SOLICITATION/CO	NTRACT/ORDER F				1. REQUISI 0011520476		BER			PAGE 1	OF 30
2 CONTRACT NO. W911SR20C0048		ECTIVE DATE	4. ORDER N				SR20R	NUMBER 0003		SOLICITAT	TION ISSUE DATE 020
7. FOR SOLICITATION INFORMATION CALL:	a. NAME (b) (6)							UMBER (No Co			JE DATE/LOCAL TIME 29 May 2020
9. ISSUED BY		W911SR	10.	THIS ACQU	JISITION IS	XU	-,	RICTED OR	SET ASIDE		% FOR:
USA CONTRACTING CME EDGEWOOD CONTRACT 8456 BRIGADE STREET BLDG E4215 ABERDEEN PROVING GR	)-APG W911SR ING DIVISION	Morror		SMALL BUS HUBZONE BUSINESS	SMALL	WON BLIG SMA	IEN-OWN	ED SMALL BUSIN ER THE WOMEN ESS PROGRAM	IESS (WOSB) I-OWNED		
TEL: FAX:				SERVICE-I VETERAN- SMALL BU	-OWNED	8(A)			SIZE 1,00	E STANDA	ARD:
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15. DELIVER TO	CODE V	/56XNH	16.	ADMINISTE	RED BY				COD		***
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25. ACCOUNTING AND A	PPROPRIATION DATA	y 0 T						26. TOTAL A	WARD AMOU	JNT (For C	Sovt. Use Only)
See Schedule										\$6,2	60,000.00
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COPIES TO ISSUING DELIVER ALL ITEMS	REQUIRED TO SIGN TH OFFICE. CONTRACTOR. SET FORTH OR OTHERW SUBJECT TO THE TERM	AGREES TO FU	D ABOVE AN	D ND ON ANY		OFFER (BLOCK	DATED 5), INC	CONTRACT: F LUDING ANY REIN, IS ACC	. YOUR OF	OR CHAN	SOLICITATION GES WHICH ARE
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30b. NAME AND TITLE C	OF SIGNER	30c. DATE 08-03-2		31b. NAME TEL:		CTING OF	FICER	(TYPE O	R PRINT)	3	lc. DATE SIGNED

SOLICITA	ITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS (CONTINUED)				MS				PAG	GE 2 OF 30
19. ПЕМ NO.	20. SCHEDULE OF SUPPLIES/ SERVICES				21. QUANTITY	22. UNIT	23. UNIT PR	ICE	24. AMOUNT	
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32b. SIGNATURE ( REPRESENT		RIZED GOVERNMENT	32c. DATE	JON INAC	32d. PRINT	ED NAME AND TIT	LE OF AUTHOR	RIZED GOVER	RNMENT	
32e. MAILING ADD	ADDRESS OF AUTHORIZED GOVERNMENT REPRESENTATIVE			Ē.	32f. TELEPHONE NUMBER OF AUTHORIZED GOVERNMEN 32g. E-MAIL OF AUTHORIZED GOVERNMENT REPRESENT				ESENTATIVE	
33. SHIP NUMBER	34.	VOUCHER NUMBER	35. AMOUNT VE CORRECT		36. 1	PAYMENT  COMPLETE	PARTIAL	_	7. CHECH	NUMBER
38. S/R ACCOUNT		39. S/R VOUCHER NUMBER	40. PAID BY							=
		NT IS CORRECT AND PROPER OF CERTIFYING OFFICER	FOR PAYMENT 41c. DATE	42a. REC	CEIVED BY	(Print)				
			42b. REC	CEIVED AT (	Location)					
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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** <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) 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
lmL
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"
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.

## **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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ITEM NO 0001	SUPPLIES/SERVICES	QUANTITY (b) (4)	UNIT Each	UNIT PRICE (b) (4)	AMOUNT (b) (4)
	Safety Needle/Syring	ge (b) (4)			
	FOB: Destination MFR PART NR: (b) (4)				
	VENDOR PART NR: (b) PURCHASE REQUEST N	(4) NUMBER: 001152	0476-0001		
	PSC CD: 6515				
				NET AMT	(b) (4)
	ACRN AA CIN: GFEBS00115204760	00001			(b) (4)
ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0002	(b) (4) Safety Needle/Syring	(b) (4)	Each	(b) (4)	(b) (4)
	FFP (b) (4)				
	FOB: Destination MFR PART NR: (b) (4)	(4)			
	VENDOR PART NR: 6 PURCHASE REQUEST N PSC CD: 6515	NUMBER: 001152	0476-0001		
	100 027 0010				
				NET AMT	(b) (4)
	ACRN AA CIN: GFEBS00115204760	00002			(D) (4)

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0003		Each	(b) (4)	(b) (4)
	(b) (4) FOB: Destination MFR PART NR: (b) (4) VENDOR PART NR: (b) (4) PURCHASE REQUEST NUMBER: 0011520476 PSC CD: 6515	5-0001		
	ACRN AA CIN: GFEBS001152047600003		NET AMT	(b) (4) (b) (4)
ITEM NO 0004	(b) (4) FFP (b) (4) FOB: Destination MFR PART NR: (b) (4) VENDOR PART NR: (b) (4)	JNIT Each	UNIT PRICE	AMOUNT (b) (4)
	PURCHASE REQUEST NUMBER: 0011520476 PSC CD: 6515  ACRN AA CIN: GFFBS001152047600004	5-0001	NET AMT	(b) (4) (b) (4)

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AMOUNT ITEM NO SUPPLIES/SERVICES QUANTITY UNIT UNIT PRICE 0005 Each Safety Needle/Syringe Combo FOB: Destination MFR PART NR: (b) (4)
VENDOR PART NR: (b) (4)
PURCHASE REQUEST NUMBER: 0011520476-0001 PSC CD: 6515 **NET AMT** ACRN AA CIN: GFEBS001152047600005 ITEM NO SUPPLIES/SERVICES UNIT UNIT PRICE AMOUNT QUANTITY 0006 Each Safety Needle/Syringe Combo FOB: Destination MFR PART NR: (b) (4)
VENDOR PART NR: (b) (4)
PURCHASE REQUEST NUMBER: 0011520476-0001 PSC CD: 6515 **NET AMT** ACRN AA

CIN: GFEBS001152047600006

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ITEM NO SUPPLIES/SERVICES QUANTITY UNIT UNIT PRICE AMOUNT 0007 1 Each NSP CDRLS FFP Contract Data Requirements List (CDRL). FOB: Destination MFR PART NR: CDLRS PSC CD: 6515

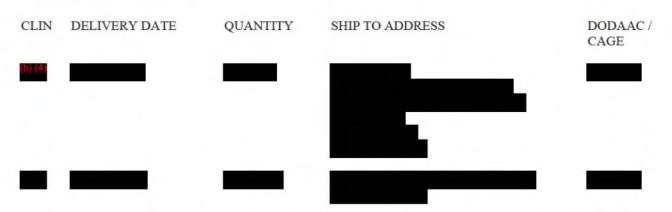
**NET AMT** 

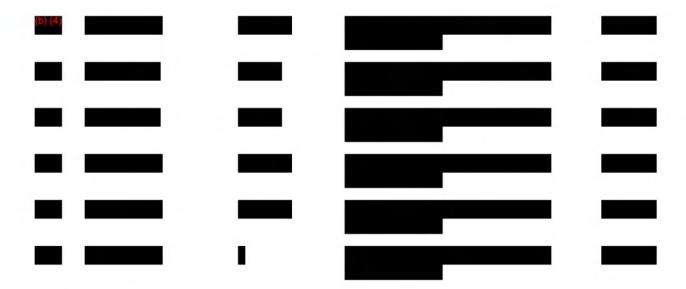
## INSPECTION AND ACCEPTANCE TERMS

## Supplies/services will be inspected/accepted at:

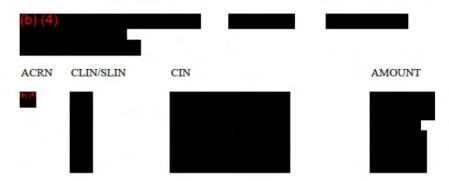
CLIN	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
0001	Destination	Government	Destination	Government
0002	Destination	Government	Destination	Government
0003	Destination	Government	Destination	Government
0004	Destination	Government	Destination	Government
0005	Destination	Government	Destination	Government
0006	Destination	Government	Destination	Government
0007	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
52.212-4	Systems Contract Terms and ConditionsCommercial Items	OCT 2018
52.232-40	Providing Accelerated Payments to Small Business Subcontractors	DEC 2013
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

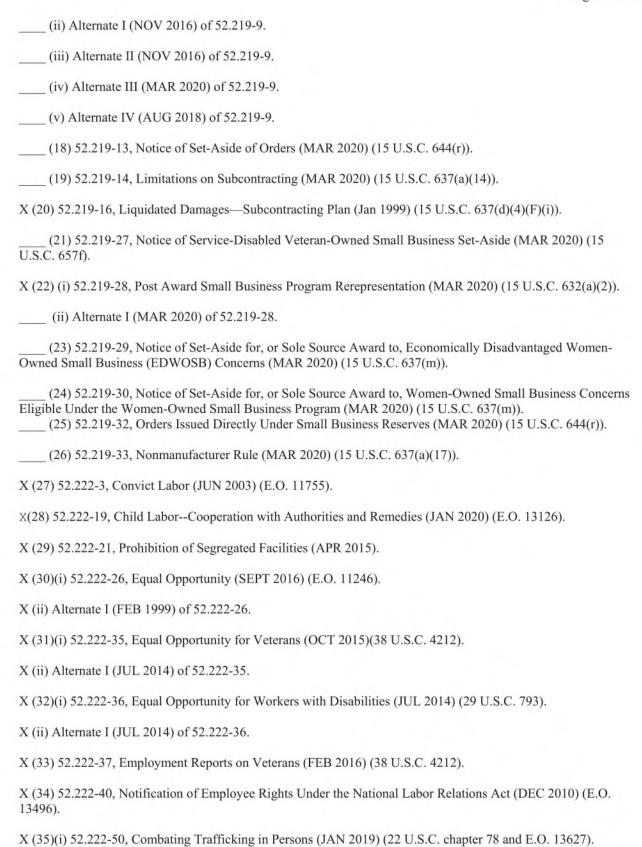
252.204-7012	Safeguarding Covered Defense Information and Cyber Incident Reporting	DEC 2019
252.204-7015	Notice of Authorized Disclosure of Information for Litigation Support	MAY 2016
252.204-7018	Prohibition on the Acquisition of Covered Defense Telecommunications Equipment or Services	DEC 2019
252.205-7000	Provision Of Information To Cooperative Agreement Holders	DEC 1991
252.219-7003	Small Business Subcontracting Plan (DOD Contracts)	DEC 2019
252.223-7008	Prohibition of Hexavalent Chromium	JUN 2013
252.225-7001	Buy American And Balance Of Payments Program Basic	DEC 2017
252.225-7012	Preference For Certain Domestic Commodities	DEC 2017
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	DEC 2006
252.232-7017	Accelerating Payments to Small Business Subcontractors- Prohibition on Fees and Consideration	APR 2020
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

#### 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 (MAR 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).
X (36) 52.222-54, Employment Eligibility Verification (OCT 2015). (E. O. 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial items as prescribed in 22.1803.)
(37)(i) 52.223-9, Estimate of Percentage of Recovered Material Content for EPA–Designated Items (MAY 2008) (42 U.S.C. 6962(c)(3)(A)(ii)). (Not applicable to the acquisition of commercially available off-the-shelf items.)
(ii) Alternate I (MAY 2008) of 52.223-9 (42 U.S.C. 6962(i)(2)(C)). (Not applicable to the acquisition of commercially available off-the-shelf items.)
(38) 52.223-11, Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (JUN 2016) (E.O. 13693).
(39) 52.223-12, Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (JUN 2016) (E.O. 13693).
(40) (i) 52.223-13, Acquisition of EPEAT® Registered Imaging Equipment (JUN 2014) (E.O.s 13423 and 13514).
(ii) Alternate I (OCT 2015) of 52.223-13.
(41)(i) 52.223-14, Acquisition of EPEAT® Registered Televisions (JUN 2014) (E.O.s 13423 and 13514).
(ii) Alternate I (JUN 2014) of 52.223-14.
(42) 52.223-15, Energy Efficiency in Energy-Consuming Products (DEC 2007) (42 U.S.C. 8259b).
(43)(i) 52.223-16, Acquisition of EPEAT®-Registered Personal Computer Products (OCT 2015) (E.O.s 13423 and 13514).
(ii) Alternate I (JUN 2014) of 52.223-16.
X (44) 52.223-18, Encouraging Contractor Policies to Ban Text Messaging While Driving (AUG 2011) (E.O. 13513).
(45) 52.223-20, Aerosols (JUN 2016) (E.O. 13693).
(46) 52.223-21, Foams (JUN 2016) (E.O. 13693).
(47)(i) 52.224-3, Privacy Training (JAN 2017) (5 U.S.C. 552a).
(ii) Alternate I (JAN 2017) of 52.224-3.
(48) 52.225-1, Buy 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. chapter 83, 19 U.S.C. 3301 note, 19 U.S.C. 2112 note, 19 U.S.C. 3805 note, 19 U.S.C. 4001 note, Pub. L. 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43.
(ii) Alternate I (MAY 2014) of 52.225-3.
(iii) Alternate II (MAY 2014) of 52.225-3.

(iv) Alternate III (MAY 2014) of 52.225-3.
(50) 52.225-5, Trade Agreements (OCT 2019) 19 U.S.C. 2501, et seq., 19 U.S.C. 3301 note).
X (51) 52.225-13, Restrictions on Certain Foreign Purchases (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.C 3332).
(58) 52.232-34, Payment by Electronic Funds Transfer—Other than System for Award Management (JUL 2013) (31 U.S.C. 3332).
(59) 52.232-36, Payment by Third Party (MAY 2014) (31 U.S.C. 3332).
(60) 52.239-1, Privacy or Security Safeguards (AUG 1996) (5 U.S.C. 552a).
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.
(c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items: (Contracting Officer check as appropriate.)
(1) 52.222-17, Nondisplacement of Qualified Workers (MAY 2014) (E.O. 13495).
(2) 52.222-41, Service Contract Labor Standards (AUG 2018) (41 U.S.C. chapter 67).
(3) 52.222-42, Statement of Equivalent Rates for Federal Hires (MAY 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).
(4) 52.222-43, Fair Labor Standards Act and Service Contract Labor StandardsPrice Adjustment (Multiple Year and Option Contracts) (AUG 2018) (29 U.S.C. 206 and 41 U.S.C. chapter 67).

- \_\_\_\_\_(5) 52.222-44, Fair Labor Standards Act and Service Contract Labor Standards--Price Adjustment (MAY 2014) (29 U.S.C 206 and 41 U.S.C. chapter 67).

  \_\_\_\_\_(6) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment--Requirements (MAY 2014) (41 U.S.C. chapter 67).

  \_\_\_\_\_(7) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services--Requirements (MAY 2014) (41 U.S.C. chapter 67).

  \_\_\_\_\_\_(8) 52.222-55, Minimum Wages Under Executive Order 13658 (DEC 2015) (E.O. 13658).

  \_\_\_\_\_\_(9) 52.222-62, Paid Sick Leave Under Executive Order 13706 (JAN 2017) (E.O. 13706).

  \_\_\_\_\_\_(10) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (MAY 2014) (42 U.S.C. 1792).
- (d) Comptroller General Examination of Record. The Contractor shall comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, and does not contain the clause at 52.215-2, Audit and Records--Negotiation.
- (1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor's directly pertinent records involving transactions related to this contract.
- (2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR Subpart 4.7, Contractor Records Retention, of the other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.
- (3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.
- (e) (1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c), and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in this paragraph (e)(1)in a subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause—
- (i) 52.203-13, Contractor Code of Business Ethics and Conduct (Oct 2015) (41 U.S.C. 3509).
- (ii) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (JAN 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).
- (iii) 52.204-23, 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) 52.224-3, Privacy Training (Jan 2017) (5 U.S.C. 552a).
- (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:

(i) Delivered items for which items:	the Government's unit acquisit	ion cost is \$5,000 or more, except for the following line
Contract line, subline, or exh	nibit	
line item No.	Item description	
(ii) Items for which the Gove the following table:	rnment's unit acquisition cost i	s less than \$5,000 that are identified in the Schedule or
Contract line, subline, or exh	nibit Item description	
(b) (4)		

- (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 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 <a href="http://dodprocurementtoolbox.com/site/uidregistry/">http://dodprocurementtoolbox.com/site/uidregistry/</a>; 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	0PMN3
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).)

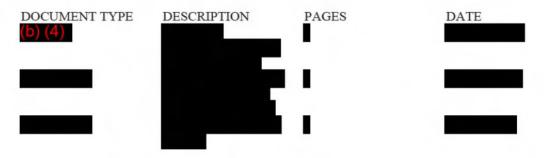
- (4) Payment request. The Contractor shall ensure a payment request includes documentation appropriate to the type of payment request in accordance with the payment clause, contract financing clause, or Federal Acquisition Regulation 52.216-7, Allowable Cost and Payment, as applicable.
- (5) Receiving 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.



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

(End of clause)

## Exhibit/Attachment Table of Contents



AMENDMENT OF SOLICI	TATION/MODII	FICATION OF CONTRACT	1 CONTRACT ID C	CODE PAGE OF PAGES  1 2
2 AMENDMENT/MODIFICATION NO P00001	3 EFFECTIVE DATE 18-Sep-2020	4 REQUISITION/PURCHASE REQ NO 0011520476-0001	5	PROJECT NO (Ifapplicable)
6 ISSUED BY CODE	W911SR	7 ADMINISTERED BY (Ifother than item 6)	CODE	
USA CONTRACTING CMD-APG W911SR EDGEWOOD CONTRACT NG DIVISION 8456 BRIGADE STREET BLDG E4215 ABERDEEN PROVING GROUND MD 21010-5401		See Item 6		
8. NAME AND ADDRESS OF CONTRACT OF MEDLINE INDUSTRIES, NC. MEDLINE  (b) (6) 31AKES DR NORTHFIELD L60093-2753	R (No., Street, County,	State and Zip Code)	9B. DATED (SEE	ONTRACT/ORDER NO.
CODE 0PMN3	FACILITY CO	DE.	X 03-Aug-2020	
		APPLIES TO AMENDMENTS OF SOLICI		
(a) By completing Items 8 and 15, and returning or (c) By separate letter or telegramwhich includes RECEIVED AT THE PLACE DESIGNATED FOR REJECTION OF YOUR OFFER Ifby virtue of this	copies of the amendment of the solicitation of the RECEIPT OF OFFERS amendment you desire to chies solicitation and this amendment.	cified in the solicitation or as amended by one of the ent; (b) By acknowledging receipt of this amendment and amendment numbers FAILURE OF YOUR AC PRIOR TO THE HOUR AND DATE SPECIFIED! ange an offer already submitted, such change may be doment, and is received prior to the opening hour and	t on each copy of the offer st CKNOWLEDGMENT TO I MAY RESULT IN made by telegram or letter,	
IT MO	DIFIES THE CONTRA	TO MODIFICATIONS OF CONTRACT S/CT/ORDER NO. AS DESCRIBED IN ITE	M 14.	
A. THIS CHANGE ORDER IS ISSUED PUR CONTRACT ORDER NO. IN ITEM 104	L.			
B. THE ABOVE NUMBERED CONTRACT office, appropriation date, etc.) SET FO. C. THIS SUPPLEMENT AL AGREEMENT	RTH IN ITEM 14, PUR	RSUANT TO THE AUTHORITY OF FAR		hanges in paying
X D. OTHER (Specify type of modification at Bilateral Changes pursuant to FAR 52.212				
E. IMPORTANT: Contractor is not,	X is required to si	gn this document and return 1	copies to the issuing of	ffice.
14. DESCRIPTION OF AMENDMENT/MODE where feasible.) Modification Control Number:  (b) (6) The purpose of this modification is to:  1) Add CDRL (6) (2) (Weekly Delivery Sched following the start of work meeting, this CD	ule Updates) as (b) (2	Per agreement betw een the Contrac		
All other terms and conditions remain the sa				
Except as provided herein, all terms and conditions of the				
15A. NAME AND TITLE OF SIGNER (Type  (b) (6)	or print)	16A. NAME AND TITLE OF CON (b) (6) TEL:	EMAL aaron.d.Ski	
(b) (6) CT OR/OFFEROR (b) (6) (6) (6) (6)	15C. DATE SIGNE	ED 16B. UNITED STATES OF AMERI (0) (6) BY	CA	16C. DATE SIGNED
(Signature of person authorized to sign)	09/17/2020	(Signature of Contracting Office	cer)	



#### SECTION SF 30 BLOCK 14 CONTINUATION PAGE

#### SUMMARY OF CHANGES

#### SECTION SF 1449 - CONTINUATION SHEET

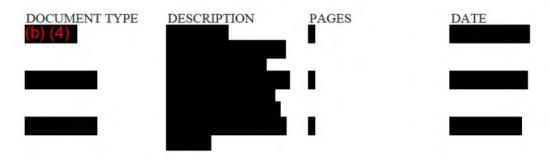
#### SOLICITATION/CONTRACT FORM

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

#### TABLE OF CONTENTS

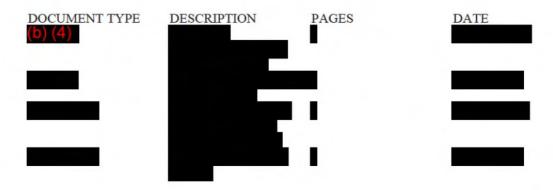
The Table of Contents has changed from:

## Exhibit/Attachment Table of Contents



to:

## Exhibit/Attachment Table of Contents



(End of Summary of Changes)

## **CONTRACT DATA REQUIREMENTS LIST**

(2 Data Items)

Form Approved OMB No. 0704-0188

Reset

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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

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17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

### CONTRACT DATA REQUIREMENTS LIST

(2 Data Items)

Form Approved OMB No. 0704-0188

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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.
- $\mbox{\it ltem 8.}$  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.
- $\mbox{\sc tem}$  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 for the

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#### INSTRUCTIONS FOR COMPLETING DD FORM 1423

(See DoD 5010.12-M for detailed instructions.)

#### FOR GOVERNMENT PERSONNEL

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- 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.

# 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 DODAAC: STORAGE RIC: OWNER RIC:

Ship to:

## 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 **packaged together** 

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 by December	Total (b) (4) after December	
Γ	Medline	(b) (4)	(b) (4)	No case configuration data

	1	Syringe Distro				-
	Point of Contact to Schedule Delivery Date/Time	Locations	Total in Cases	Total in Each (00 EA/CS)	Total in Pallets	
Medline <mark>(b) (4</mark>	(b) (6) (b) (6) (b) (6)	(b) (6) (b) (6) (b) (6)		(b) (4)	(5) (4)	
Medline (b) (4)	(b) (6) (b) (6) (b) (6)	(b) (6) (b) (6) (b) (6)		(b) (4)		
Medline (b) (4)	(b) (6) (b) (6)	(b) (6) (b) (6)		(b) (4)	1016	No product deliveries (b) (6)
Medline (0) (4)	(b) (6) (b) (6)	(b) (6) (b) (6) (b) (6)		(b) (4)	614	
Medline (b) (4)	(b) (6) (b) (6) (b) (6)	(b) (6) (b) (6) (b) (6)		(b) (4)	575	-
Medline (b) (4)	(b) (6) (b) (6) (b) (6)	(b) (6) (b) (6) (b) (6)		(b) (4)	[6] [4]	1
	(b) (6)	(b) (6) TOTAL		- (b) (4)	Total Control of the	-

Important Note: Please contact the point of contact for the respective location in order to schedule a delivery time and date before shipping any product.

Company	Total (b) (4) by December	Total (0) (4) a	fter December	
Medline	(b) (4)		(0)(	No case configuration data

		Syringe Distro				_
	Point of Contact to Schedule Delivery Date/Time	Locations	Total in Cases	Total in Each (00 EA/CS)	Total in Pallets (b) (4)	
Medline (b) (4)	(b) (6) (b) (6) (b) (6)	(b) (6) (b) (6) (b) (6)		(b) (4)		
/ledline <mark>(b) (4</mark> )	(b) (6) (b) (6) (b) (6)	(b) (6) (b) (6) (b) (6)		(b) (4)		
/ledline (b) (4)	(b) (6) (b) (6)	(b) (6) (b) (6)		(b) (4)		No product deliveries from (5) (6)
Medline (b) (4)	(b) (6) (b) (6) (b) (6)	(b) (6) (b) (6)		(b) (4)		
Medline (b) (4)	(b) (6) (b) (6)	(b) (6) (b) (6) (b) (6)		(b) (4)		1
/ledline (D) (4)	(b) (6) (b) (6)	(b) (6) (b) (6) (b) (6)		(b) (4)		
	E(b) (6)	(b) (6) TOTAL		- (b) (4)		

Important Note: Please contact the point of contact for the respective location in order to schedule a delivery time and date before shipping any product.