

1.Title: Sterile Processing Service Contract Reusable Medical Equipment (RME)

2.Purpose: The Michael E. DeBakey VAMC (MEDVAMC) hereby issues the following Sources Sought to Request Information (RFI). This RFI is to seek contractors with the capability to provide Houston MEDVAMC with all labor, tools, material, parts, equipment, cleaning supplies, license, certification, transportation, management and personnel required for Off-site Reprocessing Service of Reusable Medical Equipment (RME) Maintenance Cleaning

3.Objective: To find qualified and certified contractors with the capability to provide Off-site Reprocessing Service of Reusable Medical Equipment (RME) Maintenance Cleaning.

4. Place of Performance:

VA Community Based Outpatient Clinic (CBOC)
690 S. Loop 336
Conroe, TX 77304

5. Responses Required:

The MEDVAMC requires all the following questions answered in this RFI. Answers that are not provided shall be considered **non-responsive** to the Request for Information/Sources Sought.

- a. Does the Contractor possess the capability to provide offsite reprocessing of Reusable Medical Equipment (RME) for the Dental Service in Conroe, Texas?
- b. Does the Contractor possess the capability to ensure compliance with cleaning and the disinfection of contaminated RME as defined by the specific device manufacture Instruction for Use (IFU) and VHA Directive 1116?
- c. Does the contractor possess the capability to provide contractor technicians to pick up equipment and perform duties off-site? Does the contractor possess the capability to develop a schedule with the Contracting Officer Representative (COR) for the pickup equipment and delivery to required destination?
- d. Is the contractor a Sterrad authorized vendor with certified technicians to meet all government requirements and objectives? (Contractor shall attach authorization letter to be reviewed by the government to be considered as part of the Market Research and responsive to this Sources Sought notice).
- e. Contractors shall also provide:
 - Point(s) of contact name, address, telephone number, and email address;
 - Company's business size; Data Universal Numbering System (DUNS) Number.

- f. Is the Contractor a small business, SDBs, HUBZone, or 8A concern? (Contractor shall attach authorization letter to be reviewed by the government to be considered as part of the Market Research and responsive to this Sources Sought notice).
- g. Has Contractor provided similar services? (Contractor shall provide in capability statement a list of active contracts for commercial, federal, state, and local governments. List of contracts shall provide communication on the Government requirement illustrating the capability for comparison).
- h. Is the Contractor available under any of the following:
- Government Wide Agency Contract (GWAC),
 - General Services Administration Schedules (GSA),
 - Indefinite Delivery Indefinite Quantity (IDIQ), and/or
 - Blanket Purchase Agreement (BPA)?
- (Please list the contract number and a brief summary of the products and services provided).
- i. Provide a short summary of your potential approach to this type of contract and meeting the specific requirements per the draft Statement of Work and your experience managing similar contracts with similar requirements for the MEDVAMC.

6. Opportunity:

The MEDVAMC, is seeking information from potential contractors on their ability to provide this service. THIS IS A REQUEST FOR INFORMATION (RFI) ONLY. Small Business Concerns are encouraged to provide responses to this RFI in order to assist the MEDVAMC in determining potential levels of competition available in the industry. Contractor shall provide answers to all questions requested and shall possess the capability to provide all requirements and objectives per the **DRAFT STATEMENT OF WORK.**

7. Instructions and Response Guidelines:

RFI responses are due by April 2, 2018 at 9:00am (Central Time); size is limited to 8.5 x 11 inches, 12-point font, with 1-inch margins in Microsoft Word format via email to jeneice.mcclinton@va.gov .

All Questions shall be submitted by March 26, 2018 at 12:00 pm (Central Time) via email to jeneice.mcclinton@va.gov . Telephone requests or inquires will not be accepted.

The subject line shall read:

36C256-18-Q-9214 Sterile Processing Service Contract for Reusable Medical Equipment (RME)

(DRAFT) STATEMENT OF WORK

Off-site Reprocessing Service of Reusable Medical Equipment (RME) Maintenance

1. Purpose:

The purpose of this requirement is to seek contractors with the capability to provide the VA Community-Based Outpatient Clinic (CBOC) in Conroe, Texas with offsite reprocessing of Reusable Medical Equipment (RME) for the Dental Service. This includes Decontamination, Preparation, Sterilization, and Transporting of RME. Additional requirements pertain to complying with facility and National Program Office for Sterile Processing guidelines.

2. Background:

Sterile Processing Service (SPS) rationale for the need of contingency reprocessing relates to renovation project to meet updated standards for heating, ventilation and air conditioning (HVAC) requirements.

3. Performance Period and Billing: a performance period of 1 year plus 4 option years.

4. Scope:

Seeking contractor with the capability to ensure compliance with cleaning and the disinfection of contaminated RME as defined by the device specific manufacturer instruction for use (IFU) and VHA Directive 1116. Examples of such requirements include but are not limited to: Demineralized (DI) water utilized for final rinse, manual cleaning must be performed along with automated cleaning, and separation of intra-ocular instrument reprocessing from general instruments.

Seeking contractor with the capability to provide gravity and pre-vacuum cycles for steam sterilization. The Contractor must also be able to provide Low Temperature Gas Sterilization by use of LOW-TEMPERATURE HYDROGEN PEROXIDE PLASMA STERILIZATION.

Seeking contractor with the capability to ensure compliance with sterilization procedures as defined by the device specific manufacturer IFU and VHA Directive 1116. Examples of such requirements include but are not limited to: compliance with minimum sterilization parameters met as described in the device specific manufacturer IFU,

Seeking contractor with the capability to provide means of transporting the contaminated and sterilized RME to and from the location where reprocessing is taking place. The transportation of such items must comply with local Department of Transportation (DOT) and VHA regulations. To include but not limited to: identification of biohazard contents, temperature and humidity monitoring, competency assessment for handling of and exposure to RME, and clear separation of contaminated and sterilized products.

Seeking contractor with the capability to conduct and analyze Biological testing for each load sterilized. All sterilization documentation must be sent daily for review by SPS management.

Seeking contractor with the capability to supply operational support to maintain current workload volumes.

Seeking contractor with the capability to reprocess all instrument sets on a daily basis and provide two scheduled separate times for drop-offs of instruments.

A. Specific Mandatory Task and Associated Deliverables

Decontamination Area:

- Stainless steel and wipeable surfaces.
- Reprocessing Equipment: 3-bay sink, ultrasonic, washer disinfecter, DI water System, Medical Air
- Environmental: negative pressure, set point 66F to 72F, six (6) air exchanges per hour, and humidity range of 20% to 60%
- Cart Washer and/or by means of manual cleaning.
- Lighted magnification
- Adequate storage for MEDVAMC approved reprocessing supplies.

Preparation & Sterilization Area:

- Steam sterilization capabilities for both pre-vacuum and gravity cycles
- Low temperature sterilization capabilities by method of STERRAD series devices.
- Well light assembly stations.
- Environmental: Positive pressure, set point of 66F to 72F, four (4) air exchanges per hour, and humidity range of 20%-60%.
- Adequate storage for MEDVAMC approved reprocessing supplies.

Workload:

The Sterile Processing Service (SPS) average monthly workload for fiscal year (FY) 18 is as followed:

- Instrument Sets: 1,000 sets per month
- Peel Packs: 3000 packs per month

B. SPECIFIC MANDATORY TASK AND ASSOCIATED DELIVERABLES

Decontamination:

The contractor shall conduct manual and automated cleaning as described in the device specific IFU and by VHA Directive 1116.

The contractor shall have 3-bay sinks, ultrasonic with available irrigation, and a washer disinfecter equipment available.

The contractor shall utilize Demineralized (DI) or Reverse Osmosis (RO) water for final rinse.

The contractor shall dedicate a cleaning station and ultrasonic for the sole reprocessing of intraocular instrumentation.

The contractor shall utilize the appropriate reprocessing materials (i.e., brushes, lint free towels, etc.,) as described in the device specific manufacturer instructions for use (IFU).

The contractor's decontamination area must be VHA Directive 1116 environmental controls.

The contractor shall produce quality control data performed on reprocessing equipment at the request of the facility.

The contractor shall follow all critical steps listed within the manufacturer IFU for cleaning and disinfection of RME.

Preparation and Packaging:

The contractor shall package devices for sterilization with facility approved materials.

The contractor shall sterilize devices in accordance with device specific manufacturer IFUs. This includes cycle type, temperature, exposure, and dry times. The minimal requirements must be met.

The contractor shall be capable of providing the following sterilization methods: steam: gravity, steam: pre-vacuum, and Plasma Sterilization.

The contractor shall ensure that biologicals are processed with each load and are incubated and analyzed in accordance with the manufacturer IFU.

The contractor shall provide all sterilization records daily to the medical center for review.

The contractor's preparation area shall comply with VHA Directive 1116 in regards to temperature, humidity, and air exchange.

The contractor shall ensure that count sheets denoting accurate inventory of sets are second checked by a second staff member and placed inside the set. Count sheets will be provided by the medical center.

The contractor shall provide quality assurance testing performed as described by the device manufacturer IFU for each sterilization device (i.e., steam sterilizers and LOW-TEMPERATURE HYDROGEN PEROXIDE PLASMA STERILIZATION).

The contractor shall ensure that instrumentation is tested for proper function, sharpness, alignment, and free from any signs of bioburden prior to sterilization. If items are found to be contaminated at any point of reprocessing, the contractor will ensure that the item is sent back for reprocessing starting with manual cleaning.

Transporting Contaminated and Sterile Reusable Medical Equipment (RME):

The contractor shall comply with all VHA and Department of Transportation (DOT) regulations in regards to the transportation of biohazards.

The contractor shall have trained personnel in the handling of both sterile and contaminated RME. This includes having policies and procedures including but not limited to: handling of hazardous waste, spills of hazardous waste, and terminal cleaning of vehicles, and the maintaining of event related sterility.

A process for regularly scheduled pick-up times and deliveries must be established to facilitate prompt removal of soiled RME from Soiled utility rooms/appropriate holding areas. This will require multiple pick-ups from the using service and deliveries to decontamination areas for reprocessing. Instruments must not be left overnight or over weekends/holidays.

The contractor shall utilize the two methods of transportation both of which must comply within the preferable time frame of four (4) hours or the maximum time frame of twelve (12) hours, VHA Directive 1116, and DOT.

- Separate vehicles for soiled and clean: Soiled RME will be placed in a properly labeled medical grade puncture resistant biohazard rigid container.
- One vehicle for soiled and clean: Clean and soiled RME must be segregated and soiled RME will be placed in a properly labeled medical grade puncture resistant biohazard rigid container placed inside a second rigid transport container with an external lock.

C. Government Responsibilities:

The government will be responsible for providing reprocessing supplies as defined by the device manufacturer IFU. The government will provide all Standard Operating Procedures (SOPs), competencies and IFU for each device.

D. Contractor Experience Requirements:

The contractor shall be a qualified expert and have the required levels of professional and technical experience to perform the work required by this statement of work.

E. EQUIPMENT:

All equipment, tools, etc., shall be properly maintained while on the project and shall be adequate, in quality and capacity, for proper execution of the work.

G. SCHEDULING AND HOURS OF WORK:

Hours of Coverage: MEDVAMC requires a twenty-four (24) hours a day operative excluding the federal holidays listed as followed: New Year's Day, observance of Dr. Martin Luther King Jr, observance of President's Day, Memorial Day, Independence Day, Labor Day, observance of Columbus Day, Veterans Day, Thanksgiving Day, Christmas Day, and any other day declared as a National holiday by the President of the United States.

When one of the above designated legal holidays fall on a Sunday, the following Monday will be observed as a legal holiday. When a legal holiday fall on a Saturday, the preceding Friday is observed as a holiday by US Government Agencies.

H. SITE VISITS

The Chief of Sterile Processing System (SPS) to include facility leadership shall visit the area frequently to review the standard operation procedures are followed according to the device manufacturer IFU and VHA guidelines. The VHA Contracting Officer Representative (COR) will also be present during such visits.

I. INSPECTIONS:

All items reprocessed will be subject to random quality inspections for items listed within this statement of work at the frequency decided by MEDVAMC.

Inventory

SET NAME	DESC	QTY
DENTAL REMOVABLE KIT	SPATULAS #3R	1
	IRIS CURVED SCISSORS	1
	BOLEY GAUGE	1
	SPATULAS	1
	RED HANDLE SCALEL #6	1
	ARTICULATING PAPER HOLDER	1
	THREE PRONG CLASP #200	1
	PLASTER KNIVES 7R	1
	WAX SPATULA #7	1
	WAX SPATULA #31	1
	OCCLUSAL PLANE PLATE	1
	WAX RIM FORMER	1
	MOUTH MIRROR SIZE 5	2
	CURVED HEMOSTAT 5 1/2	1
	TRI-FLOW TIP	1
DENTAL UNIVERSAL CASSETTE	MOUTH MIRROR SIZE 5	2
	PROBE	1
	COTTON PLIERS	2
	EXPLORES #5	1
	ANESTHETIC SYRINGE	1
	CURVED HEMOSTAT 5 1/2	1
	ARTICULATING PAPER HOLDER	1
	AMALGAM CARRIER LARGE/REGULAR	1

	TOFFELMIRE MATRIX BAND	2
	LARGE SPOON EXCAVATOR 19	1
	SMALL SPOON EXCAVATOR 38/39	1
	PLASTIC INSTRUMENT	1
	CORD PACKER	1
	CLEOID-DISCOID CARVERS 3/6	1
	AMALGAM BURNISHEE #21	1
	DOUBLE ENDED DYCALD SPATULA	1
	HOLLENBACK #3	1
	HOLLENBACK 1/2	1
	AMALGAM PLUGGER 1/2	1
	AMALGAM PLUGGER 0/1	1
	BALL-FOOTBALL 26/28	1
	CEMENT SPATULA #24	1
	MOUTH PROPS (BLACK)/CHILD	1
	SICKLES SCALER U15/33	1
	CALIPERS	1
	IRIS CURVED SCISSORS	1
	CROWN & BRIDGE SCISSORS	1
	TRI-FLOW TIP	2
	CORD PACKER S5	1
	PIGTAIL SCALER	1
DENTAL XCP SENSOR HOLDER (RED, YELLOW, BLUE)	RED SENSOR RING WITH ARM HANDLE	1
	BLUE SENSOR RING WITH ARM HANDLE	1
	YELLOW SENSOR RING WITH ARM HANDLE	1
EYE SHIELD	EYE SHIELDS	1
DENTAL COMPOSITE GUN	COMPOSITE GUN	1
DENTAL IMPRESSION TRAY	IMPRESSION TRAY	1
	IMPRESSION TRAY	1
DENTAL FMX SENSOR HOLDER (PURPLE, YELLOW, & WHITE)	PURPLE SENSOR HOLDER	1
	WHITE SENSOR HOLDER	1
	YELLOW SENSOR HOLDER	1
DENTAL CURING LIGHT	CURING LIGHT	1
	MAYO	1
DENTAL SNAP-A-RAY SENSOR HOLDER (TAN/BLUE)	TAN OR BLUE INDIVIDUAL SENSOR HOLDER	1
	MAYO	1
DENTAL SPATULA	SPATULA	1
	MAYO	1

DENTAL CURING LIGHT SHIELD	CURING LIGHT SHIELD	1
	MAYO	1
DENTAL CROWN REMOVER	CROWN REMOVER	1
	MAYO	1
DENTAL CROWN TAPPER (3PC.)	MAYO	1
DENTAL RUBBER DAM CLAMPS	MAYO	1
DENTAL FOX PLANE	MAYO	1
DENTAL CROWN & BRIDGE SCISSORS	MAYO	1
DENTAL ISO LITE	MAYO	1
DENTAL MIRROR	MAYO	1
DENTAL FUJI GUN	MAYO	1
DENTAL RUBBER DAM SET-UP	MAYO	1
DENTAL O.S. EXTRACTION FORCEP #1	MAYO	1
DENTAL O.S. EXTRACTION FORCEP #150	MAYO	1
DENTAL O.S. EXTRACTION FORCEP #151	MAYO	1
DENTAL O.S. EXTRACTION FORCEP #65	MAYO	1
DENTAL O.S. EXTRACTION FORCEP #286	MAYO	1
DENTAL O.S. EXTRACTION FORCEP #88L	MAYO	1
DENTAL O.S. EXTRACTION FORCEP #88R	MAYO	1
DENTAL O.S. EXTRACTION FORCEP #53R	MAYO	1
DENTAL O.S. EXTRACTION FORCEP #53L	MAYO	1
DENTAL O.S. EXTRACTION FORCEP #23	MAYO	1
DENTAL O.S. EXTRACTION FORCEP #17	MAYO	1
DENTAL O.S. EXTRACTION FORCEP #222	MAYO	1
DENTAL HANDPC.-HYGIENE PROPHY	MAYO	1
DENTAL O.S. EXTRACTION FORCEP #10S	MAYO	1
DENTAL O.S. EXTRACTION FORCEP #13	MAYO	1
DENTAL O.S. EXTRACTION FORCEP #MD-4	MAYO	1
DENTAL O.S. EXTRACTION FORCEP #210S	MAYO	1
DENTAL EXAM PACK	MOUTH MIRROR SIZE 5	1
	PROBE	1
	EXPLORES #5	1
	COTTON PLIERS	1
	SHARP POINTED SCISSORS	1
	TRI-FLOW TIP	1
DENTAL WATER PAN	WATER PAN	1
GERNGROSS COMPOSITE INSTRUMENTS	LARGE PLACING/CONDENSING INST.	1
	MEDIUM PLACING/CONDENSING INST.	1
	#21B DE BURNISHER	1
	#27/29 DE BURNISHER	1
	PLUGGER	1

	HOLLENBACK PLUGGER	1
	GOLDFOGEL	1
	COSMETIC CONTOURING INST.	1
	GOLDSTIEN FLEXI	1
	LADMORE	1
DENTAL O.S. CRYER ELEVATOR (EAST/WEST)	CRYER ELEVATOR #39 (EAST)	1
	CRYER ELEVATOR #40 (WEST)	1
DENTAL O.S. POTTS ELEVATOR EAST/WEST	POTTS ELEVATOR #73 OR #190 (EAST)	1
	POTTS ELEVATOR #74 OR #191 (WEST)	1
DENTAL O.S. HEIDBRINK ELEVATOR RIGHT/LEFT	HEIDBRINK ELEVATOR RIGHT #2	1
	HEIDBRINK ELEVATOR LEFT #3	1
DENTAL O.S. STRAIGHT ELEVATOR #1	STRAIGHT ELEVATOR #1	1
DENTAL O.S. STRAIGHT ELEVATOR #34	STRAIGHT ELEVATOR #34	1
DENTAL O.S. STRAIGHT ELEVATOR #81	STRAIGHT ELEVATOR #81	1
DENTAL O.S. COGSWELL A	COGSWELL ELEVATOR A	1
DENTAL O.S. COGSWELL B	COGSWELL ELEVATOR B	1
DENTAL O.S. EXTRACTION FORCEP #217	EXTRACTION FORCEP #217	1
ASTRA TECH DRILL (ORAL SURGERY)	ASTRA TECH DRILL	1
	W&H ATTACHMENT STRAIGHT	1
	W&H ATTACHMENT ANGLED	1
DENTAL EXAM PACK W/O SCISSORS	MOUTH MIRROR SIZE 5	1
	PROBE	1
	EXPLORES #5	1
	COTTON PLIERS	1
	SHARP POINTED SCISSORS	1
	TRI-FLOW TIP	1
LARGE EXTRACTION PAN-ORAL SURGERY	HALSTEAD MOSQUITO CURVED 4 3/4"	4
	CRILE CURVED 5-1/2"	4
	CRILE STRAIGHT 5 -1/2 "	2
	CRILE CURVED 5-1/2"	2
	SCHNIDT HEMOSTAT LIGHT CURVE 7-1/2"	2
	ALLIS 4X5 TEETH 6"	1
	ALLIS 5X6 TEETH 6"	1
	BABCOCK 6-1/4"	2
	OCSHNER STRAIGHT 6 1/4"	2
	LAHEY 6"	2
	HALSEY NEEDLE HOLDER 5-1/2	2
	MAYO HEGAR NEEDLE HOLDER 7"	2
	WIRE TWISTER 7"	2
	FORESTER SPONGE FORCEP 9"	1
	METZENBAUM CURVED 5-1/2"	1

	METZENBAUM CURVED 7"	1
	MAYO SCISSOR STRAIGHT 6-3/4"	1
	MAYO SCISSOR CURVED 6-3/4"	1
	DEAN SCISSOR 6-3/4"	2
	IRIS SCISSOR CURVED 4-1/2"	1
	IRIS SCISSOR STRAIGHT 4-1/2"	1
	TENTOTOMY SCISSOR CURVED 4-1/2"	1
	STEVEN TENOTOMY STRAIGHT 4 1/2 "	1
	SMITH WIRE CUTTER 6-1/4"	2
	ARMY-NAVY RETRACTOR	2
	WEIDER RETRACTOR SMALL	1
	WEIDER RETRACTOR MEDIUM	1
	WEIDER RETRACTOR LARGE	1
	MOLT MOUTH GAG W/SILICON GUARDS	1
	BACKHAUS TOWEL CLIPS (NON-PERFORATING) 5 1/2"	4
	EDNA TOWEL CLIP (PERF) 4"	4
	MEAD MALLET	1
	CRYER ELEVATOR #39 (EAST)	1
	CRYER ELEVATOR #40 (WEST)	1
	POTTS ELEVATOR #73 OR #190 (EAST)	1
	POTTS ELEVATOR #74 OR #191 (WEST)	1
	HEIDBRINK ELEVATOR #2 RIGHT	1
	HEIDBRINK ELEVATOR #3 LEFT	1
	HOWARD ELEVATOR STRAIGHT	1
	STRAIGHT ELEVATOR #1	1
	STRAIGHT ELEVATOR #34	1
	STRAIGHT ELEVATOR #81	1
	COGSWELL ELEVATOR A	1
	COGSWELL ELEVATOR B	1
	FORCEPS #1 STANDARD	1
	FORCEPS #150	1
	FORCEPS #151	1
	FORCEPS #65 OR #286	1
	FORCEPS #88 L	1
	FORCEPS #88 R	1
	FORCEPS #53 L	1
	FORCEPS #53 R	1
	FORCEPS #23	1
	FORCEPS #17	1
	FORCEPS #222	1
	FORCEPS #210 S	1

	FORCEPS #13	1
	FORCEPS #MD-4	1
	STRAIGHT ELEVATOR	1

End of Statement of Work