

SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS OFFEROR TO COMPLETE BLOCKS 12, 17, 23, 24, & 30				1. REQUISITION NO. 770-17-2-830-0014		PAGE 1 OF 72	
2. CONTRACT NO.		3. AWARD/EFFECTIVE DATE		4. ORDER NO.		5. SOLICITATION NUMBER VA770-17-Q-0221	
6. SOLICITATION ISSUE DATE 03-10-2017		7. FOR SOLICITATION INFORMATION CALL:		a. NAME Reed, Doug		b. TELEPHONE NO. (No Collect Calls) 913-375-8670	
8. OFFER DUE DATE/LOCAL TIME 04-28-2017 10:00AM CST		9. ISSUED BY Department of Veterans Affairs National CMOP 3450 S. 4th St. Trafficway Leavenworth KS 66048-5581		CODE 36C770		10. THIS ACQUISITION IS <input checked="" type="checkbox"/> UNRESTRICTED OR <input type="checkbox"/> SET ASIDE: _____ % FOR: <input checked="" type="checkbox"/> SMALL BUSINESS <input type="checkbox"/> WOMEN-OWNED SMALL BUSINESS (WOSB) ELIGIBLE UNDER THE WOMEN-OWNED SMALL BUSINESS PROGRAM NAICS: 541380 <input type="checkbox"/> HUBZONE SMALL BUSINESS <input type="checkbox"/> EDWOSB <input type="checkbox"/> SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESS <input type="checkbox"/> 8(A) SIZE STANDARD: \$15 Million	
11. DELIVERY FOR FOB DESTINATION UNLESS BLOCK IS MARKED <input checked="" type="checkbox"/> SEE SCHEDULE		12. DISCOUNT TERMS		<input type="checkbox"/> 13a. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)		13b. RATING N/A	
14. METHOD OF SOLICITATION <input checked="" type="checkbox"/> RFQ <input type="checkbox"/> IFB <input type="checkbox"/> RFP		15. DELIVER TO See B.6 (Delivery Schedule)		CODE 36C770		16. ADMINISTERED BY Department of Veterans Affairs National CMOP 3450 S. 4th St. Trafficway Leavenworth KS 66048-5581	
17a. CONTRACTOR/OFFEROR CODE		FACILITY CODE		18a. PAYMENT WILL BE MADE BY http://www.fsc.va.gov/einvoice.asp Department of Veterans Affairs FSC PO Box 149971 Austin TX 78714-8971 PHONE: FAX:		CODE	
TELEPHONE NO.		DUNS:		DUNS+4:		18b. SUBMIT INVOICES TO ADDRESS SHOWN IN BLOCK 18a UNLESS BLOCK BELOW IS CHECKED <input type="checkbox"/> SEE ADDENDUM	
<input type="checkbox"/> 17b. CHECK IF REMITTANCE IS DIFFERENT AND PUT SUCH ADDRESS IN OFFER		19. ITEM NO.		20. See CONTINUATION Page SCHEDULE OF SUPPLIES/SERVICES		21. QUANTITY	
		22. UNIT		23. UNIT PRICE		24. AMOUNT	
		Description of Services: Contractor shall conduct temperature study simulating extreme transit conditions for National CMOP in accordance with terms and conditions of the solicitation. Offerors shall be registered and active at the System for Award Management (SAM) at https://www.sam.gov at time of offer to the Government. Offers are due by due date/time specified in Block 8 of Standard Form (SF) 1449 of solicitation. Specific instructions to offerors are listed in Section E.1 (m) of solicitation. Technical questions are due by due date/time cited in Section E.1 (m). Evaluation factors are listed in Section E.6 of solicitation. (Use Reverse and/or Attach Additional Sheets as Necessary)					
25. ACCOUNTING AND APPROPRIATION DATA 770-3670160-830-822400-2580 010022480		26. TOTAL AWARD AMOUNT (For Govt. Use Only)					
<input checked="" type="checkbox"/> 27a. SOLICITATION INCORPORATES BY REFERENCE FAR 52.212-1, 52.212-4. FAR 52.212-3 AND 52.212-5 ARE ATTACHED. ADDENDA		<input checked="" type="checkbox"/> ARE <input type="checkbox"/> ARE NOT ATTACHED.					
<input type="checkbox"/> 27b. CONTRACT/PURCHASE ORDER INCORPORATES BY REFERENCE FAR 52.212-4. FAR 52.212-5 IS ATTACHED. ADDENDA		<input type="checkbox"/> ARE <input type="checkbox"/> ARE NOT ATTACHED					
<input checked="" type="checkbox"/> 28. CONTRACTOR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN <u>1</u> COPIES TO ISSUING OFFICE. CONTRACTOR AGREES TO FURNISH AND DELIVER ALL ITEMS SET FORTH OR OTHERWISE IDENTIFIED ABOVE AND ON ANY ADDITIONAL SHEETS SUBJECT TO THE TERMS AND CONDITIONS SPECIFIED		<input type="checkbox"/> 29. AWARD OF CONTRACT: REF. _____ OFFER DATED _____ YOUR OFFER ON SOLICITATION (BLOCK 5), INCLUDING ANY ADDITIONS OR CHANGES WHICH ARE SET FORTH HEREIN IS ACCEPTED AS TO ITEMS:					
30a. SIGNATURE OF OFFEROR/CONTRACTOR		31a. UNITED STATES OF AMERICA (SIGNATURE OF CONTRACTING OFFICER)					
30b. NAME AND TITLE OF SIGNER (TYPE OR PRINT)		30c. DATE SIGNED		31b. NAME OF CONTRACTING OFFICER (TYPE OR PRINT) Douglas H. Reed Contracting Officer		31c. DATE SIGNED	

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SECTION B - CONTINUATION OF SF 1449 BLOCKS

B.1 CONTRACT ADMINISTRATION DATA

(continuation from Standard Form 1449, block 18A.)

1. Contract Administration: All contract administration matters will be handled by the following individuals:

a. CONTRACTOR: To be determined

b. GOVERNMENT: Contracting Officer 36C770 Doug Reed, douglas.reed3@va.gov

Department of Veterans Affairs

National CMOP

3450 S. 4th St. Trafficway

Leavenworth KS 66048-5581

2. CONTRACTOR REMITTANCE ADDRESS: All payments by the Government to the Contractor will be made in accordance with:

☒ 52.232-33, Payment by Electronic Funds Transfer— System For Award Management,
or

☐ 52.232-36, Payment by Third Party

3. INVOICES: Invoices shall be submitted in arrears:

a. Quarterly ☐

b. Semi-Annually ☐

c. Other ☒ Monthly; to be paid upon Government acceptance of services.

4. GOVERNMENT INVOICE ADDRESS: All Invoices from the Contractor shall be submitted electronically in accordance with VAAR Clause 852.232-72 Electronic Submission of Payment Requests.

<http://www.fsc.va.gov/einvoice.asp>

Department of Veterans Affairs

FSC

PO Box 149971

Austin TX 78714-8971

B.2 LIMITATIONS ON SUBCONTRACTING-- MONITORING AND COMPLIANCE (JUN 2011)

The Contractor is advised in performing contract administration functions, the CO may use the services of a support Contractor retained by VA to assist in assessing the Contractor's compliance with the limitations on subcontracting or percentage of work performance requirements specified in the clause. To that end, the support Contractor may require access to Contractor's offices where the Contractor's business records or other proprietary data are retained and to review such business records regarding the Contractor's compliance with this requirement. All support Contractors conducting this review on behalf of VA will be required to sign an "Information Protection and Non-Disclosure and Disclosure of Conflicts of Interest Agreement" to ensure the Contractor's business records or other proprietary data reviewed or obtained in the course of assisting the CO in assessing the Contractor for compliance are protected to ensure information or data is not improperly disclosed or other impropriety occurs. Furthermore, if VA determines any services the support Contractor will perform in assessing compliance are advisory and assistance services as defined in FAR 2.101, Definitions, the support Contractor must also enter into an agreement with the Contractor to protect proprietary information as required by FAR 9.505-4, obtaining access to proprietary information, paragraph (b). The Contractor is required to cooperate fully and make available any records as may be required to enable the CO to assess the Contractor's compliance with the limitations on subcontracting or percentage of work performance requirement.

B.3 SUBCONTRACTING COMMITMENTS--MONITORING AND COMPLIANCE (JUN 2011)

The Contractor is advised in performing contract administration functions, the CO may use the services of a support Contractor to assist in assessing Contractor compliance with the subcontracting commitments incorporated into the contract. To that end, the support Contractor(s) may require access to the Contractor's business records or other proprietary data to review such business records regarding contract compliance with this requirement. All support Contractors conducting this review on behalf of VA will be required to sign an "Information Protection and Non-Disclosure and Disclosure of Conflicts of Interest Agreement" to ensure the Contractor's business records or other proprietary data reviewed or obtained in the course of assisting the CO in assessing the Contractor for compliance are protected to ensure information or data is not improperly disclosed or other impropriety occurs. Furthermore, if VA determines any services the support Contractor will perform in assessing compliance are advisory and assistance services as defined in FAR 2.101, Definitions, the support Contractor must also enter into an agreement with the Contractor to protect proprietary information as required by FAR 9.505-4, obtaining access to proprietary information, paragraph (b). The Contractor is required to cooperate fully and make available any records as may be required to enable the CO to assess the Contractor compliance with the subcontracting commitments.

B.4 PERFORMANCE WORK STATEMENT (PWS)

DESCRIPTION OF SERVICE:

National CMOP Temperature Study Simulating Extreme Transit Conditions

PRODUCT SERVICE CODE (PSC)/NAICS INFORMATION:

PSC: H165 (Quality Control Services – Medical, Dental, and Veterinary)

NAICS: 541380 (Testing Laboratories)

BACKGROUND:

The Department of Veterans Affairs (VA) Consolidated Mail Outpatient Pharmacy (CMOP) program serves over 7 million enrolled Veterans, dispensing over 100 million prescriptions per year for VA medical centers (VAMCs) across the country. CMOP utilizes various mail carriers to dispense 100% of those prescriptions through the mail. Insulin and Latanoprost are heat sensitive drugs that risk chemical degradation and stability when exposed to extreme transit conditions.

The VA published an insulin stability study in the past; however, this study did not take into account the exposure of the product to extreme temperatures after the delivery to the Veteran. A study is needed to investigate the chemical degradation and stability of products shipped in non-insulated mailers and insulated containers with frozen gel packs using modified International Safe Transit Association (ISTA) Standards for simulated transit conditions. The test will simulate product exposure to extreme temperatures including the time spent in the Veteran's mailbox. Three types of injectable insulin and Latanoprost products shall be studied: Regular insulin (Novolin R, Novo Nordisk, Princeton, NJ) and two (2) zinc and protamine suspensions (NPH insulin [Novolin NPH, Novo Nordisk] and 70% isophane–30% regular [70/30] insulin [Novolin 70/30, Novo Nordisk]), and Latanoprost 0.005% OPH. A test of the exposed products shall be conducted by an accredited and certified testing laboratory at 30, 60, 90, and 120 days.

PLACE OF PERFORMANCE:

The work shall be performed at the Contractor's location and at no additional cost to the Government.

PERIOD OF PERFORMANCE:

The period of performance shall be 160 calendar days starting from the date of the signed contract. If for any reason a deliverable cannot be delivered as scheduled, the Contractor is required to submit a request for a time extension to the Contracting Officer (CO) and the Technical Point of Contact (TPOC). The request must include the reason(s) for the delay, the impact on the overall project, and the impact on the cost of the project. The CO, upon discussion with the TPOC, will consider each request on the basis of its merits and will, if approved, issue a bilateral modification to the contract. The Contractor is required to proceed as originally scheduled until such modification is issued by the CO.

ROLES AND RESPONSIBILITIES:

Contracting Officer Representative (COR)

Name: James Hinspeter

Phone: 708-786-7541

E-mail: james.hinspeter@va.gov

A COR will be designated on authority of the Contracting Officer to monitor all technical aspects and assist in administering the contract. The types of actions within the purview of the COR's authority are to ensure that Contractor performs the technical requirements of the contract; to perform or cause to be performed inspections necessary in connection with performance of the contracts; to maintain both written and oral communications with the Contractor concerning the aspects of the contract within his/her purview; to issue written interpretations of technical requirements of Government specifications; and to monitor the performance of Contractor under the contract and notify the Contractor and CO of any deficiencies observed.

At no time may the scope, work, price, delivery dates, or other mutually agreed upon terms or provisions of the contract be changed without being executed in writing by the CO via contract modification authorizing such changes.

The COR may be changed at any time by the Government without prior notice to the Contractor, but notification of the change, including the name, phone number, and e-mail address the successor COR, will be promptly provided to the Contractor by the CO in writing.

Contracting Officer (CO)

Name: Doug Reed

Phone: 913-684-0135

E-mail: douglas.reed3@va.gov

All contract administration will be effected by the CO. Communications pertaining to contract administration matters will be addressed to the CO with cc to the TPOC. No changes in or deviation from the scope of work shall be effected without a Standard Form 30 (Modification of Contract) executed by the CO authorizing such changes.

The CO is the only person authorized to make or approve any changes in any of the requirements of the contract; and notwithstanding any provisions contained elsewhere, the said authority remains solely with the CO. In the event Contractor makes any changes at the direction of any person other than the CO, the changes will be considered to have been made without authority and no adjustment will be made in the contract price to cover any increase in costs incurred as a result thereof.

SCOPE OF WORK:

The Contractor shall provide all necessary instrumentation and tools, collect and analyze data, and perform all required tasks to accomplish the deliverables described in this performance work statement (PWS) except as otherwise specified. The Contractor shall have all tools, resources, and capabilities in-house to meet the requirements described herein. The Contractor shall not outsource testing of pharmaceuticals specifically to another organization.

The Contractor shall place sample vials in non-insulated mailers and insulated containers with frozen gel pack(s) to be tested. Packaging must conform to CMOP Packing Standards (Appendix A).

The Contractor shall place temperature monitors inside each of the containers and mailers.

After packaging, sealed containers and mailers shall be placed into an environmental chamber for up to 120 hours while exposed to modified ISTA Standards for extreme summer and winter transit conditions.

The Contractor shall use a 120 hour summer/winter ISTA modified profile to represent extreme temperatures during summer and winter in a mailbox. For the summer profile the last 10 hours will be kept at 60°C (Phoenix) whereas the last 10 hours of the winter profile will be at -20°C (Fargo). Samples shall be tested by an accredited and certified laboratory to analyze the assay at 120 hour, at 30, 60, 90 and 120 days at controlled room temperature (CRT) similar to patient's home temperature. A second test will be conducted simultaneously with samples tested at 60, 90, and 120 days at 4°C controlled cold temperature (CCT) similar to a patient's refrigerator temperature.

The following profile shall be used to simulate a five day Ground Delivery:

120-Hour Modified ISTA Summer Profile:

**+25°C (10 hrs warehouse) ⇒⇒ +45°C (4 hrs mail transfer) ⇒⇒ +30°C (96 hrs transit)
⇒⇒ +60 °C (10 hrs in mailbox)**

120-Hour Modified ISTA Winter Profile:

**+25°C (10 hrs warehouse) ⇒⇒ -10°C (4 hrs mail transfer) ⇒⇒ 0°C (96 hrs transit)
⇒⇒**

-20 °C (10 hrs in mailbox)

The Contractor shall use a 120 hour summer/winter profile to represent extreme temperatures during summer and winter in a mailbox. For the summer profile the last 10 hours will be kept at 60°C (Phoenix) whereas the last 10 hours of the winter profile will be at -20°C (Fargo). Samples shall be tested by an accredited and certified laboratory to analyze the assay at 120 hour, at 30, 60, 90 and 120 days at controlled room temperature (CRT) similar to patient's home temperature. A second test will be conducted simultaneously with samples tested at 60, 90, and 120 days at 4°C controlled cold temperature (CCT) similar to a patient's refrigerator temperature. This experiment will be conducted simultaneously with the 120 hour study using another chamber.

The following profile shall be used to simulate an Overnight Delivery using air transportation:

48-Hour Modified ISTA Summer Profile:

**+25°C (10 hrs warehouse) ⇒⇒ +45°C (4 hrs mail transfer) ⇒⇒ +30°C (24 hrs transit)
⇒⇒ +60 °C (10 hrs doorstep)**

48-Hour Modified ISTA Winter Profile:

**+25°C (10 hrs warehouse) ⇒⇒ -10°C (4 hrs mail transfer) ⇒⇒ +10°C (24 hrs transit)
⇒⇒ -20 °C (10 hrs doorstep)**

The environmental chambers and temperature monitors must be capable of temperature variations between -25°C and +65°C to satisfy the temperature requirements of this study. Temperature chambers must maintain temperature within +/-3°C.

Temperatures inside the environmental chamber and packages shall be recorded every 15 minutes throughout the study.

After exposure to the extreme transit conditions, samples shall be removed from their packaging, visually inspected for changes in physical appearance, and stored at 4°C until analysis. One sample will be left out at (CRT) and tested at the end of 30 days. The remaining products will be tested at 60, 90 and 120 days.

The Contractor shall calculate mean kinetic temperatures (MKTs) using United States Pharmacopeia (USP) formulas and methods.

An accredited and certified laboratory shall perform Size-exclusion chromatography (SEC) and High-performance liquid chromatography (HPLC), and T-Testing on each product sample.

The Contractor shall design detailed graphs and digital imageries that illustrate a comparison of data from control samples, product samples, and references from the United States Pharmacopeia (USP).

The Contractor shall provide an executive summary which shall summarize all findings regarding the chemical degradation and stability of the test samples.

PARTNERING AGREEMENT:

The preference of the Government is to have the Prime Contractor handle all aspects of this requirement, including having an accredited and certified laboratory as specified in this PWS. The Government will consider partnering agreements between a Prime Contractor with no accredited and certified laboratory and an accredited and certified laboratory under the following conditions:

- Product would not be shipped from one site to another while it is undergoing testing; any movement of product that is outside the scope of the PWS would put the product through additional shipping conditions therefore making the results of the study inaccurate.
- Chambers at testing laboratories shall have the ability to perform at the level stated in the PWS and the chambers and lab shall be at same facility.
- CMOP will ship the supplies and drugs directly to the testing facility. The number of drugs to be tested, how they will be tested and the duration of testing shall be done exactly as specified in the PWS.
- A copy of partnering agreement between Prime Contractor and Testing Laboratory shall be included with Offeror proposal; see Section E.1 (m) of solicitation.

KEY PERSONNEL:

Approval of key personnel, as specified in the Contractor's technical proposal, and who will be working on this project, must be obtained from the Government **within five (5) business days** of any change in these key personnel. The Contractor's Project Manager (PM) is key personnel as defined by this section.

GENERAL REQUIREMENTS:

The Contractor shall prepare a detailed Project Management Plan (PMP). For every task, the Contractor shall identify in writing all necessary subtasks (if any), associated costs by tasks, and associated dates.

All written deliverables shall be phrased in layperson language. Statistical and other technical terminology shall not be used without providing a glossary of terms.

The Government shall complete their review of draft deliverables within **5 business days** from date of receipt. The Contractor shall have 5 business days to deliver the final deliverable from date of receipt of the government's comments.

The Contractor shall provide written weekly status updates to report on topics such as: schedule review, risk review, tasks accomplished in the past week; explanation of tasks not accomplished as expected; tasks to be accomplished in the upcoming week.

The Government shall be given the opportunity to send a Representative to the Contractor's facility to observe/witness any of the Deliverables described in Task #3 Pre-Test Setup, Task #4 Simulated Transit Condition, and Task #5 Testing by an Accredited and Certified Laboratory.

PWS DEFINITIONS:

1. *Accreditation*- Verification that laboratories have an appropriate quality management system and can properly perform certain test methods (e.g., ANSI, ASTM, and ISO test methods) and calibration parameters according to their scopes of accreditation.
2. *ANSI* – American National Standards Institute
3. *ASTM* – American Society for Testing and Materials
4. *Certification*- Verification that personnel have adequate credentials to practice certain disciplines, as well as for verifying that products meet certain requirements.
5. *Chemical Degradation*- The change of physical nature of the drug.
6. *Controlled cold temperature*- A temperature maintained thermostatically between 2°C and 8°C (36°F and 46°F).
7. *Controlled room temperature*- A temperature maintained thermostatically that encompasses the usual and customary working environment of 20°C to 25°C (68°F to 77°F).
8. *Drug Stability*- Refers to the chemical and physical integrity of the dosage unit and, when appropriate, the ability of the dosage unit to maintain protection against microbiological contamination.
9. *Environmental Chamber*- An enclosure used to test the effects of specified environmental conditions on biological items, industrial products, materials, and electronic devices and components.

10. *High-performance liquid chromatography (HPLC)*- A technique in analytic chemistry used to separate the components in a mixture, to identify each component, and to quantify each component.
11. *International Safe Transit Association (ISTA)* - A leading industry developer of testing protocols and design standards that define how packages should perform to ensure protection of their contents during the ever changing risks of the global distribution environment.
12. *ISO* – International Organization for Standardization
13. *Mean Kinetic Temperature (MKT)*- A single derived temperature which, if maintained over a defined period, would afford the same thermal challenge to a pharmaceutical product as would have been experienced over a range of both higher and lower temperatures for an equivalent defined period.
14. *Size-exclusion chromatography (SEC)*- A chromatographic method in which molecules in solution are separated by their size, and in some cases molecular weight. It is usually applied to large molecules or macromolecular complexes such as proteins and industrial polymers.
15. *Temperature monitors*- Also called a temperature data logger, is a portable measurement instrument that is capable of autonomously recording temperature over a defined period of time. The digital data can be retrieved, viewed and evaluated after it has been recorded. A data logger is commonly used to monitor shipments in a cold chain and to gather temperature data from diverse field conditions.
16. *T-Test*- A statistical examination of two population means. A two-sample t-test examines whether two samples are different and is commonly used when the variances of two normal distributions are unknown and when an experiment uses a small sample size.
17. *United States Pharmacopeia (USP)*- A scientific nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed and consumed worldwide. USP's drug standards are enforceable in the United States by the Food and Drug Administration, and these standards are used in more than 140 countries.

TASKS, ASSOCIATED DELIVERABLES, AND PERFORMANCE MEASURES:

Task 1 – Project Kick-Off Meeting and Administrative Requirements

The Contractor shall schedule the kick-off meeting within ten (10) business days after contract award with subject matter experts (SMEs) from CMOP and the Contractor. The Contractor shall present a Project Management Plan (PMP) in a Microsoft Office compatible format for review and approval by CMOP. The PMP shall include the work plan, project schedule, and deliverable dates. Work shall not commence until the CMOP TPOC approves the approach/methodology, work plan and, schedule on behalf of the CMOP project team.

The Contractor shall also complete standard administrative tasks (e.g., Background Investigation forms and expenses to be paid for by Contractor, and Staff Roster) as noted in the Deliverable descriptions below. The position sensitivity impact for this effort has been designated as **Low Risk** and the level of background investigation is **NACI (National Agency Check with Inquiries)**

The Contractor shall present an itemized list of Government Furnished Equipment (GFE) that will be necessary to complete the study. The list of GFE shall include, but not be limited to, coolers, frozen gel packs, non-insulated mailers, drug samples, and fill material. The list of GFE must be reviewed and approved by CMOP.

Deliverables for Task 1 –

Deliverable 1.1: Kick-off meeting ten (10) business days from date of award to present Approach/Plan/Schedule. The kick-off meeting may be conducted via teleconference call.

Deliverable 1.2: The Contractor shall submit to the Contracting Officer Representative (COR) within **five (5) business days** after award a full and complete list of names, Social Security Numbers, and home addresses of Contractor personnel for the Background Investigation requirement.

Deliverable 1.3: All mandatory training required during the performance of the contract shall be completed and documented within **10 business days**.

Deliverable 1.4: The list of GFE has been sent to CMOP for review.

Performance Measures for Task 1 -

CMOP successful acceptance of Deliverables 1.1, 1.2, 1.3 and 1.4

Task 2 - Project Plan / Schedule

The Contractor shall finalize the project plan and schedule **within five (5) business days** after the completion of the kick-off meeting. The project plan shall include a detailed description of the approach to successfully complete the required tasks, and must be approved by the TPOC within **five (5) business days** prior to the Contractor moving forward. The project schedule shall contain completion dates for each deliverable.

The Contractor shall finalize the itemized list of Government Furnished Equipment (GFE) within **five (5) business days** that was presented during the kick-off meeting.

The Contractor shall finalize GFE storage temperatures.

The Contractor shall submit **bi-weekly status reports** in a Microsoft Office compatible electronic format to the TPOC. The report shall describe at a minimum: project progress; percent of target deliverables achieved; other activities; problems encountered; solutions employed; and change in Contractor staff and key personnel.

Deliverables for Task 2:

Deliverable 2.1: Final Project Plan five (5) business days after kickoff meeting

Deliverable 2.2: Final Project Schedule five (5) business days after kickoff meeting

Deliverable 2.3: Final itemized list of Government Furnished Equipment (GFE) 5 business days after the kickoff meeting

Deliverable 2.4: Contractor confirmed that GFE shall be stored at specified temperatures

Deliverable 2.5: Bi-weekly Status Reports ongoing throughout project

Performance Measures for Task 2 -

CMOP successful acceptance of deliverables 2.1, 2.2, 2.3, 2.4, and 2.5

Task 3 – Pre-Test Set-Up

The Contractor shall perform all the necessary Pre-Test Requirements prior to the commencement of Task 4 and Task 5 Deliverables.

The environmental chambers temperature monitors shall be tested to ensure that they are capable of temperature variations between -25°C and +65°C to satisfy the temperature requirements of this study. Temperature chambers must maintain temperature within +/-3°C.

Temperatures inside the environmental chamber and temperature monitors shall have the ability to be recorded every 15 minutes throughout the study.

The Contractor **shall acknowledge in writing** that they have received a copy of, and shall comply with, the CMOP Packaging SOP.

The Contractor shall confirm delivery of all Government Furnished Equipment (GFE).

The Contractor shall place all GFE within the temperature ranges specified by CMOP.

Control samples shall be stored at controlled room temperature (CRT). (Quantity shall be determined at the kick-off meeting).

Control samples shall be stored at controlled cold temperature (CCT). (Quantity shall be determined at the kick-off meeting).

Control samples shall be stored according to manufacturer's recommendations. (Quantity shall be determined at the kick-off meeting).

Task 3 Deliverables -

Deliverable 3.1: The environmental chambers have been tested and verified to ensure that they are capable of temperature variations between -25°C and +65°C with no more than a +/-3°C variance.

Deliverable 3.2: The environmental chambers and temperature monitors have the ability to be record temperatures every 15 minutes throughout the study.

Deliverable 3.3: The Contractor has acknowledged in writing that they have received a copy of, and shall comply with, the CMOP Packaging SOP. (Appendix A)

Deliverable 3.4: The Contractor confirmed delivery of all Government Furnished Equipment (GFE).

Deliverable 3.5: GFE has been stored according to CMOP specifications.

Deliverable 3.6: Control samples have been properly stored at CRT and CCT.

Deliverable 3.7: Control samples have been properly stored according to manufacturer's recommendations.

Performance Measures for Task 3 -

CMOP successful acceptance of deliverables 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, and 3.7

Task 4 - Simulated Transit Condition

The Contractor shall photograph each step in the packing process to include a photograph of the sealed package.

The Contractor shall place four vials of insulin in each of the non-insulated mailers and insulated containers with frozen gel packs to be tested. Packaging must conform to CMOP Packing Standards.

The Contractor shall place temperature monitors inside each of the containers and mailers.

The Contractor shall use a 48 hour ISTA modified summer/winter profile to represent extreme temperatures during summer and winter in a mailbox. For the summer profile the last 10 hours will be kept at 60°C (Phoenix) whereas the last 10 hours of the winter profile will be at -20°C (Fargo).

48-Hour Modified ISTA Summer Profile:

**+25°C (10 hrs warehouse) ⇒⇒ +45°C (4 hrs mail transfer) ⇒⇒ +30°C (24 hrs transit)
⇒⇒ +60 °C (10 hrs doorstep)**

48-Hour Modified ISTA Winter Profile:

**+25°C (10 hrs warehouse) ⇒⇒ -10°C (4 hrs mail transfer) ⇒⇒ +10°C (24 hrs transit)
⇒⇒ -20 °C (10 hrs doorstep)**

The Contractor shall place non-insulated and insulated containers with frozen gel packs into an environmental chamber setup for a 48 hour summer profile.

The Contractor shall place non-insulated and insulated containers with frozen gel packs into an environmental chamber setup for a 48 hour winter profile.

The Contractor shall use a 48 hour summer/winter profile to represent extreme temperatures during summer and winter in a mailbox. For the summer profile the last 10 hours will be kept at 60°C (Phoenix) whereas the last 10 hours of the winter profile will be at -20°C (Fargo).

120-Hour Modified ISTA Summer Profile:

**+25°C (10 hrs warehouse) ⇒⇒ +45°C (4 hrs mail transfer) ⇒⇒ +30°C (96 hrs transit)
⇒⇒ +60 °C (10 hrs in mailbox)**

120-Hour Modified ISTA Winter Profile:

+25°C (10 hrs warehouse) ⇒⇒ -10°C (4 hrs mail transfer) ⇒⇒ 0°C (96 hrs transit)

⇒⇒

-20 °C (10 hrs in mailbox)

The Contractor shall place non-insulated and insulated containers with frozen gel packs into an environmental chamber setup for a 120 hour summer profile.

The Contractor shall place non-insulated and insulated containers with frozen gel packs into an environmental chamber setup for a 120 hour winter profile.

After exposure to the transit conditions, samples shall be removed from their packaging, visually inspected for changes in physical appearance, and stored at 4°C until analysis.

Deliverables for Task 4 -

Deliverable 4.1: The Contractor photographed each step in the packing process to include a photograph of the sealed package.

Deliverable 4.2: The Contractor placed four (4) vials of insulin in each of the non-insulated mailers and insulated containers with frozen gel packs.

Deliverable 4.3: Packaging met CMOP Packing Standards (Appendix A)

Deliverable 4.4: The Contractor placed temperature monitors inside each of the container.

Deliverable 4.5: Sealed containers and mailers were placed into an environmental chamber for up to 120 hours while exposed to either summer or winter transit conditions.

Performance Measures for Task 4 -

CMOP successful acceptance of deliverables 4.1, 4.2, 4.3, 4.4, and 4.5

Task 5 - Testing by an Accredited and Certified Laboratory

The Contractor shall use United States Pharmacopeia (USP) formulas, methods, and monographs for each of the Task 5 test requirements.

The Contractor shall analyze the assay of 120 hour, at 30 days at controlled room temperature (CRT) similar to patient's home temperature, samples shall also be tested at 60, 90, and 120 days 4°C controlled cold temperature (CCT) similar to a patient's refrigerator temperature.

The Contractor shall analyze the assay of 48 hour, at 30 days at controlled room temperature (CRT) similar to patient's home temperature, samples shall also be tested at 60, 90, and 120 days at 4°C controlled cold temperature (CCT) similar to a patient's refrigerator temperature.

The Contractor shall calculate mean kinetic temperatures (MKTs) of each product sample.

The Contractor shall perform Size-exclusion chromatography (SEC) on each product sample.

The Contractor shall perform High-performance liquid chromatography (HPLC) on each product sample according to USP monograph.

The Contractor shall perform T-Testing on each product sample. A value of < 0.05 shall be set as the level of statistical significance unless another value has been mutually agreed upon at the kick-off meeting.

The Contractor shall perform optical microscopy using a digital microscope camera on each product sample.

The Contractor shall photograph product samples to include controls samples at 100x magnification.

The Contractor shall perform additional testing elements agreed to during the kick-off meeting.

Deliverables for Task 5 -

Deliverable 5.1: The Contractor utilized United States Pharmacopeia (USP) formulas, methods, and monographs for each test.

Deliverable 5.2: The Contractor completed the assay of 120 hour, at 30 days at controlled room temperature (CRT), to include 60, 90, and 120 days at 4°C controlled cold temperature (CCT).

Deliverable 5.3: The Contractor completed the assay of 48 hour, at 30 days at controlled room temperature (CRT), to include 60, 90, and 120 days at 4°C controlled cold temperature (CCT).

Deliverable 5.4: The Contractor determined mean kinetic temperatures (MKTs) of each product sample.

Deliverable 5.5: The Contractor performed Size-exclusion chromatography (SEC) on each product sample.

Deliverable 5.6: The Contractor shall perform High-performance liquid chromatography (HPLC) on each product sample according to USP monograph.

Deliverable 5.7: The Contractor performed T-Testing on each product sample.

Deliverable 5.8: The Contractor performed optical microscopy using a digital microscope camera on each product sample.

Deliverable 5.9: The Contractor photographed product samples to include controls samples at 100x magnification.

Performance Measures for Task 5 -

CMOP successful acceptance of deliverables 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 5.8, and 5.9

Task 6 – Final Report

The Contractor shall provide a detailed report of findings regarding the chemical degradation and stability of products that were shipped in non-insulated mailers and insulated containers for the 120 hour study, at 30 days under controlled room temperature (CRT), to include 60, 90, and 120 days at 4 °C controlled cold temperature (CCT).

The Contractor shall provide a detailed report of findings regarding the chemical degradation and stability of products that were shipped in non-insulated mailers and insulated containers for the 120 hour study, at 30, 60, 90, and 120 days under controlled room temperature (CRT).

The Contractor shall provide a detailed report of findings regarding the chemical degradation and stability of products that were shipped in non-insulated mailers and insulated containers for the 48 hour study, at 30 days under controlled room temperature (CRT), to include 60, 90, and 120 days at 4 °C controlled cold temperature (CCT).

The Contractor shall design detailed graphs and digital imageries that illustrate a comparison of data from control samples, product samples, and references from the United States Pharmacopeia (USP).

The Contractor shall prepare an executive summary which summarizes all findings and recommendations contained in the various reports required by this solicitation.

Deliverables for Task 6 -

Deliverable 6.1: The Contractor provided a detailed report of findings regarding the chemical degradation and stability of products for the 120 hour study.

Deliverable 6.2: The Contractor provided a detailed report of findings regarding the chemical degradation and stability of products for the 48 hour study.

Deliverable 6.3: The Contractor designed detailed graphs and digital imageries that illustrated a comparison of data from control samples, product samples, and references from the United States Pharmacopeia (USP).

Deliverable 6.4: The Contractor prepared an executive summary which summarized all findings and recommendations contained in the various reports required by this solicitation.

Performance Measures for Task 6 -

CMOP successful acceptance of deliverables 6.1, 6.2, 6.3, and 6.4

Reference Source:

Chris Chandler et al. Insulin temperature and stability under simulated conditions. *Am J Health-Syst Pharm*. 2008; 65: 954-963.

APPENDIX A:

CMOP DISTRIBUTION PRACTICES FOR REFRIGERATED PACKAGES

CMOP and PBM agreed to the standardized refrigerated shipment of formoterol with overnight delivery from May 15 through September 15. The CMOP continues to send formoterol with overnight delivery the remainder of the year, ensuring its delivery at controlled room temperature.

CMOP runs seasonal monitoring on our refrigerated and controlled room temperature packages. Our packaging maintains refrigerated temperatures for 24-48 hours, and we test this seasonally in extreme areas such as the desert and upper Michigan. We have consulted with temperature and packaging consultants after each season's study and continually evaluate our logistics and report these findings. You can also find these results on the QA Updates section of our web site. As an example, in summer we increase the number of frozen gel packs in each of our cooler sizes from the fall and spring quantities, and to accommodate the increase in frozen gels your patients may receive a larger cooler. Additionally, when the outside temperature in Hines, IL falls below 40F we use a winter packout with less frozen gels to protect from freezing. As the interior size of the cooler increases, the number of frozen gels must increase accordingly, and in larger coolers we fill the unused space with air bags for optimal performance. **Our current packout is:**

Cooler Size (outside dimensions)	SPRING (Mar.- April) FALL (Oct-Nov.)	SUMMER (May-Sept.)	WINTER (<40F in Hines, Dec.- Feb.)
Small 11 x 9 x 7	2 frozen 12oz gels	3 frozen 12oz gels	1 frozen 12oz gel
Large 11 x 9 x 12	3 frozen 12oz gels	4 frozen 12oz gels	2 frozen 12oz gels
XXL 15 x 13 x 8	4 frozen 12oz gels	8 frozen 12oz gels	3 frozen 12oz gels

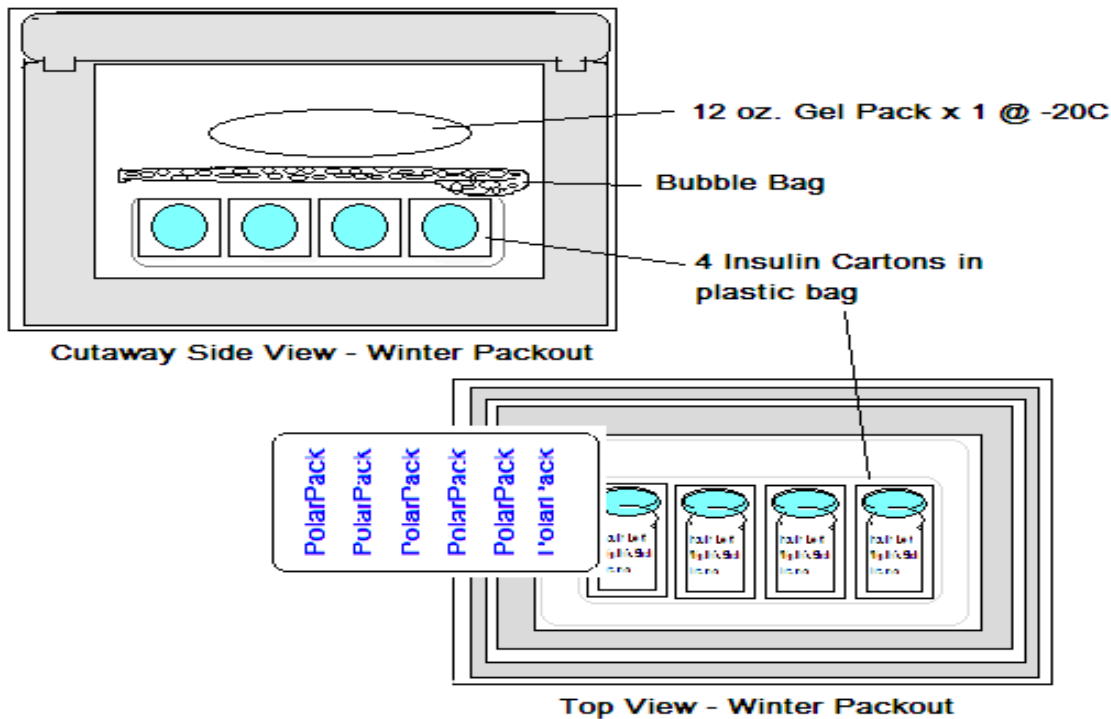
Refrigerated packages are sent FedEx Priority Overnight Service with tracking and Delivery Confirmation.

- Delivered by 10:30am and left at the door.
- Marking refrigerated shipments for signature confirmation may complicate delivery, as failed attempts are returned to the warm FedEx truck or office overnight or over weekends causing even the best refrigerated packaging to fail. Therefore, CMOP may override this option for refrigerated packages.

FedEx does not deliver to PO boxes.

- Controlled room temperature formoterol orders are shipped using US Priority Mail.
- Refrigerated items (excluding controlled room temperature formoterol) are cancelled back for local filling.

We are working on new ways to let the patients know their refrigerated package is on its way. We have also added a sticker to the box indicating the overnight delivery date so the patient's are aware of any delivery exceptions and can call their pharmacy.



B.4 PRICE SCHEDULE**ITEM INFORMATION**

ITEM NUMBER	DESCRIPTION OF SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001	Contractor shall conduct temperature study for National CMOP simulating extreme transit conditions in accordance with terms/conditions of the solicitation/award.	1.00	JB		
				GRAND TOTAL	

B.5 DELIVERY SCHEDULE

ITEM NUMBER			QUANTITY	DELIVERY DATE
0001	SHIP TO:	VA CMOP Great Lakes 5th and Roosevelt Bldg 37 NW Dock 18 Hines, IL 60141	1.00	160 Days ARO
	MARK FOR:	James Hinspeter 708-786-7541 james.hinspeter@va.gov		

SECTION C - CONTRACT CLAUSES

C.1 52.212-4 CONTRACT TERMS AND CONDITIONS—COMMERCIAL ITEMS (MAY 2015)

(a) *Inspection/Acceptance.* The Contractor shall only tender for acceptance those items that conform to the requirements of this contract. The Government reserves the right to inspect or test any supplies or services that have been tendered for acceptance. The Government may require repair or replacement of nonconforming supplies or reperformance of nonconforming services at no increase in contract price. If repair/replacement or reperformance will not correct the defects or is not possible, the Government may seek an equitable price reduction or adequate consideration for acceptance of nonconforming supplies or services. The Government must exercise its post-acceptance rights—

- (1) Within a reasonable time after the defect was discovered or should have been discovered; and
- (2) Before any substantial change occurs in the condition of the item, unless the change is due to the defect in the item.

(b) *Assignment.* The Contractor or its assignee may assign its rights to receive payment due as a result of performance of this contract to a bank, trust company, or other financing institution, including any Federal lending agency in accordance with the Assignment of Claims Act (31 U.S.C. 3727). However, when a third party makes payment (e.g., use of the Governmentwide commercial purchase card), the Contractor may not assign its rights to receive payment under this contract.

(c) *Changes.* Changes in the terms and conditions of this contract may be made only by written agreement of the parties.

(d) *Disputes.* This contract is subject to 41 U.S.C. chapter 71, Contract Disputes. Failure of the parties to this contract to reach agreement on any request for equitable adjustment, claim, appeal or action arising under or relating to this contract shall be a dispute to be resolved in accordance with the clause at FAR 52.233-1, Disputes, which is incorporated herein by reference. The Contractor shall proceed diligently with performance of this contract, pending final resolution of any dispute arising under the contract.

(e) *Definitions.* The clause at FAR 52.202-1, Definitions, is incorporated herein by reference.

(f) *Excusable delays.* The Contractor shall be liable for default unless nonperformance is caused by an occurrence beyond the reasonable control of the Contractor and without its fault or negligence such as, acts of God or the public enemy, acts of the Government in either its sovereign or contractual capacity, fires, floods, epidemics, quarantine restrictions, strikes, unusually severe weather, and delays of common carriers. The Contractor shall notify the Contracting Officer in writing as soon as it is reasonably possible after the commencement of any excusable delay, setting forth the full particulars in connection therewith, shall remedy such occurrence with all reasonable dispatch, and shall promptly give written notice to the Contracting Officer of the cessation of such occurrence.

(g) Invoice.

(1) The Contractor shall submit an original invoice and three copies (or electronic invoice, if authorized) to the address designated in the contract to receive invoices. An invoice must include—

- (i) Name and address of the Contractor;
- (ii) Invoice date and number;
- (iii) Contract number, contract line item number and, if applicable, the order number;
- (iv) Description, quantity, unit of measure, unit price and extended price of the items delivered;
- (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;
- (vii) Name and address of official to whom payment is to be sent;
- (viii) Name, title, and phone number of person to notify in event of defective invoice; and
- (ix) Taxpayer Identification Number (TIN). The Contractor shall include its TIN on the invoice only if required elsewhere in this contract.
- (x) Electronic funds transfer (EFT) banking information.

(A) The Contractor shall include EFT banking information on the invoice only if required elsewhere in this contract.

(B) If EFT banking information is not required to be on the invoice, in order for the invoice to be a proper invoice, the Contractor shall have submitted correct EFT banking information in accordance with the applicable solicitation provision, contract clause (e.g., 52.232-33, Payment by Electronic Funds Transfer—System for Award Management, or 52.232-34, Payment by Electronic Funds Transfer—Other Than System for Award Management), or applicable agency procedures.

(C) EFT banking information is not required if the Government waived the requirement to pay by EFT.

(2) Invoices will be handled in accordance with the Prompt Payment Act (31 U.S.C. 3903) and Office of Management and Budget (OMB) prompt payment regulations at 5 CFR part 1315.

(h) *Patent indemnity.* The Contractor shall indemnify the Government and its officers, employees and agents against liability, including costs, for actual or alleged direct or contributory infringement of, or inducement to infringe, any United States or foreign patent, trademark or copyright, arising out of the performance of this contract, provided the Contractor is reasonably notified of such claims and proceedings.

(i) Payment.—

(1) *Items accepted.* Payment shall be made for items accepted by the Government that have been delivered to the delivery destinations set forth in this contract.

(2) *Prompt payment.* The Government will make payment in accordance with the Prompt Payment Act (31 U.S.C. 3903) and prompt payment regulations at 5 CFR part 1315.

(3) *Electronic Funds Transfer (EFT).* If the Government makes payment by EFT, see 52.212-5(b) for the appropriate EFT clause.

(4) *Discount.* In connection with any discount offered for early payment, time shall be computed from the date of the invoice. For the purpose of computing the discount earned, payment shall be considered to have been made on the date which appears on the payment check or the specified payment date if an electronic funds transfer payment is made.

(5) *Overpayments.* If the Contractor becomes aware of a duplicate contract financing or invoice payment or that the Government has otherwise overpaid on a contract financing or invoice payment, the Contractor shall—

(i) Remit the overpayment amount to the payment office cited in the contract along with a description of the overpayment including the—

(A) Circumstances of the overpayment (e.g., duplicate payment, erroneous payment, liquidation errors, date(s) of overpayment);

(B) Affected contract number and delivery order number, if applicable;

(C) Affected contract line item or subline item, if applicable; and

(D) Contractor point of contact.

(ii) Provide a copy of the remittance and supporting documentation to the Contracting Officer.

(6) *Interest.*

(i) All amounts that become payable by the Contractor to the Government under this contract shall bear simple interest from the date due until paid unless paid within 30 days of becoming due. The interest rate shall be the interest rate established by the Secretary of the Treasury as provided in 41 U.S.C. 7109, which is applicable to the period in which the amount becomes due, as provided in (i)(6)(v) of this clause, and then at the rate applicable for each six-month period as fixed by the Secretary until the amount is paid.

(ii) The Government may issue a demand for payment to the Contractor upon finding a debt is due under the contract.

(iii) *Final decisions.* The Contracting Officer will issue a final decision as required by 33.211 if—

(A) The Contracting Officer and the Contractor are unable to reach agreement on the existence or amount of a debt within 30 days;

(B) The Contractor fails to liquidate a debt previously demanded by the Contracting Officer within the timeline specified in the demand for payment unless the amounts were not repaid because the Contractor has requested an installment payment agreement; or

(C) The Contractor requests a deferment of collection on a debt previously demanded by the Contracting Officer (see 32.607-2).

(iv) If a demand for payment was previously issued for the debt, the demand for payment included in the final decision shall identify the same due date as the original demand for payment.

(v) Amounts shall be due at the earliest of the following dates:

(A) The date fixed under this contract.

(B) The date of the first written demand for payment, including any demand for payment resulting from a default termination.

(vi) The interest charge shall be computed for the actual number of calendar days involved beginning on the due date and ending on—

(A) The date on which the designated office receives payment from the Contractor;

(B) The date of issuance of a Government check to the Contractor from which an amount otherwise payable has been withheld as a credit against the contract debt; or

(C) The date on which an amount withheld and applied to the contract debt would otherwise have become payable to the Contractor.

(vii) The interest charge made under this clause may be reduced under the procedures prescribed in 32.608-2 of the Federal Acquisition Regulation in effect on the date of this contract.

(j) *Risk of loss.* Unless the contract specifically provides otherwise, risk of loss or damage to the supplies provided under this contract shall remain with the Contractor until, and shall pass to the Government upon:

(1) Delivery of the supplies to a carrier, if transportation is f.o.b. origin; or

(2) Delivery of the supplies to the Government at the destination specified in the contract, if transportation is f.o.b. destination.

(k) *Taxes.* The contract price includes all applicable Federal, State, and local taxes and duties.

(l) *Termination for the Government's convenience.* The Government reserves the right to terminate this contract, or any part hereof, for its sole convenience. In the event of such termination, the Contractor shall immediately stop all work hereunder and shall immediately cause any and all of its suppliers and subContractors to cease work. Subject to the terms of this contract, the Contractor shall be paid a percentage of the contract price reflecting the percentage of the work performed prior to the notice of termination, plus reasonable charges the Contractor can demonstrate to the satisfaction of the Government using its standard record keeping system, have resulted from the termination. The Contractor shall not be required to comply with the cost accounting standards or contract cost principles for this purpose. This paragraph does not give the Government any right to audit the Contractor's records. The Contractor shall not be paid for any work performed or costs incurred which reasonably could have been avoided.

(m) *Termination for cause.* The Government may terminate this contract, or any part hereof, for cause in the event of any default by the Contractor, or if the Contractor fails to comply with any contract terms and conditions, or fails to provide the Government, upon request, with adequate assurances of future performance. In the event of termination for cause, the Government shall not be liable to the Contractor for any amount for supplies or services not accepted, and the Contractor shall be liable to the Government for any and all rights and remedies provided by law. If it is determined that the Government improperly terminated this contract for default, such termination shall be deemed a termination for convenience.

(n) *Title.* Unless specified elsewhere in this contract, title to items furnished under this contract shall pass to the Government upon acceptance, regardless of when or where the Government takes physical possession.

(o) *Warranty.* The Contractor warrants and implies that the items delivered hereunder are merchantable and fit for use for the particular purpose described in this contract.

(p) *Limitation of liability.* Except as otherwise provided by an express warranty, the Contractor will not be liable to the Government for consequential damages resulting from any defect or deficiencies in accepted items.

(q) *Other compliances.* The Contractor shall comply with all applicable Federal, State and local laws, executive orders, rules and regulations applicable to its performance under this contract.

(r) *Compliance with laws unique to Government contracts.* The Contractor agrees to comply with 31 U.S.C. 1352 relating to limitations on the use of appropriated funds to influence certain Federal contracts; 18 U.S.C. 431 relating to officials not to benefit; 40 U.S.C. chapter 37, Contract Work Hours and Safety Standards; 41 U.S.C. chapter 87, Kickbacks; 41 U.S.C. 4712 and 10 U.S.C. 2409 relating to whistleblower protections; 49 U.S.C. 40118, Fly American; and 41 U.S.C. chapter 21 relating to procurement integrity.

(s) *Order of precedence.* Any inconsistencies in this solicitation or contract shall be resolved by giving precedence in the following order:

- (1) The schedule of supplies/services.
- (2) The Assignments, Disputes, Payments, Invoice, Other Compliances, Compliance with Laws Unique to Government Contracts, and Unauthorized Obligations paragraphs of this clause;
- (3) The clause at 52.212-5.
- (4) Addenda to this solicitation or contract, including any license agreements for computer software.
- (5) Solicitation provisions if this is a solicitation.
- (6) Other paragraphs of this clause.
- (7) The Standard Form 1449.
- (8) Other documents, exhibits, and attachments
- (9) The specification.

(t) *System for Award Management (SAM).*

(1) Unless exempted by an addendum to this contract, the Contractor is responsible during performance and through final payment of any contract for the accuracy and completeness of the data within the SAM database, and for any liability resulting from the Government's reliance on inaccurate or incomplete data. To remain registered in the SAM database after the initial registration, the Contractor is required to review and update on an annual basis from the date of initial registration or subsequent updates its information in the SAM database to ensure it is current, accurate and complete. Updating information in the SAM does not alter the terms and conditions of this contract and is not a substitute for a properly executed contractual document.

(2)(i) If a Contractor has legally changed its business name, "doing business as" name, or division name (whichever is shown on the contract), or has transferred the assets used in performing the contract, but has not completed the necessary requirements regarding novation and change-of-name agreements in FAR subpart 42.12, the Contractor shall provide the responsible Contracting Officer a minimum of one business day's written notification of its intention to (A) change the name in the SAM database; (B) comply with the requirements of subpart 42.12; and (C) agree in writing to the timeline and procedures specified by the responsible Contracting Officer. The Contractor must provide with the notification sufficient documentation to support the legally changed name.

(ii) If the Contractor fails to comply with the requirements of paragraph (t)(2)(i) of this clause, or fails to perform the agreement at paragraph (t)(2)(i)(C) of this clause, and, in the absence of a properly executed novation or change-of-name agreement, the SAM information that shows the Contractor to be other than the Contractor indicated in the contract will be considered to be incorrect information within the meaning of the "Suspension of Payment" paragraph of the electronic funds transfer (EFT) clause of this contract.

(3) The Contractor shall not change the name or address for EFT payments or manual payments, as appropriate, in the SAM record to reflect an assignee for the purpose of assignment of claims (see Subpart 32.8, Assignment of Claims). Assignees shall be separately registered in the SAM database. Information provided to the Contractor's SAM record that indicates payments, including those made by EFT, to an ultimate recipient other than that Contractor will be considered to be incorrect information within the meaning of the "Suspension of payment" paragraph of the EFT clause of this contract.

(4) Offerors and Contractors may obtain information on registration and annual confirmation requirements via SAM accessed through <https://www.acquisition.gov>.

(u) *Unauthorized Obligations.*

(1) Except as stated in paragraph (u)(2) of this clause, when any supply or service acquired under this contract is subject to any End User License Agreement (EULA), Terms of Service (TOS), or similar legal instrument or agreement, that includes any clause requiring the Government to indemnify the Contractor or any person or entity for damages, costs, fees, or any other loss or liability that would create an Anti-Deficiency Act violation (31 U.S.C. 1341), the following shall govern:

(i) Any such clause is unenforceable against the Government.

(ii) Neither the Government nor any Government authorized end user shall be deemed to have agreed to such clause by virtue of it appearing in the EULA, TOS, or similar legal instrument or agreement. If the EULA, TOS, or similar legal instrument or agreement is invoked through an “I agree” click box or other comparable mechanism (e.g., “click-wrap” or “browse-wrap” agreements), execution does not bind the Government or any Government authorized end user to such clause.

(iii) Any such clause is deemed to be stricken from the EULA, TOS, or similar legal instrument or agreement.

(2) Paragraph (u)(1) of this clause does not apply to indemnification by the Government that is expressly authorized by statute and specifically authorized under applicable agency regulations and procedures.

(v) *Incorporation by reference.* The Contractor’s representations and certifications, including those completed electronically via the System for Award Management (SAM), are incorporated by reference into the contract.

(End of Clause)

ADDENDUM to FAR 52.212-4 CONTRACT TERMS AND CONDITIONS—COMMERCIAL ITEMS

Clauses that are incorporated by reference (by Citation Number, Title, and Date), have 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 clauses are incorporated into 52.212-4 as an addendum to this contract:

C.2 52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

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. Also, the full text of a clause may be accessed electronically at this/these address(es):

<http://www.acquisition.gov/far/index.html>
<http://www.va.gov/oal/library/vaar/>

(End of Clause)

<u>FAR</u> <u>Number</u>	<u>Title</u>	<u>Date</u>
52.204-18	COMMERCIAL AND GOVERNMENT ENTITY CODE MAINTENANCE	JUL 2016
52.232-40	PROVIDING ACCELERATED PAYMENTS TO SMALL BUSINESS SUBCONTRACTORS	DEC 2013
52.237-3	CONTINUITY OF SERVICES	JAN 1991

C.3 52.203-99 PROHIBITION ON CONTRACTING WITH ENTITIES THAT REQUIRE CERTAIN INTERNAL CONFIDENTIALITY AGREEMENTS (DEVIATION) (FEB 2015)

(a) The Contractor shall not require employees or Contractors seeking to report fraud, waste, or abuse to sign or comply with internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subContractors from lawfully reporting such waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information.

(b) The Contractor shall notify employees that the prohibitions and restrictions of any internal confidentiality agreements covered by this clause are no longer in effect.

(c) The prohibition in paragraph (a) of this clause does not contravene requirements applicable to Standard Form 312, Form 4414, or any other form issued by a Federal department or agency governing the nondisclosure of classified information.

(d)(1) In accordance with section 743 of Division E, Title VII, of the Consolidated and Further Continuing Resolution Appropriations Act, 2015 (Pub. L. 113-235), use of funds appropriated (or otherwise made available) under that or any other Act may be prohibited, if the Government determines that the Contractor is not in compliance with the provisions of this clause.

(2) The Government may seek any available remedies in the event the Contractor fails to comply with the provisions of this clause.

(End of Clause)

C.4 VAAR 852.203-70 COMMERCIAL ADVERTISING (JAN 2008)

The bidder or offeror agrees that if a contract is awarded to him/her, as a result of this solicitation, he/she will not advertise the award of the contract in his/her commercial advertising in such a manner as to state or imply that the Department of Veterans Affairs endorses a product, project or commercial line of endeavor.

(End of Clause)

C.5 VAAR 852.232-72 ELECTRONIC SUBMISSION OF PAYMENT REQUESTS (NOV 2012)

(a) *Definitions.* As used in this clause—

(1) *Contract financing payment* has the meaning given in FAR 32.001.

(2) *Designated agency office* has the meaning given in 5 CFR 1315.2(m).

(3) *Electronic form* means an automated system transmitting information electronically according to the accepted electronic data transmission methods and formats identified in paragraph (c) of this clause. Facsimile, email, and scanned documents are not acceptable electronic forms for submission of payment requests.

(4) *Invoice payment* has the meaning given in FAR 32.001.

(5) *Payment request* means any request for contract financing payment or invoice payment submitted by the Contractor under this contract.

(b) *Electronic payment requests.* Except as provided in paragraph (e) of this clause, the Contractor shall submit payment requests in electronic form. Purchases paid with a Government-wide commercial purchase card are considered to be an electronic transaction for purposes of this rule, and therefore no additional electronic invoice submission is required.

(c) *Data transmission.* A Contractor must ensure that the data transmission method and format are through one of the following:

(1) VA's Electronic Invoice Presentment and Payment System. (See Web site at <http://www.fsc.va.gov/einvoice.asp>.)

(2) Any system that conforms to the X12 electronic data interchange (EDI) formats established by the Accredited Standards Center (ASC) and chartered by the American National Standards Institute (ANSI). The X12 EDI Web site (<http://www.x12.org>) includes additional information on EDI 810 and 811 formats.

(d) *Invoice requirements.* Invoices shall comply with FAR 32.905.

(e) *Exceptions.* If, based on one of the circumstances below, the contracting officer directs that payment requests be made by mail, the Contractor shall submit payment requests by mail through the United States Postal Service to the designated agency office. Submission of payment requests by mail may be required for:

(1) Awards made to foreign vendors for work performed outside the United States;

(2) Classified contracts or purchases when electronic submission and processing of payment requests could compromise the safeguarding of classified or privacy information;

(3) Contracts awarded by contracting officers in the conduct of emergency operations, such as responses to national emergencies;

(4) Solicitations or contracts in which the designated agency office is a VA entity other than the VA Financial Services Center in Austin, Texas; or

(5) Solicitations or contracts in which the VA designated agency office does not have electronic invoicing capability as described above.

(End of Clause)

C.6 VAAR 852.237-70 CONTRACTOR RESPONSIBILITIES (APR 1984)

The Contractor shall obtain all necessary licenses and/or permits required to perform this work. He/she shall take all reasonable precautions necessary to protect persons and property from injury or damage during the performance of this contract. He/she shall be responsible for any injury to himself/herself, his/her employees, as well as for any damage to personal or public property that occurs during the performance of this contract that is caused by his/her employees fault or negligence, and shall maintain personal liability and property damage insurance having coverage for a limit as required by the laws of the State of Texas. Further, it is agreed that any negligence of the Government, its officers, agents, servants and employees, shall not be the responsibility of the Contractor hereunder with the regard to any claims, loss, damage, injury, and liability resulting there from.

(End of Clause)

(End of Addendum to 52.212-4)

C.7 52.212-5 CONTRACT TERMS AND CONDITIONS REQUIRED TO IMPLEMENT STATUTES OR EXECUTIVE ORDERS—COMMERCIAL ITEMS (JAN 2017)

(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) 52.209-10, Prohibition on Contracting with Inverted Domestic Corporations (NOV 2015).

(2) 52.233-3, Protest After Award (Aug 1996) (31 U.S.C. 3553).

(3) 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 (Sept 2006), with Alternate I (Oct 1995) (41 U.S.C. 4704 and 10 U.S.C. 2402).

☐ (2) 52.203-13, Contractor Code of Business Ethics and Conduct (OCT 2015) (41 U.S.C. 3509).

☐ (3) 52.203-15, Whistleblower Protections under the American Recovery and Reinvestment Act of 2009 (JUN 2010) (Section 1553 of Pub. L. 111-5). (Applies to contracts funded by the American Recovery and Reinvestment Act of 2009.)

☒ (4) 52.204-10, Reporting Executive Compensation and First-Tier Subcontract Awards (OCT 2016) (Pub. L. 109-282) (31 U.S.C. 6101 note).

☐ (5) [Reserved]

☐ (6) 52.204-14, Service Contract Reporting Requirements (OCT 2016) (Pub. L. 111-117, section 743 of Div. C).

☐ (7) 52.204–15, Service Contract Reporting Requirements for Indefinite-Delivery Contracts (OCT 2016) (Pub. L. 111–117, section 743 of Div. C).

☒ (8) 52.209-6, Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment. (OCT 2015) (31 U.S.C. 6101 note).

☐ (9) 52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters (Jul 2013) (41 U.S.C. 2313).

☐ (10) [Reserved]

☐ (11)(i) 52.219-3, Notice of HUBZone Set-Aside or Sole-Source Award (NOV 2011) (15 U.S.C. 657a).

☐ (ii) Alternate I (NOV 2011) of 52.219-3.

☐ (12)(i) 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (OCT 2014) (if the offeror elects to waive the preference, it shall so indicate in its offer) (15 U.S.C. 657a).

☐ (ii) Alternate I (JAN 2011) of 52.219-4.

☐ (13) [Reserved]

☒ (14)(i) 52.219-6, Notice of Total Small Business Set-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 (NOV 2011) (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 Rerepresentation (Jul 2013) (15 U.S.C. 632(a)(2)).

☐ (23) 52.219-29, Notice of Set-Aside for, or Sole Source Award to, Economically Disadvantaged Women-Owned Small Business Concerns (DEC 2015) (15 U.S.C. 637(m)).

☐ (24) 52.219-30, Notice of Set-Aside for, or Sole Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (DEC 2015) (15 U.S.C. 637(m)).

☒ (25) 52.222-3, Convict Labor (June 2003) (E.O. 11755).

☒ (26) 52.222-19, Child Labor—Cooperation with Authorities and Remedies (OCT 2016) (E.O. 13126).

☒ (27) 52.222-21, Prohibition of Segregated Facilities (APR 2015).

☒ (28) 52.222-26, Equal Opportunity (SEP 2016) (E.O. 11246).

☐ (29) 52.222-35, Equal Opportunity for Veterans (OCT 2015) (38 U.S.C. 4212).

☒ (30) 52.222-36, Equal Opportunity for Workers with Disabilities (JUL 2014) (29 U.S.C. 793).

☐ (31) 52.222-37, Employment Reports on Veterans (FEB 2016) (38 U.S.C. 4212).

☐ (32) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (DEC 2010) (E.O. 13496).

☒ (33)(i) 52.222-50, Combating Trafficking in Persons (MAR 2015) (22 U.S.C. chapter 78 and E.O. 13627).

☐ (ii) Alternate I (MAR 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).

☐ (34) 52.222-54, Employment Eligibility Verification (OCT 2015). (E. O. 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial items as prescribed in 22.1803.)

☐ (35) 52.222-59, Compliance with Labor Laws (Executive Order 13673) (OCT 2016). (Applies at \$50 million for solicitations and resultant contracts issued from October 25, 2016 through April 24, 2017; applies at \$500,000 for solicitations and resultant contracts issued after April 24, 2017).

Note to paragraph (b)(35): By a court order issued on October 24, 2016, 52.222-59 is enjoined indefinitely as of the date of the order. The enjoined paragraph will become effective immediately if the court terminates the injunction. At that time, DoD, GSA, and NASA will publish a document in the **Federal Register** advising the public of the termination of the injunction.

☐ (36) 52.222-60, Paycheck Transparency (Executive Order 13673) (OCT 2016).

☐ (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.)

☐ (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).

☐ (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.)

☐ (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 (JUN 2014) of 52.223-14.

☐ (42) 52.223-15, Energy Efficiency in Energy-Consuming Products (DEC 2007)(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.

☒ (44) 52.223-18, Encouraging Contractor Policies to Ban Text Messaging While Driving (AUG 2011)

☐ (45) 52.223-20, Aerosols (JUN 2016) (E.O. 13693).

☐ (46) 52.223-21, Foams (JUN 2016) (E.O. 13693).

☐ (47) (i) 52.224-3, Privacy Training (JAN 2017) (5 U.S.C. 552a).

☐ (ii) Alternate I (JAN 2017) of 52.224-3.

☐ (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 2016) (19 U.S.C. 2501, et seq., 19 U.S.C. 3301 note).
 - ☐ (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. 2302 Note).
 - ☐ (53) 52.226-4, Notice of Disaster or Emergency Area Set-Aside (Nov 2007) (42 U.S.C. 5150).
 - ☐ (54) 52.226-5, Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov 2007) (42 U.S.C. 5150).
 - ☐ (55) 52.232-29, Terms for Financing of Purchases of Commercial Items (Feb 2002) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).
 - ☐ (56) 52.232-30, Installment Payments for Commercial Items (Oct 1995) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).
 - ☒ (57) 52.232-33, Payment by Electronic Funds Transfer—System for Award Management (Jul 2013) (31 U.S.C. 3332).
 - ☐ (58) 52.232-34, Payment by Electronic Funds Transfer—Other than System for Award Management (Jul 2013) (31 U.S.C. 3332).
 - ☐ (59) 52.232-36, Payment by Third Party (MAY 2014) (31 U.S.C. 3332).
 - ☐ (60) 52.239-1, Privacy or Security Safeguards (Aug 1996) (5 U.S.C. 552a).
 - ☐ (61) 52.242-5, Payments to Small Business SubContractors (JAN 2017)(15 U.S.C. 637(d)(12)).
 - ☐ (62)(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, Nondisplacement 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).

☐ (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) 52.219-8, Utilization of Small Business Concerns (NOV 2016) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities.

(iii) 52.222-17, Nondisplacement of Qualified Workers (MAY 2014) (E.O. 13495). Flow down required in accordance with paragraph (1) of FAR clause 52.222-17.

- (iv) 52.222-21, Prohibition of Segregated Facilities (APR 2015).
- (v) 52.222-26, Equal Opportunity (SEP 2016) (E.O. 11246).
- (vi) 52.222-35, Equal Opportunity for Veterans (OCT 2015) (38 U.S.C. 4212).
- (vii) 52.222-36, Equal Opportunity for Workers with Disabilities (JUL 2014) (29 U.S.C. 793).
- (viii) 52.222-37, Employment Reports on Veterans (FEB 2016) (38 U.S.C. 4212).
- (ix) 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.
- (x) 52.222-41, Service Contract Labor Standards (MAY 2014) (41 U.S.C. chapter 67).
- (xi)(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 and E.O. 13627).
- (xii) 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).
- (xiii) 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).
- (xiv) 52.222-54, Employment Eligibility Verification (OCT 2015) (E. O. 12989).
- (xv) 52.222-55, Minimum Wages Under Executive Order 13658 (DEC 2015).
- (xvi) 52.222-59, Compliance with Labor Laws (Executive Order 13673) (OCT 2016) (Applies at \$50 million for solicitations and resultant contracts issued from October 25, 2016 through April 24, 2017; applies at \$500,000 for solicitations and resultant contracts issued after April 24, 2017).
- Note to paragraph (e)(1)(xvi):** By a court order issued on October 24, 2016, 52.222-59 is enjoined indefinitely as of the date of the order. The enjoined paragraph will become effective immediately if the court terminates the injunction. At that time, DoD, GSA, and NASA will publish a document in the **Federal Register** advising the public of the termination of the injunction.
- (xvii) 52.222-60, Paycheck Transparency (Executive Order 13673) (OCT 2016)).
- (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 (MAY 2014) (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)

SECTION D - CONTRACT DOCUMENTS, EXHIBITS, OR ATTACHMENTS

See attached document: Solicitation Attachment 1 - Past Performance Questionnaire.

SECTION E - SOLICITATION PROVISIONS

E.1 52.212-1 INSTRUCTIONS TO OFFERORS—COMMERCIAL ITEMS (OCT 2016)

(a) *North American Industry Classification System (NAICS) code and small business size standard.* The NAICS code and small business size standard for this acquisition appear in Block 10 of the solicitation cover sheet (SF 1449). However, the small business size standard for a concern which submits an offer in its own name, but which proposes to furnish an item which it did not itself manufacture, is 500 employees.

(b) *Submission of offers.* Submit signed and dated offers to the office specified in this solicitation at or before the exact time specified in this solicitation. Offers may be submitted on the SF 1449, letterhead stationery, or as otherwise specified in the solicitation. As a minimum, offers must show—

- (1) The solicitation number;
- (2) The time specified in the solicitation for receipt of offers;
- (3) The name, address, and telephone number of the offeror;
- (4) A technical description of the items being offered in sufficient detail to evaluate compliance with the requirements in the solicitation. This may include product literature, or other documents, if necessary;
- (5) Terms of any express warranty;
- (6) Price and any discount terms;
- (7) "Remit to" address, if different than mailing address;
- (8) A completed copy of the representations and certifications at FAR 52.212-3 (see FAR 52.212-3(b) for those representations and certifications that the offeror shall complete electronically);
- (9) Acknowledgment of Solicitation Amendments;
- (10) Past performance information, when included as an evaluation factor, to include recent and relevant contracts for the same or similar items and other references (including contract numbers, points of contact with telephone numbers and other relevant information); and
- (11) If the offer is not submitted on the SF 1449, include a statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation. Offers that fail to furnish required representations or information, or reject the terms and conditions of the solicitation may be excluded from consideration.

(c) *Period for acceptance of offers.* The offeror agrees to hold the prices in its offer firm for 30 calendar days from the date specified for receipt of offers, unless another time period is specified in an addendum to the solicitation.

(d) *Product samples.* When required by the solicitation, product samples shall be submitted at or prior to the time specified for receipt of offers. Unless otherwise specified in this solicitation, these samples shall be submitted at no expense to the Government, and returned at the sender's request and expense, unless they are destroyed during preaward testing.

(e) *Multiple offers.* Offerors are encouraged to submit multiple offers presenting alternative terms and conditions or commercial items for satisfying the requirements of this solicitation. Each offer submitted will be evaluated separately.

(f) Late submissions, modifications, revisions, and withdrawals of offers.

(1) Offerors are responsible for submitting offers, and any modifications, revisions, or withdrawals, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that offers or revisions are due.

(2)(i) Any offer, modification, revision, or withdrawal of an offer received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and—

(A) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of offers; or

(B) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

(C) If this solicitation is a request for proposals, it was the only proposal received.

(ii) However, a late modification of an otherwise successful offer, that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

(3) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the offer wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(4) If an emergency or unanticipated event interrupts normal Government processes so that offers cannot be received at the Government office designated for receipt of offers by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation or other notice of an extension of the closing date, the time specified for receipt of offers will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(5) Offers may be withdrawn by written notice received at any time before the exact time set for receipt of offers. Oral offers in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile offers, offers may be withdrawn via facsimile received at any time before the exact time set for receipt of offers, subject to the conditions specified in the solicitation concerning facsimile offers. An offer may be withdrawn in person by an offeror or its authorized representative if, before the exact time set for receipt of offers, the identity of the person requesting withdrawal is established and the person signs a receipt for the offer.

(g) *Contract award (not applicable to Invitation for Bids)*. The Government intends to evaluate offers and award a contract without discussions with offerors. Therefore, the offeror's initial offer should contain the offeror's best terms from a price and technical standpoint. However, the Government reserves the right to conduct discussions if later determined by the Contracting Officer to be necessary. The Government may reject any or all offers if such action is in the public interest; accept other than the lowest offer; and waive informalities and minor irregularities in offers received.

(h) *Multiple awards*. The Government may accept any item or group of items of an offer, unless the offeror qualifies the offer by specific limitations. Unless otherwise provided in the Schedule, offers may not be submitted for quantities less than those specified. The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit prices offered, unless the offeror specifies otherwise in the offer.

(i) Availability of requirements documents cited in the solicitation.

(1)(i) The GSA Index of Federal Specifications, Standards and Commercial Item Descriptions, FPMR Part 101-29, and copies of specifications, standards, and commercial item descriptions cited in this solicitation may be obtained for a fee by submitting a request to—

GSA Federal Supply Service Specifications Section

Suite 8100 470 East L'Enfant Plaza, SW

Washington, DC 20407

Telephone (202) 619-8925

Facsimile (202) 619-8978.

(ii) If the General Services Administration, Department of Agriculture, or Department of Veterans Affairs issued this solicitation, a single copy of specifications, standards, and commercial item descriptions cited in this solicitation may be obtained free of charge by submitting a request to the addressee in paragraph (i)(1)(i) of this provision. Additional copies will be issued for a fee.

(2) Most unclassified Defense specifications and standards may be downloaded from the following ASSIST websites:

(i) ASSIST (<https://assist.dla.mil/online/start/>);

(ii) Quick Search (<http://quicksearch.dla.mil/>);

(iii) ASSISTdocs.com (<http://assistdocs.com>).

(3) Documents not available from ASSIST may be ordered from the Department of Defense Single Stock Point (DoDSSP) by?

(i) Using the ASSIST Shopping Wizard (<https://assist.dla.mil/wizard/index.cfm>);

(ii) Phoning the DoDSSP Customer Service Desk (215) 697-2179, Mon-Fri, 0730 to 1600 EST; or

(iii) Ordering from DoDSSP, Building 4, Section D, 700 Robbins Avenue, Philadelphia, PA 19111-5094, Telephone (215) 697-2667/2179, Facsimile (215) 697-1462.

(4) Nongovernment (voluntary) standards must be obtained from the organization responsible for their preparation, publication, or maintenance.

(j) *Unique entity identifier.* (Applies to all offers exceeding \$3,500, and offers of \$3,500 or less if the solicitation requires the Contractor to be registered in the System for Award Management (SAM) database.) The Offeror shall enter, in the block with its name and address on the cover page of its offer, the annotation “Unique Entity Identifier” followed by the unique entity identifier that identifies the Offeror’s name and address. The Offeror also shall enter its Electronic Funds Transfer (EFT) indicator, if applicable. The EFT indicator is a four-character suffix to the unique entity identifier. The suffix is assigned at the discretion of the Offeror to establish additional SAM records for identifying alternative EFT accounts (see subpart 32.11) for the same entity. If the Offeror does not have a unique entity identifier, it should contact the entity designated at www.sam.gov for unique entity identifier establishment directly to obtain one. The Offeror should indicate that it is an offeror for a Government contract when contacting the entity designated at www.sam.gov for establishing the unique entity identifier.

(k) *System for Award Management.* Unless exempted by an addendum to this solicitation, by submission of an offer, the offeror acknowledges the requirement that a prospective awardee shall be registered in the SAM database prior to award, during performance and through final payment of any contract resulting from this solicitation. If the Offeror does not become registered in the SAM database in the time prescribed by the Contracting Officer, the Contracting Officer will proceed to award to the next otherwise successful registered Offeror. Offerors may obtain information on registration and annual confirmation requirements via the SAM database accessed through <https://www.acquisition.gov>.

(l) *Debriefing.* If a post-award debriefing is given to requesting offerors, the Government shall disclose the following information, if applicable:

(1) The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer.

(2) The overall evaluated cost or price and technical rating of the successful and the debriefed offeror and past performance information on the debriefed offeror.

(3) The overall ranking of all offerors, when any ranking was developed by the agency during source selection.

(4) A summary of the rationale for award;

(5) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

(6) Reasonable responses to relevant questions posed by the debriefed offeror as to whether source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities were followed by the agency.

(End of Provision)

(m) Instructions for Offer Submittal:

TECHNICAL QUESTIONS:

Technical questions shall be accepted by the Government in writing no later than Offer Due Date/Time (Block 8 of Standard Form 1449 of Solicitation). Please list “Technical Questions – VA770-17-Q-0221” in subject line of e-mail and send to Doug Reed, CO, at douglas.reed3@va.gov.

Please include in your questions the section of the solicitation/page number of the solicitation it is in reference to. The Contracting Officer will compile technical questions and provide Government responses to technical questions via solicitation amendment to www.fbo.gov if applicable.

OFFER SUBMITTAL INSTRUCTIONS:

- 1) Offeror shall submit offers by Due Date/Time specified in Block 8 of Standard Form (SF) 1449 of solicitation to Doug Reed, Contracting Officer, at douglas.reed3@va.gov.
- 2) By signing Standard Form (SF) 1449 of solicitation, Contractor attests acknowledgement of receipt of all solicitation amendments if applicable and also acknowledges IAW FAR 52.209-5 (Representation by Corporations Regarding An Unpaid Tax Liability or Felony Conviction Under Any Federal Law) that Contractor:
 - a) Does not have any unpaid Federal tax liability that has been assessed and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability.
 - b) Contractor, including its officers or agents acting on its behalf have not been convicted of a felony criminal violation under a Federal or State law within the preceding 24 months.
- 3) Subject line of e-mail shall be “Offer – VA770-17-1-0127” in subject line.
- 4) Offer shall also include the following:

Pricing: Contractor shall submit pricing in accordance with format listed in B.5 (Price Schedule); firm fixed pricing shall include all labor, overhead, profit, materials, and associated costs of the like to provide services in accordance with terms and conditions of the solicitation. Pricing may be submitted in PDF or Microsoft Excel format, but pricing shall not be handwritten on B.5 (Price Schedule) and submitted on that basis. *Page limits* are not applicable to Pricing.

Work Plan: A detailed work plan shall be submitted indicating how each aspect of the PWS is to be accomplished. The technical approach should be in as much detail as possible to fully explain the proposed technical approach. The technical approach should reflect a clear understanding of the nature of the work being undertaken. The technical approach shall include information on how the work is to be organized, staffed, and managed in-house with the Offeror. The technical approach shall address the following:

- **Partnering Agreement with accredited and certified testing laboratory if Prime Contractor is not also an accredited and certified testing laboratory**
- Personnel qualifications, including identification of key personnel; resumes shall be provided for key personnel
- Approach pertaining to contract deliverables
- Approach to delivering conforming services with minimal Government oversight
- Approach to personnel management and replacement
- Approach to measuring customer satisfaction
- Approach to risk management to include risk mitigation
- Approach to cost control
- Approach to schedule adherence
- Approach to incentives for personnel retention to ensure continual quality professionals to provide services

Page limit for Technical Approach is 25 pages. No smaller than 12-point Arial/Calibri/Times New Roman font for narrative and 10-point Arial/Calibri/TimesNew Roman font for tables. Font restrictions are not applicable to any other graphics (including flowcharts or charts).

Past Performance references, which shall be for work performed within past three (3) years and shall be relevant to the complexity, size, and scope of this requirement.

For references, offerors shall list:

- Name/address of organization contract was with
- Contract number/title
- Point of contact information (name/title/phone number/e-mail address)
- Brief description of contract scope and dollar value

Offeror shall use Solicitation Attachment 1 (Past Performance Questionnaire) to send to each reference cited to have reference e-mail to the Contracting Officer. It is the responsibility of the Offeror to verify the contact information of references and ensure references e-mail Past Performance Questionnaire to the Contracting Officer prior to offer due date/time.

There is a five (5) reference maximum.

References may be from Federal/State/Local Government organizations, academic organizations, or from commercial organizations in which the Contractor performed as a Prime Contractor. Government references are considered more relevant in priority order of Federal, State, and then Local.

(End of Provision)

ADDENDUM to FAR 52.212-1 INSTRUCTIONS TO OFFERORS—COMMERCIAL ITEMS

Provisions that are incorporated by reference (by Citation Number, Title, and Date), have 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 are incorporated into 52.212-1 as an addendum to this solicitation:

E.2 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 must be completed by the offeror and submitted with its quotation or offer. 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 its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this/these address(es):

<http://www.acquisition.gov/far/index.html>
<http://www.va.gov/oal/library/vaar/>

(End of Provision)

<u>FAR Number</u>	<u>Title</u>	<u>Date</u>
52.204-16	COMMERCIAL AND GOVERNMENT ENTITY CODE REPORTING	JUL 2016
52.204-17	OWNERSHIP OR CONTROL OF OFFEROR	JUL 2016

E.3 52.203-98 PROHIBITION ON CONTRACTING WITH ENTITIES THAT REQUIRE CERTAIN INTERNAL CONFIDENTIALITY AGREEMENTS—REPRESENTATION (DEVIATION) (FEB 2015)

(a) In accordance with section 743 of Division E, Title VII, of the Consolidated and Further Continuing Resolution Appropriations Act, 2015 (Pub. L. 113-235), Government agencies are not permitted to use funds appropriated (or otherwise made available) under that or any other Act for contracts with an entity that requires employees or subContractors of such entity seeking to report fraud, waste, or abuse to sign internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or contactors from lawfully reporting such waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information.

(b) The prohibition in paragraph (a) of this provision does not contravene requirements applicable to Standard Form 312, Form 4414, or any other form issued by a Federal department or agency governing the nondisclosure of classified information.

(c) *Representation.* By submission of its offer, the Offeror represents that it does not require employees or subContractors of such entity seeking to report fraud, waste, or abuse to sign internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subContractors from lawfully reporting such waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information.

(End of Provision)

E.4 52.209-5 REPRESENTATION BY CORPORATIONS REGARDING AN UNPAID TAX LIABILITY OR A FELONY CONVICTION UNDER ANY FEDERAL LAW (DEVIATION)(MAR 2012)

(a) In accordance with Division H, sections 8124 and 8125 of P.L. 112-74 and sections 738 and 739 of P.L. 112-55 none of the funds made available by either Act may be used to enter into a contract with any corporation that—

(1) Has an unpaid federal tax liability, unless the agency has considered suspension or debarment of the corporation and the Suspension and Debarment Official has made a determination that this action is not necessary to protect the interests of the Government.

(2) Has a felony criminal violation under any Federal or State law within the preceding 24 months, unless the agency has considered suspension or debarment of the corporation and Suspension and Debarment Official has made a determination that this action is not necessary to protect the interests of the Government.

(b) The Offeror represents that—

(1) The offeror does [] does not [] have any unpaid Federal tax liability that has been assessed and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability.

(2) The offeror, its officers or agents acting on its behalf have [] have not [] been convicted of a felony criminal violation under a Federal or State law within the preceding 24 months.

(End of Provision)

E.5 VAAR 852.270-1 REPRESENTATIVES OF CONTRACTING OFFICERS (JAN 2008)

The contracting officer reserves the right to designate representatives to act for him/her in furnishing technical guidance and advice or generally monitor the work to be performed under this contract. Such designation will be in writing and will define the scope and limitation of the designee's authority. A copy of the designation shall be furnished to the Contractor.

(End of Provision)

(End of Addendum to 52.212-1)

E.6 52.212-2 EVALUATION—COMMERCIAL ITEMS (OCT 2014) [TAILORED]

(a) The Government will award a contract resulting from this solicitation to the responsible offeror whose offer conforming to the solicitation will be most advantageous to the Government, price and other factors considered.

The Government will award on the following evaluation factor: Lowest Priced, Technically Acceptable (LPTA).

(b) A written notice of award or acceptance of an offer, e-mailed to the successful offeror within the time for acceptance specified in the offer, shall result in a binding contract without further action by either party. Before the offer's specified expiration time, the Government may accept an offer (or part of an offer), whether or not there are negotiations after its receipt, unless a written notice of withdrawal is received before award. The Government shall require the signature of offeror on contract prior to making award.

(c) Evaluation Approach

All quotes shall be subject to evaluation by a team of Government personnel. The Government reserves the right to award without discussions based on initial evaluation of offers. The quotes will be evaluated strictly in accordance with its written content. **Offerors who fail to address the minimum requirements of the solicitation will be rated “Technically Not Acceptable” and thus ineligible for award.**

The Government intends to make award based on the initial offers. If further questions are required, the Contracting Officer may contact the offerors for clarifications.

“Lowest Priced”

The Government will evaluate offers on the basis of grand total price for line item as specified on B.5 (Price Schedule). Price will be evaluated for completeness and reasonableness. The Government intends to make award of a single contract.

“Technically Acceptable”

Each offeror’s offer will be evaluated to determine if the offeror provides a sound, compliant approach that meets solicitation requirements and demonstrates a thorough understanding of those requirements; this is determined as follows:

- 1) Each offeror will also be evaluated on whether or not they provided signed **Standard Form (SF) 1449** of the solicitation in its offer, which offeror by such signature acknowledges all solicitation amendments posted to www.fbo.gov if applicable and that also certifies the following per FAR 52.209-5 (Representation by Corporations Regarding An Unpaid Tax Liability or Felony Conviction Under Any Federal Law):
 - Offeror does not have any unpaid Federal tax liability that has been assessed and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability.
 - Offeror, including its officers or agents acting on its behalf have not been convicted of a felony criminal violation under a Federal or State law within the preceding 24 months.
- 2) Each offeror will be evaluated on whether they provided a Work Plan that meets requirements as specified in Section E.1 (m) of solicitation
- 3) Each offeror will be evaluated on technical capability to provide needed services based on satisfactory past performance, as verified through offeror references provided, Past Performance Questionnaires submitted, and the Past Performance Information Retrieval System (PPIRS) at <https://www.ppirs.gov>. This will assess relative risks associated with a offeror’s likelihood of success in fulfilling the solicitation’s requirements as indicated by that offeror’s record of past performance.
- 4) The Government will assess based on the relevancy and recentness (offeror shall have relevant experience in providing services that are same or similar in nature to services being procured under this solicitation, and have recent experience within past three years) as it relates to probability of successful accomplishment of the required effort. Offerors are cautioned that the Government reserves the right to obtain past performance information from any available source (i.e., Better Business Bureau) besides those specified above. If an offeror has no record of relevant past performance or if past performance information is not available for such vendor, the offeror may not be evaluated satisfactory or unsatisfactory on past performance. Offerors will be assessed a Neutral rating. **Offerors who fail to have satisfactory or neutral past performance will be considered ineligible for award.**

(End of Provision)

E.7 52.212-3 OFFEROR REPRESENTATIONS AND CERTIFICATIONS— COMMERCIAL ITEMS (DEC 2016)

The Offeror shall complete only paragraph (b) of this provision if the Offeror has completed the annual representations and certification electronically via the System for Award Management (SAM) Web site located at <https://www.sam.gov/portal>. If the Offeror has not completed the annual representations and certifications electronically, the Offeror shall complete only paragraphs (c) through (t) of this provision.

(a) *Definitions.* As used in this provision—

Administrative merits determination means certain notices or findings of labor law violations issued by an enforcement agency following an investigation. An administrative merits determination may be final or be subject to appeal or further review. To determine whether a particular notice or finding is covered by this definition, it is necessary to consult section II.B. in the DOL Guidance.

Arbitral award or decision means an arbitrator or arbitral panel determination that a labor law violation occurred, or that enjoined or restrained a violation of labor law. It includes an award or decision that is not final or is subject to being confirmed, modified, or vacated by a court, and includes an award or decision resulting from private or confidential proceedings. To determine whether a particular award or decision is covered by this definition, it is necessary to consult section II.B. in the DOL Guidance.

Civil judgment means—

(1) In paragraph (h) of this provision: A judgment or finding of a civil offense by any court of competent jurisdiction.

(2) In paragraph (s) of this provision: Any judgment or order entered by any Federal or State court in which the court determined that a labor law violation occurred, or enjoined or restrained a violation of labor law. It includes a judgment or order that is not final or is subject to appeal. To determine whether a particular judgment or order is covered by this definition, it is necessary to consult section II.B. in the DOL Guidance.

DOL Guidance means the Department of Labor (DOL) Guidance entitled: “Guidance for Executive Order 13673, ‘Fair Pay and Safe Workplaces’ “. The DOL Guidance, dated August 25, 2016, can be obtained from www.dol.gov/fairpayandsafeworkplaces.

Economically disadvantaged women-owned small business (EDWOSB) concern means a small business concern that is at least 51 percent directly and unconditionally owned by, and the management and daily business operations of which are controlled by, one or more women who are citizens of the United States and who are economically disadvantaged in accordance with 13 CFR part 127. It automatically qualifies as a women-owned small business eligible under the WOSB Program.

Enforcement agency means any agency granted authority to enforce the Federal labor laws. It includes the enforcement components of DOL (Wage and Hour Division, Office of Federal Contract Compliance Programs, and Occupational Safety and Health Administration), the Equal Employment Opportunity Commission, the Occupational Safety and Health Review Commission, and the National Labor Relations Board. It also means a State agency designated to administer an OSHA-approved State Plan, but only to the extent that the State agency is acting in its capacity as administrator of such plan. It does not include other Federal agencies which, in their capacity as contracting agencies, conduct investigations of potential labor law violations. The enforcement agencies associated with each labor law under E.O. 13673 are—

(1) Department of Labor Wage and Hour Division (WHD) for—

(i) The Fair Labor Standards Act;

(ii) The Migrant and Seasonal Agricultural Worker Protection Act;

(iii) 40 U.S.C. chapter 31, subchapter IV, formerly known as the Davis-Bacon Act;

- (iv) 41 U.S.C. chapter 67, formerly known as the Service Contract Act;
- (v) The Family and Medical Leave Act; and
- (vi) E.O. 13658 of February 12, 2014 (Establishing a Minimum Wage for Contractors);
- (2) Department of Labor Occupational Safety and Health Administration (OSHA) for—
 - (i) The Occupational Safety and Health Act of 1970; and
 - (ii) OSHA-approved State Plans;
- (3) Department of Labor Office of Federal Contract Compliance Programs (OFCCP) for—
 - (i) Section 503 of the Rehabilitation Act of 1973;
 - (ii) The Vietnam Era Veterans' Readjustment Assistance Act of 1972 and the Vietnam Era Veterans' Readjustment Assistance Act of 1974; and
 - (iii) E.O. 11246 of September 24, 1965 (Equal Employment Opportunity);
- (4) National Labor Relations Board (NLRB) for the National Labor Relations Act; and
- (5) Equal Employment Opportunity Commission (EEOC) for—
 - (i) Title VII of the Civil Rights Act of 1964;
 - (ii) The Americans with Disabilities Act of 1990;
 - (iii) The Age Discrimination in Employment Act of 1967; and
 - (iv) Section 6(d) of the Fair Labor Standards Act (Equal Pay Act).

Forced or indentured child labor means all work or service—

- (1) Exacted from any person under the age of 18 under the menace of any penalty for its nonperformance and for which the worker does not offer himself voluntarily; or
- (2) Performed by any person under the age of 18 pursuant to a contract the enforcement of which can be accomplished by process or penalties.

Highest-level owner means the entity that owns or controls an immediate owner of the offeror, or that owns or controls one or more entities that control an immediate owner of the offeror. No entity owns or exercises control of the highest level owner.

Immediate owner means an entity, other than the offeror, that has direct control of the offeror. Indicators of control include, but are not limited to, one or more of the following: Ownership or interlocking management, identity of interests among family members, shared facilities and equipment, and the common use of employees.

Inverted domestic corporation means a foreign incorporated entity that meets the definition of an inverted domestic corporation under 6 U.S.C. 395(b), applied in accordance with the rules and definitions of 6 U.S.C. 395(c).

Labor compliance agreement means an agreement entered into between a Contractor or subContractor and an enforcement agency to address appropriate remedial measures, compliance assistance, steps to resolve issues to increase compliance with the labor laws, or other related matters.

Labor laws means the following labor laws and E.O.s:

- (1) The Fair Labor Standards Act.
- (2) The Occupational Safety and Health Act (OSHA) of 1970.
- (3) The Migrant and Seasonal Agricultural Worker Protection Act.
- (4) The National Labor Relations Act.
- (5) 40 U.S.C. chapter 31, subchapter IV, formerly known as the Davis-Bacon Act.
- (6) 41 U.S.C. chapter 67, formerly known as the Service Contract Act.
- (7) E.O. 11246 of September 24, 1965 (Equal Employment Opportunity).
- (8) Section 503 of the Rehabilitation Act of 1973.
- (9) The Vietnam Era Veterans' Readjustment Assistance Act of 1972 and the Vietnam Era Veterans' Readjustment Assistance Act of 1974.
- (10) The Family and Medical Leave Act.
- (11) Title VII of the Civil Rights Act of 1964.
- (12) The Americans with Disabilities Act of 1990.
- (13) The Age Discrimination in Employment Act of 1967.
- (14) E.O. 13658 of February 12, 2014 (Establishing a Minimum Wage for Contractors).
- (15) Equivalent State laws as defined in the DOL Guidance. (The only equivalent State laws implemented in the FAR are OSHA-approved State Plans, which can be found at www.osha.gov/dcsp/osp/approved_state_plans.html).

Labor law decision means an administrative merits determination, arbitral award or decision, or civil judgment, which resulted from a violation of one or more of the laws listed in the definition of “labor laws”.

Manufactured end product means any end product in product and service codes (PSCs) 1000-9999, except—

- (1) PSC 5510, Lumber and Related Basic Wood Materials;
- (2) Product or Service Group (PSG) 87, Agricultural Supplies;
- (3) PSG 88, Live Animals;
- (4) PSG 89, Subsistence;

- (5) PSC 9410, Crude Grades of Plant Materials;
- (6) PSC 9430, Miscellaneous Crude Animal Products, Inedible;
- (7) PSC 9440, Miscellaneous Crude Agricultural and Forestry Products;
- (8) PSC 9610, Ores;
- (9) PSC 9620, Minerals, Natural and Synthetic; and
- (10) PSC 9630, Additive Metal Materials.

Place of manufacture means the place where an end product is assembled out of components, or otherwise made or processed from raw materials into the finished product that is to be provided to the Government. If a product is disassembled and reassembled, the place of reassembly is not the place of manufacture.

Predecessor means an entity that is replaced by a successor and includes any predecessors of the predecessor.

Restricted business operations means business operations in Sudan that include power production activities, mineral extraction activities, oil-related activities, or the production of military equipment, as those terms are defined in the Sudan Accountability and Divestment Act of 2007 (Pub. L. 110-174). Restricted business operations do not include business operations that the person (as that term is defined in Section 2 of the Sudan Accountability and Divestment Act of 2007) conducting the business can demonstrate—

- (1) Are conducted under contract directly and exclusively with the regional government of southern Sudan;
- (2) Are conducted pursuant to specific authorization from the Office of Foreign Assets Control in the Department of the Treasury, or are expressly exempted under Federal law from the requirement to be conducted under such authorization;
- (3) Consist of providing goods or services to marginalized populations of Sudan;
- (4) Consist of providing goods or services to an internationally recognized peacekeeping force or humanitarian organization;
- (5) Consist of providing goods or services that are used only to promote health or education; or
- (6) Have been voluntarily suspended.

“Sensitive technology”—

- (1) Means hardware, software, telecommunications equipment, or any other technology that is to be used specifically—
 - (i) To restrict the free flow of unbiased information in Iran; or
 - (ii) To disrupt, monitor, or otherwise restrict speech of the people of Iran; and

(2) Does not include information or informational materials the export of which the President does not have the authority to regulate or prohibit pursuant to section 203(b)(3) of the International Emergency Economic Powers Act (50 U.S.C. 1702(b)(3)).

Service-disabled veteran-owned small business concern—

(1) Means a small business concern—

(i) Not less than 51 percent of which is owned by one or more service-disabled veterans or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more service-disabled veterans; and

(ii) The management and daily business operations of which are controlled by one or more service-disabled veterans or, in the case of a service-disabled veteran with permanent and severe disability, the spouse or permanent caregiver of such veteran.

(2) Service-disabled veteran means a veteran, as defined in 38 U.S.C. 101(2), with a disability that is service-connected, as defined in 38 U.S.C. 101(16).

Small business concern means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR Part 121 and size standards in this solicitation.

Small disadvantaged business concern, consistent with 13 CFR 124.1002, means a small business concern under the size standard applicable to the acquisition, that—

(1) Is at least 51 percent unconditionally and directly owned (as defined at 13 CFR 124.105) by—

(i) One or more socially disadvantaged (as defined at 13 CFR 124.103) and economically disadvantaged (as defined at 13 CFR 124.104) individuals who are citizens of the United States; and

(ii) Each individual claiming economic disadvantage has a net worth not exceeding \$750,000 after taking into account the applicable exclusions set forth at 13 CFR 124.104(c)(2); and

(2) The management and daily business operations of which are controlled (as defined at 13.CFR 124.106) by individuals, who meet the criteria in paragraphs (1)(i) and (ii) of this definition.

Subsidiary means an entity in which more than 50 percent of the entity is owned—

(1) Directly by a parent corporation; or

(2) Through another subsidiary of a parent corporation.

Successor means an entity that has replaced a predecessor by acquiring the assets and carrying out the affairs of the predecessor under a new name (often through acquisition or merger). The term “successor” does not include new offices/divisions of the same company or a company that only changes its name. The extent of the responsibility of the successor for the liabilities of the predecessor may vary, depending on State law and specific circumstances.

Veteran-owned small business concern means a small business concern—

(1) Not less than 51 percent of which is owned by one or more veterans (as defined at 38 U.S.C. 101(2)) or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more veterans; and

(2) The management and daily business operations of which are controlled by one or more veterans.

Women-owned business concern means a concern which is at least 51 percent owned by one or more women; or in the case of any publicly owned business, at least 51 percent of its stock is owned by one or more women; and whose management and daily business operations are controlled by one or more women.

Women-owned small business concern means a small business concern—

(1) That is at least 51 percent owned by one or more women; or, in the case of any publicly owned business, at least 51 percent of the stock of which is owned by one or more women; and

(2) Whose management and daily business operations are controlled by one or more women.

Women-owned small business (WOSB) concern eligible under the WOSB Program (in accordance with 13 CFR part 127), means a small business concern that is at least 51 percent directly and unconditionally owned by, and the management and daily business operations of which are controlled by, one or more women who are citizens of the United States.

Note to paragraph (a): By a court order issued on October 24, 2016, the following definitions in this paragraph (a) are enjoined indefinitely as of the date of the order: “Administrative merits determination”, “Arbitral award or decision”, paragraph (2) of “Civil judgment”, “DOL Guidance”, “Enforcement agency”, “Labor compliance agreement”, “Labor laws”, and “Labor law decision”. The enjoined definitions will become effective immediately if the court terminates the injunction. At that time, DoD, GSA, and NASA will publish a document in the **Federal Register** advising the public of the termination of the injunction.

(b)(1) *Annual Representations and Certifications.* Any changes provided by the offeror in paragraph (b)(2) of this provision do not automatically change the representations and certifications posted on the SAM website.

(2) The offeror has completed the annual representations and certifications electronically via the SAM website access through <http://www.acquisition.gov>. After reviewing the SAM database information, the offeror verifies by submission of this offer that the representations and certifications currently posted electronically at FAR 52.212-3, Offeror Representations and Certifications—Commercial Items, have been entered or updated in the last 12 months, are current, accurate, complete, and applicable to this solicitation (including the business size standard applicable to the NAICS code referenced for this solicitation), as of the date of this offer and are incorporated in this offer by reference (see FAR 4.1201), except for paragraphs NONE..

(c) Offerors must complete the following representations when the resulting contract will be performed in the United States or its outlying areas. Check all that apply.

(1) *Small business concern.* The offeror represents as part of its offer that it ☐ is, ☐ is not a small business concern.

(2) *Veteran-owned small business concern.* [Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.] The offeror represents as part of its offer that it ☐ is, ☐ is not a veteran-owned small business concern.

(3) *Service-disabled veteran-owned small business concern.* [Complete only if the offeror represented itself as a veteran-owned small business concern in paragraph (c)(2) of this provision.] The offeror represents as part of its offer that it ☐ is, ☐ is not a service-disabled veteran-owned small business concern.

(4) *Small disadvantaged business concern.* [Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.] The offeror represents that it ☐ is, ☐ is not a small disadvantaged business concern as defined in 13 CFR 124.1002.

(5) *Women-owned small business concern.* [Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.] The offeror represents that it ☐ is, ☐ is not a women-owned small business concern.

(6) WOSB concern eligible under the WOSB Program. [Complete only if the offeror represented itself as a women-owned small business concern in paragraph (c)(5) of this provision.] The offeror represents that—

(i) It ☐ is, ☐ is not a WOSB concern eligible under the WOSB Program, has provided all the required documents to the WOSB Repository, and no change in circumstances or adverse decisions have been issued that affects its eligibility; and

(ii) It ☐ is, ☐ is not a joint venture that complies with the requirements of 13 CFR part 127, and the representation in paragraph (c)(6)(i) of this provision is accurate for each WOSB concern eligible under the WOSB Program participating in the joint venture. [The offeror shall enter the name or names of the WOSB concern eligible under the WOSB Program and other small businesses that are participating in the joint venture: _____.] Each WOSB concern eligible under the WOSB Program participating in the joint venture shall submit a separate signed copy of the WOSB representation.

(7) Economically disadvantaged women-owned small business (EDWOSB) concern. [Complete only if the offeror represented itself as a WOSB concern eligible under the WOSB Program in (c)(6) of this provision.] The offeror represents that—

(i) It ☐ is, ☐ is not an EDWOSB concern, has provided all the required documents to the WOSB Repository, and no change in circumstances or adverse decisions have been issued that affects its eligibility; and

(ii) It ☐ is, ☐ is not a joint venture that complies with the requirements of 13 CFR part 127, and the representation in paragraph (c)(7)(i) of this provision is accurate for each EDWOSB concern participating in the joint venture. [The offeror shall enter the name or names of the EDWOSB concern and other small businesses that are participating in the joint venture: _____.] Each EDWOSB concern participating in the joint venture shall submit a separate signed copy of the EDWOSB representation.

Note: Complete paragraphs (c)(8) and (c)(9) only if this solicitation is expected to exceed the simplified acquisition threshold.

(8) *Women-owned business concern (other than small business concern).* [Complete only if the offeror is a women-owned business concern and did not represent itself as a small business concern in paragraph (c)(1) of this provision.] The offeror represents that it [] is a women-owned business concern.

(9) *Tie bid priority for labor surplus area concerns.* If this is an invitation for bid, small business offerors may identify the labor surplus areas in which costs to be incurred on account of manufacturing or production (by offeror or first-tier subContractors) amount to more than 50 percent of the contract price:

(10) *HUBZone small business concern.* [Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.] The offeror represents, as part of its offer, that—

(i) It [] is, [] is not a HUBZone small business concern listed, on the date of this representation, on the List of Qualified HUBZone Small Business Concerns maintained by the Small Business Administration, and no material change in ownership and control, principal office, or HUBZone employee percentage has occurred since it was certified by the Small Business Administration in accordance with 13 CFR Part 126; and

(ii) It [] is, [] is not a joint venture that complies with the requirements of 13 CFR Part 126, and the representation in paragraph (c)(10)(i) of this provision is accurate for the HUBZone small business concern or concerns that are participating in the joint venture. [The offeror shall enter the name or names of the HUBZone small business concern or concerns that are participating in the joint venture:_____.] Each HUBZone small business concern participating in the joint venture shall submit a separate signed copy of the HUBZone representation.

(d) Representations required to implement provisions of Executive Order 11246—

(1) *Previous contracts and compliance.* The offeror represents that—

(i) It [] has, [] has not participated in a previous contract or subcontract subject to the Equal Opportunity clause of this solicitation; and

(ii) It [] has, [] has not filed all required compliance reports.

(2) *Affirmative Action Compliance.* The offeror represents that—

(i) It [] has developed and has on file, [] has not developed and does not have on file, at each establishment, affirmative action programs required by rules and regulations of the Secretary of Labor (41 CFR parts 60-1 and 60-2), or

(ii) It [] has not previously had contracts subject to the written affirmative action programs requirement of the rules and regulations of the Secretary of Labor.

(e) *Certification Regarding Payments to Influence Federal Transactions* (31 U.S.C. 1352). (Applies only if the contract is expected to exceed \$150,000.) By submission of its offer, the offeror certifies to the best of its knowledge and belief that no Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress or an employee of a Member of Congress on his or her behalf in connection with the award of any resultant contract. If any registrants under the Lobbying Disclosure Act of 1995 have made a lobbying contact on behalf of the offeror with respect to this contract, the offeror shall complete and submit, with its offer, OMB Standard Form LLL, Disclosure of Lobbying Activities, to provide the name of the registrants. The offeror need not report regularly employed officers or employees of the offeror to whom payments of reasonable compensation were made.

(f) *Buy American Certificate*. (Applies only if the clause at Federal Acquisition Regulation (FAR) 52.225-1, Buy American—Supplies, is included in this solicitation.)

(1) The offeror certifies that each end product, except those listed in paragraph (f)(2) of this provision, is a domestic end product and that for other than COTS items, the offeror has considered components of unknown origin to have been mined, produced, or manufactured outside the United States. The offeror shall list as foreign end products those end products manufactured in the United States that do not qualify as domestic end products, i.e., an end product that is not a COTS item and does not meet the component test in paragraph (2) of the definition of “domestic end product.” The terms “commercially available off-the-shelf (COTS) item,” “component,” “domestic end product,” “end product,” “foreign end product,” and “United States” are defined in the clause of this solicitation entitled “Buy American—Supplies.”

(2) Foreign End Products:

Line Item No	Country of Origin
_____	_____
_____	_____
_____	_____

[List as necessary]

(3) The Government will evaluate offers in accordance with the policies and procedures of FAR Part 25.

(g)(1) *Buy American—Free Trade Agreements—Israeli Trade Act Certificate*. (Applies only if the clause at FAR 52.225-3, Buy American—Free Trade Agreements—Israeli Trade Act, is included in this solicitation.)

(i) The offeror certifies that each end product, except those listed in paragraph (g)(1)(ii) or (g)(1)(iii) of this provision, is a domestic end product and that for other than COTS items, the offeror has considered components of unknown origin to have been mined, produced, or manufactured outside the United States. The terms “Bahrainian, Moroccan, Omani, Panamanian, or Peruvian end product,” “commercially available off-the-shelf (COTS) item,” “component,” “domestic end product,” “end product,” “foreign end product,” “Free Trade Agreement country,” “Free Trade Agreement country end product,” “Israeli end product,” and “United States” are defined in the clause of this solicitation entitled “Buy American—Free Trade Agreements—Israeli Trade Act.”

(ii) The offeror certifies that the following supplies are Free Trade Agreement country end products (other than Bahrainian, Moroccan, Omani, Panamanian, or Peruvian end products) or Israeli end products as defined in the clause of this solicitation entitled “Buy American—Free Trade Agreements—Israeli Trade Act”:

Free Trade Agreement Country End Products (Other than Bahrainian, Moroccan, Omani, Panamanian, or Peruvian End Products) or Israeli End Products:

Line Item No.	Country of Origin
_____	_____
_____	_____
_____	_____

[List as necessary]

(iii) The offeror shall list those supplies that are foreign end products (other than those listed in paragraph (g)(1)(ii) of this provision) as defined in the clause of this solicitation entitled “Buy American—Free Trade Agreements—Israeli Trade Act.” The offeror shall list as other foreign end products those end products manufactured in the United States that do not qualify as domestic end products, i.e., an end product that is not a COTS item and does not meet the component test in paragraph (2) of the definition of “domestic end product.”

Other Foreign End Products:

Line Item No.	Country of Origin
_____	_____
_____	_____
_____	_____

[List as necessary]

(iv) The Government will evaluate offers in accordance with the policies and procedures of FAR Part 25.

(2) *Buy American—Free Trade Agreements—Israeli Trade Act Certificate, Alternate I.* If Alternate I to the clause at FAR 52.225-3 is included in this solicitation, substitute the following paragraph (g)(1)(ii) for paragraph (g)(1)(ii) of the basic provision:

(g)(1)(ii) The offeror certifies that the following supplies are Canadian end products as defined in the clause of this solicitation entitled “Buy American—Free Trade Agreements—Israeli Trade Act”:

Canadian End Products:

Line Item No.

[List as necessary]

(3) *Buy American—Free Trade Agreements—Israeli Trade Act Certificate, Alternate II.* If Alternate II to the clause at FAR 52.225-3 is included in this solicitation, substitute the following paragraph (g)(1)(ii) for paragraph (g)(1)(ii) of the basic provision:

(g)(1)(ii) The offeror certifies that the following supplies are Canadian end products or Israeli end products as defined in the clause of this solicitation entitled “Buy American—Free Trade Agreements—Israeli Trade Act”:

Canadian or Israeli End Products:

Line Item No.	Country of Origin
---------------	-------------------

[List as necessary]

(4) *Buy American—Free Trade Agreements—Israeli Trade Act Certificate, Alternate III.* If Alternate III to the clause at FAR 52.225-3 is included in this solicitation, substitute the following paragraph (g)(1)(ii) for paragraph (g)(1)(ii) of the basic provision:

(g)(1)(ii) The offeror certifies that the following supplies are Free Trade Agreement country end products (other than Bahrainian, Korean, Moroccan, Omani, Panamanian, or Peruvian end products) or Israeli end products as defined in the clause of this solicitation entitled “Buy American—Free Trade Agreements—Israeli Trade Act”:

Free Trade Agreement Country End Products (Other than Bahrainian, Korean, Moroccan, Omani, Panamanian, or Peruvian End Products) or Israeli End Products:

Line Item No.	Country of Origin
_____	_____
_____	_____
_____	_____

[List as necessary]

(5) *Trade Agreements Certificate*. (Applies only if the clause at FAR 52.225-5, Trade Agreements, is included in this solicitation.)

(i) The offeror certifies that each end product, except those listed in paragraph (g)(5)(ii) of this provision, is a U.S.-made or designated country end product, as defined in the clause of this solicitation entitled “Trade Agreements”.

(ii) The offeror shall list as other end products those end products that are not U.S.-made or designated country end products.

Other End Products:

Line Item No.	Country of Origin
_____	_____
_____	_____
_____	_____

[List as necessary]

(iii) The Government will evaluate offers in accordance with the policies and procedures of FAR Part 25. For line items covered by the WTO GPA, the Government will evaluate offers of U.S.-made or designated country end products without regard to the restrictions of the Buy American statute. The Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation.

(h) *Certification Regarding Responsibility Matters* (Executive Order 12689). (Applies only if the contract value is expected to exceed the simplified acquisition threshold.) The offeror certifies, to the best of its knowledge and belief, that the offeror and/or any of its principals—

(1) ☐ Are, ☐ are not presently debarred, suspended, proposed for debarment, or declared ineligible for the award of contracts by any Federal agency;

(2) [] Have, [] have not, within a three-year period preceding this offer, been convicted of or had a civil judgment rendered against them for: commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a Federal, state or local government contract or subcontract; violation of Federal or state antitrust statutes relating to the submission of offers; or Commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, violating Federal criminal tax laws, or receiving stolen property;

(3) [] Are, [] are not presently indicted for, or otherwise criminally or civilly charged by a Government entity with, commission of any of these offenses enumerated in paragraph (h)(2) of this clause; and

(4) [] Have, [] have not, within a three-year period preceding this offer, been notified of any delinquent Federal taxes in an amount that exceeds \$3,500 for which the liability remains unsatisfied.

(i) Taxes are considered delinquent if both of the following criteria apply:

(A) *The tax liability is finally determined.* The liability is finally determined if it has been assessed. A liability is not finally determined if there is a pending administrative or judicial challenge. In the case of a judicial challenge to the liability, the liability is not finally determined until all judicial appeal rights have been exhausted.

(B) *The taxpayer is delinquent in making payment.* A taxpayer is delinquent if the taxpayer has failed to pay the tax liability when full payment was due and required. A taxpayer is not delinquent in cases where enforced collection action is precluded.

(ii) *Examples.*

(A) The taxpayer has received a statutory notice of deficiency, under I.R.C. Sec. 6212, which entitles the taxpayer to seek Tax Court review of a proposed tax deficiency. This is not a delinquent tax because it is not a final tax liability. Should the taxpayer seek Tax Court review, this will not be a final tax liability until the taxpayer has exercised all judicial appeal rights.

(B) The IRS has filed a notice of Federal tax lien with respect to an assessed tax liability, and the taxpayer has been issued a notice under I.R.C. Sec. 6320 entitling the taxpayer to request a hearing with the IRS Office of Appeals contesting the lien filing, and to further appeal to the Tax Court if the IRS determines to sustain the lien filing. In the course of the hearing, the taxpayer is entitled to contest the underlying tax liability because the taxpayer has had no prior opportunity to contest the liability. This is not a delinquent tax because it is not a final tax liability. Should the taxpayer seek tax court review, this will not be a final tax liability until the taxpayer has exercised all judicial appeal rights.

(C) The taxpayer has entered into an installment agreement pursuant to I.R.C. Sec. 6159. The taxpayer is making timely payments and is in full compliance with the agreement terms. The taxpayer is not delinquent because the taxpayer is not currently required to make full payment.

(D) The taxpayer has filed for bankruptcy protection. The taxpayer is not delinquent because enforced collection action is stayed under 11 U.S.C. 362 (the Bankruptcy Code).

(i) *Certification Regarding Knowledge of Child Labor for Listed End Products (Executive Order 13126).*

(1) *Listed end products.*

Listed End Product	Listed Countries of Origin
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N/A

N/A

(2) *Certification. [If the Contracting Officer has identified end products and countries of origin in paragraph (i)(1) of this provision, then the offeror must certify to either (i)(2)(i) or (i)(2)(ii) by checking the appropriate block.]*

☐ (i) The offeror will not supply any end product listed in paragraph (i)(1) of this provision that was mined, produced, or manufactured in the corresponding country as listed for that product.

☐ (ii) The offeror may supply an end product listed in paragraph (i)(1) of this provision that was mined, produced, or manufactured in the corresponding country as listed for that product. The offeror certifies that it has made a good faith effort to determine whether forced or indentured child labor was used to mine, produce, or manufacture any such end product furnished under this contract. On the basis of those efforts, the offeror certifies that it is not aware of any such use of child labor.

(j) *Place of manufacture.* (Does not apply unless the solicitation is predominantly for the acquisition of manufactured end products.) For statistical purposes only, the offeror shall indicate whether the place of manufacture of the end products it expects to provide in response to this solicitation is predominantly—

(1) ☐ In the United States (Check this box if the total anticipated price of offered end products manufactured in the United States exceeds the total anticipated price of offered end products manufactured outside the United States); or

(2) ☐ Outside the United States.

(k) *Certificates regarding exemptions from the application of the Service Contract Labor Standards.* (Certification by the offeror as to its compliance with respect to the contract also constitutes its certification as to compliance by its subContractor if it subcontracts out the exempt services.)

☐ (1) Maintenance, calibration, or repair of certain equipment as described in FAR 22.1003-4(c)(1). The offeror ☐ does ☐ does not certify that—

(i) The items of equipment to be serviced under this contract are used regularly for other than Governmental purposes and are sold or traded by the offeror (or subContractor in the case of an exempt subcontract) in substantial quantities to the general public in the course of normal business operations;

(ii) The services will be furnished at prices which are, or are based on, established catalog or market prices (see FAR 22.1003- 4(c)(2)(ii)) for the maintenance, calibration, or repair of such equipment; and

(iii) The compensation (wage and fringe benefits) plan for all service employees performing work under the contract will be the same as that used for these employees and equivalent employees servicing the same equipment of commercial customers.

☐ (2) Certain services as described in FAR 22.1003- 4(d)(1). The offeror ☐ does ☐ does not certify that—

(i) The services under the contract are offered and sold regularly to non-Governmental customers, and are provided by the offeror (or subContractor in the case of an exempt subcontract) to the general public in substantial quantities in the course of normal business operations;

(ii) The contract services will be furnished at prices that are, or are based on, established catalog or market prices (see FAR 22.1003-4(d)(2)(iii));

(iii) Each service employee who will perform the services under the contract will spend only a small portion of his or her time (a monthly average of less than 20 percent of the available hours on an annualized basis, or less than 20 percent of available hours during the contract period if the contract period is less than a month) servicing the Government contract; and

(iv) The compensation (wage and fringe benefits) plan for all service employees performing work under the contract is the same as that used for these employees and equivalent employees servicing commercial customers.

(3) If paragraph (k)(1) or (k)(2) of this clause applies—

(i) If the offeror does not certify to the conditions in paragraph (k)(1) or (k)(2) and the Contracting Officer did not attach a Service Contract Labor Standards wage determination to the solicitation, the offeror shall notify the Contracting Officer as soon as possible; and

(ii) The Contracting Officer may not make an award to the offeror if the offeror fails to execute the certification in paragraph (k)(1) or (k)(2) of this clause or to contact the Contracting Officer as required in paragraph (k)(3)(i) of this clause.

(l) *Taxpayer Identification Number (TIN)* (26 U.S.C. 6109, 31 U.S.C. 7701). (Not applicable if the offeror is required to provide this information to the SAM database to be eligible for award.)

(1) All offerors must submit the information required in paragraphs (l)(3) through (l)(5) of this provision to comply with debt collection requirements of 31 U.S.C. 7701(c) and 3325(d), reporting requirements of 26 U.S.C. 6041, 6041A, and 6050M, and implementing regulations issued by the Internal Revenue Service (IRS).

(2) The TIN may be used by the Government to collect and report on any delinquent amounts arising out of the offeror's relationship with the Government (31 U.S.C. 7701(c)(3)). If the resulting contract is subject to the payment reporting requirements described in FAR 4.904, the TIN provided hereunder may be matched with IRS records to verify the accuracy of the offeror's TIN.

(3) *Taxpayer Identification Number (TIN)*.

☐ TIN: _____.

☐ TIN has been applied for.

☐ TIN is not required because:

☐ Offeror is a nonresident alien, foreign corporation, or foreign partnership that does not have income effectively connected with the conduct of a trade or business in the United States and does not have an office or place of business or a fiscal paying agent in the United States;

☐ Offeror is an agency or instrumentality of a foreign government;

☐ Offeror is an agency or instrumentality of the Federal Government.

(4) *Type of organization.*

☐ Sole proprietorship;

☐ Partnership;

☐ Corporate entity (not tax-exempt);

☐ Corporate entity (tax-exempt);

☐ Government entity (Federal, State, or local);

☐ Foreign government;

☐ International organization per 26 CFR 1.6049-4;

☐ Other _____.

(5) *Common parent.*

☐ Offeror is not owned or controlled by a common parent;

☐ Name and TIN of common parent:

Name _____.

TIN _____.

(m) *Restricted business operations in Sudan.* By submission of its offer, the offeror certifies that the offeror does not conduct any restricted business operations in Sudan.

(n) *Prohibition on Contracting with Inverted Domestic Corporations.*

(1) Government agencies are not permitted to use appropriated (or otherwise made available) funds for contracts with either an inverted domestic corporation, or a subsidiary of an inverted domestic corporation, unless the exception at 9.108-2(b) applies or the requirement is waived in accordance with the procedures at 9.108-4.

(2) *Representation.* The Offeror represents that—

(i) It ☐ is, ☐ is not an inverted domestic corporation; and

(ii) It ☐ is, ☐ is not a subsidiary of an inverted domestic corporation.

(o) *Prohibition on contracting with entities engaging in certain activities or transactions relating to Iran.*

(1) The offeror shall email questions concerning sensitive technology to the Department of State at CISADA106@state.gov.

(2) *Representation and certifications.* Unless a waiver is granted or an exception applies as provided in paragraph (o)(3) of this provision, by submission of its offer, the offeror—

(i) Represents, to the best of its knowledge and belief, that the offeror does not export any sensitive technology to the government of Iran or any entities or individuals owned or controlled by, or acting on behalf or at the direction of, the government of Iran;

(ii) Certifies that the offeror, or any person owned or controlled by the offeror, does not engage in any activities for which sanctions may be imposed under section 5 of the Iran Sanctions Act; and

(iii) Certifies that the offeror, and any person owned or controlled by the offeror, does not knowingly engage in any transaction that exceeds \$3,500 with Iran's Revolutionary Guard Corps or any of its officials, agents, or affiliates, the property and interests in property of which are blocked pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) (see OFAC's Specially Designated Nationals and Blocked Persons List at <http://www.treasury.gov/ofac/downloads/t11sdn.pdf>).

(3) The representation and certification requirements of paragraph (o)(2) of this provision do not apply if—

(i) This solicitation includes a trade agreements certification (*e.g.*, 52.212–3(g) or a comparable agency provision); and

(ii) The offeror has certified that all the offered products to be supplied are designated country end products.

(p) *Ownership or Control of Offeror.* (Applies in all solicitations when there is a requirement to be registered in SAM or a requirement to have a unique entity identifier in the solicitation).

(1) The Offeror represents that it ☐ has or ☐ does not have an immediate owner. If the Offeror has more than one immediate owner (such as a joint venture), then the Offeror shall respond to paragraph (2) and if applicable, paragraph (3) of this provision for each participant in the joint venture.

(2) If the Offeror indicates “has” in paragraph (p)(1) of this provision, enter the following information:

Immediate owner CAGE code: ____.

Immediate owner legal name: ____.

(Do not use a “doing business as” name)

Is the immediate owner owned or controlled by another entity: ☐ Yes or ☐ No.

(3) If the Offeror indicates “yes” in paragraph (p)(2) of this provision, indicating that the immediate owner is owned or controlled by another entity, then enter the following information:

Highest-level owner CAGE code: ____.

Highest-level owner legal name: ____.

(Do not use a “doing business as” name)

(q) Representation by Corporations Regarding Delinquent Tax Liability or a Felony Conviction under any Federal Law.

(1) As required by sections 744 and 745 of Division E of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235), and similar provisions, if contained in subsequent appropriations acts, The Government will not enter into a contract with any corporation that—

(i) Has any unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability, where the awarding agency is aware of the unpaid tax liability, unless an agency has considered suspension or debarment of the corporation and made a determination that suspension or debarment is not necessary to protect the interests of the Government; or

(ii) Was convicted of a felony criminal violation under any Federal law within the preceding 24 months, where the awarding agency is aware of the conviction, unless an agency has considered suspension or debarment of the corporation and made a determination that this action is not necessary to protect the interests of the Government.

(2) The Offeror represents that—

(i) It is ☐ is not ☐ a corporation that has any unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability; and

(ii) It is ☐ is not ☐ a corporation that was convicted of a felony criminal violation under a Federal law within the preceding 24 months.

(r) Predecessor of Offeror. (Applies in all solicitations that include the provision at 52.204-16, Commercial and Government Entity Code Reporting.)

(1) The Offeror represents that it ☐ is or ☐ is not a successor to a predecessor that held a Federal contract or grant within the last three years.

(2) If the Offeror has indicated “is” in paragraph (r)(1) of this provision, enter the following information for all predecessors that held a Federal contract or grant within the last three years (if more than one predecessor, list in reverse chronological order):

Predecessor CAGE code: ____ (or mark “Unknown”).

Predecessor legal name: ____.

(Do not use a “doing business as” name).

(s) Representation regarding compliance with labor laws (Executive Order 13673). If the offeror is a joint venture that is not itself a separate legal entity, each concern participating in the joint venture shall separately comply with the requirements of this provision.

(1)(i) For solicitations issued on or after October 25, 2016 through April 24, 2017: The Offeror ☐ does ☐ does not anticipate submitting an offer with an estimated contract value of greater than \$50 million.

(ii) For solicitations issued after April 24, 2017: The Offeror ☐ does ☐ does not anticipate submitting an offer with an estimated contract value of greater than \$500,000.

(2) If the Offeror checked “does” in paragraph (s)(1)(i) or (ii) of this provision, the Offeror represents to the best of the Offeror's knowledge and belief [Offeror to check appropriate block]:

☐ (i) There has been no administrative merits determination, arbitral award or decision, or civil judgment for any labor law violation(s) rendered against the offeror (see definitions in paragraph (a) of this section) during the period beginning on October 25, 2015 to the date of the offer, or for three years preceding the date of the offer, whichever period is shorter; or

☐ (ii) There has been an administrative merits determination, arbitral award or decision, or civil judgment for any labor law violation(s) rendered against the Offeror during the period beginning on October 25, 2015 to the date of the offer, or for three years preceding the date of the offer, whichever period is shorter.

(3)(i) If the box at paragraph (s)(2)(ii) of this provision is checked and the Contracting Officer has initiated a responsibility determination and has requested additional information, the Offeror shall provide--

(A) The following information for each disclosed labor law decision in the System for Award Management (SAM) at www.sam.gov, unless the information is already current, accurate, and complete in SAM. This information will be publicly available in the Federal Awardee Performance and Integrity Information System (FAPIS):

(1) The labor law violated.

(2) The case number, inspection number, charge number, docket number, or other unique identification number.

(3) The date rendered.

(4) The name of the court, arbitrator(s), agency, board, or commission that rendered the determination or decision;

(B) The administrative merits determination, arbitral award or decision, or civil judgment document, to the Contracting Officer, if the Contracting Officer requires it;

(C) In SAM, such additional information as the Offeror deems necessary to demonstrate its responsibility, including mitigating factors and remedial measures such as offeror actions taken to address the violations, labor compliance agreements, and other steps taken to achieve compliance with labor laws. Offerors may provide explanatory text and upload documents. This information will not be made public unless the Contractor determines that it wants the information to be made public; and

(D) The information in paragraphs (s)(3)(i)(A) and (s)(3)(i)(C) of this provision to the Contracting Officer, if the Offeror meets an exception to SAM registration (see FAR 4.1102(a)).

(ii)(A) The Contracting Officer will consider all information provided under (s)(3)(i) of this provision as part of making a responsibility determination.

(B) A representation that any labor law decision(s) were rendered against the Offeror will not necessarily result in withholding of an award under this solicitation. Failure of the Offeror to furnish a representation or provide such additional information as requested by the Contracting Officer may render the Offeror nonresponsible.

(C) The representation in paragraph (s)(2) of this provision is a material representation of fact upon which reliance was placed when making award. If it is later determined that the Offeror knowingly rendered an erroneous representation, in addition to other remedies available to the Government, the Contracting Officer may terminate the contract resulting from this solicitation in accordance with the procedures set forth in FAR 12.403.

(4) The Offeror shall provide immediate written notice to the Contracting Officer if at any time prior to contract award the Offeror learns that its representation at paragraph (s)(2) of this provision is no longer accurate.

(5) The representation in paragraph (s)(2) of this provision will be public information in the Federal Awardee Performance and Integrity Information System (FAPIIS).

Note to paragraph (s): By a court order issued on October 24, 2016, this paragraph (s) is enjoined indefinitely as of the date of the order. The enjoined paragraph will become effective immediately if the court terminates the injunction. At that time, DoD, GSA, and NASA will publish a document in the **Federal Register** advising the public of the termination of the injunction.

(t) *Public Disclosure of Greenhouse Gas Emissions and Reduction Goals.* Applies in all solicitations that require offerors to register in SAM (52.212-1(k)).

(1) This representation shall be completed if the Offeror received \$7.5 million or more in contract awards in the prior Federal fiscal year. The representation is optional if the Offeror received less than \$7.5 million in Federal contract awards in the prior Federal fiscal year.

(2) Representation. [Offeror to check applicable block(s) in paragraph (t)(2)(i) and (ii)]. (i) The Offeror (itself or through its immediate owner or highest-level owner) [] does, [] does not publicly disclose greenhouse gas emissions, i.e., makes available on a publicly accessible Web site the results of a greenhouse gas inventory, performed in accordance with an accounting standard with publicly available and consistently applied criteria, such as the Greenhouse Gas Protocol Corporate Standard.

(ii) The Offeror (itself or through its immediate owner or highest-level owner) [] does, [] does not publicly disclose a quantitative greenhouse gas emissions reduction goal, i.e., make available on a publicly accessible Web site a target to reduce absolute emissions or emissions intensity by a specific quantity or percentage.

(iii) A publicly accessible Web site includes the Offeror's own Web site or a recognized, third-party greenhouse gas emissions reporting program.

(3) If the Offeror checked “does” in paragraphs (t)(2)(i) or (t)(2)(ii) of this provision, respectively, the Offeror shall provide the publicly accessible Web site(s) where greenhouse gas emissions and/or reduction goals are reported:_____.

(End of Provision)