separate from the compounding and work areas of the pharmacy to prevent contamination in the pharmacy. [64B16-27.797(5) F.A.C.]	
140. Policies and procedures are established and followed for cleaning the lyophilizer prior to disinfection and include cleaning agents and schedules. Documentation of cleaning is maintained and available for inspection. [64B16-27.797(5) F.A.C.]	
141. Policies and procedures are established for the maintenance of the lyophilizer and at a minimum include the manufacturers recommendations. [64B16-27.797(5) F.A.C.]	
142. The maintenance schedule includes provisions for periodic testing of the chamber for leaks and all other recommended procedures described by the equipment manufacturer. Documentation of routine maintenance is available for inspection. [64B16-27.797(5) F.A.C.]	
143.SOPs and quality assurance program established to include validation of the filling process, container closure integrity, frequent monitoring of fill volumes, identification of over fills and underfills, assessment of personnel involved in compounding for lyophilization, equipment qualification, formula verification, and evaluation of finished product for conformance to specifications. [64B16-27.797(5) F.A.C.]	
144. The pharmacy has provisions for sterilizing, with filters, the inert gas or air used for backfilling during the vacuum release phase. These Sterilizing filters undergo the manufacturers recommended integrity test. [64B16-27.797(5) F.A.C.]	
145. Media fills are conducted every six months using the maximum batch size and demonstrate the filling, transport to the lyophilizer, loading and stoppering operations. Media is NOT frozen during the media fill operation. [64B16-27.797(5) F.A.C.]	
146. Personnel preparing sterile compounds for lyophilization wear sterile Personal Protective Equipment that covers all exposed skin. [64B16-27.797(5) F.A.C.]	
147. Glove Fingertip Sampling is performed with every batch after fill and transport into the lyophilizer on all personnel compounding for lyophilization. The results are incorporated into the batch record. [64B16-27.797(5) F.A.C.]	
148. In-process acceptance criteria such as color, moisture limits and visual appearance are established for each lyophilized product. [64B16-27.797(5) F.A.C.]	
149. A 100% visual examination of the finished product is conducted to determine that the product conforms to the established visual criteria and is incorporated into the batch record. [64B16-27.797(5) F.A.C.]	
150. Finished product testing is conducted on all batches. Procedures have been established for selecting test samples from the batch and are written and followed. Such procedures may include location of vials in the lyophilizer and positions in the fill line. [64B16-27.797(5) F.A.C.]	
151. Finished product testing includes sterility testing using a USP<71> method unless an alternative test method has been validated and shown to be equivalent or better. Diluents used to reconstitute the sample vials for testing are preservative free. [64B16-27.797(5) F.A.C.]	
152. Each batch of lyophilized product with a beyond use date that falls within the USP<797> guidelines and is not tested for sterility, has viable air and surface sampling that is collected in critical areas of ISO 5 locations as well as sampling of the gloves and sleeves of personnel documented in the batch record. [64B16-27.797(5) F.A.C.]	
153. Every lyophilized product has established endotoxin levels Each batch of lyophilized product is tested for endotoxin in accordance with USP<85> and confirmed to fall within the set limits and documented in the batch record. [64B16-27.797(5) F.A.C.]	
154. Potency, radiochemical purity or applicable test to assure label claim is conducted on every batch and documented in the batch record. In lieu of potency testing, weight based verification may occur based on formula verification. Potency testing shall be based on the USP monograph if one is available. [64B16-27.797(5) F.A.C.]	

CORRECTIVE ACTION PLAN

155. A corrective action plan is required to be submitted within 30 days for the non-compliant items listed above.	

Remarks:

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature: Representative:

Date: Date: