

PERFORMANCE WORK STATEMENT

Medical Instrument Repair & Maintenance Services

A. GENERAL INFORMATION

1. **Title of Project:** Medical Instrument Repair & Maintenance Services
2. **Background:** The James A. Haley Veterans' Hospital (JAHVH) Nursing Administration Services has a procurement need for surgical instrumentation and annual steam autoclave chamber cleaning. There is a large inventory of surgical instrumentation that require repair and sharpening due to the wear and tear imposed on them from daily operations.
3. **Scope of Work:** All instrumentation needs to be repaired by trained personnel using manufacturer approved parts when it fails according to the parts list referenced in its OEM manuals. Contractor shall furnish all necessary labor, materials, tools, documentation, and parts required for the repair of the surgical instrumentation. This contract shall cover the base year, plus four (4) one-year renewal options, in accordance with all terms, conditions, provisions, schedules, and specifications of this solicitation.
4. **Period of Performance:** The period of performance shall be from date of award up to 5 yrs. Base year and four (4) option years.
5. **Type of Contract:** Firm Fixed Price Contract.
6. **Place of Performance:** James A. Haley VA Medical Center located at 13000 Bruce B Downs Blvd., Tampa, FL 33612 as well as the Primary Care Annex located at 13515 Lake Terrace Lane Tampa, FL 33612.
7. **COR Authority:** In no event is the COR empowered to change any of the terms and conditions of the contract. All changes, to any section of this contract, shall be made only by the Contracting Officer pursuant to a properly executed modification. The types of actions within the purview of the COR's authority are to ensure that the Contractor performs the technical requirements of the contract, and to notify the Contracting Officer of any deficiencies observed. A Letter of Designation shall be issued to the COR and a copy shall be sent to the Contractor at the time of contract kickoff meeting or post-award conference setting forth, in full, the responsibilities and limitations of the COR.

B. CONTRACT AWARD MEETING

The Contractor shall not commence performance on this contract until the Government has conducted a contract kickoff meeting, post-award conference or the COR has advised the Contract that a kickoff meeting is waived.

C. SPECIFIC MANDATORY TASKS AND ASSOCIATED DELIVERABLES

An overview of types of repairs:

- Vendor must be able to provide repairs to surgical instruments.
 - Scissors, ring handle forceps, ring handle clamps, retractors, tissue forceps, bone instruments, needle holders, micro instrumentation, laparoscopic instruments, insulated instrumentation, dental instrumentation.
- Vendor must be able to provide the following types of repairs to the rigid endoscopes.
 - Complete disassembly and cleaning of entire optical system, functional testing of all mechanical parts, laser adjustment of optical system and ocular lens, fiber optic light connection rebonding and polishing, hermetical sealing of scope, complete repair of optical system to manufacturer specifications, recalibrations of optical lens spacers, complete rebuilding of scope, replacement of inner and outer tubing, replacement of fiber optic light bundle.
- Vendor must be able to provide repair to various pneumatic-powered equipment
- Vendor must be able to provide repair to various Video Cameras
- Vendor must be able to provide repair to powered instruments
- Vendor must be able to provide repair to phaco handpieces
- Vendor must be able to provide repair to fiberoptic cables
- Sterile Processing can request loaner equipment if a loaner is desired and available through the vendor while James Haley VA equipment is out for repair.
- Vendor must be able to pick up equipment needing repair within 2 business days from James A. Haley and Primary Care Annex.
- As part of the inspection process, pictures of damaged instrumentation must be taken and uploaded to a web-based tool. These pictures will assist in documentation of work completed, and will also be utilized as a training aid to assist SPS staff to point out appropriate errors and assist in the inspection process.
- Vendor must be able to track the quantity of non-conforming instrumentation found in instrumentation trays during inspection. Vendor must be able to state specifically, on monthly report; why the non-conforming product was a problem, what SPS could do to resolve the issue, and what the Vendor can do to assist in preventing the issue in the future.

On-site mobile repair unit:

- Vendor must have on-site mobile service repair unit/truck.
- This truck will be at James Haley VA once a week and at the Primary Care Annex once a month.
- Work shall be performed on weekdays between the hours of 0700-1530 unless given permission to change hours.
- Vendor must be able to service between 12-18 trays per on-site service visit as well any repair bin items for that week.
- The majority of all work will be done on site via the mobile repair service. The vendor may send complex surgical instrumentation to an offsite lab for repair and service.
- Mobile service instrument technician must have training program that is approved through the Department of Labor and must be able to provide certificates.
- Technical staff must be certified by either the International Association of Healthcare Central Services Materials Management (IAHCSMM) or the Certification Board for Sterile Processing and Distribution (CBSPD).
- Reporting that tracks the Instrument tray's barcode, specialty, service rotation (based upon its usage,) last repair date, and next due date is required. It must also easily show the trays due and current on service, which will be provided to facility prior to each on-site day.

All repairs will follow all approved recommendations regarding third party surgical instrument repair as set forth by the following:

- Food and Drug Administration (FDA)
- Centers for Medicare/Medicaid Services (CMS)
- Centers for Disease Control (CDC)
- Association for the Advancement of Medical Instrumentation (AAMI),
- International Association of Healthcare Central Service Materials Management (IAHCSMM)
- Association of per-Operative Registered Nurses (AORN)
- Association of Professionals in Infection Control (APIC)
- Department of Veterans Affairs, Veterans Health Administration (VHA) Directives

Vendor must provide documentation of Quality Assurance per VHA Directive 1116 that includes but is not limited to the following:

- Verification of Complete instruments and Sets
- Verification that instruments are in proper working order
- Magnified Visual Inspection of all surgical instrumentation being maintained/repared
- Proactive maintenance to maximize performance of instrumentation and provide for patient safety.
- Renewal of damaged surgical instrumentation to include but not limited to:
 - Replacement of worn, missing or broken parts, Sharpening, alignment, adjustment, tightening, Carbide-insert replacement, and general renewal.
 - Ultrasonic cleaning and revitalization
 - Buffing
 - Satin or mirror refinishing
 - Insulation-integrity testing and replacement of compromised insulation to ensure safety of the patient and surgical team.

Chamber Cleaning of steam autoclave:

- The vendor shall provide annual cleaning of all steam autoclaves at James A Haley VA and the Primary Care Annex.
- This service shall be provided after peak hours as to not interrupt work flow

Documentation required for repair service:

- When service is completed, the vendor shall document services rendered in accordance with the price schedule and track electronically. This electronic tracking document shall be submitted monthly to the COR for verification prior to invoicing.
- Documentation in electronic form must be furnished to the COR for all repairs performed by the vendor monthly prior to invoicing. Payment will not be certified if proper documentation is not provided and verified by the COR.
- The documentation shall include detailed descriptions of the repair. Each repair at a minimum, document the following data legibly and in complete detail:
 - Description of problem reported by COR
 - Identification of all equipment serviced: device name/description, device location (if applicable), manufacturer's name, model number, serial number, VA's inventory/barcode number, and other identification numbers.
 - Itemized description of service performed and parts replaced.
 - Results of calibration and/or performance testing.
 - Total price for services included in the price schedule.

Vendor will meet or exceed the following repair salient characteristics:

On-site Repairs:

- 1) All on-site repairs will be performed utilizing a mobile laboratory.
- 2) On-site laboratory will be able to handle a minimum of 600 instruments per day and/or 12-18 trays per service visit. Once a week at James A. Haley and once a month at Primary Care Annex.
- 3) Approximately 80 percent of total workload will be performed within the mobile laboratory.
- 4) Vendor must provide to the government the ability to properly maintain and track an AEM (Alternative Equipment Maintenance) program for our facility's inventories. Vendor will work with each facility to determine the volume and number of visits needed to achieve AEM compliance. Any Vendor services provided to achieve this are considered value-added. As tray utilization changes, additional on-location services may be requested based upon demand.
- 5) 24-48 hours prior to service, vendor will provide SPS management with a list of trays that are scheduled for maintenance. SPS will pull as many sets from this list as possible as not to jeopardize patient care.
- 6) On-site repair services will consist of the following for all Surgical Hand Instrumentation:
 - a) Repair, alignment, adjustment, tightening and general renewal
 - b) Sharpening of all Scissors, Curettes, Punches, biopsy forceps and other "Cutting" instruments
 - c) Refurbishment
 - d) Ultrasonic cleaning and revitalization
 - e) Replacement of worn, missing, or broken Parts (Parts must be made of German Stainless Steel approved by the Original Equipment Manufacturer (OEM))
 - f) Satin or mirror refinishing
 - g) Color-coding Tape (as needed)
 - h) Tungsten Carbide insert replacement
 - i) Needle holder re-application (including "diamond dusting" of micro needle holders)
 - j) Brazing
 - k) Soldering
 - l) Electrosurgical re-insulation and testing
 - m) Chemical Etching
 - n) Surgical Milk Lubrication
 - o) Sterilization Container Repairs (as needed utilizing OEM parts)
- 7) Tasks that cannot be performed via on-site repair may be taken to off-site lab for service.
- 8) Instruments that are unable to be repaired must not be placed back in the set, and will be delivered to SPS Management and clearly marked "Not able to be serviced, not for patient use".
- 9) Mobile Service instrument technician must have training program through Department of Labor

Off-site Repairs:

- 1) Off-Site repairs will be recommended when instrumentation cannot be repaired on-site.
- 2) Off-site repairs must not account for more than approximately 20 percent of total workload.
- 3) Off-Site repair services will consist of the following for all Surgical Hand Instrumentation:
 - a) Repair, alignment, adjustment, tightening and general renewal
 - b) Sharpening
 - c) Refurbishment
 - d) Ultrasonic cleaning and revitalization
 - e) Replacement of worn, missing, or broken Parts (Parts must be made of German Stainless Steel approved by the Original Equipment Manufacturer (OEM))
 - f) Satin or mirror refinishing
 - g) Refurbishment of gold plating
 - h) Color-Coding (as needed)
 - i) Tungsten Carbide insert replacement
 - j) Needle holder re-application (including “diamond dusting” of micro needle holders)
 - k) Brazing
 - l) Soldering
 - m) Welding and machining
 - n) Electrosurgical re-insulation and testing
 - o) Dipping of surgical instrumentation to make insulated.
 - p) Chemical markings
 - q) Surgical Milk Lubrication
 - r) Sterilization Container Repairs (as needed utilizing OEM parts)
- 4) Vendor must be able to repair various pneumatic-powered equipment
- 5) Vendor must be able to repair various video camera
- 6) Vendor must be able to repair phaco hand pieces
- 7) Vendor must be able to repair fiber optic cables
- 8) Vendor must be able to provide repairs to rigid endoscopes-complete disassembly and cleaning of entire optical system, functional testing of all mechanical parts, laser adjustment of optical system and ocular lens, fiber optic light connection, re-bonding and polishing, hermetical sealing of scope complete repair of optical system to manufacturer specifications, recalibrations of optical lens spacers, complete rebuilding of scope, replacement of inner and outer tubing, replacement of fiber optic light bundle.
- 9) As part of the inspection process, pictures of damaged instrumentation must be taken and uploaded to a web based tool. These pictures must be provided to SPS management as part of a monthly report.

Documentation and Inspection:

- 1) Verification of Complete instruments and Sets
- 2) Verification that instruments are in proper working order
- 3) Magnified Visual Inspection of all surgical instrumentation being maintained/repared
- 4) Proactive maintenance to maximize performance of instrumentation and provide for patient safety.
- 5) Documentation reports must be provided via a web-based tool that allows the end user to schedule Preventative Maintenance and management of tray rotation for stainless and laparoscopic instrument trays. Service dates should be color coded for quick identification of trays needing service. This web-based tool must allow the end user to create customized reports based on the name of the tray, quantity of trays, the last service date, and the next service date.
- 6) As part of the inspection process, pictures of damaged instrumentation must be taken and uploaded to the web-based tool. These pictures will assist in documentation of work completed, and will also be utilized as a training aid to assist SPS staff to point out appropriate errors and assist in the inspection process.
- 7) Track the quantity of non-conforming instrumentation found in instrumentation trays during inspection. State specifically, on monthly report; why the non-conforming product was a problem, what SPS could do to resolve the issue, and what the Vendor can do to assist in preventing the issue in the future.
- 8) All instrumentation with lumens will be visually inspected with a video endoscope inspection system to check for internal cracking, rust, or other issues with lumened instrumentation. Pictures taken during endoscope inspection will be uploaded to the web-based tool. These pictures will assist in documentation of work completed, and will also be utilized as a training aid to assist SPS staff to point out appropriate errors and aid in the inspection process.