PERFORMANCE WORK STATEMENT (PWS) --

Marking and Commissioning of Medical-Surgical and Dental Instrumentation

VETERANS HEALTH ADMINISTRATION – VISN *22 – VA San Diego Healthcare System*

June 2017

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1 Introduction

1.1 Purpose

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.

VISN 22 VA San Diego Healthcare System desires to initiate/complete the implementation of their Censis System with completion of marking and commissioning services for their instrument inventory. This contract establishes the requirements for the scope of services required for VISN 22 VA San Diego Healthcare System to finalize all marking and commissioning of dental and medical-surgical instruments utilizing VA developed data standards and guidance.

1.2 Scope of Work - Marking & Commissioning (M&C) Services

Tracking enhances the ability of VA to mitigate human factor concerns while ensuring world-class patient care and staff safety by providing assurances that instruments have been fully processed in accordance with regulatory guidelines and individual instrument manufacturer's Instructions for Use (IFU) for reusable medical equipment (RME) and dental/medical-surgical instrumentation.

The VA desires that the Marking & Commissioning (M&C) service offering enhance Sterile Processing Service (SPS) business processes and support SPS staff responsible for tracking, cleaning and distributing reusable medical equipment throughout the medical facility by automating the traceability of tasks, instruments, and supplies. The following table contains SPS-specific requirements:

Req. ID	Requirement
MC001	Vendor will 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.
MC002	Ensures proper placement and application of 2D matrix mark by either electrochemical or manual (e.g. 2D matrix dot/tape) processes. Placement will not impede clinician's use, nor subject any risk to the Veteran patient.
MC003	QA of applied mark ensures that the matrix is scannable by the Censitrac system within a maximum of three (3) seconds.
MC004	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 *VA RTLS Medical-Surgical and Dental Instrument Nomenclature Guidance.*
MC005	The vendor shall create/provide tray count sheets utilizing 2D matrix scanning to readily identify instrument inventory of each set.

Req. ID	Requirement
MC006	Commissioning QA: Vendor's PM/technical staff will analyze the data entries and apply VAs National Naming Convention/Data Standards and Data Quality Tool (DQT) to all of the records, ensuring 100% compliance with the standards PRIOR to submission to VA for review/acceptance.
MC006.1	Data Quality Tool (DQT) new terms derived during the commissioning effort will be submitted to the VA COR/RTLS SPW Workgroup for processing and actions/approval within five (5) business days of cessation of M&C.
MC006.2	Vendor will provide any necessary data remediation within three (3) business days of receipt from VA.
MC007	Vendor will provide at the close of each workday an e-report, capturing daily marking and commissioning activity for VA COR review.
MC008	Vendor will 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.

Under this contract, the Contractor shall utilize the Censitrac software which serves as the VHA's nationwide surgical/medical and dental instrument inventory and workflow system. The contractor will mark, fully commission all required data fields, and build instrument set count sheets as designated for assigned dental, medical-surgical instruments, and RME within each facility. Count Sheet creation will take place at the time of tray disassembly for marking/commissioning by the Contractor. Marking and commissioning will not exceed 9 weeks.

As part of this effort, the Contractor shall conduct requisite site assessments, mark and commission instruments, perform quality assurance testing, perform data validation, and load data standard-compliant data into the new system.

1.3   Marking Methods for Instrument Tracking System (ITS) Application

Some VA Medical Centers (VAMCs) and Community Based Outpatient Clinics (CBOCs) are encountering challenges related to appropriate determination of approved methods for marking medical/surgical instruments upon implementation of the ITS application. Dental and Medical/Surgical instruments are capable of being marked to facilitate unique device identification, 'owner,' and applicable tray assignment. Instruments should never be engraved or adulterated in any way that violates the protective passivation layer.

After performing an extensive review of marking methods, the Sterile Processing Workflow (SPW) Workgroup (WG) has determined that a goal of 100% instrument marking is not currently achievable due to a small subgroup of special surface characteristics (i.e. curved, knurled, titanium, etc.). Two primary methods were identified that meet the established National Program Office for Sterile Processing (NPOSP) goals:

1.3.1   Dimensional (2D) Data Matrix
This GS1-standard format is an internationally recognized marking tool designed to be read by a handheld or fixed 'reader' integrated into the Instrument Tracking System (ITS). This VHA-standardized solution is suitable for workflow traceability and is currently being deployed to all VA Medical Centers as the primary (preferred/cost-effective) solution.

1.3.2   2D Data Matrix Instrument Marking Tape/ Dots

<u>Any tape/dot utilized for this purpose MUST be utilized in full accordance with AAMI guidelines and the manufacturer's instructions for use.</u> The tape/dot matrix manufacturer's instructions should be reviewed to verify which sterilants are capable of tape penetration, as not all types of tape/dot matrix may be used for all sterilization methods or for high-level disinfection.

NOTE: RME devices that lend themselves to the use of instrument tapes, dots, and/or RFID are those non-OR items that, due to special exceptions, are incapable of being marked with GS1-standard 2D data matrices, including but certainly not limited to the following RME:

- a.   Comprised of Aluminum, Titanium, etc.
- b.   Diamond or Linear Knurled Handles
- c.   ENT/Neuro Instruments
- d.   Rounded Items (e.g.: Dental, etc.)
- e.   Small/Fine/Delicate Instruments

1.4   Beginning Instrument Marking and Commissioning

The contractor is required to mark and commission during 8 business days,

Facilities will have to work closely with the vendor to ensure that as much instrumentation as possible is provided each day (typically a minimum of 50 instruments per marking team member per day). While OR daily operational needs may exceed availability, the vendor(s) must stay on schedule. Coordination between SPS, OR, CBOCs, Clinics, and vendor are essential to a successful deployment.

1.4.1   Matrix Estimations

VA San Diego Healthcare System shall provide vendor stencil matrices to be used during marking.

1.4.2   Preliminary Activities

The facility count sheets will be provided by the facility for the contractor to review in the Censitrac software. This data will be utilized to commission items and subsequently produce Count Sheets for the Operating Room, CBOC's, and for other reporting purposes. Marking and commissioning may begin while count sheet preparations are underway.

1.5   INSTRUMENTATION NOMENCLATURE

Due to software constraints, the individual instrument descriptions in the Product Name fields are generally limited to 50 characters within Censitrac. The key data attributes that must adhere to the *VA RTLS Data Standards* (e.g. DS018, DS019, DS020) and the current version of *VA RTLS Medical-Surgical and Dental Instrument Nomenclature Guidance* (See Section 5). The following provides a general overview:

1. *Supplier*: Generally the Original Equipment Manufacturer (OEM) or primary U.S. vendor of the medical/surgical or dental instrumentation/device.

   a. The 'Master List' is stored on the RTLS SharePoint and maintained by the VA RTLS SPW WG within the VA RTLS SPW Gold Standard Instrument Library Elements (MS Excel Workbook).

   b. Additional reference materials are available within the VA RTLS Medical-Surgical and Dental Instrument Nomenclature Standard Guidance stored on the RTLS SharePoint and maintained by the VA RTLS SPW WG.

   c. Contractor will work with VA to support these field's data maintenance for the length of the contract/agreement(s).

d. Contractor to submit data for VA review in a site-specific MS Excel workbook.

e. ALL Vendor Names are recorded and submitted to VA in "ALL CAPS" format.

f. An initial list of Vendor Names was provided by Censis to the VA RTLS SPW WG for incorporation into this data standard. VA has purchased local subscriptions for Censitrac's long-term support and data maintenance. As new Vendor Names are added or received by Contractor from VA sites, routine updates and revisions to the field's Vendor Names will be provided to the VA RTLS SPW WG for review. Data submitted with missing or incorrect information will delay incorporation/completion.

g. Contractor will provide the VA RTLS SPW WG with regular (monthly) notifications of new Vendor Names via submission of an electronic list (MS Excel) for workgroup review and incorporation into the VA RTLS SPW Gold Standard Instrument Library Elements (MS Excel Workbook) on the VA RTLS SharePoint.

2. *Catalog Number*: This is the number electrochemically marked onto the side of the medical/surgical instrument by the original equipment manufacturer (OEM).

a. If this number is NOT present or illegible, please see below for guidance regarding the need for "priority replacement" of these items.

b. As each manufacturer/vendor maintains their own 'proprietary' data format, a MASTER list is not currently feasible.

c. The VA 'Master List' will be stored on the RTLS SharePoint and maintained by the VA RTLS SPW WG within the VA RTLS SPW Gold Standard Instrument Library Elements (MS Excel Workbook).

d. Additional reference materials are available within the VA RTLS Medical-Surgical and Dental Instrument Nomenclature Standard Guidance stored on the RTLS SharePoint and maintained by the VA RTLS SPW WG.

e. Contractor will support this field's data maintenance for the length of the contract/agreement(s).

f. Contractor will submit data for VA review in a site-specific MS Excel workbook.

g. Due to the wide variations of catalog reference number formats (Use of VarChar, Leading Zeros, Special Characters, etc.), this section will not be formally standardized beyond general guidance at this time.

h. ALL data will be recorded and submitted to VA in "ALL CAPS" format and parsed with special characters in place as exhibited on the actual RME item or catalog.

i. Data values will not be altered (truncated) in the production system by removing any special characters (referred to as "condensing" the data). The value that is exhibited on the instrument (or in the catalog) is the value that will be stored in the database.

j. Contractor may condense (truncate) the data to conduct data validation efforts with Censis, but VA delivered data will match that exhibited on the instrument (or in the catalog). Data submitted to VA for review/acceptance will include any special characters as exhibited on the instrument (or in the catalog).

k. Contractor will provide the VA RTLS SPW WG with regular (monthly) notifications of new Catalog Numbers via submission of an electronic list (MS Excel) for workgroup review and incorporation

into the VA RTLS SPW Gold Standard Instrument Library Elements (MS Excel Workbook) on the VA RTLS SharePoint.

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3. ***Product Name:***

   a. ***Category***: General Instrument Classification (Ex: *Clamp, Grasper, Probe, Scissors, Tunneler, etc.*)

   b. ***Common Name***: Generally the Brand/Trade Name derived from the inventing Surgeon/Creator (Ex: *Babcock, Castroviejo, DeBakey, Maryland, Mayo, etc.*)

   c. ***Primary/Secondary Descriptors***: General function of device and defining physical characteristics (Shape, Material, etc.)

      i. NOTE: A list of approved abbreviations for descriptors is available. The referenced abbreviations were developed to standardize the SPS capabilities required to meet the '50-character' limitation of the ITS Software.

   d. ***Length-Dimension***: Generally the length, weight, or primary identifying dimension(s) (e.g. Diameter, Gauge, French, etc.)

   e. ***NOTES***:

      i. The 'Master List' of Descriptors is stored on the RTLS SharePoint and maintained by the VA RTLS SPW WG within the VA RTLS SPW Gold Standard Instrument Library Elements (MS Excel Workbook).

      ii. Additional reference materials are available within the VA RTLS Medical-Surgical and Dental Instrument Nomenclature Standard Guidance stored on the RTLS SharePoint and maintained by the VA RTLS SPW WG.

      iii. ALL terms will be recorded and submitted to VA in "ALL CAPS" format.

      iv. ALL Descriptor terms will be recorded and submitted to VA with 'spaces' eliminated and replaced with hyphens (-) for compound terms.

      v. Contractor will submit their MS Excel Data Workbook to VA at the time of their request for VISN COR site acceptance with a "Site ID," Manufacturer (also called Censitrac Vendor Name) [DS018], Catalog Reference Number (also called Model Number) [DS019], and Censitrac Product Name [DS020] for each line of data.

      vi. Contractor will submit their data for acceptance review and routine updates in the full and complete table headings presented and agreed upon (in Order): [Censis] Site ID, Manufacturer, Catalog Reference Number, [Aggregated] Description (comprised of the remaining elements in order), Instrument Category, Instrument Common Name, Instrument Primary Descriptor, Instrument Special Descriptor 1, Instrument Special Descriptor 2, and Instrument Dimension.

      vii. NOTE: As Censis maintains its own 'proprietary' Site ID for use in approving data submissions related to this standard, they agree to provide an initial VA site list and necessary updates over time. Contractor will also provide any necessary 'crosswalk' to VHA STA6N as appropriate to ensure data integrity for reference and for use in discussions.

      viii. An initial list of Descriptors was provided to Censis by the VA RTLS SPW WG for incorporation into the data standards. As part of the maintenance agreement, VA has

purchased local subscriptions for Censitrac's long-term support and data maintenance. As new terms are added or received from the Contractor for VA sites, routine updates and revisions to the field's terms will provided to the VA RTLS SPW WG for review. Data submitted with missing or incorrect information will delay incorporation/completion.

ix. Contractor will provide the VA RTLS SPW WG with regular (monthly) notifications of new terms via submission of an electronic list (MS Excel) for workgroup review and incorporation into the VA RTLS SPW Gold Standard Instrument Library Elements (MS Excel Workbook) on the VA RTLS SharePoint.

Please see the ***VA RTLS Medical-Surgical and Dental Instrument Nomenclature Guidance (Attachment 1)*** for additional reference which includes the approved abbreviations.

1.5.1 Items Not In Catalog With Known Manufacturer & Catalog/Reference Numbers

1. Enter Supplier Name

2. Enter Catalog Number

3. Enter description using the data standards and/or ***VA RTLS Medical-Surgical and Dental Instrument Nomenclature Guidance*** document.

    a. ***Product Name*** field:

        i. ***Category***: General Instrument Classification

        ii. ***Common Name***: Generally the Brand/Trade Name derived from the inventing Surgeon/Creator

            a. Ex: *Clamp, Grasper, Probe, Scissors, Tunneler, etc*.

        iii. ***Primary/Secondary Descriptors***: General function of device and defining physical characteristics (Shape, Material, etc.)

            a. Ex: *Babcock, Castroviejo, DeBakey, Maryland, Mayo, etc*.

            b. **NOTE**: Please see the ***VA RTLS Medical-Surgical and Dental Instrument Nomenclature Guidance*** for additional reference, to include approved abbreviations. *The referenced abbreviations were developed to standardize the SPS capabilities required to meet the '50-character' limitation within OR Count Sheets in the Censitrac Software.*

        iv. ***Length-Dimension***: Generally the length or primary identifying dimension (Diameter, Gauge, French)

1.5.2 Items With Illegible Or No Manufacturer Or Catalog Numbers

Items that present without any easily identifiable marks (i.e. Catalog/Reference Number) will be considered for immediate removal and/or replacement by the facility.

1. Compliance with manufacturer's IFUs cannot be applied without 100% certainty of device identification.

2. Expedited replacement direction was provided directly to the VA RTLS PMO from the VHA National Program Office for Sterile Processing (NPOSP).

3. If a suitable backup instrument is available, the unmarked instrument should be expeditiously programmed for replacement.

4. Any critically required 'no-mark' instruments (those items without which will adversely impact the delivery of quality patient care) may be retained for use while a replacement is urgently procured.

a. This includes any floor grade (e.g. 'Pakistani') instrumentation that is identified within OR surgical trays.

NOTE: VA's goal is to remove medical/surgical and dental instruments from service that present without any readable OEM surface markings. Through the course of the day based on the discovery of an illegible manufacturer/part number, the contractor will clearly communicate and provide VA with medical/surgical and dental instruments which require decision and/or action by SPS personnel. The enhanced process steps are as follows:

4. All medical/surgical and dental instruments that meet the criteria (e.g. material and size requirements) for marking will be 2D electrochemically marked and commissioned. The standards for the key data entry fields and are as follows:

5. ***Supplier*** field:

   a. If the Original Equipment Manufacturer (OEM) cannot be readily determined, HPES/Sites will utilize "**NVN"** (No Vendor Name)

6. ***Catalog Number*** field:

   b. If the Catalog Number cannot be readily determined, HPES/Sites will utilize "**NMN"** (No Model Number) plus

   c. After entering 'NMN' will _**Barcode Scan**_ the 10-digit Stencil ID into the **'*Catalog Number*'** Field

   d. Result: (example) **"NMN1234567890"**

7. These values should be utilized to ensure adherence to the data standards, limiting human factors related to data entry, and to assist in reporting purposes while procuring a replacement.

   a) Facility SPS Chief will utilize the 'NVM' and 'NMN' references to monitor the expedited replacement and for required NPOSP reporting purposes.

   b) HPES/Censis will ensure that reporting of "Same Stencil ID & Catalog Number" is an established report available to the VISN and the local SPS Chief upon activation of the software.

8. All medical/surgical and dental instruments that were marked per the above procedure without a legible supplier or part number will be sequestered (e.g. bagged) and placed back into its respective tray/set. SPS staff will be notified to determine which medical/surgical and dental instruments should be considered for decommissioning and/or replacement. SPS will review the affected medical/surgical and dental instruments and take any necessary actions in accordance with the established expectations.

1.6 Data Quality and Reporting

These requirements dictate that marked instruments will be 100% accurately identified BY THE VENDOR (not VA SPS staff), data entered (also known as 'commissioned') into the Censitrac database, with all necessary quality controls in place to meet VA's nomenclature standards and guidance (See Section 5).

• The Vendor will follow the following process for physical (mark) quality and item identification assurance.

   o Post 2D electrochemical mark applications, the vendor will immediately QA the item to ensure it scans easily into the Censitrac system. Marks that do not read within 2-3 seconds will be assessed for re-application prior to commissioning.

   o VA SPS staff will perform QA on the vendor-performed work on a Censitrac workstation, which permits access to the instrument database. This access will allow VA staff to evaluate the quality of the mark and that the instrument scanned is the one displayed in Censitrac and the data is in strict accordance with VA

Data Standards. It's important that the standardized product name corresponds to the instrument being scanned. The QA of the instrument name is described below.

- o QA will be performed by the vendor in accordance with the following schedule:

  - Weeks 1-2: The facility SPS staff will perform manual and automated QA checks on not less than 5% of vendor throughput of medical/surgical instrumentation, containers, and applicable RME. The checks must be annotated and forwarded to the Contracting Officer Representative (COR) on a daily basis.

- o The QA effort will be recorded and submitted to the COR in an electronic format since aggregate results will need to be analyzed to measure contractor performance. The QA document will be reviewed by the VA SPS POC and submitted to the COR daily/weekly per the above requirements.

- o The VISN COR will aggregate and act upon vendor QA results as necessary to measure contractor performance and ensure VA receives product deliverable in full applicability to these requirements.

- o Both VA and the contractor will continue to monitor and improve upon these activities.

• Upon marking and commissioning of a site's instruments, the vendor will provide a consolidated list to the facility for review, to include any 'new' Data Quality Tool (DQT) (described in section 6.3) reference table terms which will be reviewed by the VA team. The QA list will be available to the VA for review/processing within 48 hours after each days marking and commissioning activities. The VA will be able to perform up to 100% quality assurance checks on the instrument names.

1.6.1   New Terms

The VA has developed the aforementioned Data Quality Tool to provide enterprise assurances that all data added to a new Censitrac system meets the conventional data standards as described within the current version of the *VA RTLS Medical-Surgical and Dental Instrument Nomenclature Guidance.*

1) Vendor will access the most recent DQT from the RTLS SharePoint or upon request from the COR.

2) The vendor will follow the DQT directions to load the new site's data for quality testing.

3) Any errors will be reviewed/corrected by the vendor.

4) For outstanding errors that cannot be immediately remediated by the vendor, or are otherwise known 'new' terms that need to be evaluated, these will be saved within the DQT and forwarded to the VA COR for processing by the VA RTLS SPW Workgroup.

5) Upon receipt of VA feedback/approval - vendor will load the approved terms to the DQT Reference Table and provide any necessary data remediation within three (3) business days of receipt from VA.

6) The revised DQT (Master) will be returned to VA COR/SPW WG and/or uploaded by vendor to the VA SharePoint.

7) HPE will submit the final VISN SPW Data document (in DQT format) to the COR for local approval

   a. Vendor will do this at no additional charge to VA as QA is an inherent function of the commissioning charge.

   b. VA retains all rights to the DQT and its future use beyond the vendor's contract Period of Performance (PoP).

1.7 Additional Requirements

• The preferred successful vendor will be certified by Censis indicating appropriate training and quality control for marking and commissioning services. Vendor certification by Censis may require costs to the vendor associated with any certification process.

• It is the expectation that the vendor will provide one technician to work from 1000-1830, Monday-Friday and will work with the facility SPS RTLS Program Specialist to receive the instrumentation. SPS RTLS Program Specialist will observe/learn/assist with marking, when practical.

• Instruments will be marked with the appropriate Censitrac marking workstation and consumables supplied by the successful vendor. The Vendor will need to allocate its own resources at some facilities that do not currently have electrochemical marking workstations in place.

• Upon approval, the new terms will be added to the DQT reference tables according to the process outlined below:

- Vendor will prepare all SPW data in strict accordance with VA RTLS Data Standard 020 (Section 5) and will forward any concerns to the COR.
- Vendor will propose any new marking terms to the COR for review/approval within 5 business days of completion of instrument marking at the VA facility.
- The COR will provide concurrence or feedback via email on items to be addressed/clarified by the vendor within 5 business days. For specific items to be addressed by vendor, the vendor will resubmit responses within 48 hours to those items in questions for VA concurrence as applicable.
- The Vendor will update the data quality tool reference tables with the newly accepted marking terms for VA use.
- When all of the initial errors have been addressed and new terms accepted into use, the vendor will submit facility data to each COR for acceptance of instrument marking data.
  - o Any and all errors will be returned to vendor for correction. Vendor will resubmit the facility data with the corrections addressed. The COR will be presented with error-free data for consideration of contract acceptance.
  - o CORs will use the VA data quality tool to validate vendor-submitted data is in full compliance with DS020.
- VA COR will provide written concurrence to formally accept the facility instrument marking data within 5 business days.

• SPS Marking and commissioning activities will not exceed 9 weeks.

• The contractor during the course of their marking & commissioning activities, will build a standardized list for routine submission to the VA RTLS SPW WG for incorporation into this data collection and utilization. As part of the maintenance agreement, VA has purchased local subscriptions for Censitrac's long-term support and data maintenance. As new Catalog Numbers are added or received by the contractor from VA sites, routine updates and revisions to the field's Catalog Numbers will be provided to the VA RTLS SPW WG for review. Data submitted with missing or incorrect information will delay incorporation/completion.

The following table provides the number of estimated instruments requiring marking and commissioning by facility and the date work should be completed:

VISN	Location	Estimated Number of Instruments	Task End Date
22	*San Diego, CA*	*600*	*Marking and Commissioning activities not to exceed 9 weeks*

Table 1: Estimated Number of Instruments for Marking

• Contractor will work with the local SPS Chief to determine a location at each site that will be provided for contractor storage and work space. Contractor will NOT store, or plan to store, any hardware/materials in the SPS operational work areas. All materials such as tools, packaged products, personal effects, etc. of the contractor shall be located in the centralized contractor location.

    o **NOTE**: Due to the high risk of human factor/workflow non-compliance, ALL marking of Medical-Surgical & Dental Instruments will be completed OUTSIDE of any SPS working area. Marking may be accomplished in an SPS administrative area, so long as it is not directly contained or openly connected with an SPS decontamination, reprocessing, assembly, or storage area.

    o Scheduling of the marking and commissioning services will be coordinated with the SPS Chief at each site.

2   Reference Information

2.1   General Requirements

2.1.1   Performance Period
The period of performance (POP) for this contract is 9 weeks after the award date.

2.1.2   Place of Performance / Delivery Information
VA San Diego Healthcare System

3350 La Jolla Village Drive
San Diego, CA 92161-0002

2.1.3   Travel
The Government anticipates travel under this effort to perform the tasks associated with the effort, as well as to attend program-related meetings or conferences throughout the Period of Performance. Include all estimated travel costs in the FFP line items. These costs will not be directly reimbursed by the Government.

2.1.4   Material, Equipment, and Facilities
The Contractor will be provided the following Government Furnished Property (GFP), which includes Government Furnished Material (GFM), Government Furnished Information (GFI), and Government Furnished Equipment (GFE). The GFP includes the following items:

2.2   Safety and Environmental

Safety and environmental procedures shall be identified as below.

The Contractor shall comply with the Office of Federal Procurement Policy Green Acquisition initiatives, as identified in Federal Acquisition Regulation (FAR) Part 23, and Executive Order 13693, in accordance with the policies referenced at http://www.whitehouse.gov/omb/procurement_index_green.

The contractor shall comply with the Department of Veterans Affair's Document 01 14 44, Infection control risk assessment (IRCA) requirements.

3   Project Administration

3.1   Project Manager

The Contractor shall provide a single POC (Project Manager) to oversee the overall project for the facility. The Contractor Project Manager shall be responsible for:

3.1.1   Effectively communicating the project progress to the VISN COR, VHA stakeholders and Contractor team members

3.1.2   Ensuring proper documentation is delivered to VHA

3.1.3   Coordinating, escalating, and resolving Contractor-related project issues

3.1.4   Representing the Contractor in status meetings and providing timely status reports

Deliverable

A.   Bi-weekly status report to include; percentage of work completed at the facility, number of marked per day/week; status of quality assurance testing and any issues or data compliance problems.
B.   Daily progress reports

4   General Requirements

4.1   Facility Marking and Commissioning Plan

The Contractor shall create a Facility Marking and Commissioning Plan prior to beginning the marking/commissioning process for review and approval by the COR. Once approved, this plan shall be integrated into the Contractor Program Management Plan (CPMP). This Plan shall include:

4.1.1   Guidance and instructions on marking placement will be provided by the Government to standardize commissioning activities to be compliant with established VA Standards (See Section 5)

4.1.2   Method for quality control of marking placement and commissioned data to fully manage human factors errors and prevent them from corrupting the final data submitted for acceptance.

4.1.3   Method for taking corrective actions on human factors, to include misplaced marks, defective marks, items that cannot be located, and other errors that can occur during the marking and commissioning process

4.1.3.1   Deliverable:

4.1.3.1.1   Sample: 637-06 Asheville VAMC Marking and Commissioning Plan

Performance Objective	Performance Standard	VA Method for Inspection	Acceptable Performance Levels	Incentives / Disincentives
Marking	Marking and commissioning meets all of the requirements identified in the Marking and Commissioning Plan as well as the VA EDA	Random Sampling	100% compliance with identified plans and standards	No errors in marking/commissioning will result in positive reviews by VA CORs. Errors will be remediated at the Contractor's expense.

4.2   Quality and Performance Management

The following section provides Performance and Quality Metrics for this contract.

4.2.1   Method and distribution of deliverables

The Contractor shall deliver documentation in electronic format, unless otherwise directed in Section B of the solicitation/contract. Acceptable electronic media include: MS Office Suite 2010.

4.2.2   Quality Assurance Surveillance Plan (QASP)

The Government will use a QASP throughout the life of the contract to ensure that the Contractor is performing the services required by this PWS in an acceptable manner. The Government reserves the right to alter or change the surveillance methods in the QASP at its own discretion. A Performance Based Service Assessment Survey will be used in combination with the QASP to assist the Government in determining acceptable performance levels.

4.2.3   Facility / Resource Provisions

The Government will provide office space, telephone service and system access when authorized contract staff work at a Government location as required in order to accomplish the Tasks associated with this PWS. All procedural guides, reference materials, and program documentation for the project and other Government applications will also be provided on an as-needed basis.

The Contractor shall request other Government documentation deemed pertinent to the work accomplishment directly from the Government officials with whom the Contractor has contact. The Contractor shall consider the VISN and facility POC as the final source for needed Government documentation when the Contractor fails to secure the documents by other means. The Contractor shall use common knowledge and resourcefulness in securing all other reference materials, standard industry publications, and related materials that are pertinent to the work.

VA will provide access to VA specific systems/network as required for execution of the task. The Contractor shall use Government-provided software development and test accounts, document and requirements repositories, etc. as required for the development, storage, maintenance and delivery of products within the scope of this effort. The Contractor shall not transmit, store or otherwise maintain sensitive data or products in Contractor systems (or media) within the VA firewall IAW VA Handbook 6500.6 dated March 12, 2010. All VA sensitive information shall be protected at all times in accordance with local security field office System Security Plans (SSP's) and Authority to Operate (ATO)'s for all systems/local area networks (LAN's) accessed while performing the tasks detailed in this PWS.

4.3   Performance metrics

The table below defines the Performance Metrics associated with this effort.

Performance Objective	Performance Standard	VA Method for Inspection	Acceptable Performance Levels	Incentives / Disincentives
Project Management	Vendor meets agree upon timelines and milestones and proactively address schedule slips, risks and issues. Tasks on unapproved schedules cannot be started.	100% Inspection of Project Schedule and Reports	Accurate schedules that reflect changes to tasks and activities	Accurate scheduling will result in positive reviews by VA COR(s). Inaccurate schedules will be rejected by the Government which could delay work at the Vendor expense
Qualified Staff	Vendor staff has requisite knowledge, skills and ability to perform duties, come on time and prepared to complete assign duties and respect the VA Medical Center environment and rules. Staff must be responsive to Government inquires and able to remediate issues promptly.	Reports from Facility Points of Contact and observations	Vendor staff is on-time, qualified, prepared and courteous	Providing qualified, prepared staff will result in positive reviews by VA staff. Unqualified or under-prepared staff will not be permitted to work at a Government facility and may have to reschedule activities at the contractor's expense.
Work Products	Vendor work products shall be thorough, complete, on-time and high quality.	100% Inspection of all work products	Information is available and accurate, grammatical mistakes minimal and templates used where required	High quality work products will result in positive reviews by VA COR(s). Work products that provide inaccurate (or missing) information, have excessive errors or do not use approved national templates will be rejected by the Government and may require re-work at the expense of the vendor
Design	Design complies with VA Solution standards, Facility needs/objectives and other applicable requirements including HIPAA, ICRA, OSHA and Joint Commission	100% Inspection of all design documents	Designs are inclusive of all Hardware and Software purchased and are reviewed and vetted with VA stakeholders prior to submission	Well-designed solutions will result in positive reviews by VA CORs. Poorly designed solutions will be rejected by VA and may result in rework at the contractor's expense.
Marking	Marking and commissioning meets all of the requirements identified in the Marking and Commissioning Plan as well as the VA Enterprise Data Architecture (EDA)	Random Sampling	100% compliance with identified plans and standards	No errors in marking/commissioning will result in positive reviews by VA CORs. Errors will be remediated at the Vendors expense.
Testing	Facility solution meets all national and facility-level requirements and is free of any defects	100% Inspection	Zero defect OR identified defect have a an approved corrective action plan	No errors defects/issues with testing will result in timely system acceptance, payment and positive reviews by VA CORs. Defects and issues with the Solution may cause delays in acceptance and will be remediated at the Vendors expense.
Warranty	Solution is fully covered under warranty for 12 months from the date of acceptance. Warranty issues are identified and resolved within the	Random Sampling of Ticketing	100% of warranty issues resolved within agreed upon timelines	Timely resolution of post-deployment issues will result in positive reviews by VA COR(s). Poor warranty service may result in poor user adoption and excessive

Performance Objective	Performance Standard	VA Method for Inspection	Acceptable Performance Levels	Incentives / Disincentives
	appropriate timelines agree to by VA and Contractor			issue resolution at the Contractor's expense.

5   Data Standards and Guidance Documents

See: Attachment A -- VA RTLS Medical-Surgical and Dental Instrument Nomenclature Guidance

   Attachment B -- VA RTLS SPW Instrument Data Quality Tool