

VISN 17 RTLS SPS Equipment Tagging

Issued 07/26/2017

QUALITY ASSURANCE SURVEILLANCE PLAN

For: Tagging of SPS Equipment

Contract Number:

Contract Description: Censitrac is a Dental and Medical-Surgical instrument and reusable medical equipment (RME) tracking solution developed by Censis Technologies, Inc. (Censis). Censitrac has been installed in multiple Veteran Integrated System Network (VISN) VA Medical Centers (VAMCs). All instruments require a 2-dimensional data matrix that uniquely identifies the instrument. The marking or stencil is applied by a marking station supplied by Censis and then details about the instrument are entered into the Censitrac database. As the instrument travels through the sterilization process, the electrochemical mark is scanned such that the instrument can be tracked through the process. Some instruments cannot be marked based on chemical, surface, electromagnetic, or material characteristics of which the instruments are made and these instruments are instead supplementary marked with a "dot" or "tape" which contains a pre-printed 2D matrix barcode on a small surface with a semi-permanent adhesive backing. These supplementary dots/tapes withstand repeat sterilizations without adverse effect.

The contractor shall initiate/complete the implementation of their Censis System with completion of marking and commissioning services for the instrument inventory. This requirement establishes the requirements for the scope of services required for VISN 16 and its facilities (See Attachment) to finalize all marking and commissioning of dental and medical-surgical instruments utilizing VA developed data standards and guidance.

Contractor's name: VISN 16: South Central VA Health Care Network

1. PURPOSE

This Quality Assurance Surveillance Plan (QASP) provides a systematic method to evaluate performance for the stated contract. This QASP explains the following:

- What will be monitored.
- How monitoring will take place.
- Who will conduct the monitoring.
- How monitoring efforts and results will be documented.

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.

2. 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 CO: _____

Organization or Agency: Department of Veterans Affairs, Office of Acquisition and Materiel
Management

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: Melseracarlo (Mel) Dumo

c. Other Key Government Personnel – David Miller

3. CONTRACTOR REPRESENTATIVES

The following employees of the contractor serve as the contractor's program manager for this contract.

a. Program Manager – Mel Dumo

b. Other Contractor Personnel – David Miller
Title: Staff Biomedical Engineer

4. PERFORMANCE STANDARDS

Performance standards define desired services. The Government performs surveillance to determine if the contractor exceeds, meets or does not meet these standards.

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

Task	ID	Indicator	Standard	Acceptable Quality Level	Method of Surveillance	Incentive
Tagging SPS Equipment	MC001	The contractor shall review, provide constructive feedback, approve, and pre-populate the system with the site's medical/surgical and dental instrument data, providing access to the Censis Master Library as necessary for the effort.	Within completion of a sites tagging.	100%	Observation and auditing will take place after all the Master Library has been completed.	Continue with obligated contract.
	MC002	The contractor shall ensure proper placement and application of 2D matrix mark by either electrochemical or manual (e.g. 2D matrix dot/tape) processes. Placement shall not impede clinician's use, nor subject any risk to the patient.	Within completion of a sites tagging.	100%	Observation and random inspection (auditing)	Continue with obligated contract.
	MC003	The contractor shall ensure QA of applied mark ensures that the matrix has scan capabilities by the Censitrac system within a maximum of three (3) seconds.	Within completion of a sites tagging.	100%	Observation and random inspection (auditing)	Continue with obligated contract.

Task	ID	Indicator	Standard	Acceptable Quality Level	Method of Surveillance	Incentive
	MC004	The contractor shall enter data into Censitrac dataset in strict accordance with the RTLS Sterile Processing Workflow (SPW) data standards (specifically DS018, DS019, and DS020); while qualifying as needed via the current version of <i>VA RTLS Medical-Surgical and Dental Instrument Nomenclature Guidance</i> .	Within completion of a sites tagging.	100%	Review final submission of data.	Continue with obligated contract.
	MC005	The contractor shall create/provide tray count sheets utilizing 2D matrix scanning to readily identify instrument inventory of each set.	Within completion of a sites tagging.	100%	Observation and random inspection (auditing)	Continue with obligated contract.

Task	ID	Indicator	Standard	Acceptable Quality Level	Method of Surveillance	Incentive
	MC006	Commissioning QA: The contractors PM/technical staff shall analyze the data entries and apply VAs National Naming Convention/Data Standards and Data Quality Tool (DQT) to all the records, ensuring 100% compliance with the standards PRIOR to submission to VA for review/acceptance.	Within completion of a sites tagging.	100%	Review final submission of naming standards.	Continue with obligated contract.
	MC006.1	Data Quality Tool (DQT) new terms derived during the commissioning effort shall be submitted by the contractor to the VA COR/RTLS SPW Workgroup for processing and actions/approval within five (5) business days of cessation of M&C.	Within 5 business days of cessation of M&C.	100%	Review of finalized inventory list.	Continue with obligated contract.
	MC006.2	The contractor shall provide any necessary data remediation within three (3) business days of receipt from VA.	Within 3 business days of receipt from VA.	100%	Review of finalized inventory list.	Continue with obligated contract.

Task	ID	Indicator	Standard	Acceptable Quality Level	Method of Surveillance	Incentive
	MC007	The contractor shall provide at the close of each workday an e-report, capturing daily marking and commissioning activity for VA COR review.	Submission of a daily report.	100%	Daily review of each report.	Continue with obligated contract.
	MC008	The contractor shall meet regularly (not less than weekly) with the COR to present and review progress to date, discuss constraints, project schedule, consumables (stencils, etc.) on hand, availability of instruments, and estimate number/types of instruments remaining to be marked.	Online and/or on site meetings will be held.	100%	Will attend the weekly meeting virtually or on site.	Continue with obligated contract.

5. INCENTIVES

The Government shall use continual obligation of the contract as an incentive. Incentives shall be based on exceeding, meeting, or not meeting performance standards.

6. METHODS OF QA SURVEILLANCE

Various methods exist to monitor performance. The COR will use the surveillance methods listed below in the administration of this QASP.

Observation and random inspection (auditing), reviewing weekly status updates, and reviewing final work submissions for each site.

- a. DIRECT OBSERVATION. Performed while Contractor on site and before and after maintenance is performed.
- b. PERIODIC INSPECTION. (Inspections done during all maintenance periods. Depending on the equipment this can be quarterly or semi-annually.
- c. USER SURVEY. Feedback from Radiology service will be noted by Biomed concerning maintenance of Siemens equipment.
- d. VALIDATED USER/CUSTOMER COMPLAINTS. Biomed will research all complaints and verify service reports given by the Vendor.
- e. 100% INSPECTION. (Evaluates all outcomes.)
Inspections completed after all preventive maintenance and all repairs. Equipment shall function at 100% after repairs are complete.
- f. Analysis of contractor's progress reports. Contractors service reports will be reviewed and filed.

8. RATINGS

Metrics and methods are designed to determine if performance exceeds, meets, or does not meet a given standard and acceptable quality level. A rating scale shall be used to determine a positive, neutral, or negative outcome. The following ratings shall be used:

Rating Methods will be based on customer satisfaction and 100% completion of tagging.

9. DOCUMENTING PERFORMANCE

a. ACCEPTABLE PERFORMANCE

The Government shall document positive performance. Any report may become a part of the supporting documentation for any contractual action.

b. UNACCEPTABLE PERFORMANCE

When unacceptable performance occurs, the COR will inform the contractor. This will normally be in writing unless circumstances necessitate verbal communication. In any case the COR shall document the discussion and place it in the COR file.

When the COR determines, formal written communication is required, the COR shall prepare a Contract Discrepancy Report (CDR), and present it to the contractor's program manager.

The contractor shall acknowledge receipt of the CDR in writing. The CDR will specify if the contractor is required to prepare a corrective action plan to document how the contractor shall correct the unacceptable performance and avoid a recurrence. The CDR will also state how long after receipt the contractor has to present this corrective action plan to the COR. The Government will review the contractor's corrective action plan to determine acceptability.

Any CDRs will become a part of the supporting documentation for any contractual action deemed necessary by the CO.

10. FREQUENCY OF MEASUREMENT

a. Frequency of Measurement.

During contract performance, the COR will periodically analyze whether the negotiated frequency of surveillance is appropriate for the work being performed.

b. Frequency of Performance Assessment Meetings.

The COR shall meet with the contractor, quarterly, to assess performance and shall provide a written assessment.

Signature – Contractor Program Manager

Signature – Contracting Officer's Representative