

QUALITY ASSURANCE SURVEILLANCE PLAN (QASP)

Siemens Nuclear Medicine Equipment Service Contract

Contract Description:

This contract provides a first call service/maintenance contract to provide all necessary labor, equipment, tools, materials, repair service, software updates/upgrades, parts etc for complete On-Site maintenance service and technical support for the following equipment:

#	ID#	Serial#	Manufacturer	Model	Equipment Category
1	53167	2105	Siemens	Symbia S	SCANNING SYSTEMS: CT/SPEC
2	53138	31046	Siemens	Biograph mCT 64	SCANNING SYSTEMS: CT/PET
3	53169	2032	Siemens	Symbia Intevo 6	SCANNING SYSTEMS: CT/SPEC
4	N/A	72468	Siemens	syngo MMWP	WORKSTATIONS: MEDICAL
5	53558	2UA5131VFL	Siemens	Symbia.Net Single-User	WORKSTATIONS: MEDICAL
6	N/A	TBD	Siemens	MRI Syngo	WORKSTATIONS: MEDICAL
7	N/A	CZ352628ED	Siemens	Syngo Server	INFORMATION SYSTEMS: DATA MGMT: RADIOLOGY

Purpose:

The purpose of this Quality Assurance Surveillance Plan (QASP) is to provide guidance on how the quality of services provided under this contract will be monitored, in conjunction with the Statement of Work.

This QASP does not detail how the contractor accomplishes the work. Rather, the QASP is created with the premise that the contractor is responsible for management and quality control actions to meet the terms of the contract. It is the Government's responsibility to be objective, fair, and consistent in evaluating performance.

This QASP is a "living document" and the Government may review and revise it on a regular basis. However, the Government shall coordinate changes with the contractor. Copies of the original QASP and revisions shall be provided to the contractor and Government officials implementing surveillance activities.

Scope:

To fully understand the roles and the responsibilities of the parties, it is important to first define the distinction in terminology between the Quality *Control* Plan and the Quality *Assurance Surveillance* Plan. The Contractor, and not the Government, is responsible for management and quality control actions necessary to meet the quality standards set forth in the contract. The Contractor develops and submits his/her Quality Control Plan (QCP) for Government approval in compliance with his contract deliverables. Once accepted, the Contractor then uses the QCP to guide to rigorously document the implementation of the required management and quality control actions to achieve the specified results. The QASP on the other hand, is put in place to provide Government *surveillance* oversight of the

Contractor’s quality control efforts to *assure* that they are timely, effective and are delivering the results specified in the contract. The QASP is not a part of the contract nor is it intended to duplicate the Contractor’s QCP. The Government may provide the Contractor an information copy of the QASP as an Attachment to the solicitation to support the Contractor’s efforts in developing a QCP that will interrelate with the Government’s QASP.

The areas to be addressed under the QASP are as followed:

- PM Completion
- Time to bring downed equipment back to working condition
- Certifications and Training
- Timeliness of Service Reports
- Software Updates and Upgrades

Quality Assurance Check Points:

The table below describes the areas to be reviewed in the QASP process. Quality assurance will be conducted by the Contracting Officer’s Representative (COR) or designee of the Clinical Engineering Service (CES). The results of the QASP will be approved by the COR.

Required Services (Tasks)	Performance Standards	Acceptable Quality Levels	Methods of Surveillance	Incentive (Positive and/or Negative Impact on Contractor Payments)
PM Completion	<p>PMs on equipment shall be performed according to the SOW and manufacturer specifications. The PM shall be performed during the months specified on the SOW.</p> <p>Upon completion of a PM of the equipment, the Field Service Engineer (FSE) will submit documentation of the services performed for the PM.</p>	98%	100% inspection of submitted PM documentation	10% deduction of total quarterly payment if PM not performed during scheduled month
Time to bring downed equipment back to working condition	The Contractor’s Field Service Engineer (FSE) must respond with a phone call to the COR or his/her designee within two (2) hours after receipt of	95%	100% Review of each repair performed	1% deduction of quarterly payment for each business hour after the repair/service completion

	<p>telephoned notification.</p> <p>If the problem cannot be corrected by phone, the FSE will commence work within twenty four (24) hours after receipt of notification.</p> <p>From the time when the FSE commences the on-site unscheduled maintenance, the repair/service must be completed within twenty four (24) hours.</p>			requirements
Certifications and Training	<p>Contractor shall provide certifications of each Field Service Engineer (FSE) that will be working on the equipment listed in the scope before they will be able to work on the equipment. Additionally, if a certificate will expire before the contract ends, the contractor will provide the updated certificate within fifteen (15) days of certificate expiration.</p> <p>All gauging and measuring equipment shall be calibrated according to the equipment manufacturer, and a certificate of calibration will be provided to the COR in the documentation of the repair/service performed.</p>	98%	<p>100% inspection of all certificates submitted</p> <p>Random surveillance of equipment when Field Service Engineer is on site.</p>	Contractor's past performance will be reported as deficient in meeting requirement and as a result, any option years may not be exercised
Timeliness of Service Reports	All service reports submitted within the quarter they were performed	98%	100% inspection of all service reports	10% deduction of quarterly payment if deliverables not provided for the quarter
Software Updates/ Upgrade	All Software UPDATES will be applied to the system within 1 month of OEM	95%	100% inspection of submitted Software	5% deduction of quarterly payment for each month past

Application	release. All Software UPGRADES will be applied to the system within 4 months of OEM release.		Update/Upgrade documentation	required timeframe software has not been applied
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Government roles and responsibilities:

The following personnel shall oversee and coordinate surveillance activities.

a. Contracting Officer (CO) - The CO shall ensure performance of all necessary actions for effective contracting, ensure compliance with the contract terms, and shall safeguard the interests of the United States in the contractual relationship. The CO shall also assure that the contractor receives impartial, fair, and equitable treatment under this contract. The CO is ultimately responsible for the final determination of the adequacy of the contractor’s performance.

Assigned Contract Specialist: Safa Shleiwet

b. Contracting Officer’s Representative (COR) - The COR is responsible for technical administration of the contract and shall assure proper Government surveillance of the contractor’s performance. The COR shall keep a quality assurance file. The COR is not empowered to make any contractual commitments or to authorize any contractual changes on the Government’s behalf.

Assigned COR: David Fijas

METHODS OF QA SURVEILLANCE

The below listed methods of surveillance shall be used in the administration of the QASP. In addition to specific instructions that may be mentioned, the appropriate and standardized form that is to be used for documentation of QA surveillance is the Surveillance Activity Checklist, included as Attachment A.

Customer Feedback – Customer feedback may be obtained either from the results of formal customer satisfaction surveys or from random customer complaints. Customer complaints, to be considered valid, must set forth clearly and in writing the detailed nature of the complaint, must be signed and forwarded to the COR. The COR shall maintain a summary log of all formally received customer complaints as well as a copy of each complaint in a documentation file. The COR shall also keep the tabulated results of all customer satisfaction surveys on file and shall enter the summary results into the Surveillance Activity Checklist. (Copies of all records shall be submitted to the CO upon receipt for placement in the official contract file, and when necessary, determination of actions.)

100% Inspection – The COR shall monitor each patient delivery and enter performance results into the Surveillance Activity Checklist.

Periodic Inspection - Periodic inspections shall be conducted when specified in the contract/SOW. For the potential tasks that have been identified so far and included in this QASP, the COR performs the periodic inspection on a monthly basis.

PERFORMANCE STANDARDS

The Performance Requirements Summary in the Statement Work Statement (SOW), includes performance standards. The Government shall use these standards to determine contractor performance and shall compare contractor performance to the Acceptable Quality Level (AQL), and determine incentives.

Corrective Action:

The Contractor will be notified any time a performance standard is missed or of any complaints related to services provided or personnel performance issues. The Contractor will be given an opportunity to correct any deficiency noted. The timeframe for correcting deficiencies will be determined on a case by case basis by the Contracting Officer or COR depending of the circumstances.