



August 11, 2020

SUBJECT: Request for Quote FDA-RFQ-1231783

This is a combined synopsis/solicitation for commercial services prepared in accordance with the format in FAR 12.6 as supplemented with FAR 13 and additional information included in this notice. The incorporated provisions and clauses are those in effect through Federal Acquisition Circular (FAC) 2020-07.

THIS ANNOUNCEMENT CONSTITUTES THE ONLY SOLICITATION AND A SEPARATE SOLICITATION WILL NOT BE ISSUED.

The solicitation number for this acquisition is FDA-RFQ-1231783 and is being issued as a Request for Quote (RFQ). The NAICS Code for this solicitation: 334516 (Analytical Laboratory Instrument Manufacturing). This will be awarded as Firm-Fixed Price award. The Government reserves the right to award without discussions if the Contracting Officer determines that the initial offer is providing the Best Value and discussions are not necessary. This is 100% small business set aside.

The U. S Food & Drug Administration (FDA), Office of Acquisitions and Grant Services is requesting quotes to a Brand Name or Equal Pressure-Volume (PV) Loop Catheter System and Controller.

Background:

The Food and Drug Administration (FDA) is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable, and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

The mission of the Center for Devices and Radiological Health (CDRH) is to protect and promote the public health. CDRH assures that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. CDRH provides consumers, patients, their caregivers, and providers with understandable and accessible science-based information about the products FDA oversee. CDRH facilitates medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the U.S.

The Office of Science and Engineering Laboratories (OSEL) supports CDRH's mission of protecting and promoting public health. The OSEL undertakes the highest quality science to provide their customers with the best methods, tools and expertise to:



Ensure readiness for emerging and innovative medical technologies
 Develop appropriate evaluation strategies and testing standards
 Create accessible and understandable public health information and
 Deliver timely and accurate decisions for products across their life cycle.

Within the OSEL, the Division of Applied Mechanics (DAM) participates in the Center's mission of protecting and promoting public health by identifying and using applied mechanics to investigate interactions between medical devices and the human body. The DAM specifically focuses on device issues that involve additive manufacturing, biologically relevant parameters for device and materials, blood damage, computational modeling, device and material mechanical integrity device-fluid interactions, materials durability, transport of heat, drugs, and biological pathogens, and ultrasound power measurements, phantoms and dosimetry.

The DAM seeks to order a Pressure-Volume (PV) Loop Catheter System and Controller system for their Cardiovascular Program. This equipment, which includes two identical PV loop catheters and one control unit, will help the CDRH understand the impact of therapies such as ventricular assist devices (VADs) on patients prior to beginning clinical trials. This pressure-volume loop catheter system being ordered will be able to connect to a control unit to enable real-time PV loop measurements via the admittance technique, a capability that the current program does not currently possess.

This requirement is for a PV Loop Catheter System and Controller to enhance the Cardiovascular Program’s capabilities pertaining to hemodynamic measurements within a mock circulatory loop. Within this system, two identical catheters and a control unit will enable real-time measurements of pressure and absolute volume to study simulated device-patient interactions.

The five to seven French (Fr) straight catheter is connected to a control unit to output pressure readings, left ventricular volume, phase and magnitude. Being able to make these real-time measurements using the admittance technique is a capability that the program currently does not possess. The PV loop catheter system will also enhance the Center’s scientific capabilities and support efforts to effectively evaluate emerging technologies in the cardiovascular space. The features of this requested PV loop catheter system will enhance the Center’s scientific capabilities and support efforts to effectively evaluate emerging technologies in VADs and other cardiovascular medical devices.

*****BRAND NAME OR EQUAL*****

1) STATEMENT OF WORK SPECIFICATIONS

The Contractor shall indicate if the minimum salient characteristics have been met to be considered responsive for this requirement.



- 2.1.1 The Pressure-Volume Loop Catheter System and Controller shall have the following minimum technical specifications:
- Controller Shall be brand name or equal to Transonic Scisense ADV500 PV System for Large Animals, V.5.0 (Cat #FFS-097-A004)
 - Characterize the hemodynamics in a mock circulatory loop.
 - Measure pressure and volumetric changes of the left ventricle in real-time.
 - Assess simulated heart failure conditions in a pre-clinical setting.
 - Evaluate the interactions between physiological flows and cardiovascular devices.

The features of the requested PV loop catheter system shall enhance the Center's scientific capabilities and support efforts to effectively evaluate emerging technologies in VADs and other cardiovascular medical devices.

- 2.1.2 The two ea. identical catheters provide real-time measurements of pressure and volume using the admittance technique. Each catheter shall have the following minimum technical specifications

2.1.3 Minimum Technical specifications of each catheter for the new system shall be:

- Two ea. (2) identical Pressure-Volume (PV) loop catheters and control unit will be included
- Two ea. (2) Catheters shall be brand name or equal to Transonic 5.0F VSL Straight PV Catheter, Large Animals, No lumen, R1 Series, HDMI, 70-100 mm (Cat #FDH-5018B-E545D)
- Catheter diameter shall be 5 – 7 Fr
- Catheter shall be insertable into a mock ventricle through the ventricular wall
- Catheter uses the admittance technique based on the resistive and capacitive properties of blood and muscle surrogates to determine volume
- Catheter does not require hypertonic saline injection to determine parallel conductance
- Catheter shall be capable of using the conductance volumetry technique
- Catheter measures blood analog volume, ventricular pressure, phase and magnitude in real time
- System shall be able to measure the End-Systolic PV Relationship (ESPVR) and the End-Diastolic PV Relationship (EDPVR)
- The catheter shall have at least 4 segment lengths spanning a range of ventricle sizes
- Electrode spacing (sensing length) shall be 70, 80, 90 & 100 mm
- The total effective length of the of the catheter shall have a range encompassing 95 to 115 mm to fit within the mock ventricle
- Catheter length shall be at least 40"
- Catheter tip type shall be straight tip
- Catheter connects to a control unit via an HDMI connection



- p) Control unit has five analog outputs, including 2 pressure measurements, absolute volume, phase and magnitude
- q) Pressure output range spans at least -75 mmHg to 275 mmHg
- r) Catheter measures maximum ventricular volumes up to at least 350 mL
- s) System shall be capable of making measurements for stroke volumes ranging from 40 – 110 mL/beat
- t) Compatible with PowerLab Data Acquisition System hardware and LabChart Pro software.

2.2 Warranty:

The following calibration, delivery, and warranty and technical support must be satisfied by the Vendor:

- a) Catheters shall be factory calibrated by the manufacturer
- b) Shipping shall be included in pricing
- c) Delivery shall occur within 60 days of the order being awarded
- d) Shall have at least a 3-month warranty from the date of acceptance that the catheters are free from defects not caused by misuse
- e) Shall include standard 1-year warranty from the date of acceptance of hardware accessories
- f) One-year Warranty Period shall include Recalibrations upon request at no additional charge
- g) Online or telephone technical support for at least 1 year for all equipment.

The Vendor shall include one-year Period of Warranty for hardware accessories associated with the system and a 3-month warranty on the catheters at no additional cost. No option years will be required for this requisition. There is no software requested for this requirement, and the Vendor shall not be required to come onsite for training of software.

The Vendor shall also demonstrate a well-documented customer base, preferably in the US and for government facilities, within at least the last three years. A reference list of independent users should be provided by the Vendor upon request. Pricing shall include all applicable fees including shipping and handling.

NOTE to Contractor/Vendor: Before the order is awarded, FDA is required to get Pre-Approval of all the IT Hardware and/or Software-Firmware-Freeware from the FDA Chief Information Officer (CIO). For IT Hardware, this includes any device that process or stores data or controlled by data (computers/data switches, etc..) but does not include passive hardware (rack, network cables, power supplies/cords). This shall require the applicable contractor to provide a complete list of Hardware and/or Software-Firmware-Freeware that the contractor will use in fulfilling this order.

This list shall include: IT hardware: Manufacture, nomenclature and model number
Software (all types): Manufacture, nomenclature and version number
Item(s) rejected by the CIO will need to be changed and the replacement item(s) would need to go through the same approval process.



Deliverables will conform to 36 CFR Part 1194.41, "Information, Documentation and Support," and 36 CFR Part 1194.24 "Video and Multimedia Products" which are of particular importance with regard to all written, graphical or broadcast, video materials or products produced for HHS (to include training). 36 CFR Part 1194.41 outlines the requirements supporting services for products accommodating the communication needs of end-users with disabilities. The deliverables will be provided in Microsoft Word and Adobe PDF formats and compatible with versions currently used at FDA. C.A. Section 508.

This language is applicable to Statements of Work (SOW) or Performance Work Statements (PWS) generated by the Department of Health and Human Services (HHS) that require a contractor or consultant to (1) produce content in any format that could be placed on a Department-owned or Department-funded Web site; or (2) write, create or produce any communications materials intended for public or internal use; to include reports, documents, charts, posters, presentations (such as Microsoft PowerPoint) or video material that could be placed on a Department-owned or Department-funded Web site.

2.4 Other Requirements:

1. All items shall be newly manufactured unit, not used or refurbished, or previously used for demonstration. The instrument shall meet all the technical and hardware specifications specified.

Section 3: Delivery, Acceptance and Period of Performance

3.1 Assembly and Delivery Requirements

- a) Critical need by dates for award and/or delivery: within 60 days of the award.
- b) Quote shall include system installation, system calibration (after installation), and must include all shipping and handling cost.
- c) The Vendor shall deliver this purchase order as follows:

Deliverables and schedule shall be coordinated by the Technical Point of Contact (TPOC). Completion of all deliverables, quality and timeliness of delivery, as well as incidents and types of defects, will be used to evaluate the Vendor's progress and suitability.

- d) The Government will accept goods and services only if they conform to all terms and conditions of the order and satisfy the performance standards detailed.
- e) The Vendor shall provide on-site installation of the system and/or the system shall come assembled. This installation should occur at least within three months of product delivery barring extenuating circumstances (e.g. a pandemic situation). If extenuating circumstances (e.g. a pandemic situation) are present during the above-mentioned three-month timeframe, then the U.S. FDA and Vendor shall negotiate a new appropriate timeframe in which installation shall occur.



- f) The system shall come with all components needed to be fully operational and meet all statement of work characteristics promptly after the initial installation.

- g) The Vendor shall have at least a decade of experience and have a proven track record of system quality, designed system safety, and excellent customer service.

The item(s) are to be delivered to:

U.S. Food and Drug Administration's
Attention: TBD
U.S. Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Office of Science and Engineering Laboratories (OSEL)
Division of Applied Mechanics (DAM)
10903 New Hampshire Ave
WO 62 RM 2108 HFZ-170
Silver Spring, MD 20993

If the vendor is not installing on the day of delivery, the delivery should be made to the loading dock and moved into location on the date of installation. The vendor is responsible for installation of the instrument. Delivery hours are 10AM-4PM, Monday-Friday.

FOB: Destination Inspection/Acceptance: Destination

Delivery and installation shall be made within 60 days of the award. If the offeror is not installing on the day of delivery, the delivery should be made to the loading dock and moved into location on the date of installation. The offeror is responsible for installation of the instrument.

3.2 Inspection and Acceptance:

- a) Acceptance: The vendor shall demonstrate upon installation that the item shall meet all performance specifications described by the instrument manufacturer. The instrument will not be accepted until those performance specifications have been met.
- b) The Technical Point of Contact (TPOC) will perform inspection and acceptance of the mass spectrometer system.
- c) Inspection and acceptance will be performed at the FDA location
- d) Acceptance is communicated in writing unless otherwise indicated in writing by the Contracting Officer or TPOC within 30 days of receipt

3.3 Performance Period:

The Offeror shall deliver the item within 60 days of award.



4. Pricing Schedule:

The Offeror shall submit a fixed price, including details of all costs supporting the price for the requested items/services.

The Offeror shall complete the pricing chart below. Pricing shall include all applicable fees including shipping and handling. Any charges presented after order award shall not be acceptable.

Line Item	Description	Qty.	Unit Price	Price
1				
	Pressure-Volume (PV) Loop Catheter System and Controller	1 EA		\$
	Shipping	1 EA		\$
	Installation & Training	1 EA		\$
GRAND TOTAL PRICE				\$

Pricing should be outlined as shown above.

NOTE: ONLY ONE PRICE SUMMARY REPORT AND AGREGATE TOTAL WILL BE CONSIDERED FOR EVALUATION/AWARD WITH ALL PROPOSED PRICING ASSOCIATED WITH THE RFQ REQUIREMENTS. NO ADDITIONAL PRICING SCHEDULES WILL BE EVALUATED BY THE GOVERNMENT.

- a) The Contractor’s quotation shall include: All items requested or none.
- b) Contractors are required to fill in the above pricing table
- c) Contractor shall show any pricing related to labor hours, materials associated with providing design, delivery and installation.
- d) Offerors shall submit a complete schedule of prices and a single summary total amount shall be furnished for the entire requirement.
- e) The quotation shall contain sufficient information to allow the Government to perform a basic analysis of the proposed price of the work.

5. GOVERNMENT HOLIDAYS

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

- | | |
|-----------------------------------|----------------------|
| (1) New Year's Day | (6) Labor Day |
| (2) Martin Luther King's Birthday | (7) Columbus Day |
| (3) President’s Day | (8) Veterans' Day |
| (4) Memorial Day | (9) Thanksgiving Day |
| (5) Independence Day | (10) 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 will not be able to perform on-site under this order with FDA on holidays set forth above. The Contractor will 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 order.

6. EVALUATION AND AWARD:

Lowest Priced, Technically Acceptable (LPTA)

7. INSTRUCTION TO VENDORS:

1. The Vendor shall complete the Price Breakdown above.
2. Deadline for questions: August 21, 2020 at 11 AM Eastern Time, no phone calls will be accepted. Email questions to: sarah.hussain@fda.hhs.gov
3. Offer due date/local time: August 27, 2020 at 12:00 PM Eastern Time. Email quotes to sarah.hussain@fda.hhs.gov
4. Quote submission format:

*****Quote shall be in 2 volumes: 1 Technical and 2 Price. The volumes shall be separate and complete. The volumes shall be separate and complete, so that evaluation of one may be accomplished independently of, and concurrently with, the evaluation of the other. No pricing information shall be provided in volume 1.*****

The total number of pages for the technical quote shall not exceed ten (10) pages, using 1" margins, single spaced, font type Time New Roman, and a font size of 12.

*****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.***

CONTRACTING POINT OF CONTACT:

Sarah Hussain, Contract Specialist
4041 Powder Mill Road
Beltsville, MD 20705
Email: sarah.hussain@fda.hhs.gov

8. FDA Invoice Submission Instructions.

FDA Three-Way Match Invoicing Procedures

A. The contractor shall submit all invoices to:

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 Technical Point of Contact (TPOC).

B. Invoices submitted under this contract must 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 must 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 award item number 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 (must 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 TPOC, 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;

(xiii) Any other information or documentation required by the award.

C. An electronic invoice is acceptable if submitted in Adobe Acrobat (PDF) format. All items listed in (i) through (xiii) of this clause must be included in the electronic invoice. Electronic invoices must be on company letterhead and must contain no ink changes and be legible for printing.



D. Questions regarding invoice payments should be directed to the 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.

9. PROVISIONS and CLAUSES:

The Full text of the Federal Acquisition Regulation (FAR) can be accessed on the internet at <https://www.acquisition.gov/far/>

Section 508 Standards are applicable to this requirement. Electronic and Information Technology (EIT) developed, procured, or maintained for used by federal agencies by a contractor must comply with the standards and regulations. Standards are organized into four subparts:

Subpart A – General (36 CFR §§ 1194.1-1194.5): Describes the types of covered technologies and applications, explains what is exempt, defines terminology, and recognizes that acceptable alternatives that provide equivalent access to and use of a product for people with disabilities are permissible.

Subpart B –Technical Standards (36 CFR § 1194.21-1194.26): Provides criteria specific to various types of technologies and provides performance-based requirements for systems and applications.

- i) Software applications and operating systems (36 CFR § 1194.21)
- ii) Web-based intranet and internet information and applications (1194.22)
- iii) Telecommunications products (36 CFR § 1194.23)
- iv) Video and multimedia products (36 CFR § 1194.24)
- v) Self- contained, closed products (36 CFR § 1194.25)
- vi) Desktop and portable computers (36 CFR § 1194.26)

Subpart C – Functional Performance Criteria (36 CFR § 1194.31): Provides performance requirements for overall product evaluation and for technologies or components for which there is no specific requirement under the technical standards in Subpart B.

Subpart D –Information, Documentation, and Support (36 CFR § 1194.41): Addresses access to all information, documentation, and support provided to end-users of covered technologies, and identifies formats to be used.

Additional information can be found at website: <http://www.hhs.gov/web/section-508/index.html>



52.212-4 Contract Terms and Conditions—Commercial Items (Oct 2018)

52.212-5 Contract Terms and Conditions Required to Implement Statutes or Executive Orders- Commercial Items. (Jul 2020)

(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) [52.204-23](#), Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (JUL 2018) (Section 1634 of Pub. L. 115-91).

(3) [52.204-25](#), Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (AUG 2019) (Section 889(a)(1)(A) of Pub. L. 115-232).

(4) [52.209-10](#), Prohibition on Contracting with Inverted Domestic Corporations (Nov 2015).

(5) [52.233-3](#), Protest After Award (AUG 1996) ([31 U.S.C. 3553](#)).

(6) [52.233-4](#), Applicable Law for Breach of Contract Claim (OCT 2004) (Public Laws 108-77 and 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 (JUNE 2020), with *Alternate I* (OCT 1995) ([41U.S.C.4704](#) and [10 U.S.C. 2402](#)).

___ (2) [52.203-13](#), Contractor Code of Business Ethics and Conduct (JUN 2020) ([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 (JUN 2020) (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. (JUN 2020) ([31 U.S.C. 6101 note](#)).

__ (9) [52.209-9](#), Updates of Publicly Available Information Regarding Responsibility Matters (OCT 2018) ([41 U.S.C. 2313](#)).

__ (10) [Reserved].

__ (11) (i) [52.219-3](#), Notice of HUBZone Set-Aside or Sole-Source Award (MAR 2020) ([15 U.S.C. 657a](#)).

__ (ii) Alternate I (MAR 2020) of [52.219-3](#).

__ (12) (i) [52.219-4](#), Notice of Price Evaluation Preference for HUBZone Small Business Concerns (MAR 2020) (if the offeror elects to waive the preference, it shall so indicate in its offer) ([15 U.S.C. 657a](#)).

__ (ii) Alternate I (MAR 2020) of [52.219-4](#).

__ (13) [Reserved]

(14) (i) [52.219-6](#), Notice of Total Small Business Set-Aside (MAR 2020) of [52.219-6](#) ([15 U.S.C. 644](#)).

__ (ii) Alternate I (MAR 2020) of [52.219-6](#).

__ (15) (i) [52.219-7](#), Notice of Partial Small Business Set-Aside (MAR 2020) ([15 U.S.C. 644](#)).

__ (ii) Alternate I (MAR 2020) of [52.219-7](#).

__ (16) [52.219-8](#), Utilization of Small Business Concerns (OCT 2018) ([15 U.S.C. 637\(d\)\(2\)](#) and (3)).

__ (17) (i) [52.219-9](#), Small Business Subcontracting Plan (JUN 2020) ([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 (JUN 2020) of [52.219-9](#).
- (v) Alternate IV (JUN 2020) of [52.219-9](#)
- (18) (i) [52.219-13](#), Notice of Set-Aside of Orders (MAR 2020) ([15 U.S.C. 644\(r\)](#)).
- (ii) Alternate I (MAR 2020) of [52.219-13](#).
- (19) [52.219-14](#), Limitations on Subcontracting (MAR 2020) ([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 (MAR 2020) ([15 U.S.C. 657f](#)).
- (22) (i) [52.219-28](#), Post Award Small Business Program Rerepresentation (MAY 2020) ([15 U.S.C. 632\(a\)\(2\)](#)).
- (ii) Alternate I (MAR 2020) of [52.219-28](#).
- (23) [52.219-29](#), Notice of Set-Aside for, or Sole Source Award to, Economically Disadvantaged Women-Owned Small Business Concerns (MAR 2020) ([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 (Mar2020) ([15 U.S.C. 637\(m\)](#)).
- (25) [52.219-32](#), Orders Issued Directly Under Small Business Reserves (MAR 2020) ([15 U.S.C. 644\(r\)](#)).
- (26) [52.219-33](#), Nonmanufacturer Rule (MAR 2020) ([15U.S.C. 637\(a\)\(17\)](#)).
- (27) [52.222-3](#), Convict Labor (JUN 2003) (E.O.11755).
- (28) [52.222-19](#), Child Labor-Cooperation with Authorities and Remedies (JAN2020) (E.O.13126).
- (29) [52.222-21](#), Prohibition of Segregated Facilities (APR 2015).
- (30) (i) [52.222-26](#), Equal Opportunity (SEP 2016) (E.O.11246).



___ (ii) Alternate I (FEB 1999) of [52.222-26](#).

___ (31) (i) [52.222-35](#), Equal Opportunity for Veterans (JUN 2020) ([38 U.S.C. 4212](#)).

___ (ii) Alternate I (JUL 2014) of [52.222-35](#).

x (32) (i) [52.222-36](#), Equal Opportunity for Workers with Disabilities (JUN 2020) ([29 U.S.C. 793](#)).

___ (ii) Alternate I (JUL 2014) of [52.222-36](#).

x (33) [52.222-37](#), Employment Reports on Veterans (JUN 2020) ([38 U.S.C. 4212](#)).

x (34) [52.222-40](#), Notification of Employee Rights Under the National Labor Relations Act (DEC 2010) (E.O. 13496).

x (35)(i) [52.222-50](#), Combating Trafficking in Persons (JAN 2019) ([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).

___ (36) [52.222-54](#), Employment Eligibility Verification (OCT 2015). (Executive Order 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](#).)

___ (37) (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.)

___ (38) [52.223-11](#), Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (JUN 2016) (E.O. 13693).

___ (39) [52.223-12](#), Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (JUN 2016) (E.O. 13693).

___ (40) (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](#).

___ (41)(i) [52.223-14](#), Acquisition of EPEAT®-Registered Televisions (JUN 2014) (E.O.s 13423 and 13514).



__ (ii) Alternate I (Jun2014) of [52.223-14](#).

__ (42) [52.223-15](#), Energy Efficiency in Energy-Consuming Products (MAY 2020) ([42 U.S.C. 8259b](#)).

__ (43)(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](#).

x (44) [52.223-18](#), Encouraging Contractor Policies to Ban Text Messaging While Driving (JUN 2020) (E.O. 13513).

__ (45) [52.223-20](#), Aerosols (JUN 2016) (E.O. 13693).

__ (46) [52.223-21](#), Foams (Jun2016) (E.O. 13693).

__ (47)(i) [52.224-3](#) Privacy Training (JAN 2017) (5 U.S.C. 552 a).

__ (ii) Alternate I (JAN 2017) of [52.224-3](#).

x (48) [52.225-1](#), Buy American-Supplies (May 2014) ([41 U.S.C. chapter 83](#)).

__ (49) (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](#).

__ (50) [52.225-5](#), Trade Agreements (Oct 2019) ([19 U.S.C. 2501](#), *et seq.*, [19 U.S.C. 3301](#) note).

x (51) [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).

__ (52) [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. 2302Note](#)).



___ (53) [52.226-4](#), Notice of Disaster or Emergency Area Set-Aside (Nov2007) ([42 U.S.C. 5150](#)).

___ (54) [52.226-5](#), Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov2007) ([42 U.S.C. 5150](#)).

___ (55) [52.229-12](#), Tax on Certain Foreign Procurements (JUN 2020).

___ (56) [52.232-29](#), Terms for Financing of Purchases of Commercial Items (FEB 2002) ([41 U.S.C. 4505](#), [10 U.S.C. 2307\(f\)](#)).

___ (57) [52.232-30](#), Installment Payments for Commercial Items (Jan2017) ([41 U.S.C. 4505](#), [10 U.S.C. 2307\(f\)](#)).

x (58) [52.232-33](#), Payment by Electronic Funds Transfer-System for Award Management (Oct2018) ([31 U.S.C. 3332](#)).

___ (59) [52.232-34](#), Payment by Electronic Funds Transfer-Other than System for Award Management (Jul 2013) ([31 U.S.C. 3332](#)).

___ (60) [52.232-36](#), Payment by Third Party (MAY 2014) ([31 U.S.C. 3332](#)).

___ (61) [52.239-1](#), Privacy or Security Safeguards (AUG 1996) ([5 U.S.C. 552a](#)).

___ (62) [52.242-5](#), Payments to Small Business Subcontractors (JAN 2017) ([15 U.S.C. 637\(d\)\(13\)](#)).

___ (63) (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](#).

___ (iii) Alternate II (FEB 2006) 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) [52.222-41](#), Service Contract Labor Standards (AUG 2018) ([41 U.S.C. chapter67](#)).

___ (2) [52.222-42](#), Statement of Equivalent Rates for Federal Hires (MAY 2014) ([29 U.S.C. 206](#) and [41 U.S.C. chapter 67](#)).



___ (3) [52.222-43](#), Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (Multiple Year and Option Contracts) (AUG 2018) ([29 U.S.C. 206](#) and [41 U.S.C. chapter 67](#)).

___ (4) [52.222-44](#), Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (May 2014) ([29U.S.C.206](#) and [41 U.S.C. chapter 67](#)).

___ (5) [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](#)).

___ (6) [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](#)).

___ (7) [52.222-55](#), Minimum Wages Under Executive Order 13658 (DEC 2015).

___ (8) [52.222-62](#), Paid Sick Leave Under Executive Order 13706 (JAN 2017) (E.O. 13706).

___ (9) [52.226-6](#), Promoting Excess Food Donation to Nonprofit Organizations (Jun 2020) ([42 U.S.C. 1792](#)).

(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, as defined in FAR [2.101](#), on the date of award of this contract, 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 (JUN 2020) ([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) [52.204-23](#), Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (JUL 2018) (Section 1634 of Pub. L. 115-91).

(iv) [52.204-25](#), Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (AUG 2019) (Section 889(a)(1)(A) of Pub. L. 115-232).

(v) [52.219-8](#), Utilization of Small Business Concerns (OCT 2018) ([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 the applicable threshold specified in FAR [19.702\(a\)](#) on the date of subcontract award, the subcontractor must include [52.219-8](#) in lower tier subcontracts that offer subcontracting opportunities.

(vi) [52.222-21](#), Prohibition of Segregated Facilities (APR 2015).

(vii) [52.222-26](#), Equal Opportunity (SEP 2015) (E.O.11246).

(viii) [52.222-35](#), Equal Opportunity for Veterans (JUN 2020) ([38 U.S.C. 4212](#)).

(ix) [52.222-36](#), Equal Opportunity for Workers with Disabilities (JUN 2020) ([29 U.S.C. 793](#)).

(x) [52.222-37](#), Employment Reports on Veterans (JUN 2020) ([38 U.S.C. 4212](#)).

(xi) [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](#).

(xii) [52.222-41](#), Service Contract Labor Standards (Aug2018) ([41 U.S.C. chapter 67](#)).



(xiii)(A) [52.222-50](#), Combating Trafficking in Persons (JAN 2019) ([22 U.S.C. chapter 78](#) and E.O 13627).

(B) Alternate I (Mar2015) of [52.222-50](#) ([22 U.S.C. chapter 78](#) and [E.O. 13627](#)).

(xiv) [52.222-51](#), Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May2014) ([41 U.S.C. chapter 67](#)).

(xv) [52.222-53](#), Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (MAY2014) ([41 U.S.C. chapter 67](#)).

(xvi) [52.222-54](#), Employment Eligibility Verification (OCT 2015) (E.O. 12989).

(xvii) [52.222-55](#), Minimum Wages Under Executive Order 13658 (DEC 2015).

(xviii) [52.222-62](#), Paid Sick Leave Under Executive Order 13706 (JAN 2017) (E.O. 13706).

(xix)(A) [52.224-3](#), Privacy Training (Jan 2017) ([5 U.S.C. 552a](#)).

(B) Alternate I (JAN 2017) of [52.224-3](#).

(xx) [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](#)).

(xxi) [52.226-6](#), Promoting Excess Food Donation to Nonprofit Organizations (JUN 2020) ([42 U.S.C. 1792](#)). Flow down required in accordance with paragraph (e) of FAR clause [52.226-6](#).

(xxii) [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.

(End of clause)

52.232-40 - Providing Accelerated Payments to Small Business Subcontractors (Dec 2013)

52.217-8 -- Option to Extend Services. Option to Extend Services (Nov 1999)

The Government may require continued performance of any services within the limits and at



the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 6 months. The Contracting Officer may exercise the option by written notice to the Contractor within 1 day.

HHSAR 352.222-70 Contractor Cooperation in Equal Employment Opportunity Investigations. (Dec 2015)

HHSAR 352.239-74 Electronic and Information Technology Accessibility. (Dec 2015)

HHSAR 352.223-70 Safety and Health (Dec 2015)

Provisions:

FAR 52.252-1.Solicitation Provisions Incorporated by Reference (Feb 1998).

This solicitation incorporates one or more solicitation provisions 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 offeror is cautioned that the listed provisions may include blocks that shall be completed by the offeror and submitted with the proposal. In lieu of submitting the full text of those provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with the proposal. Also, the full text of a solicitation provision may be accessed electronically at this address: www.acquisition.gov/far/index.html.

FAR 52.212-3 Offeror Representations and Certifications - Commercial Items (June 2020) applies to this acquisition.

FAR 52.211-6 Brand Name or Equal (Aug 1999)

The offeror shall complete only paragraphs (b) of this provision if the Offeror has completed the annual representations and certification electronically via the System for Award Management (SAM) Web site accessed through <http://www.acquisition.gov> . If the Offeror has not completed the annual representations and certifications electronically, the Offeror shall complete only paragraphs (c) through (p) of this provision.

Offerors that fail to complete the required representations and certifications, or reject the terms and conditions of the solicitation, may be excluded from award consideration.

Parties responding to this solicitation may submit their offer 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) Vendors shall meet



specifications as noted in the synopsis. Note: Contractor shall be registered and active in the System for Award Management (SAM) prior to the award of a order. You may register by going to www.sam.gov.