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|---|-------------------------|---|---|---|-------------------------|--|
| AWARD/CONTRACT | | 1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700) | | RATING | PAGE OF PAGES 1 53 | |
| 2. CONTRACT (Proc. Inst. Ident.) NO. W911QY20C0100 | | 3. EFFECTIVE DATE 09 Aug 2020 | | 4. REQUISITION/PURCHASE REQUEST/PROJECT NO. 0011534693 | | |
| 5. ISSUED BY W6QK ACC-APG NATICK CONTRACT NG DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011 | | CODE W911QY | 6. ADMINISTERED BY (If other than Item 5) DEFENSE CONTRACT MANAGEMENT AGENCY DCMA BOSTON 495 SUMMER STREET BOSTON MA 02210-2138 | | CODE S2206A | |
| 7. NAME AND ADDRESS OF CONTRACTOR (No., street, city, county, state and zip code) MODERNATX, INC. HAMILTON BENNETT 200 TECHNOLOGY SQ CAMBRIDGE MA 02139-3578 | | | | 8. DELIVERY [] FOB ORIGIN [X] OTHER (See below) | | |
| | | | | 9. DISCOUNT FOR PROMPT PAYMENT | | |
| | | | | 10. SUBMIT INVOICES 1 (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN: | | ITEM Section G |
| CODE 6RP85 | | FACILITY CODE | | 12. PAYMENT WILL BE MADE BY DEFENSE FINANCE AND ACCOUNTING SERVICE DFAS - COLUMBUS CENTER (HQ0337) NORTH ENTITLEMENT OPERATIONS P.O. BOX 182317 COLUMBUS OH 43218-2266 | | |
| 11. SHIP TO/MARK FOR See Schedule | | CODE | 12. PAYMENT WILL BE MADE BY DEFENSE FINANCE AND ACCOUNTING SERVICE DFAS - COLUMBUS CENTER (HQ0337) NORTH ENTITLEMENT OPERATIONS P.O. BOX 182317 COLUMBUS OH 43218-2266 | | CODE HQ0337 | |
| 13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: [X] 10 U.S.C. 2304(c)(2) [] 41 U.S.C. 253(c)() | | | | 14. ACCOUNTING AND APPROPRIATION DATA See Schedule | | |
| 15A. ITEM NO. | 15B. SUPPLIES/ SERVICES | 15C. QUANTITY | 15D. UNIT | 15E. UNIT PRICE | 15F. AMOUNT | |
| SEE SCHEDULE | | | | | | |
| 15G. TOTAL AMOUNT OF CONTRACT (b) (4) | | | | | | |
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| CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE | | | | | | |
| 17 [] CONTRACTOR'S NEGOTIATED AGREEMENT Contractor is required to sign this document and return [] copies to issuing office Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein (Attachments are listed herein) | | | | 18 [] SEALED-BID AWARD (Contractor is not required to sign this document) Your bid on Solicitation Number <u>W911QY20R0043</u> including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the terms listed above and on any continuation sheets This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract No further contractual document is necessary (Block 18 should be checked only when awarding a sealed-bid contract) | | |
| 19A. NAME AND TITLE OF SIGNER (Type or print) (b) (6) | | | | 20A. NAME OF CONTRACTING OFFICER (b) (6) TEL: _____ EMAIL: (b) (6) | | |
| 19B. NAME OF CONTRACTOR (b) (6) BY _____ (Signature of person authorized to sign) | | 19C. DATE SIGNED | | 20B. _____ (b) (6) BY _____ (Signature of Contracting Officer) | | 20C. DATE SIGNED 11-Aug-2020 |

Section A - Solicitation/Contract Form

A.1 The U.S. Army Contracting Command - Aberdeen Proving Ground (ACC-APG), Natick Division has a requirement for up to 500 million SARS-CoV-2 mRNA-1273 Vaccine doses (100 µg) in support of Joint Program Executive Office - Chemical Biological Radiological Nuclear Defense (JPEO-CBRND), the Assistant Secretary for Preparedness and Response (ASPR), and Biomedical Advanced Research and Development Authority (BARDA). All doses of mRNA-1273 Vaccine referenced herein are 100 µg doses. All doses will be delivered in a multi-dose vial with a volume sufficient for 10 doses per vial.

Section B - Supplies or Services and Prices

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---------|--|----------|------|------------|---------|
| 0001 | SARS-CoV-2 mRNA-1273 Vaccine (b) (4) The contractor shall produce and deliver (b) (4) of the SARS-CoV-2 mRNA-1273 Vaccine filled drug product (FDP), IAW Section C, Statement of Work (SOW) and CDRLs (Exhibit A) on this contract. PROJECT: Operation Warp Speed | | | | (b) (4) |
| | | | | NET AMT | (b) (4) |

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---------|---|----------|---------|------------|---------|
| 0001AA | (b) (4) (b) (4) (b) (4) PROJECT: Operation Warp Speed (b) (4) | (b) (4) | (b) (4) | (b) (4) | (b) (4) |
| | | | | NET AMT | (b) (4) |
| | ACRN AA (b) (4) | | | | (b) (4) |

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---------|-------------------|----------|---------|------------|---------|
| 0001AB | (b) (4) | (b) (4) | (b) (4) | (b) (4) | (b) (4) |

(b) (4)
PURCHASE REQUEST NUMBER: (b) (4)
PROJECT: Operation Warp Speed
(b) (4)

NET AMT (b) (4)

ACRN AB
CIN: (b) (4) (b) (4)

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---------|-------------------|----------|---------|------------|---------|
| 0001AC | (b) (4) | (b) (4) | (b) (4) | (b) (4) | (b) (4) |

(b) (4)
PURCHASE REQUEST NUMBER: (b) (4)
PROJECT: Operation Warp Speed
(b) (4)

NET AMT (b) (4)

ACRN AA
CIN: (b) (4) (b) (4)

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---------|-------------------------------|----------|---------|------------|---------|
| 0001AD | (b) (4) | (b) (4) | (b) (4) | (b) (4) | (b) (4) |
| | (b) (4) | | | | |
| | (b) (4) | | | | |
| | PURCHASE REQUEST NUMBER: | | (b) (4) | | |
| | PROJECT: Operation Warp Speed | | | | |
| | (b) (4) | | | | |

NET AMT

(b) (4)

ACRN AA

CIN: (b) (4)

(b) (4)

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---------|--|----------|------|------------|---------|
| 0002 | Vendor Managed Inventory | | | | (b) (4) |
| | (b) (4) | | | | |
| | a. The contractor shall secure, manage and maintain storage for up to (b) (4) of mRNA-1273 vaccine and deliver to the designated government facility in accordance with Section F. | | | | |
| | b. Parties to add language regarding reimbursement for storage, insurance costs, i.e., amount of reimbursement will be determined and agreed at a later date. | | | | |
| | (b) (4) | | | | |
| | PROJECT: Operation Warp Speed | | | | |
| | (b) (4) | | | | |

NET AMT

(b) (4)

| ITEM NO 0003 | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT (b) (4) |
|-----------------|-------------------|----------|------|------------|-------------------|
|-----------------|-------------------|----------|------|------------|-------------------|

| | | | | | |
|------------|------------|------------|------------|------------|------------|
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
|------------|------------|------------|------------|------------|------------|

[REDACTED]

[REDACTED]

| | | | | | |
|------------|------------|------------|------------|------------|------------|
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |

[REDACTED]

(b) (4)

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---------|-------------------|----------|---------|------------|---------|
| 0003AB | (b) (4) | (b) (4) | (b) (4) | (b) | (b) (4) |
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NET AMT (b) (4)

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---------|-------------------|----------|---------|------------|---------|
| 0003AC | (b) (4) | (b) (4) | (b) (4) | (b) | (b) (4) |
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NET AMT (b) (4)

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---------|-------------------|----------|---------|------------|---------|
| 0003AD | (b) (4) | (b) (4) | (b) (4) | (b) | (b) (4) |
| | (b) (4) | | | | |
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| | (b) (4) | | | | |

NET AMT (b) (4)

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---------|--|----------|------|------------|---------|
| 0004 | Technical Data (b) (4) The contractor shall deliver technical Data IAW Contract Data Requirements List (CDRL) IAW deliveries in Section C.4 and Section J, Exhibit A. (b) (4) PROJECT: Operation Warp Speed (b) (4) | | | | (b) (4) |
| NET AMT | | | | | |

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|----------------|---|----------|------|------------|---------|
| 1001 OPTION | SARS-CoV-2 mRNA-1273 Vaccine (b) (4) The contractor shall produce and deliver 100M doses of the SARS-CoV-2 mRNA-1273 Vaccine filled drug product (FDP), IAW Section C, Statement of Work (SOW) and CDRLs (Exhibit A) on this contract. PROJECT: Operation Warp Speed | | | | (b) (4) |
| NET AMT | | | | | (b) (4) |

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---------|-------------------------------|----------|---------|------------|---------|
| 1001AA | | (b) (4) | (b) (4) | (b) (4) | (b) (4) |
| OPTION | (b) (4) | | | | |
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| | (b) (4) | | | | |
| | PROJECT: Operation Warp Speed | | | | |
| | (b) (4) | | | | |
| | | | | NET AMT | (b) (4) |

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---------|-------------------------------|----------|---------|------------|---------|
| 1001AB | | (b) (4) | (b) (4) | (b) (4) | (b) (4) |
| OPTION | (b) (4) | | | | |
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| | (b) (4) | | | | |
| | PROJECT: Operation Warp Speed | | | | |
| | (b) (4) | | | | |
| | | | | NET AMT | (b) (4) |

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|------------------|-------------------------------|----------|---------|------------|---------|
| 1001AC OPTION | (b) (4) | (b) (4) | (b) (4) | (b) (4) | (b) (4) |
| | (b) (4) | | | | |
| | (b) (4) | | | | |
| | (b) (4) | | | | |
| | PROJECT: Operation Warp Speed | | | | |
| | (b) (4) | | | | |
| | | | | NET AMT | (b) (4) |

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|----------------|--|----------|------|------------|---------|
| 1002 OPTION | Vendor Managed Inventory | | | | (b) (4) |
| | (b) (4) | | | | |
| | a. The contractor shall secure, manage and maintain storage for up to (b) (4) of mRNA-1273 vaccine and deliver to the designated government facility in accordance with Section F. | | | | |
| | b. (b) (4) | | | | |
| | (b) (4) | | | | |
| | PROJECT: Operation Warp Speed | | | | |
| | (b) (4) | | | | |
| | | | | NET AMT | (b) (4) |

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|----------------|---|----------|------|------------|---------|
| 2001 OPTION | SARS-CoV-2 mRNA-1273 Vaccine (b) (4) | | | | (b) (4) |
| | The contractor shall produce and deliver (b) (4) of the SARS-CoV-2 mRNA-1273 Vaccine filled drug product (FDP), IAW Section C, Statement of Work (SOW) and CDRLs (Exhibit A) on this contract. PROJECT: Operation Warp Speed | | | | |

NET AMT (b) (4)

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|------------------|-------------------------------|----------|---------|------------|---------|
| 2001AA OPTION | (b) (4) | (b) (4) | (b) (4) | (b) (4) | (b) (4) |
| | (b) (4) | | | | |
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| | (b) (4) | | | | |
| | PROJECT: Operation Warp Speed | | | | |
| | (b) (4) | | | | |

NET AMT (b) (4)

| ITEM NO 2001AB OPTION | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|-----------------------------|-------------------------------|----------|---------|------------|---------|
| | (b) (4) | (b) (4) | (b) (4) | (b) (4) | (b) (4) |
| | (b) (4) | | | | |
| | (b) (4) | | | | |
| | (b) (4) | | | | |
| | PROJECT: Operation Warp Speed | | | | |
| | (b) (4) | | | | |

NET AMT

(b) (4)

| ITEM NO 2001AC OPTION | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|-----------------------------|-------------------------------|----------|---------|------------|---------|
| | (b) (4) | (b) (4) | (b) (4) | (b) (4) | (b) (4) |
| | (b) (4) | | | | |
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| | (b) (4) | | | | |
| | PROJECT: Operation Warp Speed | | | | |
| | (b) (4) | | | | |

NET AMT

(b) (4)

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|----------------|---|----------|------|------------|---------|
| 2002 OPTION | Vendor Managed Inventory (b) (4) a. The contractor shall secure, manage and maintain storage for up to (b) (4) of mRNA-1273 vaccine and deliver to the designated government facility in accordance with Section F. (b) (4) (b) (4) PROJECT: Operation Warp Speed (b) (4) | | | | (b) (4) |
| NET AMT | | | | | (b) (4) |

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|----------------|--|----------|------|------------|---------|
| 3001 OPTION | SARS-CoV-2 mRNA-1273 Vaccine (b) (4) The contractor shall produce and deliver (b) (4) of the SARS-CoV-2 mRNA-1273 Vaccine filled drug product (FDP), IAW Section C, Statement of Work (SOW) and CDRLs (Exhibit A) on this contract. PROJECT: Operation Warp Speed | | | | (b) (4) |
| NET AMT | | | | | (b) (4) |

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---------|-------------------------------|----------|---------|------------|---------|
| 3001AA | (b) (4) | (b) (4) | (b) (4) | (b) (4) | (b) (4) |
| OPTION | (b) (4) | | | | |
| | (b) (4) | | | | |
| | (b) (4) | | | | |
| | (b) (4) | | | | |
| | PROJECT: Operation Warp Speed | | | | |
| | (b) (4) | | | | |

NET AMT (b) (4)

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---------|-------------------------------|----------|---------|------------|---------|
| 3001AB | (b) (4) | (b) (4) | (b) (4) | (b) (4) | (b) (4) |
| OPTION | (b) (4) | | | | |
| | (b) (4) | | | | |
| | (b) (4) | | | | |
| | (b) (4) | | | | |
| | PROJECT: Operation Warp Speed | | | | |
| | (b) (4) | | | | |

NET AMT (b) (4)

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---------|-------------------------------|----------|---------|------------|---------|
| 3001AC | (b) (4) | (b) (4) | (b) (4) | (b) (4) | (b) (4) |
| OPTION | (b) (4) | | | | |
| | (b) (4) | | | | |
| | (b) (4) | | | | |
| | (b) (4) | | | | |
| | PROJECT: Operation Warp Speed | | | | |
| | (b) (4) | | | | |
| | | | | NET AMT | (b) (4) |

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---------|---|----------|------|------------|---------|
| 3002 | Vendor Managed Inventory | | | | (b) (4) |
| OPTION | (b) (4) | | | | |
| | The contractor shall secure, manage and maintain storage for up to (b) (4) of mRNA-1273 vaccine and deliver to the designated government facility in accordance with Section F. | | | | |
| | (b) (4) | | | | |
| | (b) (4) | | | | |
| | PROJECT: Operation Warp Speed | | | | |
| | (b) (4) | | | | |
| | | | | NET AMT | (b) (4) |

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|----------------|--|----------|------|------------|---------|
| 4001 OPTION | SARS-CoV-2 mRNA-1273 Vaccine (b) (4) | | | | (b) (4) |
| | The contractor shall produce and deliver (b) (4) of the SARS-CoV-2 mRNA-1273 Vaccine filled drug product (FDP), IAW Section C, Statement of Work (SOW) and CDRLs (Exhibit A) on this contract. | | | | |
| | PROJECT: Operation Warp Speed | | | | |

NET AMT (b) (4)

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|------------------|-------------------------------|----------|---------|------------|---------|
| 4001AA OPTION | (b) (4) | (b) (4) | (b) (4) | (b) (4) | (b) (4) |
| | (b) (4) | | | | |
| | (b) (4) | | | | |
| | (b) (4) | | | | |
| | PROJECT: Operation Warp Speed | | | | |
| | (b) (4) | | | | |

NET AMT (b) (4)

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---------|-------------------------------|----------|---------|------------|---------|
| 4001AB | (b) (4) | (b) (4) | (b) (4) | (b) (4) | (b) (4) |
| OPTION | (b) (4) | | | | |
| | (b) (4) | | | | |
| | (b) (4) | | | | |
| | (b) (4) | | | | |
| | PROJECT: Operation Warp Speed | | | | |
| | (b) (4) | | | | |

NET AMT (b) (4)

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---------|-------------------------------|----------|---------|------------|---------|
| 4001AC | (b) (4) | (b) (4) | (b) (4) | (b) (4) | (b) (4) |
| OPTION | (b) (4) | | | | |
| | (b) (4) | | | | |
| | (b) (4) | | | | |
| | (b) (4) | | | | |
| | PROJECT: Operation Warp Speed | | | | |
| | (b) (4) | | | | |

NET AMT (b) (4)

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|----------------|---|----------|------|------------|---------|
| 4002 OPTION | Vendor Managed Inventory (b) (4) The contractor shall secure, manage and maintain storage for up to (b) (4) of mRNA-1273 vaccine and deliver to the designated government facility in accordance with Section F. (b) (4) PROJECT: Operation Warp Speed (b) (4) | █ | █ | | (b) (4) |

NET AMT

(b) (4)

Section C - Descriptions and Specifications

**STATEMENT OF WORK
LARGE SCALE PRODUCTION OF SARS-CoV-2 VACCINE**

C.1 **SCOPE.** The Department of Defense and Health and Human Services (HHS) require large scale manufacturing of vaccine doses in support of the national emergency response to the Coronavirus Disease 2019 (COVID-19) for the United States Government (USG) and the US population.

C.1.1 **Background.** In December 2019, a novel coronavirus now known as SARS-CoV-2 was first detected in Wuhan, Hubei Province, People's Republic of China, causing outbreaks of the coronavirus disease COVID-19 that has now spread globally. The Secretary of Health and Human Service declared a public health emergency on January 31, 2020, under section 319 of the Public Health Service Act (42 U.S.C. 247d), in response to COVID-19. On March 1, 2020, the President of the United States, pursuant to sections 01 and 301 of the National Emergencies Act (50 U.S.C. 1601 et seq.) and consistent with section 1135 of the Social Security Act (SSA), as amended (42 U.S.C. 1320b-5), proclaimed that the COVID-19 outbreak in the United States constitutes a national emergency.

C.1.1.1 Under Operation Warp Speed (OWS), the Department of Defense and HHS are leading a whole of nation effort to ensure development of promising vaccine, diagnostic and therapeutic candidates and ensure that these medical countermeasures are available in the quantities required to reduce SARS-CoV-2 transmission, identify prior and/or current infection, and improve patient care, thereby mitigating the impact of COVID-19 on the nation and its people. The DoD Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRD) is providing expertise and contracting support to HHS, in compliance with PL 115-92 Authorization Letter for DoD Medical Priorities, through an Interagency Agreement, signed April 23, 2020. As OWS products progress to clinical trials to evaluate the safety and efficacy of vaccines and therapeutics, it is critical that, in parallel, the USG supports large scale manufacturing so that vaccine doses or therapeutic treatment courses are immediately available for nationwide access as soon as a positive efficacy signal is obtained and the medical countermeasures are authorized for widespread use.

C.1.2 **Objective:** The objective of this effort is to obtain the following:

- a. Base Period: Large scale manufacturing of 100 million vaccine doses
- b. Option Period 1: Large scale manufacturing of 100 million vaccine doses
- c. Option Period 2: Large scale manufacturing of 100 million vaccine doses
- d. Option Period 3: Large scale manufacturing of 100 million vaccine doses
- e. Option Period 4: Large scale manufacturing of 100 million vaccine doses

The Base Period is 9 months, with overlapping options for a total of 20 months if all options are exercised.

C.2 **APPLICABLE DOCUMENTS.**

C.2.1 **Federal Documents:**

C.2.1.1 Title 21 Code of Federal Regulations (CFR), Food and Drugs: Part 210, Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General; and, Part 211, Current Good Manufacturing Practice In Manufacturing, Processing, Packing, or Holding of Drugs; General.

(https://www.ecfr.gov/cgi-bin/text-idx?SID=a95cab20f443897a400bb7e44a27cf4c&mc=true&tpl=/ecfrbrowse/Title21/21cfrv4_02.tpl#0)

C.3 **REQUIREMENTS.** Independently, and not as an agent of the USG, in accordance with the Proposal submitted by ModernaTX, Inc. in response to Solicitation Number W911QY20R0043, Titled, "Advanced Procurement of mRNA-1273 Vaccine for Prevention of SARS-CoV-2 Coronavirus (COVID-19)", dated July 10, 2020 (and any subsequent USG-approved revisions thereto), the contractor shall provide all necessary services,

qualified personnel, material, equipment and facilities (not otherwise provided by the USG under the terms of this contract) to perform the specific tasks set forth below.

C.3.1 Contract Line Item Number (CLIN) 0001 - Base Period: Large Scale Manufacturing of 100 Million Vaccine Doses.

(b) (4) [Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]

(b) (4) [Redacted]

[Redacted]

C.3.2 CLIN 1001 - Option Period 1: Large Scale Manufacturing of 100 Million Vaccine Doses.

(b) (4) [Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

(b) (4) [Redacted]

C.3.3 CLIN 2001 - Option Period 2: Large Scale Manufacturing of 100 Million Vaccine Doses.

(b) (4) [Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

C.3.4 CLIN 3001 - Option Period 3: Large Scale Manufacturing of 100 Million Vaccine Doses.

(b) (4) [Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]

C.3.5 CLIN 4001 - Option Period 4: Large Scale Manufacturing of 100 Million Vaccine Doses.

(b) (4) [Redacted text block]

(b) (4) [Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

C.4 **CLIN 0002: Data Deliverables.** The contractor shall provide the following in accordance with the Contract Data Requirements List (CDRL), DD Forms 1423, provided at Appendix A.

(b) (4) [Redacted]

[Redacted]

(b) (4) [Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

C.5 Administration.

C.5.1 Post Award Teleconference. The contractor shall host a Post Award Teleconference (b) (4) after contract award.

C.5.1.1 The contractor shall provide an Agenda, IAW CDRL A020, detailing the planned activities for the (b) (4) and shall discuss agenda items for the Post Award Kickoff Meeting.

C.5.1.2 The contractor shall provide Meeting Minutes IAW CDRL A021.

C.5.2 Post Award Kickoff Meeting. The contracting officer may request the contractor host a contract Kick-Off Meeting (b) (4) after contract award via teleconference. The contracting officer shall establish the date and time of the conference and prepare the agenda to include discussion on contract activities and schedule.

C.5.3 (b) (4) Teleconference. The contractor shall participate (b) (4) teleconferences (or more frequent meetings required by the USG if warranted based on contract activities) to discuss performance on the contract.

C.5.4 The contractor shall provide an Agenda, IAW CDRL A020; Meeting Minutes in accordance with CDRL A021; and, Presentation Material in accordance with CDRL A022 for each of the aforementioned teleconferences or meetings throughout the contract period of performance.

C.5.5 Daily "Check-In". The contractor shall participate in a daily "check-in" (via teleconference or email) to address (b) (4) . (b) (4)

(b) (4) .
Upon request of the USG, (b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

C.7 (b) (4) [Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]

Section D - Packaging and Marking

D.1 Vaccine markings and labeling will be in accordance with FDA and will be finalized through a contract modification.

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 | N/A | N/A | N/A | N/A |
| 0001AA | Origin | Government | Origin | Government |
| 0001AB | Origin | Government | Origin | Government |
| 0001AC | Destination | Government | Destination | Government |
| 0001AD | Destination | Government | Destination | Government |
| 0002 | Destination | Government | Destination | Government |
| 0003 | N/A | N/A | N/A | N/A |
| 0003AA | Destination | Government | Destination | Government |
| 0003AB | Destination | Government | Destination | Government |
| 0003AC | Destination | Government | Destination | Government |
| 0003AD | Destination | Government | Destination | Government |
| 0004 | Destination | Government | Destination | Government |
| 1001 | N/A | N/A | N/A | N/A |
| 1001AA | Destination | Government | Destination | Government |
| 1001AB | Destination | Government | Destination | Government |
| 1001AC | Destination | Government | Destination | Government |
| 1002 | Destination | Government | Destination | Government |
| 2001 | N/A | N/A | N/A | N/A |
| 2001AA | Destination | Government | Destination | Government |
| 2001AB | Destination | Government | Destination | Government |
| 2001AC | Destination | Government | Destination | Government |
| 2002 | Destination | Government | Destination | Government |
| 3001 | N/A | N/A | N/A | N/A |
| 3001AA | Destination | Government | Destination | Government |
| 3001AB | Destination | Government | Destination | Government |
| 3001AC | Destination | Government | Destination | Government |
| 3002 | Destination | Government | Destination | Government |
| 4001 | N/A | N/A | N/A | N/A |
| 4001AA | Destination | Government | Destination | Government |
| 4001AB | Destination | Government | Destination | Government |
| 4001AC | Destination | Government | Destination | Government |
| 4002 | Destination | Government | Destination | Government |

CLAUSES INCORPORATED BY REFERENCE

52.246-16

Responsibility For Supplies

APR 1984

E1. Inspection:

Initial quality inspection of Filled Drug Product (FDP) shall occur when the Contractor performs release testing to confirm that products complies with Contractor's release specifications and criteria. Contractor will submit in WAWF to the Contracting Officer or the duly authorized representative of the Government with a Certificate of Analysis for quality inspection of all deliverables. Initial Inspection under this contract will be performed at the Contractor's facility, or the subcontractor facility, by the BARDA Contracting Officer Technical Representative (COTR).

Final inspection of product shall occur when the Government inspects each shipment of product delivered to it hereunder for visible damage and quantity within five (5) days of such delivery. In the event Contractor supplies any product to the Government and it is established that such Product was damaged or does not include the required quantities at the time of delivery, the Government shall promptly notify Contractor in writing within a reasonable period of time not to exceed 10 days. Final inspection shall be conducted at the CDC location identified as destination.

In the event the USG requires storage of the FDP to a Vendor Managed Inventory (VMI) location, final quantity inspection shall be conducted by submission into WAWF of shipping or other documentation confirming quantity to VMI location. Final physical inspection of the FDP shall be conducted upon receipt of product to USG location.

Inspection of all reports and Contract Data Requirement List (CDRL) under this contract will be performed at Destination by duly authorized representative of the Government.

E.2 Acceptance

a. Acceptance at origin shall occur at the contractor or subcontractor facility. Acceptance at destination shall occur at a government designated CDC location. Regardless of where acceptance occurs, the contractor is responsible for final delivery of Filled Drug Product (FDP) to a government designated CDC location.

b. Acceptance under this agreement will be performed by Army Contracting Command Aberdeen Proving Ground (ACC-APG) Natick Contracting Division (NCD) Contracting Officer.

c. Acceptance of services under VMI SubCLINs (List CLINS) shall occur upon satisfactory physical and quantity inspection of FDP upon delivery at USG designated CDC location.

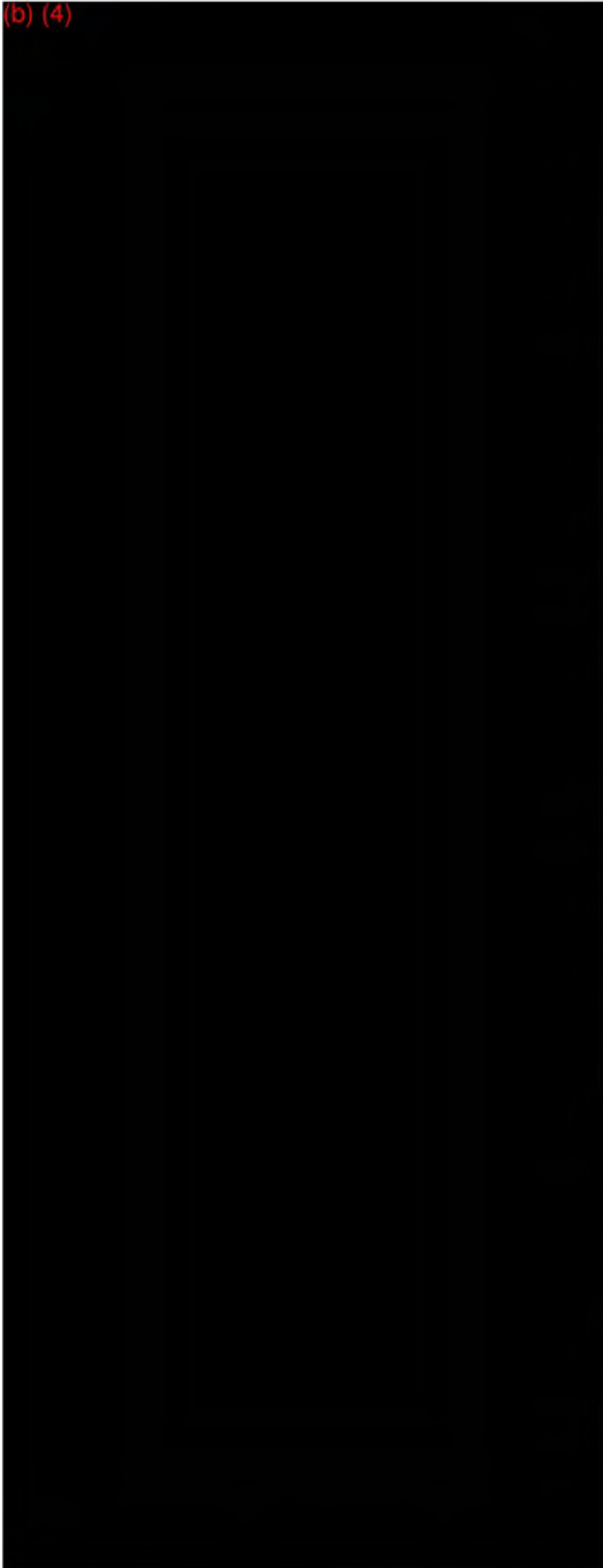
d. The parties acknowledge that acceptance may depend on the compliance with the Contractor's product specifications. The KO and COR may prior to acceptance consult with FDA under its authority under Public Law 115-92 to determine whether the material to be delivered meets the Contractor's product specifications. To this end, Contractor agrees to provide a letter to FDA authorizing the Government to engage in dialog with FDA about the ultimate compliance of this product with the Contractor's product specifications prior to acceptance. BARDA/COR will accept product according to the approved Product Acceptance Procedure.

Section F - Deliveries or Performance

DELIVERY INFORMATION

| CLIN | DELIVERY DATE | QUANTITY | SHIP TO ADDRESS | DODAAC / CAGE |
|---------|---------------|----------|------------------------------|---------------|
| (b) (4) | | | N/A | N/A |
| | | | N/A | |
| | | | FOB: Origin (Shipping Point) | |
| | | | N/A | |
| | | | FOB: Origin (Shipping Point) | |
| | | | N/A | |
| | | | FOB: Destination | |
| | | | N/A | |
| | | | FOB: Destination | |
| | | | N/A | |
| | | | FOB: Destination | |
| | | | N/A | N/A |
| | | | N/A | |
| | | | FOB: Destination | |
| | | | N/A | |
| | | | FOB: Destination | |
| | | | N/A | |
| | | | FOB: Destination | |
| | | | N/A | |
| | | | FOB: Destination | |
| | | | (b) (6) | W56XNH |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | FOB: Destination | |
| | | | N/A | N/A |
| | | | N/A | |
| | | | FOB: Destination | |

(b) (4)



N/A
FOB: Destination

N/A
FOB: Destination

N/A
FOB: Destination

N/A N/A

N/A
FOB: Destination

N/A
FOB: Destination

N/A
FOB: Destination

N/A
FOB: Destination

N/A N/A

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FOB: Destination

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FOB: Destination

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FOB: Destination

N/A
FOB: Destination

N/A N/A

N/A
FOB: Destination

N/A
FOB: Destination

N/A
FOB: Destination

N/A
FOB: Destination

| | | |
|-----------|-------------------------------|----------|
| 52.211-17 | Delivery of Excess Quantities | SEP 1989 |
| 52.242-15 | Stop-Work Order | AUG 1989 |
| 52.247-34 | F.O.B. Destination | NOV 1991 |

F.1 The contractor shall ship mRNA-1273 vaccines to designated locations in up to 10 geographic zones in the United States. The contractor shall be responsible for secure shipment of all vaccine product whether acceptance is conducted at origin or destination.

Section G - Contract Administration Data

ACCOUNTING AND APPROPRIATION DATA

AA: (b) (4) [REDACTED] [REDACTED] [REDACTED]
 COST CODE: (b) (4) [REDACTED]
 AMOUNT: (b) (4) [REDACTED]

AB: (b) (4) [REDACTED] [REDACTED] [REDACTED]
 COST CODE: (b) (4) [REDACTED]
 AMOUNT: [REDACTED]

| ACRN | CLIN/SLIN | CIN | AMOUNT |
|------|-----------|--------------------|------------|
| AA | 0001AA | (b) (4) [REDACTED] | [REDACTED] |
| | 0001AC | (b) (4) [REDACTED] | [REDACTED] |
| | 0001AD | (b) (4) [REDACTED] | [REDACTED] |
| AB | 0001AB | (b) (4) [REDACTED] | [REDACTED] |

CLAUSES INCORPORATED BY REFERENCE

| | | |
|--------------|---|----------|
| 252.204-7006 | Billing Instructions | OCT 2005 |
| 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):
- COMBO
- (ii) For fixed price line items—
- (A) That require shipment of a deliverable, submit the invoice and receiving report specified by the Contracting Officer.
- Invoice and receiving report document type
- (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.
- (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 | HQ0337 |
| Issue By DoDAAC | W911QY |
| Admin DoDAAC** | S2206A |

| | |
|-------------------|----------------|
| Inspect By DoDAAC | S2206A / BARDA |
| Acceptor | W911QY |
| Ship To | TDB |

(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) / DCMA Boston-AFAW, Administrative Contracting Officer / (b) (6)

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

(End of clause)

FOR REFERENCE:

DFARS PGI 204.7108 Payment Instructions Table

https://www.acq.osd.mil/dpap/dars/pgi/pgi_hm/current/PGI204_71.htm#payment_instructions

G.1 GOVERNMENT 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.

Procuring Contracting Officer:

(b) (6)
Bldg. 1, General Greene Avenue
Natick, MA 01760-5011

Contract Specialist:

(b) (6)
Bldg. 1, General Greene Avenue
Natick, MA 01760-5011

G.2 GOVERNMENT TECHNICAL POINT OF CONTACT

(b) (6)
Biologist/Project Officer
200 C Street, SW
Washington, DC 20201

G.3 CONTRACTOR'S CONTRACT ADMINISTRATION

(b) (6)
ModernaTX, Inc.
200 Technology SQ.
Cambridge, MA 02139-3578

G.4 PLACES OF PERFORMANCE

ModernaTX, Inc.
200 Technology SQ.
Cambridge, MA 02139-3578

G.5 NOTIFICATION OF REVISIONS AND CHANGE

Notification of revision or changes to names or email addresses will be provided by official correspondence from the PCO/ACO or office of the PCO/ACO in lieu of a contract modification. This does not apply to any such revisions or changes in the event this contract includes a key personnel clause.

G.6 PERFORMANCE BASED PAYMENT

Performance-based payments (PBP) are authorized under this contract in accordance with FAR 52.232-32. The contractor shall bill for the PBP upon achievement of the completion criteria identified in Attachment 0008, Performance-based Payment Milestone Table. Upon achievement of the completion criteria, the contractor shall bill for the PBP for the base and each option IAW the following schedule:

(b) (4)



(b) (4)



Delivery Invoicing: PBPs are a type of contract financing and are recouped by the Government through deductions of payments otherwise due to the contractor for the partial or complete delivery of contract items. The deductions are made by applying a liquidation rate to the price of delivered contract items. Attachment 0009, Performance-based Payment Milestone Billing Plan, identifies the contractor invoicing schedule for liquidation. The contractor shall submit all invoices IAW Attachment 0009.

Section H - Special Contract Requirements

H.1 Key Personnel

Any key personnel specified in this contract are considered to be essential to work performance. At least thirty (30) calendar days prior to the Contractor voluntarily diverting any of the specified individuals to other programs or contracts the Contractor shall notify the Contracting Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the Contractor is terminated for cause or separates from the Contractor voluntarily with less than thirty (30) calendar-day notice, the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the Contracting Officer. The contract will be modified to add or delete key personnel as necessary to reflect the agreement of the parties. The following individuals are determined to be key personnel:

| Name | Title |
|------------|------------|
| (b) (6) | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |

H.2 Substitution of Key Personnel

The Contractor agrees to assign to the contract those persons whose resumes/CVs were submitted with the proposal who are necessary to fill the requirements of the contract. No substitutions shall be made except in accordance with this clause.

All requests for substitution must provide a detailed explanation of the circumstance necessitating the proposed substitution, a complete resume for the proposed substitute and any other information requested by the contracting officer to approve or disapprove the proposed substitution. All proposed substitutes must have qualifications that are equal to or higher than the qualifications of the person to be replaced. The contracting officer or authorized representative will evaluate such requests and promptly notify the contractor of his approval or disapproval thereof.

H.3 Disclosure of Information:

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

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

No information related to data obtained under this contract shall be released or publicized without the prior written consent of the COR, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity' for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions. The exceptions identified in this paragraph apply to all disclosures under this Section H.3 except to the extent that a disclosure is otherwise prohibited by law.

H.4 Publication and Publicity

The contractor shall not release any reports, manuscripts, press releases, or abstracts about the work being performed under this contract without written notice in advance to the Government.

(a) Unless otherwise specified in this contract, the contractor may publish the results of its work under this contract. The contractor shall promptly send a copy of each submission to the COR for security review prior to submission. The contractor shall also inform the COR when the abstract article or other publication is published, and furnish a copy of it as finally published.

(b) Unless authorized in writing by the CO, the contractor shall not display the DoD logo including Operating Division or Staff Division logos on any publications.

(c) The contractor shall not reference the products(s) or services(s) awarded under this contract in commercial advertising, as defined in FAR 31.205-1, in any manner which states or implies DoD approval or endorsement of the product(s) or service(s) provided.

(d) The contractor shall include this clause, including this section (d) in all subcontracts where the subcontractor may propose publishing the results of its work under the subcontract. The contractor shall acknowledge the support of the Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority whenever publicizing the work under this contract in any media by including an acknowledgement substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract Number W911QY-20-C-0100."

H.5 Confidentiality of Information

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

b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor shall obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

f. Contracting Officer Determinations will reflect the result of internal coordination with appropriate program and legal officials.

g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

ALL REQUIREMENTS OF THIS SECTION H.5 MUST BE PASSED TO ALL SUB-CONTRACTOR.

H.6 Regulatory Rights

This contract involves supply of a product that requires FDA pre-market approval or clearance before commercial authorization. Contractor is seeking FDA authorization or clearance for the commercialization of mRNA-1273, Moderna vaccine for SARS-CoV-2 Coronavirus (the "Technology"). The Contractor is the Sponsor of the Regulatory Application (an investigational new drug application (IND), investigational device exemption (IDE), emergency use authorization (EUA), new drug application (NDA), biologics license application (BLA), premarket approval application (PMA), or 510(k) pre-market notification filing (510(k)) or another regulatory filing submitted to FDA) for the technology. As the Sponsor of the Regulatory Application to FDA (as the terms "sponsor" and "applicant" are defined or used in at 21 CFR §§3.2(c), 312.5, 600.3(t), 812.2(b), 812 Subpart C, or 814.20), the Contractor has certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application.

Accordingly, the Contractor and the Government agree to the following:

a. DoD Medical Product Priority. PL 115-92 allows the DoD to request, and FDA to provide, assistance to expedite development of products to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel. The contractor recognizes that only the DoD can utilize PL 115-92. As such, the contractor will work proactively with the Government to leverage this law to its maximum potential under this contract. The contractor shall submit Public Law 115-92 Sponsor Authorization Letter that will be delivered to the designated OWS POC(s) within (b) (4) of award.

(b) (4)

[REDACTED]

H.7 Performance Based Payment Liquidated under Termination

Performance Based Payments (PBPs) have been authorized as a method of financing under this contract. In the event the Moderna's mRNA-1273 COVID Vaccine is unsuccessful in its bid to obtain EUA or FDA approval, the Government may issue a Termination for Convenience (T4C) in whole or in part, on this contract. Upon notice of a T4C, the contractor shall submit a termination settlement proposal, IAW FAR 52.249-2, Termination for Convenience of the Government (Fixed-Price).

H.8 Public Readiness and Emergency Preparedness (PREP) Act:

In accordance with the Public Readiness and Emergency Preparedness Act ("PREP Act"), Pub. L. No. 109-148, Division C, Section 2, as amended (codified at 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e), as well as the Secretary of HHS's Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (Mar. 17, 2020, effective Feb. 4, 2020), and amended on April 15, 2020, 85 Fed. Reg. 21012 (together, the "Prep Act Declaration"):

- (i) This Agreement is being entered into for purposes of facilitating the manufacture, testing, development, distribution, administration, and use of "Covered Countermeasures" for responding to the COVID-19 public health emergency, in accordance with Section VI of the PREP Act Declaration;
- (ii) Contractor's performance of this Agreement falls within the scope of the "Recommended Activities" for responding to the COVID-19 public health emergency, to the extent it is in accordance with Section III of the PREP Act Declaration; and
- (iii) Contractor is a "Covered Person" to the extent it is a person defined in Section V of the PREP Act

Declaration.

Therefore, in accordance with Sections IV and VII of the PREP Act Declaration as well as the PREP Act (42 U.S.C. § 247d-6d), the Department of Defense contracting via assisted acquisition on behalf of the HHS, expressly acknowledges and agrees that the HHS Declaration cited above, specifically its language providing immunity from suit and liability is applicable to this acquisition as long as Contractors activities fall within the terms and conditions of the PREP Act and the PREP Act Declaration.

The Government may not use, or authorize the use of, any products or materials provided under this contract, unless such use occurs in the United States (or a U.S. territory where U.S. law applies such as embassies, military and NATO installations) and is protected from liability under a declaration issued under the PREP Act, or a successor COVID-19 PREP Act Declaration of equal or greater scope. Any use where the application of the PREP Act is in question will be discussed with Moderna prior to use and, if the parties disagree on such use, the dispute will be resolved according to the "Disputes Clause" (52.233-1)

The items and technology covered by this Contract are being developed for both civil and military applications.

(b) [REDACTED]
(4) [REDACTED]
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(b) (4) [Redacted]

H.12 Transportation to Final Destination

During the course of performance under this contract, the Government may require storage of the filled drug product (FDP) before delivery to the final government location. In these circumstances, the Government will accept FDP at the contractor facility (Origin). The contractor; however, shall continue to be responsible for secure delivery of the vaccine to its final destination as identified on this contract. Regardless of where acceptance occurs, risk of loss of or damage to supplies shall remain with the contractor until delivery of FDP to a government facility.

H.13 Validation of IP/Data

The Parties acknowledge that background intellectual property and technical data assertions have been made and evaluated by the parties. The parties agree that, should additional information relevant to these assertions become available, the parties will reevaluate said assertions as necessary in the future.

(b) [Redacted]
(4) [Redacted]

Section I - Contract Clauses

CLAUSES INCORPORATED BY REFERENCE

| | | |
|-----------|--|----------|
| 52.202-1 | Definitions | JUN 2020 |
| 52.203-3 | Gratuities | APR 1984 |
| 52.203-5 | Covenant Against Contingent Fees | MAY 2014 |
| 52.203-6 | Restrictions On Subcontractor Sales To The Government | JUN 2020 |
| 52.203-7 | Anti-Kickback Procedures | JUN 2020 |
| 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 |
| 52.203-13 | Contractor Code of Business Ethics and Conduct | JUN 2020 |
| 52.203-17 | Contractor Employee Whistleblower Rights and Requirement To Inform Employees of Whistleblower Rights | JUN 2020 |
| 52.204-1 | Approval of Contract | DEC 1989 |
| 52.204-4 | Printed or Copied Double-Sided on Postconsumer Fiber Content Paper | MAY 2011 |
| 52.204-10 | Reporting Executive Compensation and First-Tier Subcontract Awards | JUN 2020 |
| 52.204-13 | System for Award Management Maintenance | OCT 2018 |
| 52.204-18 | Commercial and Government Entity Code Maintenance | JUL 2016 |
| 52.204-19 | Incorporation by Reference of Representations and Certifications. | DEC 2014 |
| 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 2019 |
| 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 |
| 52.210-1 | Market Research | JUN 2020 |
| 52.215-2 | Audit and Records--Negotiation | JUN 2020 |
| 52.215-8 | Order of Precedence--Uniform Contract Format | OCT 1997 |
| 52.215-11 | Price Reduction for Defective Certified Cost or Pricing Data--Modifications | JUN 2020 |
| 52.215-13 | Subcontractor Certified Cost or Pricing Data--Modifications | JUN 2020 |
| 52.215-14 | Integrity of Unit Prices | JUN 2020 |
| 52.215-15 | Pension Adjustments and Asset Reversions | OCT 2010 |
| 52.215-18 | Reversion or Adjustment of Plans for Postretirement Benefits (PRB) Other than Pensions | JUL 2005 |
| 52.215-19 | Notification of Ownership Changes | OCT 1997 |
| 52.215-21 | Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data -- Modifications | JUN 2020 |
| 52.217-4 | Evaluation Of Options Exercised At The Time Of Contract Award | JUN 1988 |
| 52.217-7 | Option For Increased Quantity-Separately Priced Line Item | MAR 1989 |
| 52.217-8 | Option To Extend Services | NOV 1999 |
| 52.219-8 | Utilization of Small Business Concerns | OCT 2018 |

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|----------------|---|----------|
| 52.219-28 | Post-Award Small Business Program Rerepresentation | MAY 2020 |
| 52.222-1 | Notice To The Government Of Labor Disputes | FEB 1997 |
| 52.222-3 | Convict Labor | JUN 2003 |
| 52.222-19 | Child Labor -- Cooperation with Authorities and Remedies | JAN 2020 |
| 52.222-21 | Prohibition Of Segregated Facilities | APR 2015 |
| 52.222-26 | Equal Opportunity | SEP 2016 |
| 52.222-35 | Equal Opportunity for Veterans | JUN 2020 |
| 52.222-36 | Equal Opportunity for Workers with Disabilities | JUN 2020 |
| 52.222-37 | Employment Reports on Veterans | JUN 2020 |
| 52.222-40 | Notification of Employee Rights Under the National Labor Relations Act | DEC 2010 |
| 52.222-50 | Combating Trafficking in Persons | JAN 2019 |
| 52.222-54 | Employment Eligibility Verification | OCT 2015 |
| 52.223-6 | Drug-Free Workplace | MAY 2001 |
| 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 | Authorization and Consent | JUN 2020 |
| 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 |
| 52.227-11 | Patent Rights--Ownership By The Contractor | MAY 2014 |
| 52.232-9 | Limitation On Withholding Of Payments | APR 1984 |
| 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 |
| 52.243-1 | Changes--Fixed Price | AUG 1987 |
| 52.243-7 | Notification Of Changes | JAN 2017 |
| 52.244-5 | Competition In Subcontracting | DEC 1996 |
| 52.245-9 | Use And Charges | APR 2012 |
| 52.249-2 | Termination For Convenience Of The Government (Fixed-Price) | APR 2012 |
| 52.249-8 | Default (Fixed-Price Supply & Service) | APR 1984 |
| 52.249-14 | Excusable Delays | 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 |
| 252.203-7003 | Agency Office of the Inspector General | AUG 2019 |
| 252.211-7003 | Item Unique Identification and Valuation | MAR 2016 |
| 252.222-7006 | Restrictions on the Use of Mandatory Arbitration Agreements | DEC 2010 |
| 252.225-7048 | Export-Controlled Items | JUN 2013 |
| 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 |
| 252.227-7016 | Rights in Bid or Proposal Information | JAN 2011 |

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| 252.227-7017 | Identification and Assertion of Use, Release, or Disclosure Restrictions | JAN 2011 |
| 252.227-7019 | Validation of Asserted Restrictions--Computer Software | SEP 2016 |
| 252.227-7028 | Technical Data or Computer Software Previously Delivered to the Government | JUN 1995 |
| 252.227-7030 | Technical Data--Withholding Of Payment | MAR 2000 |
| 252.227-7037 | Validation of Restrictive Markings on Technical Data | SEP 2016 |
| 252.232-7007 | Limitation Of Government's Obligation | APR 2014 |
| 252.244-7000 | Subcontracts for Commercial Items | JUN 2013 |

CLAUSES INCORPORATED BY FULL TEXT

52.217-9 OPTION TO EXTEND THE TERM OF THE CONTRACT (MAR 2000)

(a) The Government may extend the term of this contract by written notice to the Contractor within 5 days for; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 30 days for Options 1 and 2, 60 days for Option 3 and 4 before the contract expires. The preliminary notice does not commit the Government to an extension.

(b) If the Government exercises this option, the extended contract shall be considered to include this option clause.

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 20 months.

(End of clause)

52.232-32 PERFORMANCE-BASED PAYMENTS (APR 2012)

(a) Amount of payments and limitations on payments. Subject to such other limitations and conditions as are specified in this contract and this clause, the amount of payments and limitations on payments shall be specified in the contract's description of the basis for payment.

(b) Contractor request for performance-based payment. The Contractor may submit requests for payment of performance-based payments not more frequently than monthly, in a form and manner acceptable to the Contracting Officer. Unless otherwise authorized by the Contracting Officer, all performance-based payments in any period for which payment is being requested shall be included in a single request, appropriately itemized and totaled. The Contractor's request shall contain the information and certification detailed in paragraphs (l) and (m) of this clause.

(c) Approval and payment of requests.

(1) The Contractor shall not be entitled to payment of a request for performance-based payment prior to successful accomplishment of the event or performance criterion for which payment is requested. The Contracting Officer shall determine whether the event or performance criterion for which payment is requested has been successfully accomplished in accordance with the terms of the contract. The Contracting Officer may, at any time, require the Contractor to substantiate the successful performance of any event or performance criterion which has been or is represented as being payable.

(2) A payment under this performance-based payment clause is a contract financing payment under the Prompt Payment clause of this contract and not subject to the interest penalty provisions of the Prompt Payment Act. The designated payment office will pay approved requests on the 30th day after receipt of the request for performance-based payment by the designated payment office. However, the designated payment office is not required to provide

payment if the Contracting Officer requires substantiation as provided in paragraph (c)(1) of this clause, or inquiries into the status of an event or performance criterion, or into any of the conditions listed in paragraph (e) of this clause, or into the Contractor certification. The payment period will not begin until the Contracting Officer approves the request.

(3) The approval by the Contracting Officer of a request for performance-based payment does not constitute an acceptance by the Government and does not excuse the Contractor from performance of obligations under this contract.

(d) Liquidation of performance-based payments.

(1) Performance-based finance amounts paid prior to payment for delivery of an item shall be liquidated by deducting a percentage or a designated dollar amount from the delivery payment. If the performance-based finance payments are on a delivery item basis, the liquidation amount for each such line item shall be the percent of that delivery item price that was previously paid under performance-based finance payments or the designated dollar amount. If the performance-based finance payments are on a whole contract basis, liquidation shall be by either predesignated liquidation amounts or a liquidation percentage.

(2) If at any time the amount of payments under this contract exceeds any limitation in this contract, the Contractor shall repay to the Government the excess. Unless otherwise determined by the Contracting Officer, such excess shall be credited as a reduction in the unliquidated performance-based payment balance(s), after adjustment of invoice payments and balances for any retroactive price adjustments.

(e) Reduction or suspension of performance-based payments. The Contracting Officer may reduce or suspend performance-based payments, liquidate performance-based payments by deduction from any payment under the contract, or take a combination of these actions after finding upon substantial evidence any of the following conditions:

(1) The Contractor failed to comply with any material requirement of this contract (which includes paragraphs (h) and (i) of this clause).

(2) Performance of this contract is endangered by the Contractor's --

(i) Failure to make progress; or

(ii) Unsatisfactory financial condition.

(3) The Contractor is delinquent in payment of any subcontractor or supplier under this contract in the ordinary course of business.

(f) Title.

(1) Title to the property described in this paragraph (f) shall vest in the Government. Vestiture shall be immediately upon the date of the first performance-based payment under 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 following 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 (f)(2)(ii) of this clause; 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 or 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, provided that any significant reduction in the value of the property to which the Government has title under this clause is reported in writing to the Contracting Officer.

(5) In order to acquire for its own use or dispose of property to which title is vested in the Government under this clause, the Contractor shall obtain the Contracting Officer's advance approval of the action and the terms. If approved, the basis for payment (the events or performance criteria) to which the property is related shall be deemed to be not in compliance with the terms of the contract and not payable (if the property is part of or needed for performance), and the Contractor shall refund the related performance-based payments in accordance with paragraph (d) of this clause.

(6) When the Contractor completes all of the obligations under this contract, including liquidation of all performance-based 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.

(g) 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. If any property is lost (see 45.101), the basis of payment (the events or performance criteria) to which the property is related shall be deemed to be not in compliance with the terms of the contract and not payable (if the property is part of or needed for performance), and the Contractor shall refund the related performance-based payments in accordance with paragraph (d) of this clause.

(h) Records and controls. The Contractor shall maintain records and controls adequate for administration of this clause. The Contractor shall have no entitlement to performance-based payments during any time the Contractor's records or controls are determined by the Contracting Officer to be inadequate for administration of this clause.

(i) Reports and Government access. The Contractor shall promptly furnish reports, certificates, financial statements, and other pertinent information requested by the Contracting Officer for the administration of this clause and to determine that an event or other criterion prompting a financing payment has been successfully accomplished. The Contractor shall give the Government reasonable opportunity to examine and verify the Contractor's records and to examine and verify the Contractor's performance of this contract for administration of this clause.

(j) Special terms regarding default. If this contract is terminated under the Default clause,

(1) the Contractor shall, on demand, repay to the Government the amount of unliquidated performance-based payments, and

(2) title shall vest in the Contractor, on full liquidation of all performance-based payments, for all property for which

the Government elects not to require delivery under the Default clause of this contract. The Government shall be liable for no payment except as provided by the Default clause.

(k) Reservation 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.

(l) Content of Contractor's request for performance-based payment. The Contractor's request for performance-based payment shall contain the following:

(1) The name and address of the Contractor;

(2) The date of the request for performance-based payment;

(3) The contract number and/or other identifier of the contract or order under which the request is made;

(4) Such information and documentation as is required by the contract's description of the basis for payment; and

(5) A certification by a Contractor official authorized to bind the Contractor, as specified in paragraph (m) of this clause.

(m) Content of Contractor's certification. As required in paragraph (l)(5) of this clause, the Contractor shall make the following certification in each request for performance-based payment:

I certify to the best of my knowledge and belief that --

(1) This request for performance-based payment is true and correct; this request (and attachments) has been prepared from the books and records of the Contractor, in accordance with the contract and the instructions of the Contracting Officer;

(2) (Except as reported in writing on _____), all payments to subcontractors and suppliers under this contract have been paid, or will be paid, currently, when due in the ordinary course of business;

(3) There are no encumbrances (except as reported in writing on _____) against the property acquired or produced for, and allocated or properly chargeable to, the contract which would affect or impair the Government's title;

(4) There has been no materially adverse change in the financial condition of the Contractor since the submission by the Contractor to the Government of the most recent written information dated _____; and

(5) After the making of this requested performance-based payment, the amount of all payments for each deliverable item for which performance-based payments have been requested will not exceed any limitation in the contract, and

the amount of all payments under the contract will not exceed any limitation in the contract.

(End of Clause)

52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es):

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

(End of clause)

52.252-6 AUTHORIZED DEVIATIONS IN CLAUSES (APR 1984)

(a) The use in this solicitation or contract of any Federal Acquisition Regulation (48 CFR Chapter 1) clause with an authorized deviation is indicated by the addition of "(DEVIATION)" after the date of the clause.

(b) The use in this solicitation or contract of any Defense Federal Acquisition Regulation Supplement (48 CFR Chapter 2) clause with an authorized deviation is indicated by the addition of "(DEVIATION)" after the name of the regulation.

(End of clause)

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| (b) (4) | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |