

Notice to the Public  
Total Organic Carbon Analyzer  
Request for Quote # 1245198  
July 27, 2021

The Food and Drug Administration (FDA) seeks competitive offers which will be awarded via a purchase order. The NAICS Code for this solicitation is 334516, Description: Analytical Laboratory Instrument Manufacturing, and the Small Business Size Standard is 1000. This will be awarded as Firm-Fixed Price.

**Line Item and Prices:**

Provide a fixed price quote in accordance with the Statement of Work and the Pricing Table. The Contractor shall indicate if the minimum required performance specifications have been met to be considered responsive for this requirement.

Pricing Table

<b>Line Item</b>	<b>Description</b>	<b>Quantity</b>	<b>Total Price</b>
1	Total Organic Carbon Analyzer	1 ea.	\$
<b>Total</b>			<b>\$</b>

**Background**

As an accredited laboratory, the Northeast Medical Products Laboratory (NMPL) is required to comply with ISO/IEC 17025 guidelines. For water used for pharmaceutical analyses, the guidelines stipulate that the water should be of USP purified water quality. One of the tests required in the United States Pharmacopeia (USP) monograph for Purified Water is Total Organic Carbon (TOC).

**Purpose**

As NMPL performs pharmaceutical analyses, it is must to comply with USP requirements for purified water. Having a Total Organic Carbon Analyzer would allow the laboratory to perform the TOC test at multiple water sampling points and ensure compliance with ISO requirements.

**Scope**

The Contractor shall provide all resources necessary to accomplish the tasks and deliverables described in this Statement of Work (SOW). The Contractor shall provide a Total Organic Carbon Analyzer to the Northeast Medical Products Laboratory.

**I. Requirements:**

Minimum Technical Requirements:

- Shall be capable of off-line test measurements to allow testing of water collected at various sampling points
- Shall have a specified limit of detection of 50ppb or lower
- Shall be have the capability of distinguishing between organic and inorganic carbon
- Shall have a sample injection system with a precision of 1.5% or less
- Shall be capable of performing auto dilutions of samples
- Shall be equipped with a personal computer
- Shall allow the generation and printing of reports
- Shall be 21 CFR Part 11 compliant
- Shall have a minimum of one-year warranty

#### Trade and Service Specifications

1. The instrument must be a newly manufactured unit, not used and refurbished or previously used for demonstration.
2. FOB Point destination to include inside delivery and clean-up of area after installation.
3. The entire system must be warranted for parts and labor for 12 months from the date of formal government acceptance. The vendor must also be capable of servicing the instrument through the covered warranty period. The system must include at least a one (1) year warranty and shall include at a minimum: coverage on all non-consumable items and parts supplied including base instrument, factory-certified replacement parts, engineer labor and travel costs. Any equipment repair and maintenance work shall be performed by an OEM-trained engineer. This factory-trained engineer shall have (verified by the OEM) the following: 1) access to OEM factory telephone support; 2) access to the most current OEM factory training for both hardware and software components; and 3) access to all current OEM factory parts, not build-to-order parts. The OEM-trained service engineer shall not use salvaged parts from other instruments for performing maintenance and repairs. All parts used in PM and repairs must be guaranteed, factory-tested, OEM quality parts.
4. Instrument operators shall have access to a technical representative call center at no additional charge, for technical assistance and trouble-shooting, which is staffed by senior engineers to provide a high level of expertise for troubleshooting the instrument.
5. Any necessary Preventative maintenance (PM) or Repair Services shall be included during the warranty period. This visit shall be inclusive of all parts, labors, travel, consumables, and supplies which are necessary to complete the OEM's suggested PM protocol. Service engineers which perform this service shall trained by the OEM.
6. Sufficient familiarization training for 3-5 users per delivery onsite location will be provided at time of installation or shortly thereafter (within 30 days), such that operators may independently operate the instrument and with increased familiarity and proficiency. The training shall include manuals and any consumables to be used during training.
7. The Contractor shall provide installation qualification with an employee who can provide proof of installation qualification/Operation qualification (IQ/OQ)

#### 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/repared 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 COR and/or COR designee 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**

**Table 1. Deliverables / Schedule**

Total Organic Carbon Analyzer	1	Not later than September 1, 2021
Familiarization Training – minimum of 5 users	1	Within two weeks after Government acceptance of instrument
Service Reports	Varies	Not later than the 5th work day following the end of each month, (during any months during which warranty work is performed)

**Shipping Destination**

POC: To Be Identified at time of award  
 Food and Drug Administration,  
 Northeast Medical Products Laboratory  
 158-15 Liberty Avenue  
 Jamaica, NY 11433-1034

The delivery or services must be during regular business hours (Monday-Friday) during the times of 8:00 AM – 4:00 PM, excluding holidays.

**Period of Performance**

The period of performance begins the date of contract award execution.

The anticipated Period of Performance is as follows:

Base Period: September 1, 2021 – August 31, 2021

### **Contract Vehicle**

It is anticipated that this award will be a Firm-Fixed-Price (FFP). All deliverables shall be clearly identified, complete with clear descriptions; due dates, and at a predetermined, agreed-upon price.

### **Government Holidays**

a. The Government hereby provides notification that Government personnel observe the listed days as holidays:

- (1) New Year's Day
- (2) Martin Luther King's Birthday
- (3) President's Day
- (4) Memorial Day
- (5) Juneteenth
- (6) Independence Day
- (7) Labor Day
- (8) Columbus Day
- (9) Veterans' Day
- (10) Thanksgiving Day
- (11) Christmas Day

b. In addition to the days designated as holidays, the Government observes the following days:

- (1) Any other day designated by Federal Statute
- (2) Any other day designated by Executive Order
- (3) Any other day designated by the President's Proclamation

c. When any such day falls on a Saturday, the following Monday is observed. Except for designated around-the-clock or emergency operations, Contractor personnel shall not be able to perform on-site under this contract with FDA on holidays set forth above. The Contractor shall not charge any holiday as direct charge to the award.

d. It is understood and agreed between the Government and the Contractor that observance of such days by Government personnel shall not otherwise be a reason for an additional period of performance, or entitlement of compensation except as set forth within the award.

e. Nothing in this clause abrogates the rights and responsibilities of the parties relating to stop work provisions as cited in other sections of this contract.

### **FDA Three-Way Match Invoicing Procedures**

#### 1. U.S. FOOD AND DRUG ADMINISTRATION

Attn: Vendor Payments  
Division of Payment Services  
10903 New Hampshire Ave  
WO32 - Second Floor  
MAIL HUB 2145  
Silver Spring, MD 20993-0002  
301-827-3742

FDAVendorPaymentsTeam@fda.hhs.gov

\*\*\* Acceptable methods of delivery include: E-mail (preferred) and Standard Mail. Provide a copy marked courtesy to the COR. The COR is (TBD)

2. Invoices submitted under this contract shall comply with the requirements set forth in FAR Clauses 52.232-25 (Prompt Payment) and 52.232-33 (Payment by Electronic Funds Transfer - System for Award Management) and/or other applicable FAR clauses specified herein. To constitute a proper invoice, the invoice shall be submitted on company letterhead and include each of the following:

(i) Name and address of the Contractor;

(ii) Invoice date and invoice number;

(iii) Contract/Order number (including a reference to any base award for Indefinite-Delivery/Indefinite-Quantity Contracts or Blanket Purchase Agreements);

(iv) Description, quantity, unit of measure, unit price, and extended price supplies delivered or services performed, including:

(a) period of performance for which costs are claimed;

(b) itemized travel costs, including origin and destination;

(c) any other supporting information necessary to clarify questionable expenditures;

(d) the Contractor shall include the Contract Line Item/Funding line item for each description, quantity, unit of measure, unit price, and extended price supplies delivered or services performed;

- (v) Shipping number and date of shipment, including the bill of lading number and weight of shipment if shipped on Government bill of lading;
- (vi) Terms of any discount for prompt payment offered (Prompt Payment terms other than NET 30);
- (vii) Name and address of official to whom payment is to be sent (shall be the same as that in the purchase order/award, or in a proper notice of assignment)
- (viii) Name, title, and phone number of person to notify in event of defective invoice;
- (ix) Taxpayer Identification Number (TIN);
- (x) banking routing transit number of the financial institution receiving payment for Electronic funds transfer (EFT);
- (xi) Name and telephone number of the FDA Contracting Officer Representative (COR) or other Program Center/Office point of contact, as referenced on the award;
- (xii) For all Inspections, Time-and-Materials and Labor-Hour Awards, Contractor is required to attach an invoice log addendum to each invoice which shall include, at a minimum, the following information for contract administration and reconciliation purposes:
  - (a) list of all invoices submitted to date under the subject award, including the following:
    - (1) invoice number, amount, & date submitted
    - (2) corresponding payment amount & date received
  - (b) total amount of all payments received to date under the subject contract or order
  - (c) and, for definitized contracts or orders only, total estimated amounts yet to be invoiced for the current, active period of performance;

3. Any other information or documentation required by the award. An electronic invoice is acceptable if submitted in adobe acrobat (PDF) format. All items listed in (i) through (xiii) of this clause shall be included in the electronic invoice. Electronic invoices shall be on company letterhead and shall contain no ink changes and be legible for printing.

4. Questions regarding invoice payments should be directed to the FDA Payment Office at the e-mail address provided above in Section 1.

## **Section B: Contract Clauses and Provisions**

## FAR 52.252-2 Clauses Incorporated by Reference:

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer shall make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es): <https://www.acquisition.gov/far/> and <https://www.hhs.gov/policies/hhsar/subpart301-1.html>.

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The following provisions and clauses apply:

### HHSAR Clauses

HHSAR 352.211-3 Paperwork Reduction Act

HHSAR 352.222-70 Contractor Cooperation in Equal Employment Opportunity Investigations

HHSAR 352.239-74 Electronic and Information Technology Accessibility

### FAR Clauses

FAR 52.212-1 Instructions to Offerors—Commercial Items (Jul 2021)

FAR 52.212-4, Contract Terms and Conditions Commercial Item (Jun 2020)

FAR 52.212-5 Contract Terms and Conditions Required to Implement Statutes or Executive Orders-Commercial Items. (JAN 2021)

(a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses, which are incorporated in this contract by reference, to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

(1) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(2) 52.209-10, Prohibition on Contracting with Inverted Domestic Corporations (Nov 2015)

(3) 52.233-3, Protest After Award (AUG 1996) (31 U.S.C. 3553).

(4) 52.233-4, Applicable Law for Breach of Contract Claim (OCT 2004) (Public Laws 108-77, 108-78 (19 U.S.C. 3805 note)).

(b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the contracting officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

  X   (1) 52.203-6, Restrictions on Subcontractor Sales to the Government (Sept 2006), with Alternate I (Oct 1995) (41 U.S.C. 4704 and 10 U.S.C. 2402).

- (2) 52.203-13, Contractor Code of Business Ethics and Conduct (Oct 2015) (41 U.S.C. 3509).
- (3) 52.203-15, Whistleblower Protections under the American Recovery and Reinvestment Act of 2009 (Jun 2010) (Section 1553 of Pub L. 111-5) (Applies to contracts funded by the American Recovery and Reinvestment Act of 2009).
- (4) 52.204-10, Reporting Executive compensation and First-Tier Subcontract Awards (Oct 2016) (Pub. L. 109-282) (31 U.S.C. 6101 note).
- (5) [Reserved]
- (6) 52.204-14, Service Contract Reporting Requirements (Oct 2016) (Pub. L. 111-117, section 743 of Div. C).
- (7) 52.204-15, Service Contract Reporting Requirements for Indefinite-Delivery Contracts (Oct 2016) (Pub. L. 111-117, section 743 of Div. C).
- (8) 52.209-6, Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment (Oct 2015) (31 U.S.C. 6101 note).
- (9) 52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters (Jul 2013) (41 U.S.C. 2313).
- (10) [Reserved]
- (11) (i) 52.219-3, Notice of HUBZone Set-Aside or Sole-Source Award (Nov 2011) (15 U.S.C. 657a).
- (ii) Alternate I (Nov 2011) of 52.219-3.
- (12) (i) 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (Oct 2014) (if the offeror elects to waive the preference, it shall so indicate in its offer (15 U.S.C. 657a).
- (ii) Alternate I (Jan 2011) of 52.219-4.
- (13) [Reserved]
- (14) (i) 52.219-6, Notice of Total Small Business Aside (Nov 2011) (15 U.S.C. 644).
- (ii) Alternate I (Nov 2011).
- (iii) Alternate II (Nov 2011).
- (15) (i) 52.219-7, Notice of Partial Small Business Set-Aside (June 2003) (15 U.S.C. 644).
- (ii) Alternate I (Oct 1995) of 52.219-7.
- (iii) Alternate II (Mar 2004) of 52.219-7.
- (16) 52.219-8, Utilization of Small Business Concerns (Nov 2016) (15 U.S.C. 637(d)(2) and (3)).
- (17) (i) 52.219-9, Small Business Subcontracting Plan (Jan 2017) (15 U.S.C. 637 (d)(4)).
- (ii) Alternate I (Nov 2016) of 52.219-9.
- (iii) Alternate II (Nov 2016) of 52.219-9.
- (iv) Alternate III (Nov 2016) of 52.219-9.
- (v) Alternate IV (Nov 2016) of 52.219-9.
- (18) 52.219-13, Notice of Set-Aside of Orders (Nov 2011) (15 U.S.C. 644(r)).
- (19) 52.219-14, Limitations on Subcontracting (Jan 2017) (15 U.S.C. 637(a) (14)).
- (20) 52.219-16, Liquidated Damages—Subcontracting Plan (Jan 1999) (15 U.S.C. 637(d)(4)(F)(i)).
- (21) 52.219-27, Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (Nov 2011) (15 U.S.C. 657f).
- (22) 52.219-28, Post Award Small Business Program Representation (Jul 2013) (15 U.S.C. 632(a)(2)).



- (23) 52.219-29, Notice of Set-Aside for, or Sole Source Award to, Economically Disadvantaged Women-Owned Small Business Concerns (Dec 2015) (15 U.S.C. 637(m)).
- (24) 52.219-30, Notice of Set-Aside for, or Sole Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (Dec 2015) (15 U.S.C. 637(m)).
- (25) 52.222-3, Convict Labor (June 2003) (E.O. 11755).
- (26) 52.222-19, Child Labor—Cooperation with Authorities and Remedies (Oct 2016) (E.O. 13126).
- (27) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).
- (28) 52.222-26, Equal Opportunity (Sep 2016) (E.O. 11246).
- (29) 52.222-35, Equal Opportunity for Veterans (Oct 2015) (38 U.S.C. 4212).
- (30) 52.222-36, Equal Opportunity for Workers with Disabilities (Jul 2014) (29 U.S.C. 793).
- (31) 52.222-37, Employment Reports on Veterans (Feb 2016) (38 U.S.C. 4212).
- (32) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496).
- (33) (i) 52.222-50, Combating Trafficking in Persons (Mar 2015) (22 U.S.C. chapter 78 and E.O. 13627).
- (ii) Alternate I (Mar 2015) of 52.222-50, (22 U.S.C. chapter 78 and E.O. 13627).
- (34) 52.222-54, Employment Eligibility Verification (Oct 2015). (E. O. 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial items as prescribed in 22.1803.)
- (35) (i) 52.223-9, Estimate of Percentage of Recovered Material Content for EPA-Designated Items (May 2008) (42 U.S.C. 6962(c)(3)(A)(ii)). (Not applicable to the acquisition of commercially available off-the-shelf items.)
- (ii) Alternate I (May 2008) of 52.223-9 (42 U.S.C. 6962(i)(2)(C)). (Not applicable to the acquisition of commercially available off-the-shelf items.)
- (36) 52.223-11, Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (Jun 2016) (E.O.13693).
- (37) 52.223-12, Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (Jun 2016) (E.O. 13693).
- (38) (i) 52.223-13, Acquisition of EPEAT® -Registered Imaging Equipment (Jun 2014) (E.O.s 13423 and 13514)
- (ii) Alternate I (Oct 2015) of 52.223-13.
- (39) (i) 52.223-14, Acquisition of EPEAT® -Registered Television (Jun 2014) (E.O.s 13423 and 13514).
- (ii) Alternate I (Jun 2014) of 52.223-14.
- (40) 52.223-15, Energy Efficiency in Energy-Consuming Products (Dec 2007) (42 U.S.C. 8259b).
- (41) (i) 52.223-16, Acquisition of EPEAT® -Registered Personal Computer Products (Oct 2015) (E.O.s 13423 and 13514).
- (ii) Alternate I (Jun 2014) of 52.223-16.
- (42) 52.223-18, Encouraging Contractor Policies to Ban Text Messaging while Driving (Aug 2011) (E.O. 13513).
- (43) 52.223-20, Aerosols (Jun 2016) (E.O. 13693).
- (44) 52.223-21, Foams (Jun 2016) (E.O. 13696).

- \_\_\_ (45) (i) 52.224-3, Privacy Training (Jan 2017) (5 U.S.C. 552a).
- \_\_\_ (ii) Alternate I (Jan 2017) of 52.224-3.
- \_\_\_ (46) 52.225-1, Buy American--Supplies (May 2014) (41 U.S.C. chapter 83).
- \_\_\_ (47) (i) 52.225-3, Buy American--Free Trade Agreements--Israeli Trade Act (May 2014) (41 U.S.C. chapter 83, 19 U.S.C. 3301 note, 19 U.S.C. 2112 note, 19 U.S.C. 3805 note, 19 U.S.C. 4001 note, Pub. L. 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43).
- \_\_\_ (ii) Alternate I (May 2014) of 52.225-3.
- \_\_\_ (iii) Alternate II (May 2014) of 52.225-3.
- \_\_\_ (iv) Alternate III (May 2014) of 52.225-3.
- \_\_\_ (48) 52.225-5, Trade Agreements (Oct 2016) (19 U.S.C. 2501, *et seq.*, 19 U.S.C. 3301 note).
- \_\_\_ (49) 52.225-13, Restrictions on Certain Foreign Purchases (Jun 2008) (E.O.'s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).
- \_\_\_ (50) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).
- \_\_\_ (51) 52.226-4, Notice of Disaster or Emergency Area Set-Aside (Nov 2007) (42 U.S.C. 5150).
- \_\_\_ (52) 52.226-5, Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov 2007) (42 U.S.C. 5150).
- \_\_\_ (53) 52.232-29, Terms for Financing of Purchases of Commercial Items (Feb 2002) (41 U.S.C. 4505), 10 U.S.C. 2307(f)).
- \_\_\_ (54) 52.232-30, Installment Payments for Commercial Items (Jan 2017) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).
- \_\_\_ x (55) 52.232-33, Payment by Electronic Funds Transfer— System for Award Management (Jul 2013) (31 U.S.C. 3332).
- \_\_\_ (56) 52.232-34, Payment by Electronic Funds Transfer—Other Than System for Award Management (Jul 2013) (31 U.S.C. 3332).
- \_\_\_ (57) 52.232-36, Payment by Third Party (May 2014) (31 U.S.C. 3332).
- \_\_\_ (58) 52.239-1, Privacy or Security Safeguards (Aug 1996) (5 U.S.C. 552a).
- \_\_\_ (59) 52.242-5, Payments to Small Business Subcontractors (Jan 2017) (15 U.S.C. 637(d)(12)).
- \_\_\_ (60) (i) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx 1241(b) and 10 U.S.C. 2631).
- \_\_\_ (ii) Alternate I (Apr 2003) of 52.247-64.

(c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or executive orders applicable to acquisitions of commercial items:

- \_\_\_ (1) 52.222-17, Non-displacement of Qualified Workers (May 2014) (E.O. 13495)
- \_\_\_ (2) 52.222-41, Service Contract Labor Standards (May 2014) (41 U.S.C. chapter 67.).
- \_\_\_ (3) 52.222-42, Statement of Equivalent Rates for Federal Hires (May 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).

- \_\_\_ (4) 52.222-43, Fair Labor Standards Act and Service Contract Labor Standards -- Price Adjustment (Multiple Year and Option Contracts) (May 2014) (29 U.S.C.206 and 41 U.S.C. chapter 67).
- \_\_\_ (5) 52.222-44, Fair Labor Standards Act and Service Contract Labor Standards -- Price Adjustment (May 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).
- \_\_\_ (6) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment--Requirements (May 2014) (41 U.S.C. chapter 67).
- \_\_\_ (7) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services--Requirements (May 2014) (41 U.S.C. chapter 67).
- \_\_\_ (8) 52.222-55, Minimum Wages Under Executive Order 13658 (Dec 2015) (E.O. 13658).
- \_\_\_ (9) 52.222-62, Paid Sick Leave Under Executive Order 13706 (JAN 2017) (E.O. 13706).
- \_\_\_ (10) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations. (May 2014) (42 U.S.C. 1792).
- \_\_\_ (11) 52.237-11, Accepting and Dispensing of \$1 Coin (Sep 2008) (31 U.S.C. 5112(p)(1)).

(d) *Comptroller General Examination of Record* The Contractor shall comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, and does not contain the clause at 52.215-2, Audit and Records -- Negotiation.

(1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor's directly pertinent records involving transactions related to this contract.

(2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR Subpart 4.7, Contractor Records Retention, of the other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.

(3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.

(e) (1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c) and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in this paragraph (e)(1) in a subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause—

(i) 52.203-13, Contractor Code of Business Ethics and Conduct (Oct 2015) (41 U.S.C. 3509).

- (ii) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).
  - (iii) 52.219-8, Utilization of Small Business Concerns (Nov 2016) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds \$700,000 (\$1.5 million for construction of any public facility), the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.
  - (iv) 52.222-17, Non-displacement of Qualified Workers (May 2014) (E.O. 13495). Flow down required in accordance with paragraph (1) of FAR clause 52.222-17.
  - (v) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).
  - (vi) 52.222-26, Equal Opportunity (Sep 2016) (E.O. 11246).
  - (vii) 52.222-35, Equal Opportunity for Veterans (Oct 2015) (38 U.S.C. 4212).
  - (viii) 52.222-36, Equal Opportunity for Workers with Disabilities (Jul 2014) (29 U.S.C. 793).
  - (ix) 52.222-37, Employment Reports on Veterans (Feb 2016) (38 U.S.C. 4212).
  - (x) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause 52.222-40.
  - (xi) 52.222-41, Service Contract Labor Standards (May 2014), (41 U.S.C. chapter 67).
  - (xii) (A) 52.222-50, Combating Trafficking in Persons (Mar 2015) (22 U.S.C. chapter 78 and E.O. 13627).
  - (B) Alternate I (Mar 2015) of 52.222-50 (22 U.S.C. chapter 78 E.O. 13627).
  - (xiii) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment--Requirements (May 2014) (41 U.S.C. chapter 67.)
  - (xiv) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services--Requirements (May 2014) (41 U.S.C. chapter 67)
  - (xv) 52.222-54, Employment Eligibility Verification (Oct 2015) (E. O. 12989).
  - (xvi) 52.222-55, Minimum Wages Under Executive Order 13658 (Dec 2015).
  - (xvii) 52.222-62, Paid sick Leave Under Executive Order 13706 (JAN 2017) (E.O. 13706).
  - (xviii) (A) 52.224-3, Privacy Training (Jan 2017) (5 U.S.C. 552a).
  - (B) Alternate I (Jan 2017) of 52.224-3.
  - (xix) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).
  - (xx) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations. (May 2014) (42 U.S.C. 1792). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.
  - (xxi) 52.247-64, Preference for Privately-Owned U.S. Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx 1241(b) and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.
- (2) While not required, the Contractor may include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

## 52.204-25 Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.

As prescribed in 4.2105(b), insert the following clause:

### Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment (Aug 2020)

(a) Definitions. As used in this clause—

Backhaul means intermediate links between the core network, or backbone network, and the small subnetworks at the edge of the network (e.g., connecting cell phones/towers to the core telephone network). Backhaul can be wireless (e.g., microwave) or wired (e.g., fiber optic, coaxial cable, Ethernet).

Covered foreign country means The People's Republic of China.

Covered telecommunications equipment or services means—

(1) Telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities);

(2) For the purpose of public safety, security of Government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities);

(3) Telecommunications or video surveillance services provided by such entities or using such equipment; or

(4) Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise connected to, the government of a covered foreign country.

Critical technology means—

(1) Defense articles or defense services included on the United States Munitions List set forth in the International Traffic in Arms Regulations under subchapter M of chapter I of title 22, Code of Federal Regulations;

(2) Items included on the Commerce Control List set forth in Supplement No. 1 to part 774 of the Export Administration Regulations under subchapter C of chapter VII of title 15, Code of Federal Regulations, and controlled-

(i) Pursuant to multilateral regimes, including for reasons relating to national security, chemical and biological weapons proliferation, nuclear nonproliferation, or missile technology; or

(ii) For reasons relating to regional stability or surreptitious listening;

(3) Specially designed and prepared nuclear equipment, parts and components, materials, software, and technology covered by part 810 of title 10, Code of Federal Regulations (relating to assistance to foreign atomic energy activities);

(4) Nuclear facilities, equipment, and material covered by part 110 of title 10, Code of Federal Regulations (relating to export and import of nuclear equipment and material);

(5) Select agents and toxins covered by part 331 of title 7, Code of Federal Regulations, part 121 of title 9 of such Code, or part 73 of title 42 of such Code; or

(6) Emerging and foundational technologies controlled pursuant to section 1758 of the Export Control Reform Act of 2018 (50 U.S.C. 4817).

Interconnection arrangements means arrangements governing the physical connection of two or more networks to allow the use of another's network to hand off traffic where it is ultimately delivered (e.g., connection of a customer of telephone provider A to a customer of telephone company B) or sharing data and other information resources.

Reasonable inquiry means an inquiry designed to uncover any information in the entity's possession about the identity of the producer or provider of covered telecommunications equipment or services used by the entity that excludes the need to include an internal or third-party audit.

Roaming means cellular communications services (e.g., voice, video, data) received from a visited network when unable to connect to the facilities of the home network either because signal coverage is too weak or because traffic is too high.

Substantial or essential component means any component necessary for the proper function or performance of a piece of equipment, system, or service.

(b) Prohibition. (1) Section 889(a)(1)(A) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) prohibits the head of an executive agency on or after August 13, 2019, from procuring or obtaining, or extending or renewing a contract to procure or obtain, any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. The Contractor is prohibited from providing to the Government any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system, unless an exception at paragraph (c) of this clause applies or the covered telecommunication equipment or services are covered by a waiver described in FAR 4.2104.

(2) Section 889(a)(1)(B) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) prohibits the head of an executive agency on or after August 13, 2020, from entering into a contract, or extending or renewing a contract, with an entity that uses any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system, unless an exception at paragraph (c) of this clause applies or the covered telecommunication equipment or services are covered by a waiver described in FAR 4.2104. This prohibition applies to the use of covered telecommunications equipment or services, regardless of whether that use is in performance of work under a Federal contract.

(c) Exceptions. This clause does not prohibit contractors from providing—

(1) A service that connects to the facilities of a third-party, such as backhaul, roaming, or interconnection arrangements; or

(2) Telecommunications equipment that cannot route or redirect user data traffic or permit visibility into any user data or packets that such equipment transmits or otherwise handles.

(d) Reporting requirement. (1) In the event the Contractor identifies covered telecommunications equipment or services used as a substantial or essential component of any system, or as critical technology as part of any system, during contract performance, or the Contractor is notified of such by a subcontractor at any tier or by any other source, the

Contractor shall report the information in paragraph (d)(2) of this clause to the Contracting Officer, unless elsewhere in this contract are established procedures for reporting the information; in the case of the Department of Defense, the Contractor shall report to the website at <https://dibnet.dod.mil>. For indefinite delivery contracts, the Contractor shall report to the Contracting Officer for the indefinite delivery contract and the Contracting Officer(s) for any affected order or, in the case of the Department of Defense, identify both the indefinite delivery contract and any affected orders in the report provided at <https://dibnet.dod.mil>.

(2) The Contractor shall report the following information pursuant to paragraph (d)(1) of this clause

(i) Within one business day from the date of such identification or notification: the contract number; the order number(s), if applicable; supplier name; supplier unique entity identifier (if known); supplier Commercial and Government Entity (CAGE) code (if known); brand; model number (original equipment manufacturer number, manufacturer part number, or wholesaler number); item description; and any readily available information about mitigation actions undertaken or recommended.

(ii) Within 10 business days of submitting the information in paragraph (d)(2)(i) of this clause: any further available information about mitigation actions undertaken or recommended. In addition, the Contractor shall describe the efforts it undertook to prevent use or submission of covered telecommunications equipment or services, and any additional efforts that will be incorporated to prevent future use or submission of covered telecommunications equipment or services.

(e) Subcontracts. The Contractor shall insert the substance of this clause, including this paragraph (e) and excluding paragraph (b)(2), in all subcontracts and other contractual instruments, including subcontracts for the acquisition of commercial items.

(End of clause)

#### 52.204-26 Covered Telecommunications Equipment or Services-Representation.

As prescribed in 4.2105(c), insert the following provision:

Covered Telecommunications Equipment or Services-Representation (Dec 2019)

(a) Definitions. As used in this provision, “covered telecommunications equipment or services” has the meaning provided in the clause 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.

(b) Procedures. The Offeror shall review the list of excluded parties in the System for Award Management (SAM) (<https://www.sam.gov>) for entities excluded from receiving federal awards for “covered telecommunications equipment or services”.

(c) Representation. The Offeror represents that it  does,  does not provide covered telecommunications equipment or services as a part of its offered products or services to the Government in the performance of any contract, subcontract, or other contractual instrument.

### **Section 508 Requirements**

The following standards are applicable for this requirement:

- Must meet WCAG 2.0 A and AA
- E101.2 Equivalent Facilitation (Appendix A, Application and Scoping Requirements)

- E203 Access to Functionality (Appendix A, Application and Scoping Requirements)
- E204 Functional Performance Criteria (Appendix A, Application and Scoping Requirements)
- E205 Electronic Content (Appendix A, Application and Scoping Requirements)
- E208 Support Documentation and Services (Appendix A, Application and Scoping Requirements)
- Chapter 6 Support Documentation and Services (Appendix C, Functional Performance Criteria and Technical Requirements)
- 302 Functional Performance Criteria (Appendix C, Functional Performance Criteria and Technical Requirements)

Electronic content must be accessible to HHS acceptance criteria. Checklist for various formats are available at <https://www.hhs.gov/web/section-508/accessibility-checklists/index.html>, or from the Section 508 Coordinator listed at <https://www.hhs.gov/web/section-508/additional-resources/section-508-contacts/index.html>. Materials that are final items for delivery should be accompanied by the appropriate checklist, except upon approval of the Contracting Officer or Representative.

Based on what is being procured you will also need to provide the following appropriate scoping and technical requirements from chapters A and C which are as follows:

Appropriate Scoping Requirement from Appendix A

- E206 Hardware (Appendix A, Application and Scoping Requirements)
- E207 Software (Appendix A, Application and Scoping Requirements)

Appropriate Technical Performance and Technical Requirement from Appendix C

- Chapter 4 Hardware (Appendix C, Functional Performance Criteria and Technical Requirements)
- Chapter 5 Software (Appendix C, Functional Performance Criteria and Technical Requirements)

**Section C: Instructions to offerors and evaluation criteria**

FAR 52.212-1 Instructions to Offerors—Commercial Items

(a) Single Award. The U.S. Government anticipates awarding approximately one (1) contract as a result of this solicitation.

(b) RFQ Instructions. If an offeror does not follow the instructions set forth herein, the offerors quoted may be eliminated from further consideration or the quote may be down-graded and not receive full or partial credit under the applicable evaluation criteria.

(c) Accurate and Complete Information. Offerors must set forth full, accurate and complete information as required by this RFQ. The penalty for making false statements to the government is prescribed in 18 U.S.C. 1001.



\*\*\*The solicitation does not commit the Government to pay any cost for the preparation and submission of a quote or proposal. It is also advised that the Contracting Officer (CO) is the only individual who can legally commit and obligate the Government to the expenditure of public funds in connection with the proposed acquisition. \*\*\*

### **Quote Due**

All quotes are due by e-mail to Cynthia Martin, [Cynthia.Martin@fda.hhs.gov](mailto:Cynthia.Martin@fda.hhs.gov) on or before August 6, 2021 at 2:00 pm (Eastern Time).

### **Evaluation Award**

The Government may award to the quoter who provided Lowest Priced, Technically Acceptable (LPTA) and whose price is deemed price reasonable.

Parties responding to this solicitation may submit their quote in accordance with their standard commercial practices (e.g. on company letterhead, formal quote form, etc) but shall include the following information: 1) company's complete mailing and remittance addresses 2) discounts for prompt payment if applicable; 3) Dun & Bradstreet number; 4) Taxpayer ID number; 5) Catalog or Published Price Listing applicable to the service; 6) Offerors shall submit information to document that it meets specifications as noted in the synopsis/solicitation and FAR 52.212-1. Offerors shall include a completed copy of the provision at 52.212-3, Offeror Representations and Certifications/Commercial Items with their offer. Note: Contractor shall be registered and active in the System for Award Management (SAM) prior to the award of a contract. You may register by going to [www.beta.sam.gov](http://www.beta.sam.gov).