

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT			1. CONTRACT ID CODE	PAGE OF PAGES
2. AMENDMENT/MODIFICATION NO.		3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
		30-Jun-2021	0011506628-0002	
6. ISSUED BY	CODE	7. ADMINISTERED BY (If other than item 6)		CODE
ACC-APG - COVID RESPONSE - W58P05 6472 INTEGRITY COURT (BUILDING 4401) ABERDEEN PROVING GROUND MD 21005-3013	W58P05	DCMA SPRINGFIELD - S3101A BLDG, 93 PICATINNY NJ 07806-5000		S3101A
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)			9A. AMENDMENT OF SOLICITATION NO.	
BECTON, DICKINSON AND COMPANY 1 BECTON DR FRANKLIN LAKES NJ 07417-1880				
			9B. DATED (SEE ITEM 11)	
			X 10A. MOD. OF CONTRACT/ORDER NO. W911SR2030001	
			X 10B. DATED (SEE ITEM 13) 01-Jul-2020	
CODE 06531	FACILITY CODE			
11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS				
<input type="checkbox"/> The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of offer <input type="checkbox"/> is extended, <input type="checkbox"/> is not extended.				
<p>Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods:</p> <p>(a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.</p>				
12. ACCOUNTING AND APPROPRIATION DATA (If required)				
13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACT ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.				
A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.				
B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).				
X C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: Mutual agreement of the parties				
D. OTHER (Specify type of modification and authority)				
E. IMPORTANT: Contractor <input type="checkbox"/> is not, <input checked="" type="checkbox"/> is required to sign this document and return <u>1</u> copies to the issuing office.				
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.) Modification Control Number: (b) (6) See block 14 continuation page				
Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.				
15A. NAME AND TITLE OF SIGNER (Type or print)			16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)	
(b) (6)			(b) (6)	
			TEL: (b) (6) EMAIL: (b) (6)	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA		16C. DATE SIGNED
(b) (6)	6/30/2021	BY (b) (6)		30 JUN 2021
(Signature of person authorized to sign)				

W911SR2030001

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:

MODIFICATION P00003

1. The purpose of this modification is to extend performance of the effort from 30 June 2021 to 30 September 2021 as reflected in Attachment B, Statement of Objectives, Paragraph C.4.
2. The Agreements Officer has changed and a BARDA Agreements Officer Representative has been added, as reflected in Section I – Terms and Conditions.
3. All other terms and conditions remain unchanged, except as noted herein.

SECTION I - CONTRACT CLAUSES

The following have been modified:

TERMS AND CONDITIONS

**TECHNOLOGY INVESTMENT AGREEMENT**

between

**Becton, Dickinson and Company**

and

**Department of Defense,  
U.S. Army Contracting Command –Aberdeen Proving Ground,  
Natick Contracting Division & Edgewood Contracting Division  
(ACC-APG, NCD & ECD)**

on behalf of

**Biomedical Advanced Research and Development Authority (BARDA)**

for

**Expanding Domestic Production of Needles & Syringes**

Agreement No: W911SR2030001

Total Amount of Government Funding for the Agreement: \$42,303,230.00

Total Cost Share for the Agreement: (b)(4)

Total Estimated Value of the Agreement: (b)(4)

W911SR2030001

Effective Date: 1 July 2020

Term of Agreement: Ten (10) Years after Date of Award

## **TECHNOLOGY INVESTMENT AGREEMENT TERMS AND CONDITIONS**

### **ARTICLES**

1. Scope of Agreement
2. Term of Agreement
3. Order of Precedence
4. Program/Administrative Management
5. Financial Management & Payment
6. Accounting & Audit
7. Purchasing & Title
8. Cost Sharing
9. Government Preference
10. Records Retention & Government Access
11. Intellectual Property & Patent Rights
12. Data Rights
13. FDA Regulatory Requirements
14. Termination
15. Disputes
16. Reports & Distribution
17. Modification
18. Miscellaneous

W911SR2030001

ATTACHMENTS

A. Recipient's Proposal

B. Statement of Objectives [SOO], dated 30 June 2021

C. BARDA Security Requirements

## RECITALS

This Agreement is entered into between the United States of America, Department of Defense, represented by ACC-APG, NCD & ECD (“Government”) and Becton, Dickinson and Company, (“Recipient”), collectively referred to as the “Parties,” pursuant to and under the statutory authority at 10 U.S.C. §2371 and/or 10 U.S.C. §2358.

The Recipient, a for-profit firm, submitted a basic, applied, or advanced research proposal to the Government in response to the publicly disseminated Medical Countermeasures System (MCS) Broad Agency Announcement (BAA) 17-01. The proposal was identified within the MCS BAA scope of: Advanced Development & Manufacturing Capabilities (ADMC), to develop a national capability and capacity to develop and produce medical countermeasures rapidly to counter known or unknown chemical, biological, radioactive, and nuclear (CBRN) threats, including novel and previously unrecognized, naturally- occurring emerging infectious diseases such as the COVID-19 virus. The specific MCS BAA Area of Interest is Mission Area 1, Medical Biological Prophylaxis.

The Government awards this Technology Investment Agreement (TIA) to fund the Recipient proposal subject to the following terms and conditions and other statutory requirements. The Parties desire to enter into this Agreement to establish said terms and conditions under which they plan to carry out the research and other activities as described below.

### **THEREFORE, THE PARTIES AGREE:**

#### **1. Scope of Agreement**

1.1 Governing Authority. This Technology Investment Agreement (TIA) is an assistance transaction other than a grant or cooperative agreement and is awarded pursuant to 10 USC §2371 and/or 10 USC §2358, as applicable, as implemented by 32 Code of Federal Regulations (CFR) Part 37, and Parts 22 and 34 where specifically referenced. The following are also incorporated in full: Definitions at Subpart J of 32 CFR Part 37; National Policies at Appendix B, 32 CFR Part 22; Audits at Appendix C of 32 CFR Part 37. This TIA is subject good manufacturing practices (cGMPS) at 21 CFR 210 and 211, as applicable. The Federal Acquisition Regulation (FAR), Defense Federal Acquisition Regulation Supplement (DFARS), DoD Grant and Agreement Regulations (DoDGARs), or other regulatory and statutory requirements apply as specifically referenced herein. If this instrument is awarded under the authority at 10 USC §2358, the Bayh-Dole Act, 35 U.S.C. §§ 200-212 applies, as applicable.

1.2 Principal Purpose. The Government and the Recipient agree that the principal purpose of this Agreement is for Government investment into the development/expansion of Recipient’s manufacturing capacity for hypodermic safety needles and corresponding syringes in response to the worldwide Coronavirus (COVID-19) global pandemic as described in the Recipient’s Final Proposal, hereinafter, the “Plan” or “Project”. This effort shall be carried out as set forth in the Recipient’s Plan and subsequent revisions, which are hereby incorporated in their entirety. This Agreement is not intended to be, nor shall it be construed as, by implication or otherwise, a partnership, a corporation, or other business organization.

**2. Term of Agreement.** This Agreement shall commence upon the effective date listed on page 1, after execution of the Agreement by both parties, for a period of 10 years, the “term” of the Agreement or “Period of Performance.” *Period of performance* means the time during which a recipient or sub-recipient may incur new obligations to carry out the work authorized under an award or sub-award, respectively.

**3. Order of Precedence.** This Agreement is subject to the laws and regulations of the United States. In the event of a conflict or inconsistency in the terms and conditions or attachments specified in this Agreement, the conflict or inconsistency shall be resolved according to the following order of precedence: (a) the Federal statute authorizing this award, or any other Federal statutes directly affecting performance of this Agreement, including attachments where applicable; (b) Federal regulations specifically references; (c) the terms and conditions contained within the Agreement, including any documents incorporated; (d) programmatic requirements.

#### **4. Program/Administrative Management**

4.1 Program Management. The Recipient has full responsibility for the project/activity supported by this Agreement,

in accordance with the Recipient's proposal and proposal revisions/appendices, and the terms and conditions specified in this Agreement. The Government will have continuous and/or substantial involvement with the Recipient pursuant to a Collaboration Plan as incorporated. The Recipient must consult the Program Office/Technical Representative through the Agreements Officer before deviating from the objectives or overall program of the research originally proposed. Non-compliance with any award provision of this clause may result in the withholding of funds and or the termination of the award.

#### 4.2 Government Representatives:

Agreements Officer (AO)

(b) (6)

Army Contracting Command – Joint COVID Response Division

(b) (6)

Agreements Specialist (AS)

(b) (6)

Army Contracting Command – Joint COVID Response Division

(b) (6)

Administrative Grants Officer (AGO)

(b) (6)

Defense Contract Management Agency (DCMA) Springfield  
Building 93

Picatinny Arsenal, NJ 07806-5000

(b) (6)

Biomedical Advanced Research and Development Authority (BARDA) Program Manager (PM)

(b) (6)

Assistant Secretary for Preparedness and Response (ASPR)/BARDA  
Department of Health and Human Services  
Washington, DC 20515

(b) (6)

Biomedical Advanced Research and Development Authority (BARDA) Agreements Officer Representative (AOR)

(b) (6)

Assistant Secretary for Preparedness and Response (ASPR)/BARDA  
Room 22B14 – O'Neill House Office Building  
Washington, DC 20515

(b) (6)

#### 4.3 Recipients Representatives

(b) (6)

– Business POC  
VP, Injection Systems  
1 Becton Drive  
Franklin Lakes, NJ 07417

(b) (6)

(b) (6) – Technical POC  
Associate Director Marketing  
1 Becton Drive  
Franklin Lakes, NJ 07417

(b) (6)

(b) (6) – Administrative POC  
Associate Director, US Region Government  
1 Becton Drive  
Franklin Lakes, NJ 07417

(b) (6)

(b) (6) – Administrative POC  
Senior Contract Consultant  
1 Becton Drive  
Franklin Lakes, NJ 07417

(b) (6)

## 5. Financial Management & Payment

5.1 Expenditure-Based. This Agreement is an expenditure type TIA as described in 32 CFR §37.1285. *Expenditure* is defined in 32 CFR §37.1290. The charges may be reported on a cash or accrual basis, as long as the methodology is disclosed and is consistently applied. In accordance with 32 CFR 37.300(a): "For an expenditure-based TIA, the amounts of interim payments or the total amount ultimately paid to the Recipient are based on the amounts the Recipient expends on project costs. If a Recipient completes the project specified at the time of award before it expends all of the agreed-upon Federal funding and Recipient cost sharing, the Federal Government may recover its share of the unexpended balance of funds or, by mutual agreement with the Recipient, amend the agreement to expand the scope of the research project. An expenditure-based TIA therefore is analogous to a cost-type procurement contract or grant."

Payments shall be made on a monthly basis for expenditures incurred up to the agreed upon project ceiling & Government investment funding amount, for the duration of the Period of Performance.

5.2 Obligation In no case shall the Government's financial obligation exceed the amount obligated on this Agreement or by amendment to the Agreement. The Government is not obligated to reimburse the Recipient for expenditures in excess of the amount of obligated funds allotted by the Government.

5.3 Wide Area Workflow. The following guidance is provided for invoicing processed under this Agreement through WAWF:

5.3.1. Acceptance within the WAWF system shall be performed by the AGO upon receipt of a confirmation email, or other form of transmittal, from the BARDA PM.

5.3.2. The Recipient shall send an email notice to the BARDA PM and upload the BARDA PM approval as an attachment upon submission of an invoice in WAWF (this can be done from within WAWF).

5.3.3. Payments shall be made by the Defense Finance and Accounting Services (DFAS) office indicated below within thirty (30) calendar days of an accepted invoice in WAWF:

5.3.4. WAWF Provision:

(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.

(b) Electronic invoicing. The WAWF system is the method to electronically process vendor payment requests and receiving reports, as authorized by DFARS 252.232- 7003, Electronic Submission of Payment Requests and Receiving Reports.

(c) WAWF access. To access WAWF, the Recipient shall (i) have a designated electronic business point of contact in the System for Award Management at <https://www.acquisition.gov>; and (ii) be registered to use WAWF at <https://wawf.eb mil/> following the step-by-step procedures for self-registration available at this website.

(d) WAWF training. The Recipient 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 Recipient must use the following information when submitting payment requests and receiving reports in WAWF for this contract/order:

(1) Document type. The Recipient shall use the following document type:

**Non-Procurement Instruments (NPI) Voucher**

(2) Inspection/acceptance location. The Recipient shall select the following inspection/acceptance location(s) in WAWF, as specified by the contracting officer.

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

Routing Data Table\*

<i>Field Name in WAWF</i>	<i>Data to be entered in WA</i>
Pay Official DoDAAC	HQ0337
Issue By DoDAAC	W58P05
Admin DoDAAC	S3101A
Inspect By DoDAAC	W56XNH
Ship To Code	W56XNH

Payee Information: As identified at the System for Award Management.



- Becton, Dickinson and Company
- Cage Code: 06531
- DUNS: 001292192

(4) Payment request and supporting documentation. The Recipient shall ensure a payment request includes appropriate contract line item and subline item descriptions of the work performed or supplies delivered, unit price/cost per unit, fee (if applicable), and all relevant back-up documentation in support of each payment request.

(5) WAWF email notifications. The Recipient shall enter the email address identified below in the "Send Additional Email Notifications" field of WAWF once a document is submitted in the system.

(g) WAWF point of contact.

(1) The Recipient may obtain clarification regarding invoicing in WAWF from the following contracting activity's WAWF point of contact.

Administrative Grants Officer (AGO)

(b) (6)

Defense Contract Management Agency (DCMA) Springfield  
Building 93  
Picatinny Arsenal, NJ 07806-5000

(b) (6)

(2) For technical WAWF help, contact the WAWF helpdesk at 866-618-5988.

## 6. Accounting & Audit

### 6.1 Accounting System.

6.1.1. The Recipient's cost accounting system shall be in compliance with Generally Accepted Accounting Principles (GAAP) in accordance with 32 CFR §37.615. The system must effectively control all Project funds, including Federal funds and any required cost share. The system must have complete, accurate, and current records that document the sources of funds and the purposes for which they are disbursed. It also must have procedures for ensuring that Project funds are used only for purposes permitted by the agreement ([§ 37.625](#)).

6.2 Annual Audit Requirement. The Recipient shall have an annual audit performed by an independent auditor, in accordance with 32 CFR §37.650. The Recipient shall provide a copy of the auditor's report to the Agreements Officer within 60 days after audit. Audits at Appendix C of 32 CFR Part 37 is incorporated into this Agreement.

6.3 Program Income. Program income derived during the initial Period of Performance from Government funding shall be allocated to finance the non-Federal share of the Project (including the amounts described in Section 8.1) in accordance with 32 CFR §34.14(d)(2). As contemplated by 32 CFR §34.14(b)(2), Recipient will have no obligation to the Government for program income generated after the end of the Period of Performance, and no recovery of funds is contemplated under 32 CFR §37.580. With the exception of the reimbursements contemplated in Paragraph 9.1, Paragraph 6.3 shall not require the Recipient to provide to the Government any income received from sales of Qualifying Product (as defined below), nor shall it alter the overall cost sharing arrangement in Section [6].

## 7. Purchasing & Title

7.1 Title to Property Acquired under Agreement. Title to real property, equipment, and supplies or intangible property that are acquired by the Recipient (whether by purchase, construction or fabrication, development, or otherwise) with Government funding vests in the Recipient conditionally as described at 32 CFR 37.685.

7.1.1 Equipment Costs. Pursuant to 32 CFR 37.685 (b)(2), the Recipient is authorized to include the full acquisition cost of equipment as part of the cost of the project.

7.1.2 Property Management. Real property and equipment acquired by the Recipient during the Agreement is subject to the property management standards in 32 CFR 34.21(b) through (d).

7.2 Disposition. Any Federal interest in the real property or equipment remaining after the term will be addressed at the time of property disposition. Disposition will be in accordance with 32 CFR 34.21.

7.3 Purchasing System. If the Recipient currently performs under DoD assistance instruments subject to the purchasing standards in [32 CFR 34.31](#), then that Part applies. Otherwise, the Recipient may use the existing purchasing systems, as long as applicable requirements are flowed down (37.705).

## **8. Cost Sharing**

8.1 To the maximum extent practicable, the recipient must provide at least half of the costs of the project, in accordance with [§ 37.215](#). *Total value* of the TIA means the total amount of costs that are currently expected to be charged to the award over its life, which includes amounts for the Federal share and any non-Federal cost sharing or matching required under the award; and any options, even if not yet exercised, for which the costs have been established in the award.

8.2 Notwithstanding 8.1 to the contrary, the Government funding is estimated to represent approximately 60% of the overall amount necessary to accomplish the scope of work cited in the proposal (inclusive of all proposal revisions and appendices). The Recipient agrees to provide the resources in the manner shown in their proposal.

8.3 Failure of either Party to provide its respective total contribution may result in a unilateral modification to this Agreement by the AO to reflect proportional reduction in funding for the other Party.

## **9. Government Preference**

9.1 Pricing. During the term of the Agreement, the Recipient agrees that, in the event that it enters into a Group Purchasing Organization (GPO) contract with a Qualifying Third Party (as defined below) with respect to a Qualifying Product (as defined below) with a per unit GPO price lower than that offered for the same Qualifying Product to the Government, the Recipient shall (i) promptly notify the Agreements Officer in writing of the lower price and (ii) extend the lower price to all future sales of the Qualifying Product to the Government. For any purchases that were made after the lower price was first extended to the Qualifying Third Party, the Recipient shall reimburse the Government, the difference between the lower price provided to the Qualifying Third Party and the price provided to the Government, multiplied by the volume/quantity provided after the lower price was first extended. Such reimbursement shall occur within thirty days (30) of the Recipient discovering that the lower price was given to the Qualifying Third Party. Notwithstanding the foregoing, the Parties may agree to apply the reimbursement toward additional quantities/volume of Qualifying Product required by the Government. For the purposes of this Article, (a) "Group Purchasing Organization (GPO)" means an entity that aggregates purchasing volume of healthcare item(s) to realize savings and efficiencies (b) "Qualifying Third Party" means the national GPO in the United States that represents the largest volume of total dollar sales of Qualifying Products in the aggregate with Recipient, as determined on an annual basis by Recipient, and communicated to the Agreements Officer and (c) a "Qualifying Product" is a syringe or needle manufactured, in whole or in part, utilizing equipment funded under this Agreement.

9.2 Precedence. During the period of performance and upon a Presidential Declaration of a Public Health Emergency (a "PHE"), Recipient shall grant the Government the right to place Priority Orders for Qualifying Product so long as the Qualifying Product is intended for use to address the PHE. For purposes of this Section, (a) "Priority Orders" shall mean purchase orders for Qualifying Product that will be prioritized by Recipient as if they were "rated orders" subject to 15 CFR § 700.14.

9.3 Maintenance of equipment and availability of capacity. Recipient agrees that, for the term of this Agreement, it shall maintain all equipment funded by the Agreement in such a way as to ensure that, should the rights established under 9.2 be in effect, there is capacity equal to that which was available at time of commissioning. Further, the Recipient agrees that should the equipment funded by this agreement be unavailable during a period in which the rights under 9.2 are in effect, the Recipient will make available to the Government equivalent capacity from any existing US-based equipment not funded under this agreement capable of producing Qualifying Product.

9.4. Inspection of equipment. The Recipient grants the Government the right to inspect at any time, upon provision of reasonable advance notice, the equipment funded by this agreement.

#### **10. Records Retention & Government Access**

The DoD, Comptroller General of the United States, or any of their duly authorized representatives, have the right of timely and unrestricted access to any books, documents, papers, or other records of the Recipient that are pertinent solely to the Recipient's technical performance under this Agreement, in order to make examinations, excerpts, transcripts and copies of such documents. This right also includes timely and reasonable access to the Recipient's personnel for the purpose of interview and discussion related to such records. Such access shall be performed during business hours on business days upon written notice and shall be subject to the security requirements of the audited Party to the extent such security requirements do not conflict with the rights of access otherwise granted by this paragraph. The rights of access in this paragraph shall last as long as records are retained. The rights of access in this paragraph do not extend to the Recipient's financial records.

**11. Intellectual Property & Patent Rights.** Reserved; the Government does not anticipate any intellectual property being generated under this Agreement.

**12. Data Rights.** The Government may only request technical data that is customarily provided to the public with a commercial item or process related to for Qualifying Products, equipment purchased under this Agreement, and repairs or maintenance to said equipment.

#### **13. U.S Food and Drug Administration (FDA) Regulatory Compliance**

13.1 Good Manufacturing Practices (GMP) Compliance. To the extent required under the Federal Food, Drug, and Cosmetic Act, the Recipient will ensure that the manufacturing capability established under this Agreement complies with current good manufacturing practices (cGMPs) under 21 CFR 210 and 211. The Recipient will notify the Government of any written cGMP inspection findings from the FDA pertinent to the manufacturing capability established under this Agreement.

13.2 FDA Communications. The Recipient will provide the Government with summaries of any Recipient formal meetings with the FDA and future correspondence between Recipient and the FDA regarding the manufacturing contemplated under this Agreement and ensure that Government representatives are invited to participate in any Recipient formal meetings with the FDA regarding topics that are material to Recipient's compliance with the terms of this Agreement.

#### **14. Termination**

Termination and Enforcement procedures are in accordance with 32 CFR §34.51 through §34.52.

#### **15. Disputes**

For any disagreement, claim, or dispute arising under this Agreement, the parties shall communicate with one another in good faith and in a timely and cooperative manner. Whenever disputes, disagreements, or misunderstandings arise, the parties shall attempt to resolve the issue by discussion and mutual agreement as soon as practicable. Failing resolution by mutual agreement, the aggrieved party shall request a resolution in writing from the AO. The AO will review the matter and render a decision in writing. Any such decision is final and binding. In the event of a decision, within 60-calendar days of the referral for review (or such other period as agreed upon by the parties), either party may pursue any right or remedy provided by law in a court of competent jurisdiction as authorized by 28 U.S.C. 1491. Alternately, the parties may agree to explore and establish and Alternate Disputes Resolution procedure to resolve this dispute.

## **16. Reports & Distribution**

16.1 Monthly Progress Reports. Submitted monthly no later than the 10<sup>th</sup> of the month. Recipient format acceptable. Electronic submission acceptable in MS Office or PDF format. Financial information shall be MS Excel format. Monthly reports shall have Distribution Statement C (U.S. Government and their contractors). Each monthly report shall, at a minimum, contain the following:

- a. Summary of monthly progress for the Recipient's facilities/capabilities associated with this effort
- b. Summary of progress towards established milestones for each facility/capability
- c. Identification of any milestone that is slipping or missed, and discussion of path forward to bring milestone back to schedule, and impact on other milestones
- d. Summary of risks, discussion of potential impacts and efforts to mitigate
- e. Summary of overall schedule and changes from previous month
- f. Financial summary of Recipient costs incurred by month to date, vouchers submitted, and Government payments made

16.2 Quarterly-In-Process Reviews. Scheduled as needed, generally not more frequently than quarterly, at the Recipient's facilities. Duration: eight (8) hours max. Face-to-face or virtual review of previous quarter's activities. Informative in nature to keep BARDA apprised of project progress and to discuss issues that may require joint resolution, such as milestone changes, political impacts on objectives, schedule, funding.

16.3 Annual Financial Status Report. (37.880)

16.4 Final Report. Final Report shall have Distribution Statement C. Final report summarizing stated objectives and the progress that was achieved in meeting those objectives; summary of risks incurred, impacts and mitigation; quantitative discussion of needle & syringe production throughput improvements achieved; financial summary of project; schedule summary for project, comparing original schedule to final schedule; recommendations for path forward as applicable.

## **17. Modification of the Agreement**

17.1 Limitation. In no event shall any understanding or agreement, modification, change order, or other matter in deviation from the terms of this agreement between the Recipient and a person other than the AO be effective or binding upon the Government. All such actions must be formalized by a proper contractual document executed by the AO. The only method by which this Agreement can be modified is by a formal, written modification signed by the AO. No other communications, whether oral or in writing, shall modify this Agreement.

17.2 Recommendation. Modifications to this Agreement may be proposed by either Party. Recipient recommendations for any modifications to this Agreement, including justifications to support any changes to the proposal (inclusive of proposal revisions, proposal appendices, and the collaboration plan), as incorporated by reference, shall be submitted in writing to the Government PM with a copy to the AO. The Recipient shall detail the technical, chronological, and financial impact of the proposed modification to the program. Changes are effective only after this Agreement has been modified. The AO is responsible for the review and verification of any recommendations.

17.3 Unilateral or Minor. The AO may unilaterally issue administrative Agreement modifications (e.g., changes in the paying office or appropriation data, or changes to Government personnel identified in this Agreement, etc.). All other modifications shall be the result of bilateral agreement of the Parties. The Government may make minor or administrative Agreement modifications unilaterally.

## **18. Miscellaneous**

18.1 Security. The Recipient shall not develop and/or handle classified information in the performance of this Agreement. No DD254 is currently required for this Agreement.

18.2 Entire Agreement. This Agreement, inclusive of the proposal, proposal revision, proposal appendices, and

collaboration plan(s), constitutes the entire Agreement between the Parties concerning the subject matter hereof and supersedes any prior understandings or written or oral Agreement relative to said matter. In the event of a conflict between the terms of this Agreement, the terms of this Agreement shall govern.

18.3 Waiver of Rights. Any waiver of any requirement contained in this Agreement shall be by mutual agreement of the Parties hereto. Any waiver shall be reduced to a signed writing and a copy of the waiver shall be provided to each Party. Failure to insist upon strict performance of any of the terms and conditions hereof, or failure or delay to exercise any rights provided herein or by law, shall not be deemed a waiver of any rights of any Party hereto.

18.4 Liability. No Party to this Agreement shall be liable to the other Party for any property consumed, damaged, or destroyed in the performance of this Agreement, unless it is due to the negligence or willful misconduct of the Party or an employee or agent of the Party. In no event shall either Party be liable for special, incidental, or consequential damages arising from or connected with this Agreement.

18.5 Non-Assignment. This Agreement may not be assigned by any Party except by operation of law resulting from the merger of a Party into or with another corporate entity.

18.6 Severability. If any clause, provision or section of this Agreement shall be held illegal or invalid by any court, the invalidity of such clause, provision, or section shall not affect any of the remaining clauses, provisions, or sections herein, and this Agreement shall be construed and enforced as if such illegal or invalid clause, provision, or section had not been contained herein.

18.7 Force Majeure. Neither Party shall be in breach of this Agreement for any failure of performance caused by any event beyond its reasonable control and not caused by the fault or negligence of that Party. If such a force majeure event occurs, the Party unable to perform shall promptly notify the other Party and shall in good faith maintain such partial performance as is reasonably possible and shall resume full performance as soon as is reasonably possible.

18.8 Foreign Access to Technology & Domestic Manufacturing.

18.8.1 Activities Abroad. The Recipient shall assure that project activities carried on outside the United States are coordinated as necessary with appropriate Government authorities and that appropriate licenses, permits, or approvals are obtained prior to undertaking proposed activities. The awarding agency does not assume responsibility for Recipient compliance with the laws and regulations of the country in which the activities are to be conducted.

18.8.2 Export. The Parties understand that information and materials provided pursuant to or resulting from this Agreement may be export controlled, sensitive, for official use only, or otherwise protected by law, executive order, or regulation. The Recipient is responsible for compliance with all applicable laws and regulations. Nothing in this Agreement shall be construed to permit any disclosure in violation of those restrictions.

18.8.3. Exclusive right to use technology in the United States must, unless the Government grants a waiver, require that products embodying the technology or produced through the use of the technology will be manufactured substantially in the United States (37.875).

IN WITNESS WHEREOF, each Party has executed this Agreement by signature of its authorized representative.

**SIGNATURES:**

<b>Recipient</b>	<b>Government</b>
_____ <b>Signature</b>	_____ <b>Signature</b>
_____ <b>Printed Name</b>	(b) (6) _____ <b>Printed Name</b>
_____ <b>Title</b>	_____ <b>Title</b>
_____ <b>Date</b>	_____ <b>Date</b>

SECTION J - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

The below Table of Contents has been added

Exhibit/Attachment Table of Contents

DOCUMENT TYPE	DESCRIPTION	PAGES	DATE
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(End of Summary of Changes)

## **B. Agreement**

B.1. The Government intends to award up to one (1) Technology Investment Agreement (TIA) or Grants to Becton Dickinson response to this solicitation, which is issued under Broad Agency Announcement MSC-BAA-17-01-W911QY-17-S-0001 Amendment 0003, Section VII.C.2 MEDICAL CHEMICAL AND BIOLOGICAL COUNTERMEASURES.

B.2. If a TIA is awarded as a result of this solicitation, it will be executed under the authority 10 USC 2371 - Research Projects other than contracts and grants, which requires cost sharing between the Government and recipient. The expenditure-based TIA cost sharing ratio shall begin with a 50/50 Government/Awardee share ratio. The recipient's cost share comprised of allowable project investment costs including, but not limited to in-house labor and subcontracted costs, equipment utilization and capital equipment costs incurred by the recipient in achieving the objectives of this effort. See 32 CFR 37.215(b).

### **B.6. Agreement Line Items (ALIN)**

ALIN 1000: Development/Expansion of manufacturing capacity for hypodermic safety needles and corresponding syringes in accordance with the Statement of Objectives outlined in Section C below.

ALIN 2000: Monthly progress reports. 2001, 2002, 2003 etc.

ALIN 3000: Quarterly In-Process Reviews (IPR) Hosted at the recipient's facilities. 3001, 3002, 3003 etc.

ALIN 4000: Annual Financial Status Report

ALIN 5000: Final Report that details the findings and issues of the completed project.

## **C. Statement of Objectives**

### **C.1. Introduction.**

### **C.2. General Objectives.**

The recipient shall expand existing domestic Continental US (CONUS) based safety needle and syringe infrastructure and surge capacity to support response for medical countermeasures, emerging infectious diseases and other threats of known and unknown origin during a public health emergency. In the event that existing capacity is unavailable, the recipient shall identify, develop and qualify new US-based manufacturing for utilization with USG (BARDA and affiliate partners) MCMs. In the event of the declaration of a public health emergency, the recipient shall provide priority access to this new or existing MCM capacity for BARDA and other Federal agencies authorized by BARDA. Expansion of existing domestic capacity shall be through accelerated expansion of assembly lines, molding lines, packaging lines, tooling and any other related manufacturing capabilities in existing recipient facilities.

### **C.3. Specific Objectives.**

C.3.1. The recipient shall increase the throughput of existing domestic manufacturing capabilities by a minimum of 50% to enable the USG to expedite MCM administration/delivery to meet US COVID-19 MCM demand. Expansion/development sites include, but are not limited to:

- Expansion safety needle and syringe manufacturing capacity in Columbus, NE

C.3.2. The minimum throughput target for Becton Dickinson's needle and syringe manufacturing capabilities is defined as achieving an added capacity of not less than 300 million safety needle and syringe units per year.

C.3.3. Upon completion of the effort, the USG, through BARDA, shall receive priority access to facilitate third party purchase of safety needles and syringes produced through this investment effort for COVID-19 medical countermeasures.

#### **C.4. Schedule Objectives.**

The schedule for this effort shall be from date of award through September 30, 2021. To date, incremental needle and syringe capacity has become available; however, more rapid acceleration is highly desired by the Government in order to meet critical COVID-19 response needs. In the interim, Becton, Dickinson and Company can supply inventory from its Singapore manufacturing plant while its plant in Nebraska is completing construction of new needle and syringe manufacturing lines. As needle and syringe manufacturer capabilities improve, needle and syringe devices shall be placed online as quickly as possible and made available to USG BARDA to meet critical national COVID-19 demands.

#### **C.5. Overall Management Objectives.**

The recipient shall be responsible for overall management and oversight of the work necessary to achieve the objectives of this agreement. The recipient shall provide the overall management, integration, and coordination of all agreement activities, including a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, and direction of all agreement activities.

The recipient shall establish project milestones for each facility/capability for which expansion and/or development is planned. Incremental progress against each milestone shall be provided to BARDA in accordance with established deliverables (see C.9 below). Any changes or deviations planned or incurred by the recipient in pursuing the objectives of this agreement shall be reported to BARDA. While primary responsibility for management and execution of the effort resides with the recipient, BARDA shall have input to the milestone review process and any changes to the objectives of the agreement. BARDA shall have the responsibility for communicating to the recipient any changes in USG MCM strategies that may impact this agreement.

#### **C.6. Risk Management Objectives.**

The recipient shall identify all anticipated project risks categorized as moderate or high and report them to BARDA in accordance with reporting requirements (see C.9 below). The recipient shall manage all project risks using its in-house risk management capabilities, and report to BARDA changes to all identified risks as they occur/arise. BARDA shall be permitted to participate in the risk management and mitigation processes associated with this project.



### **C.7 Physical Property.**

Title to all physical property developed under this Agreement shall vest with Becton Dickinson.

### **C.8. Intellectual Property.**

Intellectual Property rights for all technology developed under this agreement shall reside with Becton Dickinson, with the exception of information contained in specified deliverables, which shall be subject to distribution within US Government agencies and their contractors (Distribution Statement C). See C.9 below.

### **C.9. Deliverables.**

C.7.1. Monthly Progress Reports. See ALIN 2000. Submitted monthly no later than the 10<sup>th</sup> of the month. Contractor format acceptable. Electronic submission acceptable in MS Office or PDF format. Financial information shall be MS Excel format. Monthly reports shall NOT be marked proprietary, and shall have Distribution Statement C (US Government and their contractors). Each monthly report shall, at a minimum, contain the following:

- Summary of monthly progress for each of the recipient's facilities/capabilities associated with this effort.
- Summary of progress towards established milestones for each facility/capability.
- Identification of any milestone that is slipping or missed, and discussion of path forward to bring milestone back to schedule, and impact on other milestones.
- Summary of risks, discussion of potential impacts and efforts to mitigate.
- Summary of overall schedule and changes from previous month.
- Financial summary of recipient costs incurred by month to date, invoices submitted, and Government payments made.

C.7.2. Quarterly In Process Reviews. See ALIN 3000. Scheduled as needed, generally not more frequently than quarterly, at the recipient's facilities. Duration: 8 hrs max. Face to face review of previous quarter's activities. Informative in nature to keep BARDA apprised of project progress and to discuss issues that may require joint resolution, such as milestone changes, political impacts on objectives, schedule, funding.

C.7.3. Annual Financial Status Report. See ALIN 4000

C.7.4. Final Report. See ALIN 5000. Final Report shall NOT be marked proprietary, and shall have Distribution Statement C. Final report summarizing stated objectives and the progress that was achieved in meeting those objectives; summary of risks incurred, impacts and mitigation; quantitative discussion of needle and syringe production throughput improvements achieved; financial summary of project; schedule summary for project, comparing original schedule to final schedule; recommendations for path forward as applicable.