

**DEPARTMENT OF VETERANS AFFAIRS**  
**Justification and Approval**  
**For**  
**Other Than Full and Open Competition**

1. **Contracting Activity:** Department of Veterans Affairs, VISN 10 Network Contracting Office, Louis Stokes Cleveland VA Medical Center, Research Department, has prepared this document to serve as the "Justification for Other Than Full and Open Competition" for Purchase Request #541-14-3-2411-0525.
2. **Nature and/or Description of the Action Being Processed:** The purposed is a new fixed-price sole source action awarding a purchase order to "Scireq USA Incorporated" for Lab Nebulizer unit & accessories.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** This requirement is for Scireq USA, Inc., equipment and accessories for use on the Scireq FlexiVent FX ventilator currently in use at the Louis Stokes Cleveland VA Medical Center Medical Research Service:  
  
Aeroneb Lab Nebulizer unit, small particle size  
Rainout Characterization Kit (2)  
Integrated Aerosol Delivery Accessories for the FlexiVent FX  
FX adapter with nebulizer mount for module 1  
Upgrade to FlexiWare 7 software, full license  
FlexiWare software version 7.6 license  
FlexiWare software-minor upgrade  
  
The estimated cost is not to exceed \$6,345.00.
4. **Statutory Authority Permitting Other than Full and Open Competition:**  
(X) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):**  
Scireq, Inc. manufactures small animal ventilators used for rodent research. These "flexiVent" ventilators are considered state of the art, in that they can measure a number of ventilatory parameters in addition to and at the same time as providing ventilatory assistance to animals during research studies.


Certain studies, for example asthma related experimentation, require the introduction of small particles into the lungs of rodent experimental subjects. This is accomplished using an aerosol nebulizer. A substance is added to the nebulizer, which aerosolizes it, and it is breathed in by the animal on the ventilator. In humans, this technique is commonly used to introduce medicines into the airways of patients. In rodent research, medicines or other test compounds can be easily introduced by using an aerosol nebulizer.

The Aeroneb Lab Nebulizer unit (and needed accessories) requested for purchase here is made specifically to connect to the flexiVent ventilator used in the Jacono lab at the Louis Stokes Cleveland VA Medical Center Medical Research Service. This lab studies acute lung

injury and its treatments. As such, the addition of an aerosol nebulizer unit to the existing ventilatory apparatus will enable the study of compounds introduced into the lungs without the need for surgery to introduce them. Additionally, it will enable the ability to employ methacholine challenge testing. Methacholine is an agent that, when inhaled, causes the airways to spasm (contract involuntarily) and narrow if asthma is present. For it to be inhaled, it must be aerosolized.

This procurement is an investment in continuing research in lung disease at Louis Stokes Cleveland VA Medical Center Medical Research Service. It will be made available to any investigator in the research service who has need of this type of ventilatory equipment.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** No other source can provide the nebulizer unit and accessories necessary to use it due to proprietary rights. This unit will be used with the already purchased flexiVent FX ventilator made by Scireq. Due to its unique configuration and capabilities, no other commercially available nebulizer aerosol unit can be attached to this ventilator.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The Contractor Officer has determined the anticipated cost to the Government will be fair and reasonable. The pricing is consistent with open market pricing.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Market research was conducted and there were no distributors for the required equipment found. This equipment is proprietary and attaches and/or interfaces with equipment already onsite. Should a different nebulizer be purchased, a new ventilator would also need to be purchased to support its use.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:**
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** State "See Section VI above."
11. **A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required:** In order to remove or overcome barriers to competition in future acquisitions for this requirement, the Government will continue to conduct market research to ascertain if there are changes in the market place that would enable future actions to be fully competed.
12. **Requirements Certification:** I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.

  
Stephen Kesterson  
RESEARCH COR

Louis Stokes Cleveland VA Medical Center

9/19/14  
Date

13. **Approvals in accordance with FAR 6.304** This contract action does not exceed \$650,000, the certification below required by FAR 6.303-2(b)(12) services as approval.

- a. **Contracting Officer's Certification (required)**: I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

jason.lawson@va.gov

OV

Jason E. Lawson  
Contracting Officer  
Network Contracting Office (NCO) 10

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- b. **NCM/PCM (Required \$3K and above)**: I certify the justification meets requirements for other than full and open competition.

Terry Spitzmiller  
Director of Contracting  
Network Contracting Office (NCO) 10

Date