

The Food and Drug Administration (FDA), The Denver Laboratory (DENTL)

Orbital Shakers

Request for Quote #1255230

1.0 Background

The Denver laboratory is participating in an ongoing assignment from CFSAN to analyze Tattoo Ink. This assignment brings a larger than average sample load that requires specific analysis conditions that are provided with an orbital shaker. Two additional shakers are required to handle the additional work coming to the Denver Laboratory.

1.1 Objective

The contractor shall provide instrumentation with technical specifications and functional features that meet or exceed the orbital shaker requirements of an Incubating/Refrigerating Orbital Shaker.

- The additional equipment will allow the Denver Laboratory to analyze the required number of samples specified in the assignment.
- The additional sample numbers will be analyzed within the timeframes of the assignment.

1.2 Line Item Pricing Table

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.

Deliverable	Description	Quantity/Media
1	Orbital Shaker	2
	Installation, Setup, IQ/OQ	2
	Preventative Maintenance Service	2
2	Corrective action to fix the system under any failures during warranty as needed	Per each failure
3	Field Service Report	Per each service call

2.0 Requirements/Deliveries

The contractor shall provide instrumentation with technical specifications and functional features that meet or exceed the orbital shaker requirements of an Incubating/Refrigerating Orbital Shaker.

Orbital Shaker Specifications

The shaker shall have a temperature range of 15° below ambient up to 60°.

The shaker shall be at least 120V

The shaker shall have a max load of 35 lbs.

The shaker shall have a timer and be able to operation continuously.

Trade and Service Specifications

1. The instrument shall 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 shall be warranted for parts and labor for 12 months from the date of formal government acceptance. The vendor shall also be capable of servicing the instrument through the covered warranty period. The system shall 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 shall 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. Preventative maintenance (PM) visit shall be included for the base contract year. 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) certification.

Section 508 Compliance

The Contractor shall be familiar with Section 508 requirements as described at <http://www.section508.gov/> in order to ensure that documents generated as part of the tasks are fully Section 508-accessible using the available COTS tools. Each order will identify the standards applicable to that order

3.0 Period of Performance

The period of performance begins the date of contract award execution and continues for one year (or longer depending on the offered warranty period) from the date of formal government acceptance of equipment and services. Equipment to be delivered within 60 days of award.

4.0 Delivery / Place of Performance

Shipping Destinations:

Food and Drug Administration – POC Mike Maselli

Denver Federal Center

6th and Kipling

Building 20 Entrance W10

Denver, CO 80225

Deliverable	Description	Quantity/Media	Date Completed
1	Orbital Shaker	2	Withing 60 days of award
	Installation, Setup, IQ/OQ	2	Within 30 days of delivery
	Preventative Maintenance Service	2	Within 30 days prior to expiration of warranty
2	Corrective action to fix the system under any failures during warranty as needed	Per each failure	within 7 days of notification by Government
3	Field Service Report	Per each service call	Within 3 days of completion of service

Security

This section should identify any unique security requirements associated with contract performance (when applicable). These requirements may include, but are not limited to, such items as:

- Special pass or identification requirements;
- Special security clearance requirements; or
- Special escort requirements.

Delivery shall be during regular business hours, Monday through Friday, 8:00am – 4:30pm, excluding holidays

5.0 Inspection and Acceptance

The COR and /or COR designee will perform inspection and acceptance of equipment, installation and services to be provided. The COR and /or COR designee – to be determined upon contract award.

A final inspection and acceptance of all work performed, reports and other deliverables will be performed by the COR and /or COR designee to ensure the services/products provided meet the requirements of the Statement of Work (SOW), and the Contractor shall make changes as requested during the inspection and acceptance process.

Inspection and acceptance will occur at the place of performance and take place within five (5) business days of task being completed. The Government will provide written notification of acceptance or rejection within five (5) business days. Inspection will include review of the deliverables to ensure adequacy.

The Government will accept goods, reports, and services only if they conform to all terms and conditions of the SOW, and satisfy the performance standards developed under this SOW.

The Government will reject non-conforming products and services. The Contractor shall correct any deficiencies within fifteen (15) business days of when the Government issues the rejection notice. If the Contractor cannot correct the deficiencies within this period, the Contractor shall immediately notify the COR of the reason for the delay and provide a proposed corrective action plan within five (5) business days.

6.0 Contract Type

The anticipated contract type is firm-fixed price (FFP)

7.0 Government Points of Contacts

Contracting Specialist (CS):

Courtney Black

Courtney.Black@fda.hhs.gov

Contract Officer Representative (COR):

[To be determined](#)

8.0 Contracting Officer Authority

The Contracting Officer (CO) is the sole person authorized to make or approve any changes in any of the requirements of this order and notwithstanding any provisions contained elsewhere in the order, the said authority remains solely with the CO. In the event the Contractor makes any changes at the direction of any person other than the CO, the change shall be considered to have been made without authority and no adjustment will be made in the delivery order terms and conditions, including price. The CO shall be the only individual authorized to accept nonconforming work, waive any requirement of the order and modify any term or condition of the order. The CO is the only individual who can legally obligate Government funds.

The Contracting Officer's Representative (COR) or Project Officer is not authorized to make any commitments or otherwise obligate the Government or authorize any changes which affect the order price, terms or conditions. The COR/Project Officer is responsible for the technical aspects of the project and serves as technical liaison with the contractor and is responsible for the final inspection and acceptance, and such other responsibilities as may be specified in the order.

9.0 Order of Precedence

The Contractor shall follow the terms and conditions of this order. Should the Contractor include any additional terms and conditions resulting in conflicts between this document and the Contractor's document, the Order of Precedence shall be as specified in *FAR Clause 52.212-4*. Any indemnification language indemnifying the Contractor of any liability and governing law language in the Contractor's terms and conditions shall be null and void in this order. Any additional terms and conditions shall not be prohibited by applicable laws and regulations. Any additional terms and conditions identified with a web link and/or incorporated by reference shall be null and void.

10.0 Language for Insertion in Acquisition Documentations Based on the Change to Disable Macros in Microsoft Office Documents from Outside Sources

The offeror or applicant shall submit all electronic documents for Microsoft Office suite products without the use of "macros". If the offeror or applicant submits documents that contain macros the Government will not be able to view or open such documents and the submission will be considered non-responsive to the solicitation. No additional time will be given to an offeror or applicant to correct the document submission and the Government will not inform the offeror or applicant that their submission is non-responsive prior to award. It is the offeror's or applicant's responsibility to ensure all electronic documents are submitted without the use of macros.

52.223-99 Ensuring Adequate COVID-19 Safety Protocols for Federal Contractors.

ENSURING ADEQUATE COVID-19 SAFETY PROTOCOLS FOR FEDERAL CONTRACTORS (OCT 2021) (DEVIATION)

(a) *Definition.* As used in this clause - *United States or its outlying areas means—*

- (1) The fifty States;
- (2) The District of Columbia;
- (3) The commonwealths of Puerto Rico and the Northern Mariana Islands;
- (4) The territories of American Samoa, Guam, and the United States Virgin Islands; and
- (5) The minor outlying islands of Baker Island, Howland Island, Jarvis Island, Johnston Atoll, Kingman Reef, Midway Islands, Navassa Island, Palmyra Atoll, and Wake Atoll.

(b) *Authority.* This clause implements Executive Order 14042, Ensuring Adequate COVID Safety Protocols for Federal Contractors, dated September 9, 2021 (published in the Federal Register on September 14, 2021, 86 FR 50985).

(c) *Compliance.* The Contractor shall comply with all guidance, including guidance conveyed through Frequently Asked Questions, as amended during the performance of this contract, for contractor or subcontractor workplace locations published by the Safer Federal Workforce Task Force (Task Force Guidance) at <https://www.saferfederalworkforce.gov/contractors/>.

(d) *Subcontracts.* The Contractor shall include the substance of this clause, including this paragraph (d), in subcontracts at any tier that exceed the simplified acquisition threshold, as defined in Federal Acquisition Regulation 2.101 on the date of subcontract award, and are for services, including construction, performed in whole or in part within the United States or its outlying areas.

GOVERNMENT HOLIDAYS

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

- | | |
|-----------------------------------|--------------------|
| (1) New Year's Day | (11) Christmas 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 | |

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

352.232-71 As prescribed in HHSAR 332.7003, use the following clause:

Electronic Submission of Payment Requests

(a) Definitions. As used in this clause-

Payment request means a bill, voucher, invoice, or request for contract financing payment with associated supporting documentation. The payment request shall comply with the requirements identified in FAR 32.905(b), "Content of Invoices" and the applicable Payment clause included in this contract.

(b) Except as provided in paragraph (c) of this clause, the Contractor shall submit payment requests electronically using the Department of Treasury Invoice Processing Platform (IPP) or successor system. Information regarding IPP, including IPP Customer Support contact information, is available at www.ipp.gov or any successor site.

(c) The Contractor may submit payment requests using other than IPP only when the Contracting Officer authorizes alternate procedures in writing in accordance with HHS procedures.

(d) If alternate payment procedures are authorized, the Contractor shall include a copy of the Contracting Officer's written authorization with each payment request.

FDA Electronic Invoicing and Payment Requirements - Invoice Processing Platform (IPP) (Jan 2022)

a. All Invoice submissions for goods and or services shall be made electronically through the U.S. Department of Treasury's Invoice Processing Platform System (IPP).

<http://www.ipp.gov/vendors/index.htm>

b. Invoice Submission for Payment means any request for contract financing payment or invoice payment by the Contractor. To constitute a proper invoice, the payment request shall comply with the requirements identified in FAR 32.905(b), "Content of Invoices" and the applicable Payment clause included in this contract, or the clause 52.212-4 Contract Terms and Conditions - Commercial Items included in commercial items contracts. The IPP website address is: <https://www.ipp.gov>

c.

1. The Agency will enroll the Contractors new to IPP. The Contractor shall follow the IPP registration email instructions for enrollment to register the Collector Account for submitting invoice requests for payment. The Contractor Government Business Point of Contact (as listed in SAM) will receive Registration email from the Federal Reserve Bank of St. Louis (FRBSTL) within 3 - 5 business days of the contract award for new contracts or date of modification for existing contracts.
2. Registration emails are sent via email from ipp.noreply@mail.eroc.twai.gov. Contractor assistance with enrollment can be obtained by contacting the IPP Production Helpdesk via email to IPPCustomerSupport@fiscal.treasury.gov or phone (866) 973-3131.
3. The Contractor POC will receive two emails from **IPP Customer Support**, the first email contains the initial administrative IPP User ID. The second email, sent within 24 hours of receipt of the first email, contains a temporary password. You shall log in with the temporary password within 30 days.
4. If your company is already registered to use IPP, you will not be required to re-register.
5. If the Contractor is unable to comply with the requirement to use IPP for submitting invoices for payment as authorized by HHSAR 332.7002, a written request shall be submitted to the Contracting Officer to explain the circumstances that require the authorization of alternate payment procedures.

d. Invoices that include time and materials or labor hours Line Items shall include supporting documentation to (1) substantiate the number of labor hours invoiced for each labor category, and (2) substantiate material costs incurred (when applicable).

e. Invoices that include cost-reimbursement Line Items shall be submitted in a format showing expenditures for that month, as well as contract cumulative amounts. At a minimum the following cost information shall be included, in addition to supporting documentation to substantiate costs incurred.

- o Direct Labor - include all persons, listing the person's name, title, number of hours worked, hourly rate, the total cost per person and a total amount for this category;
- o Indirect Costs (i.e., Fringe Benefits, Overhead, General and Administrative, Other Indirects)- show rate, base and total amount;
- o Consultants (if applicable) - include the name, number of days or hours worked, daily or hourly rate, and a total amount per consultant;
- o Travel - include for each airplane or train trip taken the name of the traveler, date of travel, destination, the transportation costs including ground transportation shown separately and the per diem costs. Other travel costs shall also be listed;
- o Subcontractors (if applicable) - include, for each subcontractor, the same data as required for the prime Contractor;

- Other Direct Costs - include a listing of all other direct charges to the contract, i.e., office supplies, telephone, duplication, postage; and
- Fee - amount as allowable in accordance with the Schedule and FAR 52.216-8 if applicable.

f. 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.

g. Payment of invoices will be made based upon acceptance by the Government of the entire task or the tangible product deliverable(s) invoiced. Payments shall be based on the Government certifying that satisfactory services were provided, and the Contractor has certified that labor charges are accurate.

h. If the services are rejected for failure to conform to the technical requirements of the task order, or any other contractually legitimate reason, the Contractor shall not be paid, or shall be paid an amount negotiated by the CO.

i. Payment to the Contractor will not be made for temporary work stoppage due to circumstances beyond the control of U.S. Food and Drug Administration such as acts of God, inclement weather, power outages, and results thereof, or temporary closings of facilities at which Contractor personnel are performing. This may, however, be justification for excusable delays.

j. The Contractor agrees that the submission of an invoice to the Government for payment is a certification that the services for which the Government is being billed, have been delivered in accordance with the hours shown on the invoices, and the services are of the quality required for timely and successful completion of the effort.

k. Questions regarding invoice payments that cannot be resolved by the IPP Helpdesk should be directed to the FDA Employee Resource and Information Center (ERIC) Helpdesk at 301-827-ERIC (3742) or toll-free 866-807-ERIC (3742); or, by email at ERIC@fda.hhs.gov. Refer to the Call-in menu options and follow the phone prompts to dial the option that corresponds to the service that's needed. All ERIC Service Now Tickets will either be responded to or resolved within 48 hours (2 business days) of being received. When emailing, please be sure to include the contract number, invoice number and date of invoice, as well as your name, phone number, and a detailed description of the issue.

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:

(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).
- _x_ (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)).
- _x_ (25) 52.222-3, Convict Labor (June 2003) (E.O. 11755).
- _x_ (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 shall 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:

- Shall 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 shall 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.

11.0 Offeror Instructions and Evaluation

Offeror Instructions

This is a single award acquisition. Please read these instructions carefully. All items required to be included in the quotation as delineated in these instructions shall be provided in Quoter's quotation.

1) Quoters shall submit one (1) copy of their quotation with pricing information using a Pricing Schedule. Quoters' initial quote should contain the Quoters' best terms from a price standpoint. The firm fixed price proposed shall be inclusive of all delivery, shipping, and any other costs associated with meeting all the requirements in this solicitation. The Government requests the Contractor to provide discounts off their established pricing for each line item. All Quoters providing quotations shall clearly state the overall cost to the Government. All quotes shall be valid for 90 days.

Quoters shall submit all applicable terms, conditions, and/or assumptions, if applicable in full text as attachments, appendix, or exhibits. Quoters are advised that additional terms and conditions submitted with their quotations that are in conflict with the terms and conditions of this solicitation may be deemed as technically unacceptable and as such not be considered for award.

2) The quote shall meet all the salient characteristics in order to be considered technically acceptable. If the part/s are different from the brand name part/s, Quoters shall map their part/s to the brand name part/s. Quoters shall submit a separate Technical Quote with a detailed point-by-point description of how the product meets all the salient characteristics of this SOW.

Evaluation Criteria

The Government intends to award a firm-fixed price purchase order resulting from this solicitation to the responsible offeror whose offer conforming to the solicitation. Contractor selection will be based on the lowest price technically acceptable (LPTA) offer that can "meet or exceed" the requirements stated in this solicitation and is deemed price reasonable. The Government reserves the right to award without exchanges with offerors. The Government may 1) reject any or all quotes if such action is in the best interest of the Government; 2) accept other

than the lowest offer; and 3) waive informalities and minor irregularities in offers received. The following factors shall be used to evaluate offers:

- Technical Acceptability: The Government will evaluate the degree to which the quote meets or exceeds the requirements and specifications described in this solicitation. The Offeror's quote shall demonstrate the ability to "meet or exceed" all requirements in this solicitation.
- Total price: Prices quoted shall be evaluated to ensure is the price is fair and reasonable to the Government. The sum of the offeror's proposed prices for all items (inclusive of any delivery, shipping, and any other costs associated) will be the total evaluated price.
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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.sam.gov

All quotes shall be submitted via email to Courtney.Black@FDA.HHS.gov and Michael.Gemmill@fda.hhs.gov and be received by 1:00 PM (1300) on July 26, 2022 to the attention of Courtney Black. Offerors shall ensure the RFQ number is visible in the header of the email.