

1 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION (AAMI):
It is critical that the Contractor perform all services following the recommended practices of the Association for the Advancement of Medical Instrumentation (AAMI). Improperly treated water being used for hemodialysis may cause patient injury, or death; therefore, failure to comply with the AAMI Standards will be grounds for termination of the contract.

2 CENTER FOR DISEASE CONTROL (CDC) RECOMMENDATIONS: The Contractor shall follow the Center for Disease Control recommendations for Dialysis Water Quality and Dialysate. The recommendations include, but are not limited to:

(a) Adhere to current AAMI standards for quality-assurance performance of devices and equipment used to treat, store, and distribute water in hemodialysis centers (both acute and maintenance [chronic] settings) and for the preparation of concentrates and dialysate.

(b) Disinfect RO systems in dialysis settings:

VA Greater Los Angeles Healthcare System (West Los Angeles) – Twice a month (Both B-500 & B-213)

(c) Disinfect RO water distribution systems in dialysis settings:

(3) VA Greater Los Angeles Healthcare System (West Los Angeles) – Monthly.
(Both B-500 & B-213)

(d) Disinfect RO water storage tanks in dialysis settings: When storage tanks are used in dialysis systems, they should be routinely drained, disinfected with an EPA-registered product, and fitted with an ultrafilter or pyrogenic filter (membrane filter with a pore size sufficient to remove particles and molecules ≥ 1 kilodalton) installed in the outflow water line between the storage tank and the hemodialysis machines. Disinfection of these systems shall be done according to the schedule below:

(3) VA Greater Los Angeles Healthcare System (West Los Angeles) – Monthly

Microbiologic Limits for Product water - GLA

Product water	7-day colony count (CFU/mL*)		Maximum Endotoxin Level (Eu/mL**)	
	<u>Max</u>	<u>Action Levels</u>	<u>Max</u>	<u>Action Levels</u>
B-500/RO#1	100	50	0.25	0.125
B-500/RO#2	100	50	0.25	0.125
B-500/RO Pre-Loop	100	50	0.25	0.125
B-500/RO Post-Loop	100	50	0.25	0.125
B-213/RO#1	100	50	0.25	0.125
B-213/RO#2	100	50	0.25	0.125

B-213/RO Pre-Loop	100	50	0.25	0.125
B-213/RO Post-Loop	100	50	0.25	0.125

* = Colony forming units/milliliter.

** = Endotoxin units/milliliter.

☐ = Product water presently includes water used to prepare dialysate

☐ = AAMI/ISO 23500 American National Standards Institute, Association for the Advancement of Medical Instrumentation (AAMI).

NOTE: IF any results come back above action levels, the contractor must disinfect the system (RO units, loop, storage tank, or all of them) until satisfactory results come back from the lab at no additional cost.

3 PREVENTIVE MAINTENANCE AND INTERVENING SERVICES: Normal service requirements consist of monthly scheduled PMI's to be accomplished specifically in accordance with the manufacturer's instructions for all equipment covered, as well as additional tasks specified. PMI's are to be scheduled at least three (3) days in advance with the Contracting Officer's Technical Representative (COTR) and are to be performed within the first five (5) working days of each month specified above, unless otherwise agreed upon by COTR. Normal service requirements will also include all necessary intervening service calls required between inspections to replace any worn or defective parts needed due to instrument failure. Contractor must also maintain the brine tank level approximately ½ full of salt. Intervening services will be rendered as directed by the COTR.

4 REPORTING: Contractor or Contractor's service personnel will respond telephonically to intervening service calls within 2 hours and be on station for repair within 4 hours. Contractor will acknowledge delivery calls for tank exchange within two (2) hours and be on station within 24 hours. Contractor's failure to respond after notification by the Contracting Officer's representative may be considered grounds for invoking provisions of default.

For any repair or service that will be performed during the hours of 8:00 a.m. through 5:00 p.m., the Contractor will report, upon arrival, to:

- VA Greater Los Angeles Healthcare System (West Los Angeles): Supervisor-on-duty of the Hemodialysis Department.

For any repair or service that will be performed during scheduled work hours other than the hours of 8:00 a.m. through 5:00 p.m., the Contractor will report, upon arrival, to:

- VA Greater Los Angeles Healthcare System (West Los Angeles): Supervisor-on-duty of the Hemodialysis Department.

After reporting in, the Contractor is to notify the Hemodialysis Department that they are going to provide service **PRIOR** to providing the services so that the Hemodialysis department does not respond to false alarms when the Contractor changes granulated activated charcoal (GAC) carbon tanks, or other items.

After all work is complete, the Contractor must report in person to the appropriate department. The Contractor is to submit, in writing, a complete report of service rendered (Field Service Report). As a minimum, this report must contain a detailed description of any services or repairs performed for each item of equipment and must include a listing of replacement parts, when applicable. Contractor shall document and report to the using service and COTR, any unsafe conditions or signs of misuse or abuse in regards to this medical equipment. Contractor shall document any problems along with their corrections and all performance verification on the field service report. The report will also include any Contractor recommendations necessary to maintain the equipment in optimum operating condition. The service report must be legible and signed by the COTR or the Hemodialysis Supervisor-on-duty during the hours indicated above. The original service report must be delivered to the appropriate department.

Both the check-in and check-out procedures defined above are mandatory and will be strictly enforced. NOTE: Payment of invoices may be delayed if the appropriate reports are not completed properly and are not submitted to the appropriate department as required above.

6 LABELING REQUIREMENTS: The following labeling requirements will be adhered to:

Greater Los Angeles Healthcare Systems: Contractor to provide service tags when parts are exchanged (i.e. filters, valves, motor pumps, UV lamps, etc.).

7 PMI'S - REVERSE OSMOSIS WATER SYSTEMS: (a) All work performed shall be accomplished in accordance with manufacturer's instructions including, but not limited to, adjustments, calibrations, cleaning, lubrication, testing, disassembly, check-out, replacement of worn or defective parts, required to keep the equipment in optimum operating condition. Monthly Preventive Maintenance Inspections for the Reverse Osmosis Water Systems shall include but not be limited to:

VA Greater Los Angeles; bldg 500, Rm 6004 and bldg, 213, **Rm B50.**

All of the following periodic maintenance must be performed by the contractor as specified. Checking each required maintenance on service note by field service technician, and being verified by someone in charge at the end of the service on every visit are also required.

Monthly Service Requirements:

1. Disinfection of RO#1 (SN 1511) & RO#2 (SN 1512) for B-500 (4 Membranes)-**Twice a month**
Disinfection of RO#1 & RO#2 (SN 8908-587-1 & 8908-587-2) for B-213 (6 membranes) – **Twice a month**
2. Disinfection of treatment area loop and dialysis machines inlet hoses with all dialysis machines in rinse mode
3. Disinfection of storage tank(s) – One 1,000 – gallon tank at B-500
Two 500 – gallon tanks at B-213
4. Replacement of Pre-filters: Two 1-micron filters at B-500
Two 5-micron filters at B-500
Four 1-micron filters at B-213

5. Inspection of all fittings and tubing for leaks.
6. Inspection of all pressure gauges for acceptable ranges including distribution system pressures
7. Salt delivery for the softeners to both buildings
8. Check pre-RO UV light
9. Check recirculation loop UV light
10. Check softener functionality and timer clock
11. Municipal Water Test on TDS & Conductivity / Hardness / PH / Chloramine, Free Chlorine residual
12. R.O. Product Water test on TDS & Conductivity / Hardness / PH / Chloramine, Free Chlorine residual / product flow, reject, re-circulate rate, and percent rejection on each Reverse Osmosis unit.
13. Check 2 booster pumps at B-500
14. Check 2 distribution pumps for each building
15. Inspect 4 carbon tanks back wash heads, and update times (B-500)
16. Inspect remote alarm panels at both buildings
17. Laboratory tests of 4 colony count & 4 LAL (RO#1, RO#2, RO Pre-Loop, RO Post-Loop) for each building

Quarterly Service Requirements

1. Cleaning (de-scaling) low and high PH of 4 membranes at B-500
6 membranes at B-213
Followed by disinfection
2. Cleaning of the flow indicators
3. Replacement of absolute four 0.05 submicron filters at B-500
Two 0.05 submicron filters & one 0.25 submicron filter at B-213
4. Exchange four 5.5-cubic feet carbon tanks at B-500
Four 3-cubic feet carbon tanks at B-213
5. Inspect and service divert to drain valves at both buildings, and automatic alternator at B-500.

Annual Service Requirements

1. Replacement of absolute 0.02 micron bacterial vent filters (both buildings)
2. UV light bulbs replacement & clean UV sleeves– 2 for each building
3. AAMI water analysis of feed water
4. AAMI water analysis of product water – 2 R.O. units for each building
5. Inspect and service booster pumps x 2 and distribution pumps x 4
6. Clean out brine tanks (both buildings)
7. Service two booster pumps including replacement of seals at B-500

******* The service plan maintenance agreement will fully cover the cost of repair or replacement of the following system components.**

1. UV light system
2. Pressure gauges
3. All fittings and tubing, piping- schedule 80 / **PEX**
4. All valves and piping on pretreatment components – schedule 80 and main R.O. chassis, R.O. permeate piping valves and tubing
5. Conductivity probes

6. Manifolds
7. Pressure vessels
8. Water softener head/timer & replacement of tank if necessary
9. Automatic alternator
10. R.O. motors
11. R.O. membranes
12. R.O. pump heads
13. Electrical components within main control box
14. Disinfect and de-scaling detergent & residual strips
15. R.O. loop recirculation pumps
16. Inlet water valves
17. Divert to drain valves
18. Inlet water booster pumps
19. R.O. loop outside water treatment room – schedule 80 / PEX
20. Divert to drain valves
21. Carbon tank back-washable heads/timer

8 Expected quality of the R.O. product water shall be 90% or better than the feed water.

9 Change all filter elements, as needed, (excluding Nephros filters).

10 Exchange on each Chloramine Removal Carbon Unit per calendar month as needed (when total chlorinate is .1ppm or >). Each replacement unit to be full and contain virgin carbon. Exchange 4 carbon tanks every quarter (VA- West LA)

(a) In addition to Monthly PMI's the Contractor shall conduct the following services:

- (1) Perform Diagnostics Test of Program Logic Controller semi-annually.
- (2) Replace the back-up battery annually, or as needed, for the Program Logic Controller.
- (3) Monitor chemical contaminants yearly. Contaminants should not exceed the AAMI maximum levels of chemical contaminants as listed below:

ACTUAL VALUES OF CONTAMINANTS COMPARED WITH SUGGESTED MAXIMUM LEVELS
AND POST-RO PROJECTIONS

<u>Contaminant</u>	Tap Water Supply (MG/1)	ANSI/AAMI Suggested Maximum Level (mg/L) MG/1)	Predicted Post-RO MG/1)
Aluminum	0.099	0.01	0.005
Antimony	0.006	0.006	
Arsenic	0.05	0.005	0.002
Barium	0.03	0.1	0.0015
Beryllium	0.004	0.0004	
Cadmium	<0.01	0.001	<0.0005
Calcium	18.00	2 (0.1 mEq/L)	0.90
Chloramines	0.1	0.1	0.1
Chlorine	0.2	0.5	0.1

Chromium	<0.002	0.014	<0.001
Copper	<0.05	0.1	<0.05
Flouride	0.90	0.2	0.14
Lead	0.043	0.005	0.002
Magnesium	2.20	4.(0.3 mEq/L)	0.11
Mercury	<0.002	0.0002	<0.001
Nitrate	5.20	2	0.78
Potassium	3.70	8 (.2 mEq/L)	0.37
Selenium	<0.01	0.09	<0.01
Silver	0.001	0.005	<0.0005
Sodium	4.0	70 (3 mEq/L)	0.40
Sulfate	12.0	100	0.60
Thallium	0.002	0.002	
Zinc	0.10	0.1	<0.01

Note: Chlorine and Chloramine levels must be determined on-site.

Note: The AAMI suggested maximum levels are now maximum allowable levels 2001.

(4) Furnish detailed Field Service Report on each service call to the Contracting Officer's Technical Representative (COTR). Report to include the following information:

- A. Municipal Water Test (monthly)
 - (i) Total dissolved solids
 - (ii) Hardness
 - (iii) Chloramine residual
 - (iv) Free chlorine residual
 - (v) Temperature
- B. R.O. Feedwater Tests
 - (i) Total dissolved solids
 - (ii) Hardness
 - (iii) Chloramine residual
 - (iv) Free chlorine residual
- C. R.O. Product Water Tests
 - (i) Total dissolved solids, each Reverse Osmosis unit.
 - (ii) Product flow rate, each Reverse Osmosis unit.
- D. R.O. Reject Water Test
 - (i) Reject flow rate, each Reverse Osmosis unit.
- E. Pressure Readings
 - (i) Prefilter in/out
 - (ii) Carbon Filters in/out
 - (iii) Reverse Osmosis unit feed pressures
 - (iv) Delivery pump discharge pressure
 - (v) Post filter in/out
 - (vi) Softeners in/out
 - (vii) 5 um filters in/out pre RO's
 - (viii) H. 0.2 um filters in/out storage stank
- F. Check for Proper Operation of:
 - (i) Ultraviolet water sterilizer
 - (ii) Water softeners (timer and regeneration times recorded)
 - (iii) Stand-by delivery pump

- (iv) City water booster pump
- (v) Quality monitor (calibrate as needed)
- (vi) F. R.O. quality monitor gauges

The COTR will monitor systems per logbook.

- 11 **RENTAL TANKS:** **The Contractor's rental tanks used for hemodialysis are to be virgin carbon and are not to be used for other areas other than hemodialysis (i.e. laboratory, research, etc.)**
- 12 **TANK EXCHANGE:** Contractor will exchange filter tanks, and/or as needed, within 24 hours of notification by the COTR or his designee. The estimated rate of tank exchange is listed in Section B. However, for compliance purposes, the Contractor shall exchange the tanks, as necessary, to maintain the deionized water in accordance with the current AAMI standards.
- 13 **SALT DELIVERY:** Contractor shall provide monthly deliveries of rock salt for the Reverse Osmosis Systems in the amount required, or as needed, to maintain optimum service.
- 14 **WORK HOURS:** This is a full service contract to include all necessary service calls during the work hours listed below for each specific participating VA facility:

VA Greater Los Angeles Healthcare System (West Los Angeles): Seven (7) days per week, 24 hours per day, between the hours of 12:01 a.m. and 12:00 p.m., Sunday through Saturday, excluding holidays.
- 15 **NON-SCHEDULED WORK HOURS:** ~~Service calls placed for any of the following reasons will be billed under a separate, pre-authorized Purchase Order:~~
~~(a) before or after normal work hours,~~
~~(b) during a Federal Holiday,~~
~~(c) during a weekend (for those sites that weekends are not included in their normal work hours) or,~~
~~(d) misuse/abuse by other than the Contractor or his representative.~~
- 16 **PARTS:**
- (a) Only new standard parts shall be furnished by the Contractor. All parts shall be of current manufacture and shall have versatility with presently installed equipment.
 - (b) All newly installed replacement parts become the property of the Government. Replaced parts are to be disposed of by the Contractor after obtaining approval from the COTR
 - (c) Any worn or defective parts will be replaced free of any charges. Operating and consumable supplies are not part of this contract.
 - (d) All replacement parts furnished shall be new and carry a standard commercial warranty.

- 17** AVAILABILITY OF SPARE PARTS: At no time shall any portion of the equipment be inoperable for more than a period of 24 work hours (to be calculated from the time of request from service) due to non-availability of spare parts, unless otherwise authorized by the COTR.
- 18** TEST EQUIPMENT: The Veterans Affairs Healthcare Systems will not furnish parts and/or test equipment for the performance of this contract. It is the responsibility of the Contractor to bring the appropriate equipment and /or supplies necessary to complete the work as required.
- 19** CONTRACTOR'S GUARANTEE: Contractor guarantees all equipment covered in this contract shall be in optimum working condition at the contract expiration date, provided the Contractor is notified of deficiencies at least one (1) day before the contract expiration date. Any changes, updates, or retrofits made on any component or system shall be annotated on station equipment manuals and records. Service will also include recording all routine work, corrections, and repair work in the equipment log.
- 20** REMOVAL OF EQUIPMENT: Should a piece of equipment require repair at the Contractor's plant, Contractor agrees to provide a loaner at no extra charge, if requested. Government property cannot be removed from the facility without a signed Property Pass. This Property Pass may be obtained, after removal is authorized by the COTR, from the Material Management Section. The location of each Material Management Section at each VA facility is listed below:

VAGLA Healthcare System – West L.A. – Bldg. 500, Room 0261