CHAPTER 17

STERILE PRODUCT COMPOUNDING

Sterile Product Compounding

References:

1) **United States Pharmacopeia Chapter 797 (USP<797>)**

   The minimum standards for sterile product preparation, storage, and transport
   Ensure contaminant free, accurate and safe compounded sterile product (CSP) preparation
   Does not pertain to administration of CSPs

2) **CMS: §482.25(b)(1) - All compounding, packaging, and dispensing of drugs and biologicals must be under the supervision of a pharmacist and performed consistent with State and Federal laws.**

3) **The Joint Commission (TJC) Medication Management Standards; MM.05.01.07:**

   A pharmacist, or pharmacy staff under the supervision of a pharmacist, compounds or admixes all compounded sterile preparations **except in urgent situations in which a delay could harm the patient or when the product's stability is short.**

   - Staff use clean or sterile techniques and maintain clean, uncluttered, and functionally separate areas for product preparation to avoid contamination of medications.
   - During preparation, staff visually inspect the medication for particulates, discoloration, or other loss of integrity
   - Use of a laminar airflow hood or other ISO Class 5 environment for preparing IV admixtures or sterile products

4) **Florida Regulations: 64B16-27.797 Standards of Practice for Compounding Sterile Preparations (CSPs).**

   - United States Pharmacopeia, 36th revision adopted by FL Board of Pharmacy October 1, 2014 (includes Chapters 797, 71, 85, 731)
   - These standards are intended to apply to all sterile pharmaceuticals, notwithstanding the location of the patient
     - Pharmacy
     - Hospital
     - Nursing home
     - Hospice
     - Home care
     - Physician's office
     - Ambulatory infusion center
     - Any facility where compounded sterile preparations are prepared, stored & dispensed
   - 125 question inspection survey

Examples of CSPs:

1. Compounded biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals

- Aqueous bronchial and nasal inhalations, baths and soaks for live organs and tissues, injections, irrigations, ophthalmic drops and ointments, and tissue implants

2. Sterile products prepared in accordance with manufacturers' instructions (product package inserts) or differently than published in such labeling
3. May be compounded using a device (robotics, automated compounders, repeater pumps, etc.)

Enforceable by FDA, TJC, Florida Board of Pharmacy

ISO Classification of Particulate Matter in Room Air

ISO class	Particles $\geq$ 0.5 µm/ft^3	Reference Area
ISO 5	Class 100	Air quality inside hood; direct compounding area; unidirectional HEPA filtered air
ISO 7	Class 10,000	Buffer area - clean room area where hoods and supplies are located; prep and staging of components; HEPA filtered air
ISO 8	Class 100,000	Ante area – where hand hygiene and garbing occurs, transitional area between "clean" and "dirty" spaces

Types of hoods include:

- Laminar airflow hood/workbench (LAFW)
  - Horizontal (outward) airflow, HEPA (high efficiency particulate air) filtered air
- Biological safety cabinet (BSC)
  - Hazardous drug preparation
  - Vertical (downward) airflow, HEPA air
- Compounding aseptic isolator (CAI), Compounding aseptic containment isolator (CACI)

Laminar Air Flow Hood	Biological Safety Cabinet	Compounding Aseptic Containment Isolator
		

Compounding Sterile Product Risk Levels & Beyond Use Dating (BUD)

- Assigned based on potential for contamination (microbial, chemical, physical) during compounding
- **Indicates the maximum product beyond use dating when sterility testing is not performed**

Beyond Use Dating

Risk Level	Room Temp	Refrigeration	Frozen (-25º to -10ºC)
Immediate Use	1 hour	1 hour	NA
Low risk w/ 12 hr BUD	12 hours (max)	12 hours (max)	NA
Low risk	48 hours	14 days	45 days
Medium risk	30 hours	9 days	45 days
High risk	24 hours	3 days	45 days

*different than manufacturer expiration, stability vs. sterility

Low Risk:

- ISO Class 5 or better air quality
- Simple aseptic manipulations using sterile non-hazardous products
- No more than 3 non-hazardous drugs including infusion solution; max 2 entries into any container
- Annual media fill test for personnel (assesses aseptic technique)

Low Risk Examples: 20 mEq KCl in 1 liter 0.9% sodium chloride; cefazolin 1 gm in 50 ml D5W

Low Risk with 12 hour or less Beyond Use Dating:

- ISO Class 5 or better air quality, NOT located in ISO 7 buffer area (clean room)

- Simple aseptic manipulations using sterile non-hazardous products
- No more than 3 non-hazardous drugs including infusion solution; max 2 entries into any container
- Maintain segregated compounding area; minimal traffic flow, no adjacent doors, windows, sinks
- Follow requirements for garbing, cleaning, personnel training, environmental and personnel testing (media-fill testing)
- Use within 12 hours of preparation or as recommended by manufacturer (whichever is less)
- Annual media fill test for personnel

Immediate Use Compounding:

- Intended for emergent or immediate patient use
- Simple aseptic manipulations using sterile non-hazardous products
- No direct exposure via contact contamination
- No more than 3 products including infusion solution; max 2 entries into any container
- Administration begins within 1 hour of start of prep
- Must be labeled if not administered by the person who prepared

Medium Risk:

- Multiple individual or small doses of sterile products are compounded or pooled to prepare a sterile product that will be administered either to multiple patients or to one patient on multiple occasions (i.e. prepare a batch)
- Complex aseptic manipulations
- CSP takes a long time to compound or go into solution
- Annual media fill test for personnel

Medium Risk Examples: TPNs, filling reservoirs of infusion devices with >3 sterile drug products where the air is removed from the reservoir prior to dispensing, transferring multiple vials or ampules to one or more final containers

High Risk:

- Starting with non-sterile ingredients or ingredients that have been exposed to worse than ISO 5 air for more than one hour (including commercially manufactured sterile products, CSPs without preservatives, sterile surfaces/devices used in prep, transfer, sterilization, and packaging of CSPs)
- Semiannual media fill test for personnel

High Risk Examples:
Dissolving non-sterile powder to make solution that will be terminally sterilized, ingredients, devices or components stored or exposed to air quality with less than ISO Class 5, using non-sterile devices before sterilization is performed

*Sterilization methods are defined in the standards (filtration, steam, dry heat)

Single-dose and Multi-dose Containers

- Multi-dose containers: 28 days or as specified by manufacturer after initial opening
- Single-dose containers: 6 hours or as specified by manufacturer in ISO Class 5 or cleaner air after initial opening
- Single-dose containers: Must be used within 1 hour and remaining contents discarded if opened in worse than ISO 5 air
- Opened ampuls cannot be stored for any period of time

Personnel Training & Competency Assessment

Must be able to present documentation of training and competence for all personnel who compound sterile products and those responsible for cleaning (whether pharmacy or environmental services/external cleaning service).

Initial competence assessment (prior to preparing CSPs for patients):

Personnel must complete didactic training, pass written and observational skills assessments, media fill, and glove fingertip sampling (x3) initially

- Reinstruction, reevaluation required if failure of any of above
- Documentation of corrective action for any failures

Must demonstrate competence of garbing, hand hygiene, and cleaning/disinfection procedures

Ongoing competence assessments:

Personnel training/competence documented annually for low/med risk, semiannually for high risk

- Media fills, glove fingertip test
- Hand hygiene, garbing, and aseptic technique
- Documentation of re-training, reevaluation if necessary

Personnel Hand Cleansing and Garbing

- Artificial nails are prohibited
- Staff with sunburn, rashes, conjunctivitis, and upper respiratory infections cannot prepare sterile compounds
- Remove outer garments (jackets, sweaters, lab coats), make-up, hand, wrist, and body jewelry and visible piercings above the neck

Garbing procedure (dirtiest to cleanest)

1. Apply shoe covers
2. Apply head and facial hair covers
3. Apply face mask
4. Fingernail cleansing then wash hands and forearms for 30 seconds and dry with hand dryer or non-shedding towels
5. Put on non-shedding gown closed at neck and snug at wrists
6. Enter buffer area and use waterless alcohol-based cleanser, rub until dry
7. Put on sterile powder-free gloves
8. Disinfect sterile gloves with Sterile 70% Isopropyl Alcohol after touching non-sterile surfaces during compounding

- Repeat garbing and hand hygiene when exposed to less than ISO 8 air or after direct contamination. Gowns may be reused during work shift if maintained in ISO 8 or better.

Facility Design & Environmental Monitoring

- Primary (hoods) and secondary (buffer and ante areas) engineering controls inspected every 6 months or if moved/altered; corrective actions documented
    - Total particle counts every 6 months (conforms within ISO class limits)
- Smoke study must demonstrate unidirectional airflow across critical site (sweeping action to avoid turbulence or stagnant air)
- Log room pressures daily or continuously; must maintain positive pressure between buffer and ante area and between ante area and general work environment
- Maintain at least 30 air changes per hour in non-hazardous prep areas
- Surfaces must be nonporous, smooth, non-shedding, impermeable, cleanable, and resistant to disinfectants (includes walls, ceilings, floors, furniture, fixtures, counters, cabinets, shelving, casters)
    - Ceiling tiles must be caulked
    - Lighting must be smooth and flush with ceiling
- No sinks (or water sources) in buffer area
- No cardboard boxes to minimize air particles
- Nothing in the buffer area that doesn't need to be there
- Periodic surface and air sampling

Cleaning and Disinfecting the Compounding Area

Hood	Beginning of each shift, before each batch, every 30 minutes during compounding, after spill or contamination
Counters, work surfaces, and floors	Daily (no mopping during aseptic operations)
Walls, ceiling, shelves	Monthly

- Cleaning agents, supplies, and procedures outlined in written SOP
    - Allow disinfectant to dry on surface prior to use
- Cleaning materials must be non-shedding and dedicated to clean room areas. Clean from buffer to ante (cleanest to dirtiest)
- Wipe down all items prior to placing into compounding area using sterile 70% Isopropyl Alcohol

Hazardous Drugs

- Occupational exposure risk must be minimized
- Storage separate from other inventory, preferably a negative pressure room
    - Must have adequate ventilation and at least 12 air changes per hour (ACPH)
- Prep in ISO 7 negative pressure room within ISO 5 BSC or CACI
    - Room must maintain $\geq$ 0.01 inch water column negative pressure to adjacent

positive pressure ISO 7 or better air; differential pressure logged daily
    - At least 30 ACPH
    - Optimally, BSC or CACI 100% vented to outside through HEPA filtration
- Recommend Closed System Transfer Device (CSTD)
    - Use of CSTD within BSC or CACI in non-negative pressure room ok for low volume (defined by BOP as less than 40 doses per month)
- Spill kits must be available
- Limited access to hazardous prep room – compounding personnel only
- Environmental sampling initially as a benchmark and every 6 months
    - Surface wipe sampling of BSCs, counter tops where prepared product placed, adjacent areas including floor
- Disposal of hazardous waste per state and federal regulations
- Personnel must be trained for storage, handling, and disposal initially and annually; maintain documentation
- Personnel must wear appropriate PPE including chemo gloves for receiving, distribution, stocking, inventorying, prep, and disposal
- Compounding personnel of reproductive capability shall confirm in writing that they understand the risks of handling hazardous drugs
- All personnel who dispose of or clean hazardous waste areas must be trained
- Resources to evaluate hazardous potential:
    - National Institute for Occupational Safety and Health (NIOSH) recommendations
    - Safety Data Sheets (SDS), previously MSDS
    - FDA approved product labeling
    - Correspondence from drug manufacturers, FDA, and other professional groups and organizations
    - Animal and human studies available in the published literature
    - Evidence-based recommendations from other facilities

Radiopharmaceuticals

- TJC - in house compounding is under the supervision of an appropriately trained pharmacist or physician (MM.05.01.07)
- Primary engineering control (hood) must be in an ISO Class 8 or better environment
- If applying 12 hour or less BUD (vs. immediate use), must have segregated compounding area with line of demarcation
- Generators must be eluted in ISO 8

Allergen Extracts

- Intradermal and SQ injections prepared by simple transfer of commercially available products – requirements not as stringent due to route, less health risk to patient
- Allergen compounding personnel still required to follow similar procedures (garbing, hand hygiene, aseptic technique) to minimize contamination
- MDV must be patient specific and be labeled with BUD and storage temp range
- SDV cannot be stored

- If allergen extract is non-preserved, all 797 rules apply based on risk level requirements

Quality Control

Ensure comprehensive P&P manuals, SOPs

Maintain complete and accurate records:

- Training and competence of staff including media fills
- Cleaning and environmental controls, sampling
- Compounding logs
- Independent contractor certification every 6 months
- Written confirmation of risk for personnel handling hazardous drugs

Apply accurate beyond use dating (BUD)

Visual inspection of all CSPs prior to dispensing

Validate accuracy and precision of automated compounding devices

Consider implementation of bar-coding and robotics

Outsourcing CSPs

Hospital may outsource (non-patient specific) compounding of sterile products to facilities such as PharMEDium. PharMEDium is registered with the U.S. Food and Drug Administration (FDA) as a 503B large-scale sterile compounding "outsourcing facility" under the recently enacted Drug Quality and Security Act (DQSA).

Resources:

1. **United States Pharmacopeia, Chapter <797> Pharmaceutical Compounding – Sterile Preparations, USP36-NF31 through Second Supplement, June 2013 (version adopted by FL BOP). http://floridaspharmacy.gov/Meetings/Agendas/2014/02-february/021014-comp-rules-agenda.pdf**

2. **NIOSH Hazardous Drug list: http://www.cdc.gov/niosh/docs/2014-138/**

3. **ISMP Sterile Compounding Summit: http://www.ismp.org/tools/guidelines/IVSummit/IVCGuidelines.pdf**

4. **OSHA Hazardous Drugs Rule & Work Precautions: https://www.osha.gov/SLTC/hazardousdrugs/index.html**

5. **Quick Links to manufacturers, products, and services**

   Compounding & USP797 Resources

   - **Controlled Environments; http://www.cemag.us/**
   - **Controlled Environment Testing Association; http://www.cetainternational.org/**
   - **Critical Point, Sterile Compounding Training; http://www.criticalpoint.info/boot-camp/**
   - **International Journal of Pharmaceutical Compounding; http://www.ijpc.com/**
   - **Pharmaceutics Laboratory, UNCCH; http://pharmlabs.unc.edu/**
   - **Pharmacy OneSource; http://www.pharmacyonesource.com/usp797-webinars/**
   - **Pharmacy Purchasing & Products Magazine; http://www.pppmag.com/UsingEquipfor797Standards.htm**

   Engineering Control Manufacturers (Laminar Airflow Workbenches and Barrier Isolators)

   - The Baker Company
   - Containment Technologies Group
   - Germfree Laboratories

   Closed System Transfer Devices

   - BBraun, OnGuard

- B-D, Phaseal
- Carefusion, Texium
- Hospira, LifeShield ChemoClave
- icumedical, ChemoLock

Quality Control Kits

- Valiteq
- Q. I. Medical

Culture Media

- Hardy Diagnostics

6. Outsourcing References

- **ASHP Guidelines on Outsourcing; http://www.ashp.org/DocLibrary/Bestpractices/MgmtGdlOutsourcingSterileComp.aspx**
- **Contractor Assessment Tool; http://www.ashpfoundation.org/MainMenuCategories/PracticeTools/SterileProductsTool/SterileProductsAssessmentTool.aspx**

7. ASHP Store

64B16-27.797 The Standards of Practice for Compounding Sterile Products.

The purpose of this section is to assure positive patient outcomes through the provision of standards for 1) pharmaceutical care; 2) the preparation, labeling, and distribution of sterile pharmaceuticals by pharmacies, pursuant to or in anticipation of a prescription drug order; and 3) product quality and characteristics. These standards are intended to apply to all sterile pharmaceuticals, notwithstanding the location of the patient (e.g., home, hospital, nursing home, hospice, doctor's office, or ambulatory infusion center).

(1) Adoption of the United States Pharmacopeia: Beginning on October 1, 2014, all sterile compounding shall be performed in accordance with the minimum practice and quality standards of the following chapters of the United States Pharmacopeia (USP):

(a) Chapter 797, Pharmaceutical Compounding-Sterile Preparations;

(b) Chapter 71, Sterility Tests;

(c) Chapter 85, Bacterial Endotoxins Test;

(d) Chapter 731, Loss on Drying.

All referenced chapters of the USP, in subsection (1) are specifically referring to the United States Pharmacopeia, 36th revision, Second Supplement, which is hereby incorporated and adopted by reference with the effective chapter dates of December 1, 2013. A subscription to all relevant chapters is available for purchase at www.uspnf.com. The Board has determined that posting the incorporated material on the Internet would constitute a violation of federal copyright law. At the time of adoption, the copyrighted incorporated material will be available for public inspection and examination, but may not be copied, at the Department of Health, 4052 Bald Cypress Way, Tallahassee, Florida 32399-3254 and at the Department of State, Administrative Code and Register

Section, Room 701, The Capitol, Tallahassee, Florida 32399-0250.

(2) Minimum Standards: The minimum practice and quality standards of the USP are adopted as the minimum standards to be followed when sterile products are compounded. However, nothing in this rule shall be construed to prevent the compounding of sterile products in accordance with standards that exceed the USP.

(3) Current Good Manufacturing Practices: The Board deems that this rule is complied with for any sterile products that are compounded in strict accordance with Current Good Manufacturing Practices per 21 U.S.C. § 351 (2012), adopted and incorporated herein by reference, available at https://www.flrules.org/gateway/reference.asp?NO=Ref-04436 and 21 C.F.R. Parts 210 and 211 (2013), adopted and incorporated herein by reference, available at http://www.flrules.org/Gateway/reference.asp?No=Ref-04437.

(4) Specific Exceptions to the United States Pharmacopeia:

(a) Although the USP requires the donning of gloves prior to entry into the clean-room, all required donning of gloves can be performed after entry into the clean-room to avoid contamination of the gloves from the door handle or access device leading into the clean-room.

(b) 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 (see Table 1) 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.

(c) USP Chapter 797 provides as follows in the "Facility Design and Environmental Controls" section: "An ISO Class 7 (see Table 1) buffer area and ante-area supplied with HEPA-filtered air shall receive an ACPH of not less than 30. The PEC is a good augmentation to generating air changes in the air supply of an area but cannot be the sole source of HEPA-filtered air. If the area has an ISO Class 5 (see Table 1) recirculating devise, a minimum of 15 ACPHs through the area supply HEPA filters is adequate, providing the combined ACPH is not less than 30. More air changes may be required, depending on the number of personnel and processes. HEPA-filtered supply air shall be introduced at the ceiling, and returns should be mounted low on the wall, creating a general top-down dilution of area air with HEPA-filtered make-up air. Ceiling-mounted returns are not recommended." Notwithstanding the quoted provision, pharmacies that meet the standards set forth in the section quotes as of the effective date of this rule are not required to change the location of supply air or return filters or ducts so long as the ISO standards are maintained.

Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.0155, 465.022 FS. History–New 6-18-08, Amended 1-7-10, 10-1-14.

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

Florida HEALTH
WWW.DOH.STATE.FL.US

STERILE COMPOUNDING

FILE#_____
INSPECTION#_____

☐ROUTINE ☐NEW ☐CURRENTLY NOT OPERATING ☐CHANGE OF LOCATION

INSPECTION AUTHORITY – CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456.069, FLORIDA STATUTES

NAME OF ESTABLISHMENT		PERMIT NUMBER	EXPIRATION DATE	DATE OF INSPECTION
DOING BUSINESS AS		TELEPHONE NUMBER	EXTENSION	
STREET ADDRESS	CITY	COUNTY	STATE	ZIP

DEA NUMBER	EXPIRATION DATE
PRESCRIPTION DEPARTMENT MANAGER NAME	LICENSE NUMBER
VENDORS	

COMPOUNDING PERSONNEL	MEDIA FILL AND ASSESSMENTS CURRENT
1	Yes ☐ No ☐
2	Yes ☐ No ☐
3	Yes ☐ No ☐
4	Yes ☐ No ☐
5	Yes ☐ No ☐
6	Yes ☐ No ☐

	LOW RISK	NA	YES	NO
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 media-fill tests are completed at least annually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	☐	☐	☐
4	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	NA	YES	NO
5	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]	☐	☐	☐
6	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]	☐	☐	☐
7	Medium Risk media-fill tests 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]	☐	☐	☐

	HIGH RISK	NA	YES	NO
8	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]	☐	☐	☐
9	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]	☐	☐	☐
10	High Risk Media-fill tests 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]	☐	☐	☐
11	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]	☐	☐	☐
12	Outsourced endotoxin testing results indicate that it is compliant with USP<85>. [BACTERIAL ENDOTOXINS TEST USP<85>]	☐	☐	☐
13	Is a USP<85> Endotoxin testing done on site? [BACTERIAL ENDOTOXINS TEST USP<85>]	☐	☐	☐
14	Endotoxin testing method is compliant? Indicate: Gel clot, chromogenic or turbidimetric? [BACTERIAL ENDOTOXINS TEST USP<85>]	☐	☐	☐
15	High Risk CSP's are within allowable limits for bacterial endotoxins. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Bacterial Endotoxin (Pyrogen) Testing]	☐	☐	☐
16	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]	☐	☐	☐
17	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]	☐	☐	☐
18	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]	☐	☐	☐
19	Dry heat ovens used for sterilization have HEPA 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]	☐	☐	☐
20	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]	☐	☐	☐

	HIGH RISK	NA	YES	NO
21	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]	☐	☐	☐
22	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]	☐	☐	☐
23	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]	☐	☐	☐
24	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]	☐	☐	☐
	IMMEDIATE USE COMPOUNDING	NA	YES	NO
25	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	NA	YES	NO
26	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]	☐	☐	☐
27	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]	☐	☐	☐
28	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]	☐	☐	☐
29	Single-dose ampules are discarded immediately after use. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	☐	☐	☐

	HAZARDOUS DRUGS	NA	YES	NO
30	Hazardous drug buffer room is at least 0.01 inch water column negative pressure with 30 ACPH of HEPA filtered air. [HAZARDOUS DRUGS AS CSPs]	☐	☐	☐
31	Personnel compounding hazardous drugs wear appropriate personal protective equipment. [HAZARDOUS DRUGS AS CSPs]	☐	☐	☐
32	Appropriate primary engineering controls (BSCs and CACIs) are used for concurrent personnel protection and exposure of critical sites. [HAZARDOUS DRUGS AS CSPs]	☐	☐	☐
33	Hazardous drugs are stored separately from other inventory in a manner to prevent contamination and personnel exposure. [HAZARDOUS DRUGS AS CSPs]	☐	☐	☐
34	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]	☐	☐	☐
35	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]	☐	☐	☐
36	Hazardous drugs are prepared in an ISO Class 5 environment with protective engineering controls in place, following aseptic practices specified for the appropriate contamination risk levels. [HAZARDOUS DRUGS AS CSPs]	☐	☐	☐
37	Access to hazardous drug preparation areas is limited to authorized compounding personnel. [HAZARDOUS DRUGS AS CSPs]	☐	☐	☐
38	A pressure indicator is installed and differential pressures are monitored and documented daily for hazardous buffer room. [HAZARDOUS DRUGS AS CSPs]	☐	☐	☐
39	Annual documentation of hazardous drug training of personnel regarding storage, handling, containment techniques and disposal of hazardous drugs is available. [HAZARDOUS DRUGS AS CSPs]	☐	☐	☐
40	Compounding personnel of reproductive capability have confirmed in writing that they understand the risks of handling hazardous drugs. [HAZARDOUS DRUGS AS CSPs]	☐	☐	☐
41	Facility maintains appropriate disposal containers for all hazardous waste. [HAZARDOUS DRUGS AS CSPs]	☐	☐	☐
	RADIOPHARMACEUTICALS	NA	YES	NO
42	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]	☐	☐	☐
43	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]	☐	☐	☐

	RADIOPHARMACEUTICALS	NA	YES	NO
44	Technetium-99m/Molybdenum-99 generators are eluted in ISO Class 8 conditions. [RADIOPHARMACEUTICALS AS CSPs]	☐	☐	☐
45	When compounding activities require the manipulation of a patient's blood-derived or other biological material (e.g., radiolabeling a patient's or a donor's white blood cells), 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]	☐	☐	☐
	FACILITY DESIGN AND CERTIFICATION	NA	YES	NO
46	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]		☐	☐
47	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]	☐	☐	☐
48	Primary engineering controls provide unidirectional (i.e., laminar) HEPA air at a velocity sufficient to prevent airborne particles from contacting critical sites. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]		☐	☐
49	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]		☐	☐
50	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. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	☐	☐	☐
51	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]	☐	☐	☐
52	Primary engineering controls for nonhazardous and nonradioactive CSPs are located in buffer areas, except for CAIs that 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]		☐	☐
53	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]	☐	☐	☐
54	All HEPA filters are leak tested after installation and every six months thereafter. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]		☐	☐

	FACILITY DESIGN AND CERTIFICATION	NA	YES	NO
55	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]	☐	☐	☐
56	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]	☐	☐	☐
57	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]	☐	☐	☐
58	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]	☐	☐	☐
59	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]	☐	☐	☐
60	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]	☐	☐	☐
61	Carts are made of stainless steel wire, or nonporous plastic, or sheet metal construction with good quality, cleanable casters. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	☐	☐	☐
62	Storage shelving, counters, and cabinets in the buffer area are smooth, impervious, free from cracks and crevices, non-shedding, cleanable, and disinfectable. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	☐	☐	☐
63	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	NA	YES	NO
64	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]		☐	☐
65	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]		☐	☐
66	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]	☐	☐	☐
67	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]	☐	☐	☐

	QUALITY AND CONTROL	NA	YES	NO
68	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]	☐	☐	☐
69	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]		☐	☐
70	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]		☐	☐
71	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]	☐	☐	☐
72	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]		☐	☐
73	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]		☐	☐
74	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]		☐	☐
75	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]	☐	☐	☐
76	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]	☐	☐	☐
77	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]	☐	☐	☐
78	Shelving, walls, and ceilings in ante-areas are cleaned and disinfected at least monthly. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	☐	☐	☐
79	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]		☐	☐

	QUALITY AND CONTROL	NA	YES	NO
80	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]	☐	☐	☐
81	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]	☐	☐	☐
82	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]	☐	☐	☐
83	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]	☐	☐	☐
	PERSONNEL CLEANSING, GARBING & COMPETENCY EVALUATION	**NA**	**YES**	**NO**
84	Personnel preparing CSP's are free from rashes, sunburn, weeping sores, conjunctivitis, and active respiratory infections. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	☐	☐	☐
85	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]	☐	☐	☐
86	Facility has adequate supplies to meet PPE requirements of USP<797>. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	☐	☐	☐
87	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]	☐	☐	☐
88	Sterile gloves are donned in the buffer room 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]	☐	☐	☐
89	Gloves are routinely disinfected with sterile 70% IPA after contacting nonsterile objects. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	☐	☐	☐
90	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 workshift. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	☐	☐	☐
91	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]	☐	☐	☐

	PERSONNEL CLEANSING, GARBING & COMPETENCY EVALUATION	NA	YES	NO
92	Documentation indicates compounding personnel have successfully completed didactic training, passed written competency assessments, undergone skill assessment using observational audit tools, and media-fill testing 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]		☐	☐
93	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. 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]	☐	☐	☐
94	Corrective action is documented for compounding personnel who fail written tests or media-fill test. [PERSONNEL TRAINING AND EVALUATION IN ASEPTIC MANIPULATIONS SKILLS]	☐	☐	☐
95	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]	☐	☐	☐
96	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]		☐	☐
97	Compounding personnel are visually observed annually or semiannually (high risk) during the process of performing hand hygiene, garbing procedures and aseptic technique. The visual observation is documented on a form for Assessing Hand Hygiene, Garbing and Aseptic Technique and maintained to provide a permanent record. [ENVIRONMENTAL QUALITY AND CONTROL : Garbing and Gloving Competency Evaluation]		☐	☐
98	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]	☐	☐	☐
99	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	NA	YES	NO
100	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]		☐	☐
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]	☐	☐	☐

	VERIFICATION	NA	YES	NO
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]	☐	☐	☐
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	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]		☐	☐
	DISPENSING/DISTRIBUTION	NA	YES	NO
108	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]	☐	☐	☐
109	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]	☐	☐	☐
110	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]	☐	☐	☐
	USP <71> STERILITY TESTING	NA	YES	NO
111	Outsourced sterility testing results indicate that it is compliant with USP<71>. [STERILITY TEST USP<71>]	☐	☐	☐
112	Outsourced: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	☐	☐	☐
113	Outsourced: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	☐	☐	☐
114	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]	☐	☐	☐

	USP <71> STERILITY TESTING	NA	YES	NO
115	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]	☐	☐	☐
116	On site: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	☐	☐	☐
117	On site: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	☐	☐	☐
118	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]	☐	☐	☐
119	On site: A USP<71> method suitability test has been done with appropriate inoculum, additives and rinses. [STERILITY TEST USP<71> : Method Suitability Test]	☐	☐	☐
120	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]	☐	☐	☐
121	On site: FTM is incubated at 30-35 C for 14 days (2 incubators present). [STERILITY TEST USP<71> : Culture Media and Incubation Temperatures]	☐	☐	☐
122	On site: Sterility testing is documented including lot numbers and expiration dates of media. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	☐	☐	☐
123	Sterility testing reports are reviewed and appropriate actions taken and documented. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	☐	☐	☐
	MISCELLANEOUS	NA	YES	NO
124	Facility engaged in office use sterile compounding for human use is registered with FDA as an outsourcing facility. [FAC 64B16-27.700 (3)(g]	☐	☐	☐
125	Compounding records are properly maintained. [FAC 64B16-28.140(4)]	☐	☐	☐

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.

PRINT NAME OF RECIPIENT _____

_____ _____ _____

INSTITUTIONAL REPRESENTATIVE DATE INVESTIGATOR/SR. PHARMACIST SIGNATURE

INV 797 REVISED 10/14, 12/12, 12/11 CREATED 8/11

IV Drug Therapy in the Nursing Home

1. Current demand for IV therapy in the Nursing Home
   Less than before the Prospective Payment System started but most nursing homes do some IV therapy.

2. Policy regarding the use of IV's - often a completely separate P&P manual

   a. Who may administer IVs in Florida?
   RN's, LPN's, and the Director Of Nursing. Nurses require certification training before being allowed to administer IV drugs

   b. Training required
   The vendor Pharmacy may be asked to provided IV certification programming for the nursing staff. This is typically a 32 hour training program provided by a nurse specializing in IV therapy. There are several companies throughout the state that provided IV training and IV start services for a fee

   c. Who should mix IVs?
   Whenever possible IV's should be prepared by the Pharmacist in a laminar flow hood. There may be times when Baxter Plus or Abbott's Add-Vantage system can be mixed on the nursing unit

   d. Flexible bag IV solutions have a shortened expiration date after removing the manufacturer's "overwrap" packaging

   50 ml of less size - expires in 15 to 21 days
   100 ml or greater – expires in 30 days

Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings

Warning!

Working with or near hazardous drugs in health care settings may cause skin rashes, infertility, miscarriage, birth defects, and possibly leukemia or other cancers.

Health care workers who work with or near hazardous drugs may be exposed to these agents in the air or on work surfaces, clothing, medical equipment, or patient urine or feces. Hazardous drugs include those used for cancer chemotherapy, antiviral drugs, hormones, some bioengineered drugs, and other miscellaneous drugs (see Appendix A of *NIOSH Alert: Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings for a List of Hazardous Drugs*). The health risk depends on how much exposure a worker has to these drugs and how toxic they are.

Health care workers should take the following steps to protect themselves from hazardous drugs:

- Read all information and material safety data sheets (MSDSs) your employer provides to you for the hazardous drugs you handle.

- Participate in any training your employer provides on the hazards of the drugs you handle and the equipment and procedures you should use to prevent exposure.

- Be familiar with and able to recognize sources of exposure to hazardous drugs. Sources of exposure include

  — all procedures involving hazardous drugs (including preparation, administration, and cleaning), and

  — all materials that come into contact with hazardous drugs (including work surfaces, equipment, personal protective equipment [PPE], intravenous [IV] bags and tubing, patient waste, and soiled linens).

- Prepare hazardous drugs in an area that is devoted to that purpose alone and is restricted to authorized personnel.

- Prepare hazardous drugs inside a ventilated cabinet designed to protect workers and others from exposure and to protect all drugs that require sterile handling.

- Use two pairs of powder-free, disposable chemotherapy gloves, with the outer one covering the gown cuff whenever there is risk of exposure to hazardous drugs.

- Avoid skin contact by using a disposable gown made of polyethylene-coated polypropylene material (which is nonlinting and nonabsorbent). Make sure the gown has a closed front, long sleeves, and elastic or knit closed cuffs. Do not reuse gowns.

- Wear a face shield when splashes to the eyes, nose, or mouth may occur and when adequate engineering controls (such as the sash or window on a ventilated cabinet) are not available.

- Wash hands with soap and water immediately before using personal protective clothing (such as disposable gloves and gowns) and after removing it.

- Use syringes and IV sets with Luer-LokTM fittings for preparing and administering hazardous drugs.

- Place drug-contaminated syringes and needles in chemotherapy sharps containers for disposal.

- When supplemental protection is needed, use closed-system drug-transfer devices, glove bags, and needleless systems inside the ventilated cabinet.

- Handle hazardous wastes and contaminated materials separately from other trash.

- Clean and decontaminate work areas before and after each activity involving hazardous drugs and at the end of each shift.

- Clean up small spills of hazardous drugs immediately, using proper safety precautions and PPE.

- Clean up large spills of hazardous drugs with the help of an environmental services specialist.

Employers of health care workers should take the following steps to protect their workers from exposure to hazardous drugs:

- Make sure you have written policies about the medical surveillance of health care workers and all phases of hazardous drug handling—including receipt and storage, preparation, administration, housekeeping, decontamination and cleanup, and disposal of unused drugs, contaminated spills, and patient wastes.

- Seek input from workers who handle hazardous drugs when developing these policies and other programs to prevent exposures.

- Prepare a written inventory of all hazardous drugs used in the workplace, and establish a procedure for regular review and updating of this inventory.

- Train workers to recognize and evaluate hazardous drugs and to control exposure to them.

- Provide workers who handle or work near hazardous drugs with appropriate information and MSDSs.

- Provide a work area that is devoted solely to preparing hazardous drugs and is limited to authorized personnel.

- Do not permit workers to prepare hazardous drugs using laminar-flow work stations that move air from the drug toward the worker.

- Provide and maintain ventilated cabinets designed to protect workers and others from exposure to hazardous drugs and to protect all drugs that require sterile handling. Examples of ventilated cabinets include biological safety cabinets (BSCs) and containment isolators designed to prevent hazardous drugs from escaping into the work environment.

- Filter the exhaust from ventilated cabinets with high-efficiency particulate air filters (HEPA filters). Make sure these cabinets are exhausted to the outdoors wherever feasible—well away from windows, doors, and other air-intake locations. Consider providing supplemental equipment to protect workers further—for example, glove bags, needleless systems, and closed-system drug-transfer devices.

- Establish and oversee appropriate work practices for handling hazardous drugs, patient wastes, and contaminated materials.

- Provide workers with proper PPE on the basis of a risk assessment and train workers how to use it—as required by the Occupational Safety and Health Administration (OSHA) PPE standard [29 CFR* 1910.132]. PPE may include chemotherapy gloves, nonlinting and nonabsorbent disposable gowns and sleeve covers, and eye and face protection.

- Ensure the proper use of PPE by workers.

- Use NIOSH-certified respirators [42 CFR 84].
  Note: Surgical masks do not provide adequate respiratory protection.

- Provide syringes and IV sets with Luer-LokTM fittings for preparing and administering hazardous drugs. Also provide containers for their disposal.

- Consider using closed-system drug-transfer devices and needleless systems to protect nursing personnel during drug administration.

- Periodically evaluate hazardous drugs, equipment, training effectiveness, policies, and procedures in your workplace to reduce exposures as much as possible.

- Comply with all relevant U.S. Environmental Protection Agency/Resource Conservation and Recovery Act (EPA/RCRA) regulations related to the handling, storage, and transportation of hazardous waste.

*Code of Federal Regulations.

For additional information, see *NIOSH Alert: Preventing Occupational Exposures to Antineoplastic and other Hazardous Drugs in Health Care Settings* [DHHS (NIOSH) Publication No. 2004–165]. Single copies of the Alert are available from the following:

NIOSH—Publications Dissemination
4676 Columbia Pkwy
Cincinnati, OH 45226–1998

Telephone: 1–800–35–NIOSH (1–800–356–4674) Fax: 1–513–533–8573
E-mail: pubstaft@cdc.gov

or visit the NIOSH Web site at www.cdc.gov/NIOSH

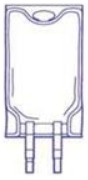
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

Printer friendly version: Summary of Worker/Employer Recommendations (PDF, 3 pages, 129kb)

EXAMPLES OF ABBREVIATED DISCARD DATES WHEN THE OUTER WRAP IS REMOVED

DRUG DELIVERY SYSTEMS

Mini-Bag™



Sodium Chloride (NaCl) Injections in Mini-Bag™ Containers

0.9% Sodium Chloride Injection, Multi-Pack (16 x Mini-Bags / pouch)

catalogue number	container type	size (mL)	mmol / L	pH (range)	mOsmol / L (calc)	stability	stability out of wrap	units / case
JB1308M	Viaflex®	50	NA 154, Cl 154	5.0 (4.5 7.0)	308	18 mos	15 days	96
JB1309M	Viaflex®	100	Na 154, Cl 154	5.0 (4.5 7.0)	308	18 mos	30 days	96

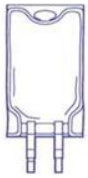
0.9% Sodium Chloride Injection, Quad Pack (4 x Mini-Bags / pouch)

catalogue number	container type	size (mL)	mmol / L	pH (range)	mOsmol / L (calc)	stability	stability out of wrap	units / case
JB1300	Viaflex®	25	Na 154, Cl 154	5.0 (4.5 7.0)	308	9 mos	15 days	144
JB1301P	Viaflex®	50	Na 154, Cl 154	5.0 (4.5 7.0)	308	12 mos	15 days	96
JB1302P	Viaflex®	100	Na 154, Cl 154	5.0 (4.5 7.0)	308	12 mos	30 days	96

3.3% Dextrose and 0.3% Sodium Chloride Injection (2/3 & 1/3), Quad Pack (4 x Mini-Bags / pouch)

catalogue number	container type	size (mL)	mmol / L	pH (range)	mOsmol / L (calc)	stability	stability out of wrap	units / case
JB1001P	Viaflex®	50	Na 51, Cl 51	4.0	269	18 mos	15 days	96
JB1002P	Viaflex®	100	Na 51, Cl 51	4.0	269	24 mos	30 days	96

Mini-Bag™



Dextrose (D5W) Injections in Mini-Bag™ Containers

5% Dextrose Injection, Quad Pack (4 x Mini-Bags / pouch)

catalogue number	container type	size (mL)	pH (range)	mOsmd / L (calc)	stability	stability out of wrap	units / case
JB0080	Viaflex®	25	4.0 (3.2 6.5)	252	18 mos	15 days	144
JB0081P	Viaflex®	50	4.0 (3.2 6.5)	252	18 mos	15 days	96
JB0082P	Viaflex®	100	4.0 (3.2 6.5)	252	24 mos	30 days	96

5% Dextrose Injection, Multi-Pack (16 x Mini-Bags / pouch)

catalogue number	container type	size (mL)	pH (range)	mOsmd / L (calc)	stability	stability out of wrap	units / case
JB0088M	Viaflex®	50	4.0 (3.2 6.5)	252	18 mos	15 days	96
JB0089M	Viaflex®	100	4.0 (3.2 6.5)	252	18 mos	30 days	96