

SCOPE OF WORK AND GENERAL SPECIFICATIONS FOR DOSE MONITORING SYSTEM

1 Background

Dose Monitoring systems are software based systems used to track radiation dose information from imaging devices. They store data in a centralized repository and provide tools, report, alerts, and other features that allow Radiologists and associated staff to monitor and track dose information to ensure patient safety by minimizing radiation exposure. New requirements by Joint Commission and the State of California have made these systems a requirement for hospitals.

2 Project Scope

VISN 21 is looking to procure a dose monitoring system for all VISN 21 sites. The system should be vendor neutral to ensure interoperability with a large number of imaging devices. These imaging devices that the dose monitoring system is collecting information from vary in basic criteria such as manufacturer and model but also include higher-level differentiation such as whether they generate a DICOM Dose Structured Report. Having a vendor neutral system will ensure dose information can be extracted regardless of imaging install base.

The offers must include all hardware and software to fully implement the requirements in this document. If the system can be housed on virtual servers, all costs to implement software on virtual environment must be included. Server requirements must be included as part of proposals. VISN 21 has 74 devices requiring dose monitoring. Device types are identified in Section 4.1.1. Systems cost structure should be exam based and not equipment based.

3 Definitions

Acceptance Signature – COR or VA designee signature; indicates COR accepts work status as stated in SOW

API - Application Program Interface

CO - Contracting Officer

COR - Contracting Officer's Representative

CVIS - Cardiovascular Information Management System

CT - Computed Tomography
CTDI - Computed Tomography Dose Index
DICOM - Digital Imaging and Communications in Medicine
DLP - Dose Length Product
DRL – Dose Reference Level
DR/CR - Digital Radiology/Computed Radiology
kV – Kilo Volts (Tube Voltage)
mAs - Milli Ampere Seconds
DMWL – DICOM Modality Work List
DAP - Dose area product
HCS – Health Care System
HL7 – Health Level 7 standard
LDAP - Lightweight Directory Access Protocol
MPPS - Modality Performed Procedure Step
OCR – Optical Character Recognition
OI&T – Office of Information and Technology
PACS – Picture Archiving and Communication System
PHI – Protected Health Information
SSDE - Size-Specific Dose Estimates
VA – Department of Veterans Affairs
VACO – Department of Veterans Affairs Central Office
VAMC – Department of Veterans Affairs Medical Center
VHA – Veterans Health Administration
VISN – Veterans Integrated Service Network
VistA – Veterans Health Information Systems and Technology Architecture
CTDI Phantom (16cm or 32cm)
 K_{air} , Air Kerma at the reference point
AGD, Average Glandular Dose

4 Specifications

The VISN 21 dose monitoring specifications are designed to outline all the VISN 21, Biomedical Engineering, Radiology, and OI&T requirements. These requirements will be provided to the COR before final approval.

Software Specifications:

4.1. Application Specific Specifications

- System shall track a volume of up to 150,000 exams of modalities listed below.
- System should be able to track dose parameters from the following imaging modalities:
 - Computed Tomography
 - Interventional Radiology Labs
 - Catheterization and Electrophysiology Labs
 - Hybrid Operating Room suites
 - Mammography
 - Fluoroscopy
 - CT used as part of a hybrid imaging system (PET or SPECT)
 - **Optional** - CR/DR
 - **Optional** - C-Arms
 - **Optional** - Contrast Media

Required number of systems listed in Section

- System shall have ability extract, catalogue, and individually store all the dose information from the following sources. The system shall be flexible to use any of these fields to extract dose values and not be limited to just one.
Sources must include:
 - DICOM header
 - DICOM Dose Structured Report
 - Dose Screening (Using OCR)
 - DICOM MPPS
 - PACS
 - Image headers
- System shall track and measure all Dose Metrics to include:
 - Effective Dose
 - CTDI
 - CTDI Phantom
 - DLP
 - SSDE
 - Patient Size/Age

- BMI
- kV
- mAs
- DAP
- Patient Skin Dose
- Patient Exposures
- K_{air} (Air Kerma at the reference point) for Fluoroscopy and Interventional labs
- Average Glandular Dose for Mammography
- System shall integrate with the following systems and protocols:
 - System shall export data to the ACR DIR.
 - **Optional** - Certified ACR partner
 - System shall integrate with PACS systems.
 - Resolves patient demographics via DMWL or ADT feed
 - VISN 21 uses Philips iSite version 4.4 (or higher) for PACS.
 - VISN 21 uses Philips Xcelera version 3.2 (or higher) for CPACS.
 - Las Vegas uses AGFA IMPAX version 6.5.5 4.X for PACS.
 - Las Vegas uses AGFA IMPAX version 7.8.4 for CPACS.
 - System shall integrate with Radiology dictation systems and incorporate all costs except for Powerscribe licensing.
 - VISN 21 uses Powerscribe 360 version 3.5.2
 - Las Vegas uses AGFA TALK 4.1.0.8607 SU3
 - System shall support and include integration with HL7 integration with VA EMR (CPRS/Vista)
 - System shall conform to the IHE REM profile.
 - System shall integrate with CVIS systems.
 - Resolves patient demographics via DMWL or ADT feed
 - Adds dose metrics into CVIS report
- System shall import historical data located in the DICOM Dose Structured Report and other dose data that is located in PACS or CPACS. Contractor is responsible for importing up to 4 years of historical dose SR located in PACS or CPACS.
 - **Preferred:** All data imported
- System shall support an API interface to work with other systems such as PACS, dictation, CPACS and CVIS systems.
- System helps compliance with Joint Commission standards for Dose Monitoring.
 - Documents in the patient's record the radiation dose index (CTDI vol, DLP, or SSDE) on every study produced during a diagnostic CT

examination. The radiation dose index must be exam specific, summarized by series or anatomic area, and documented in a retrievable format.

- Provides reports and data to assist with incidents where the radiation dose index (CTDI vol, DLP, or SSDE) from diagnostic CT examinations exceeded expected dose index ranges identified in imaging protocols.
- System shall monitor and track dose metrics per specific patient.
- System shall track dose metrics over time for specific make and model imaging devices, hospital sites, exam codes, technologists, radiologists, protocols, and other related parameters.
- System shall have ability to manage protocols for devices in a central repository. Contractor is responsible for uploading protocols into system.
- System shall calculate automatic CT SSDE.

4.2 Reporting and Alerting Features

- System shall provide a customizable dashboard or banner page for users. Dashboard or banner page can be configured per user, site, or VISN.
- System shall create customizable automated reports.
- System provides real-time notifications if an individual patient's exposure exceeds dose and/or number of exposures. Notification shall be able to be sent via:
 - Modality
 - Email
 - Text
- System shall allow for customizable reference levels for dose and exposure.
- System shall provide customizable level of alerts for notifications.
- System shall provide total cumulative dose values by either CTDI or DLP.
- System shall allow for customizable reports, including export of comprehensive data sets, in excel and at least one of the following formats:
 - **Excel (required)**
 - PDF
 - CSV
 - HTML
- System shall add dose metrics into Radiologist report.
- System shall support DRLs set locally, by registries, or by regulatory bodies.
- System shall create customizable utilization reports to provide comparative data from individual devices, technologist, clinician, device type, hospital, and others.

4.3 IT Requirements

- System shall integrate with Philips iVault, or modalities, at the VISN level to capture all dose data from sites.
 - Las Vegas will eventually be added to VISN iVault. System needs to be configured to make this change and import data from AGFA migration.
 - System will include cost to integrate with Las Vegas at facility.
- System shall support multi-site infrastructure across multiple states, Active Directory domains, and time zones.
- System shall support both physical and virtual server hardware.
 - **Preferred:** Virtual.
- Vendor shall have a remote connection with the VA.
 - Current/existing remote connection is preferred.
 - If vendor does not have access, they shall
 - Provide all costs associated with interim measure.
 - Work to get VA remote access within 1 year.
- System shall provide audit trail capability per username and time stamp.
- System shall work with LDAP for authentication and provide multiple roles for users.
- System shall comply with PHI standards.
- System shall allow for customizable data access restriction.
- All data and systems should be owned, managed, and located within VISN 21.
- System shall store data in an SQL, Oracle, or equivalent database structure.

5 Delivery Locations:

- Central California HCS (2615 E. Clinton Avenue Fresno, CA 93703)
- Sacramento Data Center (QTS, 1100 N Market Blvd, Sacramento, CA 95834)
- Sierra Nevada HCS (1000 Locust Street Reno, NV 89502)
- Pacific Island HCS (1 Jarret White Road Honolulu, HI 96859)
- San Francisco VAMC (4150 Clement Street San Francisco, CA 94121)
- Northern California HCS (10535 Hospital Way Mather, CA 95655)

- North Las Vegas VAMC (6900 North Pecos Road North Las Vegas, NV 89086)
- Palo Alto HCS (3801 Miranda Avenue Palo Alto, CA 94304-1290)

6 Support and Warranty

Support and warranty of the dose monitoring system will be provided for one year upon receipt and acceptance. The COR for the project must sign off on acceptance before the warranty cycle begins. The warranty and support must be provided in the quote to cover all contractor furnished components of the dose monitoring system. **Any annual reoccurring costs must be provided as part of the proposal.**

Key terms for warranty and contract support:

- 1 year of warranty/service contract upon initial receipt and acceptance signature
- 2 hours call back response during normal business hours of 7:30AM to 4:30PM for each site's time zone
- **Optional: Provide optional coverage for up to 4 years as part of proposal in one year increments**

VA Engineering and OI&T will have full access to the hardware and software that constitute the system, including any diagnostic software features and general administration rights. The VA Engineering and OI&T point of contacts must be briefed, by the vendor, on all software upgrades and changes and agree to each prior to installation. The vendor shall provide and install manufacturer recommended software upgrades and changes at no additional charge during warranty/contract period. The vendor will provide two (2) sets of user manuals and technical manuals to VA Engineering.

7 Installation

All work and installation will be coordinated with the COR, OI&T, and Biomedical Engineering. Phasing and work schedule will be provided and coordinated with the COR. A detailed installation schedule will be provided during the project implementation kick-off meeting. The installations will occur at the discretion of the COR and be coordinated with each site individually. The full deployment shall have a one year deployment window. This will allow for each site to plan and prepare all aspects of the dose monitoring system. In addition to the COR, an additional representative at each of the facilities will act as a liaison to ensure that the vendor meets government expectations and follows the guidelines as set by the Contracting Officer.

The vendor will confine operations (including storage of materials) on Government premises to areas authorized and approved by the Contracting Officer. The Contractor shall hold and save the Government, its officers and agents, free and harmless from liability of any nature occasioned by the Contractor's performance. Working space and space available shall be as determined by the COR.

The eight locations for the installation are as mentioned in Section 5, Delivery Locations.

8 Testing

The contractor shall verify to Biomedical Engineering, OI&T, and COR that the system meets all requirements stated on this contract through demonstration and validation.

9 Training

The Contractor will be responsible for providing on-site user training of the dose monitoring system. Each site (except for QTS) will have two days of onsite user training included to be used at their discretion. The training can occur at any location within the individual's site network of hospital or clinics. Training can be held concurrently at multiple sites or staggered as deemed by COR. Training shall have a 1 year window to be used.

The contractor shall also offer remote training and web based training.

- 100 hours per site for remote training
- Web based would be unlimited with valid support contract.

The contractor will also provide technical training on the system for two staff members.

10 Phasing

The contractor shall submit a phasing schedule in writing to the COR for approval two weeks prior to the start of any work.

VISN 21 Medical Centers are fully operational hospitals. The Contractor must schedule his work around VA operations and specifically for the convenience of the hospitals. Contractor must note work at times other than normal operating hours.

11 Sign-in Procedures

All Contractor workers are required to sign in and out at the VA Police Dispatch at the corresponding locations as directed by the COR or designee at each facility. A valid state driver's license or state identification card is mandatory for all employees to have access to these facilities. All contractor employees are required to wear the assigned VA badge at all times.

12 Work Hours

Normal business hours are 7:30AM to 4:30PM Monday thru Friday excluding Federal Holidays. Work completed outside this time must be requested through the COR.

Requests for after-hours work must be submitted in writing to the COR two (2) weeks prior to work. The VA requires that information submitted must contain: extent of work, workers involved, the affected areas, and the estimated times of operation.

13 Systems

Systems	SF	Hawaii	Palo Alto	NorCal	Fresno	Reno	Las Vegas	Total
CTs	3	1	2	3	2	2	2	15
Hybrid CT systems	3	0	5	3	0	0	2	13
Mammography	0	1	2	4	0	0	2	9
Angio	2	0	2	1	0	2	1	8
Cath and EP	2	0	2	1	1	1	1	8
Hybrid ORs	1	0	1	1	0	1	1	5
Fluoroscopy	3	0	5	3	2	2	1	16