New Mexico Board of Pharmacy
PRELIMINARY CATEGORY 2 & 3 STERILE COMPOUNDING INSPECTION REPORT

Facility Name	License #
Street Address	City
Zip Code	Phone #
Designated Person (aka PIC or Consultant RPh)	Designated Person License #
Date of Inspection:	Inspector Signature:
Official Signature:	30 Day Response

Dosage Forms of Sterile Compounding (circle all that apply)
Injections, including infusions
Ophthalmic
Aqueous preparations for pulmonary inhalation.
Baths and Soaks for live organs and tissues
Implants
Irrigations for Wounds or Body Cavities

Preparation Level (circle all that apply)	
Does the pharmacy plan to **dispense** patient-specific CSPs pursuant to a prescription?	Yes/No
Does the pharmacy plan to **distribute** CSPs without a prescription or compound sterile preparations for office use?	Yes/No
Does the pharmacy plan to dispense any CSPs out of New Mexico?	Yes/No
If so, to which states will CSPs be shipped?	

If CSPs will be shipped out of state, does the pharmacy have policies and procedures for proper shipping?	Yes/No
What volume of CSPs will be shipped out of state? (If more than 5% of total prescriptions dispensed, the pharmacy must register as an outsourcing facility)	%
Does the pharmacy plan to compound regularly or in inordinate amounts any CSPs that are essentially copies of commercially available drug products?	Yes/No

Category of Compounded Sterile Preparations (CSPs) to be made by facility. (Circle all that apply)	Category 2	Category 3

INSPECTION CHECKLIST

Inspection items with * indicate the item is a USP and/or CriticalPoint recommendation and may be considered best practice.

I. STANDARDS FOR STERILE COMPOUNDING CLEANROOM SUITE	Compliant? Yes/No/NA	COMMENTS
Buffer Room is at least 100 ft²		
Buffer Room shall maintain a well-lighted work environment with an average of 80-150 foot candles		
Ceilings, walls, floors, doors, door frames, fixtures, shelving, counters, cabinets in buffer area must be smooth, impervious, free from cracks and crevices and non-shedding so they can be cleaned and disinfected and to minimize spaces in which microorganisms and other contaminants can accumulate.		
Floors in the cleanroom suite must include coving to the sidewall, or the juncture between the floor and the wall must be caulked. Floors must be smooth, impervious and free of cracks and crevices and non-shedding. 1. Tacky Mats are not allowed in ISO Class Spaces 2. *Avoid fatigue mats, especially those that feature at waffle bottom		

Walls in the cleanroom suite must be fixed and constructed of, or may be covered with, durable material (e.g., epoxy painted walls or heavy-gauge polymer). Panels must be joined together and sealed to each other and the support structure.		
If ceilings consist of inlaid panels, the panels must be caulked around each panel to seal them to the support frame.		
Junctures between the ceiling and the walls must be sealed to eliminate cracks and crevices where dirt can accumulate.		
Dust-collecting overhangs, such as utility pipes, and ledges, such as windowsills should be minimized in the cleanroom suite. If overhangs or ledges are present, they must be easily cleanable.		
The exterior lens surface of ceiling light fixtures must be smooth, mounted flush, and sealed.		
No sources of water or floor drains in buffer area		
Work surfaces shall be constructed of smooth, impervious materials such as stainless steel or molded plastic, easily cleaned and disinfected		
Storage shelving, counters and cabinets shall be smooth, impervious materials free of cracks or crevices, non-shedding, easily cleaned and disinfected		
HEPA filtered air flow into ante and buffer areas shall be introduced at the ceiling. Air returns must be mounted low on the wall, unless a visual smoke study demonstrates an absence of stagnant airflow.		
Ante-Room has a line of demarcation between the dirty side and the clean side.		

Sink with running warm water is placed either inside or outside of the anteroom. If the sink is located outside the anteroom, it must be located in a clean space. *Sink should enable hands-free use. Sink should be deep enough to wash up to elbows.		
*The doors into the anteroom from the general pharmacy area and from the anteroom into the clean room are prevented from both being open at the same time. *By interlocking, training of personnel, or signage*. (Gaps are fine at the bottom of either door but not the top of doors). Access doors should be hands-free		
Carts used to transport components or equipment into classified areas must be constructed from nonporous materials with cleanable casters and wheels to promote mobility and ensure ease of cleaning and disinfection.		
Carts must not be moved from the dirty side to the clean side of the anteroom unless the entire cart, including casters, is cleaned and disinfected.		
* Pass-throughs are best placed between the buffer room and the non-classified space to reduce the traffic and introduction of particles/microbes into the anteroom. If a <u>pass-through</u> is located in the anteroom it should be on dirty side.		
Pass-throughs are enclosed chambers with sealed doors on both sides. Doors <u>should</u> be interlocking.		
No shipping carton(s) or other corrugated or uncoated cardboard are allowed in the cleanroom suite. Removal of immediate packaging designed to retain sterility or stability is allowed in PEC.		

Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in the cleanroom suite, and they should be low-shedding and easily cleaned and disinfected. Avoid excessive amounts of supplies.		
*Trash receptacle at least 6 feet away from PEC – Best Practice		
Temperatures and humidity are monitored in each room of cleanroom suite each day compounding is performed. Should be ≤ 68°F and relative humidity of ≤ 60%. Device accuracy must be verified annually or as required by manufacturer		
Components (ingredients used in compounding) will be handled and stored in a manner that prevents contamination, mix-ups, and deterioration and under temperature, humidity, and lighting conditions consistent with those indicated in official monographs or specified by the suppliers and/or manufacturers.		
Temperature in CSP & component storage areas are monitored at least once daily and recorded on a log on days when the facility is open or by a continuous temperature recording device; temperature data is readily retrievable.		

II. CERTIFICATION & DOCUMENTATION	Compliant? Yes/No/NA	COMMENTS
All Primary Engineering Controls are initially certified by an independent qualified contractor and maintain ISO Class 5 or better air quality during dynamic conditions.		
Buffer room initially independently certified to maintain ISO Class 7 conditions under dynamic conditions. (Request Documentation)		

Ante-room initially independently certified to maintain ISO Class 8 conditions (or ISO Class 7 if it serves Hazardous Drug compounding buffer room). (Request Documentation)		
Dynamic airflow smoke pattern testing must be performed initially in primary engineering controls under dynamic conditions to confirm unidirectional airflow. The airflow smoke patterns should be documented, ideally with video.		
If air returns in the cleanroom suite are not low on the wall a visual smoke study has been performed to demonstrate an absence of stagnant airflow. Does not need to be under dynamic operating conditions. Only performed one time but must be repeated if equipment is placed in a different location. This smoke study should be documented, ideally with video.		
HEPA filter leak test is initially performed in primary engineering controls.		
HEPA filter leak tests are initially performed in secondary engineering controls.		
Viable volumetric air sampling initially performed throughout all ISO areas using an impaction air sampler. Sampling must occur during dynamic conditions. At least 1000 liters of air must be tested. Sampling locations shall be defined in SOPs in a diagram or map. Ask for Documentation.		
Surface sampling initially performed in all ISO classified areas and pass-through chambers connecting to classified areas**.** Sampling locations shall be defined in SOPs in a diagram or map.		

Viable air and surface samples did not exceed recommended USP action levels (or internal action levels if more restrictive). Classification Air Sample Surface Sample ISO Class 5 >1 CFU/m3 >3 CFU/plate ISO Class 7 >10 CFU/m3 >5 CFU/plate ISO Class 8 >100 CFU/m3 >50 CFU/plate CFUs are TOTAL of bacterial plus fungal/mold plates.	PEC Air Buffer-Room Air Ante-Room Air	PEC Surface Buffer-Room Surface Ante-Room Surface
An attempt is made to identify any microorganism recovered to the genus level when CFUs detected by air or surface sampling exceeded action levels.		
If CFU action levels for a specified air and surface sampling are exceeded, a corrective action plan must be documented. The corrective action plan must be dependent on the cfu count and the microorganism recovered. The extent of the investigation should be consistent with the deviation and should include an evaluation of trends. Some examples of corrective action include process or facility improvements, personnel training, cleaning and disinfecting, or HEPA filter repair and/or replacement. Data collected in response to corrective actions must be reviewed to confirm that the actions taken have been effective. The corrective action plan must be documented and should include resampling of failed areas to confirm corrective action was successful.		
All certification and recertification records are reviewed by the designated person(s). A corrective action plan is implemented and documented in response to any out-of-range results on certification report and data reviewed to confirm that the actions taken have been effective.		

Buffer room must have a minimum of 30 air changes per hour (ACPH) of HEPA filtered air. At least 15 ACPH of the total air change rate in a room must come from the HVAC through HEPA filters located in the ceiling.		
Anteroom must have a minimum of 20 ACPH		
A pressure differential monitoring device is used to continuously monitor pressure differentials. Pressures must be documented at least daily on the days when compounding occurs.		
Pressure shall be at least 0.02-inch water column between buffer and ante room & at least 0.02-inch water column between ante room and unclassified areas.	Ante – Pharm Differential	
	Buffer – Ante Differential	
PECs are located within an ISO Class 7 buffer room?		
Integrated Vertical Laminar Flow Zones are separated from ISO Class 7 area with a physical barrier and there is full coverage of HEPA filters above the work surface.		
Incubators must not be put in the buffer or ante-room as they are a biohazard.		
Library of current references (hard copy or electronic) shall be available including: USP/NF or USP on Compounding: A Guide for the Compounding Practitioner or USP Compounding Compendium; New Mexico pharmacy rules and regs; specialty references as appropriate.		

Compounding activities that require the manipulation of a patient's blood-derived or other biological material (e.g., autologous serum), are clearly separated from other compounding activities and equipment used in CSP preparation activities and controlled by specific SOPs to avoid cross-contamination.		

III. CLEANING OF COMPOUNDING AREAS	Compliant? Yes/No/NA	COMMENTS
The PEC and equipment inside the PEC is cleaned and disinfected daily on days when compounding occurs. This may be accomplished in one step with an EPA-registered one-step disinfectant cleaner. Cleaning, disinfecting and sporicidal agents used within the PEC **must** be sterile. (Check if one-step disinfectant cleaner/germicidal detergent available)		
Surfaces within the PEC are disinfected with sterile 70% IPA after cleaning, disinfecting or application of a sporicidal disinfectant. Sterile 70% IPA must also be applied immediately before initiating compounding, every 30 mins during continuous compounding, and when surface contamination is known or suspected. (Check if sterile 70% IPA available)		
All cleaning materials are low-lint. Cleaning materials (sponges, wipers, mop heads) should be disposable. (Check if available)		
Cleaning tools are dedicated and only for use in classified area. Reusable cleaning tools must be made of cleanable materials (e.g., handles should not be made of wood or any other porous material) and must be cleaned and disinfected before and after each use. (Check if available)		

A sporicidal disinfectant must be applied monthly to all PECs, and all areas and equipment within the cleanroom suite for facilities compounding Category 2 CSPs. Select areas that compound Category 3 CSPs require weekly application of a sporicidal. (Check if sporicidal agent is available.)		

IV. PERSONNEL CLEANSING AND GARBING	Compliant? Yes/No/NA	COMMENTS
The following is available for handwashing Procedures: • Disposable nail cleaners • Low-lint disposable towels		
The following is available for Category 2 Garbing: • Low-lint garment with sleeves that fit snugly around the wrists and an enclosed neck (e.g., gown or coverall) • Low-lint shoes covers • Low-lint cover for head that covers the hair and ears, and if applicable, cover for facial hair • Low-lint face mask • Sterile powder-free gloves		
The following garb is required for Category 3 compounding: PPE must cover all skin. Exposed skin is not allowed in the buffer room (i.e., face and neck must be covered). • All low-lint outer garb must be sterile • PPE may include goggles, respirators, or other reusable equipment. Must have disinfection procedures for reusable PPE.		
Alcohol-based hand rub is used prior to donning sterile gloves. Sterile gloves must be donned in a classified room.		

Gowns and other garb are stored in a manner that minimizes contamination (e.g., away from sinks) and within a classified area or SCA.		

V. ASEPTIC PROCESSING, TERMINAL STERILIZATION, AND MISC.	Compliant? Yes/No/NA	COMMENTS
Will the facility prepare Category 2 or Category 3 CSPs from <u>nonsterile starting components</u>?	<u>Circle Answer</u>: Yes or No (if No, skip to letter **A**)	
Pre-sterilization procedures (weighing, mixing) must be performed in no less than ISO 8 environment (ante-room or buffer room).		
Pre-sterilization procedures must be performed in single-use containment glove bags, containment ventilated enclosures (CVEs), BSCs, or CACIs to minimize the risk of airborne contamination.		
CVEs, BSCs, or CACIs used for presterilization procedures have been initially certified.		
PECs used for sterile and nonsterile compounding (e.g., pre-sterilization procedures) are placed in separate rooms unless the buffer room can maintain an ISO Class 7 classification during particulate generating activities. **Request dynamic particle count testing results if both PECs are in buffer room**. Co-located PECs must be at least 1 meter apart.		
*Terminal Sterilization Devices (Dry-heat ovens and autoclaves) are recommended to be placed in an ISO-Class Room.		

A. Are the Category 2 or Category 3 CSPs <u>aseptically processed</u> (either compounded with only sterile starting ingredient(s) or compounded with nonsterile ingredient(s) followed by sterilization by filtration), or <u>terminally sterilized</u> (e.g., steam, dry heat, or irradiation)? <u>{Note: If one or more starting components being used to compound is not sterile, sterility must be achieved through sterilizing filtration or terminal sterilization}</u>	<u>Circle Answer</u>: Aseptically Processed (If sterilized by filtration go to **B**. below; if only sterile starting ingredients are used skip to end) Terminally Sterilized (Skip to **C** and/or **D** below)	
B. Filtration (aseptically processed)		
If Category 2 or 3 CSPs are sterilized by filtration the filters are sterile, pyrogen free, have a nominal porosity of 0.22 µm or smaller and are appropriate for pharmaceutical use. (Check if filters available)		
Each filter that is used shall undergo integrity test such as bubble-point test. All bubble-point test results are kept. Filters cannot be reused. Bubble-point testing is done after filtration not before. (Check if bubble-point test equipment available)		
C. Terminal Sterilization by Steam Heat		
The terminal sterilization process is intended to achieve a probability of a nonsterile unit (PNSU) of 10−6.		
The steam supplied in the autoclave is generated using water per the manufacturer's recommendation.		
Before filling containers to be steam sterilized, solutions are passed through a filter no larger than 1.2 µm to remove particulates. (Check if filters available)		

The effectiveness of steam sterilization must be verified and documented with each sterilization by using appropriate biological indicators, such as spores of Geobacillus stearothermophilus and other confirmation methods such as physicochemical indicators. (Check if biological indicators are available)		
A calibrated data recorder or chart is used to monitor each cycle and to examine for cycle irregularities (e.g., deviations in temperature or pressure). (Check if data recorder available)		
D. Terminal Sterilization by Dry Heat		
The terminal sterilization process is intended to achieve a probability of a nonsterile unit (PNSU) of 10−6.		
Before filling containers to be dry heat sterilized, solutions are passed through a filter no larger than 1.2 µm to remove particulates. (Check if filters available)		
The calibrated oven is equipped with temperature controls and a timer. A calibrated data recorder or chart is used to monitor each cycle and the data is reviewed to identify cycle irregularities (e.g., deviations in temperature or exposure time). (Check for temperature and time controls)		
The effectiveness of the dry heat sterilization method must be verified and documented with each sterilization run or load using appropriate biological indicators such as spores of Bacillus atrophaeus and other confirmation methods (e.g., temperature-sensing devices). (Check for biological indicators)		
E. Depyrogenation		
Dry heat depyrogenation is used to render glassware, metal, and other thermostable containers and components pyrogen free. The exposure period includes sufficient time for items to reach the depyrogenation temperature; items remain at the depyrogenation temperature for the duration		

of the depyrogenation period.		
The effectiveness of the dry heat depyrogenation cycle(s) is established initially and verified annually using ECVs to demonstrate the cycle achieves a greater than or equal to 3-log endotoxin reduction. The effectiveness of the depyrogenation cycle is re-established if there are changes to the depyrogenation cycle. Cycle verifications are documented. (Check if ECVs are available)		

X. LYOPHILIZATION	Compliant? Yes/No/NA	COMMENTS
Sterile preparations prepared for lyophilization will be maintained in ISO 5 unidirectional laminar flow air throughout sterilization, filling, and transport to the lyophilizer.		
A recorded smoke study is available and demonstrates that transport from the PEC to the lyophilizer is accomplished in ISO 5 laminar flow air at all times.		
The pharmacy validated the lyophilizer high-level disinfection procedure initially, and after changes to the cleaning process or agents. Documentation of studies is available for inspection.		
Validation studies for high level disinfection were performed with the 5-aerobic bacterial and fungal ATCC organisms referenced in USP<71> are conducted by an external vendor unless the firm has an internal laboratory capable of performing the studies. An internal laboratory is separate from the compounding and work areas of the pharmacy to prevent contamination in the pharmacy.		
The pharmacy has provisions for sterilizing, with filters, the inert gas or air used for backfilling during the vacuum release phase. These Sterilizing filters undergo the manufacturers recommended integrity test.		

BUD Limits for Category 2 CSPs

(Circle the applicable preparation characteristics and storage conditions)

Preparation Characteristics		Storage Conditions		
Compounding Method	Sterility Testing Performed and Passed	Controlled Room Temperature (20°–25°)	Refrigerator (2°–8°)	Freezer (−25° to −10°)
Aseptically processed CSPs	No	Prepared from one or more nonsterile starting components: 1 day	Prepared from one or more nonsterile starting components: 4 days	Prepared from one or more nonsterile starting components: 45 days
		Prepared from only sterile starting components: 4 days	Prepared from only sterile starting components: 10 days	Prepared from only sterile starting components: 45 days
	Yes	30 days	45 days	60 days
Terminally Sterilized CSPs	No	14 days	28 days	45 days
	Yes	45 days	60 days	90 days

BUD Limits for Category 3 CSPs

(Circle the applicable preparation characteristics and storage conditions)

Preparation Characteristics	Storage Conditions		
Compounding Method	Controlled Room Temperature (20°–25°)	Refrigerator (2°–8°)	Freezer (−25° to −10°)
Aseptically processed, sterility tested, and passing all applicable tests for Category 3 CSPs	60 days	90 days	120 days
Terminally sterilized, sterility tested, and passing all applicable tests for Category 3 CSPs	90 days	120 days	180 days

Are Beyond-Use Dates (BUDs) assigned appropriately?	Yes / No	Yes / No

Compounding Personnel and Competency Evaluation/Assessment

(Direct oversight personnel must also initially complete training and demonstrate competency and also initially complete a garbing competency evaluation and aseptic manipulation competency evaluation.)

NAME	LICENSE #	Initial Training and Competency Assessment of Core Skills	Initial Garbing Competency Evaluation	Initial Aseptic Manipulation Competency Evaluation