NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Inspection: Instruction Sheet and Form

(Revised 1/2022)

The NVBOP's established self-assessment inspection process provides management the opportunity to review the standards by which the board inspects your operation. The process recognizes you as the responsible person to implement and review policies and procedures necessary to provide a quality standard of pharmaceutical services.

Please have the self-assessment form completed and available for review by the first day of the month listed on your inspection notice. An inspector will review the form with you and inspect your facility during the month listed on your inspection notice.

To minimize any disruption to your facility during the inspection process please have the following available:

1. Completed Sterile Compounding Inspection form along with prior year inspection form
2. Most recent certification report for ISO classified areas. Documentation of corrective action taken by facility for any failures documented on the certification report
3. Prior 12 months of glove finger-tip testing results. Documentation of corrective action taken by facility for any failures.
4. Prior 12 months of media fill testing results. Documentation of corrective action taken by facility for any failures.
5. Prior 12 months of competency documentation for compounding personnel
6. Sterility/potency data for any products with a BUD in excess of USP 797 guidelines
7. Examples of compounding records
8. SOP's relevant to the sterile compounding process

Pharmacy Information	
Date Completed:	
Pharmacy Name:	
Pharmacy License #:	
Pharmacy Address:	
Pharmacy Telephone #:	
Pharmacy Fax #:	
Pharmacy Email:	
Managing Pharmacist Name:	
Managing Pharmacist start date:	

List of compounding personnel approved to compound sterile products
(Make copies of this page if additional space is needed)

#	Name (First, Last)	License Number	Position	Risk Level Qualified to Compound
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General Information				
Citation	**Question**	**Yes**	**No**	**NA**
NAC 639.757	Compounded products are only prepared to fill a patient specific prescription, a chart order for immediate use by the patient, or for a practitioner who will administer the product to a patient?			
NAC 639.67015	The pharmacy has a written standard operating procedure manual with detailed instructions that describes how, when, and by whom all relevant Nevada Revised Statutes and Administrative Codes are to be met relating to the sterile compounding process?			

Personnel Training and Evaluation Documentation				
Citation	**Question**	**Yes**	**No**	**NA**
	Documentation is on file for each person who compounds sterile products that the person is competent and proficient to correctly perform all tasks related to sterile compounding and has received initial and ongoing training to establish and maintain their competency?			
The following records for employees on hire or newly assigned to compound drugs products at a higher risk level are completed on an initial and ongoing basis:				
NAC 639.67013	Perform aseptic hand cleansing?			
	Select and appropriately don protective garb?			
	Competency in calculations, identifying, weighing, and measuring ingredients?			
	Procedures for containment, cleaning, and disposal with regard to breaks and spills?			
	Appropriate documentation of training of any non-pharmacy personnel cleaning and/or disinfecting or entering ISO areas?			
Additional training records for personnel compounding hazardous drugs including but not limited to the following:				
NAC 639.67077 NAC 639.67079	Protection of personnel and compounding environment from contamination by hazardous drugs?			
	Treatment of employees of the pharmacy with regard to contact and inhalation exposure?			
	Negative pressure techniques for BSC, CAI, and CACI?			
	Safe aseptic manipulation techniques?			
	Correct use of vial transfer devices?			
	Containment, cleanup, and disposal procedures?			
Additional radiopharmaceutical training if applicable:				
	Compounding, handling, cleaning, and special techniques?			
	Certification of and display of pharmacist's certificate in Nuclear pharmacy?			
Media Fill Testing				
NAC 639.6649 NAC 639.67053	Appropriate to risk level?			
	Minimum of every 12 months for low or medium risk compounding or every 6 months for high-risk compounding?			
	Documentation of failure and re-testing is maintained?			
Glove Finger-tip Testing				
NAC 639.6633 NAC 639.67053	Minimum of every 12 months for low or medium risk compounding or every 6 months for high-risk compounding?			
	Sampled immediately after gowning/garbing for initial testing?			
	Employees must successfully pass 3 tests with zero cfu's for initial testing?			
	Employees must successfully pass 1 test with less than 3 cfu's for annual/semi-annual training?			
	Documentation of failure and re-testing is maintained?			

Environmental and Equipment Documentation				
Citation	**Question**	**Yes**	**No**	**NA**
USP 797	Room pressurization test results are completed every 6 months?			
	Positive pressure areas maintain a pressure between 0.02 – 0.05 in water column pressure between areas?			
	Negative pressure areas maintain a pressure greater than – 0.01 in water column pressure between areas?			
	Pressure gauges are installed to monitor pressure differential between the buffer area and ante area and the general environment outside the compounding area?			
	Daily logs are maintained either electronically or hand-written to document room pressurization results?			
	Pharmacy has documentation for corrective action taken for any deviation from room pressurization limits listed above?			
	ISO-7 classified areas have a minimum of 30 ACPH with at least 15 from outside air sources?			
	ISO-8 classified areas should have a minimum of 20 ACPH?			
	If a CACI is used in a non-HEPA filtered room the room is certified to maintain a minimum of 12 ACPH?			
	Smoke studies are performed at least every 6 months and the results are reviewed by the PIC?			
	Viable air sampling by active impaction using a volumetric air sampling device is performed every 6 months?			
	Pharmacy has documentation for corrective action taken for any actionable items reported on their certification report for air viable sampling?			
	Viable surface sampling is performed every 6 months?			
	Pharmacy has documentation for corrective action taken for any actionable items reported on their certification report for surface viable sampling?			
	Non-viable particle sampling is performed every 6 months?			
	Pharmacy has documentation for corrective action taken for any actionable items reported on their certification report for non-viable air sampling?			
If an ISO-5 area fails testing then all product compounded in the area will be considered immediate use compounding only and assigned a 1 hour BUD.				
If an ISO-7 area fails testing then all product compounded in the area will have a maximum BUD of 12 hours.				

Equipment Record Keeping Documentation				
Citation	**Question**	**Yes**	**No**	**NA**
NAC 639.6701	Records are available for review for all equipment used in compounding. The records include but are not limited to equipment setup, calibration, filter changes, equipment failures and repairs, and periodic testing required, and cleaning of equipment?			
	Policies and procedures are available for the equipment used by the pharmacy to compound drug products?			
	Records of all equipment calibrations, routine maintenance, and periodic testing is kept for the life of the equipment?			
	There is a log kept for the cleaning, calibration, and maintenance of all automated compounding devices?			

Product Record Keeping Documentation				
Citation	**Question**	**Yes**	**No**	**NA**
NAC 639.6705	Buffer room temperature log maintained?			
NAC 639.525 NAC 639.527	Refrigerator and freezer temperature log maintained?			
NAC 639.6705	Pharmacy maintains a cleaning log that documents the areas cleaned, the person performing the cleaning, and frequency of the cleaning, and the products used for cleaning in all ISO classified areas?			
NAC 639.6637	A pharmacy performing high risk sterile compounding maintains a sterilization log to document results of bubble point testing, autoclave, dry oven, and biological indicator?			
NAC 639.6637	Any sterilization failures are documented and corrective action taken regarding the failures are also documented?			
NAC 639.67019	All compounding records are maintained for 2 years? *Exemption to records requirements. The record of all sterile compounded drug products compounded by a pharmacy (other than an institutional pharmacy) and for all sterile products for parenteral nutrition and sterile anti-neoplastic drug products compounded by an institutional pharmacy must be maintained for 6 months.*			
	All compounding/batch records contain the following:			
	All necessary compounding instructions?			
	A complete list of sterilization parameters if necessary?			
	The equipment used in the compounding/sterilization process?			
	Reconciliation and yield of the batch?			
	All equipment such as beakers and glassware are clearly marked with the product name and lot number during the compounding process?			
	Record of sterilization of components used including but not limited to rubber caps, vials, and products?			
	Identity of compounding personnel and the pharmacist approving the batch?			
	Documentation of all testing, including but not limited to sterility, endotoxin, and potency is attached to the compounding record or is cross referenced to the record of testing results?			
	Are beyond use dates in excess of USP-797 utilized?			
	Is documentation available (sterility, potency, endotoxin) to support BUD assigned by pharmacy?			
NAC 639.67015	Records for tracking, recalling, and destroying drug products compounded by the pharmacy, including the pharmacy's ability to ensure that all drug products which could have been compounded with a particular component be located, recalled, and destroyed?			

Single Dose and Multiple Dose Containers				
Citation	**Question**	**Yes**	**No**	**NA**
NAC 639.67057	Single dose containers entered in a worse than ISO Class 5 air quality and stored in worse than ISO Class 7 are used within 1 hour of entry?			
	Single dose containers entered in ISO Class 5 or cleaner air and are stored in ISO 7 or cleaner air are used within 6 hours of entry?			
	Single dose containers entered in ISO Class 5 or cleaner air and remains in ISO 5 air quality are used within 24 hours?			
	Opened single dose ampoules are not stored?			
	If the entire seal has been removed from a multi-use vial the contents are not stored?			
	Closure sealed multiple dose containers are used within 28 days after initial opening or entry?			
	Closure sealed multiple dose containers are dated with date of opening or entry and date is clearly identified?			

CSP Microbial Contamination Risk Levels				
Citation	**Question**	**Yes**	**No**	**NA**
Low Risk Level CSP's				
NAC 639.67061 NAC 639.67063	Does your pharmacy compound low risk level sterile products?			
	Compounding involves only transfer, measuring, and mixing manipulations using not more than 3 commercially manufactured sterile products or other entries of a sterile drug product into one container, including, without limitation, a bag or vial, to make the final compounded drug product?			
	Manipulations are limited to aseptically opening ampoules, penetrating disinfected stoppers on vials with sterile needles and syringes and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and containers for storage and dispensing?			
	In the absence of sterility or potency testing, storage is not more than 48 hours at room temperature, 14 days refrigerated, or 45 days frozen?			
Medium Risk Level CSP's				
NAC 639.67065	Does your pharmacy compound medium risk level products?			
	The final CSP is treated as medium risk if the CSP does not contain broad spectrum bacteriostatic substances and will be administered over a period which exceeds 24 hours?			
	Aseptic manipulation within an ISO Class 5 environment of unusually long duration or complex aseptic manipulation, with more than 3 sterile products or other entries into one container?			
	In the absence of sterility or potency testing, storage is not more than 30 hours at room temperature, 9 days refrigerated, or 45 days frozen?			
High Risk Level CSP's				
NAC 639.67067 NAC 639.67069 NAC 639.67071	Does your pharmacy compound high risk level products?			
	Sterilization methods are verified to achieve sterility for the quantity and types of containers?			
	Sterilization methods are chosen based on appropriate method for the pharmaceutical product being sterilized?			
	In the absence of sterility or potency, storage is not more than 24 hours at room temperature, 3 days refrigerated, and 45 days frozen?			
	High risk sterile compounded drugs for injection into the vascular or central nervous system or for inhalation or ophthalmic use must undergo sterility testing for the following scenarios: -CSP's if they are prepared in batches > 25 individual single dose packages -Compounded in multiple dose vials for administration to multiple patients -Will be exposed for a period of more than 12 hours refrigerated or 6 hours at room temperature prior to sterilization			
	Is each high risk compounded product checked for particulates against separated lighted black and white background?			
Immediate Use CSP's				
NAC 639.67073 NAC 639.67075	Does your pharmacy compound immediate use products?			
	If administration has not begun within 1 hour of being compounded, CSP is discarded unless a period longer than 1 hour is required for compounding?			
	Unless the person who prepares the CSP immediately witnesses or completely administers it, the CSP is labeled with patient identifier, names and amounts of all ingredients, initials of the compounder, and the exact 1-hour BUD and time is written on the label?			
	Administration begins not later than 1 hour following the start of the preparation of the CSP and the compounded drug product is fully administered as soon as practical but not longer than 24 hours after the administration of the drug product began or the CSP is disposed of promptly and safely?			
	No more than three sterile non-hazardous commercial drug products are used, excluding infusion solutions or diluents?			

Sterilization				
Citation	**Question**	**Yes**	**No**	**NA**
NAC 639.67069	Is an autoclave used for sterilization?			
	Is a biological indicator or other test utilized to validate the effectiveness of the autoclave?			
	Are the results of the biological indicator test documented?			
	Is each drug product exposed to steam at 121 degrees Celsius under a pressure of 15 pounds per square inch for the duration of the sterilization process?			
	Is a computer printout of the autoclave cycle attached to the compounding worksheet?			
	Before starting the sterilization process, is each product including plastic, glass, and metal devices wrapped in low particle shedding paper or fabric or sealed in envelopes that prevent microbial penetration after the sterilization of the high risk compounded drug product is completed?			
	Pharmacy personnel are verifying the mass of the container that will be sterilized using steam in an autoclave to ensure that the container will be sterile after the period of exposure in the autoclave?			
	Pharmacy personnel ensure that the solutions that will be used to fill the vials which will be steam sterilized are passed through a filter having a porosity of not more than 1.2 microns to remove particulate matter immediately before filling those vials?			
	Is a dry oven used for sterilization?			
	Is a biological indicator or other test utilized to validate the effectiveness of the dry oven?			
	The pharmacy personnel ensure that the heated air is filtered and evenly distributed by a blower throughout the chamber or oven used for the sterilization process?			
	The pharmacy personnel ensure the chamber or oven for the sterilization process is equipped with accurate temperature controls and a timer?			
	The pharmacy personnel ensure that the pharmacy only use dry heat as a method of sterilization for a high-risk sterile compounded drug product if the final product would be damaged by moisture or is impermeable to moisture?			
	Does the pharmacy utilize sterile filtration as a method to sterilize high risk products?			
	The pharmacy personnel are trained on the proper procedure for bubble point testing?			
	The results of the bubble point tests are documented on the compounding worksheet?			
	If a bubble point test failure occurs these results are documented, and the disposition of the product is also documented?			
	The specific type of filter used, and its associated bubble point threshold is listed on each compounding worksheet and available to the person completing the bubble point test?			
	Pharmacy personnel ensure that the filters used have sufficient capacity to permit the sterilization process to be completed rapidly and without compromising the sterility of the filtration process?			
	Pharmacy personnel subject the filtration to the manufacturer's recommended integrity testing, including without limitation, the bubble point test, after the filtration of the high-risk sterile compounded drug product is completed?			

Hazardous Drugs as CSP's				
Citation	**Question**	**Yes**	**No**	**NA**
NAC 639.67077 NAC 639.67079	Hazardous drugs are stored separately from other inventory?			
	Hazardous drugs are always handled with caution using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparation for administration, and disposal?			
	Hazardous drugs are prepared for administration only under conditions that protect the healthcare workers and other personnel in the preparation and storage areas?			
	Disposal of hazardous waste complies with all applicable federal, state, and local regulations?			
	CSP is prepared in a BSC or CACI that meets or exceeds standards?			

	BSC or CACI is vented outside the building if one of more components of the compounded hazardous drug is an anti-neoplastic drug?			
	Access is limited to areas where hazardous drugs are stored and prepared?			
	Personnel who compound hazardous drugs are trained in storage, handling, compounding safety procedures, and disposal of drugs prior to preparing or handling hazardous CSP's?			
	The pharmacy utilizes a closed system transfer device for hazardous CSP's?			

Radiopharmaceuticals				
Citation	**Question**	**Yes**	**No**	**NA**
NAC 639.67063 NAC 639.5802 NAC 639.584	Radiopharmaceuticals are compounded using appropriately shielded vials and syringes in a properly functioning and certified vertical laminar airflow hood or Class II type B2 BSC that is located in an environment with an air quality of ISO Class 8 or higher?			
	Only shielded vials, syringes, and other devices and containers specifically manufactured for use with radiopharmaceutical components are used in the compounding process?			
	Any special equipment or device that is used to compound radiopharmaceutical products, including, without limitation, a Molybdenum-Technetium-99m generator system are stored and operated under conditions recommended by manufacturers and applicable state and federal regulations; such generator systems are operated in an ISO Class 8 or cleaner air environment?			
	Low Risk – The final compounded drug product contains a volume of 15ml or less of a radiopharmaceutical and has an expiration time of 18 hours or less per dosage unit, including, without limitation, a dosage unit of a radiopharmaceutical prepared from an eluate by using a Molybdenum-Technetium-99m generator; or the final compounded drug product contains commercially manufactured cyclotron radiopharmaceuticals which contain preservatives, and which have expiration times of 72 hours or less.			
NAC 639.5822	A nuclear pharmacy must have adequate space and equipment commensurate with the scope of services it provides and must meet the minimum space requirements established for all pharmacies in the state.			
	The pharmacy must have a radionuclide dose calibrator			
	The pharmacy must have a refrigerator			
	The pharmacy must have an area for preparation and dispensation of radiopharmaceuticals			
	The pharmacy must have an area for shipment and receipt of radioactive materials			
	The pharmacy must have an area for storage of radioactive material			
	The pharmacy must have an area for decay of radioactive Waste			
	The pharmacy must have a single or multiple channel well scintillation counter containing the isotopes sodium iodide, thallium, germanium, and lithium			
	The pharmacy must have a radiochemical fume hood and filter system with suitable equipment for sampling air			
	The pharmacy must have an area survey meter			
	The pharmacy must have at least two Geiger Mueller survey meters, including one high-range meter			
	The pharmacy must have a microscope and hemocytometer			
	The pharmacy must have a laminar flow hood and appropriate supplies to ensure sterile practices for parenteral solutions			
	The pharmacy must utilize sterile gloves to perform all sterile compounding			
	The pharmacy must have radiation shields for syringes and vials			
	The pharmacy must have a lead-shielded drawing station			
	The pharmacy must have decontamination supplies			
	The pharmacy must have lead transport shields for transport of vials			
	The pharmacy must utilize USA Type A, 7A transport containers approved by the DOP and other labels and supplies for shipping radioactive materials			

Facility Design and Environmental Controls				
Citation	**Question**	**Yes**	**No**	**NA**
USP 797 NAC 639.6705	Maintain records of any equipment or other mechanical non-compliance, and a record of corrections or retesting done. Records of mechanical failure show the time frame the system was non-compliant and the methodology or backup processes the facility used to maintain compliance.			
	Compounding facility provides an appropriate temperature and well-lighted working environment?			
	Policies and procedures for PEC area are written and followed; determined by the scope and risk levels of aseptic compounding activities utilized during the preparation of CSP's?			
	Only the equipment, furniture, supplies, and other material required for the compounding activities are bought into the area and they are non-permeable, non-shedding, cleanable, and resistant to damage by disinfectants; before such items are brought into the area, they are cleaned and disinfected?			
	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; the surfaces are resistant to damage by disinfectant agents?			
	Junctures of ceilings to walls are coved or caulked?			
	If ceilings consist of inlaid panels, the panels are impregnated with a polymer to render them impervious and hydrophobic; they are caulked Around each perimeter?			
	The exterior lens surface of the ceiling lighting fixtures are smooth, mounted flush and sealed; any other penetrations through the ceiling or walls are sealed?			
	The buffer area does not contain sources of water (sinks) or floor drains?			
	Work surfaces are constructed of smooth, impervious materials?			
	Carts are stainless steel wire, non-porous plastic, or sheet metal with cleanable surfaces?			
	Storage shelving, counters, and cabinets are smooth, impervious, free from cracks and crevices, non-shedding, cleanable and disinfectable?			
	If there is particle generating equipment such as a computer, printer, or refrigerator in the buffer room or ante area, the equipment is located by an air return so air flows over and out of the room?			
	PEC's are located within a restricted access ISO Class 7 buffer area unless an exception is met?			
	Designated areas are maintained in a clean condition and have cleanable surfaces, including walls, ceiling, and floors?			
	If not run continuously, the recovery time to achieve ISO Class 5 air quality of PEC's used for sterile compounding is documented, pharmacy personnel are aware of the recovery time, and internal procedures are developed to ensure the ISO Class 5 environment is reached and maintained?			
NAC 639.742 NAC 639.475 NAC 639.672 NAC 639.690	Sufficient storage space is well separated from the area of the laminar flow hood for storage of bulk materials and equipment?			
	There is a sink with hot and cold running water in the ante room?			
	Refrigerator and freezer are of sufficient capacity to store all materials requiring refrigeration or freezer storage?			
	Reference material are available based on the risk level of compounding performed at the pharmacy?			
NAC 639.472 NAC 639.475 NAC 639.672 NAC 639.690	No food or drink is allowed in the ante or buffer room?			
NAC 639.6705 NAC 639.67077	All cleaning materials are non-shedding and dedicated to use in the buffer or clean area, ante area, and segregated areas and are not removed from these areas except for disposal?			
	No shipping cartons are taken into the buffer area, clean area, or segregated compounding areas?			

	All jewelry and piercings are removed prior to entering into the compounding area?			
	People with open wounds, rashes, or respiratory infections are not allowed in the compounding area?			
	Personal outer garments are not allowed in the compounding area?			
	Garbing procedures/SOP including shoe covers, head and face masks, beard covers, hand cleaning, gowning, and sterile gloves are followed?			
NAC 639.67017	If compounding a product for parenteral nutrition, maximum limits are established and are entered for each additive into the computer or an audible alarm or other mechanism alerts the pharmacist that the maximum dose has been exceeded. The automatic compounding device will cease compounding the drug product for parenteral nutrition if the maximum limit for an additive will be exceeded?			
NAC 639.67015	All CSP's are visually inspected for being intact with no abnormal particulate matter, and prescriptions and written compounding procedures are reviewed to verify accuracy of correct ingredients and amounts, aseptic mixing, high risk sterilization, packaging, labeling, and expected physical appearance before they are dispensed or administered?			
	A check system is in place that meets state regulations that include label accuracy and accuracy of the addition of all ingredients used?			
	The pharmacy has written procedures for proper packaging, and transportation conditions to maintain sterility, quality, and purity and strength of CSP's?			
	Chemotoxic and other hazardous CSP' have safeguards to maintain the integrity of the CSP and minimize the exposure potential of these products to the environment and personnel?			
	Delivery and patient care setting personnel are properly trained to deliver the CSP to the appropriate storage location?			
	Outdated and unused CSP's are returned to the compounding facility for disposition as appropriate?			

Notes

Your location will be inspected by an agent of the Nevada Board of Pharmacy. Any noted unsatisfactory conditions that require action will be sent to the email you indicate below. **All unsatisfactory conditions must be corrected within the time frames stated to ensure compliance with laws and regulations governing your business. Please attach a copy of any documentation and corrective action you have taken to this inspection form for future review on inspection.**

Date:	
Pharmacist Printed Name:	
Pharmacist Signature:	
Email address for correspondence:	