JUSTIFICATION
FOR OTHER THAN FULL AND OPEN COMPETITION

1. Contracting Activity: Department of Veterans Affairs (VA)
                            Office of Acquisition Operations
                            Technology Acquisition Center
                            23 Christopher Way
                            Eatontown, NJ 07724

2. Description of Action: The proposed action is for a sole source firm-fixed price (FFP) contract for IntelePACS servers, IntelePACS software, installation/integration, training and maintenance support services with Intelerad Medical Systems Incorporated (Intelerad), Central Station, 895 de la Gauchetiere W. Suite 400, Montreal, QC, Canada, H3B 4G1

3. Description of Supplies or Services: The Veterans Affairs National Teleradiology Program (VANTP) has a requirement for an additional functional instance of IntelePACS at the VA co-location data center in Sacramento, California for the VANTP to support review of previously reported radiology cases (i.e. Peer Review System). This additional module/functionality will allow for a dedicated worklist separate from the current production system so that the external peer review workflow does not negatively impact ongoing clinical interpretations. There is a critical need to perform comprehensive peer review of 8,000 cases from a VA facility and VA has been tasked to perform this review within an expedited timeframe to determine if there are critical, clinical issues with the reports. This external peer review module provides significant workflow enhancements, lessening the technical and operational requirements that will be required to accomplish this project. VANTP also requires the deployment of a Reading Center in New York, New York (Manhattan). The additional Reading Center in Manhattan is required to meet the operational requirements of the VANTP. The VA Central Office has mandated VANTP provide supplemental Radiology coverage to VISN 16 and VISN 10 sites due to critical staffing shortages. The contractor shall also provide Hardware and software support to include remote 24-hours x 365 days per year service/support via site-to-site Virtual Private Network (VPN) and on-site response by for hardware support within four hours, 365 days a year. VANTP's IntelePACS is a Food and Drug Administration (FDA) 510k regulated medical device. This requirement is for highly complex mission-critical medical system upgrades. Any software modifications and system configuration changes must be performed by the original equipment manufacturer (OEM). The Contractor shall deliver, install and configure the IntelePACS Servers at the VA co-location data center in Sacramento, CA and shall deliver, install and configure the IntelePACS Servers for the VA Manhattan Reading Center within 21 days of award. The period of performance for the maintenance at both the VA co-location data center in Sacramento, California and the VA Manhattan Reading Center shall commence upon successful installation for term up to September 30, 2018.

4. Statutory Authority: The statutory authority permitting other than full and open competition is 41 U.S.C.3304(a)(1) as implemented by the Federal Acquisition

Regulation (FAR) Subpart 6.302-1 entitled, "Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements."

5. <u>Rationale Supporting Use of Authority Cited Above</u>: Based on the market research, as described in Section 8 of this justification, it was determined that the IntelePACS servers, IntelePACS software, installation/integration and maintenance support services required are only available directly from Intelerad which owns the proprietary rights to the hardware and software. The current PACS is based on existing Intelerad hardware and software and requires any additional functional modules/functionality or additional reading centers to be interoperable and compatible with the existing system. The PACS hardware and software is proprietary in nature and the software/configuration to integrate an additional reading center into the VANTP PACS is intellectual property of Intelerad. Due to the proprietary nature of the hardware and software code in the existing VA PACS, which is comprised of Intelerad hardware and software, only Intelerad will meet VA's requirements due to compatibility and interoperability with the proprietary hardware software in the existing PACS as only Intelerad can communicate with the existing infrastructure. As this is an augmentation of an existing Intelerad system, the hardware, software, installation/implementation services are only available directly from the vendor that owns that hardware and software and is not sold through resellers. No other source is available for Intelerad technical or installation support. Intelerad is the only vendor with the knowledge, capability and authorization to perform this work. The OEM has exclusive access to its intellectual property and Intelerad in the only vendor that can supply a modification to its PACS. Intelerad is the only vendor with the knowledge, capability and authorization to perform this work. Failure to procure the additional module/functionality for IntelePACS will prohibit VANTP's ability to perform critical peer reviews which can lead to a significant number of missed clinical findings and have an adverse clinical impact on VA patients. Furthermore, failure to procure the added capacity provided by the additional reading center will prohibit VANTP' ability to overcome critical staffing shortages and provide multiple VA facilities critical after hours Radiology coverage which again will have an adverse impact on VA patients.

Additionally, only Intelerad can provide the required hardware and software maintenance and support for the IntelePACS hardware and software. Intelerad coding is proprietary in nature and is not released to any other party. The source code is also not available for sale to the VA. Therefore, only Intelerad has the experienced staff trained in the enterprise best practices and advanced features of Intelerad. In addition, due to the proprietary nature of the hardware and software, only Intelerad staff has the detailed understanding of the software capabilities and function to immediately address any software functionality issues. Since Intelerad does not sell through resellers, Intelerad is the only source that is able to provide the hardware and software maintenance for the IntelePACS hardware and software.

6. <u>Efforts to Obtain Competition:</u> Market research was conducted, details of which are in section 8 of this justification. This effort did not yield any additional sources that can meet the Government's requirements. There is no competition anticipated for this acquisition. Additionally, the proposed action will be synopsized on the Federal

Business Opportunities Page in accordance with FAR 5.201. Any proposals that are received shall be evaluated.

7.   <u>Actions to Increase Competition</u>: The Government will continue to conduct market research to ascertain if there are changes in the marketplace that would enable future actions to be competed.

8. <u>Market Research:</u>   IntelePACS is a commercially available off-the-shelf medical system with corresponding image review software currently in use in VA. When conducting market research in February 2017 the Government's technical experts reviewed similar clinical products such as Philips Intellispace, Agfa Impax and McKesson PACS to ascertain if these items could meet VA's requirements. Specifically, the Government's technical experts conducted research on web sites and utilized first-hand knowledge of commercial PACS that are deployed within VA. As a result of the market research, the technical experts confirmed that all of the products researched were unable to meet the functional requirements, interoperability, and compatibility requirements as outlined in Section 5. Based on the above, only Intelerad hardware, software, installation/implementation services, training and maintenance services meets all of the Government's requirements. Additionally, on March 14, 2017, the Government received confirmation from Intelerad, the original equipment manufacturer, that it is the only source for the required hardware, software and services and that no other source can upgrade existing software and hardware suite of software management products and services.

9. <u>Other Facts:</u> None