



VA Eastern Colorado Health Care System Initial Outfitting & Transition
General Conditions and Statement of Work
LV10F – GI PACS Systems

Version 4.0

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General Conditions and Statement of Work
LV10F – GI PACS Systems

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1. Introduction

The Veteran Affairs Eastern Colorado Health Care System (VA ECHCS) wishes to enter into an agreement to purchase LV10F – GI PACS Systems with an authorized contractor for materials, supplies and delivery of the items identified below, and any subsequent services required to assemble, install, integrate, warranty, and/or maintain new items for the Denver Replacement Facility, as described in the bid documents and specifications contained herein.

The Veterans Affairs, Eastern Colorado Health Care System (ECHCS), Denver, Colorado, is soliciting for the procurement of a complete Gastroenterology and Pulmonary PACS which provides a seamless integration with Vista/CPRS. The solution will provide storage and management for Gastroenterology and Pulmonary patient diagnostic images and reports. The scope of this requirement will include all necessary hardware, software, installation, training, sustainment, and support and warranty required and/or as specified within this document.

2. General Conditions

2.1. General Operation

2.1.1. On-Site assembly and installation of items, and performance of services identified in this document will take place during normal business hours which are defined as: 0700 to 1600 (i.e.: 7:00am to 4:00pm Mountain Standard Time), Monday through Friday, and excluding Federal Holidays.

2.1.2. The contractor will protect all finished spaces and surfaces at no additional cost to VA ECHCS. The contractor will be responsible for paying for and repairing any damage or noted deficiencies to finished spaces and surfaces that occur as a result of the contractor's (or associated sub-contractors) installation.

2.1.3. Prior to starting work, the contractor and associated personnel (including subcontractors) will be required to attend a VA Construction Facility Management site safety training program, and adhere to its Personal Protective Equipment (PPE) requirements (i.e. hard hat, steel toe boots, high visibility vest, safety glasses, gloves).

2.1.4. There are no dumpsters available for contractor's use. The contractor shall be responsible for removal of all trash generated from installation.

2.1.5. The contractor shall provide fill out the Pre-assessment 6550 form and submit it along with their proposal.

3. Procurement Specific Requirements

3.1. X4122.DS Technical Requirements

X4122.DS Gastroenterology (GI) and Pulmonary, Picture Archiving System (PACS) Software. Quantity - 1

The PACS system software shall meet the following salient characteristics at a minimum:

3.1.1. Provide at least 10 capture workstations license and site (unlimited) administrative license. Quantity and characteristic of capture workstation is detail in section 3.2.

3.1.2. Site administrative license shall be capable to operate on standard VA OIT workstation environment. An existing TRM approval is preferred.

3.1.3. Provide a technology platform for Endoscopy Image Management to include diagnostic report tool, capture, store and view GI and Pulmonary images.

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3.1.4. Integrate bidirectionally with Vista/CPRS through Clinical Procedure (CP) platform. If bid product doesn't integrate through Clinical Procedure, the contractor shall demonstrate the effective mean to upload endoscope image and consult/referral reports to Vista/CPRS and Vista Imaging.

3.1.5. Integrate with Rapid v8.3 Capsule Endoscopy, manufactured by GIVEN/Medtronic.

3.1.6. Capture Images – from various sources including endoscopes such as Olympus, Kaypentax, KarlStrozl, ect., endoscopy ultrasound (EUS), fluoroscopy x-ray, capsule endoscopy, pH manometry, and other imaging equipment.

- Capture & View Full Size 1080p HD Images
- HD Video Clips from up to four sources simultaneously
- Compare & annotate Images
- Capture using HDMI, HD, SDI and/or composite video sources.

3.1.7. The system shall be DICOM compatible and be HL7 compliant

3.1.8. Be capable of generating ancillary documents such as: referring physician letters, patient instructions and pathology requisition immediately after the procedure is completed.

3.1.9. Provide streamline coding processes by automatically generating the appropriate CPT, ICD-9, ICD-10 diagnostic codes. Appropriate coding in the documentation is critical for guiding clinician to quickly document information needed to support coding, compliance, quality metrics, and process improvement.

3.1.9.1 Procedure coding for GI:

- Esopagoscopy
- EGD
- ERCP
- Upper EUS
- Lower EUS
- Fine needle Aspirate
- Capsule Endoscopy
- Colonoscopy
- Sigmoidoscopy
- Radiofrequency Ablation
- Esophageal Manometry
- Ambulatory pH reflux testing
- Esophageal Dilation
- Liver Biopsy
- Paracentesis
- Liver Elastography

3.1.9.2 Procedure coding for Bronchoscopy:

Bronchoscopy, Diagnostic

- Bronchoscopy with:
 - Endobronchial Biopsy
 - Endobronchial Needle Aspiration
 - Transbronchial Biopsy

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- Transbronchial Needle Aspiration
- Bronchioalveolar Lavage/Brushings/Washings
- Endobronchial Ultrasound
- Mediastinal/Hilar Lymph Node Staging
- Foreign Body Removal
- Photodynamic Therapy
- Lung Transplant Surveillance
- Fiducial Marker Placement
- EM Navigation Bronchoscopy

Flexible Fiber Optic Laryngoscopy

- Flexible Fiber Optic Laryngoscopy, Diagnostic
- Flexible Fiber Optic Laryngoscopy with:
 - Biopsy
 - Foreign Body Removal
 - Topical Medication Application

Chest Tube Placement

- Chest Tube Placement
- Chest Tube Placement with Blind Pleurodesis

Thoracentesis

- Thoracentesis
- Thoracentesis with Blind Pleurodesis

3.1.10. The contractor shall have the Inventory Management module to track all endoscope scope, patient, and procedures. In the event of endoscope recall, the system shall have the capability to pull up all patient and procedures that the defected endoscope was used.

3.1.11. The contractor shall provide Customizable Templates, multilingual, with e-Signature capability.

3.1.12. The contractor shall provide at a minimum 100 canned report templates and unlimited custom report templates that can be pulled on-demand.

3.1.13. Pre-Endoscopy Evaluations – provides an integrated application to automatically dates and time stamp evaluations and provides clinicians with reports on measures, such as GIQuIC. Indications for Exam, ASA Classification, Sedation Goal, History. Medication, Anticoagulants, Physical Exam and Mallampati Score

3.1.14. Letter to Referring Physicians – print, email, e-Fax and/or Color Fax including images.

- Post Procedure Instructions
- Discharge Instructions

3.1.15. Generate Pathology Requisitions – allows providers to intuitively send patient information and submit tissue samples to the lab.

- Indications for Examination
- Tissue Submitted with location
- Findings
- Endoscopic Diagnosis
- Recommendations

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- Associated CPT and ICD 10 codes.

3.1.16. Capture and view full size images and/or video clips from a maximum of four sources simultaneously and compare and annotate images.

3.1.17. Reports:

3.1.17.1. The contractor shall provide Quality Reporting module with GIQUIC certified. Report shall include: guides clinician via a database of procedure-specific paths, flags specific data points to ensure they are not overlooked by the physician during documentation and eliminates reports gaps, collects many required data points directly from procedure notes, and automate data capture and reporting.

3.1.17.2. The contractor shall provide Procedure Data Export utility for clinician to run queries on discrete data elements generated from procedure notes. The data export shall have filtering capabilities that allows clinicians search the database for selected criteria. Clinician can view and export this results of the queries onto a VA OIT PC environment through editable XML, HTML, or raw text format.

3.1.17.3. GI Procedure Diagnostic report: the system shall provide reporting tool for GI clinician after each procedure. Attachment A is the sample report. At a minimal, the system shall provide all fields in the Attachment A.

3.1.17.4. Bronchoscopy Procedure Diagnostic report: the system shall provide reporting tool for Bronchoscopy clinician after each procedure. Attachment B is the sample report. At a minimal, the system shall provide all fields in the Attachment B.

3.1.17.5. Server requirements

- The contractor shall supply all servers licenses sufficient to support a minimum of 3 virtual servers:
- Database Server
- Application Server
- Test Server
- The server shall have failover for drive failure to prevent loss of data and system outages.
- ECHCS will provide VM (virtualize machine) hardware to host all servers.

3.2. X4122.D Capture Workstation, GI PACS, 17" – 19" display. Quantity 10

Overview: 6 GI Procedure rooms, 2 GI portable carts, 1 Pulmonary/Bronchoscope Procedure room, 1 Pulmonary/Bronchoscope portable cart.

3.2.1. The GI PACS High Definition Stills Capturing PC Workstation shall have the following characteristics:

3.2.1.1 Minimal Windows 7 SP1 Professional/Ultimate/Enterprise 64 bit, however, Window 10 is preferred.

3.2.1.2. Microsoft .NET Framework 4.6

3.2.1.3. Intel multi-core processor (within last 2 processor generations)

3.2.1.3. Minimal 4 GB RAM

3.2.1.4. Minimal 80 GB free hard drive space

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3.2.1.4. Image Capture Card/Device capable of capturing standard and high definition stills and video.

3.2.1.5 Integrated serial port OR a supported USB to Serial adapter

3.2.1.6 Display must be a minimum of 17" and Maximum 19" support minimum 1024 x 768 resolution

3.2.1.7. Installation shall include video cable run from Endoscopy system to the capture workstation. Endoscopy system and capture workstation may not be located in the same room. Distance can be as far as 50 feet.

3.2.1.8 Capture workstation may be on: Amico equipment boom, casework/desktop, or side mount on portable cart. If during the installation, the contractor identifies the need for mount bracket base on the environment, the contractor shall provide the appropriate bracket.

3.3. Project Management Plan (Deliverable)

3.3.1. The Contractor shall draft a Contractor Project Management Plan (CPMP) that lays out the Contractor's approach, timeline and tools to be used in execution of the contract. The PMP should take the form of both a narrative and graphic format that displays the schedule, milestones, risks and resource support. The CPMP shall include the contractor's plans for managing all subcontractors. Topic areas to be addressed shall include oversight and communications with subcontractors while onsite at VA locations, as well as executing the timely distribution and delivery of all materials to subcontractor personnel. The CPMP shall also include how the Contractor shall coordinate and execute planned, routine, and ad hoc data collection reporting requests as identified. The initial baseline CPMP shall be concurred upon and updated monthly thereafter. The Contractor shall update and maintain the VA Contracting Officer's Representative (COR) approved CPMP throughout the period of performance.

3.3.2 The CPMP include but not limited to:

3.3.2.1. Project Schedule to include Milestones, Deliverables, and Critical Path

3.3.2.2. Verification & Validation (V&V) Plan

3.3.2.3. Training Plan

3.3.2.4. Risks Management Plan

3.3.2.5. Operations & Maintenance Plan (See Section 5 for further Detail)

3.3.2.6. Project Closeout Activities/Procedures

3.3.3. Reporting Requirements

The Contractor shall provide weekly progress reports, to include schedule updates, to the VA COR and shall cover all work completed during the reporting period and work planned for the subsequent reporting period. The reports shall also identify any problems that arose and a description of how the problems were resolved. If problems have not been completely resolved, the Contractor shall provide an explanation. The Contractor shall monitor performance against the CPMP and report any deviations. It is expected that the Contractor will remain in communication with the VA COR to prevent escalation of outstanding issues.

The Contractor shall provide the VA COR with Weekly Installation Progress Reports in electronic form in Microsoft Word, Project formats or PDF. The report shall include

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detailed instructions/explanations for each task, to ensure that data is accurate and consistent. These reports shall reflect data as of the last day of the preceding month. These reports shall include a summary of the task order deliverables.

3.3.4. Verification and Validation Requirement (Testing)

3.3.4.1 The contractor shall perform testing following installation to ensure UDAS boxes are correctly interface with the Eccentric system.

3.3.4.2 The contractor shall perform testing following installation to ensure interfaces to appropriate bedside monitoring devices are correct and functioning. Contractor shall be testing through test environment prior to Live Production.

3.3.4.3 The contractor shall provide a final test plan that includes updates addressing any comments provided by the VA to the draft test plan.

3.3.4.4 Disputes shall be resolved by the Contracting Officer.

3.3.4.5 The contractor shall conduct a joint inspection with the onsite Point of Contact (POC) upon completion of delivery.

3.3.4.6 In the event deficiencies are identified, the Contractor shall provide a date when the identified deficiencies will be addressed if not addressed on the date of delivery.

3.3.4.7 The contractor shall conduct a joint inspection with the onsite POC after addressing all deficiencies.

3.3.4.8 All deficiencies identified during joint inspections shall be corrected by the contractor before Government's acceptance of the item.

3.3.5. Project Estimate Time Line

3.3.5.1. Phase I: System design with Project Kickoff Estimate Start Date: the contractor shall contact the Government POC no later than three days after contract award to begin coordinating this requirement. Contactor shall submit the CPMP to the Government POC for approval prior to Phase II, 8 January 2018.

3.3.5.2. Phase II: Hardware and software installation and configuration. Estimate Start Date: 01/08/2018

3.3.5.3. Verification and Validation: Estimate Start Date: 01/23/2018

- Medical Device Integration/testing
- Workflow and Vista/Clinical Procedure Testing
- Pre-Go-Live Training

3.3.5.4. Phase III: System Operational: Estimate Start Date: 03/25/2018

3.3.5.5. Phase IV: Go Live: Anticipated 07/30/2018

- The contractor shall provide Post-Go-Live service 4 months after Go Live
- Post Go-Live include onsite clinical training to ensure all workflow are meeting clinical needs. Adjust system configuration as need. Retrain clinical users as needed.

* These dates are estimated and subject to change.

3.4. Training Requirement

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- Contractor shall provide the following training and customer care support:
 - On-Site and On-Line Training and Support
 - Include new user system training.
 - On-Site training minimum of 40 hours not to exceed a schedule of 5 days for a minimum of 35 clinical staff and 4 Biomedical Engineering.
 - Software licensing
 - Software Support and Troubleshooting
 - Server Software and Interface Software Upgrades
 - System Administration training to 4 staff

4. Operations & Maintenance

4.1.1. The Contractor shall provide 8-5pm MST telephone technical and clinical support.

4.1.2. Software maintenance to include software upgrade and update, and integration to VISTA VA Electronic Medical Records.

4.1.3. All system maintenance shall be coordinated with VA COR and/or POC

4.1.4. The contractor may support software maintenance remotely through VA site-to-site Virtual Private Network (VPN). If the Site-to-Site VPN was not established prior to the contract agreement, the contractor shall provide resource to complete the Site-to-Site VPN application process with local Biomedical Engineering team.

5. Information Security /Privacy Requirements

5.1. Information made available to the contractor or subcontractor by VA for the performance or administration of this contract or information developed by the contractor/subcontractor in performance or administration of the contract shall be used only for those purposes and shall not be used in any other way without the prior written agreement of the VA. This clause expressly limits the contractor/subcontractor's rights to use data as described in Rights in Data

5.2. SECURITY INCIDENT INVESTIGATION

5.3. The term “security incident” means an event that has, or could have, resulted in unauthorized access to, loss or damage to VA assets, or sensitive information, or an action that breaches VA security procedures. The contractor/subcontractor shall immediately notify the COTR and simultaneously, the designated ISO and Privacy Officer for the contract of any known or suspected security/privacy incidents, or any unauthorized disclosure of sensitive information, including that contained in system(s) to which the contractor/subcontractor has access.

5.4. LIQUIDATED DAMAGES FOR DATA BREACH

5.4.1. a. Consistent with the requirements of 38 U.S.C. §5725, a contract may require access to

5.4.2. sensitive personal information. If so, the contractor is liable to VA for liquidated damages in the event of a data breach or privacy incident involving any SPI the contractor/subcontractor processes or maintains under this contract.

5.4.3. b. Based on the determinations of the independent risk analysis, the contractor shall be responsible for paying to the VA liquidated damages in the amount of \$37.50 per affected individual to cover the cost of providing credit protection services to affected individuals consisting of the following:

5.4.3.1. Notification;

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5.4.3.2. One year of credit monitoring services consisting of automatic daily monitoring of at least 3 relevant credit bureau reports;

5.4.3.3. Data breach analysis;

5.4.3.4. Fraud resolution services, including writing dispute letters, initiating fraud alerts and credit freezes, to assist affected individuals to bring matters to resolution;

5.4.3.5. One year of identity theft insurance with \$20,00.00 coverage at \$0 deductible; and necessary legal expenses the subjects may incur to repair falsified or damaged credit records, histories, or financial affairs.

5.5. TRAINING

5.5.1. All contractor employees and subcontractor employees requiring access to VA information and VA information systems shall complete the following before being granted access to VA information and its systems:

5.5.2. Sign and acknowledge (either manually or electronically) understanding of and responsibilities for compliance with the Contractor Rules of Behavior, Appendix E relating to access to VA information and information systems;

5.5.3. Successfully complete the VA Privacy and Information Security Awareness and Rules of Behavior training and annually complete required privacy and security training; and successfully complete any additional information security or privacy training, as required for VA personnel with equivalent information system access.

5.5.4. The contractor shall provide to the contracting officer and/or the COTR a copy of the training certificates and certification of signing the Contractor Rules of Behavior for each applicable employee within 1 week of the initiation of the contract and annually thereafter, as required.

5.5.5. Failure to complete the mandatory annual training and sign the Rules of Behavior annually, within the timeframe required, is grounds for suspension or termination of all physical or electronic access privileges and removal from work on the contract until such time as the training and documents are complete.

Attachments:

A: GI sample diagnostic report

B: Bronchoscopy sample diagnostic report