Ralph H. Johnson VA Medical Center

Charleston, SC

Statement of Work

DOSE WATCH/ Automated dose capture software solution

Version #2.1

4/13/2018

1. Introduction

The Ralph H. Johnson VA Medical Center (RHJ VAMC), Charleston, SC., wishes to purchase *DOSE WATCH/ Automated dose capture software solution* which includes *software applications* for the *Radiology and Cardiology Service*. This system complies with Joint Commission;s requirement to monitor and track patient radiation doses as well as record the dosage or exposure as part of the exam's summary report of findings. Dose Watch is an automated software solution that captures radiation dose from each modality. Current VAMC Charleston Services who will utilize this software include: Radiology and Cardiology. Current dose capture system is completely manual. This software will increase workflow by ensuring dose capture accuracy. It will improve patient care through enhanced software reporting tools to evaluate trends, develop lower dose protocols for each modality which ultimately reduces patient exposure. ALARA principles will be constantly maintained.

The purpose of the *DOSE WATCH/ Automated dose capture software solution is* to *provide advanced diagnostic data, run analytical reports, and automate radiation dose tracking cumulitavly for all patients*, and perform various other tasks as outlined in this Statement of Work (SOW). *The system shall support over 25 Radiology and Cardiology modality machines at the RHJVAMC as well as 4 CBOC's. The system shall support approximately 100,000+ procedures per year.*

DOSE WATCH/ Automated dose capture software solution shall be installed and configured by an authorized vendor for the materials, software, equipment, services, and supplies pertaining to this SOW. This is including any subsequent services required to assemble, install, integrate, warranty, and/or maintain the items in response to this SOW. This includes the prime and any sub-contractors.

Any subsequent services required to assemble, install, integrate, configure, program, warranty, sustain and/or maintain new items in response to this SOW for the RHJ VAMC shall be defined in the vendor's response.

2. Technical Requirements

All of the following Minimum Salient Characteristics must be achievable by the potential vendor to be deemed an acceptable product. Any vendor not able to meet all of these Characteristics will be considered unacceptable and will not be considered for procurement:

The software platform shall help to Identify variability in study descriptions, protocols, and the dose delivered to the patient. Outline the dose management goals, and establish basic knowledge of dose management methodology & process. Additionally it must help improve technologist awareness of techniques and equipment features selected and the resulting dose impact. Initiate internal & external communication strategy around dose management.

1. Software platform shall provide Core Licensing that includes the following features:
    - Zero footprint web interface, VPN accessible
    - Automatic patient dose tracking
    - Multi-modality: CT, IR, RF, Rad, Mammo and Nuclear Medicine
    - Vendor neutral compatibility
    - Support dose SR for XA procedures
    - Direct acquisition from GEHC CT scanners
    - Email templates for automated email notifications
    - Worklist of upcoming exams with proactive alerts on patient dose history
    - List of performed exams by modality, site, device
    - Patient BMI record
    - Detailed acquisition parameter data
    - Patient multimodality dose history
    - Unified patient dose history when multiple patient identifiers ore used (requires specific IT integration and associated additional cost)
    - Calculation of CT effective dose by target region
    - Image Quality Voting tool

- Local study description mopping to RSNA RadLex Playbook
- Customizable Diagnostic Reference Levels: Notionally defined and/or customer-defined reference values, regulatory alerts. preformatted exports
- Configurable automated monthly reports
- Analysis per protocol of exams and patient with dose history
- Virtual target values
- Automatic SSDE calculation for CT procedures IAAPM TG204)
- Evaluation of CT acquisition quality: isocenter shift, mA modulation
- Automatic cumulative dose incidence map for CV/Int'v procedures
- Automatic gauges of air kerma, fluoroscopy time and dose area product
- Comparison tool (per imaging device, exam procedure, date range, etc)
- Distributed acquisition architecture for multi-site configurations
- Site-specific settings for notifications. statistics, DRLs, lexicon mappings etc
- Automated exam acquisitions from PACS (exam retrieve workflow)
- Management of users functional and data access rights based on configurable user teams
- Contrast Doto Management: DoseWatch 2.0 enables Contrast Doto Management ICDMI in addition to radiation dose management. CDM is an optional, purchasable module.
- LDAP integration to enterprise user directory for user authentication
- Inbound HL7 interface for patients updates/merges & procedure updates
- Dose SR creation based on image header analysis

- HL7 or DICOM outbound interface to shore dose information for other information systems
- Exam dose report feed to Digital Dictation Software
- Scriptable templates for outbound MPPS, Dose SR and HL7
- Interactive patient's timeline
- Boxplots for exam positions in statistics
- Filtered views per site
- Contextual launch of software application from 3rd party applications
- Web service to retrieve patient dose history from software application into a calling 3rd-party application

2. Supports all DICOM standards: MPPS, RDSR, image headers. ACR DIR certified software partner: automated to send to ACR DIR. IHE REM compliant for Dose Reporter and Dose Consumer.*CE* Marked in compliance with the applicable requirements of the Directive 93/42/CEE.

3. **Device Connection CT/Interventional:**

   Device license permits the acquisition of radiation dose data from one CT or Interventional device within the software application system. This license includes, if applicable to CT or Interventional, the following:

   - The implementation of the connection of the device to the software application; only the vendor software side of the interface is covered by this license. Any additional software and/or services required on the device must be purchased by the customer. Depending on the device capabilities, the connection may require sending DICOM MPPS, DICOM Radiation Dose SR, DICOM Images or specific device Jags from the device. The actual solution implemented shall be specified by the vendor software team.

- Configuration of the software solution to process the received data and store radiation dose and acquisition-related data into the software solution database.

- Modalities supported: CT-scanner and Interventional.

4. Device Connections – Others:

- Device license permits the acquisition of radiation dose data from devices other than CT or Interventional (i.e. radiography device, mammography systems) within the software platform application. It is also used to connect a DICOM system (i.e. PACS system) so software platform can receive or retrieve data from that system. In such case, a license is needed for each device generating the data and each DICOM system connected to the software platform.

- This license includes, if applicable to X-ray or Mammography, the following:

- The implementation of the connection of the device to the software platform. Only the software platform side of the interface is covered by this license. Any additional software and/or services required on the device must be purchased by the customer. Depending on device capabilities, the connection may require sending DICOM MPPS, DICOM Radiation Dose SR, DICOM Images or specific device logs from the device. The actual solution implemented shall be specified by the vendor software team.

- Configuration of software platform to process the received data and stare radiation dose and acquisition-related data into the software platform database.

5. HL7 Interface Engine (5-channel)

The vendor software platform HL7 Interface Engine supplies the software required to implement HL7 interfaces between the vendor software platform and other systems. The software provided allows the implementation of up to 5 HL7 data flows (channels) to or from other systems.

6. HL7 Inbound Interface

The vendor software platform must be able to perform inbound HL7 interface for patient updates/merges and procedure updates.

7. Export Radiation Dose Report to Another IT System

The vendor software platform must be able to Export the Radiation Dose Report to another IT system allowing for the vendor software platform to share information with other information systems, such as; RIS, EMR or Dictation and Reporting systems. Enables information to be adopted and formatted from the vendor software platform to the target information system. This port number also allows for the configuration of other export capability: auto forwarding of MPPS and dose SR to 3rd party systems and scriptable templates for outbound MPPS and Dose SR. Multiple quantities of this port number will be required based on the export needs as well as the IT system to which the data will be exported.

8. Interface to Digital Dictation reporting software

The vendor software platform must interface with the RHJVAMC's current digital dictation software, and provide exam dose report feed to dictation reporting.

9. One-click Launch from 3rd-party Application; Contextual Coll

The vendor software platform must be accessible through a Sigle click embedded in a 3rd party application.

- Integration with applications such as AW, RIS client, PACS, or EMR client allowing user to access specified vendor software platform data using credentials supplied from origin application.

10. User Directory integration

The vendor software platform must include Integration to enterprise user directory for user authentication.

11. IT and Professional Services

The vendor software platform must include sufficient IT and Professional Services to ensure complete and successful deployment of software platform, to include:

- Installation and configuration of purchased software components
- Setup of the licensed systems
- Configuration of the network communication between the vendor software platform and imaging devices.
- Set up of initial web interface administrative access and configure user-defined thresholds and alerts.

12. Application product training

The vendor will supply 5 days of application product training.

The vendor will supply 3 days of advanced training for administrators and super users

Installation Requirements

2.1. Professional Services

2.1.1. Project Management

2.1.1.1. The Contractor shall draft a Project Management Plan (PMP) 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 PMP shall include the contractor's plans for managing all subcontractors, if applicable.

2.1.1.2. Topic areas to be addressed shall include oversight and communications with contractor's employees while onsite at VA locations, as well as executing the timely distribution and delivery of all materials to personnel. The PMP shall also include how the Contractor shall coordinate and execute planned, routine, and ad hoc data collection reporting requests when identified. The initial baseline PMP shall be concurred upon and updated monthly thereafter. The Contractor shall update and maintain the VA Contracting Officer's Representative (COR) approved PMP throughout the period of performance. The PMP will include, but not be limited to:

- Project Schedule to include Milestones, Deliverables, and Critical Path
- Verification & Validation (V&V) Plan
- Training Plan
- Risks Management Plan
- Operations & Maintenance Plan (See Section 5 for further Detail)
- Project Closeout Activities/Procedures

2.1.2. Reporting Requirements

2.1.2.1. The Contractor shall provide *bi-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 PMP and report any deviations. It is expected that the Contractor will remain in communication with the VA accordingly so that issues that arise are transparent to both parties to prevent escalation of outstanding issues.

2.1.2.2. The Contractor shall provide the COR with detailed installation progress in the *bi-weekly* progress reports. These reports shall reflect data as of the last day of the reporting period. These reports shall include a summary of the task order deliverables.

2.1.3. Verification and Validation Requirements (Testing)

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

2.1.3.2. Disputes shall be resolved by the Contracting Officer.

2.1.3.3. If requested, the Contractor shall conduct a joint inspection with the VA POC upon completion of delivery.

2.1.3.4. 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.

2.1.3.5. The Contractor shall conduct a joint inspection with the VA POC after addressing all deficiencies.

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

2.1.4. Project Estimate Time Line

2.1.4.1. Phase I: Project Kickoff. Estimated Start Date: As soon as contract Award

2.1.4.1.1. Kickoff meeting

2.1.4.1.2. Workflow design

2.1.4.2. Phase II: Installation of hardware and/or software and testing. Estimated Start Date: *Installation start date* to be agreed upon during the first kickoff meeting.

2.1.4.3. Phase III: Verification and Validation: Estimated Start Date: As soon as Phase III is complete

2.1.4.3.1. Workflow testing

2.1.4.3.2. Pre Go-Live training

2.1.4.4. Phase IV: Go Live: Estimated Start Date: *Go Live date to be determined during bi-weekly meetings.*

2.1.4.4.1. Software License 1st year: Start on the date of Go-Live

2.1.4.5. Phase V: Post Go-Live: Estimated Start Date: 4 months after Go-Live

2.1.4.5.1. Follow up training

2.1.4.5.2. Validate and review workflow

2.1.5. Project phase requirements:

2.1.5.1. Contractor shall provide a single point of contact for the implementation of this project.

2.1.5.2. Attendance for Project kick-off meeting with the onsite POC and VA Healthcare Technology Management (HTM) staff.

2.1.5.3. Provide an implementation plan and schedule an implementation meeting within two weeks from kick-off meeting. The contractor shall identify specific deployment tasks and milestones in the implementation plan.

2.1.5.4. Contractor shall lead progress update meetings, weekly, bi-weekly, or monthly, as agreed upon by the VA POC, and is responsible for communicating the delivery and implementation schedule.

2.1.5.5. The Contractor will communicate any issues and notify the appropriate resources for resolution.

2.2. Assembly and Installation

2.2.1. Requirements

2.2.1.1. The Contractor is required to manage and coordinate the installation at the RHJ VAMC with the VA POC.

2.2.2. Description and Work

2.2.2.1. Based on approved deployment work schedule, the vendor shall provide all labor necessary to install, deploy and configure the requirements of *DOSE WATCH/Automated dose capture software solution*.

2.2.2.2. The Vendor shall unpack and install all equipment in the designated area, and dispose of all trash.

2.2.2.3. Vendor shall upgrade all equipment to the latest firmware code and BIOS code prior to installing and configuring of the equipment.

3. General Conditions

3.1. Delivery

3.1.1. Requirements

3.1.1.1. 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.: 7:00 am to 4:00 pm Eastern Standard Time), Monday through Friday, excluding Federal Holidays.

3.1.2. Delivery Location

3.1.2.1. Contractor shall deliver all system components to Ralph H. Johnson VAMC, 109 Bee St., Charleston, SC 29401

3.1.3. Delivery Markings

3.1.3.1. Contractor shall deliver items in manufacturer's original sealed containers with manufacturer's name clearly marked thereon. Deliveries shall be marked with the PO Number and to the attention of the VA POC.

3.1.4. Delivery Coordination

3.1.4.1. All deliveries shall be coordinated with the onsite Points of Contacts (POC) for deliveries. Deliveries that are not properly coordinated will be the subject of deliveries being rejected.

3.2. Training:

3.2.1. System Administrator Training

3.2.1.1. The contractor shall provide System Administrator Training for 2 system administrators prior to or during the Go Live.

3.2.1.2. This training shall provide the knowledge to maintain function of the system, troubleshoot issues, install, configure and update software.

3.2.1.3. System administrators that have undergone training shall be provided with electronic copies of service manuals, system documentation, along with all default administrator and backdoor usernames and passwords.

3.2.2. User Training

3.2.2.1. The contractor shall provide User Training prior to the Go Live date.

3.2.2.2. The Contractor shall provide onsite training to various work schedule shifts to ensure end-users will be proficient with the use of the system. Contractor shall ensure a training schedule is provided to maximize staff participation. The Contractor shall provide written materials (i.e., manuals, handbook, training manual) to ensure user competency of the system.

3.2.2.3. Training shall provide skills and knowledge to effectively *navigate the system, navigate all features, major applications, document clinical notes, identify and utilize workflow processes, understand content and flow of data)* as well as understand all functions of the *DOSE WATCH/ Automated dose capture software solution*.

3.3. Use of Premises

3.3.1. Requirements

3.3.1.1. When onsite the Contractor will perform all work in such a manner that will cause minimum interference with RHJ VAMC operations and the operations of other contractors on the premises.

3.3.1.2. The Contractor will coordinate and cooperate with the VA POC or designees during delivery and installation activities.

3.3.1.3. Prior to starting work, the Contractor and associated personnel (including subcontractors) will be required to attend a general contractor's site safety training program.

3.3.1.4. The Contractor must clean up all debris and packing materials.

3.3.2. Protection of Property

3.3.2.1. The Contractor shall protect all items from damage during delivery. The Contractor shall take precaution against damage to the building(s), grounds, and furnishings. The Contractor shall repair or replace any items related to the building(s) or grounds damaged accidentally or on purpose due to action by the Contractor or their representative.

3.3.2.2. The Contactor shall be responsible for repairing or replacing any items, components, building(s), and grounds damaged due to negligence and/or actions taken by the Contractor or its personnel. Concurrence from the VA POC is required before the Contractor may perform any significant repair work. In all cases, repairs shall utilize materials of the same quality, size, texture, grade and color to match adjacent existing work.

3.3.2.3. The Contractor shall be responsible for securing all items, their work tools, and equipment used during delivery and installation.

4. Operations and Maintenance

4.1. Requirements

4.1.1. First Year Support

4.1.1.1. The Contractor shall provide a full warranty of no less than one year for parts, labor, and system configuration required as a result of manufacturer defects or issues related to installation.

4.1.1.2. The Contractor shall provide software maintenance of no less than one year to include software updates, and support with configuration and integration of the application.

4.1.1.3. The warranty and software maintenance period shall begin on the Go Live date.

4.1.2. Remote Support

4.1.2.1. The Contractor shall provide technical and application support via telephone and email during business hours, 8:00am to 5:00pm Eastern Time, at no additional cost.

4.1.2.2. The Contractor may support software maintenance remotely through the VA site-to-site Virtual Private Network (VPN) or Citrix Access Gateway. If remote access was not established prior to the contract agreement, the contractor shall provide resources to complete all requirements of the application process with the VA.

4.1.2.3. The Contractor shall comply with all VA Office of Information and Technology security requirements to perform remote technical and application support.

5. Changes to Statement of Work

5.1. Any changes to this SOW shall be authorized and approved only through written correspondence from the Contracting Officer. Costs incurred by the contractor through the actions of parties other than the Contracting Officer shall be borne by the contractor.

6. Information Security /Privacy Requirements

6.1. 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

6.2. SECURITY INCIDENT INVESTIGATION

6.2.1. 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 COR 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.

6.3. LIQUIDATED DAMAGES FOR DATA BREACH

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

6.3.2. 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:

6.3.2.1. Notification;

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

6.3.2.3. Data breach analysis;

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

6.3.2.5. 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.

6.4. TRAINING

6.4.1. 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:

6.4.2. 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;

6.4.3. 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.

6.4.4. 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.

6.4.5. 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.