

DEPARTMENT OF VETERANS AFFAIRS

**FAR 8 – Justification for Limiting Sources (LSJ)
For
Limiting Sources (<SAT)**

Acquisition Plan Action ID: 36C250-25-AP-2165

- 1. Contracting Activity:** Department of Veterans Affairs, Network Contracting Office 10, located at 6150 Oak Tree Blvd., Suite 300, Independence, OH, in support of VISN 10, VA Northeast Ohio Health Care System, located at 10701 East Blvd., Cleveland, OH 44106

Transaction: 541-25-2-250-0104

- 2. Description of Action:** Network Contracting Office (NCO) 10 intends to award a new, firm fixed price, delivery order for NuAire Inc. pharmacy IV hoods that will be sole sourced through NuAire Inc.. The request is for two (2) Laminar Airflow Workbenches and two (2) Class II, Biological Safety Cabinets for the Pharmacy Service at CLE VAMC

Order against: ☒ FSS Contract Number: GS-07F-226BA

Name of Proposed Contractor: NuAire, Inc.
Street Address: 2100 Fernbrook Lane
City, State, Zip: Plymouth, MN 55447
Phone: (763) 553-1270

3. Description of Supplies or Services:

The estimated value of the proposed action is [REDACTED]

Network Contracting Office (NCO) 10 intends to award a new, firm fixed price, delivery order for a NuAire Pharmacy IV Hoods.

The Pharmacy Service at the CLE VAMC is requesting two (2) Laminar Airflow Workbenches and two (2) Class II, Biological Safety Cabinets for the new VA Imaging and Infusion Center in Kent, OH. These units are essential for the sterile compounding of hazardous and non-hazardous medications and are required to ensure compliance with USP <800> standards.

Regulatory Compliance and Justification

USP Chapter <800> establishes practice and quality standards for handling hazardous drugs in healthcare settings, ensuring patient safety, worker protection, and environmental control. The primary engineering controls used in sterile compounding must meet the standards of USP General Chapters <797> and <800>, as well as FDA, Joint Commission, and VHA requirements.

- Laminar Airflow Workbenches (LAFW) are used for non-hazardous compounding.
- Class II, Biological Safety Cabinets (BSCs) are used for hazardous drug compounding. All primary engineering controls must be ISO Class 5 certified per CETA CAG-003-2006 procedures.

NuAire offers both Laminar Airflow Workbenches (NU-240) and Class II Biological Safety Cabinets (NU-543) that meet all regulatory requirements. These products are available on GSA contract at a discounted federal price.

4. Authority:

Order Against FSS: Authority of the Multiple Award Schedule Program, Title III of the Federal Property and Administrative Services Act of 1949 (41 USC 251, et seq.); Title 40 USC 501, Services for Executive Agencies; and Section 803 of the National Defense Authorization Act of 2002 (PL 107-107) and implemented by [FAR 8.405-6](#). Mark the applicable exception:

☒ **Items peculiar to one manufacturer.** An item peculiar to one manufacturer can be a particular brand name, product, or a feature of a product, peculiar to one manufacturer). A brand name item, whether available on one or more schedule contracts, is an item peculiar to one manufacturer ([FAR 8.405-6\(b\)](#)).

5. Rationale/explanation to support cited authority:

The new hazardous and non-hazardous IV rooms in the Kent Imaging and Infusion Center must be designed to meet USP <797> and <800> standards regarding air quality and sterility. The HVAC system and exhaust vents must be engineered specifically for the selected hoods, ensuring the required ISO Class 5 clean air environment.

The requested NuAire models have been verified to meet these exact air handling requirements. Alternative models would require different air handler specifications, causing significant facility modifications, procurement delays, and potential noncompliance with regulatory standards. The NuAire NU-240 Horizontal Laminar Airflow Workbench and NU-543 Class II, Type A2 Biological Safety Cabinet **are** solely manufactured by NuAire and contain unique specifications that distinguish them from other brands.

Unique Characteristics of the NuAire Equipment

NuAire NU-240 Horizontal Laminar Airflow Workbench (LAFW)

- 5-Year Parts and Labor Warranty (including HEPA filters).
- ISO 5 airflow across the entire work zone, validated by particle testing.
- 16/18 GA Type 304 stainless steel construction for durability and cleanability.
- HEPA filter (99.99% efficient at 0.3 microns), protected by a perforated metal diffuser.
- Air velocity of 80 to 100 FPM to ensure uniform airflow without contamination risks.

- Energy-Saver ECM Motor maximizes filter lifespan and handles 250% filter loading increase while maintaining consistent airflow.
- ADA-compliant ergonomic design with an adjustable base stand for user comfort.
- Large work surface (19 5/8" depth) with a raised rear spill lip for easy cleaning.
- IV bar with 6 hooks, adjustable to 3 height positions for improved workflow.
- User-friendly control system with LED indicators, solid-state switches, and airflow monitoring via PresurFlow™ Monitor.
- Front filter removal capability for easy maintenance without disassembly.

NuAire NU-543 Class II, Type A2 Biological Safety Cabinet (BSC)

- 5-Year Parts and Labor Warranty (including HEPA filters).
- NSF/ANSI 49 certified for biological containment, meeting UL 61010-1 electrical safety standards.
- Monolithic, sealed stainless-steel construction to prevent leaks and ensure sterility.
- Energy-Saver ECM Motor extends HEPA filter life and minimizes HVAC burden.
- Ergonomic design with an adjustable base stand and removable, non-metallic armrests for user comfort.
- Smooth, coved work tray with prop-up feature for thorough cleaning.
- IntelliFlow™ Monitoring System provides real-time airflow data, temperature display, and security password protection.
- LED lighting system for energy efficiency and optimal visibility.
- Front filter removal capability for maintenance without disassembling the control panel.

Regulatory Compliance & Cleaning Efficiency

- NuAire hoods have a smooth, crevice-free interior, eliminating areas where microorganisms can accumulate.
- Per USP <797>, sterile compounding facilities must be easily cleanable to prevent contamination.
- Surfaces are cleaned and disinfected daily and sampled monthly per USP <797> action limits.
- IV bar is height-adjustable, minimizing fatigue for multiple users while ensuring aseptic technique.

HVAC System Compatibility & Heat Reduction

- NuAire hoods generate less heat compared to other brands.
- USP <797> and the VHA HVAC Design Manual require sterile compounding suites to be ≤ 68°F.
- Lower heat output reduces strain on the HVAC system, helping maintain optimal sterility conditions.

Superior Design for Operator Comfort & Compliance

- NuAire's ADA-compliant design ensures comfortable use for diverse personnel needs.
- Adjustable features enhance workflow efficiency and reduce contamination risks.

6. BRAND NAME ONLY: This buy is estimated to exceed \$25,000 and this documentation will be posted along with the RFQ on e-Buy, as required by FAR 8.405-1(e).
7. Note that this determination satisfies the requirements of [FAR 8.405-6](#). The requirement to prepare a written justification [IAW FAR 6.303](#) does not apply to Federal Supply Schedules.

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Date: 2025.02.20
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Rachelle J. Hamer
Contract Specialist
NCO 10