	CONTRACT/ORDI			The state of the s	1. REQUISITI 0011520474-0		BER			PAGE 1	OF 28
2. CONTRACT NO. W911SR20C0049		RD/EFFECTIVE DATE ug-2020	4. ORDE	R NUMBER			SR20F	N NUMBER R0003		SOLICITATI 2-May-20	ON ISSUE DATE
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Section SF 1449 - CONTINUATION SHEET

STATEMENT OF WORK

# STATEMENT OF WORK PROCUREMENT OF SAFETY NEEDLES AND SYRINGES FOR COVID-19

**1.0 SCOPE:** The Contractor, as an independent Contractor and not as an agent of the Government, shall furnish the necessary resources as specified in this Statement of Work (SOW), to manufacture and/or supply Safety Needles and Syringes.

## 2.0 BACKGROUND:

On Friday, March 13, 2020, the President declared a national emergency concerning the novel coronavirus disease (COVID-19) under section 501(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5207 (the "Stafford Act).

The mission of the Division of Strategic National Stockpile (DSNS), of the United States (U.S.) Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR), is to ensure the availability and rapid deployment of life-saving pharmaceuticals, antidotes, other medical supplies, and equipment necessary to counter the effects of nerve agents, biological pathogens, and chemical agents. When state, local, tribal, and territorial public health and medical systems request federal assistance to support their response efforts, DSNS ensures the right medicines and supplies get to those who need them most during an emergency. When the vaccine becomes available the Government will have an immediate need to begin vaccinating the entire U.S. population. To administer the vaccine the Government will require needles and syringes to be available.

There is an insufficient domestic supply of safety needles and syringes to meet the projected needs to vaccinate the nation's entire population against COVID-19. Should vaccine programs be accelerated, demand could outpace available devices to administer a vaccine.

3.0 <u>OBJECTIVE</u>: The HHS currently has contracts in place with three (3) major manufacturers to provide needles and syringes supplies to support the initial preparedness needs at the onset of a pandemic outbreak. The objective of this acquisition is to supplement the current supply and establish contracts with additional manufacturers and suppliers to provide a quantity of up to 500 million safety needles and syringes supplies.

#### **4.0 REQUIREMENTS:**

#### 4.1. General:

4.1.1. The Contractor shall "host" a *Kick-Off Meeting* within one (1) calendar day after contract award via <u>teleconference</u>. The Contractor shall provide *Meeting Minutes* containing a detailed overview of the meeting discussions in accordance with (IAW) Contract Data Requirements List (CDRL) A001.

- 4.1.1.1. The Contractor shall provide a *Certificate of Analysis* with each shipment per the DD Form 1423, Contract Data Requirements List (CDRL) A002, confirming the supplies described below meet the Performance Specifications in paragraph 4.2 below.
- 4.1.2. The Contractor shall provide copies of 510(k) Approval Letters for ALL supplies (dispensing syringes or needles) to demonstrate compliance with Section 510(k) of the Food, Drug and Cosmetic Act as part of their proposal. The Contractor shall provide, if necessary, 510(k) Approval Letters Updates if any information from the initial 510(k) Approval Letters is changed/needs to be updated.
- 4.1.2.1.1. The Contractor shall ensure all supplies have a "Shelf-Life" with expiration dates of no less than five (5) years from the date of sterilization, <u>and</u> must have at least four (4) years of remaining expiry from the time of shipment.
- 4.1.2.1.2. The Contractor shall only use *Current Good Manufacturing Practice (cGMP)* processes to manufacture the needles and syringes.
- 4.1.2.1.3. **Period of Performance/Delivery Dates.** See the "Delivery Schedule" section of this Contract and "Attachment 2-Shipping Information" for all delivery requirements and shipping locations.

# 4.2. Technical Requirements:

4.2.1.The Contractor shall provide sterile needle (with Luer hub connection) and syringe (with Luer lock connection) units approved by the Food and Drug Administration (FDA) and comply with Occupational Safety and Health Administration (OSHA) Needlestick Safety and Prevention Act requirements as a "safety-engineered product." Safety-engineered supplies include needles preventing sharp injuries by either; being completely enclosed after use by an attached shield, or be fully retracted within the syringe. The Contractor may provide individual syringes and individual needles as long as there is a one-to-one (1:1) ratio. In order to meet the specified quantities upon contract award and comply with the specifications in this SOW, the following may be provided: (1) individually wrapped sterile syringes with individually wrapped sterile needles in a one-to-one (1:1) ratio, (2) sterile needle/syringe combination unit, or (3) a mixture of sterile combination units and individually wrapped sterile syringes with equal number of individually wrapped sterile needles.

4.2.2. The Contractor shall only provide acceptable product sizes as described below:

Individual Syringe:

Syringe
1mL
3mL

Individual Needle:

Needle Gauge	Needle Length
23G	1"
23G	1.5"
25G	1"

#### Combination Unit:

Syringe	Needle Gauge	Needle Length
1mL	23G	1"
lmL	23G	1.5"
lmL	25G	1"
3mL	23G	1"
3mL	23G	1.5"
3mL	25G	1"

- 4.2.3. **Dispensing Syringe:** Description: A dispensing syringe allows for the controlled and precise flow of liquid. The dispensing syringe is used to inject medications or other liquids into body tissues. Manual syringes consist of a barrel, stopper, and plunger.
- 4.2.3.1. The Contractor shall ensure dispensing syringes comply with Title 21 Code of Federal Regulations (CFR) 880.5860 and follow International Standards Organization (ISO) 7886-1:2017 and the following material specifications:
- 4.2.3.1.1. A device intended for medical purposes that consists of a calibrated hollow barrel and a movable plunger. At one end of the barrel there is a male connector (nozzle) for fitting the female connector (hub) of a hypodermic single lumen needle;
- 4.2.3.1.2. Heavy duty barrel The barrel has a scale showing the capacity of the syringe.
- 4.2.3.1.3. Stopper The stopper maintains the fluid in the barrel between the syringe nozzle and the plunger;
- 4.2.3.1.4. Plunger The plunger is used to aspirate and inject fluids into and out of the syringe;
- 4.2.3.1.5. Disposable;
- 4.2.3.1.6. <u>Luer lock</u> to accept luer hub applicator (e.g. needle);
- 4.2.3.1.7. Sizes as specified in Section 4.2.2 above; and
- 4.2.3.1.8. Sterile individually wrapped packaging.
- 4.2.4. **Hypodermic Needle:** *Description*: A Hypodermic needle is a slender, hollow instrument for introducing material into the body parenterally.
- 4.2.4.1. The Contractor shall ensure hypodermic needles comply with 21 CFR 880.5570, OSHA Needlestick Safety and Prevention Act, and follow International Standards Organization (ISO) 7864, and the following specifications:

- 4.2.4.1.1. Disposable;
- 4.2.4.1.2. <u>Luer hub</u> to attach to luer lock syringe;
- 4.2.4.1.3. See Tables in Sections 4.2.2 above for acceptable needle length and gauges;
- 4.2.4.1.4. Sterile individually wrapped packaging; and
- 4.2.4.1.5. Safety-engineered.
- 4.3. **Delivery Location and Shipping Requirements:** See Attachment 2-"Shipping Information" for all delivery locations and shipping requirements.
- 4.3.1. The Contractor shall provide *Packing Slips* with <u>all shipments</u> per CDRL A003. The Packing Slips shall include the following: (1) Contract number, (2) Item description, (3) Part number, (4) Lot numbers; and (5) Quantities. The Packing Slips shall include <u>BOTH</u>: (1) a *Packing Slip Paper Copy* with the shipment; and (2) a *Packing Slip Paper Emailed Copy* to the Designated Government Representative.
- 4.3.2. No Partial Case or Packages quantities will be accepted unless approved by the Contracting Officer prior to shipping.
- 4.3.3.The Contractor shall **NOT** Mixed Lot #'s per Case or per Packages. The Contractor shall only provide full <u>case</u> quantities <u>only</u>, *unless* approved by the Designated Government Representative in advance via email.
- 4.3.4. The Contractor shall ensure all pallets have the identical TyHi stack pattern, except for the final pallet; which would be a partial pallet or individual boxes.
- 4.3.5. All supplies shall be delivered on a standard 48" by 40" pallet, not to exceed 60" in height, stretch wrapped, clear-wrapped is preferred, and secured to the pallet for safe transport.
- 4.3.6. The Contractor shall contact the Designated Government Representative to schedule delivery appointments. The Government will provide the Designated Government Representative(s)' information at the Kick-Off Meeting.
- 4.3.7. Contractor shall contact the Designated Government Representative to schedule delivery appointments.

#### **Operation Warp Speed (OWS) Contract Language:**

## **Disclosure of Information**

Performance under this contract may require the Contractor to access non-public data and information proprietary to a Government agency, another Government Contractor or of such nature that its dissemination or use other than as specified in the work statement would be adverse to the interests of the Government or others. Neither the Contractor, nor Contractor personnel, shall divulge nor release data nor information developed or obtained under performance of this contract, except authorized by Government personnel or upon written approval of the CO in accordance with OWS or other Government policies and/or guidance. The

Contractor shall not use, disclose, or reproduce proprietary data that bears a restrictive legend, other than as specified in this contract, or any information at all regarding this agency.

The Contractor shall comply with all Government requirements for protection of non-public information. Unauthorized disclosure of nonpublic information is prohibited by the Government's rules. Unauthorized disclosure may result in termination of the contract, replacement of a Contractor employee, or other appropriate redress. Neither the Contractor nor the Contractor's employees shall disclose or cause to be disseminated, any information concerning the operations of the activity, which could result in, or increase the likelihood of, the possibility of a breach of the activity's security or interrupt the continuity of its operations.

No information related to data obtained under this contract shall be released or publicized without the prior written consent of the COR, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity' for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions.

## **Publications and Publicity**

The contractor shall not release any reports, manuscripts, press releases, or abstracts about the work being performed under this contract without written notice in advance to the Government. (a) Unless otherwise specified in this contract, the contractor may publish the results of its work under this contract. The contractor shall promptly send a copy of each submission to the COR for security review prior to submission. The contractor shall also inform the COR when the abstract article or other publication is published, and furnish a copy of it as finally published.

- (b) Unless authorized in writing by the CO, the contractor shall not display Government logos including Operating Division or Staff Division logos on any publications.
- (c) The contractor shall not reference the products(s) or services(s) awarded under this contract in commercial advertising, as defined in FAR 31.205-1, in any manner which states or implies Government approval or endorsement of the product(s) or service(s) provided.
- (d) The contractor shall include this clause, including this section (d) in all subcontracts where the subcontractor may propose publishing the results of its work under the subcontract. The contractor shall acknowledge the support of the Government whenever publicizing the work under this contract in any media by including an acknowledgement substantially as follows: "This project has been funded in whole or in part by the U.S. Government under Contract No. XXXX. The US Government is authorized to reproduce and distribute reprints for Governmental purposes notwithstanding any copyright notation thereon."

## **Confidentiality of Information**

a. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

- b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.
- c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.
- d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.
- e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor shall obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.
- f. Contracting Officer Determinations will reflect the result of internal coordination with appropriate program and legal officials.
- g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

All above requirements MUST be passed to all Sub-contractors.

# **Organizational Conflicts of Interest**

Performance under this contract may create an actual or potential organizational conflict of interest such as are contemplated by FAR Part 9.505-General Rules. The Contractor shall not engage in any other contractual or other activities which could create an organizational conflict of interest (OCI). This provision shall apply to the prime Contractor and all sub-Contractors. This provision shall have effect throughout the period of performance of this contract, any extensions thereto by change order or supplemental agreement, and for two (2) years thereafter. The Government may pursue such remedies as may be permitted by law or this contract, upon determination that an OCI has occurred.

The work performed under this contract may create a significant potential for certain conflicts of interest, as set forth in FAR Parts 9.505-1, 9.505-2, 9.505-3, and 9.505-4. It is the intention of the parties hereto to prevent both the potential for bias in connection with the Contractor's performance of this contract, as well as the creation of any unfair competitive advantage as a

result of knowledge gained through access to any non-public data or third party proprietary information.

The Contractor shall notify the Contracting Officer immediately whenever it becomes aware that such access or participation may result in any actual or potential OCI. Furthermore, the Contractor shall promptly submit a plan to the Contracting Officer to either avoid or mitigate any such OCI. The Contracting Officer will have sole discretion in accepting the Contractor's mitigation plan. In the event the Contracting Officer unilaterally determines that any such OCI cannot be satisfactorily avoided or mitigated, other remedies may be taken to prohibit the Contractor from participating in contract requirements related to OCI.

Whenever performance of this contract provides access to another Contractor's proprietary information, the Contractor shall enter into a written agreement with the other entities involved, as appropriate, in order to protect such proprietary information from unauthorized use or disclosure for as long as it remains proprietary; and refrain from using such proprietary information other than as agreed to, for example to provide assistance during technical evaluation of other Contractors' offers or products under this contract. An executed copy of all proprietary information agreements by individual personnel or on a corporate basis shall be furnished to the CO within fifteen (15) calendar days of execution.

## Additional Delivery Information:

The Contractor shall deliver all needles and syringes with regular monthly deliveries in accordance with their final proposal and Attachment 2 "Shipping Information" in order to meet the total quantities and delivery deadlines for each CLIN. Due to potential mission changes, the Government reserves the right to update the delivery locations per agreement between the Contractor and the Contracting Officer via email (due to the urgent nature of this requirement).

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0001	Safety Needle/Syringe Combo  FFP  (b) (4)  FOB: Destination	Each	ONIT PRICE	AMOUNT (b) (4)
	MFR PART NR: (b) (4) VENDOR PART NR: (b) (4) PURCHASE REQUEST NUMBER: 001152047- PSC CD: 6515	4-0001		
	ACRN AA CIN: GFEBS001152047400001		NET AMT	(b) (4) (b) (4)
ITEM NO	SUPPLIES/SERVICES QUANTITY U	UNIT	UNIT PRICE	AMOUNT
0002	(b) (4) Safety Needle/Syringe Combo (b) (4) FFP (b) (4) FOB: Destination	Each	(b) (4)	(b) (4)
	MFR PART NR: (b) (4) VENDOR PART NR: (b) (4) PURCHASE REQUEST NUMBER: 001152047- PSC CD: 6515	4-0001		
	ACRN AA CIN: GFEBS001152047400002		NET AMT	(b) (4) (b) (4)

Page 11 of 28

ITEM NO SUPPLIES/SERVICES QUANTITY UNIT UNIT PRICE **AMOUNT** 0003 Each (b) (4) Safety Needle/Syringe Combo (b) (4) FFP (b) (4) FOB: Destination MFR PART NR: (b) (4) VENDOR PART NR: (b) (4) PURCHASE REQUEST NUMBER: 0011520474-0001 PSC CD: 6515 **NET AMT** ACRN AA CIN: GFEBS001152047400003

ITEM NO SUPPLIES/SERVICES QUANTITY UNIT UNIT PRICE AMOUNT 0004 1 Each NSP

CDRL FFP

Contract Data Requirements List (CDRL).

FOB: Destination

MFR PART NR: CDRLS

PSC CD: 6515

**NET AMT** 

# INSPECTION AND ACCEPTANCE TERMS

Supplies/services will be inspected/accepted at:

CLIN	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
0001	Destination	Government	Destination	Government
0002	Destination	Government	Destination	Government
0003	Destination	Government	Destination	Government

0004 Destination Government Destination Government

## **DELIVERY INFORMATION**



## ACCOUNTING AND APPROPRIATION DATA



CLAUSES INCORPORATED BY REFERENCE

52.203-12	Limitation On Payments To Influence Certain Federal Transactions	OCT 2010
52.204-13	System for Award Management Maintenance	OCT 2018
52.204-18	Commercial and Government Entity Code Maintenance	JUL 2016
52.204-21	Basic Safeguarding of Covered Contractor Information	JUN 2016
	Systems	
52.212-4	Contract Terms and ConditionsCommercial Items	OCT 2018
52.232-40	Providing Accelerated Payments to Small Business	<b>DEC 2013</b>
	Subcontractors	
252.203-7000	Requirements Relating to Compensation of Former DoD Officials	SEP 2011
252.203-7003	Agency Office of the Inspector General	AUG 2019
252.204-7000	Disclosure Of Information	OCT 2016
252.204-7003	Control Of Government Personnel Work Product	APR 1992
252.204-7012	Safeguarding Covered Defense Information and Cyber	<b>DEC 2019</b>
	Incident Reporting	
252.204-7015	Notice of Authorized Disclosure of Information for Litigatio Support	n MAY 2016
252.204-7018	Prohibition on the Acquisition of Covered Defense	<b>DEC 2019</b>
	Telecommunications Equipment or Services	
252.205-7000	Provision Of Information To Cooperative Agreement Holder	s DEC 1991
252.219-7003	Small Business Subcontracting Plan (DOD Contracts)	<b>DEC 2019</b>
252.223-7008	Prohibition of Hexavalent Chromium	JUN 2013
252.225-7001	Buy American And Balance Of Payments Program Basic	<b>DEC 2017</b>
252.225-7012	Preference For Certain Domestic Commodities	<b>DEC 2017</b>
252.225-7021	Trade AgreementsBasic	SEP 2019
252.226-7001	Utilization of Indian Organizations and Indian-Owned	APR 2019
	Economic Enterprises, and Native Hawaiian Small Business Concerns	
252.227-7015	Technical DataCommercial Items	FEB 2014
252.227-7037	Validation of Restrictive Markings on Technical Data	SEP 2016
252.232-7003	Electronic Submission of Payment Requests and Receiving Reports	DEC 2018
252.232-7010	Levies on Contract Payments	<b>DEC 2006</b>
252.232-7017	Accelerating Payments to Small Business Subcontractors-	APR 2020
	Prohibition on Fees and Consideration	
252.243-7002	Requests for Equitable Adjustment	DEC 2012
252.244-7000	Subcontracts for Commercial Items	JUN 2013
252.247-7023	Transportation of Supplies by Sea	FEB 2019
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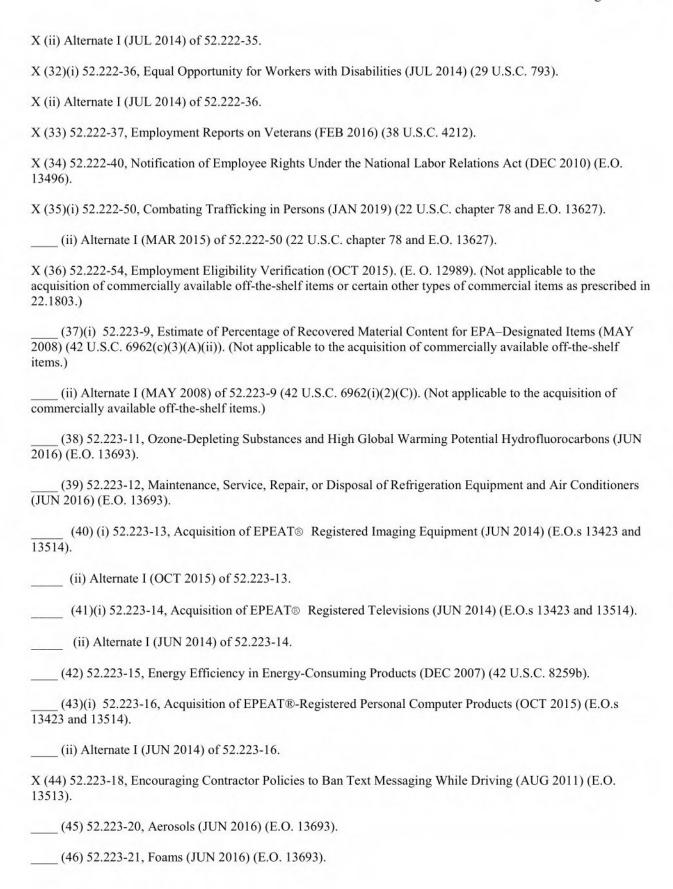
#### CLAUSES INCORPORATED BY FULL TEXT

# 52.212-5 CONTRACT TERMS AND CONDITIONS REQUIRED TO IMPLEMENT STATUTES OR EXECUTIVE ORDERS--COMMERCIAL ITEMS (MAR 2020)

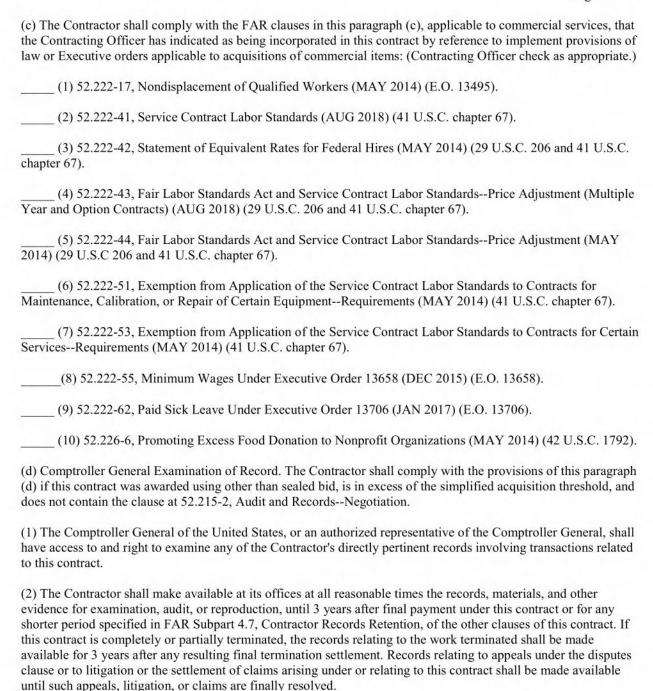
- (a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses, which are incorporated in this contract by reference, to implement provisions of law or Executive orders applicable to acquisitions of commercial items:
- (1) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (JAN 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

- (2) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 115-91).
- (3) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (AUG 2019) (Section 889(a)(1)(A) of Pub. L. 115-232).
- (4) 52.209-10, Prohibition on Contracting with Inverted Domestic Corporations (Nov 2015).
- (5) 52.233-3, Protest After Award (AUG 1996) (31 U.S.C. 3553).
- (6) 52.233-4, Applicable Law for Breach of Contract Claim (OCT 2004) (Public Laws 108-77 and 108-78 (19 U.S.C. 3805 note)).
- (b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items: (Contracting Officer check as appropriate.)
- X (1) 52.203-6, Restrictions on Subcontractor Sales to the Government (Sept 2006), with Alternate I (Oct 1995) (41 U.S.C. 4704 and 10 U.S.C. 2402).
- X (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 (June 2010) (Section 1553 of Pub. L. 111-5). (Applies to contracts funded by the American Recovery and Reinvestment Act of 2009.)
- X (4) 52.204-10, Reporting Executive Compensation and First-Tier Subcontract Awards (Oct 2018) (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.
- (7) 52.204-15, Service Contract Reporting Requirements for Indefinite-Delivery Contracts (Oct 2016) (Pub. L. 111-117, section 743 of Div. C).
- X (8) 52.209-6, Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment. (Oct 2015) (31 U.S.C. 6101 note).
- X (9) 52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters (OCT 2018) (41 U.S.C. 2313).
- \_\_\_ (10) [Reserved]
- (11)(i) 52.219-3, Notice of HUBZone Set-Aside or Sole-Source Award (MAR 2020) (15 U.S.C. 657a).
- \_\_\_\_ (ii) Alternate I (MAR 2020) of 52.219-3.
- X (12) (i) 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (MAR 2020) (if the offeror elects to waive the preference, it shall so indicate in its offer) (15 U.S.C. 657a).
- X (ii) Alternate I (MAR 2020) of 52.219-4.

(13) [Reserved]
(14)(i) 52.219-6, Notice of Total Small Business Set-Aside (MAR 2020) (15 U.S.C. 644).
(ii) Alternate I (MAR 2020).
(15)(i) 52.219-7, Notice of Partial Small Business Set-Aside (MAR 2020) (15 U.S.C. 644).
(ii) Alternate I (MAR 2020) of 52.219-7.
X (16) 52.219-8, Utilization of Small Business Concerns (OCT 2018) (15 U.S.C. 637(d)(2) and (3)).
X (17)(i) 52.219-9, Small Business Subcontracting Plan (MAR 2020) (15 U.S.C. 637(d)(4)).
(ii) Alternate I (NOV 2016) of 52.219-9.
(iii) Alternate II (NOV 2016) of 52.219-9.
(iv) Alternate III (MAR 2020) of 52.219-9.
(v) Alternate IV (AUG 2018) of 52.219-9.
(18) 52.219-13, Notice of Set-Aside of Orders (MAR 2020) (15 U.S.C. 644(r)).
(19) 52.219-14, Limitations on Subcontracting (MAR 2020) (15 U.S.C. 637(a)(14)).
X (20) 52.219-16, Liquidated Damages—Subcontracting Plan (Jan 1999) (15 U.S.C. 637(d)(4)(F)(i)).
(21) 52.219-27, Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (MAR 2020) (15 U.S.C. 657f).
X (22) (i) 52.219-28, Post Award Small Business Program Rerepresentation (MAR 2020) (15 U.S.C. 632(a)(2)).
(ii) Alternate I (MAR 2020) of 52.219-28.
(23) 52.219-29, Notice of Set-Aside for, or Sole Source Award to, Economically Disadvantaged Women-Owned Small Business (EDWOSB) Concerns (MAR 2020) (15 U.S.C. 637(m)).
(24) 52.219-30, Notice of Set-Aside for, or Sole Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (MAR 2020) (15 U.S.C. 637(m))(25) 52.219-32, Orders Issued Directly Under Small Business Reserves (MAR 2020) (15 U.S.C. 644(r)).
(26) 52.219-33, Nonmanufacturer Rule (MAR 2020) (15 U.S.C. 637(a)(17)).
X (27) 52.222-3, Convict Labor (JUN 2003) (E.O. 11755).
X(28) 52.222-19, Child LaborCooperation with Authorities and Remedies (JAN 2020) (E.O. 13126).
X (29) 52.222-21, Prohibition of Segregated Facilities (APR 2015).
X (30)(i) 52.222-26, Equal Opportunity (SEPT 2016) (E.O. 11246).
X (ii) Alternate I (FEB 1999) of 52.222-26.
X (31)(i) 52.222-35, Equal Opportunity for Veterans (OCT 2015)(38 U.S.C. 4212).



(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 AmericanSupplies (MAY 2014) (41 U.S.C. chapter 83).	
(49) (i) 52.225-3, Buy AmericanFree Trade AgreementsIsraeli Trade Act (MAY 2014) (41 U.S.C. chap 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, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43.	
(ii) Alternate I (MAY 2014) of 52.225-3.	
(iii) Alternate II (MAY 2014) of 52.225-3.	
(iv) Alternate III (MAY 2014) of 52.225-3.	
(50) 52.225-5, Trade Agreements (OCT 2019) 19 U.S.C. 2501, et seq., 19 U.S.C. 3301 note).	
X (51) 52.225-13, Restrictions on Certain Foreign Purchases (JUNE 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 (JAN 2017) (41 U.S.C. 4505, 10 U.S.C. 2307)	f))
X (57) 52.232-33, Payment by Electronic Funds Transfer—System for Award Management (OCT 2018) (31 U.S 3332).	.C
(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).	
X (61) 52.242-5, Payments to Small Business Subcontractors (JAN 2017)(15 U.S.C. 637(d)(13)).	
(62)(i) 52.247-64, Preference for Privately Owned U.SFlag Commercial Vessels (FEB 2006) (46 U.S.C. Appx. 1241(b) and 10 U.S.C. 2631).	
(ii) Alternate I (APR 2003) of 52.247-64.	
(iii) Alternate II (FEB 2006) of 52,247-64.	



- (3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.
- (e) (1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c), and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in this paragraph (e)(1)in a subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause—
- (i) 52.203-13, Contractor Code of Business Ethics and Conduct (Oct 2015) (41 U.S.C. 3509).

- (ii) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (JAN 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).
- (iii) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 115-91).
- (iv) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (AUG 2019) (Section 889(a)(1)(A) of Pub. L. 115-232).
- (v) 52.219-8, Utilization of Small Business Concerns (Oct 2018) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds \$700,000 (\$1.5 million for construction of any public facility), the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.
- (vi) 52.222-17, Nondisplacement of Qualified Workers (MAY 2014) (E.O. 13495). Flow down required in accordance with paragraph (I) of FAR clause 52.222-17.
- (vii) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).
- (viii) 52.222-26, Equal Opportunity (Sep 2016) (E.O. 11246).
- (ix) 52.222-35, Equal Opportunity for Veterans (Oct 2015) (38 U.S.C. 4212).
- (x) 52.222-36, Equal Opportunity for Workers with Disabilities (Jul 2014) (29 U.S.C. 793).
- (xi) 52.222-37, Employment Reports on Veterans (Feb 2016) (38 U.S.C. 4212).
- (xii) 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.
- (xiii) 52.222-41, Service Contract Labor Standards (Aug 2018), (41 U.S.C. chapter 67).
- (xiv) \_\_\_\_\_ (A) 52.222-50, Combating Trafficking in Persons (JAN 2019) (22 U.S.C. chapter 78 and E.O. 13627).
- (B) Alternate I (March 2, 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627). (xv) 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.)
- (xvi) 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)
- (xvii) 52.222-54, Employment Eligibility Verification (Oct 2015) (E. O. 12989).
- (xviii) 52.222-55, Minimum Wages Under Executive Order 13658 (Dec 2015) (E.O. 13658).
- (xix) 52.222-62, Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706).
- (xx) (A) <u>52.224-3</u>, Privacy Training (Jan 2017) (<u>5 U.S.C. 552a</u>).
- (B) Alternate I (Jan 2017) of <u>52.224-3</u>.

(xxi) 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).

(xxii) 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.

(xxiii) 52.247-64, Preference for Privately-Owned U.S. Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx 1241(b) and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.

(2) While not required, the Contractor may include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(End of clause)

#### 52.252-2 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):

https://www.acquisition.gov/content/regulations

(End of clause)

## 252.211-7003 ITEM UNIQUE IDENTIFICATION AND VALUATION (MAR 2016)

(a) Definitions. As used in this clause-

Automatic identification device means a device, such as a reader or interrogator, used to retrieve data encoded on machine-readable media.

Concatenated unique item identifier means--

- (1) For items that are serialized within the enterprise identifier, the linking together of the unique identifier data elements in order of the issuing agency code, enterprise identifier, and unique serial number within the enterprise identifier; or
- (2) For items that are serialized within the original part, lot, or batch number, the linking together of the unique identifier data elements in order of the issuing agency code; enterprise identifier; original part, lot, or batch number; and serial number within the original part, lot, or batch number.

Data Matrix means a two-dimensional matrix symbology, which is made up of square or, in some cases, round modules arranged within a perimeter finder pattern and uses the Error Checking and Correction 200 (ECC200) specification found within International Standards Organization (ISO)/International Electrotechnical Commission (IEC) 16022.

Data qualifier means a specified character (or string of characters) that immediately precedes a data field that defines the general category or intended use of the data that follows.

DoD recognized unique identification equivalent means a unique identification method that is in commercial use and has been recognized by DoD. All DoD recognized unique identification equivalents are listed at http://www.acq.osd.mil/dpap/pdi/uid/iuid equivalents.html.

DoD item unique identification means a system of marking items delivered to DoD with unique item identifiers that have machine-readable data elements to distinguish an item from all other like and unlike items. For items that are serialized within the enterprise identifier, the unique item identifier shall include the data elements of the enterprise identifier and a unique serial number. For items that are serialized within the part, lot, or batch number within the enterprise identifier, the unique item identifier shall include the data elements of the enterprise identifier; the original part, lot, or batch number; and the serial number.

Enterprise means the entity (e.g., a manufacturer or vendor) responsible for assigning unique item identifiers to items.

Enterprise identifier means a code that is uniquely assigned to an enterprise by an issuing agency.

Government's unit acquisition cost means--

- (1) For fixed-price type line, subline, or exhibit line items, the unit price identified in the contract at the time of delivery;
- (2) For cost-type or undefinitized line, subline, or exhibit line items, the Contractor's estimated fully burdened unit cost to the Government at the time of delivery; and
- (3) For items produced under a time-and-materials contract, the Contractor's estimated fully burdened unit cost to the Government at the time of delivery.

Issuing agency means an organization responsible for assigning a globally unique identifier to an enterprise, as indicated in the Register of Issuing Agency Codes for ISO/IEC 15459, located at <a href="http://www.aimglobal.org/?Reg">http://www.aimglobal.org/?Reg</a> Authority15459.

Issuing agency code means a code that designates the registration (or controlling) authority for the enterprise identifier.

Item means a single hardware article or a single unit formed by a grouping of subassemblies, components, or constituent parts.

Lot or batch number means an identifying number assigned by the enterprise to a designated group of items, usually referred to as either a lot or a batch, all of which were manufactured under identical conditions.

Machine-readable means an automatic identification technology media, such as bar codes, contact memory buttons, radio frequency identification, or optical memory cards.

Original part number means a combination of numbers or letters assigned by the enterprise at item creation to a class of items with the same form, fit, function, and interface.

Parent item means the item assembly, intermediate component, or subassembly that has an embedded item with a unique item identifier or DoD recognized unique identification equivalent.

Serial number within the enterprise identifier means a combination of numbers, letters, or symbols assigned by the enterprise to an item that provides for the differentiation of that item from any other like and unlike item and is never used again within the enterprise.

Serial number within the part, lot, or batch number means a combination of numbers or letters assigned by the enterprise to an item that provides for the differentiation of that item from any other like item within a part, lot, or batch number assignment.

Serialization within the enterprise identifier means each item produced is assigned a serial number that is unique among all the tangible items produced by the enterprise and is never used again. The enterprise is responsible for ensuring unique serialization within the enterprise identifier.

Serialization within the part, lot, or batch number means each item of a particular part, lot, or batch number is assigned a unique serial number within that part, lot, or batch number assignment. The enterprise is responsible for ensuring unique serialization within the part, lot, or batch number within the enterprise identifier.

Type designation means a combination of letters and numerals assigned by the Government to a major end item, assembly or subassembly, as appropriate, to provide a convenient means of differentiating between items having the same basic name and to indicate modifications and changes thereto.

Unique item identifier means a set of data elements marked on items that is globally unique and unambiguous. The term includes a concatenated unique item identifier or a DoD recognized unique identification equivalent.

Unique item identifier type means a designator to indicate which method of uniquely identifying a part has been used. The current list of accepted unique item identifier types is maintained at http://www.acq.osd.mil/dpap/pdi/uid/uii types html.

- (b) The Contractor shall deliver all items under a contract line, subline, or exhibit line item.
- (c) Unique item identifier. (1) The Contractor shall provide a unique item identifier for the following:

<ul><li>(i) Delivered items for which th items:</li></ul>	e Government's unit acquis	ition cost is \$5,000 or more, exce	ept for the following line
Contract line, subline, or exhib			
line item No.	Item description		
(ii) Items for which the Government the following table:	ment's unit acquisition cost	is less than \$5,000 that are identi	ified in the Schedule or
Contract line, subline, or exhib			
line item No.	Item description	2	
(b) (4)		I	

- (iii) Subassemblies, components, and parts embedded within delivered items, items with warranty requirements, DoD serially managed reparables and DoD serially managed nonreparables as specified in Attachment Number ----.
- (iv) Any item of special tooling or special test equipment as defined in FAR 2.101 that have been designated for preservation and storage for a Major Defense Acquisition Program as specified in Attachment Number ----.

- (v) Any item not included in paragraphs (c)(1)(i), (ii), (iii), or
- (iv) of this clause for which the contractor creates and marks a unique item identifier for traceability.
- (2) The unique item identifier assignment and its component data element combination shall not be duplicated on any other item marked or registered in the DoD Item Unique Identification Registry by the contractor.
- (3) The unique item identifier component data elements shall be marked on an item using two dimensional data matrix symbology that complies with ISO/IEC International Standard 16022, Information technology--International symbology specification--Data matrix; ECC200 data matrix specification.
- (4) Data syntax and semantics of unique item identifiers. The Contractor shall ensure that--
- (i) The data elements (except issuing agency code) of the unique item identifier are encoded within the data matrix symbol that is marked on the item using one of the following three types of data qualifiers, as determined by the Contractor:
- (A) Application Identifiers (AIs) (Format Indicator 05 of ISO/IEC International Standard 15434), in accordance with ISO/IEC International Standard 15418, Information Technology--EAN/UCC Application Identifiers and Fact Data Identifiers and Maintenance and ANSI MH 10.8.2 Data Identifier and Application Identifier Standard.
- (B) Data Identifiers (DIs) (Format Indicator 06 of ISO/IEC International Standard 15434), in accordance with ISO/IEC International Standard 15418, Information Technology--EAN/UCC Application Identifiers and Fact Data Identifiers and Maintenance and ANSI MH 10.8.2 Data Identifier and Application Identifier Standard.
- (C) Text Element Identifiers (TEIs) (Format Indicator 12 of ISO/IEC International Standard 15434), in accordance with the Air Transport Association Common Support Data Dictionary; and
- (ii) The encoded data elements of the unique item identifier conform to the transfer structure, syntax, and coding of messages and data formats specified for Format Indicators 05, 06, and 12 in ISO/IEC International Standard 15434, Information Technology-Transfer Syntax for High Capacity Automatic Data Capture Media.
- (5) Unique item identifier.
- (i) The Contractor shall--
- (A) Determine whether to--
- (1) Serialize within the enterprise identifier;
- (2) Serialize within the part, lot, or batch number; or
- (3) Use a DoD recognized unique identification equivalent (e.g. Vehicle Identification Number); and
- (B) Place the data elements of the unique item identifier (enterprise identifier; serial number; DoD recognized unique identification equivalent; and for serialization within the part, lot, or batch number only; Original part, lot, or batch number on lot, or batch number of lot, or
- identification equivalent; and for serialization within the part, lot, or batch number only: Original part, lot, or batch number) on items requiring marking by paragraph (c)(1) of this clause, based on the criteria provided in MIL-STD-130, Identification Marking of U.S. Military Property, latest version;
- (C) Label shipments, storage containers and packages that contain uniquely identified items in accordance with the requirements of MIL-STD-129, Military Marking for Shipment and Storage, latest version; and

- (D) Verify that the marks on items and labels on shipments, storage containers, and packages are machine readable and conform to the applicable standards. The contractor shall use an automatic identification technology device for this verification that has been programmed to the requirements of Appendix A, MIL-STD-130, latest version.
- (ii) The issuing agency code--
- (A) Shall not be placed on the item; and
- (B) Shall be derived from the data qualifier for the enterprise identifier.
- (d) For each item that requires item unique identification under paragraph (c)(1)(i), (ii), or (iv) of this clause or when item unique identification is provided under paragraph (c)(1)(v), in addition to the information provided as part of the Material Inspection and Receiving Report specified elsewhere in this contract, the Contractor shall report at the time of delivery, as part of the Material Inspection and Receiving Report, the following information:
- (1) Unique item identifier.
- (2) Unique item identifier type.
- (3) Issuing agency code (if concatenated unique item identifier is used).
- (4) Enterprise identifier (if concatenated unique item identifier is used).
- (5) Original part number (if there is serialization within the original part number).
- (6) Lot or batch number (if there is serialization within the lot or batch number).
- (7) Current part number (optional and only if not the same as the original part number).
- (8) Current part number effective date (optional and only if current part number is used).
- (9) Serial number (if concatenated unique item identifier is used).
- (10) Government's unit acquisition cost.
- (11) Unit of measure.
- (12) Type designation of the item as specified in the contract schedule, if any.
- (13) Whether the item is an item of Special Tooling or Special Test Equipment.
- (14) Whether the item is covered by a warranty.
- (e) For embedded subassemblies, components, and parts that require DoD unique item identification under paragraph (c)(1)(iii) of this clause, the Contractor shall report as part of, or associated with, the Material Inspection and Receiving Report specified elsewhere in this contract, the following information:
- (1) Unique item identifier of the parent item under paragraph (c)(1) of this clause that contains the embedded subassembly, component, or part.
- (2) Unique item identifier of the embedded subassembly, component, or part.
- (3) Unique item identifier type.\*\*

- (4) Issuing agency code (if concatenated unique item identifier is used).\*\*
- (5) Enterprise identifier (if concatenated unique item identifier is used).\*\*
- (6) Original part number (if there is serialization within the original part number).\*\*
- (7) Lot or batch number (if there is serialization within the lot or batch number).\*\*
- (8) Current part number (optional and only if not the same as the original part number).\*\*
- (9) Current part number effective date (optional and only if current part number is used).\*\*
- (10) Serial number (if concatenated unique item identifier is used).\*\*
- (11) Description.
- \*\* Once per item.
- (f) The Contractor shall submit the information required by paragraphs (d) and (e) of this clause as follows:
- (1) End items shall be reported using the receiving report capability in Wide Area WorkFlow (WAWF) in accordance with the clause at 252.232-7003. If WAWF is not required by this contract, and the contractor is not using WAWF, follow the procedures at <a href="http://dodprocurementtoolbox.com/site/uidregistry/">http://dodprocurementtoolbox.com/site/uidregistry/</a>.
- (2) Embedded items shall be reported by one of the following methods--
- (i) Use of the embedded items capability in WAWF;
- (ii) Direct data submission to the IUID Registry following the procedures and formats at http://dodprocurementtoolbox.com/site/uidregistry/; or
- (iii) Via WAWF as a deliverable attachment for exhibit line item number (fill in) ----, Unique Item Identifier Report for Embedded Items, Contract Data Requirements List, DD Form 1423.
- (g) Subcontracts. If the Contractor acquires by subcontract any items for which item unique identification is required in accordance with paragraph (c)(1) of this clause, the Contractor shall include this clause, including this paragraph (g), in the applicable subcontract(s), including subcontracts for commercial items.

(End of clause)

#### 252.232-7006 WIDE AREA WORKFLOW PAYMENT INSTRUCTIONS (DEC 2018)

(a) Definitions. As used in this clause-

"Department of Defense Activity Address Code (DoDAAC)" is a six position code that uniquely identifies a unit, activity, or organization.

"Document type" means the type of payment request or receiving report available for creation in Wide Area WorkFlow (WAWF).

- "Local processing office (LPO)" is the office responsible for payment certification when payment certification is done external to the entitlement system.
- "Payment request" and "receiving report" are defined in the clause at 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.
- (b) Electronic invoicing. The WAWF system provides the method to electronically process vendor payment requests and receiving reports, as authorized by Defense Federal Acquisition Regulation Supplement (DFARS) 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.
- (c) WAWF access. To access WAWF, the Contractor shall-
- (1) Have a designated electronic business point of contact in the System for Award Management at <a href="https://www.sam.gov">https://www.sam.gov</a>; and
- (2) Be registered to use WAWF at <a href="https://piee.eb.mil/">https://piee.eb.mil/</a> following the step-by-step procedures for self-registration available at this web site.
- (d) WAWF training. The Contractor should follow the training instructions of the WAWF Web-Based Training Course and use the Practice Training Site before submitting payment requests through WAWF. Both can be accessed by selecting the "Web Based Training" link on the WAWF home page at <a href="https://piee.eb mil/">https://piee.eb mil/</a>.
- (e) WAWF methods of document submission. Document submissions may be via web entry, Electronic Data Interchange, or File Transfer Protocol.
- (f) WAWF payment instructions. The Contractor shall use the following information when submitting payment requests and receiving reports in WAWF for this contract or task or delivery order:
- (1) Document type. The Contractor shall submit payment requests using the following document type(s):
- (i) For cost-type line items, including labor-hour or time-and-materials, submit a cost voucher.
- (ii) For fixed price line items—
- (A) That require shipment of a deliverable, submit the invoice and receiving report specified by the Contracting Officer.

#### Invoice 2in1

(B) For services that do not require shipment of a deliverable, submit either the Invoice 2in1, which meets the requirements for the invoice and receiving report, or the applicable invoice and receiving report, as specified by the Contracting Officer.

#### Invoice 2in1

- (iii) For customary progress payments based on costs incurred, submit a progress payment request.
- (iv) For performance based payments, submit a performance based payment request.
- (v) For commercial item financing, submit a commercial item financing request.
- (2) Fast Pay requests are only permitted when Federal Acquisition Regulation (FAR) 52.213-1 is included in the contract.

[Note: The Contractor may use a WAWF "combo" document type to create some combinations of invoice and receiving report in one step.]

(3) Document routing. The Contractor shall use the information in the Routing Data Table below only to fill in applicable fields in WAWF when creating payment requests and receiving reports in the system.

## Routing Data Table\*

Field Name in WAWF	Data to be entered in WAWF
Pay Official DoDAAC	HQ0490
Issue By DoDAAC	W911SR
Admin DoDAAC**	W911SR
Inspect By DoDAAC	W56XNH
Ship To Code	TBD at post award meeting.
Ship From Code	7TKQ9
Mark For Code	N/A
Service Approver (DoDAAC)	W56XNH
Service Acceptor (DoDAAC)	W56XNH
Accept at Other DoDAAC	N/A
LPO DoDAAC	N/A
DCAA Auditor DoDAAC	N/A
Other DoDAAC(s)	N/A

(\*Contracting Officer: Insert applicable DoDAAC information. If multiple ship to/acceptance locations apply, insert "See Schedule" or "Not applicable.")

(\*\*Contracting Officer: If the contract provides for progress payments or performance-based payments, insert the DoDAAC for the contract administration office assigned the functions under FAR 42.302(a)(13).)

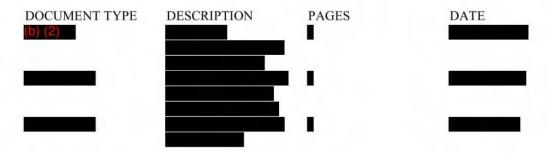
- (4) Payment request. The Contractor shall ensure a payment request includes documentation appropriate to the type of payment request in accordance with the payment clause, contract financing clause, or Federal Acquisition Regulation 52.216-7, Allowable Cost and Payment, as applicable.
- (5) Receiving report. The Contractor shall ensure a receiving report meets the requirements of DFARS Appendix F.
- (g) WAWF point of contact.
- (1) The Contractor may obtain clarification regarding invoicing in WAWF from the following contracting activity's WAWF point of contact.

(b) (6

# (2) Contact the WAWF helpdesk at 866-618-5988, if assistance is needed.

(End of clause)

Exhibit/Attachment Table of Contents



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				J			1	20
2 AMENDMENT/MODIFICATION NO	3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO SEE SCHEDULE			5 P	ROJECT	NO (Ifap	plicable)
P00001 S ISSUED BY CODE	03-Sep-2020	7 ADMINISTERED BY (Ifother than item 6)			ODE	_		
USA CONTRACT NG CMD-APG W911SR EDGEWOOD CONTRACTING DIVISION 8456 BRIGADE STREET BLDG E4215 ABERDEEN PROVING GROUND MD 21010-5401	W911SR	See Item 6			ODE			
8. NAME AND ADDRESS OF CONTRACT OF	(No., Street, County,	State and Zip Code)	9	A. AMENDI	MENT	OF SO	LICITA	TION NO
HTL-STREFA, NC. (b) (6)			9	B. DATED (	SEE I	ГЕМ 11	1)	
			X 1	0A MOD C W911SR20C	OF COI 0049	NTRAC	T/ORD	ER NO.
				0B. DATED		ITEM	13)	
CODE 7TKQ9	FACILITY CO		_	03-Aug-2020	)			
The above numbered solicitation is amended as set for		APPLIES TO AMENDMENTS OF SOLIC		TIONS s extended.		not exter	4.1	
RECEIVED AT THE PLACE DESIGNATED FOR: REJECTION OF YOUR OFFER. If by virtue of this provided each telegram or letter makes reference to the  2. ACCOUNTING AND APPROPRIATION I  See Schedule	amendment you desire to ch he solicitation and this amen	ange an offer already submitted, such change may b	e made	e by telegramor	letter,			
13. THIS IT	TEM APPLIES ONLY	TO MODIFICATIONS OF CONTRACTS	S/ORI	DERS.				
A. THIS CHANGE ORDER IS ISSUED PUR CONTRACT ORDER NO. IN ITEM 10 A	SUANT TO: (Specify	CT/ORDER NO. AS DESCRIBED IN ITE authority) THE CHANGES SET FORTH		and the same of th	MAD	E IN T	HE	
	RTH IN ITEM 14, PUI	RSUANT TO THE AUTHORITY OF FAI		The second secon	h as ch	anges ii	n payin	3
( C. THIS SUPPLEMENT AL AGREEMENT Bilateral IAW FAR 52.212-4(c)	IS ENTERED INTO P	URSUANT TO AUTHORITY OF:						
D. OTHER (Specify type of modification an	id authority)							
. IMPORTANT: Contractor is not,	X is required to si	gn this document and return 1	copi	es to the issu	ing off	ice.		
4. DESCRIPTION OF AMENDMENT/MODI where feasible.) Modification Control Number: (b) (6) The purpose of this modification is: 1) Add Time and Materials (T&M) CLIN 0005 2) Add CDRL (10) (2) for Weekly Delivery Sch. 3) Update Statement of Work to reflect the a 4) Add FAR Clause 52.212-4 Alt I due to the All other terms and conditions remain the sa	in the Not to Exceed a edule as (b) (2) (a bove changes. addition of the T&M C	mount of (b) (4) for the delta total to additional cost to the Government).					d air fre	ight.
Except as provided herein, all terms and conditions of the 15A. NAME AND TITLE OF SIGNER (Type of 15) (6)		16A. NAME AND TITLE OF CO.	NTR	ACT ING OF			or print	)
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNE	TEL: DIGITAL STATES OF AMER		EMAL: (b) (d)		160	C. DAT	E SIGNED
(b) (6)						1.0		

#### SECTION SF 30 BLOCK 14 CONTINUATION PAGE

#### SUMMARY OF CHANGES

SECTION SF 1449 - CONTINUATION SHEET

SOLICITATION/CONTRACT FORM

The total cost of this contract was increased by (b) (4)

#### SUPPLIES OR SERVICES AND PRICES

CLIN 0005 is added as follows:

ITEM NO SUPPLIES/SERVICES QUANTITY UNIT UNIT PRICE 0005 Job

AMOUNT (b) (4)

Change to Air Freight T&M

COST

This Time and Materials (T&M) CLIN is for the delta costs incurred between the already included Sea Freight (built into the FFP CLINS) and the additional estimated costs for Air Freight on all shipments (b) (4). The total invoiced amount on this CLIN cannot exceed the total Funding. The Contractor shall contact the Contracting Officer prior to incurring expense against this T&M CLIN if that expense will exceed the Contractor's proposed delta between sea freight and air freight. NOTE: Total invoiced amount against this CLIN cannot exceed the total funded amount/total line item cost.

FOB: Destination

PURCHASE REQUEST NUMBER: 0011547230

PSC CD: 6515

ESTIMATED COST



ACRN AA

CIN: GFEBS001154723000001

ACCOUNTING AND APPROPRIATION

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was increased by (b) (4)

CLIN 0005:

Funding on CLIN 0005 is initiated as follows:

ACRN: AA

CIN: GFEBS001154723000001



#### INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for CLIN 0005:
INSPECT AT INSPECT BY ACCEPT AT
Destination Government Destination

ACCEPT BY Government

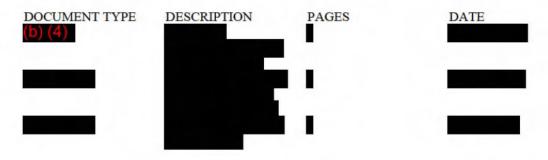
The following Technical Office was added for CLIN 0005:



#### TABLE OF CONTENTS

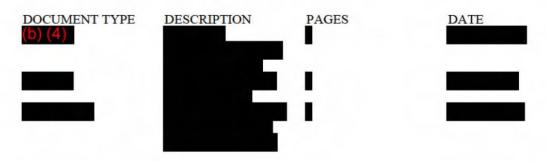
The Table of Contents has changed from:

Exhibit/Attachment Table of Contents



to:

Exhibit/Attachment Table of Contents





The following have been added by full text:

52.212-4 CONTRACT TERMS AND CONDITIONS -- COMMERCIAL ITEMS (OCT 2018) ALTERNATE I (JAN 2017)

When a time-and-materials or labor-hour contract is contemplated, substitute the following paragraphs (a), (e), (i), (l), and (m) for those in the basic clause.

- (a) Inspection/Acceptance.
- (1) The Government has the right to inspect and test all materials furnished and services performed under this contract, to the extent practicable at all places and times, including the period of performance, and in any event before acceptance. The Government may also inspect the plant or plants of the Contractor or any subcontractor engaged in contract performance. The Government will perform inspections and tests in a manner that will not unduly delay the work.
- (2) If the Government performs inspection or tests on the premises of the Contractor or a subcontractor, the Contractor shall furnish and shall require subcontractors to furnish all reasonable facilities and assistance for the safe and convenient performance of these duties.
- (3) Unless otherwise specified in the contract, the Government will accept or reject services and materials at the place of delivery as promptly as practicable after delivery, and they will be presumed accepted 60 days after the date of delivery, unless accepted earlier.
- (4) At any time during contract performance, but not later than 6 months (or such other time as may be specified in the contract) after acceptance of the services or materials last delivered under this contract, the Government may require the Contractor to replace or correct services or materials that at time of delivery failed to meet contract requirements. Except as otherwise specified in paragraph (a)(6) of this clause, the cost of replacement or correction shall be determined under paragraph (i) of this clause, but the "hourly rate" for labor hours incurred in the replacement or correction shall be reduced to exclude that portion of the rate attributable to profit. Unless otherwise specified below, the portion of the "hourly rate" attributable to profit shall be 10 percent. The Contractor shall not tender for acceptance materials and services required to be replaced or corrected without disclosing the former requirement for replacement or correction, and, when required, shall disclose the corrective action taken. <a href="https://doi.org/10.1007/journal.org/10.1007/
- (5) If the Contractor fails to proceed with reasonable promptness to perform required replacement or correction, and if the replacement or correction can be performed within the ceiling price (or the ceiling price as increased by the Government), the Government may—
- (A) By contract or otherwise, perform the replacement or correction, charge to the Contractor any increased cost, or deduct such increased cost from any amounts paid or due under this contract; or
- (B) Terminate this contract for cause.
- (ii) Failure to agree to the amount of increased cost to be charged to the Contractor shall be a dispute under the Disputes clause of the contract.

- (6) Notwithstanding paragraphs (a)(4) and (5) above, the Government may at any time require the Contractor to remedy by correction or replacement, without cost to the Government, any failure by the Contractor to comply with the requirements of this contract, if the failure is due to—
- (i) Fraud, lack of good faith, or willful misconduct on the part of the Contractor's managerial personnel; or
- (ii) The conduct of one or more of the Contractor's employees selected or retained by the Contractor after any of the Contractor's managerial personnel has reasonable grounds to believe that the employee is habitually careless or unqualified.
- (7) This clause applies in the same manner and to the same extent to corrected or replacement materials or services as to materials and services originally delivered under this contract.
- (8) The Contractor has no obligation or liability under this contract to correct or replace materials and services that at time of delivery do not meet contract requirements, except as provided in this clause or as may be otherwise specified in the contract.
- (9) Unless otherwise specified in the contract, the Contractor's obligation to correct or replace Government-furnished property shall be governed by the clause pertaining to Government property.
- (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, as amended (41 U.S.C. 601-613). 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.
- (1) The clause at FAR 52.202-1, Definitions, is incorporated herein by reference. As used in this clause—
- (i) Direct materials means those materials that enter directly into the end product, or that are used or consumed directly in connection with the furnishing of the end product or service.
- (ii) Hourly rate means the rate(s) prescribed in the contract for payment for labor that meets the labor category qualifications of a labor category specified in the contract that are—
- (A) Performed by the contractor;
- (B) Performed by the subcontractors; or
- (C) Transferred between divisions, subsidiaries, or affiliates of the contractor under a common control.
- (iii) Materials means—
- (A) Direct materials, including supplies transferred between divisions, subsidiaries, or affiliates of the contractor under a common control;

- (B) Subcontracts for supplies and incidental services for which there is not a labor category specified in the contract;
- (C) Other direct costs (e.g., incidental services for which there is not a labor category specified in the contract, travel, computer usage charges, etc.);
- (D) The following subcontracts for services which are specifically excluded from the hourly rate: **Not Applicable** (Insert any subcontracts for services to be excluded from the hourly rates prescribed in the schedule); and
- (E) Indirect costs specifically provided for in this clause.
- (iv) Subcontract means any contract, as defined in FAR Subpart 2.1, entered into with a subcontractor to furnish supplies or services for performance of the prime contract or a subcontract including transfers between divisions, subsidiaries, or affiliates of a contractor or subcontractor. It includes, but is not limited to, purchase orders, and changes and modifications to purchase orders.
- (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, 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) Payments.
- (1) Work performed. The Government will pay the Contractor as follows upon the submission of commercial invoices approved by the Contracting Officer:
- (i) Hourly rate.
- (A) The amounts shall be computed by multiplying the appropriate hourly rates prescribed in the contract by the number of direct labor hours performed. Fractional parts of an hour shall be payable on a prorated basis.
- (B) The rates shall be paid for all labor performed on the contract that meets the labor qualifications specified in the contract. Labor hours incurred to perform tasks for which labor qualifications were specified in the contract will not be paid to the extent the work is performed by individuals that do not meet the qualifications specified in the contract, unless specifically authorized by the Contracting Officer.
- (C) Invoices may be submitted once each month (or at more frequent intervals, if approved by the Contracting Officer) to the Contracting Officer or the authorized representative.
- (D) When requested by the Contracting Officer or the authorized representative, the Contractor shall substantiate invoices (including any subcontractor hours reimbursed at the hourly rate in the schedule) by evidence of actual payment, individual daily job timecards, records that verify the employees meet the qualifications for the labor categories specified in the contract, or other substantiation specified in the contract.
- (E) Unless the Schedule prescribes otherwise, the hourly rates in the Schedule shall not be varied by virtue of the Contractor having performed work on an overtime basis.
- (1) If no overtime rates are provided in the Schedule and the Contracting Officer approves overtime work in advance, overtime rates shall be negotiated.
- (2) Failure to agree upon these overtime rates shall be treated as a dispute under the Disputes clause of this contract.
- (3) If the Schedule provides rates for overtime, the premium portion of those rates will be reimbursable only to the extent the overtime is approved by the Contracting Officer.
- (ii) Materials.
- (A) If the Contractor furnishes materials that meet the definition of a commercial item at 2.101, the price to be paid for such materials shall not exceed the Contractor's established catalog or market price, adjusted to reflect the--
- (1) Quantities being acquired; and

- (2) Any modifications necessary because of contract requirements.
- (B) Except as provided for in paragraph (i)(1)(ii)(A) and (D)(2) of this clause, the Government will reimburse the Contractor the actual cost of materials (less any rebates, refunds, or discounts received by the contractor that are identifiable to the contract) provided the Contractor—
- (1) Has made payments for materials in accordance with the terms and conditions of the agreement or invoice; or
- (2) Makes these payments within 30 days of the submission of the Contractor's payment request to the Government and such payment is in accordance with the terms and conditions of the agreement or invoice.
- (C) To the extent able, the Contractor shall-
- (1) Obtain materials at the most advantageous prices available with due regard to securing prompt delivery of satisfactory materials; and
- (2) Give credit to the Government for cash and trade discounts, rebates, scrap, commissions, and other amounts that are identifiable to the contract.
- (D) Other Costs. Unless listed below, other direct and indirect costs will not be reimbursed.
- (1) Other Direct Costs. The Government will reimburse the Contractor on the basis of actual cost for the following, provided such costs comply with the requirements in paragraph (i)(1)(ii)(B) of this clause: **Any Delta in cost**between the already included Sea Freight and Air Freight for shipments (b) (4)

  (Insert each element of other direct costs (e.g., travel, computer usage charges, etc. Insert "None" if no reimbursement for other direct costs will be provided. If this is an indefinite delivery contract, the Contracting Officer may insert "Each order must list separately the elements of other direct charge(s) for that order or, if no reimbursement for other direct costs will be provided, insert 'None'.)
- (2) Indirect Costs (Material Handling, Subcontract Administration, etc.. The Government will reimburse the Contractor for indirect costs on a pro-rata basis over the period of contract performance at the following fixed price: §0 (Insert a fixed amount for the indirect costs and payment schedule. Insert "\$0" if no fixed price reimbursement for indirect costs will be provided. (If this is an indefinite delivery contract, the Contracting Officer may insert "Each order must list separately the fixed amount for the indirect costs and payment schedule or, if no reimbursement for indirect costs, insert 'None').
- (2) Total cost. It is estimated that the total cost to the Government for the performance of this contract shall not exceed the ceiling price set forth in the Schedule and the Contractor agrees to use its best efforts to perform the work specified in the Schedule and all obligations under this contract within such ceiling price. If at any time the Contractor has reason to believe that the hourly rate payments and material costs that will accrue in performing this contract in the next succeeding 30 days, if added to all other payments and costs previously accrued, will exceed 85 percent of the ceiling price in the Schedule, the Contractor shall notify the Contracting Officer giving a revised estimate of the total price to the Government for performing this contract with supporting reasons and documentation. If at any time during the performance of this contract, the Contractor has reason to believe that the total price to the Government for performing this contract will be substantially greater or less than the then stated ceiling price, the Contractor shall so notify the Contracting Officer, giving a revised estimate of the total price for performing this contract, with supporting reasons and documentation. If at any time during performance of this contract, the Government has reason to believe that the work to be required in performing this contract will be substantially greater or less than the stated ceiling price, the Contracting Officer will so advise the Contractor, giving the then revised estimate of the total amount of effort to be required under the contract.
- (3) Ceiling price. The Government will not be obligated to pay the Contractor any amount in excess of the ceiling price in the Schedule, and the Contractor shall not be obligated to continue performance if to do so would exceed the ceiling price set forth in the Schedule, unless and until the Contracting Officer notifies the Contractor in writing that the ceiling price has been increased and specifies in the notice a revised ceiling that shall constitute the ceiling price

for performance under this contract. When and to the extent that the ceiling price set forth in the Schedule has been increased, any hours expended and material costs incurred by the Contractor in excess of the ceiling price before the increase shall be allowable to the same extent as if the hours expended and material costs had been incurred after the increase in the ceiling price.

- (4) Access to records. At any time before final payment under this contract, the Contracting Officer (or authorized representative) will have access to the following (access shall be limited to the listing below unless otherwise agreed to by the Contractor and the Contracting Officer):
- (i) Records that verify that the employees whose time has been included in any invoice meet the qualifications for the labor categories specified in the contract;
- (ii) For labor hours (including any subcontractor hours reimbursed at the hourly rate in the schedule), when timecards are required as substantiation for payment—
- (A) The original timecards (paper-based or electronic);
- (B) The Contractor's timekeeping procedures;
- (C) Contractor records that show the distribution of labor between jobs or contracts; and
- (D) Employees whose time has been included in any invoice for the purpose of verifying that these employees have worked the hours shown on the invoices.
- (iii) For material and subcontract costs that are reimbursed on the basis of actual cost—
- (A) Any invoices or subcontract agreements substantiating material costs; and
- (B) Any documents supporting payment of those invoices.
- (5) Overpayments/Underpayments. Each payment previously made shall be subject to reduction to the extent of amounts, on preceding invoices, that are found by the Contracting Officer not to have been properly payable and shall also be subject to reduction for overpayments or to increase for underpayments. The Contractor shall promptly pay any such reduction within 30 days unless the parties agree otherwise. The Government within 30 days will pay any such increases, unless the parties agree otherwise. The Contractor's payment will be made by check. If the Contractor becomes aware of a duplicate invoice payment or that the Government has otherwise overpaid on an 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 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)(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, and then at the rate applicable for each six month period as established 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 in a timely manner;
- (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 FAR 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.
- (viii) Upon receipt and approval of the invoice designated by the Contractor as the ``completion invoice" and supporting documentation, and upon compliance by the Contractor with all terms of this contract, any outstanding balances will be paid within 30 days unless the parties agree otherwise. The completion invoice, and supporting documentation, shall be submitted by the Contractor as promptly as practicable following completion of the work under this contract, but in no event later than 1 year (or such longer period as the Contracting Officer may approve in writing) from the date of completion.
- (7) Release of claims. The Contractor, and each assignee under an assignment entered into under this contract and in effect at the time of final payment under this contract, shall execute and deliver, at the time of and as a condition precedent to final payment under this contract, a release discharging the Government, its officers, agents, and employees of and from all liabilities, obligations, and claims arising out of or under this contract, subject only to the following exceptions.

- (i) Specified claims in stated amounts, or in estimated amounts if the amounts are not susceptible to exact statement by the Contractor.
- (ii) Claims, together with reasonable incidental expenses, based upon the liabilities of the Contractor to third parties arising out of performing this contract, that are not known to the Contractor on the date of the execution of the release, and of which the Contractor gives notice in writing to the Contracting Officer not more than 6 years after the date of the release or the date of any notice to the Contractor that the Government is prepared to make final payment, whichever is earlier.
- (iii) Claims for reimbursement of costs (other than expenses of the Contractor by reason of its indemnification of the Government against patent liability), including reasonable incidental expenses, incurred by the Contractor under the terms of this contract relating to patents.
- (8) 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.
- (9) Electronic Funds Transfer (EFT). If the Government makes payment by EFT, see 52.212-5(b) for the appropriate EFT clause.
- (10) 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 that appears on the payment check or the specified payment date if an electronic funds transfer payment is made.
- (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 an amount for direct labor hours (as defined in the Schedule of the contract) determined by multiplying the number of direct labor hours expended before the effective date of termination by the hourly rate(s) in the contract, less any hourly rate payments already made to the Contractor plus reasonable charges the Contractor can demonstrate to the satisfaction of the Government using its standard record keeping system that 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 that 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 written request, with adequate assurances of future performance. Subject to the terms of this contract, the Contractor shall be paid an amount computed under paragraph (i) Payments of this clause, but the ''hourly rate" for labor hours expended in

furnishing work not delivered to or accepted by the Government shall be reduced to exclude that portion of the rate attributable to profit. Unless otherwise specified in paragraph (a)(4) of this clause, the portion of the ``hourly rate" attributable to profit shall be 10 percent. In the event of termination for cause, 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 <u>52.212-5</u>.
- (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) Reserved.
- (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)

The following have been modified:

STATEMENT OF WORK

This section has been modified. Changes are shown below in red font text.

# STATEMENT OF WORK PROCUREMENT OF SAFETY NEEDLES AND SYRINGES FOR COVID-19

**1.0 SCOPE:** The Contractor, as an independent Contractor and not as an agent of the Government, shall furnish the necessary resources as specified in this Statement of Work (SOW), to manufacture and/or supply Safety Needles and Syringes.

# 2.0 BACKGROUND:

On Friday, March 13, 2020, the President declared a national emergency concerning the novel coronavirus disease (COVID-19) under section 501(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5207 (the "Stafford Act).

The mission of the Division of Strategic National Stockpile (DSNS), of the United States (U.S.) Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR), is to ensure the availability and rapid deployment of life-saving pharmaceuticals, antidotes, other medical supplies, and equipment necessary to counter the effects of nerve agents, biological pathogens, and chemical agents. When state, local, tribal, and territorial public health and medical systems request federal assistance to support their response efforts, DSNS ensures the right medicines and supplies get to those who need them most during an emergency. When the vaccine becomes available the Government will have an

immediate need to begin vaccinating the entire U.S. population. To administer the vaccine the Government will require needles and syringes to be available.

There is an insufficient domestic supply of safety needles and syringes to meet the projected needs to vaccinate the nation's entire population against COVID-19. Should vaccine programs be accelerated, demand could outpace available devices to administer a vaccine.

**3.0 OBJECTIVE**: The HHS currently has contracts in place with three (3) major manufacturers to provide needles and syringes supplies to support the initial preparedness needs at the onset of a pandemic outbreak. The objective of this acquisition is to supplement the current supply and establish contracts with additional manufacturers and suppliers to provide a quantity of up to 500 million safety needles and syringes supplies.

# **4.0 REQUIREMENTS:**

# 4.1. General:

- 4.1.1. The Contractor shall "host" a *Kick-Off Meeting* within one (1) calendar day after contract award via <u>teleconference</u>. The Contractor shall provide *Meeting Minutes* containing a detailed overview of the meeting discussions in accordance with (IAW) Contract Data Requirements List (CDRL) A001.
- 4.1.1.1. The Contractor shall provide a *Certificate of Analysis* with each shipment per the DD Form 1423, Contract Data Requirements List (CDRL) A002, confirming the supplies described below meet the Performance Specifications in paragraph 4.2 below.
- 4.1.2. The Contractor shall provide copies of 510(k) Approval Letters for ALL supplies (dispensing syringes or needles) to demonstrate compliance with Section 510(k) of the Food, Drug and Cosmetic Act as part of their proposal. The Contractor shall provide, if necessary, 510(k) Approval Letters Updates if any information from the initial 510(k) Approval Letters is changed/needs to be updated.
- 4.1.2.1.1. The Contractor shall ensure all supplies have a "*Shelf-Life*" with expiration dates of no less than five (5) years from the date of sterilization, <u>and</u> must have at least four (4) years of remaining expiry from the time of shipment.
- 4.1.2.1.2. The Contractor shall only use *Current Good Manufacturing Practice (cGMP)* processes to manufacture the needles and syringes.
- 4.1.2.1.3. **Period of Performance/Delivery Dates.** See the "Delivery Schedule" section of this Contract and "Attachment 2-Shipping Information" for all delivery requirements and shipping locations.

# 4.2. Technical Requirements:

4.2.1. The Contractor shall provide sterile needle (with Luer hub connection) and syringe (with

Luer lock connection) units approved by the Food and Drug Administration (FDA) <u>and</u> comply with Occupational Safety and Health Administration (OSHA) Needlestick Safety and Prevention Act requirements as a "safety-engineered product." Safety-engineered supplies include needles preventing sharp injuries by either; being completely enclosed after use by an attached shield, or be fully retracted within the syringe. The Contractor may provide individual syringes and individual needles as long as there is a <u>one-to-one (1:1) ratio</u>. In order to meet the specified quantities upon contract award and comply with the specifications in this SOW, the following may be provided: (1) individually wrapped sterile syringes with individually wrapped sterile needles in a one-to-one (1:1) ratio, (2) sterile needle/syringe combination unit, or (3) a mixture of sterile combination units <u>and</u> individually wrapped sterile syringes with equal number of individually wrapped sterile needles.

# 4.2.2. The Contractor shall only provide acceptable product sizes as described below:

# Individual Syringe:

Syringe
1mL
3mL

# Individual Needle:

Needle Gauge	Needle Length					
23G	1"					
23G	1.5"					
25G	1"					

# Combination Unit:

Syringe	Needle Gauge	Needle Length
1mL	23G	1"
1mL	23G	1.5"
lmL	25G	1"
3mL	23G	1"
3mL	23G	1.5"
3mL	25G	1"

- 4.2.3. **Dispensing Syringe:** *Description*: A dispensing syringe allows for the controlled and precise flow of liquid. The dispensing syringe is used to inject medications or other liquids into body tissues. Manual syringes consist of a barrel, stopper, and plunger.
- 4.2.3.1. The Contractor shall ensure dispensing syringes comply with Title 21 Code of Federal Regulations (CFR) 880.5860 and follow International Standards Organization (ISO)

7886-1:2017 and the following material specifications:

- 4.2.3.1.1. A device intended for medical purposes that consists of a calibrated hollow barrel and a movable plunger. At one end of the barrel there is a male connector (nozzle) for fitting the female connector (hub) of a hypodermic single lumen needle;
- 4.2.3.1.2. Heavy duty barrel The barrel has a scale showing the capacity of the syringe.
- 4.2.3.1.3. Stopper The stopper maintains the fluid in the barrel between the syringe nozzle and the plunger;
- 4.2.3.1.4. Plunger The plunger is used to aspirate and inject fluids into and out of the syringe;
- 4.2.3.1.5. Disposable;
- 4.2.3.1.6. **Luer lock** to accept luer hub applicator (e.g. needle);
- 4.2.3.1.7. Sizes as specified in Section 4.2.2 above; and
- 4.2.3.1.8. Sterile individually wrapped packaging.
- 4.2.4. **Hypodermic Needle:** *Description*: A Hypodermic needle is a slender, hollow instrument for introducing material into the body parenterally.
- 4.2.4.1. The Contractor shall ensure hypodermic needles comply with 21 CFR 880.5570, OSHA Needlestick Safety and Prevention Act, and follow International Standards Organization (ISO) 7864, and the following specifications:
- 4.2.4.1.1. Disposable;
- 4.2.4.1.2. <u>Luer hub</u> to attach to luer lock syringe;
- 4.2.4.1.3. See Tables in Sections 4.2.2 above for acceptable needle length and gauges;
- 4.2.4.1.4. Sterile individually wrapped packaging; and
- 4.2.4.1.5. Safety-engineered.
- 4.3. **Delivery Location and Shipping Requirements:** See Attachment 2-"Shipping Information" for all delivery locations and shipping requirements.
- 4.3.1. The Contractor shall provide *Packing Slips* with <u>all shipments</u> per CDRL A003. The Packing Slips shall include the following: (1) Contract number, (2) Item description, (3) Part number, (4) Lot numbers; and (5) Quantities. The Packing Slips shall include <u>BOTH</u>: (1) a *Packing Slip Paper Copy* with the shipment; and (2) a *Packing Slip Paper Emailed Copy* to the Designated Government Representative.
- 4.3.2. No Partial Case or Packages quantities will be accepted unless approved by the Contracting Officer prior to shipping.
- 4.3.3. The Contractor shall **NOT** Mixed Lot #'s per Case or per Packages. The Contractor shall only provide full <u>case</u> quantities <u>only</u>, *unless* approved by the Designated Government Representative in advance via email.
- 4.3.4. The Contractor shall ensure all pallets have the identical TyHi stack pattern, except for the final pallet; which would be a partial pallet or individual boxes.

- 4.3.5. All supplies shall be delivered on a standard 48" by 40" pallet, not to exceed 60" in height, stretch wrapped, clear-wrapped is preferred, and secured to the pallet for safe transport.
- 4.3.6. The Contractor shall contact the Designated Government Representative to schedule delivery appointments. The Government will provide the Designated Government Representative(s)' information at the Kick-Off Meeting.
- 4.3.7. Contractor shall contact the Designated Government Representative to schedule delivery appointments.
- 4.3.8. The Contractor shall ship ALL deliverables via AIR FREIGHT (b) (4) , effective immediately. The Contractor shall charge the Delta in costs between Air Freight costs and Sea Freight costs already built into this contract. The Contractor shall NOT submit any costs (e.g. labor, overhead, profit) other than "other direct costs" per FAR Clause 52.214-4 Alternative one (1) as those cost are already included in the contract. The Contractor shall only be reimbursed for actual REASONABLE costs and shall provide documented proof (e.g. receipts and paid invoices). The Government's pallet dimension limitations (stated in Section 4.3.5) is how the pallets will be delivered, it does NOT restrict pallet heights or other packing dimensions of HOW the items are to be shipped (either by air or sea). The Contractor shall follow commercial best practices and to maximize/optimize Air Cargo Load, palletization or repalletization (if needed), and drayage. The Government reserves the right to stop this Air Freight requirement (b) (4) via email notification from the Contracting Officer due to urgency, followed by a bi-lateral modification. The Government also reserves the right to provide transportation (e.g. planes) or other logistical services (e.g. palletization) and will notify the Contractor via an email from the Contracting Officer.
- 4.3.9. Based on mutual agreement at the Post-Award Meeting for delivery schedules, the Contractor shall provide an *Initial Updated Syringe-Needle Delivery Schedule*. The template for the Initial Updated Syringe-Needle Delivery Schedule will be provided by the COR. The Initial Updated Delivery Schedule shall be provided to the COR within three (3) business days after the "Sea to Air Freight Modification." Thereafter, the Contractor shall, at a minimum, provide *Weekly Delivery Schedule Updates* to the COR by Tuesday, 1400 Eastern Time.

# 5.0 Operation Warp Speed (OWS) Contract Language:

# 5.1. Disclosure of Information:

5.1.1. Performance under this contract may require the Contractor to access non-public data and information proprietary to a Government agency, another Government Contractor or of such nature that its dissemination or use other than as specified in the work statement would be adverse to the interests of the Government or others. Neither the Contractor, nor Contractor personnel, shall divulge nor release data nor information developed or obtained under performance of this contract, except authorized by Government personnel or upon written approval of the CO in accordance with OWS or other Government policies and/or guidance. The Contractor shall not use, disclose, or reproduce proprietary data that bears a restrictive legend, other than as specified in this contract, or any information at all regarding this agency.

- 5.1.2. The Contractor shall comply with all Government requirements for protection of non-public information. Unauthorized disclosure of nonpublic information is prohibited by the Government's rules. Unauthorized disclosure may result in termination of the contract, replacement of a Contractor employee, or other appropriate redress. Neither the Contractor nor the Contractor's employees shall disclose or cause to be disseminated, any information concerning the operations of the activity, which could result in, or increase the likelihood of, the possibility of a breach of the activity's security or interrupt the continuity of its operations.
- 5.1.3. No information related to data obtained under this contract shall be released or publicized without the prior written consent of the COR, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity' for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions.

# 5.2. Publications and Publicity:

- 5.2.1. The contractor shall not release any reports, manuscripts, press releases, or abstracts about the work being performed under this contract without written notice in advance to the Government:
  - (a) Unless otherwise specified in this contract, the contractor may publish the results of its work under this contract. The contractor shall promptly send a copy of each submission to the COR for security review prior to submission. The contractor shall also inform the COR when the abstract article or other publication is published, and furnish a copy of it as finally published;
  - (b) Unless authorized in writing by the CO, the contractor shall not display Government logos including Operating Division or Staff Division logos on any publications;
  - (c) The contractor shall not reference the products(s) or services(s) awarded under this contract in commercial advertising, as defined in FAR 31.205-1, in any manner which states or implies Government approval or endorsement of the product(s) or service(s) provided;
  - (d) The contractor shall include this clause, including this section (d) in all subcontracts where the subcontractor may propose publishing the results of its work under the subcontract. The contractor shall acknowledge the support of the Government whenever publicizing the work under this contract in any media by including an acknowledgement substantially as follows: "This project has been funded in whole or in part by the U.S. Government under Contract No. XXXX. The US Government is authorized to reproduce and distribute reprints for Governmental purposes notwithstanding any copyright notation thereon."

# 5.3. **Confidentiality of Information**:

5.3.1. Confidential information, as used in this article, means information or data of a personal

nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

- 5.3.2. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.
- 5.3.3. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.
- 5.3.4. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor shall obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.
- 5.3.5. Contracting Officer Determinations will reflect the result of internal coordination with appropriate program and legal officials.
- 5.3.6. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.
- 5.3.7. All above requirements MUST be passed to all Sub-contractors.

# 5.4. Organizational Conflicts of Interest:

- 5.4.1. Performance under this contract may create an actual or potential organizational conflict of interest such as are contemplated by FAR Part 9.505-General Rules. The Contractor shall not engage in any other contractual or other activities which could create an organizational conflict of interest (OCI). This provision shall apply to the prime Contractor and all sub-Contractors. This provision shall have effect throughout the period of performance of this contract, any extensions thereto by change order or supplemental agreement, and for two (2) years thereafter. The Government may pursue such remedies as may be permitted by law or this contract, upon determination that an OCI has occurred.
- 5.4.2. The work performed under this contract may create a significant potential for certain conflicts of interest, as set forth in FAR Parts 9.505-1, 9.505-2, 9.505-3, and 9.505-4. It is the intention of the parties hereto to prevent both the potential for bias in connection with the Contractor's performance of this contract, as well as the creation of any unfair competitive

advantage as a result of knowledge gained through access to any non-public data or third party proprietary information.

- 5.4.3. The Contractor shall notify the Contracting Officer immediately whenever it becomes aware that such access or participation may result in any actual or potential OCI. Furthermore, the Contractor shall promptly submit a plan to the Contracting Officer to either avoid or mitigate any such OCI. The Contracting Officer will have sole discretion in accepting the Contractor's mitigation plan. In the event the Contracting Officer unilaterally determines that any such OCI cannot be satisfactorily avoided or mitigated, other remedies may be taken to prohibit the Contractor from participating in contract requirements related to OCI.
- 5.4.4. Whenever performance of this contract provides access to another Contractor's proprietary information, the Contractor shall enter into a written agreement with the other entities involved, as appropriate, in order to protect such proprietary information from unauthorized use or disclosure for as long as it remains proprietary; and refrain from using such proprietary information other than as agreed to, for example to provide assistance during technical evaluation of other Contractors' offers or products under this contract. An executed copy of all proprietary information agreements by individual personnel or on a corporate basis shall be furnished to the CO within fifteen (15) calendar days of execution.

(End of Summary of Changes)

# INTEGRATED SYRINGE AND NEEDLE UNITS FOR COVID-19 NATIONAL EMERGENCY RESPONSE

The Syringe and Needle Units shall include the following components: (1) individually wrapped sterile syringes with individually wrapped sterile needles, (2) sterile needle/syringe combination unit, or (3) a mixture of combinations units and individually wrapped syringes with equal number of individually wrapped sterile needles.

The Offeror shall identify the country of origin, as specified in the subsequent Tabs in this document.

The hypodermic syringes shall be FDA cleared for the use to inject medicines and vaccines into, or withdraw fluids from the body. The Offeror shall provide their preauthorization from the FDA.

**Labeling**: The Needles and Syringes Units shall be labeled in accordance with 21 CFR Part 801 as it relates to intended use.

Shipping and packaging shall be in accordance with Title 21 Code of Federal Regulations (CFR), Subpart K.

# Ship to: SHIP TO DODAAC: STORAGE RIC: OWNER RIC:

# DISPENSING SYRINGE

# CRITERIA

<u>Description</u>: Dispensing syringe shall allow for the controlled and precise flow of liquid. They are used to inject medications or other liquids into body tissues. Manual syringes shall consist of a barrel, stopper, and plunger.

**Specifications**: Dispensing syringes shall comply with the following:

The Contractor shall comply with 21 Code of Federal Regulations (CFR) 880.5860 and Current Good Manufacturing Practice (cGMP). The contractor shall follow Internaltional Standards Organization (ISO) 7886-1:2017.

- a. The device shall be intended for medical purposes that consists of a calibrated hollow barrel and a movable plunger. At one end of the barrel there is a male connector (nozzle) for fitting the female connector (hub) of a hypodermic single lumen needle.
- b. Heavy duty barrel. The barrel shall have a scale showing the capacity of the syringe.
- c. Stopper. The stopper shall maintain the fluid in the barrel between the syringe nozzle and the Plunger.
  - d. Plunger. The plunger shall aspirate and inject fluids into and out of the syringe
  - e. Disposable
  - f. Luer lock to accept luer hub applicator (e.g. needle)
  - g. Acceptable sizes are 1mL and 3mL
  - h. Sterile individually wrapped packaging

# 510(k) Approval Letters

# PERFORMANCE SPECIFICATIONS:

Class II Performance Standards: The Offeror shall:

- (1) Utilize FDA-approved dispensing syringes
- (2) Individually wrap and sterilize each syringe prior to shipment

# COMBINATION NEEDLE (SAFETY NEEDLE) AND SYRINGE UNIT:

syringe coupled with needle for safety shall be acceptable as long as the components comply with all of the specifications above, except for the needle and syringe are **packaged together**.

Syringe: Sizes acceptable are 1ml or 3ml

Needle: 23 Gauge, Length 1," or 1.5" and/or 25 Gauge, Length 1"

510(k) Approval Letters

**Country of Origin** 

# HYPODERMIC NEEDLE

# **CRITERIA**

**Description**: Hypodermic needles are slender, hollow instruments for introducing material into the body parenterally

**Specifications**: The Hypodermic Needle shall comply with the following:

The contractor shall comply with 21 Code of Federal Regulations (CFR) 880.5570 and Current Good Manufacturing Practice (cGMP). The contractor shall follow International Standards Organization (ISO) 7864, single use hypodermic needles.

- a. Shall be a device intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin. The device consists of a metal tube that is sharpened at one end and at the other end joined to a female connector (Luer hub) designed to mate with a male connector (Luer lock nozzle) of a piston syringe or intravascular administration set.
  - b. Disposable
  - c. Luer hub to attach to luer lock
  - d. Acceptable 23 Gauge, Length 1," or 1.5", and/or 25 Gauge, Length 1"
  - e. Sterile individually wrapped packaging
  - f. Safety-engineered

# 510(k) Approval Letters

**Country of Origin** 

# PERFORMANCE SPECIFICATIONS:

Class II Performance Standards: The Offeror shall:

- (1) Utilize FDA-approved needles
- (2) Individually wrap and sterilize each needle prior to shipment

# COMBINATION NEEDLE (SAFETY NEEDLE) AND SYRINGE UNIT:

Hypodermic syringe coupled with integrated needle for safety shall be acceptable as long as the components comply with all of the specifications above, except for the needle and syringe are <u>packaged together</u>

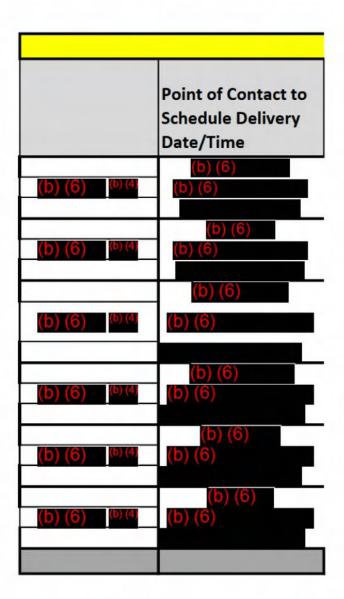
Needle: 23 Gauge, Length 1," or 1.5" and/or 25 Gauge, Length 1"

Syringe: Sizes acceptable are 1ml or 3ml

510(k) Approval Letters

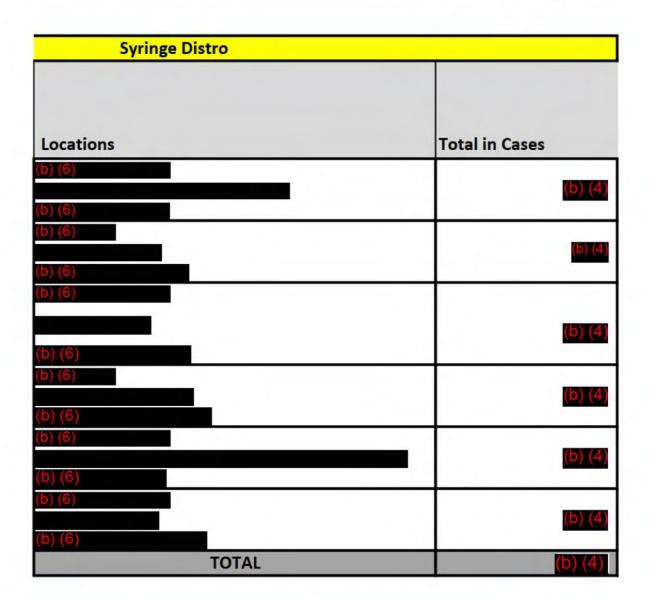
Country of Origin

Company	Total (b) (4) by December
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Important Note: Please contact the point of cand date before shipping any product.

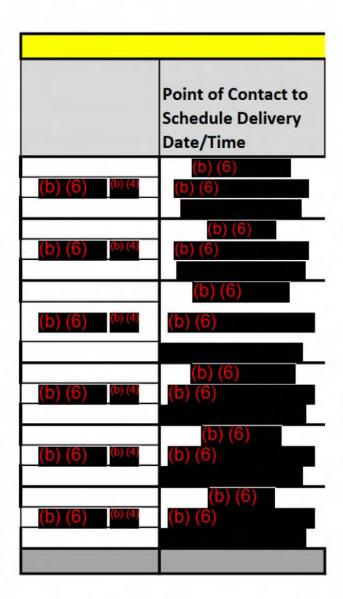
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ontact for the respective location in order to schedule a delivery time

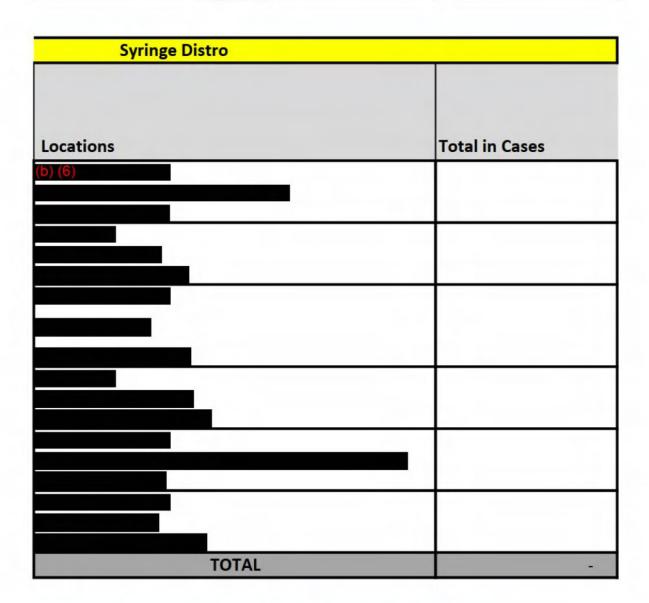
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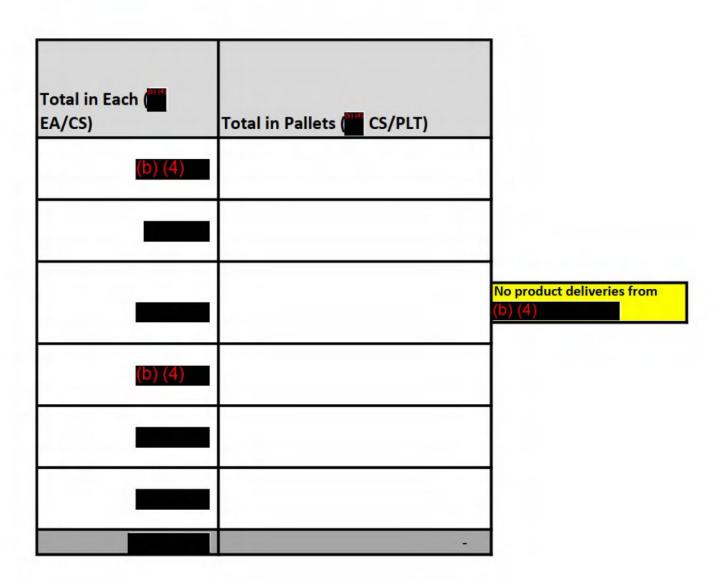
Important Note: Please contact the point of cand date before shipping any product.

Total (b) (d) by December	
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ontact for the respective location in order to schedule a delivery time

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# **CONTRACT DATA REQUIREMENTS LIST**

(2 Data Items)

Form Approved OMB No. 0704-0188

The public reporting burden for this collection of information is estimated to average 220 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense, Executive Services Directorate (0704-0188). Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. Please do not return your form to the above organization. Send completed form to the Government Issuing Contracting Officer for the Contract/PR No. listed in Block E.

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17. PRICE GROUP

# **CONTRACT DATA REQUIREMENTS LIST**

(2 Data Items)

Form Approved OMB No. 0704-0188

The public reporting burden for this collection of information is estimated to average 220 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense, Executive Services Directorate (0704-0188). Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. Please do not return your form to the above organization. Send completed form to the

	Contracting Officer for the				ATEGORY:			100000000000000000000000000000000000000			
A. CONTRACT	LINE ITEM NO.	B.EXHIE		THER General Admin D	ata						
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### INSTRUCTIONS FOR COMPLETING DD FORM 1423

(See DoD 5010.12-M for detailed instructions.)

### FOR GOVERNMENT PERSONNEL

- Item A. Self-explanatory.
- Item B. Self-explanatory.
- **Item C.** Mark (X) appropriate category: TDP Technical Data Package; TM Technical Manual; Other other category of data, such as "Provisioning," "Configuration Management," etc.
- **Item D.** Enter name of system/item being acquired that data will support.
- Item E. Self-explanatory (to be filled in after contract award).
- Item F. Self-explanatory (to be filled in after contract award).
- Item G. Signature of preparer of CDRL.
- Item H. Date CDRL was prepared.
- Item I. Signature of CDRL approval authority.
- Item J. Date CDRL was approved.
- **Item 1.** See DoD FAR Supplement Subpart 4.71 for proper numbering.
- **Item 2.** Enter title as it appears on data acquisition document cited in Item 4.
- **Item 3.** Enter subtitle of data item for further definition of data item (optional entry).
- **Item 4.** Enter Data Item Description (DID) number, military specification number, or military standard number listed in DoD 5010.12-L (AMSDL), or one-time DID number, that defines data content and format requirements.
- **Item 5.** Enter reference to tasking in contract that generates requirement for the data item (e.g., Statement of Work paragraph number).
- **Item 6.** Enter technical office responsible for ensuring adequacy of the data item.
- **Item 7.** Specify requirement for inspection/acceptance of the data item by the Government.
- **Item 8.** Specify requirement for approval of a draft before preparation of the final data item.
- **Item 9.** For technical data, specify requirement for contractor to mark the appropriate distribution statement on the data (ref. DoDD 5230.24).
- **Item 10.** Specify number of times data items are to be delivered.
- Item 11. Specify as-of date of data item, when applicable.
- Item 12. Specify when first submittal is required.
- **Item 13.** Specify when subsequent submittals are required, when applicable.
- **Item 14.** Enter addressees and number of draft/final copies to be delivered to each addressee. Explain reproducible copies in Item 16.
- Item 15. Enter total number of draft/final copies to be delivered.
- **Item 16.** Use for additional/clarifying information for Items 1 through 15. Examples are: Tailoring of documents cited in Item 4; Clarification of submittal dates in Items 12 and 13; Explanation of reproducible copies in Item 14.; Desired medium for delivery of the data item.

# FOR THE CONTRACTOR

- **Item 17.** Specify appropriate price group from one of the following groups of effort in developing estimated prices for each data item listed on the DD Form 1423.
- a. Group I. Definition Data which is not otherwise essential to the contractor's performance of the primary contracted effort (production, development, testing, and administration) but which is required by DD Form 1423.

Estimated Price - Costs to be included under Group I are those applicable to preparing and assembling the data item in conformance with Government requirements, and the administration and other expenses related to reproducing and delivering such data items to the Government.

b. Group II. Definition - Data which is essential to the performance of the primary contracted effort but the contractor is required to perform additional work to conform to Government requirements with regard to depth of content, format, frequency of submittal, preparation, control, or quality of the data item.

Estimated Price - Costs to be included under Group II are those incurred over and above the cost of the essential data item without conforming to Government requirements, and the administrative and other expenses related to reproducing and delivering such data item to the Government.

c. Group III. Definition - Data which the contractor must develop for his internal use in performance of the primary contracted effort and does not require any substantial change to conform to Government requirements with regard to depth of content, format, frequency of submittal, preparation, control, and quality of the data item.

Estimated Price - Costs to be included under Group III are the administrative and other expenses related to reproducing and delivering such data item to the Government.

d. Group IV. Definition - Data which is developed by the contractor as part of his normal operating procedures and his effort in supplying these data to the Government is minimal.

Estimated Price - Group IV items should normally be shown on the DD Form 1423 at no cost.

Item 18. For each data item, enter an amount equal to that portion of the total price which is estimated to be attributable to the production or development for the Government of that item of data. These estimated data prices shall be developed only from those costs which will be incurred as a direct result of the requirement to supply the data, over and above those costs which would otherwise be incurred in performance of the contract if no data were required. The estimated data prices shall not include any amount for rights in data. The Government's right to use the data shall be governed by the pertinent provisions of the contract.

# CONTRACT DATA REQUIREMENTS LIST

(2 Data Items)

Form Approved OMB No. 0704-0188

The public reporting burden for this collection of information is estimated to average 220 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense, Executive Services Directorate (0704-0188). Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for falling to comply with a collection of information if it does not display a currently valid OMB control number. Please do not return your form to the above organization. Send completed form to the Government Issuing Contracting Officer for the Officer

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# INSTRUCTIONS FOR COMPLETING DD FORM 1423

(See DoD 5010.12-M for detailed instructions.)

### FOR GOVERNMENT PERSONNEL

- Item A. Self-explanatory.
- Item B. Self-explanatory.
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amount for rights in data. The Government's right to use the data shall be governed by the pertinent provisions of the contract.

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AMENDMENT OF SOL	ICITA	ATION/MODIF	ICATION OF CONTRACT		J			1   2		
2 AMENDMENT/MODIFICATION NO		3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO			5 P	ROJECT	NO (Ifapplicable)		
P00002		26-Oct-2020	SEE SCHEDULE							
6 ISSUED BY CO	DDE	W911SR	7 ADMINISTERED BY (Ifother than item 6)		COI	DE				
USA CONTRACT NG CMD-APG W911SR EDGEWOOD CONTRACTING DIVISION 8456 BRIGADE STREET BLDG E4215 ABERDEEN PROVING GROUND MD 21010-5401			See Item 6							
8. NAME AND ADDRESS OF CONTRA	CTOR	No., Street, County,	State and Zip Code)		9A. AMENDM	ENT	OF SOI	LICITATION NO.		
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x					W9113R20C0049					
CODE 771/00		T. 1 CTT TTT I CO.		X	10B. DATED ( 03-Aug-2020	SEE	ITEM :	13)		
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The above numbered solicitation is amended a				$\overline{}$	is extended,	is	not exten	ıded		
Offer must acknowledge receipt of this amend (a) By completing Items 8 and 15, and returni	-	-	l ified in the solicitation or as amended by one ofth at; (b) By acknowledging receipt ofthis amendmen		-	êr sul	mitted:			
or (c) By separate letter or telegram which inc	ludes a re	ference to the solicitation	and amendment numbers FAILURE OF YOUR A	CKI	NOWLEDGMENT					
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			O MODIFICATIONS OF CONTRACTS CT/ORDER NO. AS DESCRIBED IN ITE							
A. THIS CHANGE ORDER IS ISSUED CONTRACT ORDER NO. IN ITEM		JANT TO: (Specify a	uthority) THE CHANGES SET FORTH	IN I	ITEM 14 ARE N	IAD	E IN TI	Ε		
X B. THE ABOVE NUMBERED CONTI office, appropriation date, etc.) SE			TO REFLECT THE ADMINISTRATIV SUANT TO THE AUTHORITY OF FAI			as ch	anges in	ı paying		
C. THIS SUPPLEMENTAL AGREEM	ENT IS	ENTERED INTO PU	JRSUANT TO AUTHORITY OF:							
D. OTHER (Specify type of modificate	on and	authority)								
E. IMPORTANT: Contractor X is	not,	is required to sig	n this document and return	coj	pies to the issuin	goff	ice.			
14. DESCRIPTION OF AMENDMENT/II where feasible.) Modification Control Number: The purpose of this administrative mod	(6) ificatior Septen	lis: nber-2020 to 28- Febr	by UCF section headings, including solici							
All other terms and conditions remain to	ne sam	<del>9</del> .								
Except as provided herein, all terms and condition				_						
15A. NAME AND TITLE OF SIGNER (Type or print)			16A. NAME AND TITLE OF CO.	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)				or print)		
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15B. CONTRACTOR/OFFEROR		15C. DATE SIGNE	16B UNITED STATES OF AMER BY (b) (6)	IC/	A			C. DATE SIGNED		
(Signature of person authorized to si	gn)		(Signature of Contracting Off	ice	r)		=   20	6-Oct-2020		

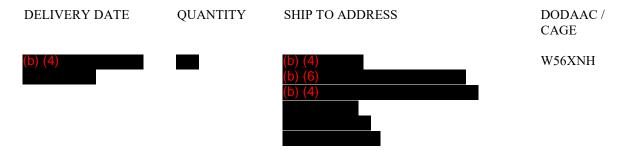
# SECTION SF 30 BLOCK 14 CONTINUATION PAGE

# **SUMMARY OF CHANGES**

SECTION SF 1449 - CONTINUATION SHEET

DELIVERIES AND PERFORMANCE

The following Delivery Schedule for CLIN 0005 has been added:



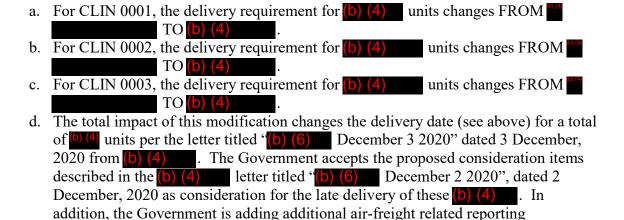
(End of Summary of Changes)

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AMENDMENT OF SOI	LICITA	TION/MODIF	ICATION OF CONTRACT		J			1	13
2 AMENDMENT/MODIFICATION NO		3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO			5 PRO	JECT N	IO (Ifapplica	able)
P00003		17-Dec-2020	SEE SCHEDULE						
6 ISSUED BY	CODE	W911SR	7 ADMINISTERED BY (Ifother than item 6)		COI	DE			
USA CONTRACT NG CMD-APG W911SR EDGEWOOD CONTRACTING DIVISION 8456 BRIGADE STREET BLDG E4215 ABERDEEN PROVING GROUND MD 21010-5401	I		See Item 6						
8. NAME AND ADDRESS OF CONTR	ACTOR (	No., Street, County,	State and Zip Code)		9A. AMENDM	ENT O	F SOL	ICIT AT I	ON NO.
HTL-STREFA, NC.	· ·		• /	_	9B. DATED (S	EE ITE	M 11)	)	
				X	10A MOD OF W911SR20C00	CONT 49	RACT	ORDER	NO.
					10B. DATED (				
CODE 7TKQ9		FACILITY COL	DE	X	03-Aug-2020				
	11.	THIS ITEM ONLY A	PPLIES TO AMENDMENTS OF SOLIC	TI.	ATIONS				
The above numbered solicitation is amende	d as set forth	in Item 14 The hour and	date specified for receipt of Offer		is extended,	is no	t extend	ied	
(a) By completing Items 8 and 15, and retur or (c) By separate letter or telegram which i RECEIVED AT THE PLACE DESIGNAT REJECTION OF YOUR OFFER If by virt provided each telegramor letter makes refer	ning ncludes a ref ED FOR TH ue of this am ence to the s	copies of the amendment ference to the solicitation of E RECEIPT OF OFFERS: endment you desire to cha colicitation and this amend	ified in the solicitation or as amended by one ofti ht; (b) By acknowledging receipt of this amendme and amendment numbers FAILURE OF YOUR A PRIOR TO THE HOUR AND DATE SPECIFIED nge an offer already submitted, such change may be dement, and is received prior to the opening hour a	nt or ACKI O MA	n each copy of the of NOWLEDGMENT AY RESULT IN ade by telegram or le	го ве	tted;		
12. ACCOUNTING AND APPROPRIA	TION DA	ATA (If required)							
			TO MODIFICATIONS OF CONTRACTS CT/ORDER NO. AS DESCRIBED IN ITE						
A. THIS CHANGE ORDER IS ISSUE CONTRACT ORDER NO. IN ITI		ANT TO: (Specify a	uthority) THE CHANGES SET FORTH	IN I	ITEM 14 ARE N	IADE I	IN TH	E	
office, appropriation date, etc.) S	ET FORT	H IN ITEM 14, PUR	TO REFLECT THE ADMINISTRATIV SUANT TO THE AUTHORITY OF FA			as chan	ges in	paying	
X C. THIS SUPPLEMENTAL AGREE Bilateral IAW FAR 52.212-4(c)	MENT IS	ENTERED INTO PU	JRSUANT TO AUTHORITY OF:						
D. OTHER (Specify type of modifica	ation and a	authority)							
E. IMPORTANT: Contractor i	s not,	X is required to sig	n this document and return 1	cop	pies to the issuin	g office	).		
14. DESCRIPTION OF AMENDMENT where feasible.) Modification Control Number: The purpose of this modification is: SEE BLOCK 14 CONTINUATION PAGE	) (6)	CATION (Organized	by UCF section headings, including solic	itati	ion/contract subj	ect mat	iter		
Except as provided herein, all terms and condition 15A. NAME AND TITLE OF SIGNER			9A or 10A, as heretofore changed, remains unchan	_			ype or	r print)	
	'	-	(b) (6)					_	
15B. CONTRACT OR/OFFEROR		15C. DATE SIGNED	(b) (6)	CICA	EMAL: (b) (6)		16C	DATE SI	IGNED
(Signature of person authorized to	sign)		(Signature of Contracting Of	fice	r)		17-	'-Dec-2020	0

# SECTION SF 30 BLOCK 14 CONTINUATION PAGE

# The following items are applicable to this modification:

The purpose of this modification (P00003 to W911SR-20-C-0049) is as follows:



requirement language to the contract on this modification (see updated Statement of

All other terms and conditions remain the same.

# **SUMMARY OF CHANGES**

SECTION SF 1449 - CONTINUATION SHEET

# SOLICITATION/CONTRACT FORM

The vendor signature required has changed from required to not required. The number of award copies required 1 has been deleted.

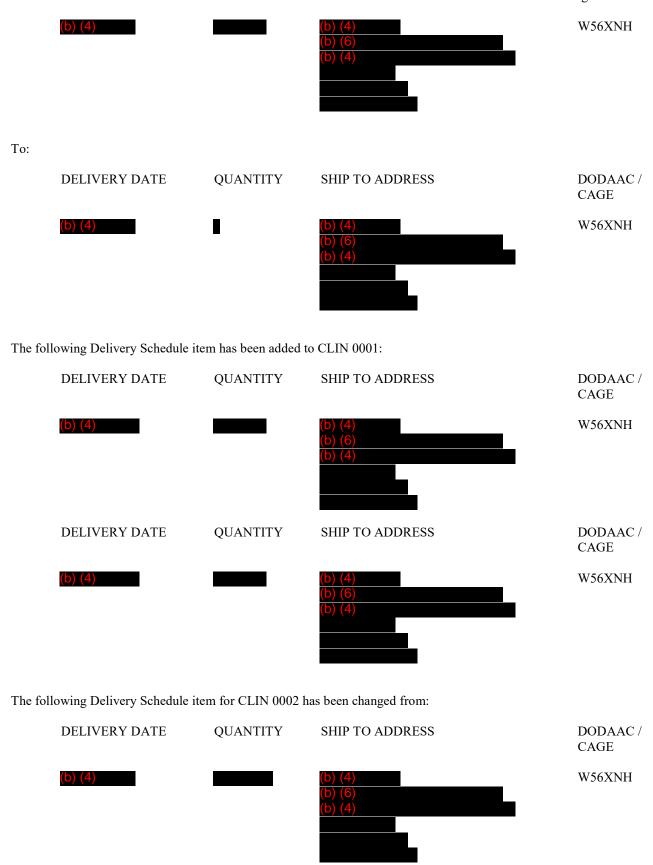
Work) as part of the consideration for late delivery.

# DELIVERIES AND PERFORMANCE

The following Delivery Schedule item for CLIN 0001 has been changed from:

DELIVERY DATE OUANTITY SHIP TO ADDRESS

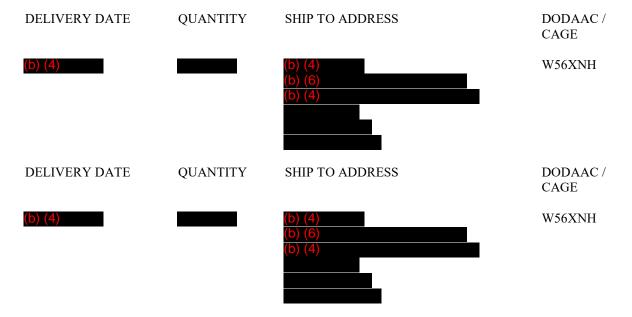
DODAAC / CAGE



To:



The following Delivery Schedule item has been added to CLIN 0002:

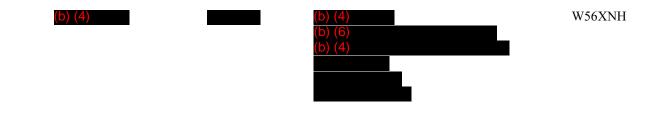


The following Delivery Schedule item for CLIN 0003 has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
(b) (4)		(b) (4) (b) (6) (b) (4)	W56XNH

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC /
			CAGE



The following Delivery Schedule item has been added to CLIN 0003:



The following have been modified:

STATEMENT OF WORK

This section has been modified. Changes are shown below in red font text.

# STATEMENT OF WORK PROCUREMENT OF SAFETY NEEDLES AND SYRINGES FOR COVID-19

**1.0** SCOPE: The Contractor, as an independent Contractor and not as an agent of the Government, shall furnish the necessary resources as specified in this Statement of Work (SOW), to manufacture and/or supply Safety Needles and Syringes.

# 2.0 BACKGROUND:

On Friday, March 13, 2020, the President declared a national emergency concerning the novel coronavirus disease (COVID-19) under section 501(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5207 (the "Stafford Act).

The mission of the Division of Strategic National Stockpile (DSNS), of the United States (U.S.) Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR), is to ensure the availability and rapid deployment of life-saving pharmaceuticals, antidotes, other medical supplies, and equipment necessary to counter the effects of nerve agents, biological pathogens, and chemical agents. When state, local, tribal, and territorial public health and medical systems request federal assistance to support their response efforts, DSNS ensures the right medicines and supplies get to those who need them most during an emergency. When the vaccine becomes available the Government will have an

immediate need to begin vaccinating the entire U.S. population. To administer the vaccine the Government will require needles and syringes to be available.

There is an insufficient domestic supply of safety needles and syringes to meet the projected needs to vaccinate the nation's entire population against COVID-19. Should vaccine programs be accelerated, demand could outpace available devices to administer a vaccine.

**3.0 OBJECTIVE**: The HHS currently has contracts in place with three (3) major manufacturers to provide needles and syringes supplies to support the initial preparedness needs at the onset of a pandemic outbreak. The objective of this acquisition is to supplement the current supply and establish contracts with additional manufacturers and suppliers to provide a quantity of up to 500 million safety needles and syringes supplies.

# 4.0 **REQUIREMENTS**:

# 4.1. **General:**

- 4.1.1. The Contractor shall "host" a *Kick-Off Meeting* within one (1) calendar day after contract award via <u>teleconference</u>. The Contractor shall provide *Meeting Minutes* containing a detailed overview of the meeting discussions in accordance with (IAW) Contract Data Requirements List (CDRL) A001.
- 4.1.1.1. The Contractor shall provide a *Certificate of Analysis* with each shipment per the DD Form 1423, Contract Data Requirements List (CDRL) A002, confirming the supplies described below meet the Performance Specifications in paragraph 4.2 below.
- 4.1.2. The Contractor shall provide copies of 510(k) Approval Letters for ALL supplies (dispensing syringes or needles) to demonstrate compliance with Section 510(k) of the Food, Drug and Cosmetic Act as part of their proposal. The Contractor shall provide, if necessary, 510(k) Approval Letters Updates if any information from the initial 510(k) Approval Letters is changed/needs to be updated.
- 4.1.2.1.1. The Contractor shall ensure all supplies have a "*Shelf-Life*" with expiration dates of no less than five (5) years from the date of sterilization, <u>and</u> must have at least four (4) years of remaining expiry from the time of shipment.
- 4.1.2.1.2. The Contractor shall only use *Current Good Manufacturing Practice (cGMP)* processes to manufacture the needles and syringes.
- 4.1.2.1.3. **Period of Performance/Delivery Dates.** See the "Delivery Schedule" section of this Contract and "Attachment 2-Shipping Information" for all delivery requirements and shipping locations.

# 4.2. <u>Technical Requirements</u>:

4.2.1. The Contractor shall provide sterile needle (with Luer hub connection) and syringe (with

Luer lock connection) units approved by the Food and Drug Administration (FDA) <u>and</u> comply with Occupational Safety and Health Administration (OSHA) Needlestick Safety and Prevention Act requirements as a "safety-engineered product." Safety-engineered supplies include needles preventing sharp injuries by either; being completely enclosed after use by an attached shield, or be fully retracted within the syringe. The Contractor may provide individual syringes and individual needles as long as there is a <u>one-to-one (1:1) ratio</u>. In order to meet the specified quantities upon contract award and comply with the specifications in this SOW, the following may be provided: (1) individually wrapped sterile syringes with individually wrapped sterile needles in a one-to-one (1:1) ratio, (2) sterile needle/syringe combination unit, or (3) a mixture of sterile combination units <u>and</u> individually wrapped sterile syringes with equal number of individually wrapped sterile needles.

4.2.2. The Contractor shall only provide acceptable product sizes as described below:

# **Individual Syringe:**

Syringe
1mL
3mL

### Individual Needle:

<u>Needle</u> <u>Gauge</u>	<u>Needle</u> <u>Length</u>
23G	1"
23G	1.5"
25G	1"

### **Combination Unit:**

Syringe	<u>Needle</u> <u>Gauge</u>	Needle Length
1mL	23G	1"
1mL	23G	1.5"
1mL	25G	1"
3mL	23G	1"
3mL	23G	1.5"
3mL	25G	1"

- 4.2.3. **Dispensing Syringe:** *Description:* A dispensing syringe allows for the controlled and precise flow of liquid. The dispensing syringe is used to inject medications or other liquids into body tissues. Manual syringes consist of a barrel, stopper, and plunger.
- 4.2.3.1. The Contractor shall ensure dispensing syringes comply with Title 21 Code of Federal Regulations (CFR) 880.5860 and follow International Standards Organization (ISO)

- 7886-1:2017 and the following material specifications:
- 4.2.3.1.1. A device intended for medical purposes that consists of a calibrated hollow barrel and a movable plunger. At one end of the barrel there is a male connector (nozzle) for fitting the female connector (hub) of a hypodermic single lumen needle;
- 4.2.3.1.2. Heavy duty barrel The barrel has a scale showing the capacity of the syringe.
- 4.2.3.1.3. Stopper The stopper maintains the fluid in the barrel between the syringe nozzle and the plunger;
- 4.2.3.1.4. Plunger The plunger is used to aspirate and inject fluids into and out of the syringe;
- 4.2.3.1.5. Disposable;
- 4.2.3.1.6. <u>Luer lock</u> to accept luer hub applicator (e.g. needle);
- 4.2.3.1.7. Sizes as specified in Section 4.2.2 above; and
- 4.2.3.1.8. Sterile individually wrapped packaging.
- 4.2.4. **Hypodermic Needle:** *Description*: A Hypodermic needle is a slender, hollow instrument for introducing material into the body parenterally.
- 4.2.4.1. The Contractor shall ensure hypodermic needles comply with 21 CFR 880.5570, OSHA Needlestick Safety and Prevention Act, and follow International Standards Organization (ISO) 7864, and the following specifications:
- 4.2.4.1.1. Disposable;
- 4.2.4.1.2. <u>Luer hub</u> to attach to luer lock syringe;
- 4.2.4.1.3. See Tables in Sections 4.2.2 above for acceptable needle length and gauges;
- 4.2.4.1.4. Sterile individually wrapped packaging; and
- 4.2.4.1.5. Safety-engineered.
- 4.3. **Delivery Location and Shipping Requirements:** See Attachment 2-"Shipping Information" for all delivery locations and shipping requirements.
- 4.3.1. The Contractor shall provide *Packing Slips* with <u>all shipments</u> per CDRL A003. The Packing Slips shall include the following: (1) Contract number, (2) Item description, (3) Part number, (4) Lot numbers; and (5) Quantities. The Packing Slips shall include <u>BOTH</u>: (1) a *Packing Slip Paper Copy* with the shipment; and (2) a *Packing Slip Paper Emailed Copy* to the Designated Government Representative.
- 4.3.2. No Partial Case or Packages quantities will be accepted unless approved by the Contracting Officer prior to shipping.
- 4.3.3. The Contractor shall **NOT** Mixed Lot #'s per Case or per Packages. The Contractor shall only provide full <u>case</u> quantities <u>only</u>, *unless* approved by the Designated Government Representative in advance via email.
- 4.3.4. The Contractor shall ensure all pallets have the identical TyHi stack pattern, except for the final pallet; which would be a partial pallet or individual boxes.

- 4.3.5. All supplies shall be delivered on a standard 48" by 40" pallet, not to exceed 60" in height, stretch wrapped, clear-wrapped is preferred, and secured to the pallet for safe transport.
- 4.3.6. The Contractor shall contact the Designated Government Representative to schedule delivery appointments. The Government will provide the Designated Government Representative(s)' information at the Kick-Off Meeting.
- 4.3.7. Contractor shall contact the Designated Government Representative to schedule delivery appointments.
- 4.3.8. The Contractor shall ship ALL deliverables via AIR FREIGHT through February 28, 2021, effective immediately. The Contractor shall charge the Delta in costs between Air Freight costs and Sea Freight costs already built into this contract. The Contractor shall NOT submit any costs (e.g. labor, overhead, profit) other than "other direct costs" per FAR Clause 52.214-4 Alternative one (1) as those cost are already included in the contract. The Contractor shall only be reimbursed for actual REASONABLE costs and shall provide documented proof (e.g. receipts and paid invoices). The Government's pallet dimension limitations (stated in Section 4.3.5) is how the pallets will be delivered, it does NOT restrict pallet heights or other packing dimensions of HOW the items are to be shipped (either by air or sea). The Contractor shall follow commercial best practices and to maximize/optimize Air Cargo Load, palletization or repalletization (if needed), and drayage. The Government reserves the right to stop this Air Freight requirement prior to February 28, 2021 via email notification from the Contracting Officer due to urgency, followed by a bi-lateral modification. The Government also reserves the right to provide transportation (e.g. planes) or other logistical services (e.g. palletization) and will notify the Contractor via an email from the Contracting Officer.
- 4.3.9. Based on mutual agreement at the Post-Award Meeting for delivery schedules, the Contractor shall provide an *Initial Updated Syringe-Needle Delivery Schedule*. The template for the Initial Updated Syringe-Needle Delivery Schedule will be provided by the COR. The Initial Updated Delivery Schedule shall be provided to the COR within three (3) business days after the "Sea to Air Freight Modification." Thereafter, the Contractor shall, at a minimum, provide *Weekly Delivery Schedule Updates* to the COR by Tuesday, 1400 Eastern Time.

### 5.0 Operation Warp Speed (OWS) Contract Language:

### 5.1. Disclosure of Information:

5.1.1. Performance under this contract may require the Contractor to access non-public data and information proprietary to a Government agency, another Government Contractor or of such nature that its dissemination or use other than as specified in the work statement would be adverse to the interests of the Government or others. Neither the Contractor, nor Contractor personnel, shall divulge nor release data nor information developed or obtained under performance of this contract, except authorized by Government personnel or upon written approval of the CO in accordance with OWS or other Government policies and/or guidance. The Contractor shall not use, disclose, or reproduce proprietary data that bears a restrictive legend, other than as specified in this contract, or any information at all regarding this agency.

- 5.1.2. The Contractor shall comply with all Government requirements for protection of non-public information. Unauthorized disclosure of nonpublic information is prohibited by the Government's rules. Unauthorized disclosure may result in termination of the contract, replacement of a Contractor employee, or other appropriate redress. Neither the Contractor nor the Contractor's employees shall disclose or cause to be disseminated, any information concerning the operations of the activity, which could result in, or increase the likelihood of, the possibility of a breach of the activity's security or interrupt the continuity of its operations.
- 5.1.3. No information related to data obtained under this contract shall be released or publicized without the prior written consent of the COR, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity' for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions.

# 5.2. Publications and Publicity:

- 5.2.1. The contractor shall not release any reports, manuscripts, press releases, or abstracts about the work being performed under this contract without written notice in advance to the Government:
  - (a) Unless otherwise specified in this contract, the contractor may publish the results of its work under this contract. The contractor shall promptly send a copy of each submission to the COR for security review prior to submission. The contractor shall also inform the COR when the abstract article or other publication is published, and furnish a copy of it as finally published;
  - (b) Unless authorized in writing by the CO, the contractor shall not display Government logos including Operating Division or Staff Division logos on any publications;
  - (c) The contractor shall not reference the products(s) or services(s) awarded under this contract in commercial advertising, as defined in FAR 31.205-1, in any manner which states or implies Government approval or endorsement of the product(s) or service(s) provided;
  - (d) The contractor shall include this clause, including this section (d) in all subcontracts where the subcontractor may propose publishing the results of its work under the subcontract. The contractor shall acknowledge the support of the Government whenever publicizing the work under this contract in any media by including an acknowledgement substantially as follows: "This project has been funded in whole or in part by the U.S. Government under Contract No. XXXX. The US Government is authorized to reproduce and distribute reprints for Governmental purposes notwithstanding any copyright notation thereon."

### 5.3. Confidentiality of Information:

5.3.1. Confidential information, as used in this article, means information or data of a personal

nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

- 5.3.2. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.
- 5.3.3. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.
- 5.3.4. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor shall obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.
- 5.3.5. Contracting Officer Determinations will reflect the result of internal coordination with appropriate program and legal officials.
- 5.3.6. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.
- 5.3.7. All above requirements MUST be passed to all Sub-contractors.

### 5.4. Organizational Conflicts of Interest:

- 5.4.1. Performance under this contract may create an actual or potential organizational conflict of interest such as are contemplated by FAR Part 9.505-General Rules. The Contractor shall not engage in any other contractual or other activities which could create an organizational conflict of interest (OCI). This provision shall apply to the prime Contractor and all sub-Contractors. This provision shall have effect throughout the period of performance of this contract, any extensions thereto by change order or supplemental agreement, and for two (2) years thereafter. The Government may pursue such remedies as may be permitted by law or this contract, upon determination that an OCI has occurred.
- 5.4.2. The work performed under this contract may create a significant potential for certain conflicts of interest, as set forth in FAR Parts 9.505-1, 9.505-2, 9.505-3, and 9.505-4. It is the intention of the parties hereto to prevent both the potential for bias in connection with the Contractor's performance of this contract, as well as the creation of any unfair competitive

advantage as a result of knowledge gained through access to any non-public data or third party proprietary information.

- 5.4.3. The Contractor shall notify the Contracting Officer immediately whenever it becomes aware that such access or participation may result in any actual or potential OCI. Furthermore, the Contractor shall promptly submit a plan to the Contracting Officer to either avoid or mitigate any such OCI. The Contracting Officer will have sole discretion in accepting the Contractor's mitigation plan. In the event the Contracting Officer unilaterally determines that any such OCI cannot be satisfactorily avoided or mitigated, other remedies may be taken to prohibit the Contractor from participating in contract requirements related to OCI.
- 5.4.4. Whenever performance of this contract provides access to another Contractor's proprietary information, the Contractor shall enter into a written agreement with the other entities involved, as appropriate, in order to protect such proprietary information from unauthorized use or disclosure for as long as it remains proprietary; and refrain from using such proprietary information other than as agreed to, for example to provide assistance during technical evaluation of other Contractors' offers or products under this contract. An executed copy of all proprietary information agreements by individual personnel or on a corporate basis shall be furnished to the CO within fifteen (15) calendar days of execution.

# **Additional Reporting Requirements.**

# **AIR SHIPMENTS:**

Within 4 hours of departure (from the airport of origin), contractor is required to provide the following information for every air shipment provided under this contract:

Carrier Name:

Aircraft Tail Number:

Aircraft Manufacture/Model (i.e. Boeing 747):

Port of Departure:

Time/Date of Departure (US Eastern Standard Time - EST):

Port of Arrival (final destination):

Schedule time/date of Arrival at Final Destination (US Eastern Standard Time - EST):

Detailed descriptions and quantities/count by individual item shall be included for each air shipment.

Actual Time/date of Arrival at final port:

If aircraft is diverted and/or anticipated to arrive at final destination more than 4 hours after scheduled arrival time/date, contractor shall provide written notification and include the new estimated arrival time/date.

<u>WAREHOUSED ITEMS</u> - Contract Items stored/staged at interim locations prior to air shipment at contractor warehouses and/or warehouses utilized by contractor subcontractors and/or transportation agents. The contractor is required to provide a daily report not later than 1700 US Eastern Standard Time (EST) including the following information:

Location of Warehouse(s):

Complete physical address of warehouse(s):

Warehouse POC:

Warehouse POC telephone number and email address:

For each warehouse location, detailed descriptions and quantities/count by individual item warehoused and ready for shipment.

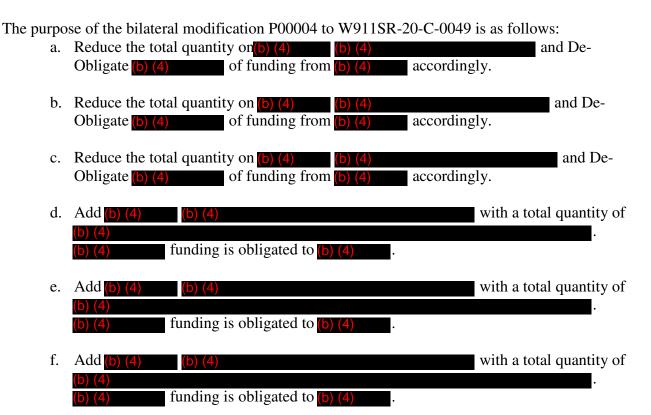
# **ADDITIONAL NOTES:**

- 1. Concurrently, all information required under this contract modification shall be provided by email to the following individuals:
- a) ACC-APG Email Address Email Address TBD via email from Contracting Officer after execution of modification.
- b) ACC HQs POC, (b) (6)

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT			1. CONTRACT	ID CODE	PAGE OF PAGES
AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT		J		1 10	
2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	•	5. PROJECT	NO.(Ifapplicable)
P00004	29-Jan-2021	SEE SCHEDULE			
6. ISSUED BY CODE	W911SR	7. ADMINISTERED BY (Ifother than item 6)	COI	DE	
USA CONTRACTING CMD-APG W911SR EDGEWOOD CONTRACTING DIVISION 8456 BRIGADE STREET BLDG E4215 ABERDEEN PROVING GROUND MD 21010-5401		See Item 6			
8. NAME AND ADDRESS OF CONTRACTOR (	No., Street, County, S	State and Zip Code)	9A. AMENDMI	ENT OF SOI	LICITATION NO.
HTL-STREFA, INC.			9B. DATED (SEE ITEM 11)		
		>	X 10A. MOD. OF CONTRACT/ORDER NO. W911SR20C0049		
CODE TROO		) AE	10B. DATED ( 03-Aug-2020	SEE ITEM	13)
CODE 7TKQ9	FACILITY COD	E			
The above numbered solicitation is amended as set forth			is extended.	is not exten	nded.
Offer must acknowledge receipt of this amendment prior  (a) By completing Items 8 and 15, and returning or (c) By separate letter or telegramwhich includes a ref RECEIVED AT THE PLACE DESIGNATED FOR TH REJECTION OF YOUR OFFER. If by virtue of this am provided each telegramor letter makes reference to the s	copies of the amendmen erence to the solicitation a E RECEIPT OF OFFERS I endment you desire to char	t; (b) By acknowledging receipt of this amendment and amendment numbers. FAILURE OF YOUR AC PRIOR TO THE HOUR AND DATE SPECIFIED Mange an offer already submitted, such change may be	on each copy of the off KNOWLEDGMENT MAY RESULT IN made by telegramor let	то ве	
12. ACCOUNTING AND APPROPRIATION DA	TA (If required)				
See Schedule	A A DDI TEC ONI N.T	O MODIFICATIONS OF CONTRACTOR	DDEDG		
IT MODI	13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS.  IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.				
A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.					
B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).					
X C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: Bilateral AW FAR 52.212-4(c)					
D. OTHER (Specify type of modification and authority)					
E. IMPORTANT: Contractor is not,	x is required to sign	n this document and return 1 c	opies to the issuing	g office.	
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)  Modification Control Number: (a) (6)  The purpose of this modification is:  SEE BLOCK 14 CONTINUATION PAGE   Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.  15A. NAME AND TITLE OF SIGNER (Type or print)  16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)					
		(b) (d) TEL:			
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNEI		EMAIL: (6) (6) CA		C. DATE SIGNED
(Signature of person authorized to sign)		(Signature of Contracting Office	er)	2	9-Jan-2021

## The following items are applicable to this modification:



- g. Update the Delivery Schedule for all affected CLINs due to the above noted CLIN changes and additions.
- h. CONSIDERATION: Due to the change from (b) (4) AND the price increase for each unit, the Government is accepting consideration from (b) (4) if the form of (b) (4) confirming they will accept a future modification to extend the air freight requirements through the end of the contract period of performance on a T&M basis (with no additional profit to (b) (4) which the Government plans to incorporate on an upcoming modification. (b) (4) confirmed that this was acceptable as consideration on a teleconference with the Government on 22 January, 2021.

All other terms and conditions remain the same.

# SECTION SF 1449 - CONTINUATION SHEET

# SOLICITATION/CONTRACT FORM

(b) (4)	he total cost of this contract was increased by (b) (4) from	(b) (4) to
SUPPLIES C	R SERVICES AND PRICES	
Replaced wit	CLIN description has changed from (b) (4)	to (b) (4) and
(b) (4)		
To: This CLIN for Government CLIN 6.	is REMOVED and replaced with o deobligate the funds from this CLIN and allow the funds with additional funding	
	pricing detail quantity has decreased by (b) (4) from (b) (4) total cost of this line item has decreased by (b) (4) from (b) (4)	
	pricing detail quantity has decreased by (b) (4) from (b) (4) total cost of this line item has decreased by (b) (4) from (b) (4)	
	pricing detail quantity has decreased by (b) (4) from (b) (4) total cost of this line item has decreased by (b) (4) from (b) (4)	
CLIN 0	06 is added as follows:	

W911SR20C0049 P00004 Page 4 of 10

ITEM NO SUPPLIES/SERVICES QUANTITY **UNIT UNIT PRICE AMOUNT** 0006 Each (b) (4) (b) (4) Safety Needle/Syringe (b) (4) FFP (b) (4) Safety Needle/Syringe (b) (4) FOB: **(b) (4)** MFR PART NR: (b) (4) Safety Needle/Syringe (b) (4) VENDOR PART NR: (b) (4) Safety Needle/Syringe (b) (4) PURCHASE REQUEST NUMBER: 0011601368 PSC CD: 6515 **NET AMT** (b) (4) ACRN AB CIN: GFEBS001160136800001 CLIN 0007 is added as follows: ITEM NO SUPPLIES/SERVICES **QUANTITY** UNIT **UNIT PRICE AMOUNT** 0007 Each (b) (4) (b) (4) (b) (4) (b) (4) Safety Needle/Syringe (b) (4) **FFP** (b) (4) Safety Needle/Syringe (b) (4) FOB: (b) (4) MFR PART NR: (b) (4) Safety Needle/Syringe (b) (4) VENDOR PART NR: (b) (4) Safety Needle/Syringe(b) (4) PURCHASE REQUEST NUMBER: 0011601368 PSC CD: 6515 **NET AMT** (b) (4) ACRN AB

CLIN 0008 is added as follows:

CIN: GFEBS001160136800002

ITEM NO SUPPLIES/SERVICES UNIT **UNIT PRICE OUANTITY AMOUNT** 0008 Each (b) (4) Safety Needle/Syringe(b) (4) (b) (4) Safety Needle/Syringe (b) (4) FOB: (b) (4) MFR PART NR: (b) (4) Safety Needle/Syringe (b) (4) VENDOR PART NR: (b) (4) Safety Needle/Syringe (b) (4) PURCHASE REQUEST NUMBER: 0011601368 PSC CD: 6515 **NET AMT** ACRN AB CIN: GFEBS001160136800003 ACCOUNTING AND APPROPRIATION Summary for the Payment Office As a result of this modification, the total funded amount for this document was increased by (6) (4) to (b) (4) from (b) (4) CLIN 0001: AA: 0212020202120400000664643255 S.0074658.5.2 6100.9000021001 A5XAH (CIN GFEBS001152047400001) was decreased by (b) (4) from (b) (4) CLIN 0002: AA: 0212020202120400000664643255 S.0074658.5.2 6100.9000021001 A5XAH (CIN GFEBS001152047400002) was decreased by (b) (4) from (b) (4) CLIN 0003: AA: 0212020202120400000664643255 S.0074658.5.2 6100.9000021001 A5XAH (CIN GFEBS001152047400003) was decreased by (b) (4) from (b) (4) CLIN 0006: Funding on CLIN 0006 is initiated as follows: ACRN: AB CIN: GFEBS001160136800001 Acctng Data: 0212021202220400000665654255 S.0074658.5.2.1 6100.9000021001 Increase: (b) (4)

Total: (b) (4)

Cost Code: A5XAH

CLIN 0007:

Funding on CLIN 0007 is initiated as follows:

ACRN: AB

CIN: GFEBS001160136800002

Acctng Data: 0212021202220400000665654255 S.0074658.5.2.1 6100.9000021001

Increase: (b) (4)

Total: (b) (4)

Cost Code: A5XAH

CLIN 0008:

Funding on CLIN 0008 is initiated as follows:

ACRN: AB

CIN: GFEBS001160136800003

Acctng Data: 0212021202220400000665654255 S.0074658.5.2.1 6100.9000021001

Increase: (b) (4)

Total: (b) (4)

Cost Code: A5XAH

### DELIVERIES AND PERFORMANCE

The following Delivery Schedule for CLIN 0001 has been deleted:

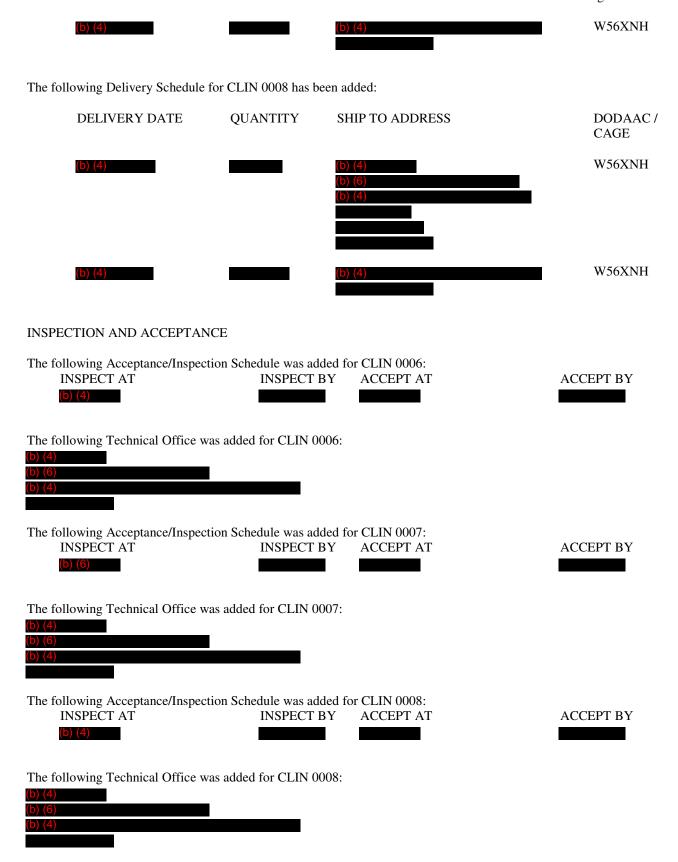


The following Delivery Schedule Item has been deleted from CLIN 0002:

The fol	The following Delivery Schedule Item has been deleted from CLIN 0002:					
	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE		
	(b) (4)		(b) (4) (b) (6) (b) (4)	W56XNH		
The fol	lowing Delivery Schedule ite	em for CLIN 0002 h	nas been changed from:			
	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE		
	(b) (4)		(b) (4) (b) (6) (b) (4)	W56XNH		
To:						
	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE		
	(b) (4)		(b) (4) (b) (6) (b) (4)	W56XNH		
The fol	lowing Delivery Schedule It	em has been deleted	1 from CLIN 0003:			
	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE		
	(b) (4)		(b) (4) (b) (6) (b) (6)	W56XNH		

The following Delivery Schedule item for CLIN 0003 has been changed from:

	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
	(b) (4)		(b) (4) (b) (6) (b) (4)	W56XNH
To:				
	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
	(b) (4)		(b) (4) (b) (6) (b) (4)	W56XNH
The foll	lowing Delivery Schedule fo	r CLIN 0006 has be	en added:	
	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
	(b) (4)		(b) (4) (b) (4) (b) (4)	W56XNH
	(b) (4)		(b) (4)	W56XNH
The foll	lowing Delivery Schedule fo	r CLIN 0007 has be	en added:	
	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
	(b) (4)		(b) (4) (b) (6) (b) (4)	W56XNH



(End of Summary of Changes)

AMENDMENT OF COLLOTATION MODIFICATION OF CONTRACT				1 CONTRACT ID CODE		PAGE OF PAGES
AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT			J		1 22	
2 AMENDMENT/MODIFICATION NO	3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO			5 PROJECT	NO (Ifapplicable)
P00005	24-Feb-2021	SEE SCHEDULE				
6 ISSUED BY CODE	W911SR	7 ADMINISTERED BY (Ifother than item 6)		COI	)E	
USA CONTRACT NG CMD-APG W911SR EDGEWOOD CONTRACTING DMSION 8456 BRIGADE STREET BLDG E4215 ABERDEEN PROVING GROUND MD 21010-5401		See Item 6				
8. NAME AND ADDRESS OF CONTRACTOR HTL-STREFA, NC.	(No., Street, County,	State and Zip Code)	9.	A. AMENDMI	ENT OF SO	LICITATION NO.
(b) (6)		•	91	B. DATED (SI	EE ITEM 11	)
			X 10A MOD OF CONTRACT/ORDER NO. W911SR20C0049			
CODE 7TKQ9	FACILITY COI	DE.	10B. DATED (SEE ITEM 13) X 03-Aug-2020			
		PPLIES TO AMENDMENTS OF SOLIC	CITAT	TIONS		
The above numbered solicitation is amended as set fo	th in Item 14 The hour and	date specified for receipt of Offer	is	extended,	is not exter	ıded
Offer must acknowledge receipt of this amendment properties of the properties of the same of the properties of the properties of the provided each telegram of the provided each telegram or letter makes reference to the	copies of the amendment reference to the solicitation HE RECEIPT OF OFFERS amendment you desire to cha	nt; (b) By acknowledging receipt of this amendmen and amendment numbers FAILURE OF YOUR A PRIOR TO THE HOUR AND DATE SPECIFIED ange an offer already submitted, such change may b	nt on ea ACKNO MAY oe made	ach copy of the off OWLEDGMENT' RESULTIN by telegramor let	го ве	
12. ACCOUNTING AND APPROPRIATION I	OATA (If required)					
See Schedule	EN ARRIVES ON THE	TO MODULICATIONS OF COMED ACTO	VODD	TD4		
13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACT S'ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.						
A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.						
B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).						
X C. THIS SUPPLEMENT AL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: Bilateral IAW FAR 52.212-4(c)						
D. OTHER (Specify type of modification and authority)						
E. IMPORTANT: Contractor is not, is required to sign this document and return copies to the issuing office.						
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)  Modification Control Number: (b) (6)  The purpose of this modification is:  1) Extend the air freight end date on T&M CLIN 0005 FROM (b) (4)  2) Increase the Not to Exceed (NTE) amount on T&M CLIN 0005 FROM (b) (4)  3) Add funding to T&M CLIN 0005 (via SubCLIN 000501) in the amount of (b) (4)  4) Update the air freight end date in the Statement of Work and FAR Clause 52.212-4 Alt I per the above changes to the Air Freight CLIN.  All other terms and conditions remain the same.  Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect  15A. NAME AND TITLE OF SIGNER (Type or print)  16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)						
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNE	(1 ) (0)		EMAL: (b) (6)	160	C. DATE SIGNED
	-	BY (b) (b)	e .		2	4-Feb-2021
(Signature of person authorized to sign)	1	(Signature of Contracting Off	ncer)		- 1	

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

### SUMMARY OF CHANGES

SECTION SF 1449 - CONTINUATION SHEET

SOLICITATION/CONTRACT FORM

The total cost of this contract was increased by (b) (4)

SUPPLIES OR SERVICES AND PRICES

CLIN 0005

The CLIN extended description has changed from:

This Time and Materials (T&M) CLIN is for the delta costs incurred between the already included Sea Freight (built into the FFP CLINS) and the additional estimated costs for Air Freight on all shipments by (b) (4). The total invoiced amount on this CLIN cannot exceed the total Funding. The Contractor shall contact the Contracting Officer prior to incurring expense against this T&M CLIN if that expense will exceed the Contractor's proposed delta between sea freight and air freight. NOTE: Total invoiced amount against this CLIN cannot exceed the total funded amount/total line item cost.

To:

This Time and Materials (T&M) CLIN is for the delta costs incurred between the already included Sea Freight (built into the FFP CLINS) and the additional estimated costs for Air Freight on all shipments by (b) (4) (this date was extended on Mod P00005 from the previous air freight requirement that ended (b) (4)). The total invoiced amount on this CLIN cannot exceed the total Funding. The Contractor shall contact the Contracting Officer prior to incurring expense against this T&M CLIN if that expense will exceed the Contractor's proposed delta between sea freight and air freight. NOTE: Total invoiced amount against this CLIN cannot exceed the total funded amount/total line item cost.

The estimated/max cost has increased by (b) (4)

The total cost of this line item has increased by (b) (4)

SUBCLIN 000501 is added as follows:

ITEM NO 000501 SUPPLIES/SERVICES

QUANTITY

UNIT

UNIT PRICE

AMOUNT (b) (4)

Additional funding for T&M CLIN 0005

COST

The purpose of this funding-only subCLIN is to add additional funding to CLIN 0005 (T&M CLIN for Air Freight) in the amount of (b) (4) to support the extension of the air freight end date from (b) (4) or modification P00005.

PURCHASE REQUEST NUMBER: 0011612752

ESTIMATED COST

(b) (4)

ACRN AC

CIN: GFEBS001161275200001

#### ACCOUNTING AND APPROPRIATION

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was increased by (b) (4)

SUBCLIN 000501:

Funding on SUBCLIN 000501 is initiated as follows:

ACRN: AC

CIN: GFEBS001161275200001

Acctng Data: 021202020212040000066464322N S.0074658.5.2 6100.9000021001

Increase: (b) (4)

Total: (b) (4)

Cost Code: A5XAH

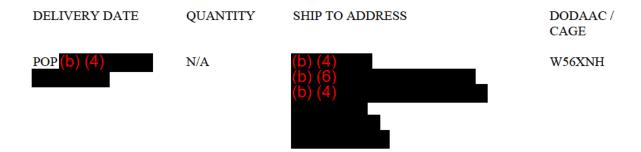
### DELIVERIES AND PERFORMANCE

The following Delivery Schedule item for CLIN 0005 has been changed from:

DELIVERY DATE
QUANTITY
SHIP TO ADDRESS
DODAAC / CAGE

POP (b) (4)
N/A
(b) (4)
(b) (6)
(b) (4)

To:



### INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for SUBCLIN 000501:

The following have been modified:

STATEMENT OF WORK

This section has been modified. Changes are shown below in red font text.

# STATEMENT OF WORK PROCUREMENT OF SAFETY NEEDLES AND SYRINGES FOR COVID-19

**1.0** <u>SCOPE</u>: The Contractor, as an independent Contractor and not as an agent of the Government, shall furnish the necessary resources as specified in this Statement of Work (SOW), to manufacture and/or supply Safety Needles and Syringes.

## 2.0 BACKGROUND:

On Friday, March 13, 2020, the President declared a national emergency concerning the novel coronavirus disease (COVID-19) under section 501(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5207 (the "Stafford Act).

The mission of the Division of Strategic National Stockpile (DSNS), of the United States (U.S.) Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR), is to ensure the availability and rapid deployment of life-saving pharmaceuticals, antidotes, other medical supplies, and equipment necessary to counter the effects of nerve agents, biological pathogens, and chemical agents. When state, local, tribal, and territorial public health and medical systems request federal assistance to support their response efforts, DSNS ensures the right medicines and supplies get to those who need them most during an emergency. When the vaccine becomes available the Government will have an immediate need to begin vaccinating the entire U.S. population. To administer the vaccine the Government will require needles and syringes to be available.

There is an insufficient domestic supply of safety needles and syringes to meet the projected needs to vaccinate the nation's entire population against COVID-19. Should vaccine programs be accelerated, demand could outpace available devices to administer a vaccine.

**3.0 OBJECTIVE**: The HHS currently has contracts in place with three (3) major manufacturers to provide needles and syringes supplies to support the initial preparedness needs at the onset of a pandemic outbreak. The objective of this acquisition is to supplement the current supply and establish contracts with additional manufacturers and suppliers to provide a quantity of up to 500 million safety needles and syringes supplies.

### 4.0 **REQUIREMENTS**:

## 4.1. **General:**

- 4.1.1. The Contractor shall "host" a *Kick-Off Meeting* within one (1) calendar day after contract award via <u>teleconference</u>. The Contractor shall provide *Meeting Minutes* containing a detailed overview of the meeting discussions in accordance with (IAW) Contract Data Requirements List (CDRL) A001.
- 4.1.1.1. The Contractor shall provide a *Certificate of Analysis* with each shipment per the DD Form 1423, Contract Data Requirements List (CDRL) A002, confirming the supplies described below meet the Performance Specifications in paragraph 4.2 below.
- 4.1.2. The Contractor shall provide copies of 510(k) Approval Letters for ALL supplies (dispensing syringes or needles) to demonstrate compliance with Section 510(k) of the Food, Drug and Cosmetic Act as part of their proposal. The Contractor shall provide, if necessary, 510(k) Approval Letters Updates if any information from the initial 510(k) Approval Letters is changed/needs to be updated.
- 4.1.2.1.1. The Contractor shall ensure all supplies have a "*Shelf-Life*" with expiration dates of no less than five (5) years from the date of sterilization, <u>and</u> must have at least four (4) years of remaining expiry from the time of shipment.
- 4.1.2.1.2. The Contractor shall only use *Current Good Manufacturing Practice (cGMP)* processes to manufacture the needles and syringes.
- 4.1.2.1.3. **Period of Performance/Delivery Dates.** See the "Delivery Schedule" section of this Contract and "Attachment 2-Shipping Information" for all delivery requirements and shipping locations.

## 4.2. Technical Requirements:

4.2.1.The Contractor shall provide sterile needle (with Luer hub connection) and syringe (with Luer lock connection) units approved by the Food and Drug Administration (FDA) <u>and</u> comply with Occupational Safety and Health Administration (OSHA) Needlestick Safety and Prevention

Act requirements as a "safety-engineered product." Safety-engineered supplies include needles preventing sharp injuries by either; being completely enclosed after use by an attached shield, or be fully retracted within the syringe. The Contractor may provide individual syringes and individual needles as long as there is a one-to-one (1:1) ratio. In order to meet the specified quantities upon contract award and comply with the specifications in this SOW, the following may be provided: (1) individually wrapped sterile syringes with individually wrapped sterile needles in a one-to-one (1:1) ratio, (2) sterile needle/syringe combination unit, or (3) a mixture of sterile combination units and individually wrapped sterile syringes with equal number of individually wrapped sterile needles.

4.2.2. The Contractor shall only provide acceptable product sizes as described below:

### Individual Syringe:

<b>Syringe</b>
1mL
3mL

### Individual Needle:

<u>Needle</u> <u>Gauge</u>	<u>Needle</u> <u>Length</u>
23G	1"
23G	1.5"
25G	1"

### **Combination Unit:**

Syringe	<u>Needle</u> Gauge	<u>Needle</u> Length
1mL	23G	1"
1mL	23G	1.5"
1mL	25G	1"
3mL	23G	1"
3mL	23G	1.5"
3mL	25G	1"

- 4.2.3. **Dispensing Syringe:** *Description*: A dispensing syringe allows for the controlled and precise flow of liquid. The dispensing syringe is used to inject medications or other liquids into body tissues. Manual syringes consist of a barrel, stopper, and plunger.
- 4.2.3.1. The Contractor shall ensure dispensing syringes comply with Title 21 Code of Federal Regulations (CFR) 880.5860 and follow International Standards Organization (ISO) 7886-1:2017 and the following material specifications:
- 4.2.3.1.1. A device intended for medical purposes that consists of a calibrated hollow

barrel and a movable plunger. At one end of the barrel there is a male connector (nozzle) for fitting the female connector (hub) of a hypodermic single lumen needle;

- 4.2.3.1.2. Heavy duty barrel The barrel has a scale showing the capacity of the syringe.
- 4.2.3.1.3. Stopper The stopper maintains the fluid in the barrel between the syringe nozzle and the plunger;
- 4.2.3.1.4. Plunger The plunger is used to aspirate and inject fluids into and out of the syringe;
- 4.2.3.1.5. Disposable;
- 4.2.3.1.6. <u>Luer lock</u> to accept luer hub applicator (e.g. needle);
- 4.2.3.1.7. Sizes as specified in Section 4.2.2 above; and
- 4.2.3.1.8. Sterile individually wrapped packaging.
- 4.2.4. **Hypodermic Needle:** *Description*: A Hypodermic needle is a slender, hollow instrument for introducing material into the body parenterally.
- 4.2.4.1. The Contractor shall ensure hypodermic needles comply with 21 CFR 880.5570, OSHA Needlestick Safety and Prevention Act, and follow International Standards Organization (ISO) 7864, and the following specifications:
- 4.2.4.1.1. Disposable;
- 4.2.4.1.2. Luer hub to attach to luer lock syringe;
- 4.2.4.1.3. See Tables in Sections 4.2.2 above for acceptable needle length and gauges;
- 4.2.4.1.4. Sterile individually wrapped packaging; and
- 4.2.4.1.5. Safety-engineered.
- 4.3. **Delivery Location and Shipping Requirements:** See Attachment 2-"Shipping Information" for all delivery locations and shipping requirements.
- 4.3.1. The Contractor shall provide *Packing Slips* with <u>all shipments</u> per CDRL A003. The Packing Slips shall include the following: (1) Contract number, (2) Item description, (3) Part number, (4) Lot numbers; and (5) Quantities. The Packing Slips shall include <u>BOTH</u>: (1) a *Packing Slip Paper Copy* with the shipment; and (2) a *Packing Slip Paper Emailed Copy* to the Designated Government Representative.
- 4.3.2. No Partial Case or Packages quantities will be accepted unless approved by the Contracting Officer prior to shipping.
- 4.3.3. The Contractor shall **NOT** Mixed Lot #'s per Case or per Packages. The Contractor shall only provide full <u>case</u> quantities <u>only</u>, *unless* approved by the Designated Government Representative in advance via email.
- 4.3.4. The Contractor shall ensure all pallets have the identical TyHi stack pattern, except for the final pallet; which would be a partial pallet or individual boxes.
- 4.3.5. All supplies shall be delivered on a standard 48" by 40" pallet, not to exceed 60" in height, stretch wrapped, clear-wrapped is preferred, and secured to the pallet for safe transport.

- 4.3.6. The Contractor shall contact the Designated Government Representative to schedule delivery appointments. The Government will provide the Designated Government Representative(s)' information at the Kick-Off Meeting.
- 4.3.7. Contractor shall contact the Designated Government Representative to schedule delivery appointments.
- 4.3.8. The Contractor shall ship ALL deliverables via AIR FREIGHT from (b) (4) (extension of the previous Air Freight requirement that ended (b) ). The Contractor shall charge the Delta in costs between Air Freight costs and Sea Freight costs already built into this contract. The Contractor shall NOT submit any costs (e.g. labor, overhead, profit) other than "other direct costs" per FAR Clause 52.214-4 Alternative one (1) as those cost are already included in the contract. The Contractor shall only be reimbursed for actual REASONABLE costs and shall provide documented proof (e.g. receipts and paid invoices). The Government's pallet dimension limitations (stated in Section 4.3.5) is how the pallets will be delivered, it does NOT restrict pallet heights or other packing dimensions of HOW the items are to be shipped (either by air or sea). The Contractor shall follow commercial best practices and to maximize/optimize Air Cargo Load, palletization or re-palletization (if needed), and drayage. The Government reserves the right to stop this Air Freight requirement prior to via email notification from the Contracting Officer due to urgency, followed by a bi-lateral modification. The Government also reserves the right to provide transportation (e.g. planes) or other logistical services (e.g. palletization) and will notify the Contractor via an email from the Contracting Officer.
- 4.3.9. Based on mutual agreement at the Post-Award Meeting for delivery schedules, the Contractor shall provide an *Initial Updated Syringe-Needle Delivery Schedule*. The template for the Initial Updated Syringe-Needle Delivery Schedule will be provided by the COR. The Initial Updated Delivery Schedule shall be provided to the COR within three (3) business days after the "Sea to Air Freight Modification." Thereafter, the Contractor shall, at a minimum, provide *Weekly Delivery Schedule Updates* to the COR by Tuesday, 1400 Eastern Time.

# 5.0 Operation Warp Speed (OWS) Contract Language:

### 5.1. Disclosure of Information:

5.1.1. Performance under this contract may require the Contractor to access non-public data and information proprietary to a Government agency, another Government Contractor or of such nature that its dissemination or use other than as specified in the work statement would be adverse to the interests of the Government or others. Neither the Contractor, nor Contractor personnel, shall divulge nor release data nor information developed or obtained under performance of this contract, except authorized by Government personnel or upon written approval of the CO in accordance with OWS or other Government policies and/or guidance. The Contractor shall not use, disclose, or reproduce proprietary data that bears a restrictive legend, other than as specified in this contract, or any information at all regarding this agency.

- 5.1.2. The Contractor shall comply with all Government requirements for protection of non-public information. Unauthorized disclosure of nonpublic information is prohibited by the Government's rules. Unauthorized disclosure may result in termination of the contract, replacement of a Contractor employee, or other appropriate redress. Neither the Contractor nor the Contractor's employees shall disclose or cause to be disseminated, any information concerning the operations of the activity, which could result in, or increase the likelihood of, the possibility of a breach of the activity's security or interrupt the continuity of its operations.
- 5.1.3. No information related to data obtained under this contract shall be released or publicized without the prior written consent of the COR, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity' for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions.

## 5.2. **Publications and Publicity**:

- 5.2.1. The contractor shall not release any reports, manuscripts, press releases, or abstracts about the work being performed under this contract without written notice in advance to the Government:
  - (a) Unless otherwise specified in this contract, the contractor may publish the results of its work under this contract. The contractor shall promptly send a copy of each submission to the COR for security review prior to submission. The contractor shall also inform the COR when the abstract article or other publication is published, and furnish a copy of it as finally published;
  - (b) Unless authorized in writing by the CO, the contractor shall not display Government logos including Operating Division or Staff Division logos on any publications;
  - (c) The contractor shall not reference the products(s) or services(s) awarded under this contract in commercial advertising, as defined in FAR 31.205-1, in any manner which states or implies Government approval or endorsement of the product(s) or service(s) provided;
  - (d) The contractor shall include this clause, including this section (d) in all subcontracts where the subcontractor may propose publishing the results of its work under the subcontract. The contractor shall acknowledge the support of the Government whenever publicizing the work under this contract in any media by including an acknowledgement substantially as follows: "This project has been funded in whole or in part by the U.S. Government under Contract No. XXXX. The US Government is authorized to reproduce and distribute reprints for Governmental purposes notwithstanding any copyright notation thereon."

### 5.3. Confidentiality of Information:

5.3.1. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an

institution or organization.

- 5.3.2. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.
- 5.3.3. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.
- 5.3.4. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor shall obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.
- 5.3.5. Contracting Officer Determinations will reflect the result of internal coordination with appropriate program and legal officials.
- 5.3.6. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.
- 5.3.7. All above requirements MUST be passed to all Sub-contractors.

## 5.4. Organizational Conflicts of Interest:

- 5.4.1. Performance under this contract may create an actual or potential organizational conflict of interest such as are contemplated by FAR Part 9.505-General Rules. The Contractor shall not engage in any other contractual or other activities which could create an organizational conflict of interest (OCI). This provision shall apply to the prime Contractor and all sub-Contractors. This provision shall have effect throughout the period of performance of this contract, any extensions thereto by change order or supplemental agreement, and for two (2) years thereafter. The Government may pursue such remedies as may be permitted by law or this contract, upon determination that an OCI has occurred.
- 5.4.2. The work performed under this contract may create a significant potential for certain conflicts of interest, as set forth in FAR Parts 9.505-1, 9.505-2, 9.505-3, and 9.505-4. It is the intention of the parties hereto to prevent both the potential for bias in connection with the Contractor's performance of this contract, as well as the creation of any unfair competitive advantage as a result of knowledge gained through access to any non-public data or third party

proprietary information.

- 5.4.3. The Contractor shall notify the Contracting Officer immediately whenever it becomes aware that such access or participation may result in any actual or potential OCI. Furthermore, the Contractor shall promptly submit a plan to the Contracting Officer to either avoid or mitigate any such OCI. The Contracting Officer will have sole discretion in accepting the Contractor's mitigation plan. In the event the Contracting Officer unilaterally determines that any such OCI cannot be satisfactorily avoided or mitigated, other remedies may be taken to prohibit the Contractor from participating in contract requirements related to OCI.
- 5.4.4. Whenever performance of this contract provides access to another Contractor's proprietary information, the Contractor shall enter into a written agreement with the other entities involved, as appropriate, in order to protect such proprietary information from unauthorized use or disclosure for as long as it remains proprietary; and refrain from using such proprietary information other than as agreed to, for example to provide assistance during technical evaluation of other Contractors' offers or products under this contract. An executed copy of all proprietary information agreements by individual personnel or on a corporate basis shall be furnished to the CO within fifteen (15) calendar days of execution.

### Additional Reporting Requirements.

# **AIR SHIPMENTS:**

Within 4 hours of departure (from the airport of origin), contractor is required to provide the following information for every air shipment provided under this contract:

Carrier Name:

Aircraft Tail Number:

Aircraft Manufacture/Model (i.e. Boeing 747):

Port of Departure:

Time/Date of Departure (US Eastern Standard Time - EST):

Port of Arrival (final destination):

Schedule time/date of Arrival at Final Destination (US Eastern Standard Time - EST):

Detailed descriptions and quantities/count by individual item shall be included for each air shipment.

Actual Time/date of Arrival at final port:

If aircraft is diverted and/or anticipated to arrive at final destination more than 4 hours after scheduled arrival time/date, contractor shall provide written notification and include the new estimated arrival time/date.

<u>WAREHOUSED ITEMS</u> - Contract Items stored/staged at interim locations prior to air shipment at contractor warehouses and/or warehouses utilized by contractor subcontractors and/or transportation agents. The contractor is required to provide a daily report not later than 1700 US Eastern Standard Time (EST) including the following information:

Location of Warehouse(s):

Complete physical address of warehouse(s):

Warehouse POC:

Warehouse POC telephone number and email address:

For each warehouse location, detailed descriptions and quantities/count by individual item warehoused and ready for shipment.

# **ADDITIONAL NOTES:**

- 1. Concurrently, all information required under this contract modification shall be provided by email to the following individuals:
- a) ACC-APG Email Address Email Address TBD via email from Contracting Officer after execution of modification.
- b) ACC HQs POC, (b) (6)

This clause has been updated. Changes are shown below in red font text.

52.212-4 Contract terms and conditions -- commercial items (oct 2018) alternate i (Jan 2017)

When a time-and-materials or labor-hour contract is contemplated, substitute the following paragraphs (a), (e), (i), (l), and (m) for those in the basic clause.

- (a) Inspection/Acceptance.
- (1) The Government has the right to inspect and test all materials furnished and services performed under this contract, to the extent practicable at all places and times, including the period of performance, and in any event before acceptance. The Government may also inspect the plant or plants of the Contractor or any subcontractor engaged in contract performance. The Government will perform inspections and tests in a manner that will not unduly delay the work.

- (2) If the Government performs inspection or tests on the premises of the Contractor or a subcontractor, the Contractor shall furnish and shall require subcontractors to furnish all reasonable facilities and assistance for the safe and convenient performance of these duties.
- (3) Unless otherwise specified in the contract, the Government will accept or reject services and materials at the place of delivery as promptly as practicable after delivery, and they will be presumed accepted 60 days after the date of delivery, unless accepted earlier.
- (4) At any time during contract performance, but not later than 6 months (or such other time as may be specified in the contract) after acceptance of the services or materials last delivered under this contract, the Government may require the Contractor to replace or correct services or materials that at time of delivery failed to meet contract requirements. Except as otherwise specified in paragraph (a)(6) of this clause, the cost of replacement or correction shall be determined under paragraph (i) of this clause, but the "hourly rate" for labor hours incurred in the replacement or correction shall be reduced to exclude that portion of the rate attributable to profit. Unless otherwise specified below, the portion of the "hourly rate" attributable to profit shall be 10 percent. The Contractor shall not tender for acceptance materials and services required to be replaced or corrected without disclosing the former requirement for replacement or correction, and, when required, shall disclose the corrective action taken. 0% (Insert portion of labor rate attributable to profit.)
- (5) If the Contractor fails to proceed with reasonable promptness to perform required replacement or correction, and if the replacement or correction can be performed within the ceiling price (or the ceiling price as increased by the Government), the Government may—
- (A) By contract or otherwise, perform the replacement or correction, charge to the Contractor any increased cost, or deduct such increased cost from any amounts paid or due under this contract; or
- (B) Terminate this contract for cause.
- (ii) Failure to agree to the amount of increased cost to be charged to the Contractor shall be a dispute under the Disputes clause of the contract.
- (6) Notwithstanding paragraphs (a)(4) and (5) above, the Government may at any time require the Contractor to remedy by correction or replacement, without cost to the Government, any failure by the Contractor to comply with the requirements of this contract, if the failure is due to—
- (i) Fraud, lack of good faith, or willful misconduct on the part of the Contractor's managerial personnel; or
- (ii) The conduct of one or more of the Contractor's employees selected or retained by the Contractor after any of the Contractor's managerial personnel has reasonable grounds to believe that the employee is habitually careless or unqualified.
- (7) This clause applies in the same manner and to the same extent to corrected or replacement materials or services as to materials and services originally delivered under this contract.
- (8) The Contractor has no obligation or liability under this contract to correct or replace materials and services that at time of delivery do not meet contract requirements, except as provided in this clause or as may be otherwise specified in the contract.
- (9) Unless otherwise specified in the contract, the Contractor's obligation to correct or replace Government-furnished property shall be governed by the clause pertaining to Government property.
- (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, as amended (41 U.S.C. 601-613). 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.
- (1) The clause at FAR 52.202-1, Definitions, is incorporated herein by reference. As used in this clause—
- (i) Direct materials means those materials that enter directly into the end product, or that are used or consumed directly in connection with the furnishing of the end product or service.
- (ii) Hourly rate means the rate(s) prescribed in the contract for payment for labor that meets the labor category qualifications of a labor category specified in the contract that are—
- (A) Performed by the contractor;
- (B) Performed by the subcontractors; or
- (C) Transferred between divisions, subsidiaries, or affiliates of the contractor under a common control.
- (iii) Materials means—
- (A) Direct materials, including supplies transferred between divisions, subsidiaries, or affiliates of the contractor under a common control;
- (B) Subcontracts for supplies and incidental services for which there is not a labor category specified in the contract;
- (C) Other direct costs (e.g., incidental services for which there is not a labor category specified in the contract, travel, computer usage charges, etc.);
- (D) The following subcontracts for services which are specifically excluded from the hourly rate: **Not Applicable** (Insert any subcontracts for services to be excluded from the hourly rates prescribed in the schedule); and
- (E) Indirect costs specifically provided for in this clause.
- (iv) Subcontract means any contract, as defined in FAR Subpart 2.1, entered into with a subcontractor to furnish supplies or services for performance of the prime contract or a subcontract including transfers between divisions, subsidiaries, or affiliates of a contractor or subcontractor. It includes, but is not limited to, purchase orders, and changes and modifications to purchase orders.
- (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, 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) Payments.
- (1) Work performed. The Government will pay the Contractor as follows upon the submission of commercial invoices approved by the Contracting Officer:
- (i) Hourly rate.
- (A) The amounts shall be computed by multiplying the appropriate hourly rates prescribed in the contract by the number of direct labor hours performed. Fractional parts of an hour shall be payable on a prorated basis.

- (B) The rates shall be paid for all labor performed on the contract that meets the labor qualifications specified in the contract. Labor hours incurred to perform tasks for which labor qualifications were specified in the contract will not be paid to the extent the work is performed by individuals that do not meet the qualifications specified in the contract, unless specifically authorized by the Contracting Officer.
- (C) Invoices may be submitted once each month (or at more frequent intervals, if approved by the Contracting Officer) to the Contracting Officer or the authorized representative.
- (D) When requested by the Contracting Officer or the authorized representative, the Contractor shall substantiate invoices (including any subcontractor hours reimbursed at the hourly rate in the schedule) by evidence of actual payment, individual daily job timecards, records that verify the employees meet the qualifications for the labor categories specified in the contract, or other substantiation specified in the contract.
- (E) Unless the Schedule prescribes otherwise, the hourly rates in the Schedule shall not be varied by virtue of the Contractor having performed work on an overtime basis.
- (1) If no overtime rates are provided in the Schedule and the Contracting Officer approves overtime work in advance, overtime rates shall be negotiated.
- (2) Failure to agree upon these overtime rates shall be treated as a dispute under the Disputes clause of this contract.
- (3) If the Schedule provides rates for overtime, the premium portion of those rates will be reimbursable only to the extent the overtime is approved by the Contracting Officer.
- (ii) Materials.
- (A) If the Contractor furnishes materials that meet the definition of a commercial item at 2.101, the price to be paid for such materials shall not exceed the Contractor's established catalog or market price, adjusted to reflect the--
- (1) Quantities being acquired; and
- (2) Any modifications necessary because of contract requirements.
- (B) Except as provided for in paragraph (i)(1)(ii)(A) and (D)(2) of this clause, the Government will reimburse the Contractor the actual cost of materials (less any rebates, refunds, or discounts received by the contractor that are identifiable to the contract) provided the Contractor—
- (1) Has made payments for materials in accordance with the terms and conditions of the agreement or invoice; or
- (2) Makes these payments within 30 days of the submission of the Contractor's payment request to the Government and such payment is in accordance with the terms and conditions of the agreement or invoice.
- (C) To the extent able, the Contractor shall—
- (I) Obtain materials at the most advantageous prices available with due regard to securing prompt delivery of satisfactory materials; and
- (2) Give credit to the Government for cash and trade discounts, rebates, scrap, commissions, and other amounts that are identifiable to the contract.
- (D) Other Costs. Unless listed below, other direct and indirect costs will not be reimbursed.
- (1) Other Direct Costs. The Government will reimburse the Contractor on the basis of actual cost for the following, provided such costs comply with the requirements in paragraph (i)(1)(ii)(B) of this clause: **Any Delta in cost**

between the already included Sea Freight and Air Freight for shipments prior to (1) (4). (Insert each element of other direct costs (e.g., travel, computer usage charges, etc. Insert "None" if no reimbursement for other direct costs will be provided. If this is an indefinite delivery contract, the Contracting Officer may insert "Each order must list separately the elements of other direct charge(s) for that order or, if no reimbursement for other direct costs will be provided, insert 'None'.)

- (2) Indirect Costs (Material Handling, Subcontract Administration, etc.. The Government will reimburse the Contractor for indirect costs on a pro-rata basis over the period of contract performance at the following fixed price: §0 (Insert a fixed amount for the indirect costs and payment schedule. Insert "\$0" if no fixed price reimbursement for indirect costs will be provided. (If this is an indefinite delivery contract, the Contracting Officer may insert "Each order must list separately the fixed amount for the indirect costs and payment schedule or, if no reimbursement for indirect costs, insert 'None').
- (2) Total cost. It is estimated that the total cost to the Government for the performance of this contract shall not exceed the ceiling price set forth in the Schedule and the Contractor agrees to use its best efforts to perform the work specified in the Schedule and all obligations under this contract within such ceiling price. If at any time the Contractor has reason to believe that the hourly rate payments and material costs that will accrue in performing this contract in the next succeeding 30 days, if added to all other payments and costs previously accrued, will exceed 85 percent of the ceiling price in the Schedule, the Contractor shall notify the Contracting Officer giving a revised estimate of the total price to the Government for performing this contract with supporting reasons and documentation. If at any time during the performance of this contract, the Contractor has reason to believe that the total price to the Government for performing this contract will be substantially greater or less than the then stated ceiling price, the Contractor shall so notify the Contracting Officer, giving a revised estimate of the total price for performing this contract, with supporting reasons and documentation. If at any time during performance of this contract, the Government has reason to believe that the work to be required in performing this contract will be substantially greater or less than the stated ceiling price, the Contracting Officer will so advise the Contractor, giving the then revised estimate of the total amount of effort to be required under the contract.
- (3) Ceiling price. The Government will not be obligated to pay the Contractor any amount in excess of the ceiling price in the Schedule, and the Contractor shall not be obligated to continue performance if to do so would exceed the ceiling price set forth in the Schedule, unless and until the Contracting Officer notifies the Contractor in writing that the ceiling price has been increased and specifies in the notice a revised ceiling that shall constitute the ceiling price for performance under this contract. When and to the extent that the ceiling price set forth in the Schedule has been increased, any hours expended and material costs incurred by the Contractor in excess of the ceiling price before the increase shall be allowable to the same extent as if the hours expended and material costs had been incurred after the increase in the ceiling price.
- (4) Access to records. At any time before final payment under this contract, the Contracting Officer (or authorized representative) will have access to the following (access shall be limited to the listing below unless otherwise agreed to by the Contractor and the Contracting Officer):
- (i) Records that verify that the employees whose time has been included in any invoice meet the qualifications for the labor categories specified in the contract;
- (ii) For labor hours (including any subcontractor hours reimbursed at the hourly rate in the schedule), when timecards are required as substantiation for payment—
- (A) The original timecards (paper-based or electronic);
- (B) The Contractor's timekeeping procedures;
- (C) Contractor records that show the distribution of labor between jobs or contracts; and
- (D) Employees whose time has been included in any invoice for the purpose of verifying that these employees have worked the hours shown on the invoices.

- (iii) For material and subcontract costs that are reimbursed on the basis of actual cost—
- (A) Any invoices or subcontract agreements substantiating material costs; and
- (B) Any documents supporting payment of those invoices.
- (5) Overpayments/Underpayments. Each payment previously made shall be subject to reduction to the extent of amounts, on preceding invoices, that are found by the Contracting Officer not to have been properly payable and shall also be subject to reduction for overpayments or to increase for underpayments. The Contractor shall promptly pay any such reduction within 30 days unless the parties agree otherwise. The Government within 30 days will pay any such increases, unless the parties agree otherwise. The Contractor's payment will be made by check. If the Contractor becomes aware of a duplicate invoice payment or that the Government has otherwise overpaid on an 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 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)(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, and then at the rate applicable for each six month period as established 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 in a timely manner;
- (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 FAR 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.
- (viii) Upon receipt and approval of the invoice designated by the Contractor as the ``completion invoice" and supporting documentation, and upon compliance by the Contractor with all terms of this contract, any outstanding balances will be paid within 30 days unless the parties agree otherwise. The completion invoice, and supporting documentation, shall be submitted by the Contractor as promptly as practicable following completion of the work under this contract, but in no event later than 1 year (or such longer period as the Contracting Officer may approve in writing) from the date of completion.
- (7) Release of claims. The Contractor, and each assignee under an assignment entered into under this contract and in effect at the time of final payment under this contract, shall execute and deliver, at the time of and as a condition precedent to final payment under this contract, a release discharging the Government, its officers, agents, and employees of and from all liabilities, obligations, and claims arising out of or under this contract, subject only to the following exceptions.
- (i) Specified claims in stated amounts, or in estimated amounts if the amounts are not susceptible to exact statement by the Contractor.
- (ii) Claims, together with reasonable incidental expenses, based upon the liabilities of the Contractor to third parties arising out of performing this contract, that are not known to the Contractor on the date of the execution of the release, and of which the Contractor gives notice in writing to the Contracting Officer not more than 6 years after the date of the release or the date of any notice to the Contractor that the Government is prepared to make final payment, whichever is earlier.
- (iii) Claims for reimbursement of costs (other than expenses of the Contractor by reason of its indemnification of the Government against patent liability), including reasonable incidental expenses, incurred by the Contractor under the terms of this contract relating to patents.
- (8) 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.
- (9) Electronic Funds Transfer (EFT). If the Government makes payment by EFT, see 52.212-5(b) for the appropriate EFT clause.
- (10) 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 that appears on the payment check or the specified payment date if an electronic funds transfer payment is made.

- (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 an amount for direct labor hours (as defined in the Schedule of the contract) determined by multiplying the number of direct labor hours expended before the effective date of termination by the hourly rate(s) in the contract, less any hourly rate payments already made to the Contractor plus reasonable charges the Contractor can demonstrate to the satisfaction of the Government using its standard record keeping system that 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 that 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 written request, with adequate assurances of future performance. Subject to the terms of this contract, the Contractor shall be paid an amount computed under paragraph (i) Payments of this clause, but the ``hourly rate" for labor hours expended in

furnishing work not delivered to or accepted by the Government shall be reduced to exclude that portion of the rate attributable to profit. Unless otherwise specified in paragraph (a)(4) of this clause, the portion of the ``hourly rate" attributable to profit shall be 10 percent. In the event of termination for cause, 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.

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 <u>52.212-5</u>.
- (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) Reserved.
- (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)

(End of Summary of Changes)

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