PERFORMANCE WORK STATEMENT (PWS)

Sterile Processing Workflow and Inventory Management System

DEPARTMENT OF VETERANS AFFAIRS

Veterans Integrated Service Network (VISN) 12

June 24, 2017

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1 Introduction

1.1 Purpose

The VISN 12 Network is responsible for providing health care to Veterans throughout the upper Midwest region. VISN 12 is a health care system that includes 9 Medical Centers, and 40+ Community Based Outpatient Clinics, all working together to provide efficient, accessible health care to Veterans in their areas.

Like all health care facilities, VISN 12 faces numerous clinical and business challenges, including inventorying, monitoring and distributing high-level disinfected (HLD) and sterilized reusable medical equipment (RME). These challenges can be met through the implementation of a Sterile Processing Inventory and Workflow Management Solution. In doing so, VISN 12 plans to improve the efficiency and effectiveness of patient care, with reductions in staff hours spent searching for medical, surgical, and dental devices while maintaining more efficient (i.e. less expensive, utilization tailored) inventory levels. VISN 12 intends to implement a Sterile Processing Inventory and Workflow Management Solution as a means of achieving the aforementioned benefits.

This contract establishes the requirements for the Contractor provided solutions for the Sterile Processing Inventory and Workflow Management Solution implementation in VISN 12. The Contractor shall provide a fully integrated, seamless, turnkey solution encompassing hardware, software, and incidental services to VISN 12 facilities comprising this contract.

1.2 Scope of Work

Tracking enhances the ability of VA to ensure patient and staff safety by providing reasonable assurance that instruments have been 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 Sterile Processing Inventory and Workflow Management Solution shall establish a solid foundation of enterprise-wide compliance with generally accepted recommendations from the World Health Organization (WHO), Centers for Disease Control and Prevention (CDC), Association of periOperative Registered Nurses (AORN), The Joint Commission (TJC), International Organization for Standardization (ISO), International Association of Healthcare Central Service Materiel Management (IAHCSMM), Association for the Advancement of Medical Instrumentation (AAMI), and applicable VA Directives and Handbooks.

The Sterile Processing Inventory and Workflow Management Solution workflows shall be based on the CDC Spaulding Classification, which has been used to categorize RME, surgical instruments, and patient care equipment (items) for over 40 years (See Section 3.3.4 for specific items.) This classification is based on the degree of risk for infection involved in the use of these items, which are categorized as Critical, Semi-Critical, and Non-Critical devices. "Items" will be used when referencing surgical / medical / and dental instruments throughout this document.

- Critical items are those that come into contact with sterile tissue and must be sterilized prior to use. This category includes surgical instruments, dental instruments, emergency procedure

trays, loaner instruments, and implant sets. The category may include endoscopes that enter a sterile body cavity or items used on a sterile field.

- Semi-Critical items contact mucous membranes or non-intact skin. Examples of Semi-Critical items include, but are not limited to, flexible endoscopes and ultrasound transducers that enter an intact body cavity.
- Non-Critical items are those that come in contact with intact skin only.

The Sterile Processing Inventory and Workflow Management Solution shall record the location, time stamp, and the status of a device/instrument/surgical container (set), etc. as it goes through the Sterile Processing System (SPS) reprocessing workflow. Locations to be scanned include, but may not be limited to Decontamination, Assembly and Preparation, Sterilization, Quality Assurance (QA), and Storage areas. Within these locations, there will be at least one scan point where work instructions are needed, a work step needs to be recorded, and/or a location update is required. Facility processes, number of stations, physical layout, and the complexity of the workflow in a facility may increase the number of scan points in each area.

The Sterile Processing Inventory and Workflow Management Solution shall capture the movement of VAMC's Critical and Semi-Critical RME, and Non-Critical RME that have or shall receive an electrochemical or similar supplemental mark. It is assumed that any Non-Critical RME reprocessed by a VAMC Sterile Processing Services (SPS) will have or shall generally receive a linear barcode or 2-dimensional electrochemical mark that can be scanned into the solution.

Some individual items, as well as instrument baskets and packages, cannot be marked electrochemically. These items shall be affixed with a linear barcode label which allows a handheld scanner to read and identify these items as they are inventoried, assembled, disinfected/sterilized, and prepared for distribution or storage.

Under this contract the Contractor shall provide the Censitrac solution to serve as a VISN-wide Sterile Processing Inventory Tracking and Workflow Management Solution (ITS). The Contractor shall ensure the system is deployed to meet the needs of each unique VA facility based on their current business processes that will be impacted by the new technology. The Contractor shall provide hardware and software components as described in paragraph 3.2.2.

As part of this effort, the Contractor shall conduct site assessments, update facility drawings, develop implementation plans, document system configuration unique to each site, install, configure and test hardware and software, provide **pre-testing** training to VA staff, provide roles-based training, warranty overview, and facility transition support.

1.3 Related Initiatives

1.3.1 Contractor will collaborate to refresh existing medical technology by evaluating and replacing legacy ITS equipment as appropriate.

1.3.2 Contractor will deploy additional ITS hardware/software to advance VHA-wide strategic initiatives such as VISN-centered technology standardization efforts facilitating increases in health care efficiency.

1.3.3 VA has defined this effort as standardization of Censitrac equipment across facilities within the network. The goal is to simplify towards one manufacturer's line of products within a Network per type of equipment. Networks are expected to use the same vendor's equipment across all facilities for each service type of equipment. Each equipment modality should be contained to one manufacturer.

1.3.4 Contractor will contribute toward recurring efficiencies through ITS equipment standardization, primarily across the medical facilities within the Network based upon VA enterprise initiatives.

1.3.5 Contractor will ensure to align team members with respective VA subject matter experts in Nursing, Infection Control, Biomedical Engineering, Information Technology, Facilities Engineering, and Sterile Processing Services.

1.3.6 Contractor will ensure that the solution and its network connectivity is in strict compliance with VA information security initiatives, up to and including FISMA requirements employed by RTLS ITS for the Amazon GovCloud connection to the Censitrac Business Intelligence and Database.

2 Reference Information

2.1 General Information

2.1.1 Category: 70 -- Information Technology (ADP) Equipment (Including Firmware), Software, Supplies and Support Equipment

2.1.2 Sub Category: 7035 -- IT Support Equipment

2.1.3 NAICS: 334118 -- Computer Terminal and Other Computer Peripheral Equipment Manufacturing

2.1.4 Set-Aside Requirement:

2.2 General Buying Terms

2.2.1 Equipment Condition

New equipment ONLY, NO remanufactured or used products. No "GREY" market items.

2.3 General Requirements

2.3.1 Order Type

This effort shall be proposed as a performance based Firm-fixed-price (FFP) CONTRACT.

2.3.2 Performance Period

The period of performance (PoP) for this CONTRACT is 22 months, from July 1, 2018 – May 31, 2020.

2.3.3 Place of Performance / Delivery Information

Efforts under this CONTRACT shall be performed at the VA facilities identified in the section below. Work may be performed under this CONTRACT at remote locations with prior approval of the Contracting Officer's Representative (COR).

The VISN 12 VHA facilities to be provided the Sterile Processing Inventory and Workflow Management Solution are:

2.3.3.1	*537-12*	*Jesse Brown VAMC*	*(Chicago, IL)*
2.3.3.2	*550-12*	*Illiana VAMC*	*(Danville, IL)*
2.3.3.3	*578-12*	*Edward Hines VAMC*	*(Hines, IL)*
2.3.3.4	*585-12*	*Oscar G. Johnson VAMC*	*(Iron Mountain, MI)*
2.3.3.5	*607-12*	*William S. Middleton VAMC*	*(Madison, WI)*
2.3.3.6	*695-12*	*Clement J. Zoblocki VAMC*	*(Milwaukee, WI)*
2.3.3.7	*695-12*	*Milo C. Heumpfner CBOC*	*(Green Bay, WI)*
2.3.3.8	*556-12*	*Capt. James A. Lovell FHCC*	*(North Chicago, IL)*
2.3.3.9	*676-12*	*Tomah VAMC*	*(Tomah, WI)*

2.3.4 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 PoP. Include all estimated travel costs in the FFP line items. These costs will not be directly reimbursed by the Government.

The total estimated number of trips in support of the program related meetings for this effort is three per site.

2.3.5 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:

2.3.5.1 Facility Drawings (e.g., CAD Drawings), most recent version available (due to Contractor at the time of the Acquisition Requirements Package submission)

2.3.5.2 Current Facility Level Business Process Flows (due to Contractor 3 weeks prior to facility Site Assessment)

2.3.5.3 Sterile Processing Inventory List (due to Contractor 3 weeks prior to the facility Site Assessment)

2.3.5.4 Infection Control Risk Assessment (ICRA) (due to the Contractor at the time of award)

2.3.6 Shipping

2.3.6.1 Deliverable Schedule

The deliverables table is part of the VISN 12 CONTRACT Schedule of Supplies or Services and Price, and directly aligns with the deliverables identified in this PWS. All deliverables associated with a CONTRACT shall be subject to review and acceptance by the CONTRACT COR.

Note: Days used in the attached table refer to calendar days unless otherwise stated. Deliverables with due dates falling on a weekend or holiday shall be submitted the following Government workday after the weekend or holiday.

2.3.6.2 Shipping Conditions

FOB Destination CONUS (Continental U.S.) Shipping charges shall be included in the purchase cost of the products. Sellers shall deliver the products on the own conveyance to the location listed on the purchase order.

2.3.6.3 Shipping Information

No partial shipments unless otherwise specified at time of order.

2.3.6.4 INSPECTION and ACCEPTANCE / Free on board (FOB) for Shipped Deliverables

Inspection and acceptance shall be at Destination and FOB shall be N/A. Please see “Points of Contact” table below for facility contacts and shipping addresses.

2.3.6.5 Special Shipping Instructions:

Prior to shipping, Contractor shall notify Site POCs, by phone ***AND*** followed by email, of all incoming deliveries including line-by-line details for review of requirements. Contractor shall not make any changes to the delivery schedule except as directed by the Site POC upon written request.

Contractors shall coordinate deliveries with Site POCs prior to shipment of hardware to ensure sites have adequate storage space. All shipments, either single or multiple container deliveries, will bear VA Purchase Order number on external shipping labels and associated manifests or packing lists. In the case of multiple container deliveries, a statement readable near VA PO number shall indicate total number of containers for the complete shipment (i.e. “Package 1 of 2”), clearly readable on manifests and external shipping labels.

2.3.6.6 Packing Slips/Labels and Lists shall also include the following:

Note: The Contracting Office will provide the PO# to the contractor. Upon award, the PO# numbers will be listed on the schedule of supplies and services.

IFCAP PO #: _____ (i.e., 166-E11234 (the IFCAP PO number is located in block #20 of the SF 1449))

Total number of Containers: Package ___ of ___. (i.e., Package 1 of 3)

2.4 Section 508

On August 7, 1998, Section 508 of the Rehabilitation Act of 1973 was amended to require that when Federal departments or agencies develop, procure, maintain, or use Electronic and Information Technology, that they shall ensure it allows Federal employees with disabilities to have access to and use of information and data that is comparable to the access to and use of information and data by other Federal employees. Section 508 required the Architectural and Transportation Barriers Compliance Board (Access Board) to publish standards setting forth a definition of electronic and information technology and the technical and functional criteria for such technology to comply with Section 508. These standards have been developed and published with an effective date of December 21, 2000. Federal departments and agencies shall develop all Electronic and Information Technology requirements to comply with the standards found in 36 CFR 1194.

The Section 508 standards established by the Architectural and Transportation Barriers Compliance Board (Access Board) are incorporated into, and made part of all VA orders, solicitations and purchase orders developed to procure Electronic and Information Technology (EIT). These standards are found in their entirety at: https://www.access-board.gov/guidelines-and-standards/communications-and-it/about-the-section-508-standards/section-508-standards and http://www.section508.gov/content/learn/standards. A printed copy of the standards will be supplied upon request. The Contractor shall comply with the technical standards as marked:

- ☒ § 1194.21 Software applications and operating systems
- ☒ § 1194.22 Web-based intranet and internet information and applications
- ☒ § 1194.23 Telecommunications products
- ☒ § 1194.24 Video and multimedia products
- ☒ § 1194.25 Self-contained, closed products
- ☒ § 1194.26 Desktop and portable computers
- ☒ § 1194.31 Functional Performance Criteria
- ☒ § 1194.41 Information, Documentation, and Support

2.5.1 Equivalent Facilitation

Alternatively, offerors may propose products and services that provide equivalent facilitation, pursuant to Section 508, subpart A, §1194.5. Such offerors will be considered to have provided equivalent facilitation when the proposed deliverables result in substantially equivalent or greater access to and use of information for those with disabilities.

2.5.2 Compatibility with Assistive Technology

The Section 508 standards do not require the installation of specific accessibility-related software or the attachment of an assistive technology device. Section 508 requires that the EIT be compatible with such software and devices so that EIT can be accessible to and usable by individuals using assistive technology, including but not limited to screen readers, screen magnifiers, and speech recognition software.

2.5.3 Acceptance and Acceptance Testing

Deliverables resulting from this solicitation will be accepted based in part on satisfaction of the identified Section 508 standards' requirements for accessibility and must include final test results demonstrating Section 508 compliance.

Deliverables should meet applicable accessibility requirements and should not adversely affect accessibility features of existing EIT technologies. The Government reserves the right to independently test for Section 508 Compliance before delivery. The Contractor shall be able to demonstrate Section 508 Compliance upon delivery.

Automated test tools and manual techniques are used in the VA Section 508 compliance assessment. Additional information concerning tools and resources can be found at http://www.section508.va.gov/section508/Resources.asp.

Deliverables:

A. Final Section 508 Compliance Test Results

2.5 Safety and Environmental

Safety and environmental procedures shall be identified in individual contract requirements.

The Contractor shall comply with the Office of Federal Procurement Policy Green Acquisition initiatives, as identified in individual CONTRACTs, in accordance with the policies referenced at http://www.whitehouse.gov/omb/procurement_index_green.

2.5.1 Security and Privacy Requirements

It has been determined that protected health information may be disclosed or accessed and a signed Business Associate Agreement (BAA) shall be required. The Contractor shall adhere to the requirements set forth within the BAA, referenced in Section D of the contract, and shall comply with VA Directive 6066.

2.5.1 POSITION/TASK RISK DESIGNATION LEVEL(S)

Position Sensitivity	**Background Investigation** (in accordance with Department of Veterans Affairs 0710 Handbook, "Personnel Suitability and Security Program," Appendix A)
Low / Tier 1	**Tier 1 / National Agency Check with Written Inquiries (NACI)** A Tier 1/NACI is conducted by OPM and covers a 5-year period. It consists of a review of records

Position Sensitivity	**Background Investigation** (in accordance with Department of Veterans Affairs 0710 Handbook, "Personnel Suitability and Security Program," Appendix A)
	contained in the OPM Security Investigations Index (SII) and the DOD Defense Central Investigations Index (DCII), Federal Bureau of Investigation (FBI) name check, FBI fingerprint check, and written inquiries to previous employers and references listed on the application for employment. In VA it is used for Non-sensitive or Low Risk positions.
Moderate / Tier 2	**Tier 2 / Moderate Background Investigation (MBI)** A Tier 2/MBI is conducted by OPM and covers a 5-year period. It consists of a review of National Agency Check (NAC) records [OPM Security Investigations Index (SII), DOD Defense Central Investigations Index (DCII), FBI name check, and a FBI fingerprint check], a credit report covering a period of 5 years, written inquiries to previous employers and references listed on the application for employment; an interview with the subject, law enforcement check; and a verification of the educational degree.
High / Tier 4	**Tier 4 / Background Investigation (BI)** A Tier 4/BI is conducted by OPM and covers a 10-year period. It consists of a review of National Agency Check (NAC) records [OPM Security Investigations Index (SII), DOD Defense Central Investigations Index (DCII), FBI name check, and a FBI fingerprint check report], a credit report covering a period of 10 years, written inquiries to previous employers and references listed on the application for employment; an interview with the subject, spouse, neighbors, supervisor, co-workers; court records, law enforcement check, and a verification of the educational degree.

The position sensitivity and the level of background investigation commensurate with the required level of access for the following tasks within the PWS are:

Position Sensitivity and Background Investigation Requirements by Task

Task Number	Tier1 / Low / NACI	Tier 2 / Moderate / MBI	Tier 4 / High / BI
	☒	☐	☐
	☒	☐	☐
	☒	☐	☐
	☒	☐	☐
	☒	☐	☐
	☒	☐	☐

The Tasks identified above and the resulting Position Sensitivity and Background Investigation requirements identify, in effect, the Background Investigation requirements for Contractor individuals, based upon the tasks the particular Contractor individual will be working. The submitted Contractor Staff Roster must indicate the required Background Investigation Level for each Contractor individual

based upon the tasks the Contractor individual will be working, in accordance with their submitted proposal.

2.5.2 CONTRACTOR PERSONNEL SECURITY REQUIREMENTS

Contractor Responsibilities:

a. The Contractor shall prescreen all personnel requiring access to the computer systems to ensure they maintain the appropriate Background Investigation, and are able to read, write, speak and understand the English language.
b. The Contractor shall bear the expense of obtaining background investigations.
c. Within 3 business days after award, the Contractor shall provide a roster of Contractor and Subcontractor employees to the COR to begin their background investigations in accordance with the ProPath template. The Contractor Staff Roster shall contain the Contractor's Full Name, Date of Birth, Place of Birth, individual background investigation level requirement (based upon Section 6.2 Tasks), etc. The Contractor shall submit full Social Security Numbers either within the Contractor Staff Roster or under separate cover to the COR. The Contractor Staff Roster shall be updated and provided to VA within 1 day of any changes in employee status, training certification completion status, Background Investigation level status, additions/removal of employees, etc. throughout the Period of Performance. The Contractor Staff Roster shall remain a historical document indicating all past information and the Contractor shall indicate in the Comment field, employees no longer supporting this contract. The preferred method to send the Contractor Staff Roster or Social Security Number is by encrypted e-mail. If unable to send encrypted e-mail, other methods which comply with FIPS 140-2 are to encrypt the file, use a secure fax, or use a traceable mail service.
d. The Contractor should coordinate the location of the nearest VA fingerprinting office through the COR. Only electronic fingerprints are authorized.
e. The Contractor personnel shall submit all required information related to their background investigations (completion of the investigation documents (SF85, SF85P, or SF 86) utilizing the Office of Personnel Management's (OPM) Electronic Questionnaire for Investigations Processing (e-QIP) after receiving an email notification from the Security and Investigation Center (SIC).
f. The Contractor employee shall certify and release the e-QIP document, print and sign the signature pages, and send them encrypted to the COR for electronic submission to the SIC. These documents shall be submitted to the COR within 3 business days of receipt of the e-QIP notification email. (Note: OPM is moving towards a "click to sign" process. If click to sign is used, the Contractor employee should notify the COR within 3 business days that documents were signed via eQIP).
g. The Contractor shall be responsible for the actions of all personnel provided to work for VA under this contract. In the event that damages arise from work performed by Contractor provided personnel, under the auspices of this contract, the Contractor shall be responsible for all resources necessary to remedy the incident.
h. A Contractor may be granted unescorted access to VA facilities and/or access to VA Information Technology resources (network and/or protected data) with a favorably adjudicated Special Agreement Check (SAC), training delineated in VA Handbook 6500.6 (Appendix C, Section 9), and, the signed "Contractor Rules of Behavior." However, the Contractor will be responsible for the actions of the Contractor personnel they provide to

perform work for VA. The investigative history for Contractor personnel working under this contract must be maintained in the database of the Office of Personnel Management (OPM).

i. The Contractor, when notified of an unfavorably adjudicated background investigation on a Contractor employee as determined by the Government, shall withdraw the employee from consideration in working under the contract.

j. Failure to comply with the Contractor personnel security investigative requirements may result in loss of physical and/or logical access to VA facilities and systems by Contractor and Subcontractor employees and/or termination of the contract for default.

k. Identity Credential Holders must follow all HSPD-12 policies and procedures as well as use and protect their assigned identity credentials in accordance with VA policies and procedures, displaying their badges at all times, and returning the identity credentials upon termination of their relationship with VA.

Deliverable:

A. Contractor Staff Roster

2.6 Transition and Orientation Support at end of Contract

The Contractor shall perform transition and orientation services (e.g., develop Phase-In/Phase-Out Transition Plan) to insure continuity of services as specified in the individual CONTRACT upon completion of contract. Transition and orientation support may include transitioning to Government or Contractor personnel.

2.7 CONTRACT Administration

2.7.1 Contracting Officer's Representative (COR)

The COR designated for this CONTRACT will provide the Contractor access to all available GFI, facilities, material, equipment, and services required to complete this CONTRACT. In addition to the COR, there will be a facility-specific VHA point of contact (POC) assigned for each facility installation. The Contractor shall coordinate on-site activities with the designated site-specific facility POC.

2.7.2 Deliverable Review

The Contractor shall submit all deliverables within a timeframe that allows for proper review and acceptance in accordance with the due date(s) identified in the Schedule B of this order. The Contractor shall provide the CONTRACT COR the final updates and revisions within 5 business days after receiving the COR's comments.

2.8 Locations/Points of Contact

Role	Name	Telephone #	Email
V12 Project Champion	Barry O'Brien	906-774-3300x32124	barry.obrien@va.gov
COR	Mike Frydach	414-384-2000x49494	michael.frydach@va.gov
Contracting Officer	TBD		
Contracting Specialist	TBD		

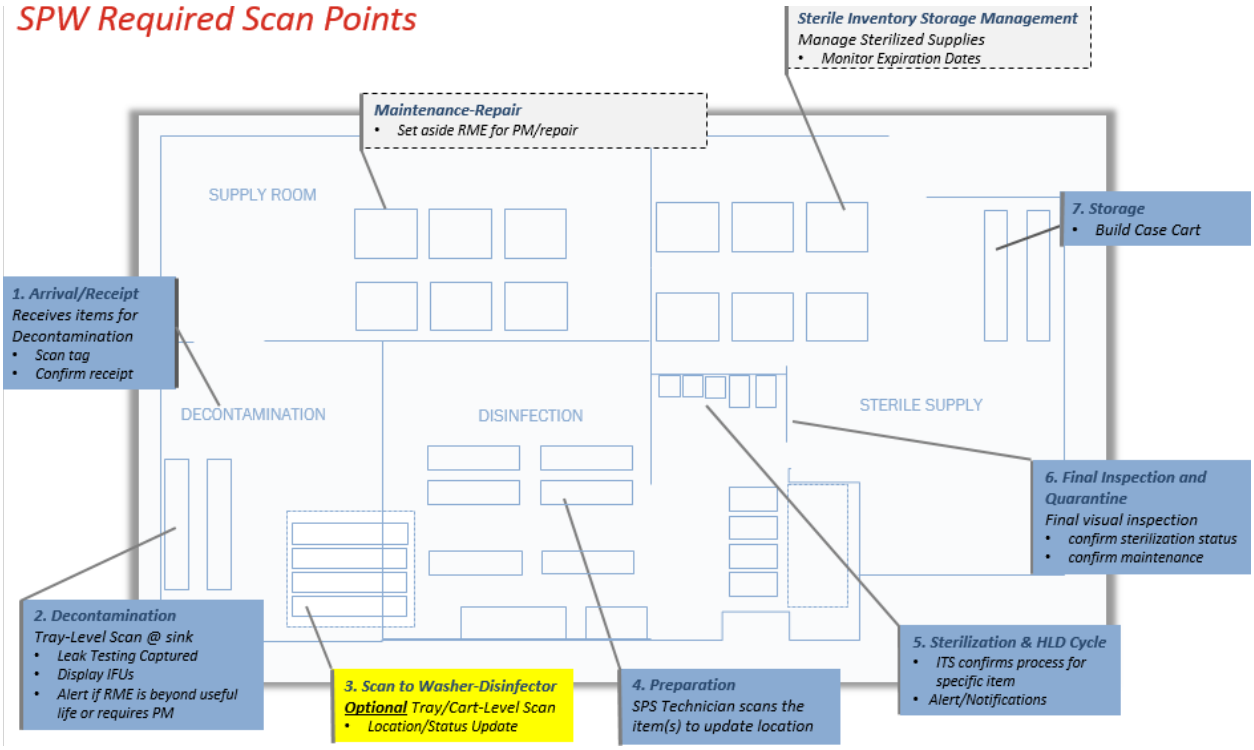
Role	Name	Telephone #	Email
Budget POC	TBD		
Station POC's	537- Jewel Givens 550- Eric Powell 556- Sam Thorell 578- Sherry Lewis 585- Barry O'Brien 607- Rhonda Reals 676- Kelley Lecy 695- Gwynne Roberts	312-569-8375 217-554-5491 224-610-4178 708-202-4734 906-774-3300x32124 608-256-1901x11270 608-372-3971x61783 414-384-2000x44071	

3 Specific tasks and deliverables

The Contractor shall perform the following requirements:

3.1 Application

The Contractor shall provide the Censitrac Sterile Processing Inventory Tracking and Workflow Management Solution (ITS) to VISN 12 to satisfy the functional and business requirements detailed by the figure below and in Section 5.0.



The Government will support a pre-CONTRACT award Vendor site visit, at the Vendor's cost, should one be requested.

3.2 Hardware/Software

3.2.1 Salient ITS Characteristics to be provided by contractor

3.2.1.1 Inventory Control Provides:

3.2.1.1.1 Pictures of individual instruments

3.2.1.1.2 Pictures of correctly assembled trays.

3.2.1.1.3 Individually marked instruments will be visible and traceable throughout the facility

3.2.1.1.4 System shall display readiness status of any queried item/tray/RME

3.2.1.1.5 Electronically create and manage count sheets.

3.2.1.2 Workflow Efficiency & Patient Safety provide:

3.2.1.2.1 Permanent 2-D marking to identify each surgical instrument.

3.2.1.2.2 Electronically capture pass/fail status, cycle type, sterilizer alarms, information and results for process monitoring devices (Biologic Indicator (BI), Chemical Indicator (CI), etc.).

3.2.1.2.3 Reason and surgical case ID captured for Immediate Use Steam Sterilization (IUSS) loads.

3.2.1.2.4 Visual and audible error alerts for any incomplete tray assembly or any sterilization method mismatched with load contents.

3.2.1.2.5 Target patient notification (via surgical case ID) when instrument recalls are required for sterilization load failures

3.2.1.2.6 Manufacturers' and customer-generated instructions/Standard Operating Procedures (SOPs) for every RME/endoscope in inventory needs to automatically appear on screen when specific RME/endoscope ID is manually entered or scanned

3.2.1.3 Administration Tools for Benchmarking & Continuous Improvement provide:

3.2.1.3.1 Extensive standard and custom management reporting i.e., Summaries and details for inventory, maintenance, utilization, location, etc.

3.2.1.3.2 Ability to export data to Excel for integration with other Information and further analysis.

3.2.2 Solution Hardware, Software, and Services

VA requires Contractor to provide for the following solution hardware, software, and related services.

Surgical Instrument Tracking and Management System (ITS) includes the following Censis Technologies, Inc. part numbers:

3.2.2.1 Medical Grade Touch Screen (CT0141) Hardware 22" All in one medical grade touch screen PC. This is a brand name or equal request; see Section 3.2.1 for baseline salient system characteristics. PCs will possess not less than 4 GB RAM to accommodate VA standard Gold Image.

3.2.2.2 Non-Medical Grade Touch Screen Workstation (CT0143) Hardware 24" All in one non-medical grade touch screen PC. This is a brand name or equal request; see Section 3.2.1 for baseline salient system characteristics. PCs will posess not less than 4 GB RAM to accommodate VA standard Gold Image.

3.2.2.3 Waterproof Keyboard (CT0104): Hardware Waterproof Keyboard with Integrated Touchpad Mouse. This is a brand name or equal request; see Section 3.2.1 for salient characteristics.

3.2.2.4 Instrument Scanner-Tethered (CT0058A): Hardware Instrument Scanner tethered. This is a brand name or equal request; see Section 3.2.1 for salient characteristics.

3.2.2.5 Bar Code Scanner (CT0147): This is a brand name or equal request; see Section 3.2.1 for salient characteristics.

3.2.2.6 FIPS Compliant Wireless Scanner (CT0128): Hardware FIPS Compliant wireless scanner. This is a brand name or equal request; see Section 3.2.1 for salient characteristics.

3.2.2.7 Label Printer With Network Card (CT0024): Hardware Label printer with network card. This is a brand name or equal request; see Section 3.2.1 for salient characteristics.

3.2.2.8 Laser Jet Printer (CT0071): Hardware Laser Jet Printer Open Market Item. This is a brand name or equal request; see Section 3.2.1 for salient characteristics.

3.2.2.9 Document Scanner (CT0098): Hardware Document Scanner Open Market Item. This is a brand name or equal request; see Section 3.2.1 for salient characteristics.

3.2.2.10 Electrochemical Marking Kit (CT0088): Hardware Electrochemical Marking Kit. This is a brand name or equal request; see Section 3.2.1 for salient characteristics

3.2.2.11 Electrochemical Marking Stencils (CT0087a): Supplies Electrochemical Marking Stencils Standard (per 1,000). This is a brand name or equal request; see Section 3.2.1 for salient characteristics.

3.2.2.12 Electrochemical Marking Stencils (CT0087b): Supplies Electrochemical Marking Stencils Small (per 1,000). This is a brand name or equal request; see Section 3.2.1 for salient characteristics.

3.2.2.13 Implementation Consumables Package (ICONS): Implementation Consumables Package (tray, location/labels, printer ribbons). This is a brand name or equal request; see Section 3.2.1 for salient characteristics.

3.2.2.14 Instrument Management Implementation Fee (IMT 301): Implementation Instrument Management Implementation Fee. This is a brand name or equal request; see Section 3.2.1 for salient characteristics.

3.2.2.14.1 Loading of Available Images, this includes both

3.2.2.14.1.1 *Images provided to Censis since 2014.*

3.2.2.14.1.2 *Images from previous VA sites that have undergone upgrade and standardization efforts resulting in full compliance with current data (nomenclature) standards.*

3.2.2.14.2 Sterilization Methods

3.2.2.14.3 Consumables

3.2.2.14.3.1 *Packaging Materials*

3.2.2.14.3.2 *Biological/Chemical Indicators/Integrators*

3.2.2.14.4 Count Sheets Created with Marked Instruments associated to Trays

3.2.2.14.4.1 *Pre-load of existing electronic count sheets*

3.2.2.14.5 Item Tray Placement

NOTE: ALL system configuration and data entry activities MUST be delivered in full compliance with the existing VA Data Standards, to include the VA Medical-Surgical and Dental Instrument Nomenclature Guidance standards.

3.2.2.15 Tier 3 InstrumentTrac (SUT301): Subscription, Tier 3 InstrumentTrac. This is a brand name request; see Section 3.2.1 for salient characteristics.

3.2.2.16 Tier 3 Subscription Renewal (SRE202) Year 2. This is a brand name request; see Section 3.2.1 for salient characteristics.

3.3 Technical Requirements

3.3.1 Requirement of the Solution

Workflow data is collected for barcoded or 2D marked items whenever items return to SPS through the SPS decontamination area, throughout the SPS assembly and sterilization processes, to storage, and/or point-of-use location. Case carts are scanned into decontamination, emptied, sent through automatic cart washers, and then to cart storage or to the assembly and preparation area. Items are manually washed in decontamination area sinks. After the decontamination processes are complete, items arrive via pass-through windows or washer disinfectors into the SPS assembly and preparation area. At the assembly and preparation workstation, the SPS Technician uses a tethered handheld scanner to scan a barcode on an instrument tray/basket and an electronic count sheet displays on the monitor which lists all items needed for a specific surgical set. Items are assembled into instrument sets by using a tethered scanner to read the 2D electrochemical data matrix mark (on those items capable of being marked). Wrapped item(s)/sets and peel pouch(es) hold surgical items that are not included in an instrument tray.

Barcodes are printed in the assembly and preparation area and attached to the wrapped item(s) sets or peel pouch(es) to identify their contents.

Assembled trays, wrapped items, and peel packs are placed on a sterilizer loading cart and scanned to build a load for the sterilizer. The load is assigned to a sterilizer by scanning the sterilizer to record information about the contents, such as sterilization cycle duration and temperature. After sterilization is complete, the instrument trays and items are scanned using a mobile handheld scanner to a clean case cart, distribution/storage area, or point of service location such as the Operating Room (OR), dental clinic, or emergency room.

Case cart content identification occurs when the tray or individual peel pack are scanned to the case cart. This association provides information of what instruments are in a tray(s) within a case cart.

3.3.2 System Interfaces

Sterilizer interfaces, where applicable (not all sterilizers can be integrated with Censitrac, and others require an OEM service event to complete the interface), are provided as part of the annual license agreement, and will allow the ITS solution to store data about the sterilizer. Typically, the data includes the sterilizer cycle time, cycle temperature, and a time stamp related to sterilizer cycles which is stored for the purpose of electronic documentation.

Table 1: Sterilizers

Sterilizers with Instrument Tracking System Interface	Compatible Version(s)
Belimed	Determined by manufacturer
Getinge	Determined by manufacturer
Advanced Sterilization Products (ASP)	Currently STERRAD NX and STERRAD 100NX
STERIS	Determined by manufacturer
***NOTE**: Other products may be included as COTS developments since onset of this project/document.*	

3.3.3 Location Types

Location types allow for creating business rules that apply to a specific grouping of locations. The table below shows the established VA data standards for SPS-related locations. The current data standard hierarchy format for entering locations is entered as facility, building, floor, and optional configurable locations: wing, zone, sub-zone, room, and sub-room. Additional “custom” locations are available upon approval by the Government.

Table 2: SPS Location Types

ID	Name	Description
1	General Equipment Storage	Any walled storage location not labeled/designated as clean or dirty storage, for example General Equipment Storage in clinical areas (ITS Monitored Location).

ID	Name	Description
2	Patient Care	Any area where patient care may occur (most often triggers Patient Care Use status, also supports Cross-Contamination use case) (ITS Monitored Location).
3	Dirty Storage	Any area in a clinical department that is considered dirty (most often triggers Dirty status) (ITS Monitored Location).
4	Clean Storage	Any area in a clinical department that is considered clean (most often triggers Clean status, also supports Cross-Contamination use case) (ITS Monitored Location). This includes scope storage that may not be in SPS area.
5	Cleaning-Space	Any area that is a predefined area for cleaning equipment (e.g., SPS, central supply, etc.) (most often triggers Cleaning in Progress status) (ITS Monitored Location).
6	Decontamination	Area within SPS where items are cleaned. The decontamination area is utilized for removing bulk contaminants/bioburden from SPS instruments/items (Most often triggers Decontamination status) (ITS monitored and/or ITS Scanned Location).
7	High Level Disinfection	Area within SPS and/or Gastroenterology (GI) Lab where Semi-Critical devices are scanned for reprocessing (ITS Scanned Location)
8	Cart Washer	Area within SPS where case carts are cleaned (most often triggers Cart Washing status) (ITS Monitored Location).
9	Preparation	Area within SPS where tracked items are prepared for sterilization/reprocessing. The preparation area is utilized for sorting and holding decontaminated instruments/items before they are placed into their respective trays/packages (most often triggers Preparation status) (ITS Scanned Location) (optional tracking location).
10	Packaging	Area within SPS utilized for placing decontaminated instruments/items into trays or packages before sterilization (most often triggers Packaging status) (ITS Scanned Location).
11	Sterilizer	A sterilizer in SPS that tracked items are scanned into prior to sterilization. The area within SPS where sterilizing equipment is located, and equipment that has been packaged is loaded (Most often triggers Sterilization status) (ITS Scanned Location).
12	Quarantine	Area within SPS where quarantine storage is performed to ensure that sterilization processes have been completed and mechanical and biological indicators are evaluated for results (Most often triggers Quarantine status) (ITS Scanned Location) (optional tracking location).

ID	Name	Description
13	Storage	A physical room that is denoted as storage for holding instruments, trays, or case carts ready for use. It is the area within SPS where instruments, trays, and other equipment that has completed the SPS sterilization process are stored, inventoried, and tracked prior to distribution to clinical areas for use (most often triggers SPS Storage status) (ITS Monitored and/or ITS Scanned Location).
14	Service	Any area that is a predefined area for maintaining or repairing equipment (most often triggers In Maintenance Repair Area status for repair, also supports Cross-Contamination use case) (ITS Monitored and/or ITS Scanned Location).
15	Exit	Any area that is considered a building exit (most often triggers Exited status) (ITS Monitored Location).
16	Area.* [multiple]	The creation of location types that are designated as an 'Area' will allow for equipment that are assigned to an area to trigger notifications when equipment leaves or returns to this area and for equipment to appear on the Out of Area report. (ITS Monitored Location).
17	Long-Term Storage (Warehouse)	Any long-term storage area, like a warehouse or other storage area that are not in a clinical department where 'clean' equipment is stored. Equipment leaving this area that follows a predefined cleaning cycle would be considered 'dirty.' (Most often triggers In Storage status, also supports Cross-Contamination use case). Equipment must be cleaned prior to entering and after leaving this area. (ITS Monitored Location).
18	Assembly	Area of the SPS where tracked items are packaged and scanned into a tray.
19	On Case Cart	Equipment is located within a mobile cart for transport to patient care areas (surgical suites). Item is considered to be clean and ready to use on a patient.
20	Sterilization – Not for Use	Item removed from the sterilizer, but has not yet passed QA checks. (i.e., In Quarantine)
21	Sterilization – Ready for Use	Item is located within the Quarantine area of SPS location, but has passed its QA checks.

3.3.4 SPS Equipment Types

Equipment types allow for easy searching for a specific type of equipment and for creating use cases (business rules) for a specific type of equipment. The following list outlines examples of equipment types based upon CDC's Spaulding Classification model that are commissioned into the Censitrac software when the system is installed.

- Critical Surgical Items:
  - Scissors
  - Forceps
  - Needle Holders

    - Retractors
    - Scalpels
    - Instrument Trays
- Semi-Critical Items:
    - Flexible Endoscopes
    - Transesophageal Endoscope (TEE) probes
    - Ultrasound transducers
- Non-Critical Items
    - Infusion Pumps
    - Case Carts
    - Transportation Totes

3.3.5 Reports and Queries

Solution will contain a Business Analytics and Reporting Management Suite that allows the generation of standard and customized reports within a variety of categories. Sorting and filtering options are available and users have the ability to save reports to Favorites.

The standard reports within each category are as listed in the following table.

Table 3: Reporting Requirements

Category/Report Name	Description
Dashboard	Configurable set of charts to monitor metrics on demand
Case Tracking	
Case List	List of surgical cases by date.
Cross Reference	List of surgical cases that have reused items since they were in the selected case.
Cross Reference Detail	Detailed list of instruments reused since being used in selected surgical case.
Instrument Detail	Instrument details by case ID.
Charts	
Average Container Assembly Time	Actual and standard assembly time averages for containers.
Container Completion Rate	Percent of containers assembled completely and percent of containers assembled with all Critical items included.
Containers by Process Step	Current tally or percent of containers in each step of processing, such as Decontamination, Assembly, Sterilization, etc.
Processing Flow Times	Average container processing times by process type.
Processing Priorities	Current tally or percent of containers by priority level based on OR schedule interface (if present).
Throughput	Volume by time period of sets assembled, sterilizer loads, case carts assembled, sets washed, items sterilized, location scans, peel packs.
User Logon Count	Number of unique users that logged on per time period.

Category/Report Name	Description
Container Reports	
Assembly History Detail	Assembly history by container.
Average Assembly Times	Average assembly times by container for selected time period.
Completion Rates	Summary of container completions.
Cost	Total instrument costs by container, with ability to drill down to detailed instrument costs.
Cost and Product Detail	Container pick list detail with extended cost.
General Information	General information fields for each container name.
Hourly Assembly Trends	Assembly trends by container, date, and hour.
Hourly Assembly Trends Summary	Assembly trends summary by date and hour.
Inventory	List of containers with current location, status, case cart, and last updated information.
Inventory by Location	Tally of containers by current location type, with ability to drill down to specific location details.
Loaner Activity	Loaner tallies by surgical case date with drill down to case details and history.
Location History	Location history by container.
Processing Flow Times	Average container processing times by process type, including maximum and minimum times spent in each of the reprocessing steps.
Utilization Rate	Utilization rates compared with the number of actual sets.
Employee Reports	
Assembly History	Container assembly history by technician.
Efficiency	Hours earned over hours worked.
General Information	User logon IDs, names, and access levels.
Hourly Assembly Trends	Sets assembled by technician, by date, by hour.
My Productivity	My (user's) individual processing activity, by activity type.
Productivity	Processing activity by technician and activity type.
Equipment Reports	
Cost	Equipment costs by equipment type.
Inventory	Detailed equipment inventory report.
Inventory by Location	Equipment sorted by current location.
Location History	Location history for each equipment item.
Maintenance Due	Equipment maintenance due by date.
Maintenance History	Maintenance history by request date and supplier.
Open Maintenance	List of equipment currently in maintenance cycle.

Category/Report Name	Description
General Reports	
Implementation Status	Overview of Censitrac system utilization.
Inventory by Location	Containers, case carts, loose instruments and equipment sorted by current location.
Inventory Throughput	Inventory throughput by location type for containers, case carts, and equipment.
Out-of-Sequence Warnings	Out of sequence warnings issued by date.
Quality Feedback	Feedback tallies by event type with ability to drill down to event details.
Queue Time Snapshot	Elapsed time in current locations for containers, case carts, and equipment.
User Last Logon	List each user with the date and time of that user's most recent logon.
User Logon Audit	List logon attempts from the Censitrac security log.
Instrument Reports	
Inactive Instruments	List of instruments not scanned since specified date.
Inactive Instruments Identification	Move all instruments not scanned during a specified period to Missing.
Inventory by Location	Loose instruments sorted by location.
Inventory Summary	Summary of the instrument inventory by supplier and catalog number.
Items Missing History	Instruments that were missing from previous assemblies.
Items Missing from Assembly	Instruments that are currently missing from sets.
Maintenance Due	List of all instruments or containers with maintenance due based on usage parameters.
Maintenance History	Maintenance history by request date and supplier.
Maintenance in Progress	List of instruments currently in maintenance cycle.
Product Catalog	Browse and audit your instrument catalog.
Substitutions by Container	Instrument substitutions by service and container.
Utilization and Shortages	Monthly statistics by container of percent instruments utilized, missing, and unmarked for assembled containers.
PAR Inventory Levels	
Inventory Levels	Actual and required quantities of instruments and containers by location.
Sterilization Reports	
Container Level	Containers sterilized by sterilizer, date, and time.
Container Level by Load	Containers sterilized by load number, sterilizer, date, and time.
Indicator Results Summary	Summary of load indicator results by sterilizer and date.
Instrument Level	Instruments sterilized by sterilizer, date, and time, including instruments in containers and peel packs.

Category/Report Name	Description
Instrument Level by Load	Instruments sterilized by load number, sterilizer, date, and time, including instruments in containers and peel packs.
Sterilizer Load Summary	Tally of loads and contents by sterilizer and time period.
Sterilizer Loads	List of sterilizer loads by sterilizer and date.
Sterilizer Status	Summary of current status of each sterilizer
AER Reports	Endoscope Reprocessing Reports
Immediate Use Steam Sterilization Rate	Report should be structured to run monthly with goal of less than 5% based upon surgical cases.

3.3.6 Technical package should include a signed written statement stating all, not partial, items required can be supplied by them as required by FAR 52.212-2(a).

3.3.7 Evaluation Factors are located in FAR 52.212-2 and will be used to evaluate offers based on the written information submitted.

3.4 Marking and Commissioning

3.4.1 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 12 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 12 and its facilities to finalize all marking and commissioning of dental and medical-surgical instruments utilizing VA developed data standards and guidance.

3.4.2 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.
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 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. Estimations of need are derived from site complexity levels for the provision of marks, commissioning, and type of stencils (i.e., standard or small).

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.

3.4.3 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:

3.4.4 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.

3.4.5 2D Data Matrix Instrument Marking Tape/ Dots

Any tape/dot utilized for this purpose MUST be utilized in full accordance with AAMI guidelines and the manufacturer's instructions for use. 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

3.4.6 Beginning Instrument Marking and Commissioning

The vendor is required to mark and commission approximately 100% of agreed instrumentation. The COR and local SPS Chief will closely monitor the status of sets completed against lists provided to vendor.

Facilities will have to work closely with the contractor to ensure that as much instrumentation as possible is provided each day (typically a minimum of 200 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.

3.4.7 Matrix Estimations

The ITS vendor will consider the following VA stencil estimation table, which was produced utilizing legacy ITS site data in 2013 and reaffirmed in late 2014:

VHA Medical Center Complexity Levels	Current Surgical Instrument Quantity Ranges (2014)	Recommended ITS Stencil Start Count*
1A	15,000-30,000	**20,000**
1B	13,000-20,000	**15,000**
1C	10,000-20,000	**12,000**
2	4,000-10,000	**8,000**
3	3,000-10,000	**5,000**
NOTE: * Facility is strongly encouraged to consider placing an additional order with sufficient lead time to maintain operations (30-day production time from date order is **received** by vendor)		

. The Contracting Officer (and/or Contracting Officer's Representative (COR)) understand(s) that complexity level 1A sites are limited to 50,000 stencils per quarter to prevent over-procurement, thus surpassing actual facility requirements.

3.4.8 Preliminary Activities

The facility count sheets will be provided by the facility for the contractor to review. Upon acceptance, contractor will pre-load the Censitrac software with the site's RME, medical/surgical, and dental instrument data and provide access to the library. 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.

3.4.9 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.

l.

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*** for additional reference which includes the approved abbreviations.

3.4.10 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)

3.4.11 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 vendor 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, Sites will utilize "**NVN"** (No Vendor Name)
6. ***Catalog Number*** field:
    b. If the Catalog Number cannot be readily determined, 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) 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.

3.4.12 Data Quality and Reporting

These requirements dictate that marked instruments will be 100% accurately identified BY THE CONTRACTOR (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 contractor will follow the following process for physical (mark) quality and item identification assurance.

- Post 2D electrochemical mark applications, the contractor 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.
- VA SPS staff will perform QA on the contractor -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.
- QA will be performed by the contractor in accordance with the following schedule:
    - Weeks 1-2: The facility SPS staff will perform manual and automated QA checks on not less than 15% of contractor 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.
    - Weeks 3+: The facility SPS staff will perform manual and automated QA checks on not less than 10% of contractor throughput of medical/surgical instrumentation, containers, and applicable RME. The QA checks must be annotated and forwarded to the COR on a weekly basis for the remainder of the contract,
- 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.

- The VISN COR will aggregate and act upon contractor QA results as necessary to measure contractor performance and ensure VA receives product deliverable in full applicability to these requirements.
- Both VA and the contractor will continue to monitor and improve upon these activities.

• Upon marking and commissioning of a site's instruments, the contractor 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.

3.4.13 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) Contractor will access the most recent DQT from the RTLS SharePoint or upon request from the COR.
2) The contractor will follow the DQT directions to load the new site's data for quality testing.
3) Any errors will be reviewed/corrected by the contractor.
4) For outstanding errors that cannot be immediately remediated by the contractor, 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 - contractor 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 contractor to the VA SharePoint.
7) Contractor will submit the final VISN SPW Data document (in DQT format) to the COR for local approval
    a. Contractor 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).

3.4.14 Additional Requirements

• The contractor shall provide unique stencil numbers. The solution shall not allow duplicate numbers within the entire VA system. VA currently utilizes an alphanumeric nomenclature to identify their assets and instruments (example: 528A4-EE12345, where "528A4" is the station number and "123456" is the unique identification number for the instrument). The list of facilities under this scope is provided on the following SharePoint site, with their designated station numbers, which can be used to populate the

table in Section 6: https://vaww.vha.vaco.portal.va.gov/sites/DUSHOM/HTM/RTLS/Lists/Facility_Directory/All%20Items.aspx

• The contractor will coordinate access to instruments for marking and commissioning with the Sterile Processing Service (SPS) Chief at each facility, in such a manner as to minimize disruption to patient care and to minimize the period of time required to complete marking and commissioning. It is the expectation that the contractor will schedule any necessary work during timeframes when the items are in less demand by the OR, Clinics, etc., to include evenings, nights, and/or weekends (as applicable). Coordination between SPS, Operating Room (OR), Community Based Outpatient Clinics (CBOC), and Hospital based clinical departments (from here on knows as Clinics), and the contractor is essential to a successful deployment. VA facilities are prepared to monitor and strategically plan around the "OR Block" and clinic treatment schedules to most efficiently permit the vendor access to medical/surgical and dental instruments while not impacting patient care. **The contractor is hereby clearly informed by VA that the work to be performed may NOT be possible during normal business hours.**

• Instruments will be marked with the appropriate Censitrac marking workstation and consumables. The contractor 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:

- Contractor will prepare all SPW data in strict accordance with VA RTLS Data Standard 020 (Section 5) and will forward any concerns to the COR.
- Contractor 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 contractor within 5 business days. For specific items to be addressed by contractor, the contractor will resubmit responses within 48 hours to those items in questions for VA concurrence as applicable.
- The contractor 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 contractor will submit facility data to each COR for acceptance of instrument marking data.
    - Any and all errors will be returned to contractor for correction. Contractor will resubmit the facility data with the corrections addressed. The COR will be presented with error-free data for consideration of Task Order acceptance.
    - CORs will use the VA data quality tool to validate contractor-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.

• The COR will begin considerations of the SPS Marking activities to be nearing completion/goal(s) when facilities are unable to provide any additional items to be marked and/or commissioned. These discussions will occur after facilities have determined available instrument sets have been marked and commissioned along with the majority of loose instrument (e.g. backup) inventory.

• Considering the exact number of medical/surgical and dental instruments to be marked and commissioned at each site is currently unknown, the following metric has been agreed upon by VA to trigger dialogue surrounding activities related to contractual completion of the marking and commissioning activities. The contractor routinely captures daily marking and commissioning activity which are reported to the COR or their designee. The "Number of Instruments Marked/Commissioned" is recorded daily during the lifespan of the project and routinely trended by the COR. When the "Number of Instruments Marked/Commissioned" metric's daily output falls below 70% of the trended average, the COR and Vendor will discuss determining an agreeable completion date.

• 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:

VISN	Location	Estimated Number of Instruments to be Marked
12	*Chicago*	*10,000*
12	*Hines*	*30,000*
12	*FHCC*	*15,000*
12	*Danville*	*0*
12	*Milwaukee*	*30,000*
12	*Green Bay*	*15,000*
12	*Madison*	*20,000*
12	*Tomah*	*7,000*
12	*Iron Mountain*	*7,000*

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.

- **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.

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

3.4.15 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.

3.4.16 Deliverable

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

3.4.17 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:

3.4.18 Identification of all items to be marked.

3.4.19 A schedule (not to interrupt business operations) to mark and commission all items. Hours may occur outside of normal patient care business, to include weekends, holidays, etc.,

3.4.20 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)

3.4.21 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.

3.4.22 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

3.4.22.1 Deliverable:

3.4.22.1.1 537-12 Chicago VAMC Marking and Commissioning Plan

3.4.22.1.2 550-12 Danville VAMC Marking and Commissioning Plan

3.4.22.1.3 556-12 North Chicago VAMC Marking and Commissioning Plan

3.4.22.1.4 578-12 Hines VAMC Marking and Commissioning Plan

3.4.22.1.5 585-12 Iron Mountain VAMC Marking and Commissioning Plan

3.4.22.1.6 607-12 Madison VAMC Marking and Commissioning Plan

3.4.22.1.7 676-12 Tomah VAMC Marking and Commissioning Plan

3.4.22.1.8 695-12 Milwaukee VAMC Marking and Commissioning Plan

3.4.23 Completion of facility Infection Control Risk Assessment

An ICRA is a multidisciplinary, organizational, documented process that after considering the facility's patient population and program:

3.4.24 Focuses on reduction of risk from infection,

3.4.25 Acts through phases of facility planning, design, construction, renovation, facility maintenance, and

3.4.26 Coordinates and weighs knowledge about infection, infectious agents, and care environment, permitting the organization to anticipate potential impact.

3.4.27 Coordinated through the Infection Control Office.

Deliverable

A. ICRA for each facility.

3.4.28 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	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

Performance Objective	Performance Standard	VA Method for Inspection	Acceptable Performance Levels	Incentives / Disincentives
	Data Architecture (EDA)			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 appropriate timelines agree to by VA and Contractor	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 issue resolution at the vendors expense.

3.4.29 Data Standards and Guidance Documents

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

VA RTLS Medical-Surgical and I

See: VA RTLS SPW Instrument Data Quality Tool

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4 Project Administration

4.1 Implementation Manager

The Contractor shall provide a single POC (Implementation Manager) to oversee the overall implementation for the VISN. The Contractor Implementation Manager shall be responsible for:

4.1.1 Effectively communicating the project progress to the VISN 12 COR, VHA stakeholders and Contractor team members

4.1.2 Ensuring proper documentation is delivered to VHA

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

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

4.2 Kick-Off Meeting

The Contractor shall conduct a project kick-off meeting to introduce the Government team to the Contractor's overall operating plans and approach to this CONTRACT. The Contractor shall present its draft Contractor Project Management Plan (CPMP) (see Section 4.3.1 below) for review with the Government. The Contractor shall update the based on the outcomes of the kick-off meeting. The meeting shall be held face to face at a Government designated facility.

4.2.1 Deliverables:

4.2.1.1 Kick-Off Meeting Briefing Materials (hard/electronic)

4.2.1.2 Kick Off Meeting Minutes (electronic)

4.3 Project Management

4.3.1 Contractor Project Management Plan (CPMP)

The Contractor shall deliver a CPMP that lays out the Contractor's approach, timeline and tools to be used in execution of the contract. The CPMP should take the form of both a narrative and graphic format that displays the schedule, milestones, risks and resource support. The CPMP shall also include how the Contractor shall coordinate and run planned, routine, and ad hoc data collection reporting requests as identified within the PWS. The initial baseline CPMP shall be concurred upon and updated monthly thereafter. The Contractor shall update and maintain the VA PM approved CPMP throughout the PoP. The Contractor shall submit a draft Project Schedule (see item #1 below) as part of the Proposal. In addition to the above, the CPMP shall contain:

4.3.1.1 A comprehensive Project Schedule including milestones and deliverable dates for the deployment at each VISN 12 facility. The project schedule shall include Government dependencies (e.g., document acceptance) and be broken out by facility and application. The project schedule shall be baselined upon initial acceptance with all baselined task data and dates retained. Deviations from the baseline schedule shall be documented and the rationale behind these deviations and reviewed with the COR.

4.3.1.2 A detailed communication strategy that outlines the distribution and communication of deliverable review/acceptance as well as the how and when critical information (e.g. project tasks, milestones, status) will be disseminated throughout the VISN and referenced Facilities.

4.3.1.3 Quality Assurance Plan

4.3.2 Deliverables:

4.3.2.1 Contractor Project Management Plan

4.3.2.2 QA Plan

4.3.3 Server and Database Infrastructure

VA OIT will provide the application and database server resources to support the Censitrac system, therefor the Server Performance Specification document should include the technical approach which includes the VA-provided resources and the associated performance specifications to clearly define the technical resources required to fulfill the performance requirement of the VISN. The Contractor shall deliver a Server Performance Specification document that lists the server requirements for VISN 12 and each of its designated facilities. The Contractor shall submit the Server Performance Specification Document to the VA as part of the proposal. This Server Performance Specification Document shall include:

- A diagram that lays out the server requirements at each location
- Expected bandwidth utilization for the wide area network (WAN) links
- Expected application latency requirements
- Server performance specifications

4.3.3.1 Deliverable:

4.3.3.1.1 Server Performance Specification Document

4.3.4 Meeting and Report Requirements

4.3.4.1 On-going Progress Meetings

The Contractor shall conduct in-process review meetings weekly using the updated CPMP to update VA on Contractor project status, schedule, risks, risk mitigation, issues and issue resolution plans.

4.3.4.2 Monthly Status Reports

The Contractor shall submit a monthly status report to include:

4.3.4.2.1 Deliverable:

4.3.4.2.1.1 *Monthly Status Report*

5 General Requirements

5.1 Solution

The Contractor shall provide Censitrac COTS Instrument Tracking System as a VISN solution infrastructure conforming to the following:

5.1.1 The Contractor shall install supporting hardware and components to blend in (or not be visible at all), with the general surface treatments of the facility

5.1.2 The Contractor shall install solution components to have minimal impact on the business operations of the facility and meet applicable infection control and health and safety requirements such as Joint Commission and Infection Control Risk Assessment (ICRA) findings and standards.

5.1.3 The Contractor's solution MUST be fully capable of integration with existing VHA and VISN 12 enterprise ITS solutions in order to achieve national standardization goals.

5.2 ITS Time Stamp

The Contractor shall ensure all applications synchronize with VISN facility time zone standard.

5.3 Single Sign-on

Users sign into the solution with their current VA credentials. The PIV card and PIN combination for access to the solution's UI utilizes VA's Active Directory Lightweight Directory Access Protocol (LDAP) environment which allows for Single Sign-On (SSO). The UI complies with all applicable VA standards and guidelines. The UI is compatible with Internet Explorer version 7 (or later). The browser and desktop configuration are in accordance with Federal Desktop Core Configuration (FDCC). The Solution does not require custom browser configuration.

5.4 Component Delivery

The Contractor shall order and have all of the necessary hardware and software components delivered to the VISN facility locations provided in this PWS.

VA will attempt to safeguard stored equipment pending installation but shall not assume liability of said equipment until it is fully installed, tested, operational, and staff have been trained.

5.5 System Administration

The Contractor shall provide start-up, education, and System Administration services. All of these activities will be documented and provided electronically to VA for longevity.

5.6 Pre-Deployment

5.6.1 Site Assessment

The Contractor shall perform post-award Site Assessments of each VISN facility deploying the solution to collect the information necessary for successful implementation. The following subsections define the deliverables due following each Site Assessment.

5.6.2 Preliminary Hardware Deployment Design Document

Following the site assessment, the Contractor shall develop a Preliminary Hardware Deployment Design (PHDD) document for each VISN facility for approval by the COR prior to beginning the hardware installation process. The PHDD document shall illustrate the Contractor's design of hardware to meet the requirements defined in this PWS and in the VISN 12 Section B.1-Supplies or Services and Price.

The Contractor shall submit the PHDD document in the form of facility drawings that include markups noting location, type and quantity of all hardware and supporting equipment (e.g., user access / monitors) that needs to be installed and how that hardware meets the needs of each facility's business processes being affected by the solution. This document shall also include:

5.6.2.1 Preliminary quantity and proposed location of SPW scanning stations and / or workstations to achieve the goals of the application in strict accordance with established facility workflows.

5.6.2.2 Refresh existing medical technology by evaluating and replacing legacy ITS equipment and systems as appropriate. Facility will be provided with a written justification for replacement as part of the PHDD as applicable.

5.6.2.3 Solution-specific requirements for Contractor installation of any additional power, ethernet, or other solution-specific pre-installation items required for fully operational hardware/software.

5.6.2.4 Proposed changes, corrections and/or updates to the VA-provided maps

5.6.2.5 Delivery and storage space requirements for proposed facility equipment.

5.6.2.6 Any other tools and templates that help to define the design (e.g., configuration, components, business rules, etc.) of the VISN Solution to aid the VISN facility in making design decisions to achieve stated goals.

The Contractor shall also update the CPMP schedule based on any findings from the Site assessment.

5.6.2.7 Deliverables:

5.6.2.7.1 537-12 Jesse Brown VAMC Preliminary Hardware Deployment Design Document

5.6.2.7.2 550-12 Illiana VAMC Preliminary Hardware Deployment Design Document

5.6.2.7.3 578-12 Edward Hines VAMC Preliminary Hardware Deployment Design Document

5.6.2.7.4 585-12 Oscar G. Johnson VAMC Preliminary Hardware Deployment Design Document

5.6.2.7.5 607-12 William S. Middleton VAMC Preliminary Hardware Deployment Design Document

5.6.2.7.6 695-12 Clement J. Zabolocki VAMC Preliminary Hardware Deployment Design Document

5.6.2.7.7 695-12 Milo C. Heumpfner CBOC Preliminary Hardware Deployment Design Document

5.6.2.7.8 556-12 Capt. James A. Lovell VAMC Preliminary Hardware Deployment Design Document

5.6.2.7.9 676-12 Tomah VAMC Preliminary Hardware Deployment Design Document

5.7 Deployment: SPW Application Installation

The Contractor shall install the SPW application in accordance with the approved PHDD document and the guidance provided in the National ITS SPW Application Usage Document (see Addendum A). The Contractor shall report on installation progress during Weekly Meetings with the COR (Section 4.3.4) and in the MSR (Section 4.3.4.2).

5.7.1 SPW Application Matrices and Hardware

The Contractor shall provide workstation hardware (e.g., assembly workstation, sterilization workstation, 2D electrochemical marking workstation, etc.) where no existing VA equipment can be leveraged. The Contractor shall propose the quantities of additional consumables and spares as needed.

5.7.2 SPW Application Software Configuration

The Contractor shall configure the SPW software for each of the applicable facilities identified in this PWS. The Contractor shall configure the solution so that it represents the physical layout of each facility.

The SPW application shall be configured to meet the National Standards set forth in the National ITS SPW Application Usage Documents and meet the needs of the Facility's cross-functional business process flows including the facility-specific business rules, alerts, notifications, and reporting requirements as identified during the Site Assessment, in the approved PHDD document, and the SPW Usage Document Addendum. The Contractor shall report on the progress of software configuration during Weekly Meetings with the COR (Section 4.3.4) and in the MSR (Section 4.3.4.2).

5.8 Post Deployment Support Services

5.8.1 Warranty Services

The Contractor shall provide Warranty services to include a facility Warranty Status Report.

5.8.1.1 Deliverables:

5.8.1.1.1 537-12 Jesse Brown VAMC Warranty Status Report

5.8.1.1.2 550-12 Illiana VAMC Warranty Status Report

5.8.1.1.3 578-12 Edward Hines VAMC Warranty Status Report

5.8.1.1.4 585-12 Oscar G. Johnson VAMC Warranty Status Report

5.8.1.1.5 607-12 William S. Middleton VAMC Warranty Status Report

5.8.1.1.6 695-12 Clement J. Zabolocki VAMC Warranty Status Report

5.8.1.1.7 695-12 Milo C. Heumpfner CBOC Warranty Status Report

5.8.1.1.8 556-12 Capt. James A. Lovell VAMC Warranty Status Report

5.8.1.1.9 676-12 Tomah VAMC Warranty Status Report

5.9 Quality and Performance Management

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

5.9.1 Method and distribution of deliverables

The Contractor shall deliver documentation in electronic format, unless otherwise directed in Section B of the solicitation/TO. Acceptable electronic media include: MS Word 2000/2003/2007/2010, MS Excel 2000/2003/2007/2010, MS PowerPoint 2000/2003/2007/2010, MS Project 2000/2003/2007/2010, MS Access 2000/2003/ 2007/2010, MS Visio 2000/2002/2003/2007/2010, AutoCAD 2002/2004/2007/2010, and Adobe Postscript Data Format (PDF).

5.9.2 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.

5.9.3 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 COR 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 via remote access technology (e.g., Citrix Access Gateway (CAG), site-to-site virtual private network (VPN), or VA Remote Access Security Compliance Update Environment (RESCUE)). This remote access will provide access to VA specific software such as Veterans Health Information System and Technology Architecture (VistA), ClearQuest, ProPath, Primavera, and Remedy, including appropriate seat management and user licenses. 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.

5.10 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

Performance Objective	Performance Standard	VA Method for Inspection	Acceptable Performance Levels	Incentives / Disincentives
				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.
Installation	Hardware is functioning and installed in accordance with approved design documents. Software and interfaces are installed and configured to meet both the Facility requirements as well as the Facilities Objectives / Goals.	100% Inspection	100% configured / functioning hardware and software for all applications	Properly installed and configured components will result in positive reviews by VA CORs. Improperly installed and configured components will not be accepted by VA and may result in rework at the contractor's 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 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.
Training	The right stakeholders and users are identified and trained on the new solution, changes to business and clinical operations.	User surveys	100% of identified users are trained on ITS	Good training and user adoption will result in positive reviews by VA CORs. Incomplete training and poor user adoption may result in repeat training events at the vendor's expense.
Warranty	Solution is fully covered under warranty for 12 months from the date of acceptance. Warranty issues are identified and resolved within the appropriate timelines agree to by VA and Contractor	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 issue resolution at the vendor's expense.

5.11 Facility Acceptance Test Plan

The Contractor shall create a Facility Acceptance Test Plan. The Facility Acceptance Test Plan will define testing methodology, test scripts, and test metrics for the solution.

5.11.1 Deliverables:

5.11.1.1 537-12 Jesse Brown VAMC Facility Acceptance Test Plan

5.11.1.2 550-12 Illiana VAMC Facility Acceptance Test Plan

5.11.1.3 578-12 Edward Hines VAMC Facility Acceptance Test Plan

5.11.1.4 585-12 Oscar G. Johnson VAMC Facility Acceptance Test Plan

5.11.1.5 607-12 William S. Middleton VAMC Facility Acceptance Test Plan

5.11.1.6 695-12 Clement J. Zabolocki VAMC Facility Acceptance Test Plan

5.11.1.7 695-12 Milo C. Heumpfner CBOC Facility Acceptance Test Plan

5.11.1.8 556-12 Capt. James A. Lovell VAMC Facility Acceptance Test Plan

5.11.1.9 676-12 Tomah VAMC Facility Acceptance Test Plan

5.12 Training

The Contractor shall provide on-site and web based training at each VISN facility. The Contractor shall work with VA to determine the best time and location for training events. On-site training sessions shall be conducted at the VA facility. The Contractor shall provide training material and schedules for all training events and complete those events in accordance with the approved Facility Training Plan. The Contractor shall submit a Training Plan for each VISN facility for review and approval by the COR. The Training Plan shall include:

5.12.1 Training locations, training dates, and training times

5.12.1.1 Pre-System Operational Readiness Testing (ORT)

5.12.1.2 Post-ORT Formal Site User Training

5.12.2 Format, method and / or delivery of training (e.g., on-site, web based)

5.12.3 Training audience (e.g., technical repair, system user, system administrator)

5.12.4 Instructor profile and content information

Once training is completed, the Contractor shall include the following in the MSR:

5.12.5 Facility-specific list of the attendees for each training session

5.12.6 The contractor staff that conducted the training

5.12.7 Deliverables:

5.12.7.1 537-12 Jesse Brown VAMC Training Plan

5.12.7.2 550-12 Illiana VAMC Training Plan

5.12.7.3 578-12 Edward Hines VAMC Training Plan

5.12.7.4 585-12 Oscar G. Johnson VAMC Training Plan

5.12.7.5 607-12 William S. Middleton VAMC Training Plan

5.12.7.6 695-12 Clement J. Zabolocki VAMC Training Plan

5.12.7.7 695-12 Milo C. Heumpfner CBOC Training Plan

5.12.7.8 556-12 Capt. James A. Lovell VAMC Training Plan

5.12.7.9 676-12 Tomah VAMC Training Plan

5.13 Component Delivery and Implementation

5.13.1 VISN and Facility Component Delivery

The Contractor shall order and have all of the necessary hardware and software components delivered to the VISN facility locations noted in this PWS.

The Contractor shall ensure that a copy of the signed Receiving Report is furnished to the COR once components are delivered. The Contractor shall submit a copy of the final signed Receiving Reports for each facility.

5.13.1.1 Confirmation of the order and delivery of the components

5.13.1.2 Reconciliation (if any) of what was planned to be delivered versus what was actually delivered

5.13.1.3 Details of where items were delivered, what time they were delivered, and who from the Government received them

5.13.1.4 Details of Contractor representative that the aforementioned components were released to for installation, to include names, dates, items, etc.

5.13.1.5 Deliverables:

5.13.1.5.1 537-12 Jesse Brown VAMC Receiving Report

5.13.1.5.2 550-12 Illiana VAMC Receiving Report

5.13.1.5.3 578-12 Edward Hines VAMC Receiving Report

5.13.1.5.4 585-12 Oscar G. Johnson VAMC Receiving Report

5.13.1.5.5 607-12 William S. Middleton VAMC Receiving Report

5.13.1.5.6 695-12 Clement J. Zabolocki VAMC Receiving Report

5.13.1.5.7 695-12 Milo C. Heumpfner CBOC Receiving Report

5.13.1.5.8 556-12 Capt. James A. Lovell VAMC Receiving Report

5.13.1.5.9 676-12 Tomah VAMC Receiving Report

5.14 Facility Acceptance Report

The Contractor shall run the approved Facility Acceptance Test Plan and create a Facility Acceptance Test Report for the solution being deployed at each facility. The Contractor shall submit a Facility Acceptance Test Report in accordance with the approved Facility Acceptance Test Plan.

5.14.1 Deliverables:

5.14.1.1 537-12 Jesse Brown VAMC Acceptance Testing Report

5.14.1.2 550-12 Illiana VAMC Acceptance Testing Report

5.14.1.3 578-12 Edward Hines VAMC Acceptance Testing Report

5.14.1.4 585-12 Oscar G. Johnson VAMC Acceptance Testing Report

5.14.1.5 607-12 William S. Middleton VAMC Acceptance Testing Report

5.14.1.6 695-12 Clement J. Zabolocki VAMC Acceptance Testing Report

5.14.1.7 695-12 Milo C. Heumpfner CBOC Acceptance Testing Report

5.14.1.8 556-12 Capt. James A. Lovell VAMC Acceptance Testing Report

5.14.1.9 676-12 Tomah VAMC Acceptance Testing Report

5.15 Final Hardware Deployment Design Document(s)

The Contractor shall update the PHDD document from 5.6.2 with the final application hardware configuration for each facility following the hardware installation and acceptance of the applications. The Contractor shall provide the Final Hardware Deployment Design (FHDD) document to the VA 10 days after the Facility Test Report is accepted. The FHDD document will be reviewed and approved by the COR. This document shall include:

5.15.1 Final quantity and location of hardware identified in the PHDD document that was installed to meet the goals of the solution being deployed at each facility.

5.15.2 Deliverables:

5.15.2.1 537-12 Jesse Brown VAMC Final Hardware Deployment Document

5.15.2.2 550-12 Illiana VAMC Final Hardware Deployment Document

5.15.2.3 578-12 Edward Hines VAMC Final Hardware Deployment Document

5.15.2.4 585-12 Oscar G. Johnson VAMC Final Hardware Deployment Document

5.15.2.5 607-12 William S. Middleton VAMC Final Hardware Deployment Document

5.15.2.6 695-12 Clement J. Zabolocki VAMC Final Hardware Deployment Document

5.15.2.7 695-12 Milo C. Heumpfner CBOC Final Hardware Deployment Document

5.15.2.8 556-12 Capt. James A. Lovell VAMC Final Hardware Deployment Document

5.15.2.9 676-12 Tomah VAMC Final Hardware Deployment Document

6 Appendices

Appendix A: Glossary

Term	Definition
2D	Two-dimensional
AAMI	Association for the Advancement of Medical Instrumentation
AD	Active Directory
AEMS/MERS	Automated Engineering Management System/Medical Equipment Reporting System
AER	Automated Endoscope Reprocessor
AITC	Austin Information Technology Center
AM	Asset Management
AORN	Association of periOperative Registered Nurses
API	Application Programming Interface
ASP	Advanced Sterilization Products
Auto-ID	Automatic-identification
BI	Business Intelligence
BI	Biological Indicator(s)
CART-CL	Cardiovascular Assessment Reporting and Tracking system for Catheterization Labs
CBOC	Community Based Outpatient Clinic
CDC	Centers for Disease Control and Prevention
CDW	Corporate Data Warehouse
CI	Chemical Integrator(s)
CIA	Confidentiality, Integrity, and Availability
CLIN	Contract Line Item Number
CMOP	Consolidated Mail Outpatient Pharmacy
COOP	Continuity of Operations Plan
DRP	Disaster Recovery Plan
ENT	Ear, Nose, and Throat
ESB	Enterprise Service Bus

Term	Definition
FDCC	Federal Desktop Core Configuration
FIPS	Federal Information Processing Standards
GIP	Generic Inventory Package
GUI	Graphical User Interface
HA	High Availability
HDR	Hemodynamic Reporting
HIPAA	Health Insurance Portability and Accountability Act
HLD/AER	High Level Disinfection/Automatic Endoscope Reprocessor
HF	High Frequency
HP	Hewlett-Packard
Hz	Hertz
IAHCSMM	International Association of Healthcare Central Service Materiel Management
ID	Identification
IEEE	Institute of Electrical and Electronic Engineering
IFU	Instructions for Use
ITS	Instrument Tracking System
IR	Infrared
ISO	International Organization for Standardization
LAN	Local Area Network
LCD	Liquid Crystal Display
LDAP	Lightweight Directory Access Protocol
LF	Low Frequency
MEC	Minimum Effective Concentration
NIST	National Institute of Standards and Technology
NDC	National Data Center
NDR	National Data Repository
NPOSP	National Program Office for Sterile Processing
NSOC	Network Security Operations Center

Term	Definition
NX	Non-Expendable
QA	Quality Assurance
OR	Operating Room
PC	Personal Computer
PCD	Process Challenge Device
PHI	Protected Health Information
PII	Personally Identifiable Information
PIN	Personal Identification Number
PIV	Personal Identification Verification
PMAS	Project Management Accountability System
RDC	Regional Data Center
RFID	Radio Frequency Identification
RME	Reusable Medical Equipment
RTLS	Real Time Location System
SAN	Storage Area Network
SDD	System Design Document
SEDR	Systems Engineering Design Review
SOA	Service Oriented Architecture
SOP	Standard Operating Procedure
SP	Special Publication
SPS	Sterile Processing Services
SPW	Sterile Processing Workflow
SSO	Single Sign-On
TEE	Transesophageal Endoscope
TJC	The Joint Commission
UHF	Ultra-High Frequency
UI	User Interface
VA	Department of Veterans Affairs

Term	Definition
VAMC	VA Medical Center
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network
VistA	Veterans Health Information Systems and Technology Architecture
WAN	Wide Area Network
WHO	World Health Organization
Wi-Fi	Wireless Fidelity

Appendix B: Sterile Processing Workflow Business Processes

1 Sterile Processing Workflow Business Processes

Prior to ITS, there was not an automated method for capturing or analyzing the SPS workflow or maintaining inventory of surgical RME items. With ITS in the SPS environment, interacting with the software and performing instrument scans at various reprocessing stages facilitates reasonable assurance that all processes are followed according to manufacturer IFUs. In addition, the use of ITS provides insight into SPS workflows enabling improved inventory control and availability of RME while enhancing patient safety and staff competency.

1.1 SPW Business Process: Critical Item Processing

The Critical Item Processing Business Process describes the interaction between the ITS and SPS staff to successfully locate, decontaminate, sterilize, and distribute reprocessed Critical RME items throughout a medical system. Critical items are those that come into contact with sterile tissue and must be sterilized prior to use. This category includes surgical instruments, dental instruments, emergency procedure trays, loaner instruments, and implant sets. The category may include endoscopes that enter a sterile body cavity or items used on a sterile field.

Within the SPS environment, the ITS implementation is used to record the location, time stamp, and the status of an SPS device/instrument/surgical container (set) as it goes through the reprocessing workflow. Locations to be scanned include, but may not be limited to Decontamination, Assembly and Preparation, Sterilization, Quality Assurance (QA), and Storage areas. Within these locations, there will be at least one scan point where work instructions are needed, a work step needs to be recorded, and/or a location update is required. Facility processes, number of stations, physical layout, and the complexity of the workflow in a facility may increase the number of scan points in each area.

This section should be used by the designated SPS staff who will be responsible for performing or overseeing the tasks in order to compare how the workflow will change when ITS is implemented.

1.2 SPW Application Process

The following tables present the manual and ITS Critical Item Processes side-by-side:

Table 1: Pre and Post ITS Critical for Decontamination

Pre – ITS	Post - ITS
Items received into SPS Decontamination.	Depending on VAMC workflow, SPS Technician scans each item barcode to update location in ITS to “Decontamination”
	SPS Technician scans items(s) to update the status in ITS to “Decontaminating” at a Decontamination workstation.

Pre – ITS	Post - ITS
If applicable to the set, SPS Technician acquires instrument-specific reprocessing instructions (e.g., SOP, diagram, pictures, reminders, etc.) and visually validates the correct instructions and decontamination steps used for the item in hand.	If applicable to the set, SPS Technician acquires instrument-specific reprocessing instructions (e.g., SOP, diagram, pictures, reminders, etc.) from the ITS and visually validates the correct instructions and decontamination steps used for the item in hand.
Depending on the type of cleaning required to render the item(s) safe for handling, the SPS Technician manually cleans and sends item(s) through a mechanical washer, an ultrasonic cleaner, a tube dryer, manually disinfects them clean prior to sending to next step via pass-through window.	Depending on the type of cleaning required to render the item(s) safe for handling, the SPS Technician manually cleans and sends item(s) through a mechanical washer, an ultrasonic cleaner, a tube dryer, or manually disinfects them clean prior to sending to next step via pass-through window. If a VAMC requires a location capture at these points, the ITS system is capable of generating a linear barcode for location assignment/scanning purposes.

Table 2: Pre and Post ITS Critical for Assembly and Preparation

Pre-ITS	Post-ITS
Item(s) received into SPS clean area.	If a VAMC desires a scan/capture of item(s) location or status after cleaning, SPS Technician scans wire baskets (sets) to update location to “Preparation” in ITS.

Pre-ITS	Post-ITS
SPS Technician receives instrument(s)/set at an Assembly and Preparation Workstation. Preparation involves performing a QA Functional Inspection (visual and manual examination of instrument integrity, functionality, and presence of bioburden) of each item before placing items in a container, a peel pouch, or wrap. If an item or set does not Pass the Functional QA Inspection: SPS Technician initiates a VAMC-defined process for remediation of item repair. If the set is usable without the item(s) needing repair, the SPS Technician may continue with the next step.	SPS Technician receives and scans instrument(s)/set to update location and production of electronic count sheet in ITS at Assembly and Preparation Workstation. Preparation involves performing a QA Functional Inspection (visual and manual examination of instrument integrity, functionality, and presence of bioburden) of each item before scanning and placing items in a container, a peel pouch, or wrap. If an item or set does not Pass the Functional QA Inspection: i. SPS Technician scans the instrument or set as Out for Repair using the ITS maintenance function to initiate the repair/replacement process and update the location status in ITS as "In Maintenance-Repair Area." ii. In accordance with VAMC protocol, ITS generates an alert and notifies designees that a Critical item is out of service and needs to be repaired/replaced. iii. SPS Technician initiates a VAMC-defined process for item repair. If the set is usable without the item(s) needing to be repaired, the SPS Technician may continue with the next step.
The same SPS Technician or a second SPS Technician performs a secondary inspection.	The same SPS Technician or a second SPS Technician performs a secondary inspection.
The same SPS Technician or a second user verifies manually that the correct instrumentation is in the set.	ITS automatically verifies that the correct instrumentation was scanned into the set.
SPS Technician manually creates a label and applies to peel pouches and produces a hard copy count sheet to be placed in the container for sets.	SPS Technician uses ITS to produce labels for peel pouches and a hard copy count sheet to be placed in the container for sets.
SPS Technician sends item to a wrapping station, which may be the same workspace used for assembly.	SPS Technician sends item to a wrapping station, which may be the same workspace used for assembly.

Pre-ITS	Post-ITS
SPS Technician places item(s) in peel pouch(es) and seals or single or double wraps item(s)/sets or places item/set in a container and affixes tamper seals.	SPS Technician places item(s) in peel pouch(es) and seals or single or double wraps item(s)/sets or places item/set in a container and affixes tamper seals.

Table 3: Pre and Post ITS Critical for Sterilization Preparation

Pre-ITS	Post ITS
SPS Technician populates the required sterilizer log sheet per facility protocol.	SPS Technician scans the sterilizer in ITS.
	SPS Technician scans or manually enters sterilization parameters into ITS.
	SPS Technician scans the item(s) in ITS. This includes any Biological Indicator (BI) test pack, Process Challenge Device (PCD) or any other challenge device for that load. (The system will alert if an item is not allowed for that setting and if a BI has not been scanned when required for an item on the set.)
	The ITS process verifies that the sterilization method of the items (sets or peel pouches) that were scanned to the load match the sterilization method of the sterilizer. If the item or load is not appropriate for the sterilizer or settings: i. ITS rejects the item and presents an error message to the SPS Technician. ii. SPS Technician corrects the issue or removes the item from the sterilizer rack. iii. ITS generates an alert and notifies the VAMC-specified SPS Administrator that the item or load is not appropriate for the sterilizer/ parameters. iv. The process continues once corrective action has occurred.

Table 4: Pre and Post ITS Critical for Sterilization

Pre-ITS	Post ITS
SPS Technician initiates the sterilization cycle.	SPS Technician initiates the sterilization cycle.
Sterilizers provide a Mechanical process confirmation receipt (listing pressure, time, temperature, and/or concentration) through the sterilization cycle.	Sterilizers provide a Mechanical process confirmation receipt (listing pressure, time, temperature, and/or concentration) through the sterilization cycle. This QA check is user-confirmed as well in the ITS system.

Pre-ITS	Post ITS
SPS Technician checks the sterilizer mechanical tape after the sterilizer cycle completes to validate that the cycle completed and assure the sterilizer operated at selected parameters.	SPS Technician checks the sterilizer mechanical tape after the sterilizer cycle completes to validate that the cycle completed and assure the sterilizer operated at selected parameters.
SPS Technician records sterilizer mechanical tape Pass/Fail in Sterilizer Record. If it failed, the SPS Technician initiates recall protocol.	SPS Technician records sterilizer mechanical tape Pass/Fail in ITS. If it failed, the SPS Technician initiates recall protocol.
	If the sterilizer has an optional interface to ITS, an electronic copy of the tape for the specific load is stored in a data file attached to the sterilization file.
	If the sterilizer does NOT have an interface to ITS, SPS Technician (flatbed) scans the sterilizer mechanical strip to store an electronic image associating the strip with the appropriate sterilizer load.

Table 5: Pre and Post ITS Critical for Post-Sterilization

Pre-ITS	Post ITS
SPS Technician removes the load from the sterilizer.	SPS Technician removes the load from the sterilizer.
If applicable to the sterilizer load, the SPS Technician opens the Biological Indicator (BI) pack from the sterilizer load and collects BI as well as verifying Chemical Integrator (CI) that internal load exposure occurred. If it failed, the SPS Technician initiates recall protocol and applicable notifications.	If applicable to the sterilizer load, the SPS Technician opens the BI pack from the sterilizer load and collects BI as well as verifying CI that internal load exposure occurred. SPS Technician checks CI results and records either Pass or Fail for CI in ITS. If it failed, the SPS Technician initiates recall protocol and the system generates applicable notifications.
SPS Technician begins the incubation and quarantine processes. (Applies specifically to implants, not all items are quarantined)	SPS Technician begins the incubation and quarantine processes for implants.
SPS Technician allows the load to cool down.	SPS Technician allows the load to cool down.
Depending on VAMC workflow, the cart may be moved to a final cool down/ pre-delivery area.	Depending on VAMC workflow, the cart may be moved to a final cool down/pre-delivery area. If this step is applicable, the SPS Technician scans items or the sterilizer cart to update the location to "Cool-Down" in ITS.

Pre-ITS	Post ITS
SPS Technician performs a Sterilization Physical QA Check during removal from sterilization rack and prior to scanning to storage location. If the Sterilization Physical QA Check Fails: i. SPS Technician removes items from sterilizer rack and removes item from packaging. ii. If the entire sterilizer load is physically unacceptable, SPS Technician removes/manually recalls all items from packaging for that load. iii. VAMC-dependent and manufacturer processes for sterilizer diagnosis occurs.	SPS Technician performs a Sterilization Physical QA Check during removal from sterilization rack and prior to scanning to storage location. If the Sterilization Physical QA Check Fails: i. SPS Technician removes items from sterilizer rack and removes item from packaging. ii. If the entire sterilizer load is physically unacceptable, SPS Technician initiates load recall through ITS and removes all items from packaging for that load. iii. ITS generates an alert and notifies SPS Administrator designees that a load has not been sterilized successfully and was recalled. iv. VAMC-dependent and manufacturer processes for sterilizer diagnosis occurs.
For items requiring a more rigid Quarantine period, such as VAMC-sterilized implant sets, SPS Technician places items in Quarantine.	For items requiring a more rigid Quarantine period, such as VAMC-sterilized implant sets, SPS Technician scans items to a user-defined Quarantine location with an associated time stamp in ITS. If the Quarantined Item QA process fails, SPS Technician records "Fail" in the appropriate sterilizer record in ITS. ITS initiates load recall of all items packaged for that load. ITS generates an alert and notifies SPS Administrator designees that a load has not been sterilized successfully and is being recalled.
SPS Technician checks BI results after incubation period ends and records results. If BI Fails, the SPS Technician initiates load recall protocol.	SPS Technician checks BI results after incubation period ends and records either Positive or Negative for BI in ITS. Positive results recorded in ITS initiates load recall of all items packaged for that load. ITS generates an alert and notifies SPS Administrator designees that a load has not been sterilized successfully and is being recalled.
	Note: This step may be enhanced with the use of an interfaced incubator to electronically capture Pass/Fail data for an associated load.

Table 6: Pre and Post ITS Critical for Storage

Pre-ITS	Post ITS
SPS Technician moves items to the appropriate Storage location (for example, bin, shelf, cart or room).	SPS Technician moves items to the appropriate Storage location (for example, bin, shelf, cart or room).

	SPS Technician scans the Storage location (for instance, bin, shelf, cart or room) barcode in ITS.
	SPS Technician scans the item's storage location *or* transport cart location *or* delivery to a usage area to update the ITS. This indicates that the item is ready for use.
	ITS establishes item shelf life based on individualized parameters for sterilized items.

1.3 SPW Critical Item Processing Base Configuration

The table below lists the standard business rules defined at the national level for Critical Item processing using the standard statuses and locations defined in the preceding sections.

Table 7: Standard Business Rules

Rule Name	**Item enters Decontamination**
Change Item Status	Change the status of the item to "Decontamination".
Example	An orthopedic surgical tray returns in a case cart to SPS after being used in OR 7. Once the tray is scanned into the Decontamination location of SPS and when it is removed from the cart, the status of all instruments assigned to that tray is changed to "Decontamination".
Rule Name	**Item enters Preparation**
Change Item Status	Change the status of the item to "Preparation".
Example	An orthopedic surgical tray is pulled from the washer after completing the Decontamination stage of processing in SPS. Once the tray is scanned onto the Assembly and Preparation work area, the status of the tray and all of its instruments changes to "Preparation". (Normally captured with initial scan to assembly workstation.)
Rule Name	**Item enters Sterilizer**
Change Item Status	Change the status of the item to "Sterilization".
Example	An orthopedic surgical tray is scanned into Censis as being placed into the sterilizer after completing the Assembly stage of processing in SPS. Once the tray is scanned into the Sterilizer, the status of the tray and all of its instruments changes to "Sterilization".
Rule Name	**Item enters Quarantine**
Change Item Status	Change the status of the item to "Quarantine".
Example	A surgical tray holding implant sets is taken from the Sterilizer and placed into the Quarantine area awaiting the results of the biological indicator. Once it arrives in the Quarantine area, the status of the tray and all its instruments changes to "Quarantine".
Rule Name	**Item enters SPS Storage**

Change Item Status	Change the status of the item to “SPS Storage”.
Example	A surgical peel pack is scanned into the sterile storage area. Once the instrument is scanned into that area, the status changes to “SPS Storage”.
Rule Name	**Item enters Maintenance-Repair Area**
Change Item Status	Change the status of the item to “In Maintenance-Repair Area”.
Example	An individual instrument being processed in SPS needs repair or maintenance and is routed per facility protocol. Once the instrument is scanned into ‘x’ location, the status of that instrument is changed to “In Maintenance-Repair Area” and not available for use.
Rule Name	**Item sent Off-Site for Repair**
Change Item Status	Change the status of the item to “Off-Site.”
Example	An individual instrument being processed in SPS needs repair or maintenance and is routed to an off-site vendor/manufacturer. Once the instrument is scanned into a location either designated for the specific vendor or to a generic “Off-Site” listing, the status of that instrument is changed to “Off-Site_ [repair vendor]” or “Off-Site”.

1.4 SPW Business Process: Semi-Critical Item Processing

The Semi-Critical Item Processing Business Process describes the interaction between ITS, SPS Technicians, and VA Staff to successfully locate, decontaminate, high-level disinfect, sterilize (as applicable), and distribute reprocessed Semi-Critical items throughout a medical system. Semi-Critical items contact mucous membranes or non-intact skin. Examples of Semi-Critical items include, but are not limited to, flexible endoscopes and ultrasound transducers that enter an intact body cavity.

The following tables present the manual and ITS Semi-Critical Item Processes side-by-side:

Table 8: Pre and Post ITS Semi-Critical for Decontamination

Manual (Current Workflow)	ITS (Future State Workflow)
Item received into SPS Decontamination.	Depending on facility workflow, SPS Technician scans each item 2D matrix or barcode to update location in ITS to “Decontamination.”
	SPS Technician scans items(s) to update the location in ITS to “Decontaminating” at a Decontamination workstation.
SPS Technician acquires instrument-specific reprocessing instructions (e.g., SOP, diagram, pictures, reminders, etc.).	SPS Technician acquires instrument-specific reprocessing instructions (e.g., SOP, diagram, pictures, reminders, etc.) from the ITS and visually validates the correct instructions and decontamination steps used for the item on hand.

Manual (Current Workflow)	ITS (Future State Workflow)
As specified by the SOP, when IFU required, SPS Technician manually performs a Functional QA Check (Leak Test) to confirm the integrity of the item, manually washes and rinses the item.	As specified by the SOP, when IFU required, SPS Technician manually performs a Functional QA Check (Leak Test) to confirm the integrity of the item, manually washes and rinses the item. Pass/Fail values are recorded in the ITS.
SPS Technician documents Leak Test Pass status.	SPS Technician updates ITS with Leak Test Pass status. If failed, the item is processed per facility protocols for disinfection and transported for repair.
SPS Technician performs SOP-defined bio-burden check to verify visually that the item does not contain any residual.	SPS Technician performs SOP-defined bio-burden check to verify visually that the item does not contain any remaining tissue. Related values are recorded in the ITS.
SPS Technician manually documents or uploads to vendor software with a pass or fail status	SPS Technician updates ITS with a pass or fail status. Exception: if a failed test is recorded the device must be returned to decontamination for manual reprocessing.
Depending on the type of cleaning required for the item, the SPS Technician sends item(s) through a mechanical washer, an ultrasonic cleaner, and a tube dryer, or manually disinfectant wipes them clean prior to sending to next step via pass-through window.	Depending on the type of cleaning required for item(s) other than endoscopes, the SPS Technician manually washes, rinses and may low-level disinfect item(s) prior to sending to next step via pass-through window. If a facility needs or requires a location capture at these points, the ITS system is capable of generating a linear barcode for location assignment/scan.

Table 18: Pre and Post ITS Semi- Critical for Device Preparation for HLD/AER

Manual (Current Workflow)	ITS (Future State Workflow)
	If a facility desires a scan/capture of item(s) location or status after cleaning, SPS Technician scans Semi-Critical device to update location to “Prep or HLD – in queue” in ITS.
SPS Technician receives device at a High Level Disinfection Preparation Workstation. Preparation involves performing a QA Functional Inspection (visual and manual examination of instrument integrity, functionality, and presence of bioburden) of each item before placing items in a HLD/AER. If a device does not Pass the Functional QA	SPS Technician receives and scans device to update location in ITS at HLD Preparation (Prep) Workstation. Preparation involves performing a QA Functional Inspection (visual and manual examination of instrument integrity, functionality, and presence of bioburden) of each item before scanning items into an AER. If an item or set does not Pass the Functional QA

Inspection: SPS Technician initiates a facility-defined process for device repair.	Inspection: i. SPS Technician scans the device as "Out for Repair" utilizing the ITS maintenance function to initiate the repair/replacement process and update the location in ITS as "Service." ii. Upon facility protocol, ITS generates an alert and notifies SPS Administrator designees that device is out of service and needs to be repaired/replaced. iii. SPS Technician initiates a facility-defined process for item repair.

Table 9: Pre and Post ITS Semi- Critical for HLD Preparation/Manual Soak Station

Manual (Current Workflow)	ITS (Future State Workflow)
SPS Technician receives item and populates any facility required HLD Soak Station log per facility protocol.	SPS Technician scans the item(s) to update location in ITS to Manual Soak Disinfection.
Facility dependent based on products used, SPS Technician performs Minimum Effective Concentration (MEC) verification and enters documents Pass/Fail.	Facility dependent based on products used, SPS Technician performs Minimum Effective Concentration (MEC) verification and enters information Pass/Fail in ITS.
SPS Technician places item in disinfect basin per SOP.	SPS Technician places item in disinfect basin per SOP and scans location.

Table 10: Pre and Post ITS Semi- Critical for HLD/AER Cycle

Manual (Current Workflow)	ITS (Future State Workflow)
SPS Technician initiates the HLD/AER cycle.	SPS Technician scans the item and the reprocessor to update location in ITS and retrieve item specific SOP.
User performs MEC verification and enters information in the AER system of record, if applicable to that machine.	User performs MEC verification and enters information in the AER system of record, if applicable to that machine.
	Note: Flexible Endoscopes are classified as Non-Expendable (NX) equipment; therefore, AEMS/MERS remains the system of record, not ITS.
	User then enters Pass/Fail in ITS (SPS reprocessing system of record (log).
	SPS Technician places device in AER and initiates the HLD/AER cycle per displayed SOP.

Manual (Current Workflow)	ITS (Future State Workflow)
AER provides a mechanical process confirmation receipt for cycle. HLD may require manual soaking and recording on paper log.	AER provides a visual or mechanical process confirmation receipt for each cycle. This QA check is user-confirmed as well in the ITS system.
	Note: This step may be further automated in the future with the advent of optional electronic interfaces.
	HLD may require manual soaking and recording in ITS. This QA check is user-confirmed and recorded within the ITS system.
SPS Technician checks the AER mechanical tape after the cycle completes to validate and assure the reprocessor operated within parameters.	SPS Technician checks the AER mechanical strip after the cycle completes or visually validates and assures the reprocessor operated at selected/prescribed parameters. Data is entered into ITS.
Note: Not all facilities AER produce a mechanical tape.	
If applicable, SPS Technician completes manual alcohol flush SPS Technician documents "Load results" for the AER cycle.	If applicable, SPS Technician completes manual alcohol flush. SPS Technician documents "Load results" section for the AER cycle in ITS.
If the scope is to be sterilized for an upcoming case, after AER the SPS Technician prepares the scope for the sterilizer, loads the scope into the sterilizer, then records sterilizer mechanical tape Pass/Fail in log book. If Fail, initiates recall protocol.	If the scope is to be sterilized for an upcoming case, after AER the SPS Technician prepares the scope for the sterilizer. The scope is scanned into the sterilizer to update location in ITS. After sterilization cycle is complete, the SPS Technician reviews the sterilizer mechanical tape Pass/Fail. If Fail, initiates recall protocol and notifies SPS Administrator designees.
	If the sterilizer has an optional interface to ITS, an electronic copy of the tape for the specific load is stored in a data file attached to the sterilization file. (System will alert if a parameter is not met in accordance with IFUs.)
	If the sterilizer does NOT have an interface to ITS, SPS Technician (flatbed) scans the sterilizer mechanical strip to store an electronic image associating the strip with the appropriate AER load.

Table 11: Pre and Post ITS Semi- Critical for Post-Manual Soak and AER Processing

Manual (Current Workflow)	ITS (Future State Workflow)
SPS Technician removes the device from manual soak HLD or AER.	SPS Technician removes the device from manual soak HLD or AER.
	If AER, SPS Technician records Pass/Fail for MEC in ITS (and as applicable in AER). If it Fails, endoscope is returned to Decontamination for full re-processing
Devices that have been manually soaked are removed from HLD and rinsed according to disinfectant's IFU.	If manual soak HLD, SPS Technician removes the device and rinses according to disinfectant's IFU.

Manual (Current Workflow)	ITS (Future State Workflow)
SPS Technician performs a Physical QA Check during removal from HLD/AER prior to scanning to storage location. If the Physical QA Check Fails: i. SPS Technician removes device. ii. If the entire HLD/AER load is physically unacceptable, SPS Technician removes device from area for reprocessing as applicable. iii. Facility-dependent and manufacturer processes for HLD/AER diagnosis occurs.	SPS Technician performs a Physical QA Check during removal from HLD/AER prior to scanning to storage location. If the Physical QA Check Fails: i. SPS Technician removes device, scans item, selects resume, disinfect and enters note in "Load Results" for Physical QA Check in ITS. ii. SPS Technician scans item "out of service" to update ITS with time, status, and location. iii. If the entire HLD/AER load is physically unacceptable, SPS Technician removes device from area for reprocessing as applicable. iv. Facility-dependent and manufacturer processes for HLD/AER diagnosis occurs.

Table 12: Pre and Post ITS Semi-Critical for Storage

Manual (Current Workflow)	ITS (Future State Workflow)
SPS Technician moves device to the appropriate Storage location (for example, bin, shelf, cart, or room).	SPS Technician generates facility-defined label identifying the process used, load, and expiration date.
	SPS Technician packages the item by either hanging it or placing it in a clean bin or placing it in a clean plastic bag.
	SPS Technician scans item/scope to update ITS with time, status, and location as "Storage" as well as the start of storage time. Facilities may be more restrictive and allow less time in storage.
	SPS Technician sends item/scope to storage or case cart and scans item to update ITS with facility-variable location.

1.5 SPW Semi-Critical Item Processing Base Configuration

The table below lists the standard business rules defined at the national level for Semi-Critical Item Processing using the standard statuses and locations defined in the preceding sections.

Table 13: Standard Business Rules

Rule Name	Item enters Decontamination
Change Item Status	Change the status of the item to "Decontamination".
Example	An endoscope returns to SPS after being used in a procedure. Once the endoscope is scanned into the Decontamination location of SPS, the status of the endoscope changes to "Decontamination".
Rule Name	**Item enters Preparation**
Change Item Status	Change the status of the item to "Preparation".

Example	An endoscope arrives at a High Level Disinfection Preparation Workstation after completing the Decontamination stage of processing in SPS. Once the endoscope is detected in the Preparation area, the status is changed to "Preparation". Normally captured with initial scan to assembly workstation.
Rule Name	**Item enters AER**
Change Item Status	Change the status of the item to "High Level Disinfection/Automatic Endoscope Reprocessor (HLD/AER)".
Example	An endoscope is scanned into Censis as being placed into the AER after completing the Preparation stage of processing in SPS. Once the endoscope is scanned into the AER, the status changes to "High Level Disinfection/Automatic Endoscope Reprocessor (HLD/AER)".
Rule Name	**Item enters Sterile Storage**
Change Item Status	Change the status of the item to "Sterile Storage".
Example	A sterilized endoscope is scanned into the sterile storage area. Once the endoscope is scanned into that area, the status changes to "Sterile Storage".
Rule Name	**Item enters Maintenance-Repair Area**
Change Item Status	Change the status of the item to "In Maintenance-Repair Area".
Example	An endoscope being processed in SPS needs repair or maintenance and is routed per facility protocol. Once the endoscope is scanned into the 'x' location, the status of that endoscope is changed to "In Maintenance Repair Area."
Rule Name	**Item sent Off-Site for Repair**
Change Item Status	Change the status of the item to "Off-Site."
Example	An endoscope being processed in SPS needs repair or maintenance and is routed to an off-site vendor/manufacturer. Once the endoscope is scanned into a location either designated for the specific vendor or to a generic "Off-Site" listing, the status of that instrument is changed to "Off-Site_ [repair vendor]" or "Off-Site".

1.6 SPW Business Process: Non-Critical Item Processing

The Non-Critical Item Processing Business Process describes the interaction between the system and VA staff to successfully locate and disinfect Non-Critical items that are reprocessed in a VAMC SPS and distribute them throughout a VAMC. Non-Critical items are those that come in contact with intact skin only.

The following application process applies only to Non-Critical items sent to an applicable VAMC SPS for reprocessing. Not all VAMC's SPS clean Non-Critical RME and not all RME is cleaned in SPS decontamination (some RME is cleaned at point of care). For Non-Critical items that are cleaned by a VAMC SPS, the 'post-ITS' items are assumed to have a barcode or electrochemical mark that can be scanned into ITS.

1.6.1 SPW Non-Critical Application Process

Table 24: Pre and Post ITS SPW Non-Critical Application Process cleaned in SPS department

Pre-ITS	Post-ITS
Item received into SPS Decontamination.	Depending on VAMC workflow, the SPS Technician scans item or ITS updates location.
SPS Technician acquires VAMC-specific Non-Critical item's IFU.	SPS Technician acquires VAMC-specific Non-Critical items IFU as required. Note: This function is not currently available for Non-Critical items in ITS, so a VAMC-defined process for accessing IFUs may be necessary.
Based on the Non-Critical item's IFU, the SPS Technician manually cleans the item.	Based on the Non-Critical item's IFU, the SPS Technician manually cleans the item.
SPS Technician disinfects item with a low-level disinfectant. The Non-Critical item IFU identifies VAMC approved cleaning agents such as bleach wipes or disinfecting towelettes.	SPS Technician disinfects item with a low-level disinfectant. The Non-Critical item IFU and/or Infection Control Preventionist identifies local VAMC approved cleaning agents such as disinfecting towelettes.
If indicated by IFU, the SPS Technician rinses the item after disinfecting.	If indicated by IFU, the SPS Technician rinses the item after disinfecting.
SPS Technician performs Visual QA Check. If the item does not Pass a Visual QA inspection, then a VAMC-dependent process will result in Work Order generation for repair of the item.	SPS Technician performs Visual QA Check. If the item does not Pass a Visual QA inspection, then a VAMC-dependent process will result in Work Order generation for repair of the item.
SPS Technician bags and tags item with a label that includes initials of the SPS Technician who cleaned the item and the date of cleaning.	SPS Technician bags and tags item with a label generated by ITS that can be configured to include the SPS Technician's ITS User ID and the current date when printed.
SPS Technician sends item to storage or use area.	ITS is updated with item's location and status.

1.7 SPW Business Process: Case Cart and Transportation Tote Processing

The Case Cart and Transportation Tote Business Process describes the interaction between the system and the SPS Technician to successfully locate, clean, stock, and distribute surgical/SPS case carts and/or transfer transportation totes to clinical areas throughout a VAMC or its CBOCs. Movement of case carts within the VAMC is tracked by Censitrac. For locations where the VAMC and Censis have identified as appropriate for tracking instruments scanned into the case cart (e.g., the surgical suite or case cart staging area). Censitrac updates the case cart location and updates the location of the scanned case cart contents.

1.7.1 SPW Case Cart and Transportation Tote Processing

Table 14: Pre and Post ITS SPW Case Cart and Transportation Tote Processing

Pre-ITS	Post-ITS

Pre-ITS	Post-ITS
Item received into SPS Decontamination.	ITS technology actively tracks the case cart or transportation tote when entering the Decontamination area. The SPS Technician may manually scan the case cart or transportation tote into ITS to associate the contents inside.
SPS Technician empties the contents of the case cart or transportation tote. If a transportation tote, manual cleaning per VAMC's SOP is initiated.	SPS Technician empties the contents of the case cart or transportation tote. If a transportation tote, manual cleaning of the transportation tote per VAMC's SOP is initiated.
SPS Technician initiates manual case cart cleaning.	SPS Technician initiates manual case cart cleaning.
If the VAMC has an automated cart washer, SPS Technician places the case cart into the automated cart washer. If the cart washer does not Pass Functional QA, a VAMC-dependent process results in Work Order generation for repair of the cart washer.	If the VAMC has an automated cart washer, SPS Technician scans the case cart into the automated cart washer. If the cart washer does not Pass Functional QA, a facility-dependent process results in Work Order generation for repair of the cart washer.
	ITS Technology confirms case cart status from dirty to available when scanned upon removal from cart washer on the clean side.
SPS Technician performs Visual QA Check, a visual examination for any residual bioburden present. If bioburden is present, the cart will be returned to Decontamination.	SPS Technician performs Visual QA Check, a visual examination for any residual bioburden present. If bioburden is present, the cart will be returned to Decontamination.
SPS Technician places clean case cart or transportation tote in a VAMC-dependent location to dry.	SPS Technician places clean case cart or transportation tote in a VAMC-dependent location to dry.
Case cart is moved back into use.	SPS Technician scans and ITS Technology updates location with the surgical or clinical area upon arrival and ITS location is updated.

1.7.2 SPW Case Cart and Transportation Tote Processing Base Configuration

The table below lists the standard business rules defined at the national level for case cart or transportation tote processing using the standard statuses and locations defined in the preceding sections.

Table 15: SPW Business Rules

Rule Name	Tracked Case Cart enters Cart Washer
Change Item Status	Change the status of the case cart to "Cart-Washing"
Example	A mobile case cart/transportation tote is taken from the receiving section of Decontamination area and placed into a cart washer. Once the case cart is scanned in the cart washer area, the status of the case cart is changed to "Cart-Washing". Manually scanning at the entrance to and exit from the cart washer signal Censitrac of the location changes.

Rule Name	Item enters Maintenance-Repair Area
Change Item Status	Change the status of the case cart/transportation tote to “In Maintenance-Repair Area”.
Example	A case cart or transportation tote needs repair or maintenance and is routed per facility protocol. Once the case cart or transportation tote is scanned into the ’x’ location, the status of that case cart or transportation tote is changed to “In Maintenance-Repair Area”.
Rule Name	**Item sent Off-Site for Repair**
Change Item Status	Change the status of the case cart/transportation tote to “Off-Site”.
Example	A case cart or transportation tote needs repair or maintenance and is routed to an off-site vendor/manufacturer. Once the case cart or transportation tote is scanned into a location either designated for the specific vendor or to a generic “Off-Site” listing, the status of that cart or tote is changed to “Off-Site_ [repair vendor]” or “Off-Site”.