

STATEMENT OF NEED

Mobile Pharmacy Cleanroom Trailer

Purpose: The purchase of a Mobile Pharmacy Cleanroom (MPC) trailer to ensure uninterrupted provision of essential medical and hospital services requiring compounded sterile products.

The Mobile Pharmacy Cleanroom trailer will allow Department of Veterans Affairs Pharmacy employees to prepare pharmaceutical compounded sterile preparations (CSPs) that meet the standards of the United States Pharmacopoeia (USP) Chapter 797 (USP <797>) “Pharmaceutical Compounding-Sterile Preparations” and Chapter (USP <800>) “Hazardous Drugs-Handling in Healthcare Settings”, and complies with the National Institute of Occupational Safety and Health (NIOSH) recommendations for pharmacy practices for both hazardous and nonhazardous medications.

Additionally, this mobile pharmacy shall meet the guidelines within CETA CAG-003-2006 Certification guide for Sterile Compounding and any other applicable Federal, State, Local, Industry standards Policies, Procedures, Codes, Permit for the proper intended performance of all items herein.

Mobility Requirements: The MPC must be a mobile trailer on wheels with connections that enable it to be moved by commercial tractor/trailer. Placement of air conditioning units or other external components on the front of the MPC shall allow an adequate turning radius of the truck when attached to the MPC. The exterior of the MPC shall contain all required lighting and signage to meet DOT regulations and be resistant to high and low temperatures, high humidity, wind, and rain. Additionally, the MPC shall be equipped with a levelling system to be employed when placed on uneven surfaces. The trailer shall not exceed 55 feet in length.

Entry Room - Pharmacist Work Area

The pharmacist work area shall provide a minimum space of 8' X 8' X 7' high ceiling and shall have a ADA compliant ramp or portable stairs with handrails and the stairs must be adjustable to provide stability on solid parking surface such as asphalt that is not level to enter into an entry/office area. The main door will have a removable exterior awning capable of covering the entrance and stairs or ramp and exterior lighting at the entrance door. The room shall contain one work station large enough to utilize a computer and one office chair. This room shall contain a stainless-steel work bench/desk that is a minimum of 4 ft. wide and 24 inches deep and one stainless steel rolling cart minimally measuring 2'WX2'Dx3'H containing at least 2 solid shelves. This room shall have an intercom capable of communicating between all rooms.

Hazardous Drug Buffer Room Preparation Area (ISO Class 7)

The Hazardous Drug preparation area will provide a minimum space of 12' X 8' X 7' high ceiling and must be maintained under negative pressure relative to the anteroom. The anteroom shall also be maintained under the International Organization for Standardization (ISO) Class 7 positive pressure air quality relative to the outside to create an inward directional airflow from the anteroom to the compounding area. Within the ISO Class 7 Hazardous Drug Preparation area, at least two Class II Type A2 or A3 Biological Safety Cabinets (BSCs) with a laminar airflow ISO class 5 shall be provided for compounding activities. BSCs will contain audible and visual alarms to alarm in the absence of negative pressure. BSC will contain a camera system and software solution that allows for pharmacist to validate all components utilized for compounding hazardous drugs during the compounding process. The Class II Type A2 or A3 Biological Safety Cabinets (minimum 3 ft. each) must be externally exhausted in accordance with applicable building codes, USP 800, VA TIL Mechanical Specification, and NSF-ANSI

regulations as appropriate. The dedicated exhaust and stack pipe must be a distance of at least 25 feet from other intake areas. The unit must be equipped with an adjustable fan at the top of the pipe with slightly more power than the exhaust of the unit to pull the hazardous drug (HD) exhaust to the exterior of the roof of the unit.

Ample storage space shall also be included so that hazardous drugs can be stored in the negative pressure area in accordance with USP 800 Hazardous Drugs- Handling in Healthcare Settings (a minimum of 16 feet metal shelving, 12 inches deep [i.e. shelf 4ft wide x 12 in deep x 6ft High containing 4 solid metal shelves] to store non-refrigerated products). The BSCs must be positioned a minimum of eight inches from the wall of the unit's HD buffer room wall to allow for cleaning and equipped with an audible alarm to alert of possible failures in the air handling system or if service is disrupted. A medical grade refrigerator (minimum 20 cubic ft. with a minimum of 4 shelves) with capability for remote continuous temperature monitoring and audible alarm must also be included for storage of hazardous drugs. If a refrigerator is placed in a negative pressure buffer room, an exhaust located adjacent to the refrigerator's compressor and behind the refrigerator is preferred. The refrigerator shall be positioned a minimum of one meter from the BSCs.

The hazardous drug compounding room shall be equipped with an interlocking passthrough connected directly from the compounding area to the pharmacist work area. Additionally, this room shall have monitors with numerical displays and continuous recording of differential pressure, humidity, temperature and an audible and visual alarm when out of range. This room shall have an intercom capable of communicating between all rooms. Two stainless steel swivel top chairs and one stainless steel rolling cart minimally measuring 2'WX2'Dx3'H containing at least 2 solid shelves should be supplied for use in this compounding room.

Non-Hazardous Drug/Buffer Room (ISO Class 7):

The Non-Hazardous Drug/Buffer room will provide a minimum space of 12' X 8' X 7' high ceiling and have positive pressure in relation to the anteroom and will provide ISO Class 7 air quality. The room shall be equipped with at least two 4 ft. minimum horizontal Laminar Airflow Workstations (LAFW) with an ISO class 5 environment for preparation of sterile non-hazardous compounds. LAFW should contain a camera system and software solution that allows for pharmacist to validate all components utilized for compounding non-hazardous drugs during the compounding process. The room must have return air vents placed low to the floor of the unit and positioned behind particle generating areas with one return located near the door. The Sterile IV Preparation/Buffer room must contain ample storage space including a medical grade refrigerator (minimum 20 cubic ft. with a minimum of 4 shelves) with capability for remote continuous temperature monitoring and audible alarm. This room requires a minimum of 16 feet metal shelving, 12 inches deep (i.e. shelf 4ft wide x 12 in deep x 6ft High containing 4 solid metal shelves) to store non-refrigerated products. The non-hazardous drug compounding room shall be equipped with an interlocking passthrough connected directly from the compounding area to the pharmacist work area. Additionally, this room shall will have monitors with numerical displays and continuous recording of differential pressure, humidity, temperature and an audible and visual alarm when out of range. This room shall have an intercom capable of communicating between all rooms. Two stainless steel swivel top chairs and one stainless steel rolling cart minimally measuring 2'WX2'Dx3'H containing at least 2 solid shelves should be supplied for use in this compounding room.

Anteroom(s)

The MPC may have one anteroom capable of accessing both buffer rooms or may have an anteroom for each buffer room. Anteroom(s) will provide a minimum space of 5' X 8' X 7' high ceiling and will serve

as a changing area for personnel to don their Personal Protective Equipment (PPE) with a line of demarcation to indicate the separation of where personnel are required to put on or remove PPE as required. The room shall contain ample storage and changing space for PPE. The ante-room shall contain a hands-free activated sink(s) for performing hand washing on the clean side of the ante-room. Water sources and drains must be located at least 1 meter away from the buffer rooms. Sink(s) will have a soap dispenser and dedicated location (dispenser, shelf, etc.) for lint-free towels. An eyewash station and/or other emergency or safety precautions that meet applicable laws and regulations must be readily available. Water sources and drains must be located at least 1 meter away from the buffer rooms. The anteroom must have return air vents placed low to the floor of the unit and positioned behind particle generating areas with one air vent located near the door. The room shall be maintained at positive pressure relative to the outside. The anteroom shall be maintained under an ISO Class 7 air quality. Ante room(s) will have monitors with continuous recording of differential pressure monitoring.

Mechanical, Electrical, and Plumbing Systems

Mechanical: A heating, ventilation, and air conditioning (HVAC) system will be installed in the MPC in order to maintain comfortable working temperature and humidity level within the unit.

Electrical. The unit shall be equipped with a diesel generator to power critical systems with a fuel tank capable of storing 50 gallons of fuel, and power inputs with a minimum length of 50-foot cables. The MPC should have the capability to connect to facility power utilizing a 200-amp, 480-volt 3 phase outlet. Internal electrical outlets will be provided in each room to support equipment specified in the statement of need.

Plumbing: Unit shall be equipped with an on-board fresh water tank with a minimum of 70 gallons of clean water storage and a separate container for a minimum of 80 gallons of waste water with electrical water pump to provide running water for the sink. The unit shall also have connections in place so that a water utility tap can be used if needed for continuous operation.

Lighting: Unit shall will be provided with interior lighting in accordance with the CFR, Lighting Design Manual, <https://www.cfm.va.gov/til/dManual/dmLighting.pdf>.

Data Network

Data lines will be provided in the following areas with the minimum number per area as follows; 6 in the office area, 3 in the hazardous compounding room, 3 in the non-hazardous compounding room. Data lines shall each be at a minimum Cat6 copper UTP cable. All lines shall be run from a central location patch panel out to a terminal end RJ45 jack. One additional data line shall be provided with a jack accessible from outside the trailer (uplink port). A single NEMA 5-15 electrical receptacle is required at the central patch panel location. The vehicle must be able to hook up to a portable VA Very Small Aperture Terminal (VSAT) system, per VA VSAT requirements.

Security

The main door shall be a minimum of 36" W X 76" H and equipped with a key and deadbolt lock. Locking system must provide single motion egress from the interior. The MPC will have a motion intrusion detection system meeting specification in VA Handbook 0730/4 and an external security camera system to control access to the pharmacy areas. Exterior doors for the generator or HVAC system must be able to be secured by deadbolt or key lock.

Factory Certification

At the time of delivery, the unit, as well as the BSCs and Horizontal (LAFW) will be certified by an outside vendor, other than the manufacturer of the unit, as fully compliant with USP 797 and USP 800.

Delivery and Training will be provided at that location determined by the customer.

Warranty

The contractor shall repair or replace any item that malfunctions during the warranty period.

Each quoting vendor will include drawing of proposal at a detailed level.

Each vendor will submit brochure of like product(s) as this request.