July 21, 2021

NOTICE TO THE PUBLIC

An award is anticipated to be made by the Food and Drug Administration for the acquisition **for Nitrogen Generators and Compressors Service Agreement for** The FDA Southeast Food and Feed Laboratory Chemistry Branch**.**

This announcement constitutes the only solicitation and a written solicitation will not be issued.

"**Brand Name or Equal product only". The following FAR Clause applies: Clause 52.211-6 - Brand Name or Equal (AUG 1999)**

This requirement is "Subject to the Availability of Funds" The Following FAR Clause applies: AVAILABILITY OF FUNDS (52.232-18) (APR 1984)

This synopsis, NAICS code 811219, identified as **RFQ#1245135** is to notify contractors that the government intends to issue a Purchase Order in accordance with FAR Part 13.106 for the following specifications, under the simplified acquisition procedures.

Specifications:

Potential vendors must demonstrate the ability to provide **Nitrogen Generators and Compressors Service Agreement for** nitrogen generators to supply nitrogen gas to its LC-MS/MS instruments. These instruments are utilized to analyze food and feed samples for the presence of mycotoxins, chemotherapeutic drugs, and other food contaminates. It is essential to operations that the nitrogen generators run optimally and with minimal downtime. To ensure reliability of this equipment, routine maintenance is required. The following maintenance services at a minimum are required for Maintenance Service Agreement for N2 generators

Serial Numbers: LCMS-5000NA-1353B, LCMSSF1012B, LCMS1117

- One site technician visit
- Installation inspection

Generator:

Filter replacement and disposal
Silencer replacement and disposal
Carbon tower replacement and disposal

Compressor:

- Air intake filter replacement and disposal
- Tip seal replacement & disposal
- Compressor pump replacement and disposal
- Cosmetic cleaning
- Restart activities
- Inspection Service Sticker/Report

The service contract also requires factory-certified replacement parts. The service agreement shall provide for telephone troubleshooting support to determine instrument-related problems.

The service maintenance shall be performed in accordance with the specifications contained in the manufacturer's service manual.

The service maintenance must be performed by the manufacturer-trained service engineers.

All parts replaced will be new replacement parts which meet the original manufacturer's specifications.

Specification/Technical Requirements

The Contractor shall be capable of providing the Preventative Maintenance and Qualification Service for all systems specified in the Statement of Work **"Brand Name or Equal"** to that which is provided by the **Nitrogen Generators and Compressors Service ontract** to ensure uninterrupted performance within manufacturer's specification.

Preventative Maintenance - Repair Service

- The Contractor shall provide full coverage of parts, labor, and travel for all repairs within any restrictions stated in the warranty.
- The Contractor shall provide at least one (1) preventative maintenance inspection (PMI) for the instrument during the one (1) year period of performances. The PMI shall be scheduled through communication with the FDA Project Officer or Alternate.
- The PM shall include all consumables, parts, labor, and travel for remedial repair.
- The Contractor shall repair or replace any part or parts which prove to be defective at no additional charge to the government.
- The Contractor shall make arrangement for the fastest delivery and will resume work upon receipt of parts within 72 business hours (3 days) or a mutually agreed upon timeframe.
- All parts replaced shall be new replacement parts which meet the original manufacturer's specifications.
- The Contractor Officer Representative (COR) shall contact the Contractor to schedule a mutually acceptable date and time for the preventive maintenance visit. All visits must be scheduled at least 48 hours in advance with the COR.
- Documentation of preventative maintenance duties performed must be provided. (See Records and Reports section).

Qualification Service

- The Qualification service for the system shall include operation qualification/performance verification (OQ/PV) to be performed after the planned preventative maintenance (PM) and in the event of a critical repair.
- The Contractor shall perform at least one (1) annual OQ/PV verification for the system that is equal to or exceeds the qualification requirements of the manufacturer.
- The OQ/PV service shall be performed by a qualified engineer and must provide documentation that the instrument is functioning according to the manufacturer's specifications.
- The OQ/PV must include all supplies needed to perform the service. Both OQ/PV shall be scheduled through communication with the FDA Project Officer or Alternate FDA Project Officer.
- The Contractor shall provide documentation calibrations and an instrument performance run.
- If at any point during the qualification and the instrument fails a test, the Contractor shall

provide onsite service to remedy the failure and re-execute the qualification and must demonstrate to the COR that the instrument passed the test. If parts are needed to re-execute the OQ, the Contractor shall schedule delivery of the necessary parts and a return service visit shall occur within 48 hours.

Service Calls

- The Contractor shall respond onsite within 72 hours after receipt of a service call.
- Contractor must wear a mask at all times while performing services at the FDA facility.
- The Contractor shall provide unlimited telephone and email access to instrument technical support.
- All repairs must result in the instrument(s) serviced meeting the manufacturer specifications and must use factory new replacement parts.
- Any parts or components removed for replacement shall become the property of the Contractor unless otherwise agreed to by the parties. The Contractor shall remove the parts from the site at the time of the service call or provide shipping instructions and return shipping information that the FDA may return the parts to the Contractor at the Contractor's cost within 3 days after the service visit is completed. The Contractor shall assume all charges and liability for all shipments.
- Removal of any packaging materials shall be the responsibility of the Contractor.
- The Contractor shall perform a diagnostic test results or narrative summary demonstrating that the instrument is meeting the manufacturer's specifications.

Service Conditions

- To the maximum extent practicable, service must be rendered on-site at the FDA.
- In the event a part needs to be repaired off-site, the Contractor shall be responsible for all packaging, shipping, and transportation costs as well as liability for the shipment to and from the FDA, 60 8^{ths} ST.NE, Atlanta, GA. The Contractor shall be responsible for providing a "Return Authorization Number" or other information authorizing return of the shipment to their facility prior to the shipment. The Contractor shall also provide a shipping account number to pay for the shipment.
- The Contractor shall only employ tools, parts, instruments, test apparatus, methodologies, techniques, and practices approved for use by the original manufacturer with specified in this contract.
- The Contractor shall remove all packaging materials from the site at the time of service.

Records and Reports

The Contractor shall, commensurate with the completion of each service call (inclusive of warranty service), provide the end-user of the equipment with a copy of a field service report/ticket identifying the equipment name, manufacturer, model number, and serial number of the equipment being serviced/repaired and detailing the reason for the service call, a detailed description of the work performed, the test instruments or other equipment used to affect the repair or otherwise perform the service, the name(s) and contact information of the technician who performed the repair/service, and for information purposes, the on-site hours expended and parts/components replaced. In addition, the Contractor shall provide monthly reports to the FDA Project Officer and Contract Specialist, not later than the 5th work day following the end of each month, summarizing all

maintenance and repair activities (including warranty work) for the previous month during months that work is performed.

Deliverables

Deliverable	Quantity	Delivery Date
PMA Scheduled Visit	1	Annually during the POP
Operation Qualification	1	Annually during the POP or after critical repair
Service Reports	Varies	NLT 5th workday following the end of each month during any months which work is performed on the instrument.

Warranty

All labor, replacement parts and components (excluding consumables) shall be warrantied for at least a 12-month period.

Place of Performance

Maintenance Service Agreement for N2 generators
US FDA Southeast Regional Laboratory, Chemistry Branch
60 8th Street
Atlanta GA 30309
404 575-1532
POC: TBD

Period of Performance

The period of performance shall be for a one (1) base year, including the warranty

The Contractor shall contact the Government POC at least 48 hours prior to delivery or service. Unless otherwise specified, deliveries and installation shall occur at the Place of Performance specified above, Monday through Friday (excluding Federal Holidays between the hours of 8:00 a.m. and 5:00 p.m. EST.

Current Period of Performance:

Unless otherwise specified, services shall be performed Monday through Friday (excluding Federal Holidays) between the hours of 8:00 a.m. and 4:00 p.m. EST. Supplies or services scheduled for delivery on a Federal holiday shall be made the next business day.

When the Contractor representative/s arrive on site to deliver / install equipment, they must provide proper U.S. photo identification to check-in with the Federal Protective Service (FPS) Security Guards in order to enter the building. Due to COVID-19, a face covering must always be worn. The representatives will receive an "Escort Required" temporary badge, which must always be worn in the building and will remain escorted by lab personnel during their visit. If the Contractors representative need to enter the laboratory, safety glasses must be worn. When their work is complete, the representative/s must provide the lab personnel a work order or service receipt detailing the requirements of the visit. The representatives must check-out with the same FPS

Security Guards, turning in their temporary badge. Tobacco, of any form, and e-cigarettes are not permitted on Federal Property, in Federal Buildings or parking lots.

Government Holidays

Workplace is not available on the Government Holidays stated below, or as prescribed by an Executive Order (EO) due to inclement weather.

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

Pricing

Total Price $_____

Basis of Award

The Government will award a contract resulting from this solicitation to the responsible quoter as a fixed-price contract on the lowest price technically acceptable (LPTA) evaluation method. Award will be made on the basis of the lowest evaluated price meeting or exceeding the non-cost factor (technical conformance to the requirements of the solicitation). The Quoter's initial quotation shall contain the Quoter's best terms from a price standpoint. Failure to demonstrate meeting any of the requirements will result in a rating of technically unacceptable and will not be considered for award.

In order to facilitate the award process, ALL quotes shall include a statement regarding the terms and conditions herein. Additionally, all quotes shall include price (s); FOB point; a poc (name and telephone number); a statement from the offeror verifying that they are Registered in SAM under NAICS code; 811219 delivery date (delivery date is of the utmost importance); business size; and payment terms. Delivery shall be to FDA.

FDA intends to make an award soon after the response date of this notice and all bids must be submitted via email to Maryrose.nicol@fdahhs.gov and be, **received by 5:00 PM (1700) on July 29, 2021** to the attention of Mary Rose A. Nicol, marysrose.nicol@fda.hhs.gov. Offerors shall ensure the RFQ number is visible in the header of the email.

ALL QUESTIONS REGARDING THIS SYNOPSIS/SOLICIATION MUST BE SUBMITTED IN WRITING NO LATER THAN 5:00 PM (1630) EST ON July 27, 2021.

FAX QUOTES SHALL NOT BE ACCEPTED.