

Background

The FDA Southeast Labs (SEL) conduct analysis on human and animal food, ceramics, makeup and tobacco products. These labs use deionized water to perform their analysis in accordance with FDA certified methodology in accordance with their ISO 17025 accreditation.

Objective

The SEL have three independent DI water systems in the Atlanta FDA facility located at 60 8th Street NE. These systems require periodic tank, filter and bulb replacements, periodic Preventative Maintenance and troubleshooting by qualified technical personnel and the lab has no such personnel on staff. As such SEL needs to contract these services out to a qualified local vendor who can provide all required services stated below, in a timely manner.

Statement of Work

The Southeast Laborites require preventative maintenance, purchase, replacement, and disposal of consumable system components for three independent DI water systems located at 60 8th Street, NE, Atlanta, GA 30309.

- System A is a Reverse Osmosis De-Ionized (DI) Water Unit located in Room 12 of Annex 2 basement.
- System B located in Room 318 of Annex 2.
- System C located in Room 217 2nd floor mechanical room.

NOTE: Neither System B nor System C has an RO or storage tank.

A. System A Specifics:

SRL has a Reverse Osmosis (RO) feed, De-Ionized (DI) Water System which generates 6400 gallons of demineralized water per day which is utilized for scientific analysis of food, feed, and other products regulated by the US Food and Drug Administration. This system must be maintained to provide water that is between 3 – 10 megohms-CM at room temp, contains less than 0.1 mg/L of Chlorine, has a microbial purity of less than 100 CFU/ml, individual trace element level of less than 0.05mg/L for Cd, Cr, Cu, Li, Pb and ZN and less than 0.1 mg/L total for all listed elements. To ensure this capability is maintained within the limits specified above, SRL requires that preventative maintenance, replenishment of consumable supplies, and replacement of worn parts be performed throughout the year. The following is a list of systems/components that need maintenance to ensure full operational capability in accordance with the specified operating parameters:

6400 gallon/day RO Water System
14" Simplex Softener Tank
14" Simplex Carbon Tank

12" Simplex Multi-Media Filter Tank
5000 Gallon Storage Reservoir with Level Switch
Manual On/Off Switch Control Boxes
Recirculation Pump
Resistivity Gauge
24gpm UV System
20" 1mic Pre-Filter
30" 5-Round 0.2mic Final Filter
20" 0.2mic Vent Filter
3.6cft Mixed Bed Worker Tank
3.6cft Mixed Bed Polisher Tank

B. System B Specifics:

De-Ionized (DI) water system used to provide demineralized water utilized for scientific analysis of food, feed, and other products regulated by the US Food and Drug Administration. This system must be maintained to provide water that is between 3 – 10 megohms-CM at room temp. To ensure this capability is maintained within the specified limits above, SRL requires that preventative maintenance, replenish of consumable supplies, and replacement of worn parts be performed the entire year. The following is a list of the system's components that need to be maintained to ensure full operational capability in accordance with the specified operating parameters:

SDI React Carbon 3.6 CF Fiberglass Std POT
2 – SDI Mixbed1 3.6 CF
UV Sterilizer Lamp – 3084 LM Low
20 "1UM Cartridge No Gasket PP
20" 0.2 UM Cartridge CDE 0 Asym Ploy
Pump

C. System C Specifics:

De-Ionized (DI) water system used to provide demineralized water utilized for scientific analysis of food, feed, and other products regulated by the US Food and Drug Administration. This system must be maintained to provide water that is between 3 – 10 megohms-CM at room temp. To ensure this capability is maintained within the specified limits above, SRL requires that preventative maintenance, replenish of consumable supplies, and replacement of worn parts be performed the entire year. The following is a list of the system and its components that need to be maintained to ensure full operational capability in accordance with the specified operating parameters:

SDI React Carbon 3.6 CF Fiberglass Std POT
2 – SDI Mixbed1 3.6 CF
UV Sterilizer Lamp – 3050
20 "1UM Cartridge No Gasket PP

20" 0.2 UM Cartridge CDE 0 Asym Ploy
Pump

Delivery:

- A. SRL requires inspection of the system components listed for each of the three systems on a quarterly basis as follows:
 - A. Systems will be inspected and adjusted, as necessary, by the vendor to maintain peak performance. In addition to inspection(s) and adjustment(s), the vendor is responsible for adhering to a minimum required schedule for various replaceable/consumable components that shall be changed by the vendor in accordance with the schedule provided below, or as deemed necessary, by the vendor in consultation with the SEL system monitor(s) or co-monitor(s), to ensure operational performance is maintained within the specifications stated for each system until the next scheduled quarterly maintenance visit. Results of each inspection shall be provided as a written report stating how the components are performing against the defined operational range for each component, as well as, on a system wide level against the resistivity and purity levels listed for each system.
 - i. At the initial Purchase Order (PO) phase, the vendor shall perform a one-time Mechanical Function Check and provide SEL with a written report on the condition of each component, listed for each system as to conformance with normal operating parameters for this system and its component(s), and against the SRL provided Annex 2 DI Water System performance standards. The purpose of the function check is to determine the operational status of the system and identify any problems that could result in future down time so preventative maintenance can be accomplished to avoid future system outages. At a minimum, the Mechanical Function Check will include a review, a report, and recommendation(s) to SEL regarding any maintenance that may be deemed necessary or prudent with regards to the following on all systems:
 - i. UV intensity
 - ii. efficiency
 - iii. Test SDI Water Quality Specs-Within 1 Meg
 - iv. Perform Pump Function Check
 - v. Perform Carbon Function Check
 - vi. Perform MMF Function Check
 - vii. Perform UV Function Check

- viii. Document Site, Record Readings and Deliver to Customer
 - ix. Per quarter, on System A Perform Softener Function Check
 - x. Test Feed Water Chemistry (TDS, Chlorine, Hardness, Temperature)
 - xi. Test RO Feed Water Chemistry (TDS, Chlorine, Hardness, Temperature)
 - xii. Verify and Test RO Performance (Product Quality, Product Flow, Reject %, Reject Flow)
 - xiii. Verify Tank Level Switch and Low-Level Pump Switch are Operational
 - xiv. Perform Softener Function Check
- ii. Per Quarter on Systems A, B and C, the vendor will perform the following:
 - i. Test SDI Water Quality Specs-Within 1 Meg
 - ii. Perform Pump Function Check
 - iii. Perform Carbon Function Check
 - iv. Perform MMF Function Check
 - v. Perform UV Function Check
 - vi. Document Site findings, Record Readings and Deliver to Customer
- iii. Per quarter, the vendor shall provide and install the following parts/components on:
 - i. On System A:
 - 1. 1 - 3.6cft Mixed Bed SDI Worker Tank*
 - 2. 1 - 3.6cft Mixed Bed SDI Polisher Tank*
 - 3. * Extra tanks, if required, for purchase by Govt IMPAC at contract pricing.
 - ii. On Systems B and C:
 - 1. 1 – 20” 1UM CART No Gasket PP, per system
- iv. Biannually, the vendor shall provide and install the following:
 - i. On System A:
 - 1. 1 - MP2SL 24gpm UV bulb
 - ii. On Systems B:
 - 1. 1 - 3084LM Low UV Sterilizer Bulb
 - iii. On Systems B and C:
 - 1. 1 – 20” 0.2UM CDE 0 ASYM POLY
 - 2. 1 - 3.6CF SDI MIXBD Fiberglass STD POT
 - 3. 1 – 3.6 CF SDI Reactive Carbon Fiberglass STD POT

- v. Annually, the vendor will provide and install the following:
 - i. On system A:
 - 1. 1- 20" 1 mic Pre-filter
 - 2. 1 - 30" 5-Round 0.2 mic Final Filter for SS Housing
 - 3. 1- 20" 0.2 mic Vent Filter
 - vi. The vendor shall test Silica annually on Systems B and C.
- B. **SRL Additional Requirements** for the DIW Systems (System, A System B and System C) are as following:
- a. **Vendor shall notify the lab at least 24 hours prior to scheduled site visits to perform routine maintenance and/or repairs.**
 - b. Vendor will remove all disposables such as bulbs, filters plus Resin, Carbon, and Media tanks after each replacement.
 - c. Although not funded under this PO, SRL requires a predetermined cost per hour for service calls to deal with outages occurrences during the following time frames:
 - i. During normal business hours, 7:30 AM to 4:00 PM, Monday – Friday (excluding federal holidays)
 - ii. After Normal Business hours, Monday – Friday (excluding federal holidays)
 - iii. Weekends (Saturday/Sunday) anytime of the day

Acceptance

- A. Any operational system or component parameter found to be outside those specified for that system, or otherwise stated by the original equipment manufacturer, shall be immediately reported to the SEL system monitor(s), or assistant monitor(s), along with any recommended corrective actions that may be required to return or maintain the system within the required operational parameters stated by SEL above.
- B. No corrective action or component replacement that will incur additional costs outside the scope of this Purchase Order shall be implemented by the vendor without the express approval of the Contracting Officer of Record (COR) for this Purchase Order.
- C. To deal with deficiencies or malfunctions discovered during the stated routine inspections or at other times when reported by the SEL System Monitor(s), SEL requires the ability to purchase service labor and parts separate from this PO, via the small purchase card process, when they are needed in numbers greater than those stated in the requirements section (e.g. paragraphs 5 – 8) of this PO when/if required to ensure the continuous operational capability of, or to return the RO DI System in Annex 2 to operational status, as the result of a malfunction and/or consumption rates that exceed those projected by SRL and stated in this PO. Purchase of said service labor and parts shall be at the same cost as they are quoted under this PO.

Period of Performance

SRL requires a base year for this PO. No options. Base year to start on 1 Sep 2022.

Place of Performance

Place of Performance

Food and Drug Administration
Southeast Tobacco Laboratory
60 Eighth Street NE
Atlanta, GA 30309
POC: To be identified at time of award

Unless otherwise specified, the Contractor shall perform work Monday through Friday (excluding Federal Holidays) between the hours of 8:00 a.m. and 4:30 p.m. EST. Supplies or services scheduled for delivery on a Federal holiday shall be made the next business day. Workplace is not available on the Government Holidays stated below, or as prescribed by an Executive Order (EO) due to inclement weather.

Government Holidays

January (New Year’s Day)	September (Labor Day)
January (Martin Luther King Day)	October (Columbus Day)
February (President’s Day)	November (Veterans Day)
May (Memorial Day)	November (Thanksgiving Day)
July (Independence Day)	December (Christmas Day)

Quotation Instructions

All quotes are due by e-mail to Nina Montgomery, Nina.Montgomery@fda.hhs.gov on or before August 9, 2022 at 10:00 am (Eastern Standard Time).