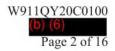
AMENDMENT OF SOLICIT	ATION/MODII	FICATION OF CONTRACT	1 CONTRACT ID COD	PAGE OF PAGES 1 16	
2 AMENDMENT/MODIFICATION NO	3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO 0011534693	5 PRO	JECTNO (Ifapplicable)	
6 ISSUED BY CODE  W6QK ACC-APG NATICK DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011	W911QY	7 ADMINISTERED BY (Ifother than item 6) DEFENSE CONTRACT MANAGEMENT AGENCY DCMA BOSTON 495 SUMMER STREET BOSTON MA 02210-2138	CODE S	S2206A	
8. NAME AND ADDRESS OF CONTRACTOR MODERNA US INC	(No., Street, County,	State and Zip Code)		F SOLICITATION NO.	
200 TECHNOLOGY SQ CAMBRIDGE MA 02139-3578			9B. DATED (SEE ITE 10A. MOD. OF CONT		
	<u> </u>	^	10A MOD OF CONT W911QY20C0100 10B DATED (SEE IT		
CODE 8PTM0	FACILITY CO		00 7 tag 2020		
11.	THIS ITEM ONLY	APPLIES TO AMENDMENTS OF SOLICIT	ATIONS		
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)					
		TO MODIFICATIONS OF CONTRACTS/OI CT/ORDER NO. AS DESCRIBED IN ITEM			
A. THIS CHANGE ORDER IS ISSUED PURSI CONTRACT ORDER NO. IN ITEM 10A.	UANT TO: (Specify a	authority) THE CHANGES SET FORTH IN	ITEM 14 ARE MADE	N THE	
	TH IN ITEM 14, PUR	RSUANT TO THE AUTHORITY OF FAR 4		ges in paying	
X C. THIS SUPPLEMENTAL AGREEMENT IS Mutual Agreement of the parties, FAR 43.10		URSUANT TO AUTHORITY OF:			
D. OTHER (Specify type of modification and	authority)				
E. IMPORTANT: Contractor is not,	X is required to sig	gn this document and return 1 co	pies to the issuing office	ú.	
<ol> <li>DESCRIPTION OF AMENDMENT/MODIF where feasible.) Modification Control Number: dsoto2025</li> </ol>		d by UCF section headings, including solicitat	ion/contract subject ma	ter	
The purpose of this modification is to  1. Novation Change from Moderna TX to Moderna US  2. Section C make administrative revisions to correct type-o and update company name  3. Section G update company name, correct type-o in subCLINs, and revise WAWF Clause inspect by from S2206A to W911QY  4. Section I add FAR 52.204-25 and update information in FAR 252.232-7007  5. Section J revised page number on Exh bits and Attachments					
The total obligated amount and contract price remains the unchanged.  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		16A. NAME AND TITLE OF CONT		ype or print)	
(b) (6)		(b) (6) TE:(b) (6)	EMAL:	,,,,,	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNE	16B. UNITED STATES OF AMERIC	A BY	16C. DATE SIGNED 9/08/2020	
(mn)		(Signature of Contracting Office	r)		



#### SECTION SF 30 BLOCK 14 CONTINUATION PAGE

#### SUMMARY OF CHANGES

SECTION C - DESCRIPTIONS AND SPECIFICATIONS

The following have been modified:

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

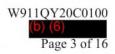
- C.1 **SCOPE**. The Department of Defense and Health and Human Services (HHS) require large scale manufacturing of vaccine doses in support of the national emergency response to the Coronavirus Disease 2019 (COVID-19) for the United States Government (USG) and the US population.
- C.1.1 <u>Background</u>. 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 Moderna US, 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.

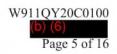
# C.3.1 <u>Contract Line Item Number (CLIN) 0001 - Base Period: Large Scale Manufacturing of 100 Million Vaccine Doses.</u>

- C.3.1.1 The contractor shall complete all scope required for the production, release and delivery use of 100 million Final Drug Product (FDP) doses of a SARS-CoV-2 mRNA-1273 vaccine. This shall include, the following tasks and other activities reasonably contemplated by such task:
- C.3.1.1.1 Storage of FDP doses prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Storage and maintenance of the vaccine prior to delivery shall be under conditions and at temperatures necessary to retain stability for use as prescribed in this contract for a period of 12 months. (Based on FDP stability data that supports a 12-month shelf-life, subject to FDA confirmation of the assigned shelf-life.) Ensure requirements of 21CFR207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution are met prior to distribution to the CDC. Documents shall be provided under CDRL A002, FDA Interactions and Inspections Documentation.
- C.3.1.1.2 cGMP manufacturing of 100 million doses fully compliant with 21 CFR 210 and 211.
- C.3.1.1.3 Ensuring that vial labeling and packaging is consistent with FDA guidance for use in target populations and that labeling is updated as appropriate.
- C.3.1.1.4 Coordinating with FDA to establish an approved commercial vial label, carton and packaging insert (printed or electronic).
- C.3.1.1.5 Ensuring the product complies with the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov. 27, 2013), including product verification, serialization, traceability and detection and response requirements, subject to any exceptions established by or the enforcement discretion of the FDA, including "Exemption from Certain Product Tracing and Product Identification Requirements Under Section 582 of the FD&C Act" (April 2020).
- C.3.1.1.6 In coordination with the USG, the contractor shall conduct a demonstration of the vaccine shipping process prior to the first delivery of FDP doses at a time mutually agreed to by the contractor and the USG. Moderna shall provide specifications and details associated with the shipping process and containers (IAW CDRL A005) to enable the USG to adequately plan and prepare for potential distribution of the vaccine.
- C.3.1.1.7 Following release of product the contractor shall, promptly deliver product to the designated delivery site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. In the unforeseen event that a designated delivery site cannot receive product and the contractor provides storage beyond 20 days of product release, the contract will be subject to modification for acceptance purposes.
- C.3.1.2 Site Visits and Audits. The contractor shall accommodate periodic or ad hoc site visits by BARDA and FDA representatives for required site visits and audits at facilities used to support this contract throughout the period of performance of the contract.
- C.3.1.2.1 BARDA Audits. If issues are identified during an audit, the contractor shall submit a report detailing the finding and corrective action(s) in accordance with CDRL A001.

- C.3.1.2.2 FDA Audits. The Contractor shall notify the Contracting Officer and Contracting Officer's Representative (COR) within (b) (4) of a scheduled FDA audit or within (b) (4) of an ad hoc site visit or audit if the FDA does not provide advance notice. The contractor shall provide copies of any FDA Audit Report received from subcontractors that occur as a result of this contract or for this product within (b) (4) day of receiving correspondence from the FDA or third party in accordance with CDRL A002. The Contractor shall provide the Contracting Officer with a plan for addressing areas of nonconformance, if any are identified, within of submittal of the audit report in accordance with CDRL A002.
- C.3.1.2.3 FDA Interactions. The contractor shall provide copies of the plan and processes that will ensure the USG has visibility and input on all FDA communications regarding the drugs and biologics for the following, but not limited to: FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation in accordance with CDRL A002.

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

- C.3.2.1 The contractor shall complete all scope required for the production, release and delivery use of 100 million FDP doses of a SARS-CoV-2 mRNA-1273 vaccine. This shall include the following tasks and other activities reasonably contemplated by such tasks:
- C.3.2.1.1 Storage of FDP doses prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Storage and maintenance of the vaccine prior to delivery shall be under conditions and at temperatures necessary to retain stability for use as prescribed in this contract for a period of 12 months. (Based on FDP stability data that supports a 12-month shelf-life, subject to FDA confirmation of the assigned shelf-life.) Ensure requirements of 21CFR207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution are met prior to distribution to the CDC. Documents shall be provided under CDRL A002, FDA Interactions and Inspections Documentation.
- C.3.2.1.2 cGMP manufacturing of 100 million doses, subject to any exceptions established by or the enforcement discretion of the FDA.
- C.3.2.1.3 Ensuring that vial labeling and packaging is consistent with FDA guidance for use in target populations and that labeling is updated.
- C.3.2.1.4 Ensuring the product complies with the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov. 27, 2013), including product verification, serialization, traceability and detection and response requirements subject to any exceptions established by or the enforcement discretion of the FDA.
- C.3.2.1.5 Following release of the product the contractor shall deliver the product to the designated distribution site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. To the extent a natural disaster or other emergency affecting a designated delivery site restricts such site's ability to receive product, the Contractor and the USG will promptly agree on an alternate USG delivery location, or storage as Vendor Managed Inventory (VMI) at the contractor site.
- C.3.2.2 Site Visits and Audits. The contractor shall accommodate periodic or ad hoc site visits by BARDA and FDA representatives for required site visits and audits at facilities used to support this contract throughout the period of performance of the contract.
- C.3.2.2.1 BARDA Audits. If issues are identified during an audit, the contractor shall submit a report detailing the finding and corrective action(s) in accordance with CDRL A001.
- C.3.2.2.2 FDA Audits. The Contractor shall notify the Contracting Officer and COR within (b) (4) of a scheduled FDA audit or within (b) (4) of an ad hoc site visit or audit if the FDA does not provide advance notice. The contractor shall provide copies of any FDA Audit Report received from subcontractors that occur as a result of this contract or for this product within (b) (4) of receiving correspondence from the FDA or third party in

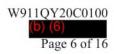


accordance with CDRL A015. The Contractor shall provide the Contracting Officer with a plan for addressing areas of nonconformance, if any are identified, within (b) (4) of submittal of the audit report in accordance with CDRL A002.

C.3.2.2.3 FDA Interactions. The contractor shall provide copies of the plan and processes that will ensure the USG has visibility and input on all FDA communications regarding the drugs and biologics for the following, but not limited to: FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation in accordance with CDRL A002.

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

- C.3.3.1 The contractor shall complete all scope required for the production, release and delivery use of 100 million FDP doses of a SARS-CoV-2 mRNA-1273 vaccine. This shall include the following tasks and other activities reasonably contemplated by such tasks:
- C.3.3.1.1 Storage of FDP doses prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Storage and maintenance of the vaccine prior to delivery shall be under conditions and at temperatures necessary to retain stability for use as prescribed in this contract for a period of 12 months. (Based on FDP stability data that supports a 12-month shelf-life, subject to FDA confirmation of the assigned shelf-life.) Ensure requirements of 21CFR207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution are met prior to distribution to the CDC. Documents shall be provided under CDRL A002, FDA Interactions and Inspections Documentation.
- C.3.3.1.2 cGMP manufacturing of 100 million doses, subject to any exceptions established by or the enforcement discretion of the FDA.
- C.3.3.1.3 Ensuring that vial labeling and packaging is consistent with FDA guidance for use in target populations and that labeling is updated as appropriate.
- C.3.3.1.4 Ensuring that the product complies with the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov. 27, 2013), including product verification, serialization, traceability and detection and response requirements, subject to any exceptions established by or the enforcement discretion of the FDA.
- C.3.3.1.5 Following release the contractor shall deliver product to the nearest designated distribution site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. To the extent a natural disaster or other emergency affecting a designated delivery site restricts such site's ability to receive product, the Contractor and the USG will promptly agree on an alternate USG delivery location, or storage as Vendor Managed Inventory (VMI) at the contractor site.
- C.3.3.2 Site Visits and Audits. The contractor shall accommodate periodic or ad hoc site visits by BARDA and FDA representatives for required site visits and audits at facilities used to support this contract throughout the period of performance of the contract.
- C.3.3.2.1 BARDA Audits. If issues are identified during an audit, the contractor shall submit a report detailing the finding and corrective action(s) in accordance with CDRL A001.
- C.3.3.2.2 FDA Audits. The Contractor shall notify the Contracting Officer and COR within (b) (4) of a scheduled FDA audit or within (b) (4) of an ad hoc site visit or audit if the FDA does not provide advance notice. The contractor shall provide copies of any FDA Audit Report received from subcontractors that occur as a result of this contract or for this product within (b) (4) of receiving correspondence from the FDA or third party in accordance with CDRL A002. The Contractor shall provide the Contracting Officer with a plan for addressing areas of nonconformance, if any are identified, within (b) (4) of submittal of the audit report in accordance with CDRL A002.



C.3.3.2.3 FDA Interactions. The contractor shall provide copies of the plan and processes that will ensure the USG has visibility and input on all FDA communications regarding the drugs and biologics for the following, but not limited to: FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation in accordance with CDRL A002.

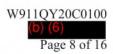
#### C.3.4 CLIN 3001 - Option Period 3: Large Scale Manufacturing of 100 Million Vaccine Doses.

- C.3.4.1 The contractor shall complete all scope required for the production, release and delivery use of 100 million FDP doses of a SARS-CoV-2 mRNA-1273 vaccine. This shall include the following tasks and other activities reasonably contemplated by such tasks:
- C.3.4.1.1 Storage of FDP doses prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Storage and maintenance of the vaccine prior to delivery shall be under conditions and at temperatures necessary to retain stability for use as prescribed in this contract for a period of 12 months. (Based on FDP stability data that supports a 12-month shelf-life, subject to FDA confirmation of the assigned shelf-life.) Ensure requirements of 21CFR207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution are met prior to distribution to the CDC. Documents shall be provided under CDRL A002, FDA Interactions and Inspections Documentation.
- C.3.4.1.2 cGMP manufacturing of 100 million doses, subject to any exceptions established by or the enforcement discretion of the FDA.
- C.3.4.1.3 Ensuring that vial labeling and packaging is consistent with FDA guidance for use in target populations and that labeling is updated.
- C.3.4.1.4 Ensuring the product complies with the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov. 27, 2013), including product verification, serialization, traceability and detection and response requirements subject to any exceptions established by or the enforcement discretion of the FDA.
- C.3.4.1.5 Following release of the product the contractor shall deliver the product to the designated distribution site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. To the extent a natural disaster or other emergency affecting a designated delivery site restricts such site's ability to receive product, the Contractor and the USG will promptly agree on an alternate USG delivery location, or storage as Vendor Managed Inventory (VMI) at the contractor site.
- C.3.4.2 Site Visits and Audits. The contractor shall accommodate periodic or ad hoc site visits by BARDA and FDA representatives for required site visits and audits at facilities used to support this contract throughout the period of performance of the contract.
- C.3.4.2.1 BARDA Audits. If issues are identified during an audit, the contractor shall submit a report detailing the finding and corrective action(s) in accordance with CDRL A001.
- C.3.4.2.2 FDA Audits. The Contractor shall notify the Contracting Officer and COR within (b) (4) of a scheduled FDA audit or within (b) (4) of an ad hoc site visit or audit if the FDA does not provide advance notice. The contractor shall provide copies of any FDA Audit Report received from subcontractors that occur as a result of this contract or for this product within (b) (4) of receiving correspondence from the FDA or third party in accordance with CDRL A015. The Contractor shall provide the Contracting Officer with a plan for addressing areas of nonconformance, if any are identified, within (b) (4) of submittal of the audit report in accordance with CDRL A002.
- C.3.4.2.3 FDA Interactions. The contractor shall provide copies of the plan and processes that will ensure the USG has visibility and input on all FDA communications regarding mRNA-1273 for the following, but not limited to: FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation in accordance with CDRL A002.

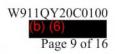


# C.3.5 CLIN 4001 - Option Period 4: Large Scale Manufacturing of 100 Million Vaccine Doses.

- C.3.5.1 The contractor shall complete all scope required for the production, release and delivery use of 100 million FDP doses of a SARS-CoV-2 mRNA-1273 vaccine. This shall include the following tasks and other activities reasonably contemplated by such tasks:
- C.3.5.1.1 Storage of FDP doses prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Storage and maintenance of the vaccine prior to delivery shall be under conditions and at temperatures necessary to retain stability for use as prescribed in this contract for a period of 12 months. (Based on FDP stability data that supports a 12-month shelf-life, subject to FDA confirmation of the assigned shelf-life.) Ensure requirements of 21CFR207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution are met prior to distribution to the CDC. Documents shall be provided under CDRL A002, FDA Interactions and Inspections Documentation.
- C.3.5.1.2 cGMP manufacturing of 100 million doses, subject to any exceptions established by or the enforcement discretion of the FDA.
- C.3.5.1.3 Ensuring that vial labeling and packaging is consistent with FDA guidance for use in target populations and that labeling is updated.
- C.3.5.1.4 Ensuring the product complies with the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov. 27, 2013), including product verification, serialization, traceability and detection and response requirements subject to any exceptions established by or the enforcement discretion of the FDA.
- C.3.5.1.5 Following release of the product the contractor shall deliver the product to the designated distribution site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. To the extent a natural disaster or other emergency affecting a designated delivery site restricts such site's ability to receive product, the Contractor and the USG will promptly agree on an alternate USG delivery location, or storage as Vendor Managed Inventory (VMI) at the contractor site.
- C.3.5.2 Site Visits and Audits. The contractor shall accommodate periodic or ad hoc site visits by BARDA and FDA representatives for required site visits and audits at facilities used to support this contract throughout the period of performance of the contract.
- C.3.5.2.1 BARDA Audits. If issues are identified during an audit, the contractor shall submit a report detailing the finding and corrective action(s) in accordance with CDRL A001.
- C.3.5.2.2 FDA Audits. The Contractor shall notify the Contracting Officer and COR within (b) (4) of a scheduled FDA audit or within (b) (4) of an ad hoc site visit or audit if the FDA does not provide advance notice. The contractor shall provide copies of any FDA Audit Report received from subcontractors that occur as a result of this contract or for this product within (b) (4) of receiving correspondence from the FDA or third party in accordance with CDRL A015. The Contractor shall provide the Contracting Officer with a plan for addressing areas of nonconformance, if any are identified, within (b) (4) of submittal of the audit report in accordance with CDRL A002.
- C.3.5.2.3 FDA Interactions. The contractor shall provide copies of the plan and processes that will ensure the USG has visibility and input on all FDA communications regarding the drugs and biologics for the following, but not limited to: FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation in accordance with CDRL A002.
- C.4 <u>CLIN 0002</u>: <u>Data Deliverables</u>. The contractor shall provide the following in accordance with the Contract Data Requirements List (CDRL), DD Forms 1423, provided at Appendix A.
- C.4.1 Monthly Inventory Report (CDRL A003), detailing at a minimum, raw materials, Bulk mRNA, formulated LNPs, and the fill, finish, and released product.



- C.4.2 Quality Management Plan. The contractor shall provide a Quality Management Plan, in accordance with CDRL A004, describing the quality policy and objectives, management review, competencies and training, process document control, feedback, evaluation, corrective action and preventive action, process improvement, measurement, and data analysis processes. The framework is normally divided into infrastructure, senior management responsibility, resource management, lifecycle management, and quality management system evaluation.
- C.4.3 Shipping Documentation (CDRL A005) for all Finished Drug Product (FDP) transferring from the contractor's fill/finish facility to a USG facility. The contractor shall obtain concurrence on planned shipment protocols prior to transport.
- C.4.4 Expiring Items Report (CDRL A006) for all FDP in the USG's possession.
- C.4.5 Key Personnel Listing (CDRL A007).
- C.4.6 Monthly Technical Progress Report (CDRL A008), to include an Integrated Master Schedule, identifying key activities and contract status.
- C.4.7 Final Technical Report (CDRL A009), documenting the work performed and results obtained for the entire contract period of performance.
- C.4.8 Supply Chain Resiliency Plan (SCRP). The contractor shall provide, in accordance with CDRL A010 and CDRL Attachment 0001, a comprehensive SCRP that provides for identification and reporting of critical components associated with the secure supply of drug substance, drug product, and work-in-process through to finished goods, and key equipment suppliers and their locations, including addresses, points of contact, and work performed per location, to include subcontractors.
- C.4.9 Risk Management Plan (RMP). The Contractor shall provide an RMP in accordance with CDRL A011 that outlines the impacts of each risk in relation to the cost, schedule, and performance objectives. The plan shall include risk mitigation strategies. Each risk mitigation strategy shall capture how the corrective action will reduce impacts on cost, schedule and performance.
- C.4.10 Manufacturing Reports and Dose Tracking. The Contractor shall provide, in accordance with CDRL A013, manufacturing reports and manufacturing dose tracking projections and actuals utilizing the USG-provided "COVID-19 Dose Tracking Template" (CDRL Attachment 0003).
- C.4.11 Product Acceptance Report (for each lot of Drug Product). The contractor shall provide, in accordance with CDRL A014, pictures of the drug product with lot number, drug product lot tree, list of associated deviations (from drug substance and product), and a Certificate of Analysis.
- C.4.12 Incident Report. The contractor shall communicate to BARDA and document all critical programmatic concerns, issues, or probable risks that have or are likely to significantly impact project schedule and/or cost and/or performance in accordance with CDRL A016. "Significant" is frequently defined as a 10% or greater cost or schedule variance within a control account, but should be confirmed in consultation with the COR. Incidents that present liability to the project even without cost/schedule impact, such as breach of GCP during a clinical study, shall also be reported.
- C.4.13 FDA Correspondence. The contractor shall provide any correspondence between Contractor and FDA relevant to the scope of this contract and submit in accordance with CDRL A017.
- C.4.14 Press Releases. The contractor shall accurately and factually represent the work conducted under this contract in all press releases. The contractor shall provide an advance copy of any press release in accordance with CDRL A018.



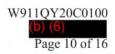
C.4.15 Manufacturing Development Plan. The contractor shall provide a Manufacturing Development Plan, in accordance with CDRL A025, describing the manufacturing process for the drug/biologic product to ensure conformity with §501(a)(2)(B) of the Food, Drug, and Cosmetics Act (FD&C Act, Title 21 United States Code (USC) §351 (a)(2)(B)), regarding good manufacturing practices (GMP).

#### C.5 Administration.

- C.5.1 <u>Post Award Teleconference</u>. The contractor shall host a Post Award Teleconference within 15 7 calendar days after contract award.
- C.5.1.1 The contractor shall provide an Agenda, IAW CDRL A020, detailing the planned activities for the subsequent 30 calendar days 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 <u>Post Award Kickoff Meeting</u>. The contracting officer may request the contractor host a contract Kick-Off Meeting within 30 calendar days 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 <u>Bi-Weekly Teleconference</u>. The contractor shall participate in bi-weekly 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 <u>Daily "Check-In"</u>. The contractor shall participate in a daily "check-in" (via teleconference or email) to address key cost, schedule and technical updates. Daily updates may be shared with senior USG leaders during the COVID- 19 response and should be provided on a non-confidential basis, unless the update includes confidential information in which case, the contractor shall provide the update in both confidential and non-confidential formats. Daily check-ins may occur on weekdays, excluding federal holidays. Upon request of the USG, check-ins may also occur on weekends and on federal holidays, provided at least 24 hours' notice.

#### C.6 Security.

- C.6.1 Access and General Protection/Security Policy and Procedures. The contractor shall provide all information required for background checks necessary to access critical information related to OWS, and to meet USG installation access requirements to be accomplished by the installation Director of Emergency Services or Security Office. The contractor employees shall comply with all personnel identity verification requirements as directed by the USG and/or local policy. In addition to the changes otherwise authorized by the changes clause of this contract, should the security status of OWS change the USG may require changes in the contractor's security matters or processes. In addition to the industry standards for employment background checks, the contractor shall be willing to have key individuals, in exceptionally sensitive positions, identified for additional vetting by the United States USG.
- C.6.2 Security Program and Plan. The contractor shall implement a comprehensive security program that provides overall protection of personnel, information, data, and facilities associated with fulfilling the USG's requirement. The contractor's security practices and procedures shall be detailed in a Security Plan, in accordance with CDRL A019, and shall demonstrate how the contractor shall meet and adhere to the security requirements outlined in CDRL Attachment 0002. This plan shall be delivered to the USG within 45 days of award, and the USG will review in detail and submit comments within ten (10) business days to the Contracting Officer (CO) to be forwarded to the Contractor. The Contractor shall review the Security Plan comments, and, submit a final Security Plan to the U.S. USG within thirty (30) calendar days after receipt of the comments. The Security Plan shall include a timeline for compliance of all the required security measures outlined in CDRL Attachment 0002.



- C.6.3 Operational Security (OPSEC). The contractor shall develop and submit an OPSEC Standard Operating Procedure (SOP)/Plan IAW CDRL A024. The contractor shall identify in the SOP/Plan critical information related to this contract, why it needs to be protected, where it is located, who is responsible for it, and how to protect it.
- C.7 <u>CLIN 0002 Vendor Managed Inventory (VMI)</u>. The Contractor shall provide the capability to store the vaccine for up to 52 weeks, up to 100M doses of mRNA-1273 vaccine, in accordance with product labeling. The contractor shall, in accordance with paragraph C.3.1.1.6, ensure the product storage of FDP doses for up to 12 months prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Risk of loss of or damage to supplies shall remain with the contractor until delivery of Filled Drug Product (FDP) to a government facility. The contractor shall store the product to insure product quality with audible alarms and contacting. The contractor shall notify the USG within of detection of an incident with the potential to impact product quality, and implement corrective actions to mitigate the incident. BARDA/JPEO-CBRND personnel may conduct Quality Audits of the storage facility, when deemed necessary. The contractor shall notify the USG of Corrective/Preventive actions within of detection of an incident with potential to impacts product quality. BARDA/JPEO-CBRND personnel may conduct Quality Audits of the storage facility, when deemed necessary.
- C.7.1 The USG will provide the contractor advance notice of the required delivery locations for the vaccine. 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 shipment of all vaccine product whether acceptance is conducted at origin or destination. Regardless of where acceptance occurs, risk of loss of or damage to supplies shall remain with the contractor until delivery of Filled Drug Product (FDP) to a government facility.
- C.7.2 The vaccine product shall be shipped and tracked by the distribution vendor's shipping tracking number, to the USG-designated sites within the continental United States.
- C.7.3 The contractor shall retain physical risk of loss for all product stored as VMI until subsequent delivery to and acceptance by the USG at the USG-designated site. Implementation of a Vendor Managed Inventory Plan/SOP (CDRL A012) shall be provided to the USG. If the drug product is initially delivered to a USG site instead of VMI, risk of loss will transfer upon delivery and acceptance at the USG-designated site. Notwithstanding either of the foregoing sentences, the contractor shall not be liable for loss of or damage to supplies caused by the negligence of officers, agents, or employees of the USG acting within the scope of their employment.

SECTION G - CONTRACT ADMINISTRATION DATA

The following have been modified:

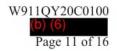
# G.1 GOVERNMENT CONTRACT ADMINISTRATION

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

Moderna US, Inc.

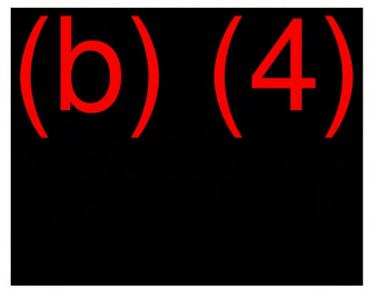
200 Technology SQ. Cambridge, MA 02139-3578

#### 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 0007, 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:



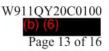


Delivery Invoicing: PBPs are a type of contract financing and are recouped by the Government through deductions of payments otherwise due to the contractor for the partial or complete delivery of contract items. The deductions are made by applying a liquidation rate to the price of delivered contract items. Attachment 0008, Performance-based Payment Milestone Billing Plan, identifies the contractor invoicing schedule for liquidation. The contractor shall submit all invoices IAW Attachment 0008.

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

- (a) Definitions. As used in this clause-
- "Department of Defense Activity Address Code (DoDAAC)" is a six position code that uniquely identifies a unit, activity, or organization.
- "Document type" means the type of payment request or receiving report available for creation in Wide Area WorkFlow (WAWF).
- "Local processing office (LPO)" is the office responsible for payment certification when payment certification is done external to the entitlement system.
- "Payment request" and "receiving report" are defined in the clause at 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.
- (b) Electronic invoicing. The WAWF system provides the method to electronically process vendor payment requests and receiving reports, as authorized by Defense Federal Acquisition Regulation Supplement (DFARS) 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.
- (c) WAWF access. To access WAWF, the Contractor shall-
- (1) Have a designated electronic business point of contact in the System for Award Management at <a href="https://www.sam.gov">https://www.sam.gov</a>; and
- (2) Be registered to use WAWF at <a href="https://wawf.eb mil/">https://wawf.eb mil/</a> following the step-by-step procedures for self-registration available at this web site.
- (d) WAWF training. The Contractor should follow the training instructions of the WAWF Web-Based Training Course and use the Practice Training Site before submitting payment requests through WAWF. Both can be accessed by selecting the "Web Based Training" link on the WAWF home page at <a href="https://wawf.eb mil/">https://wawf.eb mil/</a>.
- (e) WAWF methods of document submission. Document submissions may be via web entry, Electronic Data Interchange, or File Transfer Protocol.
- (f) WAWF payment instructions. The Contractor shall use the following information when submitting payment requests and receiving reports in WAWF for this contract or task or delivery order:
- (1) Document type. The Contractor shall submit payment requests using the following document type(s):

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.

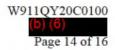
# N/A

- (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

Field Name in WAWF	Data to be entered in WAWF
Pay Official DoDAAC	HQ0337
Issue By DoDAAC	W911QY
Admin DoDAAC**	S2206A
Inspect By DoDAAC	W911QY / 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.



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

(End of clause)

FOR REFERANCE:

DFARS PGI 204.7108 Payment Instructions Table

https://www.acq.osd.mil/dpap/dars/pgi/pgi htm/current/PGI204 71.htm#payment instructions

SECTION I - CONTRACT CLAUSES

The following have been added by reference:

52.204-25 Prohibition on Contracting for Certain Telecomm

Prohibition on Contracting for Certain Telecommunications AUG 2020 and Video Surveillance Services or Equipment.

The following have been modified:

252.232-7007 LIMITATION OF GOVERNMENT'S OBLIGATION (APR 2014)

- (a) Contract line item (b) (4) \_\_is incrementally funded. For this item, (b) (4) \_\_ (4) \_\_ (4) \_\_ (4) \_\_ (4) \_\_ (4) \_\_ (5) (4) \_\_ (6) (6) \_\_\_ (6) \_\_\_ (6) \_\_\_ (6) \_
- (b) For items(s) identified in paragraph (a) of this clause, the Contractor agrees to perform up to the point at which the total amount payable by the Government, including reimbursement in the event of termination of those item(s) for the Government's convenience, approximates the total amount currently allotted to the contract. The Contractor is not authorized to continue work on those item(s) beyond that point. The Government will not be obligated in any event to reimburse the Contractor in excess of the amount allotted to the contract for those item(s) regardless of anything to the contrary in the clause entitled "TERMINATION FOR THE CONVENIENCE OF THE GOVERNMENT." As used in this clause, the total amount payable by the Government in the event of termination of applicable contract line item(s) for convenience includes costs, profit and estimated termination settlement costs for those item(s).

- (c) Notwithstanding the dates specified in the allotment schedule in paragraph (j) of this clause, the Contractor will notify the Contracting Officer in writing at least innety days prior to the date when, in the Contractor's best judgment, the work will reach the point at which the total amount payable by the Government, including any cost for termination for convenience, will approximate 85 percent of the total amount then allotted to the contract for performance of the applicable item(s). The notification will state (1) the estimated date when that point will be reached and (2) an estimate of additional funding, if any, needed to continue performance of applicable line items up to the next scheduled date for allotment of funds identified in paragraph (j) of this clause, or to a mutually agreed upon substitute date. The notification will also advise the Contracting Officer of the estimated amount of additional funds that will be required for the timely performance of the item(s) funded pursuant to this clause, for subsequent period as may be specified in the allotment schedule in paragraph (j) of this clause, or otherwise agreed to by the parties. If after such notification additional funds are not allotted by the date identified in the Contractor's notification, or by an agreed substitute date, the Contracting Officer will terminate any item(s) for which additional funds have not been allotted, pursuant to the clause of this contract entitled "TERMINATION FOR THE CONVENIENCE OF THE GOVERNMENT".
- (d) When additional funds are allotted for continued performance of the contract line item(s) identified in paragraph (a) of this clause, the parties will agree as to the period of contract performance which will be covered by the funds. The provisions of paragraph (b) through (d) of this clause will apply in like manner to the additional allotted funds and agreed substitute date, and the contract will be modified accordingly.
- (e) If, solely by reason of failure of the Government to allot additional funds, by the dates indicated below, in amounts sufficient for timely performance of the contract line item(s) identified in paragraph (a) of this clause, the Contractor incurs additional costs or is delayed in the performance of the work under this contract and if additional funds are allotted, an equitable adjustment will be made in the price or prices (including appropriate target, billing, and ceiling prices where applicable) of the item(s), or in the time of delivery, or both. Failure to agree to any such equitable adjustment hereunder will be a dispute concerning a question of fact within the meaning of the clause entitled "disputes."
- (f) The Government may at any time prior to termination allot additional funds for the performance of the contract line item(s) identified in paragraph (a) of this clause.
- (g) The termination provisions of this clause do not limit the rights of the Government under the clause entitled "DEFAULT." The provisions of this clause are limited to work and allotment of funds for the contract line item(s) set forth in paragraph (a) of this clause. This clause no longer applies once the contract if fully funded except with regard to the rights or obligations of the parties concerning equitable adjustments negotiated under paragraphs (d) or (e) of this clause.
- (h) Nothing in this clause affects the right of the Government to this contract pursuant to the clause of this contract entitled "TERMINATION FOR CONVENIENCE OF THE GOVERNMENT."
- (i) Nothing in this clause shall be construed as authorization of voluntary services whose acceptance is otherwise prohibited under 31 U.S.C. 1342.

(j) The parties contemplate that the Government will allot funds to this contract in accordance with the following schedule:



(End of clause)

# SECTION J - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

The following have been modified:

Document Type	Description	Page #	Date
Exhibit A	CDRLs	15	18 July 2020
Attachment 0001	Supply Chain Resiliency Plan for CDRL A010	3	23 July 2020
Attachment 0002	Security Plan	7	23 July 2020
Attachment 0003	Dose Tracking Template Draft Moderna	Excel	15 July 2020
Attachment 0004	Data Rights	3	7 August 2020
Attachment 0005	(b) (4)	2	7 August 2020
Attachment 0006	ModernaTx, Inc. Background Intellectual Property	3	6 August 2020
Attachment 0007	Performance Base Payment Milestone Schedule	2	7 August 2020
Attachment 0008	Performance Base Payment Milestone Billing Plan	16	7 August 2020

(End of Summary of Changes)

AMENDMENT OF SOLICIT	1 CONTRACT I	1 CONTRACT ID CODE PAGE O			
AMENDMENT OF SOLICIT	ATION/MODI	IFICATION OF CONTRACT			1   3
2 AMENDMENT/MODIFICATION NO	EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO	· I	5 PROJECT	NO (Ifapplicable)
P00002	11-Sep-2020	0011534693			
6 ISSUED BY CODE  W60K ACC-APG NATICK DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011	W911QY	7 ADMINISTERED BY (If other than item 6) DEFENSE CONTRACT MANAGEMENT AGENCY DCMA BOSTON 495 SUMMER STREET BOSTON MA 02210-2138	COD	S220	βA
8. NAME AND ADDRESS OF CONTRACTOR	No Street Counts	State and Zin Code)	9A. AMENDME	NT OF SO	LICITATION NO.
MODERNA US, NC.  100 TECHNOLOGY SQ CAMBRIDGE MA 02139-3578	t (110., orzeci, county	, saic and Exp code)	9B. DATED (SE	E ITEM 1	1)
CANIDALOGE MA 02130-3376		×	10A MOD OF W911QY20C01	CONTRAC 00	T/ORDER NO.
			10B. DATED (S	SEE ITEM	13)
CODE 8PTM0	FACILITY CO		09-Aug-2020		
The above numbered solicitation is amended as set fo		APPLIES TO AMENDMENTS OF SOLICI	is extended.	is not exter	nded
REJECTION OF YOUR OFFER. If by virtue of this provided each telegram or letter makes reference to the second state of the second state of the second state of the second state of the second second state of the second second state of the second sta	amendment you desire to do see solicitation and this ame DATA (If required)  TEM APPLIES ONLY DIFIES THE CONTR. SUANT TO: (Specify the contract of the contrac	AS PRIOR TO THE HOUR AND DATE SPECIFIED No.  Change an offer already submitted, such change may be rendment, and is received prior to the opening hour and  TO MODIFICATIONS OF CONTRACT S/C  ACT/ORDER NO. AS DESCRIBED IN ITEM  Y authority) THE CHANGES SET FORTH IN	made by telegram or lett date specified DRDERS. I 14. VITEM 14 ARE M	IADE IN T	
office, appropriation date, etc.) SET FOR X C. THIS SUPPLEMENTAL AGREEMENT	RTH IN ITEM 14, PU IS ENTERED INTO I			is changes i	n paying
45 CFR part 101, Health Resources and Pr D. OTHER (Specify type of modification an		ystem (HRPAS)			
E. IMPORTANT: Contractor is not,	X is required to	sign this document and return 1 c	opies to the issuing	office.	
14. DESCRIPTION OF AMENDMENT/MODI where feasible.) Modification Control Number: (b) (6)  OBLIGATION AMOUNT: \$0.00  See Block 14 continuation page	FICATION (Organiz				
Except as provided herein, all terms and conditions of the					or print)
(b) (6)	of Diffit	16A, NAME AND TITLE OF CONT (b) (6)  TEL: (b) (6)	EMAL:	EK (1 vpe	or print)
15B. CONTRACTOR/OFFEROR (S'n) (6)	15C. DATE SIGN	16B. UNITED STATES OF AMERIC	CA		C. 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:

The purpose of this modification is to:

 Add a Health Resources Priorities and Allocations System (HRPAS) priority rating of DO-HR to this contract:

This is a DO rated contract for the purpose of emergency preparedness and the Contractor shall follow all the provisions of the Health Resources Priorities and Allocations System regulation (45 CFR Part 101). If the contractor needs to utilize industrial resources to fulfill this rated order for a health resource, it is authorized pursuant to 45 CFR §101.36(b) to place the same priority rating and program identification symbol for health resources on its orders for industrial resources with its suppliers.

- 2. Add a Defense Priorites and Allocation System (DPAS) priority rating of DO-C9 to this contract to act as the equivalent to the HRPAS priority rating of DO-HR.
- 3. Add FAR 52.211-15, Defense Priority and Allocation Requirements

This is a rated order certified for national defense, emergency preparedness, and energy program use, and the Contractor shall follow all the requirements of the Defense Priorities and Allocations System regulation (15 CFR 700).

4. Add Attachment 0009 - HRPAS Moderna Letter to Section J

The total funded amount and total contract price remain unchanged.

#### SECTION A - SOLICITATION/CONTRACT FORM

The DPAS code DO-C9 has been added.
The contractor organization has changed from

MODERNATX, INC. (b) (6)

200 TECHNOLOGY SQ CAMBRIDGE MA 02139-3578

to

MODERNA US, INC.

b) (6

200 TECHNOLOGY SQ CAMBRIDGE MA 02139-3578



The following have been added by full text:

# 52.211-15 DEFENSE PRIORITY AND ALLOCATION REQUIREMENTS (APR 2008)

This is a rated order certified for national defense, emergency preparedness, and energy program use, and the Contractor shall follow all the requirements of the Defense Priorities and Allocations System regulation (15 CFR 700).

(End of clause)

# SECTION J - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

The following have been modified:

Document Type	Description	Page #	Date
Exhibit A	CDRLs	15	18 July 2020
Attachment 0001	Supply Chain Resiliency Plan for CDRL A010	3	23 July 2020
Attachment 0002	Security Plan	7	23 July 2020
Attachment 0003	Dose Tracking Template Draft Moderna	Excel	15 July 2020
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Attachment 0007	Performance Base Payment Milestone Schedule	2	7 August 2020
Attachment 0008	Performance Base Payment Milestone Billing Plan	16	7 August 2020
Attachment 0009	HRPAS Moderna Letter	1	3 September 2020

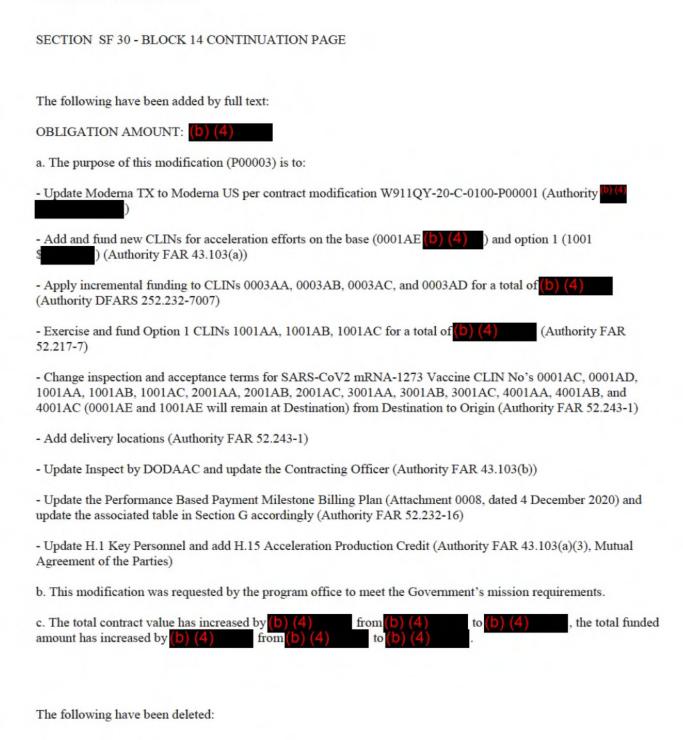
(End of Summary of Changes)

AMENDMENT OF SO	LICIT	ATION/MODII	FICATION OF CONTI	RACT	1 CONTRACT	ID CODE	PAGE OF PAGES
2 AMENDMENT/MODIFICATION NO		3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ	) NO		5 PROJECT	NO (Ifapplicable)
P00003		11-Dec-2020	SEE SCHEDULE	2 110		J I ROSECI	ivo (irappicaoie)
6 ISSUED BY WEQK ACC-APG NATICK DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011	CODE	W911QY	7 ADMINISTERED BY (Ifother th DEFENSE CONTRACT MANAGEM DCMA BOSTON 495 SUMMER STREET BOSTON MA 02210-2138		CO	DE   S220	6A
8. NAME AND ADDRESS OF CONTR MODERNAUS, NC.  200 TECHNOLOGY SQ CAMBRIDGE MA 02139-3578  CODE 8PTM0		FACILITY CO		x i	PB. DATED (S 10A MOD OF W911QY20C0 10B. DATED ( 09-Aug-2020	EE ITEM 1 CONTRAC	T/ORDER NO.
The above numbered solicitation is amende Offer must acknowledge receipt of this ame (a) By completing Items 8 and 15, and return or (c) By separate letter or telegram which it RECEIVED AT THE PLACE DESIGNAT REJECTION OF YOUR OFFER. If by virtiprovided each telegram or letter makes reference.	ndment pri ning ncludes a : ED FOR T ue of this a	copies of the amendment copies of the amendment reference to the solicitation HE RECEIPT OF OFFERS amendment you desire to ch	ecified in the solicitation or as amended ent; (b) By acknowledging receipt of thi a and amendment numbers FAILURE O BPRIOR TO THE HOUR AND DATE S ange an offer already submitted, such ch	by one of the foll is amendment on of F YOUR ACKN SPECIFIED MAY ange may be mad	each copy of the of OWLEDGMENT RESULTIN e by telegramor le	TO BE	nded
12. ACCOUNTING AND APPROPRIA	TION D	ATA (If required)					
See Schedule	тизт	EM ADDITES ONI V	TO MODIFICATIONS OF CON	TRACTSORI	DEBS		
A. THIS CHANGE ORDER IS ISSUE CONTRACT ORDER NO. IN IT	ED PURS EM 10A	UANT TO: (Specify ORDER IS MODIFIED	O TO REFLECT THE ADMINIS	FORTH IN IT	TEM 14 ARE M		
office, appropriation date, etc.) S  X C. THIS SUPPLEMENTAL AGREE See Block 14 Continuation Page					103(B).		
D. OTHER (Specify type of modific	ation and	l authority)					
E. IMPORTANT: Contractor i	s not,	X is required to si	gn this document and return	1 copi	es to the issuin	g office.	
14. DESCRIPTION OF AMENDMENT where feasible.) Modification Control Number:  See Block 14 Continuation Page	(6)	FICATION (Organized	d by UCF section headings, includ	ling solicitatio	n/contract subj	ect matter	
Except as provided herein, all terms and conditi	ons of the	document referenced in Item	n9A or 10A, as heretofore changed, rema	ains unchanged a	nd in fall force and	l effect	
15A. NAME AND TITLE OF SIGNER	(Type o	r print)	16A. NAME AND TITL!  (b) (6)  TEL: (b) (6)	E OF CONTR	ACTING OFFI	CER (Type	or print)
15B. CON (b) (6)		15C. DATE SIGNE		acting Officer)		16	C. DATE SIGNED 11 Dec 2020
EXCEPTION TO SF 30			30-105-04			ANDARD F	ORM 30 (Rev. 10-83)

APPROVED BY OIRM 11-84

#### SECTION SF 30 BLOCK 14 CONTINUATION PAGE

#### SUMMARY OF CHANGES



SECTION A - SOLICITATION/CONTRACT FORM



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

#### SECTION B - SUPPLIES OR SERVICES AND PRICES

# Global Changes

CLIN 0001 -- CLIN 4002

The manufacturer organization has changed from MODERNATX, INC.
200 TECHNOLOGY SQ
CAMBRIDGE MA 02139-3578 to
MODERNA US, INC.
200 TECHNOLOGY SQ
CAMBRIDGE MA 02139-3578

#### SUBCLIN 0003AA

The project Operation Warp Speed has been added.

# SUBCLIN 0003AB

The project Operation Warp Speed has been added.

# SUBCLIN 0003AC

The project Operation Warp Speed has been added.

# SUBCLIN 0003AD

The project Operation Warp Speed has been added.

#### **CLIN 1001**

The option status has changed from Option to Option Exercised.

#### SUBCLIN 1001AA

The option status has changed from Option to Option Exercised.

SUBCLIN 1001AB



The option status has changed from Option to Option Exercised.

# SUBCLIN 1001AC

The option status has changed from Option to Option Exercised.

SUBCLIN 0001AE is added as follows:

ITEM NO 0001AE	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE (b) (4)		AMOUNT (b) (4)	
	a. Efforts to stimulate a podoses of up-to one to two						
	b. This subCLIN shall be invoiced in full at the completion of all deliveries on the base period.  (b) (4)  PURCHASE REQUEST NUMBER: (b) (4)  PROJECT: Operation Warp Speed						
				NET AMT	_	(b) (d)	
	ACRN AC	_		NEI AMI		(b) (4)	

SUBCLIN 1001AD is added as follows:



ITEM NO 1001AD EXERCISED OPTION SUPPLIES/SERVICES

QUANTITY

UNIT

UNIT PRICE (b) (4)

AMOUNT

Acceleration Efforts

a. Efforts to stimulate a possible delivery acceleration to the option period doses of up-to two to four weeks, IAW contractor's proposal dated 4 December 2020.

 This subCLIN shall be invoiced in full at the completion of all deliveries on the option period.

(b) (4)

PURCHASE REQUEST NUMBER: (b) (4)

PROJECT: Operation Warp Speed

(b) (4)

**NET AMT** 

o) (4)

ACRN AC

CIN: (b) (4)

SECTION E - INSPECTION AND ACCEPTANCE

The Acceptance/Inspection Schedule for SUBCLIN 0001AC has been changed from:

INSPECT AT INSPECT BY ACCEPT AT ACCEPT BY Destination Government Government

To:

INSPECT AT INSPECT BY ACCEPT AT ACCEPT BY
Origin Government Origin Government

The Acceptance/Inspection Schedule for SUBCLIN 0001AD has been changed from:

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

To:

INSPECT AT INSPECT BY ACCEPT AT ACCEPT BY
Origin Government Origin Government

The following Acceptance/Inspection Schedule was added for SUBCLIN 0001AE:

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

The Acceptance/Inspection Schedule for SUBCLIN 1001AA has been changed from:

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

To:				
	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
	Origin	Government	Origin	Government
The	Acceptance/Inspection Schedu	ile for SUBCLIN 1001Al	B has been changed from:	
	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
	Destination	Government	Destination	Government
To:				
	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
	Origin	Government	Origin	Government
The	Acceptance/Inspection Schedu	ile for SUBCLIN 1001A	C has been changed from:	
	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
	Destination	Government	Destination	Government
To:	nyannan i n			
	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
	Origin	Government	Origin	Government
The	following Acceptance/Inspecti	ion Schedule was added f	for SUBCLIN 1001AD:	
	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
	Destination	Government	Destination	Government
The	Acceptance/Inspection Schedu	ule for SUBCLIN 2001 A	A has been changed from:	
1110	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
	Destination	Government	Destination	Government
To:				
	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
	Origin	Government	Origin	Government
The	Acceptance/Inspection Schedu	ale for SUBCLIN 2001 A	B has been changed from:	
1110	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
	Destination	Government	Destination	Government
To:				
	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
	Origin	Government	Origin	Government
The	Acceptance/Inspection Schedu	ale for SUBCLIN 2001A	C has been changed from:	
	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
	Destination	Government	Destination	Government
To:	DIODECT AT	n.en	A COURT AT	
	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
	Origin	Government	Origin	Government

The	Acceptance/Inspection Schedule for		A has been changed from: ACCEPT AT	ACCEPT DV
	INSPECT AT	INSPECT BY		ACCEPT BY
	Destination	Government	Destination	Government
To:				
	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
	Origin	Government	Origin	Government
The	Acceptance/Inspection Schedule for	SUBCLIN 3001AI	3 has been changed from:	
	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
	Destination	Government	Destination	Government
To:				
10.	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
	Origin	Government	Origin	Government
The	Acceptance/Inspection Schedule for	SUBCLIN 3001A0	C has been changed from:	
	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
	Destination	Government	Destination	Government
To:				
	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
	Origin	Government	Origin	Government
The	Acceptance/Inspection Schedule for INSPECT AT Destination	SUBCLIN 4001A/ INSPECT BY Government	A has been changed from: ACCEPT AT Destination	ACCEPT BY Government
To:				
	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
	Origin	Government	Origin	Government
The	Acceptance/Inspection Schedule for	SUBCLIN 4001 AI	3 has been changed from:	
	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
	Destination	Government	Destination	Government
To:				
	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
	Origin	Government	Origin	Government
The	Acceptance/Inspection Schedule for	SUBCLIN 4001A0	C has been changed from:	
	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
	Destination	Government	Destination	Government
To:				
	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
	Origin	Government	Origin	Government
			7.7	



The following have been modified:

E1. Inspection:

#### Vaccine CLINs:

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 the Certificate of Analysis for quality inspection of all drug product lots in BARDA Data Infrastructure (BDI) system. 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).

The Government shall inspect each shipment of product delivered to it hereunder for visible damage and quantity

(b) (4)

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 final delivery, the Government shall promptly notify Contractor in writing (b) (4)

A BDI extract of the inspection documentation shall also be submitted in Wide Area Workflow (WAWF) as supporting documentation for invoice submittals.

#### Storage CLIN:

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

#### Data CLIN:

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.

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 (b) (4) . 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 (b) (4) . 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 of vaccines under this agreement will be performed by the COTR in the BDI system, which constitutes government acceptance at origin. Documentation of acceptance shall be submitted in accordance with WAWF instructions.

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 storage services under VMI CLIN No. 0002 shall occur upon satisfactory physical and quantity inspection of FDP upon delivery at USG designated CDC location. Acceptance of Data CLIN No. 0004 shall occur in WAWF by the KO.
- 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

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

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

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

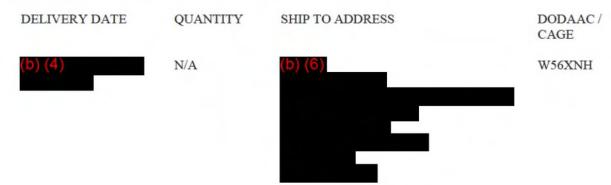
DELIVERY DATE QUANTITY SHIP TO ADDRESS DODAAC / CAGE N/A FOB: Origin (Shipping Point) To: DELIVERY DATE QUANTITY SHIP TO ADDRESS DODAAC / CAGE W56XNH The following Delivery Schedule item for SUBCLIN 0001AC has been changed from: DELIVERY DATE QUANTITY SHIP TO ADDRESS DODAAC / CAGE N/A FOB: Destination To: DELIVERY DATE QUANTITY SHIP TO ADDRESS DODAAC / CAGE W56XNH The following Delivery Schedule item for SUBCLIN 0001AD has been changed from: **DELIVERY DATE** QUANTITY SHIP TO ADDRESS DODAAC / CAGE N/A FOB: Destination

To:

DELIVERY DATE QUANTITY SHIP TO ADDRESS DODAAC / CAGE

(b) (4) (6) W56XNH

The following Delivery Schedule for SUBCLIN 0001AE has been added:



The following Delivery Schedule item for SUBCLIN 1001AA has been changed from:

DELIVERY DATE
QUANTITY
SHIP TO ADDRESS
DODAAC / CAGE

N/A
FOB: Destination

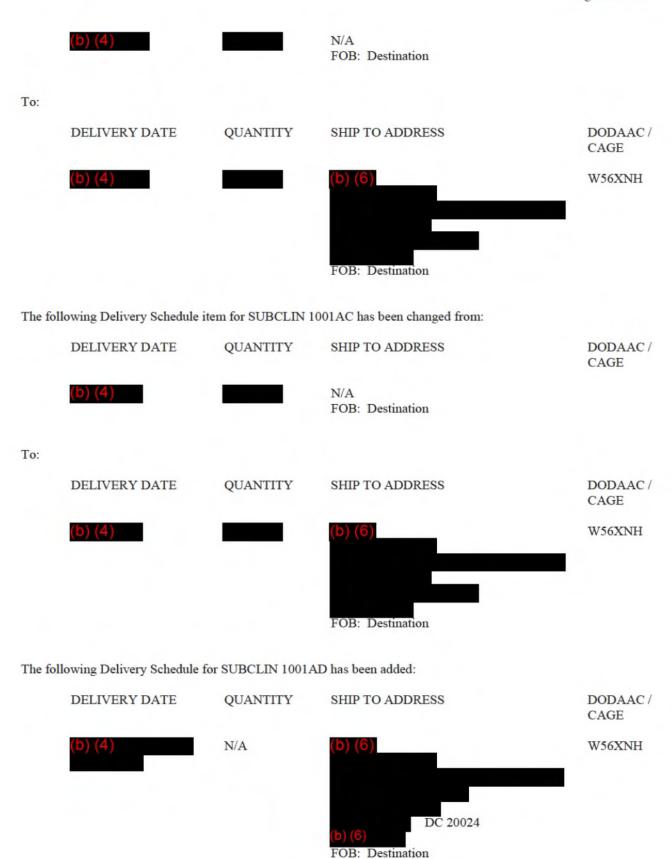
To:

DELIVERY DATE
QUANTITY
SHIP TO ADDRESS
DODAAC / CAGE

(b) (4)
(b) (6)
W56XNH

The following Delivery Schedule item for SUBCLIN 1001AB has been changed from:

DELIVERY DATE QUANTITY SHIP TO ADDRESS DODAAC / CAGE



The following Delivery Schedule item for SUBCLIN 2001AA has been changed from:

DELIVERY DATE
QUANTITY
SHIP TO ADDRESS
DODAAC / CAGE

N/A
FOB: Destination

To:

DELIVERY DATE
QUANTITY
SHIP TO ADDRESS
DODAAC / CAGE

(b) (4)

(b) (6)

W56XNH

FOB: Destination

The following Delivery Schedule item for SUBCLIN 2001AB has been changed from:

DELIVERY DATE QUANTITY SHIP TO ADDRESS DODAAC / CAGE

(b) (4) N/A FOB: Destination

To:

DELIVERY DATE QUANTITY SHIP TO ADDRESS DODAAC / CAGE

(b) (4) W56XNH

FOB: Destination

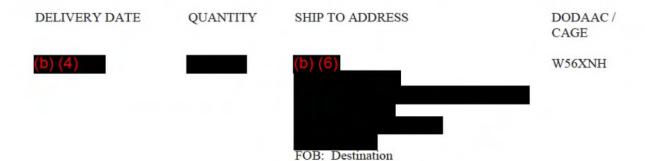
The following Delivery Schedule item for SUBCLIN 2001AC has been changed from:

DELIVERY DATE QUANTITY SHIP TO ADDRESS DODAAC / CAGE

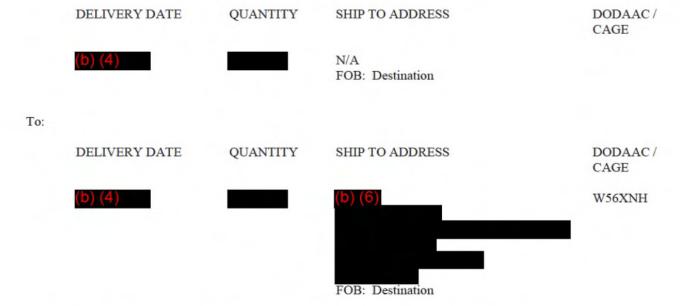
(b) (4) N/A

FOB: Destination

To:



The following Delivery Schedule item for SUBCLIN 3001AA has been changed from:



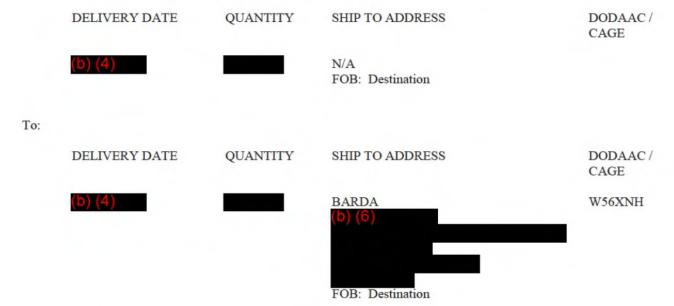
The following Delivery Schedule item for SUBCLIN 3001AB has been changed from:

	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC /
	(b) (4)	_	N/A FOB: Destination	CAGE
То:				
	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE





The following Delivery Schedule item for SUBCLIN 3001AC has been changed from:



The following Delivery Schedule item for SUBCLIN 4001AA has been changed from:

	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
	(b) (4)		N/A FOB: Destination	
To:				
	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
	(b) (4)		(b) (6)	W56XNH
				7

FOB: Destination



The following Delivery Schedule item for SUBCLIN 4001AB has been changed from:



The following Delivery Schedule item for SUBCLIN 4001AC has been changed from:



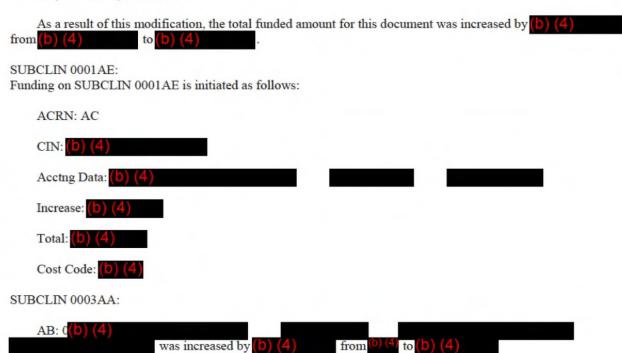
The following have been modified:

F.1 The contractor shall ship mRNA-1273 vaccines to the designated locations listed below. 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.

Delivery Locations:

# Location 1 Location 2 SECTION G - CONTRACT ADMINISTRATION DATA Accounting and Appropriation Summary for the Payment Office

The contract ACRN AB has been added.



SUBCLIN 0003AB: AB: (b) (4) was increased by The contract ACRN AB has been added. The CIN (b) (4) has been added. The Cost Code has been added. SUBCLIN 0003AC: AB: was increased by from to (b) The contract ACRN AB has been added. The CIN (b) (4) has been added. The Cost Code has been added. SUBCLIN 0003AD: AB: (b) (4) was increased by from The contract ACRN AB has been added. The CIN(b) (4 has been added. The Cost Code has been added. SUBCLIN 1001AA: AC: (b) (4) as increased by The contract ACRN AC has been added. The CIN (b) (4) has been added. The Cost Code has been added. SUBCLIN 1001AB: AD: (b) (4) was increased by (b) (4 The contract ACRN AD has been added. has been added. The CIN The Cost Code has been added. SUBCLIN 1001AC: AE: (b) (4) as increased by from The contract ACRN AE has been added. The CIN (b) (4) has been added. has been added. The Cost Code SUBCLIN 1001AD: Funding on SUBCLIN 1001AD is initiated as follows:

The CIN GFEBS001158485000002 has been added.

The Cost Code (b) (4) has been added.

ACRN: AC

CIN: (b) (4)	
Acctng Data: (b) (4)	
Increase: (b) (4)	
Total: (b) (4)	
Cost Code: (b) (4)	

The following have been modified:

### 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

# G.2 GOVERNMENT TECHNICAL POINT OF CONTACT



#### G.3 CONTRACTOR'S CONTRACT ADMINISTRATION

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

### G.4 PLACES OF PERFORMANCE

Natick, MA 01760-5011

Moderna US, Inc. 200 Technology SQ. Cambridge, MA 02139-3578

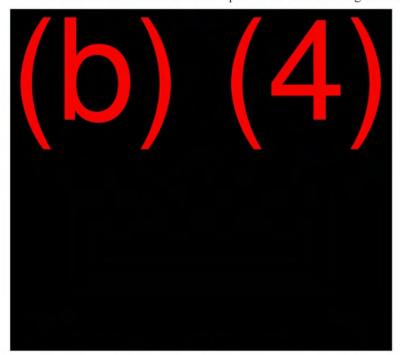
# G.5 NOTIFICATION OF REVISIONS AND CHANGE



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 0007, 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:



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 0008, Performance-based Payment Milestone Billing Plan, identifies the contractor invoicing schedule for liquidation. The contractor shall submit all invoices IAW Attachment 0008 dated 4 December 2020.

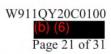
# 252.232-7006 WIDE AREA WORKFLOW PAYMENT INSTRUCTIONS (DEC 2018)

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

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

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

"Local processing office (LPO)" is the office responsible for payment certification when payment certification is done external to the entitlement system.



- "Payment request" and "receiving report" are defined in the clause at 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.
- (b) Electronic invoicing. The WAWF system provides the method to electronically process vendor payment requests and receiving reports, as authorized by Defense Federal Acquisition Regulation Supplement (DFARS) 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.
- (c) WAWF access. To access WAWF, the Contractor shall-
- (1) Have a designated electronic business point of contact in the System for Award Management at <a href="https://www.sam.gov">https://www.sam.gov</a>; and
- (2) Be registered to use WAWF at <a href="https://wawf.eb mil/">https://wawf.eb mil/</a> following the step-by-step procedures for self-registration available at this web site.
- (d) WAWF training. The Contractor should follow the training instructions of the WAWF Web-Based Training Course and use the Practice Training Site before submitting payment requests through WAWF. Both can be accessed by selecting the "Web Based Training" link on the WAWF home page at 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

Field Name in WAWF	Data to be entered in WAWF
Pay Official DoDAAC	HQ0337
Issue By DoDAAC	W911QY
Admin DoDAAC	S2206A
Inspect By DoDAAC	W56XNH
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.
- 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 REFERANCE:

DFARS PGI 204.7108 Payment Instructions Table

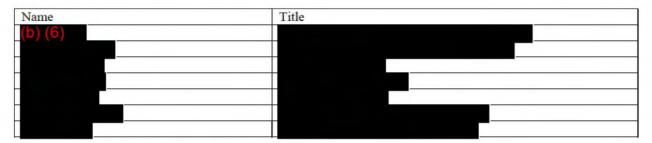
https://www.acq.osd.mil/dpap/dars/pgi/pgi htm/current/PGI204 71.htm#payment instructions

SECTION H - SPECIAL CONTRACT REQUIREMENTS

The following have been modified:

# 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:



# 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.



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

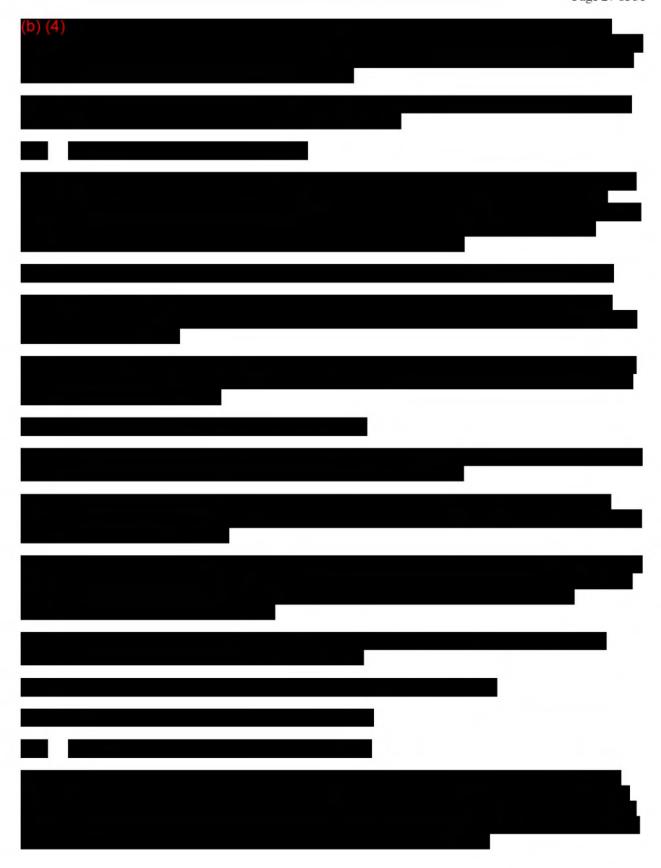
#### Declaration.

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.



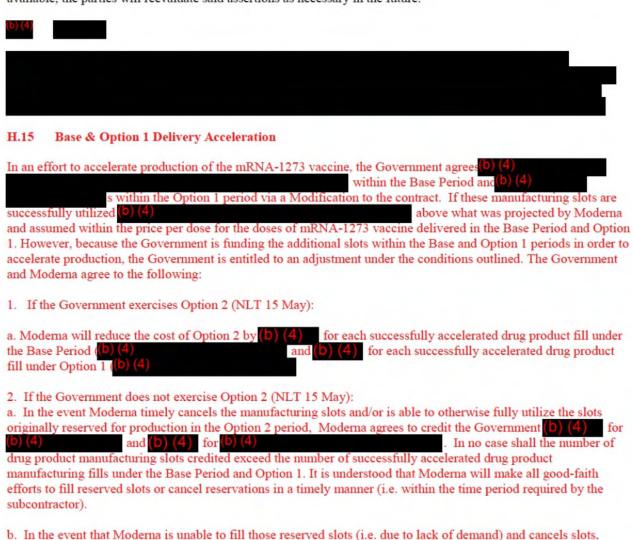


## H.12 Transportation to Final Destination

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.



Moderna shall be entitled to recoup those reservation cancellation costs from the USG. The process is outlined as

- 1.) Moderna shall submit documentation to the USG of the following:
  - i.) Cancellation notice to the subcontractor,
  - ii.) The basis of the cancellation. and

follows:



# iii.) Cancellation fees incurred.

- Moderna shall reduce credits to the USG under paragraph 2a) of this clause, IAW agreed cancellation costs incurred.
- Bi-lateral agreement of the final credit shall be included in a modification to the contract. Net credit shall be deducted from final payments under the contract.

SECTION I - CONTRACT CLAUSES

The following have been modified:

252.232-7007 LIMITATION OF GOVERNMENT'S OBLIGATION (APR 2014)

- (b) For items(s) identified in paragraph (a) of this clause, the Contractor agrees to perform up to the point at which the total amount payable by the Government, including reimbursement in the event of termination of those item(s) for the Government's convenience, approximates the total amount currently allotted to the contract. The Contractor is not authorized to continue work on those item(s) beyond that point. The Government will not be obligated in any event to reimburse the Contractor in excess of the amount allotted to the contract for those item(s) regardless of anything to the contrary in the clause entitled "TERMINATION FOR THE CONVENIENCE OF THE GOVERNMENT." As used in this clause, the total amount payable by the Government in the event of termination of applicable contract line item(s) for convenience includes costs, profit and estimated termination settlement costs for those item(s).
- (c) Notwithstanding the dates specified in the allotment schedule in paragraph (j) of this clause, the Contractor will notify the Contracting Officer in writing at least innety days prior to the date when, in the Contractor's best judgment, the work will reach the point at which the total amount payable by the Government, including any cost for termination for convenience, will approximate 85 percent of the total amount then allotted to the contract for performance of the applicable item(s). The notification will state (1) the estimated date when that point will be reached and (2) an estimate of additional funding, if any, needed to continue performance of applicable line items up to the next scheduled date for allotment of funds identified in paragraph (j) of this clause, or to a mutually agreed upon substitute date. The notification will also advise the Contracting Officer of the estimated amount of additional funds that will be required for the timely performance of the item(s) funded pursuant to this clause, for subsequent period as may be specified in the allotment schedule in paragraph (j) of this clause, or otherwise agreed to by the parties. If after such notification additional funds are not allotted by the date identified in the Contractor's notification, or by an agreed substitute date, the Contracting Officer will terminate any item(s) for which additional funds have not been allotted, pursuant to the clause of this contract entitled "TERMINATION FOR THE CONVENIENCE OF THE GOVERNMENT".

- (d) When additional funds are allotted for continued performance of the contract line item(s) identified in paragraph (a) of this clause, the parties will agree as to the period of contract performance which will be covered by the funds. The provisions of paragraph (b) through (d) of this clause will apply in like manner to the additional allotted funds and agreed substitute date, and the contract will be modified accordingly.
- (e) If, solely by reason of failure of the Government to allot additional funds, by the dates indicated below, in amounts sufficient for timely performance of the contract line item(s) identified in paragraph (a) of this clause, the Contractor incurs additional costs or is delayed in the performance of the work under this contract and if additional funds are allotted, an equitable adjustment will be made in the price or prices (including appropriate target, billing, and ceiling prices where applicable) of the item(s), or in the time of delivery, or both. Failure to agree to any such equitable adjustment hereunder will be a dispute concerning a question of fact within the meaning of the clause entitled "disputes."
- (f) The Government may at any time prior to termination allot additional funds for the performance of the contract line item(s) identified in paragraph (a) of this clause.
- (g) The termination provisions of this clause do not limit the rights of the Government under the clause entitled "DEFAULT." The provisions of this clause are limited to work and allotment of funds for the contract line item(s) set forth in paragraph (a) of this clause. This clause no longer applies once the contract if fully funded except with regard to the rights or obligations of the parties concerning equitable adjustments negotiated under paragraphs (d) or (e) of this clause.
- (h) Nothing in this clause affects the right of the Government to this contract pursuant to the clause of this contract entitled "TERMINATION FOR CONVENIENCE OF THE GOVERNMENT."
- (i) Nothing in this clause shall be construed as authorization of voluntary services whose acceptance is otherwise prohibited under 31 U.S.C. 1342.
- (j) The parties contemplate that the Government will allot funds to this contract in accordance with the following schedule:

(b) (4)	
(End of clause)	

SECTION J - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

The following have been modified:

Document Type	Description	Page #	Date



Exhibit A	CDRLs	15	18 July 2020
Attachment 0001	Supply Chain Resiliency Plan for CDRL A010	3	23 July 2020
Attachment 0002	Security Plan	7	23 July 2020
Attachment 0003	Dose Tracking Template Draft Moderna	Excel	15 July 2020
Attachment 0004	Data Rights	3	7 August 2020
Attachment 0005	(b) (4)	2	7 August 2020
Attachment 0006	ModernaTx, Inc. Background Intellectual Property	3	6 August 2020
Attachment 0007	Performance Base Payment Milestone Schedule	2	7 August 2020
Attachment 0008	Performance Base Payment Milestone Billing Plan	17	4 December 2020
Attachment 0009	HRPAS Moderna Letter	1	3 September 2020

(End of Summary of Changes)