**Alabama State Board of Pharmacy**
**111 Village Street**
**Hoover, Alabama 35242**
**(205) 981-2280**

# STERILE COMPOUNDING/NUCLEAR INSPECTION

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| **Name of Pharmacy** | | **Corporate Name if different** | | **Al. license number** |
| **Street Address** | | **Street Address additional** | | **DEA Number** |
| **City** | **State** | **Zip** | **County** | |
| **Phone number** | **FAX number** | | **Owner** | |
| **Pharmacist-in-charge** | **email** | | | **license** |
| **Case Number** | **Inspection type (drop-down)** | **Status (drop-down)** | | **Date** |
| | **Inspection type (drop-down)** | **Status (drop-down)** | | **Date** |

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| **Risk levels used:** | | **LOW MEDIUM HIGH 12 HOUR/LOW RISK EMERGENT** |
| **Products:** | | **Injectable Ophthalmic Nasal Irrigation Baths Other** |
| **Special categories:** | | **Hazardous Nuclear Other** |
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| **STANDARDS FOR ALL STERILE COMPOUNDING** | **YES** | **COMMENT** |
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| **Compounded drugs are only dispensed pursuant to a prescription or chart order. Products prepared for specific patient and delivered to patient, patient's representative or to physician to administer to specific patient.** | | |
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| **Pharmacy prepares and sells products on invoice to a practitioner without product being intended for specific patient--manufactures** | | |
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| **Policy manual to outline and explain all components of operation of the sterile compounding pharmacy. Documentation** | | |
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| **All pharmacists and technicians hold active registration with the Alabama Board of Pharmacy. Attached appendix Documentation** | | |
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| **All personnel who compound sterile products have received initial training and competency testing in proper sterile methods and compounding techniques. Documentation** | | |

| All personnel who clean in the buffer or ante rooms have been trained to do so. Documentation | YES | COMMENTS |
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| Compounding personnel shall perform didactic review and pass written tests annually for low or medium compounding; and semiannually for high risk compounding. Documentation | | |
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| **DESIGN STANDARDS FOR STERILE COMPOUNDING** | **YES** | **COMMENTS** |
| Designated separate buffer area and ante area for low or medium risk, but wall not required. Buffer room and ante areas must be separated by wall for high risk or hazardous products. | | |
| Ceilings, walls, floors, fixtures, shelving, counters, cabinets in buffer area to be smooth, impervious, free from cracks and crevices and non-shedding. Also resistant to disinfectants | | |
| Floors in both buffer and ante areas are 1 piece or sealed pieces, coved at wall, smooth. NO rugs | | |
| Walls are smooth: epoxy-coated gypsum or heavy gauged polymer which lock together and are sealed | | |
| Inlaid ceiling tiles are impregnated with polymer and caulked around perimeter to seal to support frame. | | |
| Junction of wall to ceiling is coved or caulked to avoid cracks or crevices. | | |
| No dust collecting overhangs, ledges or other items hanging from ceilings or walls. | | |
| Ceiling lighting surfaces are smooth, mounted flush and sealed | | |
| No sources of water or floor drains in buffer area | | |
| Work surfaces to be smooth, impervious materials such as stainless steel or molded plastic, easily cleaned and disinfected | | |
| Storage shelving, counters and cabinets to be smooth, impervious materials free of cracks or crevices, non-shedding, easily cleaned and disinfected | | |
| The buffer area shall maintain at least ISO Class 7 conditions for 0.5 mcg and larger particles under dynamic operating conditions. The room shall be segregated from surrounding, unclassified spaces to reduce the risk of contaminants being blown, dragged, or otherwise introduced into the filtered unidirectional airflow environment, and this segregation shall be continuously monitored. (ISO 8 for nuclear) | | |
| Primary engineering control (LAFH, BSC, CAI or CACI) in an ISO 7 environment. (ISO 8 for radiopharmaceuticals). Not required for 12-hour, low risk. | | |
| **Iso 5, 3,520 part/$m^3$ , Max 1 CFU**<br>**Iso 7, 352,000 part/$m^3$, Max 10 CFU**<br>**Iso 8, 3,520,000 part/$m^3$ Max 100 CFU** | | |
| Only authorized personnel and materials required for compounding and cleaning allowed in buffer area. | | |

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| **Facilities should maintain a well-lighted work environment with a temperature at or below 20 degrees C. Documentation** | | |
| **HEPA filtered air flow into ante and buffer areas should be from top of wall and air returns should be near floor.** | **YES** | **COMMENTS** |
| **Air flow from HEPA filtered HVAC to move between buffer and ante areas at minimum of 0.2 meters/sec or 40 ft./minute. This is for buffer and ante areas not separated by a wall.** | | |
| **Velocity meter required at point marking separation of buffer from ante areas in rooms without a wall separating the buffer and ante areas** | | |
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| **DESIGN STANDARDS FOR COMPOUNDING AREAS** | **YES** | **COMMENTS** |
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| **Buffer room to have 30 air exchanges per hour (ACPH). [CFM X 60/(width x depth x height of room in feet)] = ACPH. CFM is cubic feet of air supplied per minute by HVAC. Should be in HVAC specifications. For walled-off buffer rooms** | | |
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| **Primary Engineering Controls (PEC)** | | |
| **PECs shall be placed in an ISO 7 environment, unless in radiopharmaceutical compounding, or 12 hour low risk compounding. Compounding Aseptic Isolators (CAI) or Compounding Aseptic Containment Isolators (CACI) may be placed in less than ISO 8 environments, if manufacturers provide documentation that the isolator meets such specifications.** | | |
| **PEC may not be turned off unless it will remain off for 8 or more hours.** | | |
| **PEC (hood) located out of traffic patterns away from air currents. Also placed in the room in a manner to prevent disruption to air flow and prevent disruption from the HVAC system, and room cross-drafts.** | | |
| **PEC shall be cleaned and allowed to operate for a minimum of 30 minutes when restarted before any sterile compounding takes place. Only 1 person allowed in buffer room during that time.** | | |
| **Surfaces within the PEC and intimate to the exposure of critical sites are to be cleaned and disinfected at the beginning of each work shift; Direct Compounding Areas within PEC to be cleaned before each batch preparation and every 30 minutes during continuous compounding periods, plus when there are spills or surface contamination.** | | |
| **All Primary engineering controls (hoods, glove boxes, biologic safety cabinets, compounding aseptic isolators (CAI) or compounding aseptic containment isolators (CACI)) must be inspected and certified on schedule. PECs used for low, medium, or 12-hour low risk compounding, must be recertified every 12 months. PECs used for high risk or hazardous product compounding must be recertified every** | | |

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| **6 months.** | | |
| **PECs must be recertified when moved .** | | |
| **CLEANING OF COMPOUNDING AREAS** | | |
| **General** | **YES** | **COMMENTS** |
| **Before compounding in PEC, or after a spill, direct compounding environment may be cleaned with USP purified water, and then should be disinfected with non-residue-generating agent using a non-linting wipe.** | | |
| **All cleaning materials are non-shedding. These materials are only for use in described areas and may not be removed from areas.** | | |
| **If reused, there must be manufacturer evidence of effectiveness and that bioburden is not increased with reuse.** | | |
| **Supplies and equipment removed from shipping cartons shall be wiped with a disinfecting agent before entering the buffer area.** | | |
| **Carts used in the ante area, may not enter buffer area. Buffer room carts should not enter ante area, unless being cleaned and disinfected.** | | |
| **Outer sealed pouches for sterile supplies are to be removed as supplies are introduced into the buffer area. These items do not need to be wiped with disinfectant.** | | |
| **Frequently used items are decontaminated and stored in the ante area.** | | |
| **Daily** | | |
| **Floors in buffer area and ante–area are cleaned by mopping with a cleaning and disinfecting agent once daily at a time when no aseptic operations are in progress. LOG** | | |
| **Counters and easily cleanable surfaces cleaned daily. LOG** | | |
| **Supplies used for daily planned compounding are wiped with disinfecting agent and brought into buffer area. Supplies used to support such compounding may be wiped down and stored on shelves in buffer area. Such supplies are to be kept to a minimum.** | | |
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| **Monthly** | | |
| **Monthly cleans walls, ceilings, storage shelving of ante and buffer areas. LOG** | | |
| **Record of cleaning/calibration/maintenance of automated compounding devices LOG** | | |
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| **FUNCTIONING WITHIN COMPOUNDING AREAS** | **YES** | **COMMENTS** |
| **Nonessential items which shed particles shall not be brought into the buffer area.** | | |
| **While compounding, supplies in PEC should be minimized to those required for present operation, and should be placed to minimize clutter and increase efficiency.** | | |
| **Sterile, non-shedding alcohol wipes are used to wipe entry points of vials, bottles, bags, and ampule necks. Wait at least 10 seconds before entry.** | | |
| **Critical sites should always have benefit of HEPA filtered First Air.** | | |
| **Practitioner must not bring an exposed critical surface into 6 inch front of hood.** | | |
| **Practitioner must not block first air when compounding.** | | |
| **Gloves must be cleaned with 70% sterile IPA at least every 30 minutes.** | | |
| **After preparation, CSP is mixed and checked for defects or signs of particulate matter.** | | |
| **All products being compounded or stored must be properly labeled and dated.** | | |
| **Practitioner should function with the understanding that the primary cause of compounding contamination of sterile products is human touch.** | | |
| **Supplies are so arranged in the PEC that a clear, uninterrupted path of HEPA-filtered air will bathe all critical sites at all times during the planned procedures. Nothing may block first air from the HEPA filter and an exposed critical site.** | | |
| **Finished products individually receive a physical inspection** | | |
| **All products receive visual inspection, review of label and review of compounding process. All compounds checked by a pharmacist.** | | |
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| **SINGLE AND MULTI-DOSE CONTAINERS** | | **COMMENTS** |
| **Closed, sealed, multidose containers (contain preservative) have a BUD of 28 days once entered, unless otherwise specified by manufacturer.** | | |
| **Closed, sealed, single dose containers (no preservative) have a BUD of 6 hours once entered if remain in an ISO 5 environment** | | |
| **Closed, sealed, single dose containers have a BUD of 1 hour once entered, if entered in less than ISO 5 environment** | | |
| **Ampules are always single use and may never be saved or stored** | | |

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| **Preserved solutions lose their 28 day BUD if removed from original container and placed in a syringe or other container.** | | |
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| **PERSONNEL CLEANSING AND GARBING** | **YES** | **COMMENT** |
| **Before entering buffer area, staff is to remove outer jackets, sweaters, bandanas, coats, hats, piercings, cosmetics and jewelry.** | | |
| **Nails are to be short and neat, with no polish, extenders or adornments** | | |
| **Garbing for buffer area: start in ante-room**<br>**Shoe coverings**<br>**Hair and facial hair coverings**<br>**Mask**<br>**Wash hands to elbow for 30 seconds**<br>**Don cuffed gown**<br>**Enter buffer room without touching door or entry way;**<br>**Wash hands with gel, waterless alcohol**<br>**Don sterile gloves** | | |
| **No chewing gum, drinks, snacks or food are not allowed in the ante-area or the buffer area.** | | |
| **Garbing procedures are not required for immediate use sterile products, or for glove boxes for which manufacturers have provided tested documentation that such garbing is not needed to maintain sterility . (USP appendix 1)** | | |
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| **QUALITY TESTING and DOCUMENTATION** | **YES** | **COMMENTS** |
| **ISO 5, 7 and 8 areas checked by qualified individual for particle counts at least every 6 months. Non-viable Particle count must be verified no less than every 6 months; as part of commissioning and certification of new facilities; following servicing of facilities and equipment; and in response to problems with end products or staff technique. Documentation** | | |
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| **Required training for new employees and annually for all who do sterile compounding. Documentation** | | |
| **Pressure gauge between separated buffer and ante area if these two are physically separated by a wall and another pressure gauge between the ante-room and the general pharmacy. Readings should be recorded at least daily or by continuous reading device. Pressure should be no less that 5Pa (0.02 inch water column) positive pressure of buffer room over ante room and positive pressure of ante room over general pharmacy. Documentation** | | |
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| **For non-separated buffer and ante areas, a velocity meter shall be placed at junction of buffer area and ante room to determine airflow between the two areas. Air velocity between areas at minimum of 0.2** | | |

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| **meters/sec or 40 ft./minute. Measure each shift, minimum daily. Documentation** | | |
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| **QUALITY TESTING and DOCUMENTATION** | **YES** | **COMMENTS** |
| **For areas dependent on the displacement concept, (described in item above) there must be a minimum of 30 complete air changes per hour. The PEC may contribute only 15 of those air exchanges; the rest must come from the air handling system. Documentation** | | |
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| **All who compound have passed fingertip test before being allowed to compound and every 12 months thereafter for low and medium risk compounding. Documentation** | | |
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| **All employees who compound have passed media fill test before being allowed to compound and every 12 months thereafter for low and medium risk compounding. Documentation** | | |
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| **Viable air sampling should occur at various points throughout all ISO areas at least every 6 months. Samples should be collected from areas of high activity, such as staging, labeling, gowning, and compounding. Attention to high risk areas such as entrance areas, and areas around hoods. Volumetric collection methods are preferred, and impaction over settling. Documentation** | | |
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| **Surface sampling shall be performed in all ISO classified areas on a periodic basis.** | | |
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| **Must keep a daily record of accuracy assessment and weekly review for automated compounding devices** | | |
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| **High risk/hazardous**<br>**All employees who compound have passed fingertip test before being allowed to compound and every 6 months thereafter for high risk and hazardous product compounding. Documentation** | | |
| **High risk/hazardous**<br>**All employees who compound have passed media fill test before being allowed to compound and every 6 months thereafter for high risk and hazardous product compounding. Documentation** | | |
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| **Quantitative stability-indicating chemical assay is recommended to ensure compounding accuracy, especially with a narrow therapeutic plasma concentration range. Documentation** | | |
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| **STANDARDS for HAZARDOUS PRODUCT COMPOUNDING** | **YES** | **COMMENT** |
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| **All staff who compound must pass both a finger-tip test and a media fill test before starting work and every 6 months thereafter.** | | |
| **All persons involved with preparation of hazardous products must receive training on compounding with hazardous products before beginning such compounding. Each person at an age of ability to reproduce, must sign informed consent statement. <u>Documentation</u>** | | |
| **All staff who work with hazardous products must be trained about any new hazardous product which is going to be used within facility. <u>Documentation</u>** | | |
| **No one to be in buffer room other than those involved in compounding.** | | |
| **Hazardous product spill kit available in all areas that prepare or use or store hazardous products** | | |
| **All sharps are disposed of in a yellow, hazardous product sharps container, and container is kept closed. (Special containers for excess drug)** | | |
| **All non-sharps products used in compounding hazardous products are disposed of in a red bag or hazardous product disposal container and container is kept closed.** | | |
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| **All hazardous product compounding is done in an ISO 5 environment with protective engineering controls (vertical flow hood, or a biological safety cabinet, or a CACI—Compounding Aseptic Containment Isolator)** | | |
| **The ISO 5 compounding device shall be in an ISO 7 environment that is physically separated (walled off) from other compounding areas.** | | |
| **ISO 5 device (PEC) must be vented outside building.** | | |
| **ISO 5 device must have HEPA filter certified every 6 months** | | |
| **The ISO 7 compounding area must have a negative pressure (no less than 0.01 inch water column) relative to adjacent areas. Pressure device at door to record pressure difference.** | | |
| **Air from negative pressure room must be expelled outside building.** | | |
| **The ante-area for hazardous product compounding must be ISO 7, since this air will be pulled into the buffer area.** | | |
| **If a CACI is used outside a buffer area, the compounding area shall maintain a minimum negative pressure of 0.01 inch water column and have a minimum of 12 ACPHs.** | | |
| **<u>Exception:</u> When closed-system transfer devices are used, they shall be used in an ISO 5 environment. If preparing a low volume of** | | |

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| **hazardous drugs, the use of two tiers of containment in a non-negative pressure room is acceptable.** | | |
| **STANDARDS for HAZARDOUS PRODUCT COMPOUNDING** | **YES** | **COMMENT** |
| **Hazardous products should be stored separately from other inventory in a manner to prevent contamination and personnel exposure.** | | |
| **Once opened, hazardous products must be stored in a negative pressure environment, with 12 air exchanges per hour.** | | |
| **Anyone who receives, distributes, stocks, inventories, prepares or disposes of hazardous drugs must wear chemo gloves and gown.** | | |
| **All compounded hazardous products must be labeled as hazardous products.** | | |
| **A PEC used for compounding hazardous products may not be used for compounding of nonhazardous products.** | | |
| **Compounding of non-hazardous drugs may not take place in a buffer room which is used for compounding of hazardous products.** | | |
| **All products should be wiped down after compounding and before leaving PEC** | | |
| **Staff are to wash hands after compounding and removing gloves** | | |
| **Staff must wear 2 pairs of sterile chemo-type gloves when compounding.** | | |
| **Staff must wear a mask when doing sterile compounding** | | |
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| **STANDARDS HIGH RISK COMPOUNDING** | **YES** | **COMMENT** |
| **There must be a wall between the buffer room and the ante room.** | | |
| **Hoods and other ISO 5 devices (PECs) must be recertified every 6 months** | | |
| **All staff who compound must pass both a finger tip test and a media fill test every 6 months** | | |
| **No one to be in buffer room other than those involved in compounding. Minimize traffic in and out of buffer room** | | |
| **Pre-sterilization procedures (weighing, mixing) to be performed in no less than ISO 8 environment.** | | |
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| **High risk**<br>**High risk products require sterility testing if prepared in a batch of 25 or more, or in multiple dose vials for administration to multiple patients. Documentation** | | |
| **High risk**<br>**High risk products exposed longer than 12 hours to temperatures of 2C to 8C. before being sterilized require sterility testing. Documentation** | | |
| **High risk**<br>**High risk products exposed longer than 6 hours to temperatures of higher than 8C before being sterilized require sterility testing. Documentation** | | |
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| **High risk**<br>**High risk products require pyrogen testing if prepared in a batch of 25 or more, or in multiple dose vials for administration to multiple patients. Documentation** | | |
| **High risk**<br>**High risk products exposed longer than 12 hours to temperatures of 2C to 8C. before being sterilized require pyrogen testing. Documentation** | | |
| **High risk**<br>**High risk products exposed longer than 6 hours to temperatures of higher than 8C before being sterilized require pyrogen testing. Documentation** | | |
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| **Sterile filters used to sterilized CSPs shall be pyrogen free and have a nominal porosity of 0.2 or 0.22 µm.** | | |
| **The accuracy of identities, concentrations, amounts and purities of ingredients in CPSs shall be confirmed.** | | |
| **Staff should determine that filters have sufficient capacity for required volume and to filter quickly without replacement.** | | |

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| **Filter shall undergo integrity test such as bubble point test.** | | |
| **STANDARDS HIGH RISK COMPOUNDING** | **YES** | **COMMENT** |
| **Steam sterilization shall occur at a temperature of 121 C under 1 atmosphere of pressure for 20 to 60 minutes.** | | |
| **Before filling containers to be steam sterilized, solutions are passed through a filter no larger than 1.2 µm** | | |
| **Effectiveness of any process shall be verified with method such as biological indicators.** | | |
| **Dry heat sterilization shall be used only when steam sterilization cannot be used due to product damage or ineffectiveness. Time and temperature should be accurately determined for items being processed.** | | |
| **Dry heat may be used for depyrogenation of glassware or containers.** | | |
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| **STANDARDS FOR NUCLEAR COMPOUNDING** | **YES** | **COMMENT** |
| **USP Chapter 823, Radiopharmaceuticals for Positron Emission Tomography—Compounding, supersedes USP 797** | | |
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| **Products with volume of 100 mL or less for a single dose injection, or not more than 30 mL taken from a multiple-dose container, shall be designated as, and conform to, the standards for Low-Risk Level** | | |
| **Compounded in ISO 5 PEC** | | |
| **ISO 5 PEC in an ISO 8 environment** | | |
| **Radiopharmaceuticals prepared as Low-Risk Level CSP's with 12 Hour or Less BUD shall be prepared in a segregated compounding area.** | | |
| **A line of demarcation defining the segregated compounding area shall be established.** | | |
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**Documentation to be viewed during inspection**

1. _____ **Particle count for each room and proof of ISO level.**
2. _____ **Particle count for each hood and/or isolator and proof of ISO level.**
3. _____ **Bacterial growth (viable particle count) for each room**
4. _____ **Bacterial growth (viable particle count) for each hood and/or isolator**
5. _____ **Hood/isolator certification (air speed, leaks, smoke test, noise)**
6. _____ **Number of air exchanges for each room**
7. _____ **Daily and monthly cleaning log for rooms**
8. _____ **Log of daily pressure readings where required**
9. _____ **Log of temperature readings for room and refrigerator**
10. _____ **Documentation of initial and annual training for staff in sterile products**
11. _____ **Documentation of initial and annual training for staff doing hazardous products**
12. _____ **Policy and procedure manual**
13. _____ **Sample of compounding sheets**
14. _____ **Beyond use date policy**
15. _____ **(If using an isolator) Statement from manufacturer the isolator can be used effectively outside an ISO 7 room.**
16. _____ **Automated compounding devices calibrated daily**
17. _____ **Compounding records to show :**
    - i. ____ **Master formula**
    - ii. ____ **Date of compounding**
    - iii. ____ **Manufacturer, lot number and expiration date of each component**
    - iv. ____ **Name and quantity of each ingredient**
    - v. ____ **Pharmacy assigned number and expiration date**
    - vi. ____ **Name of person who compounded**
    - vii. ____ **Amount compounded**
    - viii. ____ **Calculations**

**IF DOING HAZARDOUS DRUG COMPOUNDING**

18. _____ **Signed informed consent for all people compounding hazardous products**

**IF HIGH RISK COMPOUNDING**

19. _____ **Proof of testing for bacteria, fungus, endotoxins, potency on compounded items**
20. _____ **Prove methods of sterilization**
21. _____ **Records of quarantine**
22. _____ **Copy of label for final preparation**

**Revised 12/18/13**