

## **VA262-16-Q-0776**

### **SECTION B – STATEMENT OF WORK (SOW)**

#### **1. Background:**

The VASDHS hemodialysis clinic has a requirement for one (1) RO hemodialysis water treatment system that includes a distribution system, installation, and training. The new RO hemodialysis water treatment system will replace an existing hemodialysis water treatment system at VASDHS, and will be installed in the hemodialysis clinic in the main hospital building. The hemodialysis clinic provides life-saving dialysis treatments for more than ninety (90) veterans in San Diego County, California, and the clinic operates six (6) days per week, three hundred twelve (312) days per year.

#### **2. Supplies/Services:**

A new RO hemodialysis water treatment system (including distribution loop) will be delivered and installed alongside the existing RO hemodialysis water treatment system. The existing system will continue to be in operation until the new system has been installed, setup, tested, validated, accepted, and is ready for use. The new RO hemodialysis water treatment system shall be completely new. It shall not be used, refurbished, or in any other form, including substitutions. Contractor shall not add or substitute any component(s) without prior approval from the CO.

##### **2.1 Contractor will be responsible for:**

- 2.1.1** Delivery of items to the warehouse,
- 2.1.2** Inspection of all components prior to installation,
- 2.1.3** Coordination of installation plan with the point of contact (POC) and lead hemodialysis medical instrument technician (MIT),
- 2.1.4** Installation of new system alongside existing system ,
- 2.1.5** Connecting the new system to the feed water supply,
- 2.1.6** Using reasonable efforts to comply with *Environmental Standard Operating Procedure (ESOP) Dated October 1, 2014* at all times (See section *D.2 Contract Documents Exhibits or Attachments*),
- 2.1.7** Ensuring that work areas are cleaned up each day,
- 2.1.8** Setting up, testing, and validating the new RO hemodialysis water treatment system, and
- 2.1.9** Providing operational, programming, and maintenance training for on-site VA staff (See section *7.2 Clinical Training*).

##### **2.2 VASDHS will be responsible for:**

- 2.2.1** Reducing existing four hundred eighty (480) volt supply into two (2) two hundred eight (208) volt lines, and installing watertight shut-off switches,

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**2.2.2** Installation of manufacturer-provided transformer,

**2.2.3** Removal of existing RO hemodialysis water treatment system, and

**2.2.4** Monitoring, testing, and maintenance of new RO hemodialysis water treatment system after installation.

**2.3 Salient characteristics required of new RO hemodialysis water treatment system:**

**2.3.1** Must be medical grade, designed to be used at dialysis clinics or hospitals, and designed to be used for hemodialysis applications,

**2.3.2** Must be Section 510(k) cleared for use in hemodialysis by the US Food and Drug Administration (FDA),

**2.3.3** Must be designed for use with cold (non-tempered), pre-treatment water,

**2.3.4** Must use heat to disinfect entire system,

**2.3.5** Must be chemical free, and not use any chemicals for disinfection or maintenance,

**2.3.6** Must be a double-stage RO hemodialysis water treatment system with a fully redundant backup system capable of producing AAMI-quality water,

**2.3.7** Must be capable of producing AAMI-quality water in the event of a stage failure,

**2.3.8** Must not need corrosive and/or toxic chemicals for disinfection and/or cleaning,

**2.3.9** Must include an automatic, self-cleaning system that cleans the RO hemodialysis water treatment system's membranes without the aid of corrosive chemicals and disinfectants,

**2.3.10** Must allow for twenty (20) machine connections that are in four (4) treatment rooms in the main clinic,

**2.3.11** Must be of "direct-feed" design and not employ the use of a post-membrane water tank for heating or storage,

**2.3.12** Must have a distribution system where each tap from the distribution system employs a dual-hose, crush-proof tubing design that provides a constant flow of water through the tubing, and extends approximately three (3) meters from the point of connection directly to the dialysis machine water inlet connection at each bedside,

**2.3.13** Must employ a chemical-free, in-line heat disinfection method,

**2.3.14** Must be capable of disinfecting the RO hemodialysis water treatment system, distribution lines, and inlet of connected dialysis machines for complete end-to-end disinfection,

**2.3.15** Entire RO hemodialysis water treatment system must incorporate the use of pharmaceutical quality, orbital-welded three hundred sixteen (316)L stainless steel or flexible, insulated high-grade crosslinked polyethylene (PEX) tubing,

**2.3.16** Flexible tubing must be used for all connections inside walls and cabinets to aid in installation,

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**2.3.17** Must include an automatic, self-cleaning system that continuously cleans the RO hemodialysis water treatment system's membranes without using chemicals,

**2.3.18** Must be a double-pass RO hemodialysis water treatment system capable of providing ultrapure water or near ultrapure water, without the aid of ultrafiltration (UF), ultraviolet (UV), or endotoxin filters,

**2.3.19** Must be designed to recover at least seventy-five (75) percent of the feed water consumed into product water,

**2.3.20** Must not use water tanks in order to reduce electrical demand required for heat disinfection,

**2.3.21** Must monitor for system leakage and notify hemodialysis staff when it occurs,

**2.3.22** Must be designed to shut down the water supply if a leak is detected,

**2.3.23** Heating system must be capable of disinfecting the RO hemodialysis water treatment system, distribution lines, and connected dialysis machines; for complete end-to-end disinfection, and

**2.3.24** Prefer an RO hemodialysis water treatment system that requires an annual maintenance schedule to minimize downtime,

**2.3.25** Must have a user interface, controls, and devices that include the following:

**2.3.25.1** A graphical user interface that displays:

**2.3.25.1.1** Mode of operation,

**2.3.25.1.2** Status of operation,

**2.3.25.1.3** Real-time process information against vs. limits,

**2.3.25.1.4** Logging of process information,

**2.3.25.1.5** Notification of alarm conditions,

**2.3.25.1.6** Logging of fault codes and conditions,

**2.3.25.1.7** Flow diagram that indicates current process conditions,

**2.3.25.2** A remote monitor at nurses' station,

**2.3.25.3** Desktop software:

**2.3.25.3.1** Must be designed to monitor RO hemodialysis water treatment systems from a remote location via a local area network (LAN),

**2.3.25.3.2** Must be compatible with Windows 7 and 64-bit encryption,

**2.3.25.4** Heating system must be programmable, and

**2.3.25.5** Must allow for a signal from an external hard water monitor.

**3. Qualifications of Personnel:**

**3.1** The level of operations certifications required of contractor personnel depends on whether personnel will come into contact with asbestos during installation of the system or not.

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**3.1.1** If asbestos is not going to be disturbed, proof of completion of Class III operations certification is required prior to performing services for each of the contractor's workers. A copy of the 16-hour training certificate shall be provided to the CO for each of the contractor's employees who will be working on installation of the system within two (2) days of award.

**3.1.2** If asbestos is going to be disturbed, proof of completion of Class I operations certification is required prior to performing services for each of the contractor's workers. A copy of the 4-5 day training certificate shall be provided to the CO for each of the contractor's employees who will be working on installation of the system within two (2) days of award.

**3.1.3** Approved asbestos trainers and courses can be found at [http://www.dir.ca.gov/databases/doshcaccsst/DOSH\\_ApprovedTrainingCoursesProviders.pdf](http://www.dir.ca.gov/databases/doshcaccsst/DOSH_ApprovedTrainingCoursesProviders.pdf).

**3.2** Additional site-specific asbestos training shall be conducted by the VASDHS asbestos manager.

**3.3** Contractor's personnel assigned to install the system as described in this solicitation must have been trained by the manufacturer on the specific system being installed. Proof of training must be provided to either the CO or VASDHS POC within two (2) days of a request for proof of training at any time after award.

**4. Installation:**

**4.1** Installation must not impede/impact patient care, and shall be performed as follows:

**4.1** In patient care areas, work shall be performed during evenings and on weekends.

**4.1.1** On Mondays, Wednesdays, and Fridays, work shall be performed between the hours of 7:30 p.m. and 4:30 a.m. Pacific Standard Time (PST)

**4.1.2** On Tuesdays, Thursdays, and Saturdays, work shall be performed between the hours of 4:30 p.m. and 4:30 a.m. PST

**4.1.3** On Sundays, work shall be performed during all daytime hours.

**4.1.4** At the discretion of the nursing department some approved work may be done during normal operations. A POC will be provided to assist with any requests.

**4.2** System shall be installed in the hemodialysis clinic of the main hospital, which is on the 3<sup>rd</sup> floor west, in rooms 3090 - 3119.

**5. Acceptance Phase:** Upon completion of installation, validation, and training, VASDHS shall monitor and verify the equipment and installation during operations as outlined by the manufacturer for a three (3) contiguous, consecutive, uninterrupted business days. This period of three (3) days shall be the acceptance phase of the equipment and installation. The contractor is required to supply VASDHS with an acceptance form to be signed off at the end of the acceptance phase to indicate acceptance of the RO hemodialysis water treatment system. Any

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problems with the RO hemodialysis water treatment system during the acceptance phase will result in a reset of the acceptance phase, resulting in a new three (3) day acceptance phase. The contractor shall provide a brief descriptive resolution of any repairs that may be required to the POC.

**6. Risk Control:** Contractor will use reasonable efforts to not impede/impact hemodialysis patient care. The following must be observed by the contractor:

- 6.1** Existing water system and/or solution delivery system may not be shut-down,
- 6.2** There may not be any loud noises that can be heard in patient areas, direct patient care area, and/or any adjacent surrounding area(s) during patient hours,
- 6.3** Areas accessed must be kept clean and free of contamination, and
- 6.4** Equipment may not block entrance(s) or exit(s).

**7. Support Features:**

**7.1 User and Service Manuals:** The contractor shall provide to VASDHS, at no additional charge, two (2) complete and unabridged printed copies and one (1) electronic version (CD) of operator manuals, service manuals, troubleshooting guides, any necessary diagnostic software and tools to the POC overseeing installation of equipment at the time of installation or at the time of technician training, as applicable and as provided to other nongovernmental commercial customers. Additionally, any modifications of these documents shall be provided by the contractor at no additional charge. These manuals shall include all components and subassemblies, including those not manufactured by the contractor. These manuals and documentation shall be identical to the ones supplied to the contractor's service representatives and shall contain, if applicable, any diagnostic codes, commands, and passwords utilized in maintenance, repair, and calibration of the equipment and provided for the life of the system at no additional cost.

**7.2 Clinical Training:**

**7.2.1** A training plan shall be provided to the POC for approval within twenty (20) days from the date of contract award and/or receipt of the contract award.

**7.2.2** The contractor shall provide operational, programming, and maintenance training on the use of the RO hemodialysis water treatment system.

**7.2.2.1** Operation training for MIT staff, maintenance training for biomedical staff, and programming training shall be from 7 a.m. to 3 p.m. PST, Monday through Friday.

**7.2.2.2** Training shall take place on the 3<sup>rd</sup> floor west in the hemodialysis area of the VASDHS hospital.

**7.3 Software Upgrades/Updates:** The contractor shall provide safety-related updates to software at no additional charge to the Government. Safety-related updates shall be provided

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as they become commercially available, and at the same time that they are provided to commercial customers. Contractor has no responsibilities with respect to software support, software maintenance, software upgrades, or new software releases, other than providing safety-related updates.

(End of Section B)