

ORDER FOR SUPPLIES OR SERVICES

1 CONTRACT/PURCH ORDER/ AGREEMENT NO W911SR21C0008	2 DELIVERY ORDER/ CALL NO	3 DATE OF ORDER/ CALL (YYYYMMDD) 2020 Nov 13	4 REQ / PURCH REQUEST NO 0011574631-0001	5 PRIORITY
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6. ISSUED BY USA CONTRACTING CMD-APG. - W911SR EDGEWOOD CONTRACTING DIVISION 8456 BRIGADE STREET BLDG E4215 ABERDEEN PROVNG GROUND MD 21010-5401	CODE W911SR	7. ADMINISTERED BY (if other than 6) SEE ITEM 6	CODE	8 DELIVERY FOB <input checked="" type="checkbox"/> DESTINATION <input type="checkbox"/> OTHER (See Schedule if other)
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9 CONTRACTOR WORLDS ENTERPRISES NC NAME [REDACTED] AND 5350 ALPHA RD ADDRESS DALLAS TX 75240-3428	CODE 8KUF6	FACILITY	10 DELIVER TO FOB POINT BY (Date) (YYYYMMDD) SEE SCHEDULE 12 DISCOUNT TERMS Net 14 Days	11 MARK IF BUSINESS IS <input type="checkbox"/> SMALL <input type="checkbox"/> SMALL DISADVANTAGED <input type="checkbox"/> WOMEN-OWNED
13. MAIL INVOICES TO THE ADDRESS IN BLOCK See Item 15				

14 SHIP TO [REDACTED]	CODE	15. PAYMENT WILL BE MADE BY D FAS-INDY VP GFEB5 8899 E 56TH STREET INDIANAPOLIS IN 46249-3800	CODE HQ0490	MARK ALL PACKAGES AND PAPERS WITH IDENTIFICATION NUMBERS IN BLOCKS 1 AND 2.
16 TYPE OF ORDER DELIVERY/ CALL PURCHASE <input checked="" type="checkbox"/>				

This delivery order/call is issued on another Government agency or in accordance with and subject to terms and conditions of above numbered contract

Reference your quote dated _____

Furnish the following on terms specified herein REF: _____

ACCEPTANCE. THE CONTRACTOR HEREBY ACCEPTS THE OFFER REPRESENTED BY THE NUMBERED PURCHASE ORDER AS IT MAY BE AMENDED OR IS NOW MODIFIED. SUBJECT TO ALL OF THE TERMS AND CONDITIONS SET FORTH IN THE ORDER AND ANY ADDENDUMS ATTACHED TO PERFORM THE SAME.

worlds Enterprises, Inc. **(b) (6)** **(b) (6)** 11/13/2020

NAME OF CONTRACTOR _____ TYPED NAME AND TITLE _____ DATE SIGNED (YYYYMMDD)

If this box is marked, supplier must sign Acceptance and return the following number of copies: 1

17 ACCOUNTING AND APPROPRIATION DATA/ LOCAL USE

See Schedule

18. ITEM NO.	19 SCHEDULE OF SUPPLIES/ SERVICES	20 QUANTITY ORDERED/ ACCEPTED*	21. UNIT	22. UNIT PRICE	23. AMOUNT
SEE SCHEDULE					

* If quantity accepted by the Government is same as quantity ordered, indicate by X. If different, enter actual quantity accepted below quantity ordered and encircle.	24. UNITED STATES OF AMERICA TEL: [REDACTED] BY: JENNIFER M. BUCHNESS	(b) (6)	25. TOTAL 26 DIFFERENCE \$	\$402,350.00
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27a. QUANTITY IN COLUMN 20 HAS BEEN

INSPECTED RECEIVED ACCEPTED. AND CONFORMS TO THE CONTRACT EXCEPT AS NOTED

b SIGNATURE OF AUTHORIZED GOVERNMENT REPRESENTATIVE	c DATE (YYYYMMDD)	d. PRINTED NAME AND TITLE OF AUTHORIZED GOVERNMENT REPRESENTATIVE
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e MAILING ADDRESS OF AUTHORIZED GOVERNMENT REPRESENTATIVE	28 SHIP NO	29 DO VOUCHER NO	30 INITIALS
f TELEPHONE NUMBER	g E-MAIL ADDRESS	<input type="checkbox"/> PARTIAL <input type="checkbox"/> FINAL	32. PAID BY
36. I certify this account is correct and proper for payment.			33. AMOUNT VERIFIED CORRECT FOR

a DATE (YYYYMMDD)	b SIGNATURE AND TITLE OF CERTIFYING OFFICER	31. PAYMENT <input type="checkbox"/> COMPLETE <input type="checkbox"/> PARTIAL <input type="checkbox"/> FINAL	34. CHECK NUMBER
37. RECEIVED AT		38. RECEIVED BY	39 DATE RECEIVED (YYYYMMDD)
40. TOTAL CONTRACTORS		41 S/R ACCOUNT NO	42 S/R VOUCHER NO

37. RECEIVED AT	38. RECEIVED BY	39 DATE RECEIVED (YYYYMMDD)	40. TOTAL CONTRACTORS	41 S/R ACCOUNT NO	42 S/R VOUCHER NO
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Section B - Supplies or Services and Prices

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001	<p>Prototype Screening Devices FFP The contractor shall provide (b) (4) prototype devices to detect for Volatile Organic Compounds (VOC) in a non-invasive manner as described in the attached Statement of Objectives (SOO). Unit price includes the cost to manufacture the devices, packaging and shipping, preparation and submission of Contract Data Requirements List (CDRL) A001 - A008, a Software license agreement for the duration of performance, troubleshooting, calibration, and repair of non-consumables, and all necessary consumables for the duration of performance.</p> <p>All devices shall be delivered to the initial location by 21 January 2021. FOB: Destination PURCHASE REQUEST NUMBER: 0011574631-0001 PSC CD: AN22</p>	■	Unit	(b) (4)	(b) (4)
				NET AMT	(b) (4)
ACRN AA					(b) (4)
CIN: GFEBS001157463100001					

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0002	Initial Screening Device Training FFP The contractor shall provide one-day, on-site, training on the prototype screening device implementation, equipment calibration, system startup and shutdown, system operation, testing procedures, data analysis, and system trouble shooting as described in the attached SOO. Training occurs at the designated location. Travel costs shall conform to FAR 31.205-46 and shall be in accordance with Federal Travel Regulations. FOB: Destination PURCHASE REQUEST NUMBER: 0011574631-0001 PSC CD: AN22	1	Days	(b) (4)	(b) (4)
				NET AMT	(b) (4)
ACRN AA CIN: GFEBS001157463100002					(b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0003	Travel COST Travel aside from the initial screening device training event, will be approved only in the event that remote assistance and troubleshooting is unsuccessful. Travel costs shall conform to FAR 31.205-46 and shall be in accordance with Federal Travel Regulations. No travel is authorized unless previously approved by the Government Program Manager, with a copy of the request furnished to the Contracting Officer. FOB: Destination PURCHASE REQUEST NUMBER: 0011574631-0001 PSC CD: AN22	4	Job		(b) (4)
				ESTIMATED COST	(b) (4)
ACRN AA CIN: GFEBS001157463100003					(b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0004	Data Requirements FFP The contractor shall complete data requirements as described in the attached SOO and Contract Data Requirements Lists (CDRLs) Exhibits (A001 - A008). This CLIN is Not Separately Priced (NSP) FOB: Destination PSC CD: AN22	1	Job		NSP

NET AMT

Section C - Descriptions and Specifications

STATEMENT OF OBJECTIVES

STATEMENT OF OBJECTIVES (SOO)
Non-Invasive Rapid Detection System (NIRDS) Phase 1
13 November 2020

1. BACKGROUND:

Technology to screen individuals for COVID-19 using Volatile Organic Compounds (VOC) in breath, within the order of magnitude of seconds, can be leveraged to combat the global COVID-19 pandemic and potential future bio-threats. VOCs are low molecular weight metabolic compounds present in human breath and may be indicative of infectious disease. COVID-19 critically impacts the DoDs' effectiveness and poses potential national security risks. Additionally, VOC-based diagnostics have great potential to be the next generation of screening tools for disease identification, infectious disease management, and natural/synthetic biological warfare early detection.

Current COVID-19 diagnostic procedures do not deliver rapid responses for effective infectious disease identification, management, and flexible mission planning due to result wait time in the order of magnitude of 1 day. Additionally, current diagnostic tools rely on end users or minimally trained personnel introducing significant human error margins that reduce field accuracy (b) (4). In order to maintain warfighter mission effectiveness, the DoD requires the cutting-edge capability to screen for COVID-19.

2. REQUIREMENT:

Rapidly deploy a non-invasive VOC analysis technology for infectious diseases such as COVID-19, in order to minimize Service member downtime, maximize mission effectiveness, and prevent the spread of COVID-19.

3. OBJECTIVE:

The Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) Non-Invasive Rapid Detection System (NIRDS) Program seeks to procure (b) (4) prototype screening devices and associated systems for Government optimization and verification testing in the intended use setting.

4. SCOPE:

- 4.1 Prototype devices and associated systems will be used in order for the Government to evaluate their potential to rapidly screen for COVID-19 in a non-invasive manner.
- 4.2 As the devices and associated systems procured under this award will not yet have obtained FDA authorization, they must be labeled, distributed and managed in accordance with applicable regulations (ie. 21 CFR 812 and 809).
- 4.3 These prototype devices will be used in research protocol in compliance with applicable laws, regulations, DoD policies and ethical standards regardless of their DoD-intramural/extramural nature or geographical location.
- 4.4 In part, the Government assessment of the systems will include correlation of the research data with de-identified validated clinical data. It will also include assessments of operational effectiveness and operational suitability. Operational effectiveness is a measure of the overall ability of a system to accomplish a mission when used by representative personnel in the environment planned or expected for operational employment of the system. Operational suitability is the degree to which a system can be placed and sustained satisfactorily in fielded use with consideration being given to

availability, compatibility, transportability, natural environment effect and impacts, documentation, and training requirements.

- 4.5 The Government must be informed of and given the option to receive any hardware and software modification and improvements proposed or made to the commercial system being developed during the period of performance. Modifications and improvements on the prototype screening device hardware may include, but are not limited to, investigation into hardware upgrades and changes, Government Furnished Equipment (GFE) reuse (if requested by the government) and any additional hardware capabilities to assist in the requirement. Modifications and improvements on the prototype screening device software may include, but are not limited to software upgrades to the machine learning algorithm or upgrades to any other applicable software, and any additional software capabilities to assist in the requirement. The Contractor shall provide a Software Design Description (SDD) for the software release at the point of delivering prototype systems to the Government. The document shall describe the NIRDS analyzer software by functional area IAW Contract Data Requirements List (CDRL) A004.
- 4.6 (b) (4) prototype screening devices will be retained by the contractor and considered Contractor Acquired Property (CAP). The CAP shall be used strictly for the purposes of this contract effort to collect additional data to mature the algorithm and obtain data for regulatory filing with the FDA. The contractor shall provide Scientific/Study Plans for all testing conducted using CAP, to the government for review and comment within ten business day of contract award, IAW CDRL A002. The contractor shall provide biweekly status updates to the government program manager on the production, delivery, implementation, repairs, and training status of the CAP prototype devices, IAW CDRL A001. Additionally, the contractor shall provide biweekly updates on the accuracy, sensitivity, and specificity values of the algorithm, as well as, time to result based on tests performed with CAP IAW CDRL A001. Upon completion of the period of performance, the contractor shall promptly ship all CAP back to the Government in good, working condition. Once delivered and accepted by the Government, the Government assumes title. All items meeting the IUID criteria of DFARS 211.274-2 shall be marked and reported in the IUID registry upon delivery IAW DFARS 252.211-7003.
- 4.7 (b) (4) prototype screening devices will be used in the government testing events at the locations in Table 1 below. The contractor shall review and if necessary, provide input to Government developed test plans and protocols. The contractor shall provide biweekly status updates to the government program manager on the production, delivery, implementation, repairs, and training status of the government testing prototype devices IAW CDRL A001. Additionally, the contractor shall provide biweekly updates on the accuracy, sensitivity, and specificity values of the algorithm, as well as, time to result, based on tests performed with government testing prototype devices IAW CDRL A001. The raw data collected by the prototypes on government installations shall be delivered to the government upon request IAW A002.
- 4.8 It is estimated that at least two testing events will occur during the contract period of performance. For proposal purposes, the contractor shall assume the following testing events listed below in Table 1. Actual events will be finalized with the contractor prior to commencement.

Table 1

Testing Event Location	Duration of Test Event
(b) (4)	

- 4.9 At the conclusion of the Period of Performance the contractor shall provide a Scientific/Technical Report in IAW CDRL A002.

4.10 Intellectual Property (IP)

Awardee represents that the intellectual property license(s) and other rights held by or granted to Awardee are sufficient to enable Awardee to perform its obligations under this award.

Background IP and Materials. The Awardee and the Government each retain any intellectual property (IP) rights to their own materials, technical data (as defined in DFARS 252.227-7013), technology, information, documents, or know-how—or potential rights, such as issued patents, patent applications, invention disclosures, copyrighted works, or other written documentation—that exist prior to execution of this award or are developed outside the scope of this award (“Background IP”).

Patent Indemnity. The Awardee 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 this award and Awardee’s actions under this award, provided the Awardee is reasonably notified of such claims and proceedings.

4.11 Data and Computer/Software Documentation Rights

Background Data. “Background Data” shall mean all technical data, as defined in DFARS 252.227-7013, that exists prior to execution of this award, or are developed outside the scope of this award. Awardee Background Data shall include any data associated with Awardee’s Background IP and Materials, that was not generated solely with Government funding. All Background Data shall be owned by the Awardee. The Government shall have the right, subject to applicable law and the terms of this award, to use, modify, reproduce, release, perform, display, or disclose Background Data only within the Government. The Government may, under a separate agreement or by bilateral modification to this award, negotiate rights to use or disclose the Awardee’s Background Data.

Technical Data. All data generated in connection with the performance of this award, or that arises out of the use of any materials or enabling technology provided or used by the Awardee in the performance of this award, other Awardee materials or Awardee confidential information, whether conducted by the Government or the Awardee (collectively, the "Technical Data"), shall be owned by the Awardee. The Government shall have the right, subject to applicable law and the terms of this award, to use, modify, reproduce, release, perform, display, or disclose data first produced in the performance of this award within the Government and otherwise for "Government Purpose Rights," as this term is defined in DFARS 252.227-7013(a)(13).

Background Computer Software and Computer Software Documentation. “Background Computer Software and Computer Software Documentation” shall mean all computer software and computer software documentation, as defined in DFARS 252.227-7014(a)(4) and (5), that exists prior to execution of this award, or are developed outside the scope of this award. Awardee Background Computer Software and Computer Software Documentation shall include any computer software or software documentation associated with Awardee’s Background Computer Software and Computer Software Documentation, that was not generated with Government funding. All Background Computer Software and Computer Software Documentation shall be owned by the Awardee. The Government shall have the right, subject to compliance with applicable law, the terms of this award and the terms of applicable contracts, to use, release, perform, display, or disclose Background Computer Software and Computer Software Documentation solely within the Government. The Government may, under a separate or by bilateral modification to this award, negotiate rights to use or disclose the Awardee’s Background Computer Software and Computer Software Documentation.

Noncommercial Computer Software and Noncommercial Computer Software Documentation. All noncommercial computer software and noncommercial computer software documentation data generated in connection with the performance of this award, or that arises out of the use of any materials or enabling technology provided or used by the Awardee in the performance of this award,

(collectively, the "Agreement Software and Software Documentation"), shall be owned by the Awardee. The Government shall have the right, subject to compliance with applicable law and the terms of this award, to use, release, perform, display, or disclose data first produced in the performance of this award within the Government and otherwise for "Government Purpose Rights," as this term is defined in DFARS 252.227-7014(a)(12).

The Awardee agrees to retain and maintain in good condition until seven (7) years after completion or termination of this award, all Technical Data and all Agreement Software and Software Documentation generated under this award. In the event of exercise of the Government's rights hereunder, the Awardee agrees to deliver at no additional cost to the Government, all data, in Awardee's possession and developed under this award, necessary to deliver the supplies within sixty (60) calendar days from the date of the written request.

Marking of Data. The Awardee will mark any data delivered under this award with the following legend: "Use, duplication, or disclosure is subject to the restrictions as stated in Award No. W911SR-21-C-0008 between the Government and the Awardee."

Any rights that the Awardee or the Government may have in data delivered under this award, whether arising under this award or otherwise, will not be affected by Awardee's failure to mark data pursuant to this Article.

All other Technical Data and Software developed under funding of this award shall be delivered with Government Purpose rights as provided for within this Article.

The U.S. Government may purchase, under a separate agreement, a license for greater use of Background IP and Materials, Background Data, Background Computer Software and Computer Software Documentation, Technical Data and Agreement Software and Software Documentation as necessary. Such agreement will be negotiated between the parties in good faith at customary industry rates and under commercially reasonable terms and conditions.

5. TECHNICAL REQUIREMENTS

5.1. Performance Parameters:

- 5.1.1. The delivery of the prototype devices shall be within 65 calendar days of contract award. All devices shall be delivered by Thursday, 21 January 2021. Four (4) additional days have been added to account for federal holidays (Thanksgiving, Christmas, New Year's, and Martin Luther King, Jr's Birthday). The testing period of performance is four (4) months.
- 5.1.2. The prototype screening devices shall provide rapid screening results.
- 5.1.3. The prototype screening devices shall provide non-invasive screening; using breath and not blood, saliva (excluding aerosolized breath particles), or any other bodily fluid.
- 5.1.4. The prototype screening devices shall be dual communication enabled through Wi-Fi and Global System for Mobile Communications (GSM). The contractor shall provide data rates for up to 75GB for U.S. coverage for the duration of the performance period.
- 5.1.5. The prototype screening devices shall include all hardware for a fully functioning prototype to include a (b) (4) and all disposable support equipment.

5.2. Regulatory and Quality Requirements:

- 5.2.1. Systems shall be labeled, distributed and managed in accordance with applicable laws and regulations (i.e. 21 CFR 812 and 809)

- 5.2.2. Receipt, management and use of de-identified comparator clinical data shall be in accordance with applicable regulations, policies, and standards for human subjects and data protections as well as device design control.
- 5.2.3. The contractor shall provide a manufacturing development plan IAW CDRL A007, and a quality assurance program plan IAW CDRL A003.
- 5.2.4. Proposed or planned hardware and software modification and improvements must be done in accordance with applicable regulations and standards for design control.
- 5.2.5. The contractor shall provide a Regulatory Strategy IAW CDRL A006 and documentation of FDA correspondence and engagements IAW CDRL A008.

5.3. Management Requirements:

The contractor shall provide biweekly status updates to the government program manager on the production, delivery, implementation, repairs, and training status of the prototype devices IAW CDRL A001.

- 5.3.1. The contractor shall maintain a qualified staff at all times. The Government restricts access or work hereunder to United States citizens only. All cybersecurity risk management related positions must have baseline certifications as designated in DoD Approved 8570 Baseline Certifications (DoD 8570.01M) prior to employment.
- 5.3.2. Travel costs shall conform to FAR 31.205- 46 and be in accordance with the Federal Travel Regulations. Travel can only be conducted upon prior approval by the government program manager with a copy of the request furnished to the Contracting Officer. If unexpected travel due to unplanned system outage is required, the contractor must show due diligence that costs were kept to a minimum. For proposal purposes, the contractor shall assume only the following; travel for two trainers to conduct a one day training event at the testing location listed in table 1.
- 5.3.3. If contractor personnel cannot physically travel due to COVID-19 travel restrictions, the following contingency plan will be implemented: (1) Remote connectivity to each unit will be performed via an internal built-in Ethernet router that offers both a physical port and WiFi access; (2) the contractor will leverage trained Government personnel on-site to provide video to provide visual support and assistance; (3) the contractor will leverage trained Government personnel on-site to provide hands-on support for parts replacement at the FRU (Field Replaceable Unit) level; and/or (4) should all travel options be prohibited, as a last resort, the unit could be repackaged and shipped to contractor for repair.
- 5.3.4. The contractor is required to hold a virtual kick off meeting within 10 calendar days of contract award and submit meeting minutes IAW CDRL A001. The specific date and time shall be coordinated with the government program manager at least five (5) calendar days prior to the proposed meeting. The structure and content is at the contractor's discretion but should include at a minimum a project schedule outline and identification/introduction of key personnel.

5.4. Support Requirements:

- 5.4.1. The contractor shall provide maintenance support to the devices for the entire period of performance of the contract. The maintenance and support shall include equipment calibration, troubleshooting, and repair of all non-consumable items (8x5 support).
- 5.4.2. The prototype screening devices shall include a 4 month software license from date of delivery.
- 5.4.3. The contractor shall provide on-site training at the direction of the government on the prototype screening device implementation, equipment calibration, system startup and shutdown, system operation, testing procedures, data analysis, and system trouble shooting. Training occurs at the prototype system deployment location. Training shall be for the duration of 1 day. Virtual training shall be permitted in the event that travel restrictions prohibit travel to deployment locations.
- 5.4.4. The contractor shall provide an Operator's Manual and Instructions for Use with the delivery of each prototype screening device IAW CDRL A005.

6. REFERENCE DOCUMENTS

DoDM 5200.01
DoDM 5105.21
DoD-5220.22M
DoD 8570.01M
DOD 3216.02I
21 CFR 50, 52, 54, 801, 803, 812, 820

7. DATA DELIVERABLE ITEMS

- 7.1. A001 – Biweekly Status and Kick Off Minutes
- 7.2. A002 - Scientific/Technical Study Plans/Reports
- 7.3. A003 – Quality Assurance Program Plan
- 7.4. A004 - Software Design Description (SDD)
- 7.5. A005 – System Operator Technical Manual & Training Materials
- 7.6. A006- Regulatory Strategy
- 7.7. A007 – Manufacturing Development Plan
- 7.8. A008 – FDA Correspondence/Engagements

8. POINTS OF CONTACT

Program Management

(b) (6)
JPEO JPM CBRN Medical

(b) (6)

Contracting Officer

(b) (6)
Army Contracting Command – Aberdeen Proving Ground
Edgewood Contracting Division

(b) (6)

Section E - Inspection and Acceptance

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

Section F - Deliveries or Performance

DELIVERY INFORMATION

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
0001	POP 13-NOV-2020 TO 21-MAY-2021	N/A	(b) (6) [REDACTED] [REDACTED] [REDACTED] FOB: Destination	
0002	26-JAN-2021	1	(SAME AS PREVIOUS LOCATION) FOB: Destination	
0003	POP 26-JAN-2021 TO 21-MAY-2021	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	
0004	POP 13-NOV-2020 TO 21-MAY-2021	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	

CLAUSES INCORPORATED BY REFERENCE

52.242-15	Stop-Work Order	AUG 1989
52.247-34	F.O.B. Destination	NOV 1991

Section G - Contract Administration Data

CONTRACT ADMINISTRATION

In no event shall any understanding or agreement, contract modification, change order, or other matter in deviation from the terms of this contract between the contractor and a person other than the Contracting Officer be effective or binding upon the Government. All such actions must be formalized by a proper contractual document executed by the Contracting Officer.

252.232-7004 DEVIATION**DOD PROGRESS PAYMENT RATES (MAR 2020) (DEVIATION 2020-O0010)**

If the Contractor is a small business concern, the Progress Payments clause of this contract is modified to change each mention of the progress payment rate and liquidation rate (excepting paragraph (k), Limitations on Unfinalized Contract Actions) to 95 percent.

(End of clause)

52.232-15 DEVIATION**52.232-16 Progress Payments. (DEVIATION 2020-O0010)**

Use the following deviation clause in lieu of the clause at FAR 52.232-16 as prescribed in 32.502-4(a):

PROGRESS PAYMENTS (MAR 2020) (DEVIATION 2020-O0010)

The Government will make progress payments to the Contractor when requested as work progresses, but not more frequently than monthly, in amounts of \$2,500 or more approved by the Contracting Officer, under the following conditions:

(a) Computation of amounts.

(1) Unless the Contractor requests a smaller amount, the Government will compute each progress payment as 90 percent of the Contractor's total costs incurred under this contract whether or not actually paid, plus financing payments to subcontractors (see paragraph (j) of this clause), less the sum of all previous progress payments made by the Government under this contract. The Contracting Officer will consider cost of money that would be allowable under FAR 31.205-10 as an incurred cost for progress payment purposes.

(2) The amount of financing and other payments for supplies and services purchased directly for the contract are limited to the amounts that have been paid by cash, check, or other forms of payment, or that are determined due and will be paid to subcontractors—

(i) In accordance with the terms and conditions of a subcontract or invoice; and

(ii) Ordinarily within 30 days of the submission of the Contractor's payment request to the Government.

(3) The Government will exclude accrued costs of Contractor contributions under employee pension plans until actually paid unless-

(i) The Contractor's practice is to make contributions to the retirement fund quarterly or more frequently; and

(ii) The contribution does not remain unpaid 30 days after the end of the applicable quarter or shorter payment period (any contribution remaining unpaid shall be excluded from the Contractor's total costs for progress payments until paid).

(4) The Contractor shall not include the following in total costs for progress payment purposes in paragraph (a)(1) of this clause:

(i) Costs that are not reasonable, allocable to this contract, and consistent with sound and generally accepted accounting principles and practices.

(ii) Costs incurred by subcontractors or suppliers.

(iii) Costs ordinarily capitalized and subject to depreciation or amortization except for the properly depreciated or amortized portion of such costs.

(iv) Payments made or amounts payable to subcontractors or suppliers, except for-

(A) Completed work, including partial deliveries, to which the Contractor has acquired title; and

(B) Work under cost-reimbursement or time-and-material subcontracts to which the Contractor has acquired title.

(5) The amount of unliquidated progress payments may exceed neither (i) the progress payments made against incomplete work (including allowable unliquidated progress payments to subcontractors) nor (ii) the value, for progress payment purposes, of the incomplete work. Incomplete work shall be considered to be the supplies and services required by this contract, for which delivery and invoicing by the Contractor and acceptance by the Government are incomplete.

(6) The total amount of progress payments shall not exceed 90 percent of the total contract price.

(7) If a progress payment or the unliquidated progress payments exceed the amounts permitted by subparagraphs (a)(4) or (a)(5) above, the Contractor shall repay the amount of such excess to the Government on demand.

(8) Notwithstanding any other terms of the contract, the Contractor agrees not to request progress payments in dollar amounts of less than \$2,500. The Contracting Officer may make exceptions.

(9) The costs applicable to items delivered, invoiced, and accepted shall not include costs in excess of the contract price of the items.

(b) *Liquidation.* Except as provided in the Termination for Convenience of the Government clause, all progress payments shall be liquidated by deducting from any payment under this contract, other than advance or progress payments, the unliquidated progress payments, or 90 percent of the amount invoiced, whichever is less. The Contractor shall repay to the Government any amounts required by a retroactive price reduction, after computing liquidations and payments on past invoices at the reduced prices and adjusting the unliquidated progress payments accordingly. The Government reserves the right to unilaterally change from the ordinary liquidation rate to an alternate rate when deemed appropriate for proper contract financing.

(c) *Reduction or suspension.* The Contracting Officer may reduce or suspend progress payments, increase the rate of liquidation, or take a combination of these actions, after finding on substantial evidence any of the following conditions:

(1) The Contractor failed to comply with any material requirement of this contract (which includes paragraphs (f) and (g) below).

(2) Performance of this contract is endangered by the Contractor's (i) failure to make progress or (ii) unsatisfactory financial condition.

(3) Inventory allocated to this contract substantially exceeds reasonable requirements.

(4) The Contractor is delinquent in payment of the costs of performing this contract in the ordinary course of business.

(5) The fair value of the undelivered work is less than the amount of unliquidated progress payments for that work.

(6) The Contractor is realizing less profit than that reflected in the establishment of any alternate liquidation rate in paragraph (b) above, and that rate is less than the progress payment rate stated in subparagraph (a)(1) above.

(d) *Title.*

(1) Title to the property described in this paragraph (d) shall vest in the Government. Vestiture shall be immediately upon the date of this contract, for property acquired or produced before that date. Otherwise, vestiture shall occur when the property is or should have been allocable or properly chargeable to this contract.

(2) Property, as used in this clause, includes all of the below-described items acquired or produced by the Contractor that are or should be allocable or properly chargeable to this contract under sound and generally accepted accounting principles and practices.

(i) Parts, materials, inventories, and work in process;

(ii) Special tooling and special test equipment to which the Government is to acquire title;

(iii) Nondurable (i.e., noncapital) tools, jigs, dies, fixtures, molds, patterns, taps, gauges, test equipment, and other similar manufacturing aids, title to which would not be obtained as special tooling under subparagraph (ii) above; and

(iv) Drawings and technical data, to the extent the Contractor or subcontractors are required to deliver them to the Government by other clauses of this contract.

(3) Although title to property is in the Government under this clause, other applicable clauses of this contract, e.g., the termination clauses, shall determine the handling and disposition of the property.

(4) The Contractor may sell any scrap resulting from production under this contract without requesting the Contracting Officer's approval, but the proceeds shall be credited against the costs of performance.

(5) To acquire for its own use or dispose of property to which title is vested in the Government under this clause, the Contractor must obtain the Contracting Officer's advance approval of the action and the terms. The Contractor shall (i) exclude the allocable costs of the property from the costs of contract performance, and (ii) repay to the Government any amount of unliquidated progress payments allocable to the property. Repayment may be by cash or credit memorandum.

(6) When the Contractor completes all of the obligations under this contract, including liquidation of all progress payments, title shall vest in the Contractor for all property (or the proceeds thereof) not—

(i) Delivered to, and accepted by, the Government under this contract; or

(ii) Incorporated in supplies delivered to, and accepted by, the Government under this contract and to which title is vested in the Government under this clause.

(7) The terms of this contract concerning liability for Government-furnished property shall not apply to property to which the Government acquired title solely under this clause.

(e) *Risk of loss.* Before delivery to and acceptance by the Government, the Contractor shall bear the risk of loss for property, the title to which vests in the Government under this clause, except to the extent the Government expressly assumes the risk. The Contractor shall repay the Government an amount equal to the unliquidated progress payments that are based on costs allocable to property that is lost (see 45.101).

(f) *Control of costs and property.* The Contractor shall maintain an accounting system and controls adequate for the proper administration of this clause.

(g) *Reports, forms, and access to records.*

(1) The Contractor shall promptly furnish reports, certificates, financial statements, and other pertinent information (including estimates to complete) reasonably requested by the Contracting Officer for the administration of this clause. Also, the Contractor shall give the Government reasonable opportunity to examine and verify the Contractor's books, records, and accounts.

(2) The Contractor shall furnish estimates to complete that have been developed or updated within six months of the date of the progress payment request. The estimates to complete shall represent the Contractor's best estimate of total costs to complete all remaining contract work required under the contract. The estimates shall include sufficient detail to permit Government verification.

(3) Each Contractor request for progress payment shall:

(i) Be submitted on Standard Form 1443, Contractor's Request for Progress Payment, or the electronic equivalent as required by agency regulations, in accordance with the form instructions and the contract terms; and

(ii) Include any additional supporting documentation requested by the Contracting Officer.

(h) *Special terms regarding default.* If this contract is terminated under the Default clause, (i) the Contractor shall, on demand, repay to the Government the amount of unliquidated progress payments, and (ii) title shall vest in the Contractor, on full liquidation of progress payments, for all property for which the Government elects not to require delivery under the Default clause. The Government shall be liable for no payment except as provided by the Default clause.

(i) *Reservations of rights.*

(1) No payment or vesting of title under this clause shall (i) excuse the Contractor from performance of obligations under this contract or (ii) constitute a waiver of any of the rights or remedies of the parties under the contract.

(2) The Government's rights and remedies under this clause (i) shall not be exclusive but rather shall be in addition to any other rights and remedies provided by law or this contract and (ii) shall not be affected by delayed, partial, or omitted exercise of any right, remedy, power, or privilege, nor shall such exercise or any single exercise preclude or impair any further exercise under this clause or the exercise of any other right, power, or privilege of the Government.

(j) *Financing payments to subcontractors.* The financing payments to subcontractors mentioned in paragraphs (a)(1) and (a)(2) of this clause shall be all financing payments to subcontractors or divisions, if the following conditions are met:

- (1) The amounts included are limited to—
 - (i) The unliquidated remainder of financing payments made; plus
 - (ii) Any unpaid subcontractor requests for financing payments.
- (2) The subcontract or interdivisional order is expected to involve a minimum of approximately 6 months between the beginning of work and the first delivery; or, if the subcontractor is a small business concern, 4 months.
- (3) If the financing payments are in the form of progress payments, the terms of the subcontract or interdivisional order concerning progress payments—
 - (i) Are substantially similar to the terms of this clause for any subcontractor that is a large business concern, or this clause with its Alternate I for any subcontractor that is a small business concern;
 - (ii) Are at least as favorable to the Government as the terms of this clause;
 - (iii) Are not more favorable to the subcontractor or division than the terms of this clause are to the Contractor;
 - (iv) Are in conformance with the requirements of FAR 32.504(e); and
 - (v) Subordinate all subcontractor rights concerning property to which the Government has title under the subcontract to the Government's right to require delivery of the property to the Government if—
 - (A) The Contractor defaults; or
 - (B) The subcontractor becomes bankrupt or insolvent.
- (4) If the financing payments are in the form of performance-based payments, the terms of the subcontract or interdivisional order concerning payments—
 - (i) Are substantially similar to the Performance-Based Payments clause at FAR 52.232-32 and meet the criteria for, and definition of, performance-based payments in FAR Part 32;
 - (ii) Are in conformance with the requirements of FAR 32.504(f); and
 - (iii) Subordinate all subcontractor rights concerning property to which the Government has title under the subcontract to the Government's right to require delivery of the property to the Government if—
 - (A) The Contractor defaults; or
 - (B) The subcontractor becomes bankrupt or insolvent.
- (5) If the financing payments are in the form of commercial item financing payments, the terms of the subcontract or interdivisional order concerning payments—
 - (i) Are constructed in accordance with FAR 32.206(c) and included in a subcontract for a commercial item purchase that meets the definition and standards for acquisition of commercial items in FAR Parts 2 and 12;
 - (ii) Are in conformance with the requirements of FAR 32.504(g); and
 - (iii) Subordinate all subcontractor rights concerning property to which the Government has title under the subcontract to the Government's right to require delivery of the property to the Government if—
 - (A) The Contractor defaults; or

(B) The subcontractor becomes bankrupt or insolvent.

(6) If financing is in the form of progress payments, the progress payment rate in the subcontract is the customary rate used by the contracting agency, depending on whether the subcontractor is or is not a small business concern.

(7) Concerning any proceeds received by the Government for property to which title has vested in the Government under the subcontract terms, the parties agree that the proceeds shall be applied to reducing any unliquidated financing payments by the Government to the Contractor under this contract.

(8) If no unliquidated financing payments to the Contractor remain, but there are unliquidated financing payments that the Contractor has made to any subcontractor, the Contractor shall be subrogated to all the rights the Government obtained through the terms required by this clause to be in any subcontract, as if all such rights had been assigned and transferred to the Contractor.

(9) To facilitate small business participation in subcontracting under this contract, the Contractor shall provide financing payments to small business concerns, in conformity with the standards for customary contract financing payments stated in FAR 32.113. The Contractor shall not consider the need for such financing payments as a handicap or adverse factor in the award of subcontracts.

(k) *Limitations on undefinitized contract actions.* Notwithstanding any other progress payment provisions in this contract, progress payments may not exceed 80 percent of costs incurred on work accomplished under undefinitized contract actions. A contract action is any action resulting in a contract, as defined in subpart 2.1, including contract modifications for additional supplies or services, but not including contract modifications that are within the scope and under the terms of the contract, such as contract modifications issued pursuant to the Changes clause, or funding and other administrative changes. This limitation shall apply to the costs incurred, as computed in accordance with paragraph (a) of this clause, and shall remain in effect until the contract action is definitized. Costs incurred which are subject to this limitation shall be segregated on Contractor progress payment requests and invoices from those costs eligible for higher progress payment rates. For purposes of progress payment liquidation, as described in paragraph (b) of this clause, progress payments for undefinitized contract actions shall be liquidated at 80 percent of the amount invoiced for work performed under the undefinitized contract action as long as the contract action remains undefinitized. The amount of unliquidated progress payments for undefinitized contract actions shall not exceed 80 percent of the maximum liability of the Government under the undefinitized contract action or such lower limit specified elsewhere in the contract. Separate limits may be specified for separate actions.

(l) *Due date.* The designated payment office will make progress payments on the 7th day after the designated billing office receives a proper progress payment request. In the event that the Government requires an audit or other review of a specific progress payment request to ensure compliance with the terms and conditions of the contract, the designated payment office is not compelled to make payment by the specified due date. Progress payments are considered contract financing and are not subject to the interest penalty provisions of the Prompt Payment Act.

(m) *Progress payments under indefinite-delivery contracts.* The Contractor shall account for and submit progress payment requests under individual orders as if the order constituted a separate contract, unless otherwise specified in this contract.

(End of clause)

ACCOUNTING AND APPROPRIATION DATA

AA: 5703600 290 RL4B 645350 68WXL0 58800 64858F 503000 F03000 JON:99930000 ESP:C1 CSN:J0XQD7 ALD:AA FSR: 065086
 COST CODE: A5XAF
 AMOUNT: \$402,350.00

ACRN	CLIN/SLIN	CIN	AMOUNT
AA	0001	GFEB001157463100001	(b) (4)
	0002	GFEB001157463100002	(b) (4)
	0003	GFEB001157463100003	(b) (4)

CLAUSES INCORPORATED BY REFERENCE

252.232-7003 Electronic Submission of Payment Requests and Receiving Reports DEC 2018

CLAUSES INCORPORATED BY FULL TEXT

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 <https://www.sam.gov>; and

(2) Be registered to use WAWF at <https://wawf.eb.mil/> 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 <https://wawf.eb.mil/>.

(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. CLINs 0003 Cost Voucher

(ii) For fixed price line items— CLINs 0001-0002 Invoice and Receiving Report (Combo)

(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.

N/A

(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*

<i>Field Name in WAWF</i>	<i>Data to be entered in WAWF</i>
Pay Official DoDAAC	HQ0490
Issue By DoDAAC	W911SR
Admin DoDAAC**	W911SR
Inspect By DoDAAC	
Ship To Code	
Ship From Code	
Mark For Code	N/A
Service Approver (DoDAAC)	
Service Acceptor (DoDAAC)	
Accept at Other DoDAAC	N/A
LPO DoDAAC	N/A
DCAA Auditor DoDAAC	N/A
Other DoDAAC(s)	N/A

(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)
JPEO JPM CBRN Medical

(b) (6)

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

(End of clause)

Section H - Special Contract Requirements

HUMAN SUBJECTS PROHIBITION

Prohibition of Use of Human Subjects:

Research under this award involving the use of human subjects may not begin until the U.S. Army Medical Research and Materiel Command's Office of Research Protections, Human Research Protections Office (HRPO) approves the protocol. Written approval to begin research or subcontract for the use of human subjects under the applicable protocol proposed for this award will be issued from the US Army Medical Research and Materiel Command, HRPO, under separate letter to the funded institution and the Principal Investigator. A copy of this approval will be provided to the Contracting Officer for the official file. Non-compliance with any provision of this clause may result in withholding of funds and or the termination of the award. Information and guidance is provided at the following web site:

https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo

Section I - Contract Clauses

CLAUSES INCORPORATED BY REFERENCE

52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity	MAY 2014
52.203-10	Price Or Fee Adjustment For Illegal Or Improper Activity	MAY 2014
52.203-12	Limitation On Payments To Influence Certain Federal Transactions	JUN 2020
52.203-19	Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements	JAN 2017
52.204-9	Personal Identity Verification of Contractor Personnel	JAN 2011
52.204-10	Reporting Executive Compensation and First-Tier Subcontract Awards	JUN 2020
52.204-13	System for Award Management Maintenance	OCT 2018
52.204-19	Incorporation by Reference of Representations and Certifications.	DEC 2014
52.204-21	Basic Safeguarding of Covered Contractor Information Systems	JUN 2016
52.204-23	Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities.	JUL 2018
52.204-25	Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.	AUG 2020
52.209-6	Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment	JUN 2020
52.209-10	Prohibition on Contracting With Inverted Domestic Corporations	NOV 2015
52.211-5	Material Requirements	AUG 2000
52.216-7	Allowable Cost And Payment	AUG 2018
52.219-28	Post-Award Small Business Program Rerepresentation	MAY 2020
52.222-3	Convict Labor	JUN 2003
52.222-21	Prohibition Of Segregated Facilities	APR 2015
52.222-26	Equal Opportunity	SEP 2016
52.222-37	Employment Reports on Veterans	JUN 2020
52.222-50	Combating Trafficking in Persons	OCT 2020
52.222-54	Employment Eligibility Verification	OCT 2015
52.223-18	Encouraging Contractor Policies To Ban Text Messaging While Driving	JUN 2020
52.225-13	Restrictions on Certain Foreign Purchases	JUN 2008
52.227-1 Alt I	Authorization And Consent (JUN 2020) - Alternate I	APR 1984
52.227-2	Notice And Assistance Regarding Patent And Copyright Infringement	JUN 2020
52.227-14	Rights in Data--General	MAY 2014
52.232-17	Interest	MAY 2014
52.232-23	Assignment Of Claims	MAY 2014
52.232-25	Prompt Payment	JAN 2017
52.232-33	Payment by Electronic Funds Transfer--System for Award Management	OCT 2018
52.232-39	Unenforceability of Unauthorized Obligations	JUN 2013
52.232-40	Providing Accelerated Payments to Small Business Subcontractors	DEC 2013
52.233-1	Disputes	MAY 2014

52.233-3	Protest After Award	AUG 1996
52.233-4	Applicable Law for Breach of Contract Claim	OCT 2004
52.242-13	Bankruptcy	JUL 1995
52.242-17	Government Delay Of Work	APR 1984
52.243-1 Alt V	Changes--Fixed-Price (Aug 1987) - Alternate V	APR 1984
52.243-2 Alt V	Changes--Cost-Reimbursement (Aug 1987) - Alternate V	APR 1984
52.244-6	Subcontracts for Commercial Items	OCT 2020
52.245-1	Government Property	JAN 2017
52.245-9	Use And Charges	APR 2012
52.246-4	Inspection Of Services--Fixed Price	AUG 1996
52.249-9	Default (Fixed-Priced Research And Development)	APR 1984
252.203-7000	Requirements Relating to Compensation of Former DoD Officials	SEP 2011
252.203-7002	Requirement to Inform Employees of Whistleblower Rights	SEP 2013
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
252.209-7004	Subcontracting With Firms That Are Owned or Controlled By The Government of a Country that is a State Sponsor of Terrorism	MAY 2019
252.211-7007	Reporting of Government-Furnished Property	AUG 2012
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
252.225-7048	Export-Controlled Items	JUN 2013
252.226-7001	Utilization of Indian Organizations and Indian-Owned Economic Enterprises, and Native Hawaiian Small Business Concerns	APR 2019
252.227-7013	Rights in Technical Data--Noncommercial Items	FEB 2014
252.227-7014	Rights in Noncommercial Computer Software and Noncommercial Computer Software Documentation	FEB 2014
252.227-7027	Deferred Ordering Of Technical Data Or Computer Software	APR 1988
252.232-7010	Levies on Contract Payments	DEC 2006
252.232-7011	Payments in Support of Emergencies and Contingency Operations	MAY 2013
252.235-7004	Protection of Human Subjects	JUL 2009
252.235-7010	Acknowledgment of Support and Disclaimer	MAY 1995
252.235-7011	Final Scientific or Technical Report	DEC 2019
252.243-7002	Requests for Equitable Adjustment	DEC 2012
252.244-7000	Subcontracts for Commercial Items	OCT 2020
252.245-7001	Tagging, Labeling, and Marking of Government-Furnished Property	APR 2012
252.245-7002	Reporting Loss of Government Property	DEC 2017
252.245-7003	Contractor Property Management System Administration	APR 2012
252.245-7004	Reporting, Reutilization, and Disposal	DEC 2017

CLAUSES INCORPORATED BY FULL TEXT

52.222-35 EQUAL OPPORTUNITY FOR VETERANS (JUN 2020)

(a) Definitions. As used in this clause--

"Active duty wartime or campaign badge veteran," "Armed Forces service medal veteran," "disabled veteran," "protected veteran," "qualified disabled veteran," and "recently separated veteran" have the meanings given at Federal Acquisition Regulation (FAR) 22.1301.

(b) Equal opportunity clause. The Contractor shall abide by the requirements of the equal opportunity clause at 41 CFR 60-300.5(a), as of March 24, 2014. This clause prohibits discrimination against qualified protected veterans, and requires affirmative action by the Contractor to employ and advance in employment qualified protected veterans.

(c) Subcontracts. The Contractor shall insert the terms of this clause in subcontracts valued at or above the threshold specified in FAR 22.1303(a) on the date of subcontract award, unless exempted by rules, regulations, or orders of the Secretary of Labor. The Contractor shall act as specified by the Director, Office of Federal Contract Compliance Programs, to enforce the terms, including action for noncompliance. Such necessary changes in language may be made as shall be appropriate to identify properly the parties and their undertakings.

(End of clause)

52.222-36 EQUAL OPPORTUNITY FOR WORKERS WITH DISABILITIES (JUN 2020)

(a) Equal opportunity clause. The Contractor shall abide by the requirements of the equal opportunity clause at 41 CFR 60-741.5(a), as of March 24, 2014. This clause prohibits discrimination against qualified individuals on the basis of disability, and requires affirmative action by the Contractor to employ and advance in employment qualified individuals with disabilities.

(b) Subcontracts. The Contractor shall include the terms of this clause in every subcontract or purchase order in excess of the threshold specified in Federal Acquisition Regulation (FAR) 22.1408(a) on the date of subcontract award, unless exempted by rules, regulations, or orders of the Secretary, so that such provisions will be binding upon each subcontractor or vendor. The Contractor shall act as specified by the Director, Office of Federal Contract Compliance Programs of the U.S. Department of Labor, to enforce the terms, including action for noncompliance. Such necessary changes in language may be made as shall be appropriate to identify properly the parties and their undertakings.

(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/>

(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 http://www.aimglobal.org/?Reg_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 the Government's unit acquisition cost is \$5,000 or more, except for the following line items:

Contract line, subline, or exhibit line item No.	Item description
.....	

(ii) Items for which the Government's unit acquisition cost is less than \$5,000 that are identified in the Schedule or the following table:

Contract line, subline, or exhibit line item No.	Item description
.....	

(If items are identified in the Schedule, insert ``See Schedule" in this table.)

(iii) Subassemblies, components, and parts embedded within delivered items, items with warranty requirements, DoD serially managed reparable 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 <http://dodprocurementtoolbox.com/site/uidregistry/>.
- (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)

Section J - List of Documents, Exhibits and Other Attachments

ATTACHMENTS

Contract Data Requirements Listing

The below attachments are included by reference, with the same force and effect as if provided in the body of this contract by full text.

- 8.1. A001 – Biweekly Status and Kick Off Minutes
- 8.2. A002 - Scientific/Technical Study Plans/Reports
- 8.3. A003 – Quality Assurance Program Plan
- 8.4. A004 - Software Design Description (SDD)
- 8.5. A005 – System Operator Technical Manual & Training Materials
- 8.6. A006- Regulatory Strategy
- 8.7. A007 – Manufacturing Development Plan
- 8.8. A008 – FDA Correspondence/Engagements

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT			1 CONTRACT ID CODE	PAGE OF PAGES
			J	1 13
2 AMENDMENT/MODIFICATION NO P00001	3 EFFECTIVE DATE 09-Dec-2020	4 REQUISITION/PURCHASE REQ NO 0011574631-0001	5 PROJECT NO (If applicable)	
6 ISSUED BY USA CONTRACTING CMD-APG - W911SR EDGEWOOD CONTRACT NG DIVISION 8456 BRIGADE STREET BLDG E4215 ABERDEEN PROVING GROUND MD 21010-5401	CODE W911SR	7 ADMINISTERED BY (If other than item 6) See Item 6		
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) WORLDS ENTERPRISES NC (b) (6) 5350 ALPHA RD DALLAS TX 75240-3428		9A. AMENDMENT OF SOLICITATION NO.		
		9B. DATED (SEE ITEM 11)		
		X 10A. MOD. OF CONTRACT/ORDER NO. W911SR21C0008		
		X 10B. DATED (SEE ITEM 13) 13-Nov-2020		
CODE 8KUF6	FACILITY CODE			
11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS				
<input type="checkbox"/> The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer <input type="checkbox"/> is extended, <input type="checkbox"/> is not extended. Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.				
12. ACCOUNTING AND APPROPRIATION DATA (If required)				
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.				
X 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).				
C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:				
D. OTHER (Specify type of modification and authority)				
E. IMPORTANT: Contractor <input type="checkbox"/> is not, <input checked="" type="checkbox"/> 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) \$0.00 Obligated a. The purpose of this modification is to implement several administrative changes to the contract. These administrative changes result in a \$0 increase to the overall contract value. b. DoDAAC W56SQD has been added to the "Ship To" location; the WideArea Workflow clause has been updated to add several administrative codes; Mandatory DFARS clause 252.222-7999, Combating Race and Sex Stereotyping, is incorporated by full text; Contractor Acquired Property (CAP) CDRL A009 is incorporated by reference and the SOO has been modified accordingly. f. This modification is a complete settlement as agreed by both parties. The contractor releases the Government from any and all liability resulting from this modification including interest, and for any other adjustments relating to the facts and circumstances arising out of the contractor's performance for all claims of unabsorbed and extended overhead.				
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) (b) (6)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) JENNIFER M. BUCHNESS / CONTRACT NG OFFICER (b) (6)		
15B. CONTRACTOR/OFFEROR (Signature of Contractor/Offeror) (b) (6)		15C. DATE SIGNED 12/9/2020		16B. UNITED STATES OF AMERICA BY (b) (6) (Signature of Contracting Officer)
				16C. DATE SIGNED 09-Dec-2020

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION C - DESCRIPTIONS AND SPECIFICATIONS

The following have been modified:

STATEMENT OF OBJECTIVES

STATEMENT OF OBJECTIVES (SOO)
Non-Invasive Rapid Detection System (NIRDS) Phase 1
3 December 2020

1. BACKGROUND:

Technology to screen individuals for COVID-19 using Volatile Organic Compounds (VOC) in breath, within the order of magnitude of seconds, can be leveraged to combat the global COVID-19 pandemic and potential future bio-threats. VOCs are low molecular weight metabolic compounds present in human breath and may be indicative of infectious disease. COVID-19 critically impacts the DoDs' effectiveness and poses potential national security risks. Additionally, VOC-based diagnostics have great potential to be the next generation of screening tools for disease identification, infectious disease management, and natural/synthetic biological warfare early detection.

Current COVID-19 diagnostic procedures do not deliver rapid responses for effective infectious disease identification, management, and flexible mission planning due to result wait time in the order of magnitude of 1 day. Additionally, current diagnostic tools rely on end users or minimally trained personnel introducing significant human error margins that reduce field accuracy (b) (4). In order to maintain warfighter mission effectiveness, the DoD requires the cutting-edge capability to screen for COVID-19.

2. REQUIREMENT:

Rapidly deploy a non-invasive VOC analysis technology for infectious diseases such as COVID-19, in order to minimize Service member downtime, maximize mission effectiveness, and prevent the spread of COVID-19.

3. OBJECTIVE:

The Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) Non-Invasive Rapid Detection System (NIRDS) Program seeks to procure (b) (4) prototype screening devices and associated systems for Government optimization and verification testing in the intended use setting.

4. SCOPE:

- 4.1 Prototype devices and associated systems will be used in order for the Government to evaluate their potential to rapidly screen for COVID-19 in a non-invasive manner.
- 4.2 As the devices and associated systems procured under this award will not yet have obtained FDA authorization, they must be labeled, distributed and managed in accordance with applicable regulations (ie. 21 CFR 812 and 809).
- 4.3 These prototype devices will be used in research protocol in compliance with applicable laws, regulations, DoD policies and ethical standards regardless of their DoD-intramural/extramural nature or geographical location.

- 4.4 In part, the Government assessment of the systems will include correlation of the research data with de-identified validated clinical data. It will also include assessments of operational effectiveness and operational suitability. Operational effectiveness is a measure of the overall ability of a system to accomplish a mission when used by representative personnel in the environment planned or expected for operational employment of the system. Operational suitability is the degree to which a system can be placed and sustained satisfactorily in fielded use with consideration being given to availability, compatibility, transportability, natural environment effect and impacts, documentation, and training requirements.
- 4.5 The Government must be informed of and given the option to receive any hardware and software modification and improvements proposed or made to the commercial system being developed during the period of performance. Modifications and improvements on the prototype screening device hardware may include, but are not limited to, investigation into hardware upgrades and changes, Government Furnished Equipment (GFE) reuse (if requested by the government) and any additional hardware capabilities to assist in the requirement. Modifications and improvements on the prototype screening device software may include, but are not limited to software upgrades to the machine learning algorithm or upgrades to any other applicable software, and any additional software capabilities to assist in the requirement. The Contractor shall provide a Software Design Description (SDD) for the software release at the point of delivering prototype systems to the Government. The document shall describe the NIRDS analyzer software by functional area IAW Contract Data Requirements List (CDRL) A004.
- 4.6 (b) (4) prototype screening devices will be retained by the contractor and considered Contractor Acquired Property (CAP) and shall be inventoried when it arrives at its initial destination, and monthly thereafter IAW CDRL A009. The CAP shall be used strictly for the purposes of this contract effort to collect additional data to mature the algorithm and obtain data for regulatory filing with the FDA. The contractor shall provide Scientific/Study Plans for all testing conducted using CAP, to the government for review and comment within ten business day of contract award, IAW CDRL A002. The contractor shall provide biweekly status updates to the government program manager on the production, delivery, implementation, repairs, and training status of the CAP prototype devices, IAW CDRL A001. Additionally, the contractor shall provide biweekly updates on the accuracy, sensitivity, and specificity values of the algorithm, as well as, time to result based on tests performed with CAP IAW CDRL A001. Upon completion of the period of performance, the contractor shall promptly ship all CAP back to the Government in good, working condition IAW CDRL A009. Once delivered and accepted by the Government, the Government assumes title. All items meeting the IUID criteria of DFARS 211.274-2 shall be marked and reported in the IUID registry upon delivery IAW DFARS 252.211-7003.
- 4.7 (b) (4) prototype screening devices will be used in the government testing events at the locations in Table 1 below. The contractor shall review and if necessary, provide input to Government developed test plans and protocols. The contractor shall provide biweekly status updates to the government program manager on the production, delivery, implementation, repairs, and training status of the government testing prototype devices IAW CDRL A001. Additionally, the contractor shall provide biweekly updates on the accuracy, sensitivity, and specificity values of the algorithm, as well as, time to result, based on tests performed with government testing prototype devices IAW CDRL A001. The raw data collected by the prototypes on government installations shall be delivered to the government upon request IAW A002.
- 4.8 It is estimated that at least two testing events will occur during the contract period of performance. For proposal purposes, the contractor shall assume the following testing events listed below in Table 1. Actual events will be finalized with the contractor prior to commencement.

Table 1

Testing Event Location	Duration of Test Event
(b) (4)	

(b) (4)		
---------	--	--

- 4.9 At the conclusion of the Period of Performance the contractor shall provide a Scientific/Technical Report in IAW CDRL A002.

4.10 Intellectual Property (IP)

Awardee represents that the intellectual property license(s) and other rights held by or granted to Awardee are sufficient to enable Awardee to perform its obligations under this award.

Background IP and Materials. The Awardee and the Government each retain any intellectual property (IP) rights to their own materials, technical data (as defined in DFARS 252.227-7013), technology, information, documents, or know-how—or potential rights, such as issued patents, patent applications, invention disclosures, copyrighted works, or other written documentation—that exist prior to execution of this award or are developed outside the scope of this award (“Background IP”).

Patent Indemnity. The Awardee 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 this award and Awardee’s actions under this award, provided the Awardee is reasonably notified of such claims and proceedings.

4.11 Data and Computer/Software Documentation Rights

Background Data. “Background Data” shall mean all technical data, as defined in DFARS 252.227-7013, that exists prior to execution of this award, or are developed outside the scope of this award. Awardee Background Data shall include any data associated with Awardee’s Background IP and Materials, that was not generated solely with Government funding. All Background Data shall be owned by the Awardee. The Government shall have the right, subject to applicable law and the terms of this award, to use, modify, reproduce, release, perform, display, or disclose Background Data only within the Government. The Government may, under a separate agreement or by bilateral modification to this award, negotiate rights to use or disclose the Awardee’s Background Data.

Technical Data. All data generated in connection with the performance of this award, or that arises out of the use of any materials or enabling technology provided or used by the Awardee in the performance of this award, other Awardee materials or Awardee confidential information, whether conducted by the Government or the Awardee (collectively, the “Technical Data”), shall be owned by the Awardee. The Government shall have the right, subject to applicable law and the terms of this award, to use, modify, reproduce, release, perform, display, or disclose data first produced in the performance of this award within the Government and otherwise for “Government Purpose Rights,” as this term is defined in DFARS 252.227-7013(a)(13).

Background Computer Software and Computer Software Documentation. “Background Computer Software and Computer Software Documentation” shall mean all computer software and computer software documentation, as defined in DFARS 252.227-7014(a)(4) and (5), that exists prior to execution of this award, or are developed outside the scope of this award. Awardee Background Computer Software and Computer Software Documentation shall include any computer software or software documentation associated with Awardee’s Background Computer Software and Computer Software Documentation, that was not generated with Government funding. All Background Computer Software and Computer Software Documentation shall be owned by the Awardee. The Government shall have the right, subject to compliance with applicable law, the terms of this award and the terms of applicable contracts, to use, release, perform, display, or disclose Background Computer Software and Computer Software Documentation solely within the Government. The

Government may, under a separate or by bilateral modification to this award, negotiate rights to use or disclose the Awardee's Background Computer Software and Computer Software Documentation.

Noncommercial Computer Software and Noncommercial Computer Software Documentation.

All noncommercial computer software and noncommercial computer software documentation data generated in connection with the performance of this award, or that arises out of the use of any materials or enabling technology provided or used by the Awardee in the performance of this award, (collectively, the "Agreement Software and Software Documentation"), shall be owned by the Awardee. The Government shall have the right, subject to compliance with applicable law and the terms of this award, to use, release, perform, display, or disclose data first produced in the performance of this award within the Government and otherwise for "Government Purpose Rights," as this term is defined in DFARS 252.227-7014(a)(12).

The Awardee agrees to retain and maintain in good condition until seven (7) years after completion or termination of this award, all Technical Data and all Agreement Software and Software Documentation generated under this award. In the event of exercise of the Government's rights hereunder, the Awardee agrees to deliver at no additional cost to the Government, all data, in Awardee's possession and developed under this award, necessary to deliver the supplies within sixty (60) calendar days from the date of the written request.

Marking of Data. The Awardee will mark any data delivered under this award with the following legend: "Use, duplication, or disclosure is subject to the restrictions as stated in Award No. W911SR-21-C-0008 between the Government and the Awardee."

Any rights that the Awardee or the Government may have in data delivered under this award, whether arising under this award or otherwise, will not be affected by Awardee's failure to mark data pursuant to this Article.

All other Technical Data and Software developed under funding of this award shall be delivered with Government Purpose rights as provided for within this Article.

The U.S. Government may purchase, under a separate agreement, a license for greater use of Background IP and Materials, Background Data, Background Computer Software and Computer Software Documentation, Technical Data and Agreement Software and Software Documentation as necessary. Such agreement will be negotiated between the parties in good faith at customary industry rates and under commercially reasonable terms and conditions.

5. TECHNICAL REQUIREMENTS

5.1. Performance Parameters:

- 5.1.1. The delivery of the prototype devices shall be within 65 calendar days of contract award. All devices shall be delivered by Thursday, 21 January 2021. Four (4) additional days have been added to account for federal holidays (Thanksgiving, Christmas, New Year's, and Martin Luther King, Jr's Birthday). The testing period of performance is four (4) months.
- 5.1.2. The prototype screening devices shall provide rapid screening results.
- 5.1.3. The prototype screening devices shall provide non-invasive screening; using breath and not blood, saliva (excluding aerosolized breath particles), or any other bodily fluid.
- 5.1.4. The prototype screening devices shall be dual communication enabled through Wi-Fi and Global System for Mobile Communications (GSM). The contractor shall provide data rates for up to 75GB for U.S. coverage for the duration of the performance period.
- 5.1.5. The prototype screening devices shall include all hardware for a fully functioning prototype to include a (b) (4) and all disposable support equipment.

5.2. Regulatory and Quality Requirements:

- 5.2.1. Systems shall be labeled, distributed and managed in accordance with applicable laws and regulations (i.e.21 CFR 812 and 809)
- 5.2.2. Receipt, management and use of de-identified comparator clinical data shall be in accordance with applicable regulations, policies, and standards for human subjects and data protections as well as device design control.
- 5.2.3. The contractor shall provide a manufacturing development plan IAW CDRL A007, and a quality assurance program plan IAW CDRL A003.
- 5.2.4. Proposed or planned hardware and software modification and improvements must be done in accordance with applicable regulations and standards for design control.
- 5.2.5. The contractor shall provide a Regulatory Strategy IAW CDRL A006 and documentation of FDA correspondence and engagements IAW CDRL A008.

5.3. Management Requirements:

The contractor shall provide biweekly status updates to the government program manager on the production, delivery, implementation, repairs, and training status of the prototype devices IAW CDRL A001.

- 5.3.1. The contractor shall maintain a qualified staff at all times. The Government restricts access or work hereunder to United States citizens only. All cybersecurity risk management related positions must have baseline certifications as designated in DoD Approved 8570 Baseline Certifications (DoD 8570.01M) prior to employment.
- 5.3.2. Travel costs shall conform to FAR 31.205- 46 and be in accordance with the Federal Travel Regulations. Travel can only be conducted upon prior approval by the government program manager with a copy of the request furnished to the Contracting Officer. If unexpected travel due to unplanned system outage is required, the contractor must show due diligence that costs were kept to a minimum. For proposal purposes, the contractor shall assume only the following; travel for two trainers to conduct a one day training event at the testing location listed in table 1.
- 5.3.3. If contractor personnel cannot physically travel due to COVID-19 travel restrictions, the following contingency plan will be implemented: (1) Remote connectivity to each unit will be performed via an internal built-in Ethernet router that offers both a physical port and WiFi access; (2) the contractor will leverage trained Government personnel on-site to provide video to provide visual support and assistance; (3) the contractor will leverage trained Government personnel on-site to provide hands-on support for parts replacement at the FRU (Field Replaceable Unit) level; and/or (4) should all travel options be prohibited, as a last resort, the unit could be repackaged and shipped to contractor for repair.
- 5.3.4. The contractor is required to hold a virtual kick off meeting within 10 calendar days of contract award and submit meeting minutes IAW CDRL A001. The specific date and time shall be coordinated with the government program manager at least five (5) calendar days prior to the proposed meeting. The structure and content is at the contractor's discretion but should include at a minimum a project schedule outline and identification/introduction of key personnel.

5.4. Support Requirements:

- 5.4.1. The contractor shall provide maintenance support to the devices for the entire period of performance of the contract. The maintenance and support shall include equipment calibration, troubleshooting, and repair of all non-consumable items (8x5 support).
- 5.4.2. The prototype screening devices shall include a 4 month software license from date of delivery.
- 5.4.3. The contractor shall provide on-site training at the direction of the government on the prototype screening device implementation, equipment calibration, system startup and shutdown, system operation, testing procedures, data analysis, and system trouble shooting. Training occurs at the prototype system deployment location. Training shall be for the duration of 1 day. Virtual training shall be permitted in the event that travel restrictions prohibit travel to deployment locations.

- 5.4.4. The contractor shall provide an Operator's Manual and Instructions for Use with the delivery of each prototype screening device IAW CDRL A005.

6. REFERENCE DOCUMENTS

DoDM 5200.01
 DoDM 5105.21
 DoD-5220.22M
 DoD 8570.01M
 DOD 3216.02I
 21 CFR 50, 52, 54, 801, 803, 812, 820

7. DATA DELIVERABLE ITEMS

- 7.1. A001 – Biweekly Status and Kick Off Minutes
 7.2. A002 - Scientific/Technical Study Plans/Reports
 7.3. A003 – Quality Assurance Program Plan
 7.4. A004 - Software Design Description (SDD)
 7.5. A005 – System Operator Technical Manual & Training Materials
 7.6. A006- Regulatory Strategy
 A007 – Manufacturing Development Plan
 7.7. A008 – FDA Correspondence/Engagements
 7.8. A009 – Contractor Acquired Property Inventory

8. POINTS OF CONTACT

Program Management

(b) (4)

JPEO JPM CBRN Medical

(b) (6)

Contracting Officer

(b) (6)

Army Contracting Command – Aberdeen Proving Ground

Edgewood Contracting Division

(b) (6)

SECTION E - INSPECTION AND ACCEPTANCE

The Technical Office for CLIN 0001 has been deleted.

SECTION F - DELIVERIES OR PERFORMANCE

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

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS
---------------	----------	-----------------

DODAAC /
CAGE

POP 13-NOV-2020 TO
21-MAY-2021

N/A

(b) (6)
[Redacted]

FOB: Destination

To:

DELIVERY DATE

QUANTITY

SHIP TO ADDRESS

DODAAC /
CAGE

POP 13-NOV-2020 TO
21-MAY-2021

N/A

(b) (6)
[Redacted]

FOB: Destination

W56XNH

The following Delivery Schedule item for CLIN 0002 has been changed from:

DELIVERY DATE

QUANTITY

SHIP TO ADDRESS

DODAAC /
CAGE

26-JAN-2021

1

(b) (6)
[Redacted]

FOB: Destination

To:

DELIVERY DATE

QUANTITY

SHIP TO ADDRESS

DODAAC /
CAGE

26-JAN-2021

1

(b) (6)
[Redacted]

FOB: Destination

W56XNH

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

DELIVERY DATE

QUANTITY

SHIP TO ADDRESS

DODAAC /
CAGE

POP 26-JAN-2021 TO
21-MAY-2021

N/A

(b) (6)
[Redacted]

FOB: Destination

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 26-JAN-2021 TO 21-MAY-2021	N/A	(b) (6) [REDACTED] FOB: Destination	W56XNH

The following Delivery Schedule item for CLIN 0004 has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 13-NOV-2020 TO 21-MAY-2021	N/A	(b) (6) [REDACTED] FOB: Destination	

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 13-NOV-2020 TO 21-MAY-2021	N/A	(b) (6) [REDACTED] FOB: Destination	W56XNH

SECTION G - CONTRACT ADMINISTRATION DATA

The following have been modified:

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 <https://www.sam.gov>; and

(2) Be registered to use WAWF at <https://wawf.eb.mil/> 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 <https://wawf.eb.mil/>.

(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. CLINs 0003 Cost Voucher

(ii) For fixed price line items— CLINs 0001-0002 Invoice and Receiving Report (Combo)

(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.

N/A

(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*

<i>Field Name in WAWF</i>	<i>Data to be entered in WAWF</i>
Pay Official DoDAAC	HQ0490
Issue By DoDAAC	W911SR
Admin DoDAAC**	W911SR
Inspect By DoDAAC	W56SQD
Ship To Code	W56SQD
Ship From Code	8KUF6
Mark For Code	N/A
Service Approver (DoDAAC)	W56SQD
Service Acceptor (DoDAAC)	W56SQD
Accept at Other DoDAAC	N/A
LPO DoDAAC	N/A
DCAA Auditor DoDAAC	N/A
Other DoDAAC(s)	N/A

(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)
JPEO JPM CBRN Medical
(b) (6)

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

(End of clause)

SECTION I - CONTRACT CLAUSES

The following have been added by full text:

252.222-7999 DEVIATION

252.222-7999 Combating Race and Sex Stereotyping (DEVIATION 2021-O0001)

COMBATING RACE AND SEX STEREOTYPING

(DEVIATION 2021-O0001) (NOV 2020)

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

“Race or sex scapegoating” means assigning fault, blame, or bias to a race or sex, or to members of a race or sex because of their race or sex.

“Race or sex stereotyping” means ascribing character traits, values, moral and ethical codes, privileges, status, or beliefs to a race or sex, or to an individual because of his or her race or sex.

(b) *Exemptions.* The exemptions that apply to Executive Order (E.O.) 11246 (see FAR 22.807) also apply to E.O. 13950 and the requirements of this clause.

(c) *Compliance with E.O. 13950, Combating Race and Sex Stereotyping.* Unless exempted under paragraph (b) of this clause, the Contractor shall not use any workplace training that inculcates in its employees any form of race or sex stereotyping or any form of race or sex scapegoating, including the concepts that—

- (1) One race or sex is inherently superior to another race or sex;
- (2) An individual, by virtue of his or her race or sex, is inherently racist, sexist, or oppressive, whether consciously or unconsciously;
- (3) An individual should be discriminated against or receive adverse treatment solely or partly because of his or her race or sex;
- (4) Members of one race or sex cannot and should not attempt to treat others without respect to race or sex;
- (5) An individual’s moral character is necessarily determined by his or her race or sex;
- (6) An individual, by virtue of his or her race or sex, bears responsibility for actions committed in the past by other members of the same race or sex;
- (7) Any individual should feel discomfort, guilt, anguish, or any other form of psychological distress on account of his or her race or sex; or
- (8) Meritocracy or traits such as a hard work ethic are racist or sexist, or were created by a particular race to oppress another race.

(d) *Notice.* The Contractor shall send, to each labor union or representative of workers with which it has a collective bargaining agreement or other contract or understanding, the notice provided below advising the labor union or workers’ representative of the Contractor’s commitments under this clause, and post copies of the notice in conspicuous places available to employees and applicants for employment.

NOTICE

**E.O. 13950, Combating Race and Sex Stereotyping
Employers Holding Federal Contracts or Subcontracts**

Contractors shall not use any workplace training that inculcates in its employees any form of race or sex stereotyping or any form of race or sex scapegoating, including the following concepts that—

- (1) One race or sex is inherently superior to another race or sex;
- (2) An individual, by virtue of his or her race or sex, is inherently racist, sexist, or oppressive, whether consciously or unconsciously;
- (3) An individual should be discriminated against or receive adverse treatment solely or partly because of his or her race or sex;
- (4) Members of one race or sex cannot and should not attempt to treat others without respect to race or sex;
- (5) An individual’s moral character is necessarily determined by his or her race or sex;
- (6) An individual, by virtue of his or her race or sex, bears responsibility for actions committed in the past by other members of the same race or sex;
- (7) Any individual should feel discomfort, guilt, anguish, or any other form of psychological distress on account of his or her race or sex; or

(8) Meritocracy or traits such as a hard work ethic are racist or sexist, or were created by a particular race to oppress another race.

For use in this notice—

“Race or sex scapegoating” means assigning fault, blame, or bias to a race or sex, or to members of a race or sex because of their race or sex; and

“Race or sex stereotyping” means ascribing character traits, values, moral and ethical codes, privileges, status, or beliefs to a race or sex, or to an individual because of his or her race or sex.

Any person who believes a contractor has violated its nondiscrimination or affirmative action obligations under this notice should immediately contact the Office of Federal Contract Compliance Programs (OFCCP) Complaint Hotline to Combat Race and Sex Stereotyping at 202-343-2008 or via email at OFCCPComplaintHotline@dol.gov.
(End of notice)

(e) *Noncompliance.* In the event it is determined that the Contractor is not in compliance with this clause or any rule, regulation, or order of the Secretary of Labor, this contract may be canceled, terminated, or suspended in whole or in part, and the Contractor may be declared ineligible for further Government contracts, under the procedures authorized in E.O. 11246, as amended. In addition, sanctions may be imposed and remedies invoked against the Contractor as provided in E.O. 11246, as amended; in the rules, regulations, and orders of the Secretary of Labor; or as otherwise provided by law.

(f) *Subcontracts.* (1) The Contractor shall include the substance of this clause, including this paragraph (f), in all subcontracts that exceed \$10,000 and are not exempted by the rules, regulations, or orders of the Secretary of Labor issued under E.O. 11246, as amended, so that these terms and conditions will be binding upon each subcontractor.

(2) The Contractor shall take such action with respect to any subcontract as the Director of OFCCP may direct as a means of enforcing these terms and conditions, including sanctions for noncompliance, provided, that if the Contractor becomes involved in, or is threatened with, litigation with a subcontractor as a result of such direction, the Contractor may request the United States to enter into the litigation to protect the interests of the United States.

(End of clause)

SECTION J - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

The following have been modified:

ATTACHMENTS

Contract Data Requirements Listing

The below attachments are included by reference, with the same force and effect as if provided in the body of this contract by full text.

- 8.1. A001 – Biweekly Status and Kick Off Minutes
- 8.2. A002 - Scientific/Technical Study Plans/Reports
- 8.3. A003 – Quality Assurance Program Plan
- 8.4. A004 - Software Design Description (SDD)
- 8.5. A005 – System Operator Technical Manual & Training Materials
- 8.6. A006- Regulatory Strategy
- 8.7. A007 – Manufacturing Development Plan
- 8.8. A008 – FDA Correspondence/Engagements
- 8.9. A009 – Contractor Acquired Property Inventory

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT			1 CONTRACT ID CODE	PAGE OF PAGES
			J	1 12
2 AMENDMENT/MODIFICATION NO P00002	3 EFFECTIVE DATE 20-Jan-2021	4 REQUISITION/PURCHASE REQ NO 0011574631-0001	5 PROJECT NO (If applicable)	
6 ISSUED BY USA CONTRACT NG CMD-APG - W911SR EDGEWOOD CONTRACTING DIVISION 8456 BRIGADE STREET BLDG E4215 ABERDEEN PROVING GROUND MD 21010-5401	CODE W911SR	7 ADMINISTERED BY (If other than item 6) See Item 6		
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) WORLDS ENTERPRISES NC (b) (6) 5350 ALPHA RD DALLAS TX 75240-3428		9A. AMENDMENT OF SOLICITATION NO.		
		9B. DATED (SEE ITEM 11)		
		X 10A. MOD. OF CONTRACT/ORDER NO. W911SR21C0008		
		X 10B. DATED (SEE ITEM 13) 13-Nov-2020		
CODE 8KUF6	FACILITY CODE			
11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS				
<input type="checkbox"/> The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer <input type="checkbox"/> is extended, <input type="checkbox"/> is not extended. Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.				
12. ACCOUNTING AND APPROPRIATION DATA (If required)				
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: FAR 52.243-1, Changes				
D. OTHER (Specify type of modification and authority)				
E. IMPORTANT: Contractor <input type="checkbox"/> is not, <input checked="" type="checkbox"/> is required to sign this document and return <u>1</u> 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) \$0.00 Obligated a. See summary of changes.				
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) JENNIFER M. BUCHNESS / CONTRACTING OFFICER (b) (6)		
15B. CONTRACTOR/OFFEROR (Signature of person authorized to sign)	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA BY (b) (6) (Signature of Contracting Officer)	16C. DATE SIGNED 20-Jan-2021	

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT			1 CONTRACT ID CODE j	PAGE OF PAGES 1 12
2 AMENDMENT/MODIFICATION NO	3 EFFECTIVE DATE 20-jan-2021	4 REVISION/PURCHASE REF NO 0011574631-0001	5 PROJECT NO (If applicable)	
6 ISSUED BY USA CONTRACTING CMD-APG - W911SR EDGEWOOD CONTRACTING DIVISION 8456 BRIGADE STREET BLDG E4215 ABERDEEN PROVING GROUND MD 21010-5401	CODE W911SR	7 ADMINISTERED BY (If other than item 6) CODE		
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) WORLDS ENTERPRISES INC (b) (6) 5350 ALP A RD DALLAS TX 75240-3428		A. AMENDMENT OF SOLICITATION NO.		
		B. DATED (SEE ITEM 11)		
		X 1 A. MOD. OF CONTRACT/ORDER NO. W911SR21C0008		
		X 1 B. DATED (SEE ITEM 13) 13-Nov-2020		
CODE 8KUF6	FACILITY CODE			
11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS				
<input type="checkbox"/> The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer <input type="checkbox"/> is extended, <input type="checkbox"/> is not extended. Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.				
12. ACCOUNTING AND APPROPRIATION DATA (If required)				
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 1 A.				
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 43.1 3(B).				
X C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR 52.243-1, Changes				
D. OTHER (Specify type of modification and authority)				
E. IMPORTANT: Contractor <input type="checkbox"/> is not, <input checked="" type="checkbox"/> is required to sign this document and return <u>1</u> 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) \$0.00 Obligated a. See summary of changes.				
Except as provided herein, all terms and conditions of the document referenced in Item A or 1 A, 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)		
		TEL: _____ EMAIL: _____		
15B. CONTRACTING OFFICER (Signature)	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA BY _____ (Signature of Contracting Officer)	16C. DATE SIGNED	
(b) (6)				

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text:

SUMMARY OF CHANGES P00002

\$0.00 Obligated

a. The purpose of this modification is to extend the initial prototype delivery date from 21 January 2021 to No Later Than (NLT) 31 March 2021 as well as revise the initial training event date from 26 January 2021 to NLT 31 March 2021. The one-day training event will take place at the (b) (4). This mutually agreed upon extension is further described in the "Worlds Modification Request_ACC Addendum" dated 20 January 2021 (referenced herein) and is in accordance with section 4.5 of the Statement of Objectives (SOO) which allows for hardware and software modifications and improvements of the prototypes. This extension also allows for Government preparation and finalization of the initial testing event at a Government facility IAW section 4.8 of the SOO.

b. There is no additional cost associated with the extensions described above and the overall price remains unchanged.

c. IAW Class Deviation 2021-O0001 Rev 1 Combating Race and Sex Stereotyping, 252.222-7999 (DEVIATION 2021-O0001) (NOV 2020) is removed and replaced with the revised clause, 252.222-7999 (DEVIATION 2021-O0001) (JAN 2021).

d. This modification is a complete settlement as agreed by both parties. The contractor releases the Government from any and all liability resulting from this modification including interest, and for any other adjustments relating to the facts and circumstances arising out of the contractor's performance for all claims of unabsorbed and extended overhead.

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0001

The CLIN extended description has changed from:

The contractor shall provide (b) (4) prototype devices to detect for Volatile Organic Compounds (VOC) in a non-invasive manner as described in the attached Statement of Objectives (SOO). Unit price includes the cost to manufacture the devices, packaging and shipping, preparation and submission of Contract Data Requirements List (CDRL) A001 - A008, a Software license agreement for the duration of performance, troubleshooting, calibration, and repair of non-consumables, and all necessary consumables for the duration of performance. All devices shall be delivered to the initial location by 21 January 2021.

To:

The contractor shall provide (b) (4) prototype devices to detect for Volatile Organic Compounds (VOC) in a non-invasive manner as described in the attached Statement of Objectives (SOO). Unit price includes the cost to manufacture the devices, packaging and shipping, preparation and submission of Contract Data Requirements List (CDRL) A001 - A008, a Software license agreement for the duration of performance, troubleshooting, calibration,

and repair of non-consumables, and all necessary consumables for the duration of performance. All devices shall be delivered to the initial location NLT 31 March 2021.

SECTION C - DESCRIPTIONS AND SPECIFICATIONS

The following have been modified:

STATEMENT OF OBJECTIVES

STATEMENT OF OBJECTIVES (SOO) Non-Invasive Rapid Detection System (NIRDS) Phase 1 20 January 2021

1. BACKGROUND:

Technology to screen individuals for COVID-19 using Volatile Organic Compounds (VOC) in breath, within the order of magnitude of seconds, can be leveraged to combat the global COVID-19 pandemic and potential future bio-threats. VOCs are low molecular weight metabolic compounds present in human breath and may be indicative of infectious disease. COVID-19 critically impacts the DoDs' effectiveness and poses potential national security risks. Additionally, VOC-based diagnostics have great potential to be the next generation of screening tools for disease identification, infectious disease management, and natural/synthetic biological warfare early detection.

Current COVID-19 diagnostic procedures do not deliver rapid responses for effective infectious disease identification, management, and flexible mission planning due to result wait time in the order of magnitude of 1 day. Additionally, current diagnostic tools rely on end users or minimally trained personnel introducing significant human error margins that reduce field accuracy (b) (4). In order to maintain warfighter mission effectiveness, the DoD requires the cutting-edge capability to screen for COVID-19.

2. REQUIREMENT:

Rapidly deploy a non-invasive VOC analysis technology for infectious diseases such as COVID-19, in order to minimize Service member downtime, maximize mission effectiveness, and prevent the spread of COVID-19.

3. OBJECTIVE:

The Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) Non-Invasive Rapid Detection System (NIRDS) Program seeks to procure five (5) prototype screening devices and associated systems for Government optimization and verification testing in the intended use setting.

4. SCOPE:

- 4.1 Prototype devices and associated systems will be used in order for the Government to evaluate their potential to rapidly screen for COVID-19 in a non-invasive manner.
- 4.2 As the devices and associated systems procured under this award will not yet have obtained FDA authorization, they must be labeled, distributed and managed in accordance with applicable regulations (ie. 21 CFR 812 and 809).
- 4.3 These prototype devices will be used in research protocol in compliance with applicable laws, regulations, DoD policies and ethical standards regardless of their DoD-intramural/extramural nature or geographical location.

- 4.4 In part, the Government assessment of the systems will include correlation of the research data with de-identified validated clinical data. It will also include assessments of operational effectiveness and operational suitability. Operational effectiveness is a measure of the overall ability of a system to accomplish a mission when used by representative personnel in the environment planned or expected for operational employment of the system. Operational suitability is the degree to which a system can be placed and sustained satisfactorily in fielded use with consideration being given to availability, compatibility, transportability, natural environment effect and impacts, documentation, and training requirements.
- 4.5 The Government must be informed of and given the option to receive any hardware and software modification and improvements proposed or made to the commercial system being developed during the period of performance. Modifications and improvements on the prototype screening device hardware may include, but are not limited to, investigation into hardware upgrades and changes, Government Furnished Equipment (GFE) reuse (if requested by the government) and any additional hardware capabilities to assist in the requirement. Modifications and improvements on the prototype screening device software may include, but are not limited to software upgrades to the machine learning algorithm or upgrades to any other applicable software, and any additional software capabilities to assist in the requirement. The Contractor shall provide a Software Design Description (SDD) for the software release at the point of delivering prototype systems to the Government. The document shall describe the NIRDS analyzer software by functional area IAW Contract Data Requirements List (CDRL) A004.
- 4.6 (b) (4) prototype screening devices will be retained by the contractor and considered Contractor Acquired Property (CAP) and shall be inventoried when it arrives at its initial destination, and monthly thereafter IAW CDRL A009. The CAP shall be used strictly for the purposes of this contract effort to collect additional data to mature the algorithm and obtain data for regulatory filing with the FDA. The contractor shall provide Scientific/Study Plans for all testing conducted using CAP, to the government for review and comment within ten business day of contract award, IAW CDRL A002. The contractor shall provide biweekly status updates to the government program manager on the production, delivery, implementation, repairs, and training status of the CAP prototype devices, IAW CDRL A001. Additionally, the contractor shall provide biweekly updates on the accuracy, sensitivity, and specificity values of the algorithm, as well as, time to result based on tests performed with CAP IAW CDRL A001. Upon completion of the period of performance, the contractor shall promptly ship all CAP back to the Government in good, working condition IAW CDRL A009. Once delivered and accepted by the Government, the Government assumes title. All items meeting the IUID criteria of DFARS 211.274-2 shall be marked and reported in the IUID registry upon delivery IAW DFARS 252.211-7003.
- 4.7 (b) (4) prototype screening devices will be used in the government testing events at the locations in Table 1 below. The contractor shall review and if necessary, provide input to Government developed test plans and protocols. The contractor shall provide biweekly status updates to the government program manager on the production, delivery, implementation, repairs, and training status of the government testing prototype devices IAW CDRL A001. Additionally, the contractor shall provide biweekly updates on the accuracy, sensitivity, and specificity values of the algorithm, as well as, time to result, based on tests performed with government testing prototype devices IAW CDRL A001. The raw data collected by the prototypes on government installations shall be delivered to the government upon request IAW A002.
- 4.8 It is estimated that at least two testing events will occur during the contract period of performance. For proposal purposes, the contractor shall assume the following testing events listed below in Table 1. Actual events will be finalized with the contractor prior to commencement.

Table 1

Testing Event Location	Duration of Test Event
(b) (4)	

(b) (4)	

- 4.9 At the conclusion of the Period of Performance the contractor shall provide a Scientific/Technical Report in IAW CDRL A002.

4.10 Intellectual Property (IP)

Awardee represents that the intellectual property license(s) and other rights held by or granted to Awardee are sufficient to enable Awardee to perform its obligations under this award.

Background IP and Materials. The Awardee and the Government each retain any intellectual property (IP) rights to their own materials, technical data (as defined in DFARS 252.227-7013), technology, information, documents, or know-how—or potential rights, such as issued patents, patent applications, invention disclosures, copyrighted works, or other written documentation—that exist prior to execution of this award or are developed outside the scope of this award (“Background IP”).

Patent Indemnity. The Awardee 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 this award and Awardee’s actions under this award, provided the Awardee is reasonably notified of such claims and proceedings.

4.11 Data and Computer/Software Documentation Rights

Background Data. “Background Data” shall mean all technical data, as defined in DFARS 252.227-7013, that exists prior to execution of this award, or are developed outside the scope of this award. Awardee Background Data shall include any data associated with Awardee’s Background IP and Materials, that was not generated solely with Government funding. All Background Data shall be owned by the Awardee. The Government shall have the right, subject to applicable law and the terms of this award, to use, modify, reproduce, release, perform, display, or disclose Background Data only within the Government. The Government may, under a separate agreement or by bilateral modification to this award, negotiate rights to use or disclose the Awardee’s Background Data.

Technical Data. All data generated in connection with the performance of this award, or that arises out of the use of any materials or enabling technology provided or used by the Awardee in the performance of this award, other Awardee materials or Awardee confidential information, whether conducted by the Government or the Awardee (collectively, the “Technical Data”), shall be owned by the Awardee. The Government shall have the right, subject to applicable law and the terms of this award, to use, modify, reproduce, release, perform, display, or disclose data first produced in the performance of this award within the Government and otherwise for “Government Purpose Rights,” as this term is defined in DFARS 252.227-7013(a)(13).

Background Computer Software and Computer Software Documentation. “Background Computer Software and Computer Software Documentation” shall mean all computer software and computer software documentation, as defined in DFARS 252.227-7014(a)(4) and (5), that exists prior to execution of this award, or are developed outside the scope of this award. Awardee Background Computer Software and Computer Software Documentation shall include any computer software or software documentation associated with Awardee’s Background Computer Software and Computer Software Documentation, that was not generated with Government funding. All Background Computer Software and Computer Software Documentation shall be owned by the Awardee. The Government shall have the right, subject to compliance with applicable law, the terms of this award and the terms of applicable contracts, to use, release, perform, display, or disclose Background Computer Software and Computer Software Documentation solely within the Government. The

Government may, under a separate or by bilateral modification to this award, negotiate rights to use or disclose the Awardee's Background Computer Software and Computer Software Documentation.

Noncommercial Computer Software and Noncommercial Computer Software Documentation.

All noncommercial computer software and noncommercial computer software documentation data generated in connection with the performance of this award, or that arises out of the use of any materials or enabling technology provided or used by the Awardee in the performance of this award, (collectively, the "Agreement Software and Software Documentation"), shall be owned by the Awardee. The Government shall have the right, subject to compliance with applicable law and the terms of this award, to use, release, perform, display, or disclose data first produced in the performance of this award within the Government and otherwise for "Government Purpose Rights," as this term is defined in DFARS 252.227-7014(a)(12).

The Awardee agrees to retain and maintain in good condition until seven (7) years after completion or termination of this award, all Technical Data and all Agreement Software and Software Documentation generated under this award. In the event of exercise of the Government's rights hereunder, the Awardee agrees to deliver at no additional cost to the Government, all data, in Awardee's possession and developed under this award, necessary to deliver the supplies within sixty (60) calendar days from the date of the written request.

Marking of Data. The Awardee will mark any data delivered under this award with the following legend: "Use, duplication, or disclosure is subject to the restrictions as stated in Award No. W911SR-21-C-0008 between the Government and the Awardee."

Any rights that the Awardee or the Government may have in data delivered under this award, whether arising under this award or otherwise, will not be affected by Awardee's failure to mark data pursuant to this Article.

All other Technical Data and Software developed under funding of this award shall be delivered with Government Purpose rights as provided for within this Article.

The U.S. Government may purchase, under a separate agreement, a license for greater use of Background IP and Materials, Background Data, Background Computer Software and Computer Software Documentation, Technical Data and Agreement Software and Software Documentation as necessary. Such agreement will be negotiated between the parties in good faith at customary industry rates and under commercially reasonable terms and conditions.

5. TECHNICAL REQUIREMENTS

5.1. Performance Parameters:

5.1.1. The delivery of the prototype devices shall be No Later Than (NLT) 31 March 2021. The testing period of performance is four (4) months.

5.1.2. The prototype screening devices shall provide rapid screening results.

5.1.3. The prototype screening devices shall provide non-invasive screening; using breath and not blood, saliva (excluding aerosolized breath particles), or any other bodily fluid.

5.1.4. The prototype screening devices shall be dual communication enabled through Wi-Fi and Global System for Mobile Communications (GSM). The contractor shall provide data rates for up to 75GB for U.S. coverage for the duration of the performance period.

5.1.5. The prototype screening devices shall include all hardware for a fully functioning prototype to include a (b) (4) and all disposable support equipment.

5.2. Regulatory and Quality Requirements:

- 5.2.1. Systems shall be labeled, distributed and managed in accordance with applicable laws and regulations (i.e.21 CFR 812 and 809)
- 5.2.2. Receipt, management and use of de-identified comparator clinical data shall be in accordance with applicable regulations, policies, and standards for human subjects and data protections as well as device design control.
- 5.2.3. The contractor shall provide a manufacturing development plan IAW CDRL A007, and a quality assurance program plan IAW CDRL A003.
- 5.2.4. Proposed or planned hardware and software modification and improvements must be done in accordance with applicable regulations and standards for design control.
- 5.2.5. The contractor shall provide a Regulatory Strategy IAW CDRL A006 and documentation of FDA correspondence and engagements IAW CDRL A008.

5.3. Management Requirements:

The contractor shall provide biweekly status updates to the government program manager on the production, delivery, implementation, repairs, and training status of the prototype devices IAW CDRL A001.

- 5.3.1. The contractor shall maintain a qualified staff at all times. The Government restricts access or work hereunder to United States citizens only. All cybersecurity risk management related positions must have baseline certifications as designated in DoD Approved 8570 Baseline Certifications (DoD 8570.01M) prior to employment.
- 5.3.2. Travel costs shall conform to FAR 31.205- 46 and be in accordance with the Federal Travel Regulations. Travel can only be conducted upon prior approval by the government program manager with a copy of the request furnished to the Contracting Officer. If unexpected travel due to unplanned system outage is required, the contractor must show due diligence that costs were kept to a minimum. For proposal purposes, the contractor shall assume only the following; travel for two trainers to conduct a one day training event at the testing location listed in table 1.
- 5.3.3. If contractor personnel cannot physically travel due to COVID-19 travel restrictions, the following contingency plan will be implemented: (1) Remote connectivity to each unit will be performed via an internal built-in Ethernet router that offers both a physical port and WiFi access; (2) the contractor will leverage trained Government personnel on-site to provide video to provide visual support and assistance; (3) the contractor will leverage trained Government personnel on-site to provide hands-on support for parts replacement at the FRU (Field Replaceable Unit) level; and/or (4) should all travel options be prohibited, as a last resort, the unit could be repackaged and shipped to contractor for repair.
- 5.3.4. The contractor is required to hold a virtual kick off meeting within 10 calendar days of contract award and submit meeting minutes IAW CDRL A001. The specific date and time shall be coordinated with the government program manager at least five (5) calendar days prior to the proposed meeting. The structure and content is at the contractor's discretion but should include at a minimum a project schedule outline and identification/introduction of key personnel.

5.4. Support Requirements:

- 5.4.1. The contractor shall provide maintenance support to the devices for the entire period of performance of the contract. The maintenance and support shall include equipment calibration, troubleshooting, and repair of all non-consumable items (8x5 support).
- 5.4.2. The prototype screening devices shall include a 4 month software license from date of delivery.
- 5.4.3. The contractor shall provide on-site training at the direction of the government on the prototype screening device implementation, equipment calibration, system startup and shutdown, system operation, testing procedures, data analysis, and system trouble shooting. Training occurs at the prototype system deployment location. Training shall be for the duration of 1 day. Virtual training shall be permitted in the event that travel restrictions prohibit travel to deployment locations.
- 5.4.4. The contractor shall provide an Operator's Manual and Instructions for Use with the delivery of each prototype screening device IAW CDRL A005.

6. REFERENCE DOCUMENTS

DoDM 5200.01
DoDM 5105.21
DoD-5220.22M
DoD 8570.01M
DOD 3216.02I
21 CFR 50, 52, 54, 801, 803, 812, 820

7. DATA DELIVERABLE ITEMS

- 7.1. A001 – Biweekly Status and Kick Off Minutes
- 7.2. A002 - Scientific/Technical Study Plans/Reports
- 7.3. A003 – Quality Assurance Program Plan
- 7.4. A004 - Software Design Description (SDD)
- 7.5. A005 – System Operator Technical Manual & Training Materials
- 7.6. A006- Regulatory Strategy
A007 – Manufacturing Development Plan
- 7.7. A008 – FDA Correspondence/Engagements
- 7.8. A009 – Contractor Acquired Property Inventory

8. POINTS OF CONTACT

Program Management

(b) (6)
JPEO JPM CBRN Medical

(b) (6)

Contracting Officer

(b) (6)
Army Contracting Command – Aberdeen Proving Ground
Edgewood Contracting Division

(b) (6)

SECTION F - DELIVERIES OR PERFORMANCE

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

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 13-NOV-2020 TO 21-MAY-2021	N/A	(b) (6) [Redacted] [Redacted] [Redacted] FOB: Destination	W56XNH

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 13-NOV-2020 TO 30-JUL-2021	N/A	(b) (6) [REDACTED] [REDACTED] [REDACTED] FOB: Destination	W56XNH

The following Delivery Schedule item for CLIN 0002 has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
26-JAN-2021	1	(b) (6) [REDACTED] [REDACTED] [REDACTED] FOB: Destination	W56XNH

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
31-MAR-2021	1	(b) (6) [REDACTED] [REDACTED] [REDACTED] FOB: Destination	W56XNH

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

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 26-JAN-2021 TO 21-MAY-2021	N/A	(b) (6) [REDACTED] [REDACTED] [REDACTED] FOB: Destination	W56XNH

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
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POP 26-JAN-2021 TO 30-JUL-2021	N/A	(b) (6) [REDACTED] [REDACTED] [REDACTED]	W56XNH
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FOB: Destination

The following Delivery Schedule item for CLIN 0004 has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 13-NOV-2020 TO 21-MAY-2021	N/A	(b) (6) [REDACTED] [REDACTED] [REDACTED]	W56XNH

FOB: Destination

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 13-NOV-2020 TO 30-JUL-2021	N/A	(b) (6) [REDACTED] [REDACTED] [REDACTED]	W56XNH

FOB: Destination

SECTION I - CONTRACT CLAUSES

The following have been modified:

252.222-7999 DEVIATION

252.222-7999 Combating Race and Sex Stereotyping (DEVIATION 2021-O0001)

COMBATING RACE AND SEX STEREOTYPING

(DEVIATION 2021-O0001) (JAN 2021)

Notice: On December 22, 2020, the United States District Court for the Northern District of California issued a preliminary injunction, enjoining Sections 4 and 5 of Executive Order 13950 "Combating Race and Sex Stereotyping." So long as the December 22, 2020 preliminary injunction remains in force, the Government shall not enforce any provisions contained in Government contracts or subcontracts added pursuant to Section 4(a) of Executive Order 13950; the Government shall not cancel, terminate, suspend in whole or in part, any contractor or subcontractors' Government contracts, nor declare any contractor or subcontractor ineligible for further Government contracts, nor impose any other sanctions, on the basis of purported noncompliance with the Executive Order or any agency action implementing Section 4 or 5 of the Executive Order; and the Government will not require contractors or subcontractors to provide notice of any commitments under the Executive Order or any contract term inserted pursuant to the Executive Order to their respective labor unions or employee representatives. To the extent that you have included the Executive Order's provisions in subcontracts, please provide them with a copy of this notice.

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

“Race or sex scapegoating” means assigning fault, blame, or bias to a race or sex, or to members of a race or sex because of their race or sex.

“Race or sex stereotyping” means ascribing character traits, values, moral and ethical codes, privileges, status, or beliefs to a race or sex, or to an individual because of his or her race or sex.

(b) *Exemptions.* The exemptions that apply to Executive Order (E.O.) 11246 (see FAR 22.807) also apply to E.O. 13950 and the requirements of this clause.

(c) *Compliance with E.O. 13950, Combating Race and Sex Stereotyping.* Unless exempted under paragraph (b) of this clause, the Contractor shall not use any workplace training that inculcates in its employees any form of race or sex stereotyping or any form of race or sex scapegoating, including the concepts that—

- (1) One race or sex is inherently superior to another race or sex;
- (2) An individual, by virtue of his or her race or sex, is inherently racist, sexist, or oppressive, whether consciously or unconsciously;
- (3) An individual should be discriminated against or receive adverse treatment solely or partly because of his or her race or sex;
- (4) Members of one race or sex cannot and should not attempt to treat others without respect to race or sex;
- (5) An individual’s moral character is necessarily determined by his or her race or sex;
- (6) An individual, by virtue of his or her race or sex, bears responsibility for actions committed in the past by other members of the same race or sex;
- (7) Any individual should feel discomfort, guilt, anguish, or any other form of psychological distress on account of his or her race or sex; or
- (8) Meritocracy or traits such as a hard work ethic are racist or sexist, or were created by a particular race to oppress another race.

(d) *Notice.* The Contractor shall send, to each labor union or representative of workers with which it has a collective bargaining agreement or other contract or understanding, the notice provided below advising the labor union or workers’ representative of the Contractor’s commitments under this clause, and post copies of the notice in conspicuous places available to employees and applicants for employment.

NOTICE

E.O. 13950, Combating Race and Sex Stereotyping Employers Holding Federal Contracts or Subcontracts

Contractors shall not use any workplace training that inculcates in its employees any form of race or sex stereotyping or any form of race or sex scapegoating, including the following concepts that—

- (1) One race or sex is inherently superior to another race or sex;
- (2) An individual, by virtue of his or her race or sex, is inherently racist, sexist, or oppressive, whether consciously or unconsciously;
- (3) An individual should be discriminated against or receive adverse treatment solely or partly because of his or her race or sex;
- (4) Members of one race or sex cannot and should not attempt to treat others without respect to race or sex;
- (5) An individual’s moral character is necessarily determined by his or her race or sex;
- (6) An individual, by virtue of his or her race or sex, bears responsibility for actions committed in the past by other members of the same race or sex;
- (7) Any individual should feel discomfort, guilt, anguish, or any other form of psychological distress on account of his or her race or sex; or
- (8) Meritocracy or traits such as a hard work ethic are racist or sexist, or were created by a particular race to oppress another race.

For use in this notice—

“Race or sex scapegoating” means assigning fault, blame, or bias to a race or sex, or to members of a race or sex because of their race or sex; and

“Race or sex stereotyping” means ascribing character traits, values, moral and ethical codes, privileges, status, or beliefs to a race or sex, or to an individual because of his or her race or sex.

Any person who believes a contractor has violated its nondiscrimination or affirmative action obligations under this notice should immediately contact the Office of Federal Contract Compliance Programs (OFCCP) Complaint Hotline to Combat Race and Sex Stereotyping at 202-343-2008 or via email at OFCCPComplaintHotline@dol.gov.
(End of notice)

(e) *Noncompliance.* In the event it is determined that the Contractor is not in compliance with this clause or any rule, regulation, or order of the Secretary of Labor, this contract may be canceled, terminated, or suspended in whole or in part, and the Contractor may be declared ineligible for further Government contracts, under the procedures authorized in E.O. 11246, as amended. In addition, sanctions may be imposed and remedies invoked against the Contractor as provided in E.O. 11246, as amended; in the rules, regulations, and orders of the Secretary of Labor; or as otherwise provided by law.

(f) *Subcontracts.* (1) The Contractor shall include the substance of this clause, including this paragraph (f), in all subcontracts that exceed \$10,000 and are not exempted by the rules, regulations, or orders of the Secretary of Labor issued under E.O. 11246, as amended, so that these terms and conditions will be binding upon each subcontractor.

(2) The Contractor shall take such action with respect to any subcontract as the Director of OFCCP may direct as a means of enforcing these terms and conditions, including sanctions for noncompliance, provided, that if the Contractor becomes involved in, or is threatened with, litigation with a subcontractor as a result of such direction, the Contractor may request the United States to enter into the litigation to protect the interests of the United States.

(End of clause)

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT				1 CONTRACT ID CODE J	PAGE OF PAGES 1 10	
2 AMENDMENT/MODIFICATION NO P00003	3 EFFECTIVE DATE 27-May-2021	4 REQUISITION/PURCHASE REQ NO SEE SCHEDULE		5 PROJECT NO (If applicable)		
6 ISSUED BY USA CONTRACT NG CMD-APG. - W911SR EDGEWOOD CONTRACTING DIVISION 8456 BRIGADE STREET BLDG E4215 ABERDEEN PROVING GROUND MD 21010-5401	CODE W911SR	7 ADMINISTERED BY (If other than item 6) See Item 6				
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) WORLDS ENTERPRISES NC (b) (6) 5350 ALPHA RD DALLAS TX 75240-3428				9A. AMENDMENT OF SOLICITATION NO.		
				9B. DATED (SEE ITEM 11)		
				X	10A. MOD. OF CONTRACT/ORDER NO. W911SR21C0008	
				X	10B. DATED (SEE ITEM 13) 13-Nov-2020	
CODE 8KUF6	FACILITY CODE					
11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS						
<input type="checkbox"/> The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer <input type="checkbox"/> is extended, <input type="checkbox"/> is not extended Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.						
12. ACCOUNTING AND APPROPRIATION DATA (If required) See Schedule						
13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.						
X	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. FAR 52.243-1, Changes					
	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).					
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:					
	D. OTHER (Specify type of modification and authority)					
E. IMPORTANT: Contractor <input type="checkbox"/> is not, <input checked="" type="checkbox"/> is required to sign this document and return <u>1</u> 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) \$0 Obligated a. The purpose of this modification is to transfer one (1) additional prototype to the contractor to be utilized as Contractor Acquired Property (CAP) for the duration of contract performance as well as realign remaining funds on CLIN 0001 to CLIN 0005 to allow for final billing. See Summary of Changes. c. This modification is a complete settlement as agreed by both parties. The contractor releases the Government from any and all liability resulting from this modification including interest, and for any other adjustments relating to the facts and circumstances arising out of the contractor's performance for all claims of unabsorbed and extended overhead.						
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) (6) / CONTRACTING OFFICER (b) (6)			
15B. CONTRACTOR/OFFEROR (Signature of person authorized to sign)	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA BY (b) (6) (Signature of Contracting Officer)		16C. DATE SIGNED 27-May-2021		

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT				1 CONTRACT ID CODE	PAGE OF PAGES
				J	1 10
2 AMENDMENT/MODIFICATION NO	3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO SEE SCHEDULE		5 PROJECT NO (If applicable)	
6 ISSUED BY USA CONTRACT NG CMD-APG - W911SR EDGEWOOD CONTRACTING DIVISION 8456 BRIGADE STREET BLDG E4215 ABERDEEN PROVING GROUND MD 21010-5401	CODE W911SR	7 ADMINISTERED BY (If other than item 6) See Item 6		CODE	
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) WORLD'S ENTERPRISES NC (b) (6) 5350 ALPHARD DALLAS TX 75240-3428				9A. AMENDMENT OF SOLICITATION NO.	
				9B. DATED (SEE ITEM 11)	
				X 10A. MOD. OF CONTRACT/ORDER NO. W911SR21C0008	
				X 10B. DATED (SEE ITEM 13) 13-Nov-2020	
CODE 8KUF6	FACILITY CODE				
11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS					
<input type="checkbox"/> The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of offer <input type="checkbox"/> is extended, <input type="checkbox"/> is not extended.					
<p>Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods:</p> <p>(a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.</p>					
12. ACCOUNTING AND APPROPRIATION DATA (If required) See Schedule					
13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.					
X	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. FAR 52.243-1, Changes				
	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).				
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:				
	D. OTHER (Specify type of modification and authority)				
E. IMPORTANT: Contractor <input type="checkbox"/> is not, <input checked="" type="checkbox"/> 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) \$0 Obligated					
<p>a. The purpose of this modification is to transfer one (1) additional prototype to the contractor to be utilized as Contractor Acquired Property (CAP) for the duration of contract performance as well as realign remaining funds on CLIN 0001 to CLIN 0005 to allow for final billing. See Summary of Changes.</p> <p>c. This modification is a complete settlement as agreed by both parties. The contractor releases the Government from any and all liability resulting from this modification including interest, and for any other adjustments relating to the facts and circumstances arising out of the contractor's performance for all claims of unabsorbed and extended overhead.</p>					
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) (b) (6)			16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) TEL: _____ EMAIL: _____		
15B. CONTRACTOR/OFFICER (b) (6) (Signature of person authorized to sign)		15C. DATE SIGNED 05/25/21	16B. UNITED STATES OF AMERICA BY _____ (Signature of Contracting Officer)		16C. DATE SIGNED

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text:

SUMMARY OF CHANGES P00003

\$0.00 Obligated

- a. The purpose of this modification is to transfer (b) (4) additional prototype to the contractor to be utilized as Contractor Acquired Property (CAP) for the duration of contract performance. (b) (4) CAP shall be used for the purposes outlined in section 4.6 of the Statement of Objectives, shall be properly inventoried IAW CDRL 0009, and shall be returned promptly to the Government upon contract conclusion. Neither the overall price nor the period of performance is increased or extended as a result of this transfer.
- b. (b) (4) has been deobligated from CLIN 0001 and realigned to CLIN 0005 to allow for final billing upon conclusion of the contract.

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0001

The CLIN extended description has changed from:

The contractor shall provide (b) (4) prototype devices to detect for Volatile Organic Compounds (VOC) in a non-invasive manner as described in the attached Statement of Objectives (SOO). Unit price includes the cost to manufacture the devices, packaging and shipping, preparation and submission of Contract Data Requirements List (CDRL) A001 - A008, a Software license agreement for the duration of performance, troubleshooting, calibration, and repair of non-consumables, and all necessary consumables for the duration of performance. All devices shall be delivered to the initial location NLT 31 March 2021.

To:

The contractor shall provide (b) (4) prototype devices to detect for Volatile Organic Compounds (VOC) in a non-invasive manner as described in the attached Statement of Objectives (SOO). Unit price includes the cost to manufacture the devices, packaging and shipping, preparation and submission of Contract Data Requirements List (CDRL) A001 - A009, a Software license agreement for the duration of performance, troubleshooting, calibration, and repair of non-consumables, and all necessary consumables for the duration of performance. All devices shall be delivered to the initial location NLT 31 March 2021.

The unit price amount has decreased by (b) (4).

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

(b) (4).

CLIN 0004

The CLIN extended description has changed from:

The contractor shall complete data requirements as described in the attached SOO and Contract Data Requirements Lists (CDRLs) Exhibits (A001 - A008). This CLIN is Not Separately Priced (NSP)

To:

The contractor shall complete data requirements as described in the attached SOO and Contract Data Requirements Lists (CDRLs) Exhibits (A001 - A009). This CLIN is Not Separately Priced (NSP)

CLIN 0005 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0005	Prototype Screening Devices FFP		Job	(b) (4)	(b) (4)
The remaining funds on CLIN 0001 for Prototype Screening Devices is hereby realigned to CLIN 0005 for final invoicing purposes.					
FOB: Destination					
PURCHASE REQUEST NUMBER: 0011645821					
PSC CD: AN22					

NET AMT (b) (4)

ACRN AA (b) (4)
CIN: GFEB001164582100001

SECTION C - DESCRIPTIONS AND SPECIFICATIONS

The following have been modified:

STATEMENT OF OBJECTIVES

**STATEMENT OF OBJECTIVES (SOO)
Non-Invasive Rapid Detection System (NIRDS) Phase 1
20 January 2021**

1. **BACKGROUND:**

Technology to screen individuals for COVID-19 using Volatile Organic Compounds (VOC) in breath, within the order of magnitude of seconds, can be leveraged to combat the global COVID-19 pandemic and potential future bio-threats. VOCs are low molecular weight metabolic compounds present in human breath and may be indicative of infectious disease. COVID-19 critically impacts the DoDs' effectiveness and poses potential national security risks. Additionally, VOC-based diagnostics have great potential to be the next generation of screening tools for disease identification, infectious disease management, and natural/synthetic biological warfare early detection.

Current COVID-19 diagnostic procedures do not deliver rapid responses for effective infectious disease identification, management, and flexible mission planning due to result wait time in the order of magnitude of 1 day. Additionally, current diagnostic tools rely on end users or minimally trained personnel introducing significant human error margins that reduce field accuracy (b) (4). In order to maintain warfighter mission effectiveness, the DoD requires the cutting-edge capability to screen for COVID-19.

2. **REQUIREMENT:**

Rapidly deploy a non-invasive VOC analysis technology for infectious diseases such as COVID-19, in order to minimize Service member downtime, maximize mission effectiveness, and prevent the spread of COVID-19.

3. **OBJECTIVE:**

The Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) Non-Invasive Rapid Detection System (NIRDS) Program seeks to procure (b) (4) prototype screening devices and associated systems for Government optimization and verification testing in the intended use setting.

4. **SCOPE:**

- 4.1 Prototype devices and associated systems will be used in order for the Government to evaluate their potential to rapidly screen for COVID-19 in a non-invasive manner.
- 4.2 As the devices and associated systems procured under this award will not yet have obtained FDA authorization, they must be labeled, distributed and managed in accordance with applicable regulations (ie. 21 CFR 812 and 809).
- 4.3 These prototype devices will be used in research protocol in compliance with applicable laws, regulations, DoD policies and ethical standards regardless of their DoD-intramural/extramural nature or geographical location.
- 4.4 In part, the Government assessment of the systems will include correlation of the research data with de-identified validated clinical data. It will also include assessments of operational effectiveness and operational suitability. Operational effectiveness is a measure of the overall ability of a system to accomplish a mission when used by representative personnel in the environment planned or expected for operational employment of the system. Operational suitability is the degree to which a system can be placed and sustained satisfactorily in fielded use with consideration being given to

availability, compatibility, transportability, natural environment effect and impacts, documentation, and training requirements.

4.5 The Government must be informed of and given the option to receive any hardware and software modification and improvements proposed or made to the commercial system being developed during the period of performance. Modifications and improvements on the prototype screening device hardware may include, but are not limited to, investigation into hardware upgrades and changes, Government Furnished Equipment (GFE) reuse (if requested by the government) and any additional hardware capabilities to assist in the requirement. Modifications and improvements on the prototype screening device software may include, but are not limited to software upgrades to the machine learning algorithm or upgrades to any other applicable software, and any additional software capabilities to assist in the requirement. The Contractor shall provide a Software Design Description (SDD) for the software release at the point of delivering prototype systems to the Government. The document shall describe the NIRDS analyzer software by functional area IAW Contract Data Requirements List (CDRL) A004.

4.6 (b) (4) prototype screening devices will be retained by the contractor and considered Contractor Acquired Property (CAP) and shall be inventoried when it arrives at its initial destination, and monthly thereafter IAW CDRL A009. The CAP shall be used strictly for the purposes of this contract effort to collect additional data to mature the algorithm and obtain data for regulatory filing with the FDA. The contractor shall provide Scientific/Study Plans for all testing conducted using CAP, to the government for review and comment within ten business day of contract award, IAW CDRL A002. The contractor shall provide biweekly status updates to the government program manager on the production, delivery, implementation, repairs, and training status of the CAP prototype devices, IAW CDRL A001. Additionally, the contractor shall provide biweekly updates on the accuracy, sensitivity, and specificity values of the algorithm, as well as, time to result based on tests performed with CAP IAW CDRL A001. Upon completion of the period of performance, the contractor shall promptly ship all CAP back to the Government in good, working condition IAW CDRL A009. Once delivered and accepted by the Government, the Government assumes title. All items meeting the IUID criteria of DFARS 211.274-2 shall be marked and reported in the IUID registry upon delivery IAW DFARS 252.211-7003.

4.7 (b) (4) prototype screening devices will be used in the government testing events at the locations in Table 1 below. The contractor shall review and if necessary, provide input to Government developed test plans and protocols. The contractor shall provide biweekly status updates to the government program manager on the production, delivery, implementation, repairs, and training status of the government testing prototype devices IAW CDRL A001. Additionally, the contractor shall provide biweekly updates on the accuracy, sensitivity, and specificity values of the algorithm, as well as, time to result, based on tests performed with government testing prototype devices IAW CDRL A001. The raw data collected by the prototypes on government installations shall be delivered to the government upon request IAW A002.

4.8 It is estimated that at least two testing events will occur during the contract period of performance. For proposal purposes, the contractor shall assume the following testing events listed below in Table 1. Actual events will be finalized with the contractor prior to commencement.

Table 1

Testing Event Location	Duration of Test Event
(b) (4)	

4.9 At the conclusion of the Period of Performance the contractor shall provide a Scientific/Technical Report in IAW CDRL A002.

4.10 Intellectual Property (IP)

Awardee represents that the intellectual property license(s) and other rights held by or granted to Awardee are sufficient to enable Awardee to perform its obligations under this award.

Background IP and Materials. The Awardee and the Government each retain any intellectual property (IP) rights to their own materials, technical data (as defined in DFARS 252.227-7013), technology, information, documents, or know-how—or potential rights, such as issued patents, patent applications, invention disclosures, copyrighted works, or other written documentation—that exist prior to execution of this award or are developed outside the scope of this award (“Background IP”).

Patent Indemnity. The Awardee 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 this award and Awardee’s actions under this award, provided the Awardee is reasonably notified of such claims and proceedings.

4.11 **Data and Computer/Software Documentation Rights**

Background Data. “Background Data” shall mean all technical data, as defined in DFARS 252.227-7013, that exists prior to execution of this award, or are developed outside the scope of this award. Awardee Background Data shall include any data associated with Awardee’s Background IP and Materials, that was not generated solely with Government funding. All Background Data shall be owned by the Awardee. The Government shall have the right, subject to applicable law and the terms of this award, to use, modify, reproduce, release, perform, display, or disclose Background Data only within the Government. The Government may, under a separate agreement or by bilateral modification to this award, negotiate rights to use or disclose the Awardee’s Background Data.

Technical Data. All data generated in connection with the performance of this award, or that arises out of the use of any materials or enabling technology provided or used by the Awardee in the performance of this award, other Awardee materials or Awardee confidential information, whether conducted by the Government or the Awardee (collectively, the "Technical Data"), shall be owned by the Awardee. The Government shall have the right, subject to applicable law and the terms of this award, to use, modify, reproduce, release, perform, display, or disclose data first produced in the performance of this award within the Government and otherwise for "Government Purpose Rights," as this term is defined in DFARS 252.227-7013(a)(13).

Background Computer Software and Computer Software Documentation. “Background Computer Software and Computer Software Documentation” shall mean all computer software and computer software documentation, as defined in DFARS 252.227-7014(a)(4) and (5), that exists prior to execution of this award, or are developed outside the scope of this award. Awardee Background Computer Software and Computer Software Documentation shall include any computer software or software documentation associated with Awardee’s Background Computer Software and Computer Software Documentation, that was not generated with Government funding. All Background Computer Software and Computer Software Documentation shall be owned by the Awardee. The Government shall have the right, subject to compliance with applicable law, the terms of this award and the terms of applicable contracts, to use, release, perform, display, or disclose Background Computer Software and Computer Software Documentation solely within the Government. The Government may, under a separate or by bilateral modification to this award, negotiate rights to use or disclose the Awardee’s Background Computer Software and Computer Software Documentation.

Noncommercial Computer Software and Noncommercial Computer Software Documentation. All noncommercial computer software and noncommercial computer software documentation data generated in connection with the performance of this award, or that arises out of the use of any materials or enabling technology provided or used by the Awardee in the performance of this award, (collectively, the "Agreement Software and Software Documentation"), shall be owned by the

Awardee. The Government shall have the right, subject to compliance with applicable law and the terms of this award, to use, release, perform, display, or disclose data first produced in the performance of this award within the Government and otherwise for "Government Purpose Rights," as this term is defined in DFARS 252.227-7014(a)(12).

The Awardee agrees to retain and maintain in good condition until seven (7) years after completion or termination of this award, all Technical Data and all Agreement Software and Software Documentation generated under this award. In the event of exercise of the Government's rights hereunder, the Awardee agrees to deliver at no additional cost to the Government, all data, in Awardee's possession and developed under this award, necessary to deliver the supplies within sixty (60) calendar days from the date of the written request.

Marking of Data. The Awardee will mark any data delivered under this award with the following legend: "Use, duplication, or disclosure is subject to the restrictions as stated in Award No. W911SR-21-C-0008 between the Government and the Awardee."

Any rights that the Awardee or the Government may have in data delivered under this award, whether arising under this award or otherwise, will not be affected by Awardee's failure to mark data pursuant to this Article.

All other Technical Data and Software developed under funding of this award shall be delivered with Government Purpose rights as provided for within this Article.

The U.S. Government may purchase, under a separate agreement, a license for greater use of Background IP and Materials, Background Data, Background Computer Software and Computer Software Documentation, Technical Data and Agreement Software and Software Documentation as necessary. Such agreement will be negotiated between the parties in good faith at customary industry rates and under commercially reasonable terms and conditions.

5. TECHNICAL REQUIREMENTS

5.1. Performance Parameters:

- 5.1.1. **The delivery of the prototype devices shall be No Later Than (NLT) 31 March 2021. The testing period of performance is four (4) months.**
- 5.1.2. The prototype screening devices shall provide rapid screening results.
- 5.1.3. The prototype screening devices shall provide non-invasive screening; using breath and not blood, saliva (excluding aerosolized breath particles), or any other bodily fluid.
- 5.1.4. The prototype screening devices shall be dual communication enabled through Wi-Fi and Global System for Mobile Communications (GSM). The contractor shall provide data rates for up to 75GB for U.S. coverage for the duration of the performance period.
- 5.1.5. The prototype screening devices shall include all hardware for a fully functioning prototype to include a (b) (4) and all disposable support equipment.

5.2. Regulatory and Quality Requirements:

- 5.2.1. Systems shall be labeled, distributed and managed in accordance with applicable laws and regulations (i.e. 21 CFR 812 and 809)
- 5.2.2. Receipt, management and use of de-identified comparator clinical data shall be in accordance with applicable regulations, policies, and standards for human subjects and data protections as well as device design control.
- 5.2.3. The contractor shall provide a manufacturing development plan IAW CDRL A007, and a quality assurance program plan IAW CDRL A003.

- 5.2.4. Proposed or planned hardware and software modification and improvements must be done in accordance with applicable regulations and standards for design control.
- 5.2.5. The contractor shall provide a Regulatory Strategy IAW CDRL A006 and documentation of FDA correspondence and engagements IAW CDRL A008.

5.3. Management Requirements:

The contractor shall provide biweekly status updates to the government program manager on the production, delivery, implementation, repairs, and training status of the prototype devices IAW CDRL A001.

- 5.3.1. The contractor shall maintain a qualified staff at all times. The Government restricts access or work hereunder to United States citizens only. All cybersecurity risk management related positions must have baseline certifications as designated in DoD Approved 8570 Baseline Certifications (DoD 8570.01M) prior to employment.
- 5.3.2. Travel costs shall conform to FAR 31.205- 46 and be in accordance with the Federal Travel Regulations. Travel can only be conducted upon prior approval by the government program manager with a copy of the request furnished to the Contracting Officer. If unexpected travel due to unplanned system outage is required, the contractor must show due diligence that costs were kept to a minimum. For proposal purposes, the contractor shall assume only the following; travel for two trainers to conduct a one day training event at the testing location listed in table 1.
- 5.3.3. If contractor personnel cannot physically travel due to COVID-19 travel restrictions, the following contingency plan will be implemented: (1) Remote connectivity to each unit will be performed via an internal built-in Ethernet router that offers both a physical port and WiFi access; (2) the contractor will leverage trained Government personnel on-site to provide video to provide visual support and assistance; (3) the contractor will leverage trained Government personnel on-site to provide hands-on support for parts replacement at the FRU (Field Replaceable Unit) level; and/or (4) should all travel options be prohibited, as a last resort, the unit could be repackaged and shipped to contractor for repair.
- 5.3.4. The contractor is required to hold a virtual kick off meeting within 10 calendar days of contract award and submit meeting minutes IAW CDRL A001. The specific date and time shall be coordinated with the government program manager at least five (5) calendar days prior to the proposed meeting. The structure and content is at the contractor's discretion but should include at a minimum a project schedule outline and identification/introduction of key personnel.

5.4. Support Requirements:

- 5.4.1. The contractor shall provide maintenance support to the devices for the entire period of performance of the contract. The maintenance and support shall include equipment calibration, troubleshooting, and repair of all non-consumable items (8x5 support).
- 5.4.2. The prototype screening devices shall include a 4 month software license from date of delivery.
- 5.4.3. The contractor shall provide on-site training at the direction of the government on the prototype screening device implementation, equipment calibration, system startup and shutdown, system operation, testing procedures, data analysis, and system trouble shooting. Training occurs at the prototype system deployment location. Training shall be for the duration of 1 day. Virtual training shall be permitted in the event that travel restrictions prohibit travel to deployment locations.
- 5.4.4. The contractor shall provide an Operator's Manual and Instructions for Use with the delivery of each prototype screening device IAW CDRL A005.

6. REFERENCE DOCUMENTS

DoDM 5200.01

DoDM 5105.21

DoD-5220.22M

DoD 8570.01M

DOD 3216.02I
21 CFR 50, 52, 54, 801, 803, 812, 820

7. DATA DELIVERABLE ITEMS

- 7.1. A001 – Biweekly Status and Kick Off Minutes
- 7.2. A002 - Scientific/Technical Study Plans/Reports
- 7.3. A003 – Quality Assurance Program Plan
- 7.4. A004 - Software Design Description (SDD)
- 7.5. A005 – System Operator Technical Manual & Training Materials
- 7.6. A006- Regulatory Strategy
A007 – Manufacturing Development Plan
- 7.7. A008 – FDA Correspondence/Engagements
- 7.8. A009 – Contractor Acquired Property Inventory

8. POINTS OF CONTACT

Program Management

(b) (6)

JPEO JPM CBRN Medical

(b) (6)

Contracting Officer

(b) (6)

Army Contracting Command – Aberdeen Proving Ground

Edgewood Contracting Division

(b) (6)

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for CLIN 0005:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
Destination	Government	Destination	Government

SECTION F - DELIVERIES OR PERFORMANCE

The following Delivery Schedule for CLIN 0005 has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
30-JUL-2021	1	(b) (6) FOB: Destination	W56XNH

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

CLIN 0001:

AA: 5703600 290 RL4B 645350 68WXL0 58800 64858F 503000 F03000 JON:99930000 ESP:C1
CSN:J0XQD7 ALD:AA FSR: 065086 A5XAF (CIN GFEB001157463100001) was (b) (4)

CLIN 0005:

Funding on CLIN 0005 is initiated as follows:

ACRN: AA

CIN: GFEB001164582100001

Acctng Data: 5703600 290 RL4B 645350 68WXL0 58800 64858F 503000 F03000 JON:99930000 ESP:C1
CSN:J0XQD7 ALD:AA FSR: 065086

Increase: (b) (4)

Total: (b) (4)

Cost Code: A5XAF

(End of Summary of Changes)

CONTRACT DATA REQUIREMENTS LIST
(1 Data Item)

Form Approved
OMB No. 0704-0188

The public reporting burden for this collection of information is estimated to average 110 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 and Communications 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.

A. CONTRACT LINE ITEM NO.	B. EXHIBIT J-1	C. CATEGORY: TDP _____ TM _____ OTHER _____
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D. SYSTEM/ITEM NIRDS	E. CONTRACT/PR NO. TBD	F. CONTRACTOR Worlds Enterprises Inc.
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1. DATA ITEM NO. A001	2. TITLE OF DATA ITEM Status Report	3. SUBTITLE Biweekly Status Update & Kick Off Minutes
---------------------------------	-----------------------------------------------	-----------------------------------------------------------------

4. AUTHORITY (Data Acquisition Document No.) DI-MGMT-80368A	5. CONTRACT REFERENCE SOO Para 4.6; 4.7; 5.3; 5.3.3	6. REQUIRING OFFICE JPEO-CBRND
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7. DD 250 REQ No No	9. DIST STATEMENT REQUIRED	10. FREQUENCY WEEKLY	12. DATE OF FIRST SUBMISSION See Block 16	14. DISTRIBUTION												
8. APP CODE N/A	C	11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION See Block 16	<table border="1"> <tr> <th>a. ADDRESSEE</th> <th colspan="3">b. COPIES</th> </tr> <tr> <th></th> <th>Draft</th> <th colspan="2">Final</th> </tr> <tr> <th></th> <th></th> <th>Reg</th> <th>Repro</th> </tr> </table>	a. ADDRESSEE	b. COPIES				Draft	Final				Reg	Repro
a. ADDRESSEE	b. COPIES															
	Draft	Final														
		Reg	Repro													

16. REMARKS	JPEO PM	1	1	
	Regulatory Affairs	1	1	
15. TOTAL	▶	2	2	0

G. PREPARED BY	H. DATE	I. APPROVED BY	J. DATE
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17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

Reset

CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

A. CONTRACT LINE ITEM NO.	B. EXHIBIT J-1	C. CATEGORY: TDP _____ TM _____ OTHER _____
D. SYSTEM/ITEM NIRDS	E. CONTRACT/PR NO. TBD	F. CONTRACTOR Worlds Enterprises Inc.

16. REMARKS *(Continued)*

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 <i>(1 Data Item)</i>	<i>Form Approved</i> OMB No. 0704-0188
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The public reporting burden for this collection of information is estimated to average 110 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 and Communications 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.

A. CONTRACT LINE ITEM NO.	B. EXHIBIT J-1	C. CATEGORY: TDP _____ TM _____ OTHER _____
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D. SYSTEM/ITEM NIRDS	E. CONTRACT/PR NO. TBD	F. CONTRACTOR Worlds Enterprises Inc.
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1. DATA ITEM NO. A002	2. TITLE OF DATA ITEM Scientific and Technical Study Plans/Protocols and Study Reports	3. SUBTITLE
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4. AUTHORITY (Data Acquisition Document No.) DI-MS- 80711	5. CONTRACT REFERENCE SOO Para 4.6; 4.7; 4.9; 5.2	6. REQUIRING OFFICE JPEO-CBRND
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7. DD 250 REQ No	9. DIST STATEMENT REQUIRED C	10. FREQUENCY ASREQ	12. DATE OF FIRST SUBMISSION ASREQ	14. DISTRIBUTION		
8. APP CODE N/A	11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION ASREQ		a. ADDRESSEE	b. COPIES	
					Draft	Final
						Reg
						Repro

17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

16. REMARKS 1. The Contractor shall provide Scientific and Technical Study Plans/Protocols within ten business days of contract award and Scientific and Technical Study Reports with 30 calendar days of the end of the period of performance IAW SOO requirements. 2. Format. Submit in electronic format in Microsoft Office (Word, Excel & PowerPoint) or in another format approved by the Government. 3. Block 12 - The contractor shall provide study plans/protocols and reports to support the prototype that the Government is procuring. Test plans and reports shall include supportive data on how the contractor tested sensitivity and specificity of the system (biomarkers, software algorithm) to support the claim that the device can identify subjects that have COVID-19. 4. Distribution Statement. Study Plans/Protocols and Study Reports distribution is authorized to only the DoD staff and their support contractors engaged on this effort. 5. Block 14 - Distribution and addresses. All Test Plans/Protocols and Study Reports and related documents must be electronically forwarded to the following addresses: (b) (6)	JPEO PM	1	1		
	Regulatory Affairs	1	1		
15. TOTAL →					
		2	2	0	

G. PREPARED BY	H. DATE	I. APPROVED BY	J. DATE
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CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

A. CONTRACT LINE ITEM NO.	B. EXHIBIT J-1	C. CATEGORY: TDP _____ TM _____ OTHER _____
D. SYSTEM/ITEM NIRDS	E. CONTRACT/PR NO. TBD	F. CONTRACTOR Worlds Enterprises Inc.

16. REMARKS *(Continued)*

INSTRUCTIONS FOR COMPLETING DD FORM 1423

(See DoD 5010.12-M for detailed instructions.)

FOR GOVERNMENT PERSONNEL

- Item A.** Self-explanatory.
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- Item C.** Mark (X) appropriate category: TDP - Technical Data Package; TM - Technical Manual; Other - other category of data, such as "Provisioning," "Configuration Management," etc.
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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 <i>(1 Data Item)</i>	Form Approved OMB No. 0704-0188
----------------------------------------------------------------	------------------------------------

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A. CONTRACT LINE ITEM NO.	B. EXHIBIT J-1	C. CATEGORY: TDP _____ TM _____ OTHER _____
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D. SYSTEM/ITEM NIRDS	E. CONTRACT/PR NO. W911SR-21-C-0008	F. CONTRACTOR Worlds Enterprises Inc.
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1. DATA ITEM NO. A003	2. TITLE OF DATA ITEM Quality Assurance Program Plan	3. SUBTITLE
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4. AUTHORITY <i>(Data Acquisition Document No.)</i> DI-QCIC-81198	5. CONTRACT REFERENCE SOO Para 5.2.3	6. REQUIRING OFFICE JPEO-CBRND
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7. DD 250 REQ No	9. DIST STATEMENT REQUIRED C	10. FREQUENCY ASREQ	12. DATE OF FIRST SUBMISSION See block 16	14. DISTRIBUTION		
8. APP CODE N/A		11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION See block 16	a. ADDRESSEE	b. COPIES	
					Draft	Final
					Reg	Repro

16. REMARKS

Block 4. The Data Item Description (DID) may be obtained at:
<http://quicksearch.dla.mil>

Block 5: The Quality Assurance Program Plan shall be in Contractor format and detail all information, instructions, and documentation necessary to product an FDA compliant quality device. A draft Quality Assurance Program Plan shall be submitted within 30 calendar days of contract award for Government's approval. A final Quality Assurance Program Plan shall be submitted within 30 calendar days of the one-day training event for Government's approval. The Quality Assurance program Plan shall reflect the stage of development for the prototype.

Block 14 - Distribution and addresses. The Quality Assurance Program Plan and related documents must be electronically forwarded to the following addresses:

(b) (6)

JPEO PM	1	1	0
Regulatory Affairs	1	1	
15. TOTAL →	2	2	0

17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

G. PREPARED BY	H. DATE	I. APPROVED BY	J. DATE
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CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

A. CONTRACT LINE ITEM NO.	B. EXHIBIT J-1	C. CATEGORY: TDP _____ TM _____ OTHER _____
D. SYSTEM/ITEM NIRDS	E. CONTRACT/PR NO. W911SR-21-C-0008	F. CONTRACTOR Worlds Enterprises Inc.

16. REMARKS *(Continued)*

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.
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- 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

(1 Data Item)

Form Approved
OMB No. 0704-0188

The public reporting burden for this collection of information is estimated to average 110 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 and Communications 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.

A. CONTRACT LINE ITEM NO.	B. EXHIBIT J-1	C. CATEGORY: TDP _____ TM _____ OTHER _____
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D. SYSTEM/ITEM NIRDS	E. CONTRACT/PR NO. W911SR-21-C-0008	F. CONTRACTOR Worlds Enterprises Inc.
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1. DATA ITEM NO. A004	2. TITLE OF DATA ITEM NIRDS Software Design Description (SDD), Other Software Documents	3. SUBTITLE Software Design Description
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4. AUTHORITY (Data Acquisition Document No.) DI-IPSC-81435A NOT 1	5. CONTRACT REFERENCE SOO 5.2	6. REQUIRING OFFICE JPEO-CBRND
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7. DD 250 REQ No	9. DIST STATEMENT REQUIRED C	10. FREQUENCY ASREQ	12. DATE OF FIRST SUBMISSION See block 16	14. DISTRIBUTION		
8. APP CODE N/A		11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION See block 16	a. ADDRESSEE	b. COPIES	
					Draft	Final
					Reg	Repro

17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

<p>16. REMARKS</p> <p>Block 4. The Data Item Description (DID) may be obtained at: http://quicksearch.dla.mil.</p> <p>The Contractor shall provide a Software Design Description (SDD) for the software release at the point of delivering prototype systems to the Government. The document shall describe the NIRDS analyzer software by functional area. The document shall include descriptive information if there are internal software updates on-going in parallel.</p> <p>The Contractor shall provide the following information as applicable</p> <ul style="list-style-type: none"> (1) Component Type (Diagnostics Device, Mobile Phone/Tablet, Laptop) (2) Machine Name (Name of Dx Device, Type of Laptop, etc) (3) All Operating Systems and Firmware, including version numbers <p>The Contractor shall provide the draft SDD within 14 business days after contract award. The Government will respond with comments within 10 business days. The Contractor shall provide an updated SDD within 5 business days of the prototype delivery and the Government will respond with comments within 10 business days. The final SDD shall be delivered within 30 calendar days of the end of the period of performance.</p> <p>Block 14 - Distribution and addresses. The Software Design Description (SDD) and related documents must be submitted in electronic format in Microsoft Office (Word, Excel & PowerPoint) or in another format approved by the Government to:</p> <p>(b) (6)</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 70%;"></th> <th style="width: 10%;">Draft</th> <th colspan="2" style="width: 20%;">Final</th> </tr> <tr> <th></th> <th></th> <th style="width: 10%;">Reg</th> <th style="width: 10%;">Repro</th> </tr> </thead> <tbody> <tr> <td>JPEO PM</td> <td style="text-align: center;">1</td> <td style="text-align: center;">1</td> <td></td> </tr> <tr> <td>Regulatory Affairs</td> <td style="text-align: center;">1</td> <td style="text-align: center;">1</td> <td></td> </tr> <tr><td> </td><td></td><td></td><td></td></tr> <tr><td> </td><td></td><td></td><td></td></tr> <tr><td> </td><td></td><td></td><td></td></tr> <tr><td> </td><td></td><td></td><td></td></tr> <tr><td> </td><td></td><td></td><td></td></tr> <tr><td> </td><td></td><td></td><td></td></tr> <tr><td> </td><td></td><td></td><td></td></tr> <tr><td> </td><td></td><td></td><td></td></tr> <tr><td> </td><td></td><td></td><td></td></tr> <tr><td> </td><td></td><td></td><td></td></tr> <tr><td> </td><td></td><td></td><td></td></tr> <tr><td> </td><td></td><td></td><td></td></tr> <tr><td> </td><td></td><td></td><td></td></tr> <tr><td> </td><td></td><td></td><td></td></tr> <tr><td> </td><td></td><td></td><td></td></tr> <tr><td> </td><td></td><td></td><td></td></tr> <tr><td> </td><td></td><td></td><td></td></tr> <tr><td> </td><td></td><td></td><td></td></tr> <tr><td> </td><td></td><td></td><td></td></tr> <tr><td> </td><td></td><td></td><td></td></tr> <tr><td> </td><td></td><td></td><td></td></tr> <tr> <td>15. TOTAL</td> <td style="text-align: center;">2</td> <td style="text-align: center;">2</td> <td style="text-align: center;">0</td> </tr> </tbody> </table>		Draft	Final				Reg	Repro	JPEO PM	1	1		Regulatory Affairs	1	1																																																																																						15. TOTAL	2	2	0
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G. PREPARED BY	H. DATE	I. APPROVED BY	J. DATE
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CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

A. CONTRACT LINE ITEM NO.	B. EXHIBIT J-1	C. CATEGORY: TDP _____ TM _____ OTHER _____
D. SYSTEM/ITEM NIRDS	E. CONTRACT/PR NO. W911SR-21-C-0008	F. CONTRACTOR Worlds Enterprises Inc.

16. REMARKS *(Continued)*

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.
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- Item G.** Signature of preparer of CDRL.
- Item H.** Date CDRL was prepared.
- Item I.** Signature of CDRL approval authority.
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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.

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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
(1 Data Item)

Form Approved
OMB No. 0704-0188

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A. CONTRACT LINE ITEM NO.		B. EXHIBIT J-1		C. CATEGORY: TDP _____ TM _____ OTHER _____								
D. SYSTEM/ITEM NIRDS			E. CONTRACT/PR NO. W911SR-21-C-0008		F. CONTRACTOR Worlds Enterprises Inc.							
1. DATA ITEM NO. A005	2. TITLE OF DATA ITEM NIRDS Technical Operator Manual & Training Materials			3. SUBTITLE Operator's Manual								
4. AUTHORITY (Data Acquisition Document No.) DI-MISC-81414A		5. CONTRACT REFERENCE SOO Para 5.4.4			6. REQUIRING OFFICE JPEO-CBRND							
7. DD 250 REQ No	9. DIST STATEMENT REQUIRED C	10. FREQUENCY ASREQ		12. DATE OF FIRST SUBMISSION See block 16		14. DISTRIBUTION						
8. APP CODE N/A		11. AS OF DATE		13. DATE OF SUBSEQUENT SUBMISSION See block 16		a. ADDRESSEE						
16. REMARKS				JPEO PM				1	1			
				Regulatory Affairs				1	1			
<p>Block 4. The Data Item Description (DID) may be obtained at: http://quicksearch.dla.mil</p> <p>The Contractor shall provide a technical operator manual within 5 business days of prototype delivery to include any publication, illustrated parts breakdown or other forms of documented necessary to install, operate, or provide logistics repair support on-site for the system. Within 10 business days upon receipt, or 3 business days prior to the one-day training event (whichever occurs first), the Government will provide comments. The final technical operator manual is due within 10 business days after the one-day training event.</p> <p>Contractor format is acceptable.</p> <p>Block 14 - Distribution and addresses. All Technical Operator Manuals, Instructions for Use, Training Materials and related documents must be electronically forwarded to the following addresses:</p> <p>(b) (6)</p>												
				15. TOTAL	→	2	2	0				
G. PREPARED BY			H. DATE		I. APPROVED BY		J. DATE					

17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

CONTRACT DATA REQUIREMENTS LIST

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16. REMARKS *(Continued)*

INSTRUCTIONS FOR COMPLETING DD FORM 1423

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CONTRACT DATA REQUIREMENTS LIST <i>(1 Data Item)</i>							<i>Form Approved</i> <i>OMB No. 0704-0188</i>			
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A. CONTRACT LINE ITEM NO.			B. EXHIBIT J-1		C. CATEGORY: TDP _____ TM _____ OTHER _____					
D. SYSTEM/ITEM NIRDS			E. CONTRACT/PR NO. W911SR-21-C-0008		F. CONTRACTOR Worlds Enterprises Inc.					
1. DATA ITEM NO. A006	2. TITLE OF DATA ITEM NIRDS Regulatory Strategy				3. SUBTITLE					
4. AUTHORITY (Data Acquisition Document No.) DI-MSC-80508B			5. CONTRACT REFERENCE SOO Para 5.2.5			6. REQUIRING OFFICE JPEO-CBRND				
7. DD 250 REQ No	9. DIST STATEMENT REQUIRED C		10. FREQUENCY ASREQ		12. DATE OF FIRST SUBMISSION See block 16		14. DISTRIBUTION			
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							Draft	Final		
								Reg	Repro	
16. REMARKS Block 4. The Data Item Description (DID) may be obtained at: http://quicksearch.dla.mil The Contractor shall provide a draft regulatory strategy in MS Word within 10 business days of contract award that describes the regulatory pathway for FDA regulatory approval/clearance that includes but not limited to the following: (a) Product Nomenclature and Classification – describe product name; proposed trade name; device panel (FDA review center and review division); classification (Class I, II, III). If not yet classified, details regarding the 513(g) Request for Information submission to the FDA to obtain FDA evaluation and ruling on how device should be classified, regulation number, and product code. (References: Classification Regulations 21 CFR Parts 862-892; section 513(g) of the FD&C Act, 21 USC 360c(g)). (b) Device Description – concise summary and explanation of the medical device that may include: Key design features such as new technology or is the technology similar to an identified predicate; number of component parts the device will have and descriptions; device included software; technical features of the device which restricts user environment; or any other descriptive elements that describes what the medical device is and does (e.g., engineering diagrams, pictures of the finished device, physical properties, chemical composition, labeling instructions). (c) Intended use/indications for use statement (i.e., how it will be used) such as target patient population(s); use environment (e.g., home, hospital, military, field use, etc.); target user(s) (e.g., military users, trained laboratory or medical professional, untrained lay person, etc.; description of use environment (e.g., combat support hospital, hospital, ambulance, home, etc.); and target. (d) Regulatory Pathway – describe how the device will be regulated; proposed type of marketing applications (e.g., Class I Exempt, Class I or II requiring Premarket Notification (§510k), de novo submission, or Class III Pre-market Approval Application [PMA]); key data considerations to extent known; list of key risks/barriers to proposed pathways; and discussion of relevant FDA guidance.							JPEO PM	1	1	
							Regulatory Affairs	1	1	
15. TOTAL →							2	2	0	
G. PREPARED BY			H. DATE		I. APPROVED BY			J. DATE		

17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

A. CONTRACT LINE ITEM NO.	B. EXHIBIT J-1	C. CATEGORY: TDP _____ TM _____ OTHER _____
D. SYSTEM/ITEM NIRDS	E. CONTRACT/PR NO. W911SR-21-C-0008	F. CONTRACTOR Worlds Enterprises Inc.

16. REMARKS *(Continued)*

Block 16 Continued.

(e) Current development status and regulatory status of the product and previous FDA interactions or submissions.

(f) For those devices that will potentially require a 510(k), provide information about the proposed predicate and approach to substantial equivalence (predicate analysis) identifying relevant similarities or differences in areas such as intended use; indications for use; target population; anatomical site; use environment; human factors; energy used/delivered; design; materials; performance; chemical composition; chemical characteristics etc. as applicable to the type of device or in vitro diagnostic being developed.

(g) Life Cycle Considerations – describe future device generations, modifications, indications, or claims that will build on prior/initial/subsequent approvals or clearances.

(h) Previous regulatory communication information – describe information or commitments from previous meetings with regulatory agencies (e.g., tracking table of previous communications, interactions, and submissions with submission numbers where applicable).

The Contractor shall provide a subsequent draft regulatory strategy in MS Word within 10 business days of the one-day training event. The Government will provide comments within 10 business days of receipt. The final regulatory strategy shall be provided in MS Word within 30 calendar days of the end of the period of performance.

Block 14 - Distribution and addresses. The Regulatory Strategy and related documents must be electronically forwarded to the following addresses:

(b) (6) [Redacted]

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.

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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.

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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

(1 Data Item)

A. CONTRACT LINE ITEM NO.	B. EXHIBIT J-1	C. CATEGORY: TDP _____ TM _____ OTHER _____
D. SYSTEM/ITEM NIRDS	E. CONTRACT/PR NO. W911SR-21-C-0008	F. CONTRACTOR Worlds Enterprises Inc.

16. REMARKS *(Continued)*

INSTRUCTIONS FOR COMPLETING DD FORM 1423

(See DoD 5010.12-M for detailed instructions.)

FOR GOVERNMENT PERSONNEL

- Item A.** Self-explanatory.
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CONTRACT DATA REQUIREMENTS LIST
(1 Data Item)

Form Approved
OMB No. 0704-0188

The public reporting burden for this collection of information is estimated to average 110 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 and Communications 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.

A. CONTRACT LINE ITEM NO.	B. EXHIBIT J-1	C. CATEGORY: TDP _____ TM _____ OTHER _____
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D. SYSTEM/ITEM NIRDS	E. CONTRACT/PR NO. TBD	F. CONTRACTOR Worlds Enterprises Inc.
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1. DATA ITEM NO. A008	2. TITLE OF DATA ITEM Technical Report Study/Services	3. SUBTITLE FDA Correspondence/Engagements
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4. AUTHORITY (Data Acquisition Document No.) DI-MS-80508B	5. CONTRACT REFERENCE SOO Para 5.2.5	6. REQUIRING OFFICE JPEO-CBRND
---------------------------------------------------------------------	------------------------------------------------	------------------------------------------

7. DD 250 REQ No	9. DIST STATEMENT REQUIRED C	10. FREQUENCY ASREQ	12. DATE OF FIRST SUBMISSION See block 16	14. DISTRIBUTION		
8. APP CODE N/A		11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION See block 16	a. ADDRESSEE	b. COPIES	
					Draft	Final
					Reg	Repro

16. REMARKS

Block 4. The Data Item Description (DID) may be obtained at:
<http://quicksearch.dla.mil>

The Contractor shall provide all FDA communication and documentation related to meetings and submissions. By Sponsor designation as FDA co-contact, the JPEO-CBRND Senior Director Medical Regulatory or representative shall receive copies of sponsor meeting request letters or submissions, briefing packages, meeting minutes, FDA contact reports, informal and email communications, official communication letters, and the Emergency Use Authorization submission package (cover letters and required forms/templates completed).

Block 14 - Distribution and addresses. FDA correspondence/engagement documents shall be submitted in electronic format in Microsoft Office (Word, Excel & PowerPoint) or in another format approved by the Government to:

(b) (6) [REDACTED]

a. ADDRESSEE	b. COPIES		
	Draft	Reg	Repro
JPEO PM	1	1	
Regulatory Affairs	1	1	
15. TOTAL	2	2	0

G. PREPARED BY	H. DATE	I. APPROVED BY	J. DATE
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17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

A. CONTRACT LINE ITEM NO.	B. EXHIBIT J-1	C. CATEGORY: TDP _____ TM _____ OTHER _____
D. SYSTEM/ITEM NIRDS	E. CONTRACT/PR NO. TBD	F. CONTRACTOR Worlds Enterprises Inc.

16. REMARKS (Continued)

Block 16 Continued.

INSTRUCTIONS FOR COMPLETING DD FORM 1423

(See DoD 5010.12-M for detailed instructions.)

FOR GOVERNMENT PERSONNEL

- Item A.** Self-explanatory.
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- Item H.** Date CDRL was prepared.
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- Item 1.** See DoD FAR Supplement Subpart 4.71 for proper numbering.
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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

(1 Data Item)

A. CONTRACT LINE ITEM NO.	B. EXHIBIT	C. CATEGORY: TDP _____ TM _____ OTHER _____
D. SYSTEM/ITEM NIRDS	E. CONTRACT/PR NO. W911SR-21-C-0008	F. CONTRACTOR Worlds Enterprises Inc.

16. REMARKS (Continued)

Block 16 Continued.

INSTRUCTIONS FOR COMPLETING DD FORM 1423

(See DoD 5010.12-M for detailed instructions.)

FOR GOVERNMENT PERSONNEL

- Item A.** Self-explanatory.
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CONTRACT DATA REQUIREMENTS LIST
(1 Data Item)

Form Approved
OMB No. 0704-0188

The public reporting burden for this collection of information is estimated to average 110 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 and Communications 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.

A. CONTRACT LINE ITEM NO.	B. EXHIBIT J-1	C. CATEGORY: TDP _____ TM _____ OTHER _____
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D. SYSTEM/ITEM NIRDS	E. CONTRACT/PR NO. TBD	F. CONTRACTOR Worlds Enterprises Inc.
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1. DATA ITEM NO. A002	2. TITLE OF DATA ITEM Scientific and Technical Study Plans/Protocols and Study Reports	3. SUBTITLE
--------------------------	-------------------------------------------------------------------------------------------	-------------

4. AUTHORITY (Data Acquisition Document No.) DI-MS-C- 80711	5. CONTRACT REFERENCE SOO Para 4.6; 4.7; 4.9; 5.2	6. REQUIRING OFFICE JPEO-CBRND
----------------------------------------------------------------	------------------------------------------------------	-----------------------------------

7. DD 250 REQ No	9. DIST STATEMENT REQUIRED C	10. FREQUENCY ASREQ	12. DATE OF FIRST SUBMISSION ASREQ	14. DISTRIBUTION		
8. APP CODE N/A					11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION ASREQ

16. REMARKS

1. The Contractor shall provide Scientific and Technical Study Plans/Protocols within ten business days of contract award and Scientific and Technical Study Reports with 30 calendar days of the end of the period of performance IAW SOO requirements.

2. Format. Submit in electronic format in Microsoft Office (Word, Excel & PowerPoint) or in another format approved by the Government.

3. Block 12 - The contractor shall provide study plans/protocols and reports to support the prototype that the Government is procuring. Test plans and reports shall include supportive data on how the contractor tested sensitivity and specificity of the system (biomarkers, software algorithm) to support the claim that the device can identify subjects that have COVID-19.

4. Distribution Statement. Study Plans/Protocols and Study Reports distribution is authorized to only the DoD staff and their support contractors engaged on this effort.

5. Block 14 - Distribution and addresses. All Test Plans/Protocols and Study Reports and related documents must be electronically forwarded to the following addresses:

(b) (6) [REDACTED]

a. ADDRESSEE	b. COPIES		
	Draft	Final Reg	Final Repro
JPEO PM	1	1	
Regulatory Affairs	1	1	
15. TOTAL	2	2	0

17. PRICE GROUP

18. ESTIMATED
TOTAL PRICE

G. PREPARED BY	H. DATE	I. APPROVED BY	J. DATE
----------------	---------	----------------	---------

CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

A. CONTRACT LINE ITEM NO.	B. EXHIBIT J-1	C. CATEGORY: TDP _____ TM _____ OTHER _____
D. SYSTEM/ITEM NIRDS	E. CONTRACT/PR NO. TBD	F. CONTRACTOR Worlds Enterprises Inc.

16. REMARKS *(Continued)*

INSTRUCTIONS FOR COMPLETING DD FORM 1423

(See DoD 5010.12-M for detailed instructions.)

FOR GOVERNMENT PERSONNEL

- Item A.** Self-explanatory.
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CONTRACT DATA REQUIREMENTS LIST
(1 Data Item)

Form Approved
OMB No. 0704-0188

The public reporting burden for this collection of information is estimated to average 110 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 and Communications 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.

A. CONTRACT LINE ITEM NO.	B. EXHIBIT J-1	C. CATEGORY: TDP _____ TM _____ OTHER _____
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D. SYSTEM/ITEM NIRDS	E. CONTRACT/PR NO. W911SR-21-C-0008	F. CONTRACTOR Worlds Enterprises Inc.
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1. DATA ITEM NO. A003	2. TITLE OF DATA ITEM Quality Assurance Program Plan	3. SUBTITLE
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4. AUTHORITY (Data Acquisition Document No.) DI-QCIC-81198	5. CONTRACT REFERENCE SOO Para 5.2.3	6. REQUIRING OFFICE JPEO-CBRND
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7. DD 250 REQ No	9. DIST STATEMENT REQUIRED C	10. FREQUENCY ASREQ	12. DATE OF FIRST SUBMISSION See block 16	14. DISTRIBUTION		
8. APP CODE N/A		11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION See block 16	a. ADDRESSEE	b. COPIES	

16. REMARKS	a. ADDRESSEE	b. COPIES		
		Draft	Final Reg	Repro
	JPEO PM	1	1	
	Regulatory Affairs	1	1	
15. TOTAL →		2	2	0

G. PREPARED BY	H. DATE	I. APPROVED BY	J. DATE
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17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

A. CONTRACT LINE ITEM NO.	B. EXHIBIT J-1	C. CATEGORY: TDP _____ TM _____ OTHER _____
D. SYSTEM/ITEM NIRDS	E. CONTRACT/PR NO. W911SR-21-C-0008	F. CONTRACTOR Worlds Enterprises Inc.

16. REMARKS *(Continued)*

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
(1 Data Item)

Form Approved
OMB No. 0704-0188

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A. CONTRACT LINE ITEM NO.	B. EXHIBIT J-1	C. CATEGORY: TDP _____ TM _____ OTHER _____
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D. SYSTEM/ITEM NIRDS	E. CONTRACT/PR NO. W911SR-21-C-0008	F. CONTRACTOR Worlds Enterprises Inc.
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1. DATA ITEM NO. A004	2. TITLE OF DATA ITEM NIRDS Software Design Description (SDD), Other Software Documents	3. SUBTITLE Software Design Description
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4. AUTHORITY (Data Acquisition Document No.) DI-IPSC-81435A NOT 1	5. CONTRACT REFERENCE SOO 5.2	6. REQUIRING OFFICE JPEO-CBRND
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7. DD 250 REQ No	9. DIST STATEMENT REQUIRED C	10. FREQUENCY ASREQ	12. DATE OF FIRST SUBMISSION See block 16	14. DISTRIBUTION		
8. APP CODE N/A		11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION See block 16	a. ADDRESSEE	b. COPIES	
					Draft	Final

17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

<p>16. REMARKS</p> <p>Block 4. The Data Item Description (DID) may be obtained at: http://quicksearch.dla.mil</p> <p>The Contractor shall provide a Software Design Description (SDD) for the software release at the point of delivering prototype systems to the Government. The document shall describe the NIRDS analyzer software by functional area. The document shall include descriptive information if there are internal software updates on-going in parallel.</p> <p>The Contractor shall provide the following information as applicable</p> <ol style="list-style-type: none"> (1) Component Type (Diagnostics Device, Mobile Phone/Tablet, Laptop) (2) Machine Name (Name of Dx Device, Type of Laptop, etc) (3) All Operating Systems and Firmware, including version numbers <p>The Contractor shall provide the draft SDD within 14 business days after contract award. The Government will respond with comments within 10 business days. The Contractor shall provide an updated SDD within 5 business days of the prototype delivery and the Government will respond with comments within 10 business days. The final SDD shall be delivered within 30 calendar days of the end of the period of performance.</p> <p>Block 14 - Distribution and addresses. The Software Design Description (SDD) and related documents must be submitted in electronic format in Microsoft Office (Word, Excel & PowerPoint) or in another format approved by the Government to:</p> <p>(b) (6)</p>	<table border="1" style="width:100%"> <tr> <td>JPEO PM</td> <td>1</td> <td>1</td> <td></td> </tr> <tr> <td>Regulatory Affairs</td> <td>1</td> <td>1</td> <td></td> </tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr> <td>15. TOTAL</td> <td>2</td> <td>2</td> <td>0</td> </tr> </table>	JPEO PM	1	1		Regulatory Affairs	1	1																																																																																														15. TOTAL	2	2	0
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G. PREPARED BY	H. DATE	I. APPROVED BY	J. DATE
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CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

A. CONTRACT LINE ITEM NO.	B. EXHIBIT J-1	C. CATEGORY: TDP _____ TM _____ OTHER _____
D. SYSTEM/ITEM NIRDS	E. CONTRACT/PR NO. W911SR-21-C-0008	F. CONTRACTOR Worlds Enterprises Inc.

16. REMARKS *(Continued)*

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.
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- Item F.** Self-explanatory (to be filled in after contract award).
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- 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.
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- 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.
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CONTRACT DATA REQUIREMENTS LIST
(1 Data Item)

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A. CONTRACT LINE ITEM NO.	B. EXHIBIT J-1	C. CATEGORY: TDP _____ TM _____ OTHER _____
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D. SYSTEM/ITEM NIRDS	E. CONTRACT/PR NO. W911SR-21-C-0008	F. CONTRACTOR Worlds Enterprises Inc.
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1. DATA ITEM NO. A005	2. TITLE OF DATA ITEM NIRDS Technical Operator Manual & Training Materials	3. SUBTITLE Operator's Manual
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4. AUTHORITY (Data Acquisition Document No.) DI-MISC-81414A	5. CONTRACT REFERENCE SOO Para 5.4.4	6. REQUIRING OFFICE JPEO-CBRND
-----------------------------------------------------------------------	------------------------------------------------	------------------------------------------

7. DD 250 REQ No	9. DIST STATEMENT REQUIRED C	10. FREQUENCY ASREQ	12. DATE OF FIRST SUBMISSION See block 16	14. DISTRIBUTION			
8. APP CODE N/A		11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION See block 16	a. ADDRESSEE	b. COPIES		
					Draft	Final	
						Reg	Repro

16. REMARKS Block 4. The Data Item Description (DID) may be obtained at: http://quicksearch.dla.mil The Contractor shall provide a technical operator manual within 5 business days of prototype delivery to include any publication, illustrated parts breakdown or other forms of documented necessary to install, operate, or provide logistics repair support on-site for the system. Within 10 business days upon receipt, or 3 business days prior to the one-day training event (whichever occurs first), the Government will provide comments. The final technical operator manual is due within 10 business days after the one-day training event. Contractor format is acceptable. Block 14 - Distribution and addresses. All Technical Operator Manuals, Instructions for Use, Training Materials and related documents must be electronically forwarded to the following addresses: (b) (6)	JPEO PM	1	1		
	Regulatory Affairs	1	1		
15. TOTAL →	2	2	0		

G. PREPARED BY	H. DATE	I. APPROVED BY	J. DATE
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17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

A. CONTRACT LINE ITEM NO.	B. EXHIBIT J-1	C. CATEGORY: TDP _____ TM _____ OTHER _____
D. SYSTEM/ITEM NIRDS	E. CONTRACT/PR NO. W911SR-21-C-0008	F. CONTRACTOR Worlds Enterprises Inc.

16. REMARKS *(Continued)*

INSTRUCTIONS FOR COMPLETING DD FORM 1423

(See DoD 5010.12-M for detailed instructions.)

FOR GOVERNMENT PERSONNEL

- Item A.** Self-explanatory.
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CONTRACT DATA REQUIREMENTS LIST
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A. CONTRACT LINE ITEM NO.	B. EXHIBIT J-1	C. CATEGORY: TDP _____ TM _____ OTHER _____
----------------------------------	--------------------------	-------------------------------------------------------

D. SYSTEM/ITEM NIRDS	E. CONTRACT/PR NO. W911SR-21-C-0008	F. CONTRACTOR Worlds Enterprises Inc.
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1. DATA ITEM NO. A006	2. TITLE OF DATA ITEM NIRDS Regulatory Strategy	3. SUBTITLE
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4. AUTHORITY (Data Acquisition Document No.) DI-MSC-80508B	5. CONTRACT REFERENCE SOO Para 5.2.5	6. REQUIRING OFFICE JPEO-CBRND
----------------------------------------------------------------------	------------------------------------------------	------------------------------------------

7. DD 250 REQ No	9. DIST STATEMENT REQUIRED C	10. FREQUENCY ASREQ	12. DATE OF FIRST SUBMISSION See block 16	14. DISTRIBUTION			
8. APP CODE N/A		11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION See block 16	a. ADDRESSEE	b. COPIES		
					Draft	Final	
						Reg	Repro

16. REMARKS

Block 4. The Data Item Description (DID) may be obtained at:
<http://quicksearch.dla.mil>

The Contractor shall provide a draft regulatory strategy in MS Word within 10 business days of contract award that describes the regulatory pathway for FDA regulatory approval/clearance that includes but not limited to the following:

(a) Product Nomenclature and Classification – describe product name; proposed trade name; device panel (FDA review center and review division); classification (Class I, II, III). If not yet classified, details regarding the 513(g) Request for Information submission to the FDA to obtain FDA evaluation and ruling on how device should be classified, regulation number, and product code. (References: Classification Regulations 21 CFR Parts 862-892; section 513(g) of the FD&C Act, 21 USC 360c(g)).

(b) Device Description – concise summary and explanation of the medical device that may include: Key design features such as new technology or is the technology similar to an identified predicate; number of component parts the device will have and descriptions; device included software; technical features of the device which restricts user environment; or any other descriptive elements that describes what the medical device is and does (e.g., engineering diagrams, pictures of the finished device, physical properties, chemical composition, labeling instructions).

(c) Intended use/indications for use statement (i.e., how it will be used) such as target patient population(s); use environment (e.g., home, hospital, military, field use, etc.); target user(s) (e.g., military users, trained laboratory or medical professional, untrained lay person, etc.; description of use environment (e.g., combat support hospital, hospital, ambulance, home, etc.); and target.

(d) Regulatory Pathway – describe how the device will be regulated; proposed type of marketing applications (e.g., Class I Exempt, Class I or II requiring Premarket Notification (§510k), de novo submission, or Class III Pre-market Approval Application [PMA]); key data considerations to extent known; list of key risks/barriers to proposed pathways; and discussion of relevant FDA guidance.

JPEO PM	1	1	
Regulatory Affairs	1	1	
15. TOTAL	2	2	0

G. PREPARED BY	H. DATE	I. APPROVED BY	J. DATE
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17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

A. CONTRACT LINE ITEM NO.	B. EXHIBIT J-1	C. CATEGORY: TDP _____ TM _____ OTHER _____
D. SYSTEM/ITEM NIRDS	E. CONTRACT/PR NO. W911SR-21-C-0008	F. CONTRACTOR Worlds Enterprises Inc.

16. REMARKS *(Continued)*

Block 16 Continued.

(e) Current development status and regulatory status of the product and previous FDA interactions or submissions.

(f) For those devices that will potentially require a 510(k), provide information about the proposed predicate and approach to substantial equivalence (predicate analysis) identifying relevant similarities or differences in areas such as intended use; indications for use; target population; anatomical site; use environment; human factors; energy used/delivered; design; materials; performance; chemical composition; chemical characteristics etc. as applicable to the type of device or in vitro diagnostic being developed.

(g) Life Cycle Considerations – describe future device generations, modifications, indications, or claims that will build on prior/initial/subsequent approvals or clearances.

(h) Previous regulatory communication information – describe information or commitments from previous meetings with regulatory agencies (e.g., tracking table of previous communications, interactions, and submissions with submission numbers where applicable).

The Contractor shall provide a subsequent draft regulatory strategy in MS Word within 10 business days of the one-day training event. The Government will provide comments within 10 business days of receipt. The final regulatory strategy shall be provided in MS Word within 30 calendar days of the end of the period of performance.

Block 14 - Distribution and addresses. The Regulatory Strategy and related documents must be electronically forwarded to the following addresses:

(b) (6) 

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
(1 Data Item)

Form Approved
OMB No. 0704-0188

The public reporting burden for this collection of information is estimated to average 110 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 and Communications 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.

A. CONTRACT LINE ITEM NO.	B. EXHIBIT J-1	C. CATEGORY: TDP _____ TM _____ OTHER _____
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D. SYSTEM/ITEM NIRDS	E. CONTRACT/PR NO. W911SR-21-C-0008	F. CONTRACTOR Worlds Enterprises Inc.
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1. DATA ITEM NO. A007	2. TITLE OF DATA ITEM Manufacturing and Quality Assurance Status Report (MQASR)	3. SUBTITLE NIRDS Manufacturing Development Plan
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4. AUTHORITY (Data Acquisition Document No.) DI-QCIC-82323	5. CONTRACT REFERENCE SOO Para 5.2.3	6. REQUIRING OFFICE JPEO-CBRND
----------------------------------------------------------------------	------------------------------------------------	------------------------------------------

7. DD 250 REQ No	9. DIST STATEMENT REQUIRED C	10. FREQUENCY ASREQ	12. DATE OF FIRST SUBMISSION See block 16	14. DISTRIBUTION			
8. APP CODE N/A		11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION See block 16	a. ADDRESSEE	b. COPIES		
					Draft	Final	
						Reg	Repro

16. REMARKS Block 4. http://quicksearch.dla.mil The Contractor shall provide a draft manufacturing development plan within 30 days of award that describes (1) The individual and/or organizational responsibilities for each activity (a) Explain the internal review, update, and approval processes that ensures the device design is completed, verified, and validated, as appropriate. (2) The quality objectives and design control requirements being met (a) Identification and traceability, of components included in prototype units (b) Purchasing controls (c) Acceptance activities (d) Labeling and packaging documentation (e) Handling, storage, and distribution, records (3) The device design and development activities (a) Hazard analysis (b) Design verification plans, protocols, and reports (c) Design validation plans, protocols, and reports (d) List of off-the-shelf parts in the device and list of components for all off-the-shelf parts. (e) List of custom parts used in the device (f) List of assigned parts numbers for all parts. (g) Part and prototype assembly drawings, schematics, or photographs (h) Safety, compliance, and packaging testing plans, protocols, and results The Contractor shall provide a subsequent draft manufacturing development plan within 10 business days of prototype delivery. The Government will provide comments within 20 business days of receipt. The contractor shall provide the final manufacturing development plan within 10 business days of receipt of comments from the Government. Block 14 - Distribution and addresses. The Microsoft 2016 compatible Plan and related documents must be electronically forwarded to the following addresses: (b) (6)	JPEO COR	1	1		
	Regulatory Affairs	1	1		
	15. TOTAL →		2	2	0

G. PREPARED BY	H. DATE	I. APPROVED BY	J. DATE
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17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

A. CONTRACT LINE ITEM NO.	B. EXHIBIT J-1	C. CATEGORY: TDP _____ TM _____ OTHER _____
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D. SYSTEM/ITEM NIRDS	E. CONTRACT/PR NO. W911SR-21-C-0008	F. CONTRACTOR Worlds Enterprises Inc.
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<p>16. REMARKS <i>(Continued)</i></p>

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).
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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.

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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.

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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.

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CONTRACT DATA REQUIREMENTS LIST
(1 Data Item)

Form Approved
OMB No. 0704-0188

The public reporting burden for this collection of information is estimated to average 110 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 and Communications 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.

A. CONTRACT LINE ITEM NO.	B. EXHIBIT J-1	C. CATEGORY: TDP _____ TM _____ OTHER _____
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D. SYSTEM/ITEM NIRDS	E. CONTRACT/PR NO. TBD	F. CONTRACTOR Worlds Enterprises Inc.
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1. DATA ITEM NO. A008	2. TITLE OF DATA ITEM Technical Report Study/Services	3. SUBTITLE FDA Correspondence/Engagements
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4. AUTHORITY (Data Acquisition Document No.) DI-MS-C-80508B	5. CONTRACT REFERENCE SOO Para 5.2.5	6. REQUIRING OFFICE JPEO-CBRND
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7. DD 250 REQ No	9. DIST STATEMENT REQUIRED C	10. FREQUENCY ASREQ	12. DATE OF FIRST SUBMISSION See block 16	14. DISTRIBUTION		
8. APP CODE N/A			11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION See block 16	a. ADDRESSEE	b. COPIES
					Draft	Final
					Reg	Repro

<p>16. REMARKS</p> <p>Block 4. The Data Item Description (DID) may be obtained at: http://quicksearch.dla.mil</p> <p>The Contractor shall provide all FDA communication and documentation related to meetings and submissions. By Sponsor designation as FDA co-contact, the JPEO-CBRND Senior Director Medical Regulatory or representative shall receive copies of sponsor meeting request letters or submissions, briefing packages, meeting minutes, FDA contact reports, informal and email communications, official communication letters, and the Emergency Use Authorization submission package (cover letters and required forms/templates completed).</p> <p>Block 14 - Distribution and addresses. FDA correspondence/engagement documents shall be submitted in electronic format in Microsoft Office (Word, Excel & PowerPoint) or in another format approved by the Government to:</p> <p>(b) (6)</p>	<p>JPEO PM</p> <p>Regulatory Affairs</p>	<p>1</p> <p>1</p>	<p>1</p> <p>1</p>	<p></p> <p></p>
15. TOTAL \longrightarrow				
2 2 0				

17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

G. PREPARED BY	H. DATE	I. APPROVED BY	J. DATE
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CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

A. CONTRACT LINE ITEM NO.	B. EXHIBIT J-1	C. CATEGORY: TDP _____ TM _____ OTHER _____
D. SYSTEM/ITEM NIRDS	E. CONTRACT/PR NO. TBD	F. CONTRACTOR Worlds Enterprises Inc.

16. REMARKS *(Continued)*

Block 16 Continued.

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.
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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.

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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
(1 Data Item)

Form Approved
OMB No. 0704-0188

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A. CONTRACT LINE ITEM NO.	B. EXHIBIT	C. CATEGORY: TDP _____ TM _____ OTHER _____
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D. SYSTEM/ITEM NIRDS	E. CONTRACT/PR NO. W911SR-21-C-0008	F. CONTRACTOR Worlds Enterprises Inc.
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1. DATA ITEM NO. A009	2. TITLE OF DATA ITEM Government Property (GP) Inventory Report	3. SUBTITLE Contractor Acquired Property Inventory
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4. AUTHORITY (Data Acquisition Document No.) DI-MGMT-80441D	5. CONTRACT REFERENCE SOO Para 4.6	6. REQUIRING OFFICE JPEO-CBRND
-----------------------------------------------------------------------	----------------------------------------------	------------------------------------------

7. DD 250 REQ No No	9. DIST STATEMENT REQUIRED	10. FREQUENCY MTHLY	12. DATE OF FIRST SUBMISSION See block 16	14. DISTRIBUTION		
8. APP CODE N/A	A	11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION See block 16	a. ADDRESSEE	b. COPIES	
					Draft	Final
						Reg
						Repro

16. REMARKS

Block 4. The Data Item Description (DID) may be obtained at: <http://quicksearch.dla mil>.

The Contractor shall conduct initial and monthly inventory on all Contractor Acquired Property (CAP) during performance of the contract.

Block 12 - Initial inventory shall be conducted and submitted to the Government when the CAP arrives at its destination.

Block 13 - Inventory shall be accounted for monthly (every 30 calendar days). In addition, inventory shall be accounted for if CAP is moved to a new destination. Final inventory submission shall be within 30 calendar days of contract completion/termination.

Block 14 - Distribution and addresses. CAP inventory documents shall be submitted in electronic format in Microsoft Office (Word, Excel & PowerPoint) or in another format approved by the Government to:

(b) (6)

14. DISTRIBUTION	b. COPIES		
	a. ADDRESSEE	Draft	Final
			Reg
JPEO PM	1	1	
ACC-APG	1	1	
15. TOTAL	→ 2	2	0

17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

G. PREPARED BY	H. DATE	I. APPROVED BY	J. DATE
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CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

A. CONTRACT LINE ITEM NO.	B. EXHIBIT	C. CATEGORY: TDP _____ TM _____ OTHER _____
D. SYSTEM/ITEM NIRDS	E. CONTRACT/PR NO. W911SR-21-C-0008	F. CONTRACTOR Worlds Enterprises Inc.

16. REMARKS (Continued)

Block 16 Continued.

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.
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- Item G.** Signature of preparer of CDRL.
- Item H.** Date CDRL was prepared.
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- Item J.** Date CDRL was approved.
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