# AWARD/CONTRACT

| | | | |
|---|---|---|---|
| 1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700) | | RATING | PAGE 1 OF PAGES 21 |
| 2. CONTRACT *(Proc. Inst. Ident.)* NO. W911SR2030001 | 3. EFFECTIVE DATE 20200701 | 4. REQUISITION/PURCHASE REQUEST/PROJECT NO. 0011506628-0002 | |

**5. ISSUED BY** CODE W911SR
USA CONTRACT NG CMD-APG. - W911SR
EDGEWOOD CONTRACTING DIVISION
8456 BRIGADE STREET
BLDG E4215
ABERDEEN PROV NG GROUND MD 21010-5401

**6. ADMINISTERED BY** *(If other than Item 5)* CODE S3101A
DCMA SPR NGF ELD - S3101A
BLDG. 93
PICATINNY NJ 07806-5000

**7. NAME AND ADDRESS OF CONTRACTOR** *(No., street, city, county, state and zip code)*
BECTON, DICKINSON AND COMPANY
1 BECTON DR
FRANKLIN LAKES NJ 07417-1880

**8. DELIVERY**
[ ] FOB ORIGIN [ X ] OTHER *(See below)*

**9 DISCOUNT FOR PROMPT PAYMENT**
Net 30 Days

**10 SUBMIT INVOICES** 1
*(4 copies unless otherwise specified)*
TO THE ADDRESS SHOWN IN:

ITEM
Section G

CODE 06531 FACILITY CODE

**11. SHIP TO/MARK FOR** CODE W56XNH
BIOMEDICAL ADVANCED RESEARCH DEVELOPMENT
(b) (4)
ROOM 23E07
O'NEILL HOUSE OFFICE BUILDING
WASHINGTON DC 20515

**12. PAYMENT WILL BE MADE BY** CODE HQ0337
DFAS-COLUMBUS CENTER
NORTH ENTITLEMENT OPERATIONS
P.O. BOX 182266
COLUMBUS OH 43218-2266

**13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION:**
[ ] 10 U.S.C. 2304(c)( ) [ ] 41 U.S.C. 253(c)( )

**14. ACCOUNTING AND APPROPRIATION DATA**
See Schedule

| 15A. ITEM NO. | 15B. SUPPLIES/ SERVICES | 15C. QUANTITY | 15D. UNIT | 15E. UNIT PRICE | 15F. AMOUNT |
|---|---|---|---|---|---|
| | **SEE SCHEDULE** | | | | |

**15G. TOTAL AMOUNT OF CONTRACT** **$42,303,230.00**

**16. TABLE OF CONTENTS**

| (X) | SEC. | DESCRIPTION | PAGE(S) | (X) | SEC. | DESCRIPTION | PAGE(S) |
|---|---|---|---|---|---|---|---|
| | | **PART I - THE SCHEDULE** | | | | **PART II - CONTRACT CLAUSES** | |
| X | A | SOLICITATION/ CONTRACT FORM | 1 | X | I | CONTRACT CLAUSES | 10 - 21 |
| X | B | SUPPLIES OR SERVICES AND PRICES/ COSTS | 2 | | | **PART III – LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.** | |
| | C | DESCRIPTION/ SPECS./ WORK STATEMENT | | | J | LIST OF ATTACHMENTS | |
| | D | PACKAGING AND MARKING | | | | **PART IV - REPRESENTATIONS AND INSTRUCTIONS** | |
| X | E | INSPECTION AND ACCEPTANCE | 3 | | K | REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS | |
| X | F | DELIVERIES OR PERFORMANCE | 4 | | | | |
| X | G | CONTRACT ADMINISTRATION DATA | 5 | | L | INSTRS., CONDS., AND NOTICES TO OFFERORS | |
| X | H | SPECIAL CONTRACT REQUIREMENTS | 6 - 9 | | M | EVALUATION FACTORS FOR AWARD | |

CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE

17 [X] CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return 1 copies to issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein.)

18 [ ] SEALED-BID AWARD (Contractor is not required to sign this document.)
Your bid on Solicitation Number _____
including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the terms listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract.)

**19A. NAME AND TITLE OF SIGNER** *(Type or print)*
(b) (6)

**20A. NAME OF CONTRACTING OFFICER**
(b) (6)
TEL: EMAIL: (b) (6)

**19B. NAME OF CONTRACTOR**
Becton, Dickinson, and Company
BY (b) (6)
*(Signature of person authorized to sign)*

**19C. DATE SIGNED**
7/1/2020

**20B. UNITED STATES OF AMERICA**
BY (b) (6) (b) (6)
*(Signature of Contracting Officer)*

**20C. DATE SIGNED**
20200701

Section B - Supplies or Services and Prices

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

TECHNOLOGY INVESTMENT AGREEMENT
COST
Technology Investment Agreement (TIA) for Expanding Domestic Production of Needles and Syringes in accordance with (IAW) Recipient Proposal dated 25 June 2020.
FOB: Destination
PSC CD: 6515

ESTIMATED COST (b) (4)

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 000101 | | | | | $0.00 |

Funding for CLIN 0001
COST
This line item is created for funding purposes only.
PURCHASE REQUEST NUMBER: 0011506628-0002

ESTIMATED COST $0.00

ACRN AA (b) (4)
CIN: GFEBS001150662800001

## INSPECTION AND ACCEPTANCE TERMS

Supplies/services will be inspected/accepted at:

| CLIN | INSPECT AT | INSPECT BY | ACCEPT AT | ACCEPT BY |
|---|---|---|---|---|
| 0001 | Destination | Government | Destination | Government |
| 000101 | N/A | N/A | N/A | N/A |

Section F - Deliveries or Performance

## DELIVERY INFORMATION

| CLIN | DELIVERY DATE | QUANTITY | SHIP TO ADDRESS | DODAAC / CAGE |
|---|---|---|---|---|
| 0001 | POP 01-JUL-2020 TO 30-JUN-2030 | N/A | BIOMEDICAL ADVANCED RESEARCH DEVELOPMENT<br>(b) (6)<br>ROOM 23E07<br>O'NEILL HOUSE OFFICE BUILDING<br>WASHINGTON DC 20515<br>FOB: Destination | W56XNH |
| 000101 | N/A | N/A | N/A | N/A |

Section G - Contract Administration Data

## ACCOUNTING AND APPROPRIATION DATA

AA: 021202020212040000664643255 S.0074658.5.1 6100.9000021001
COST CODE: A5XAH
AMOUNT: $42,303,230.00

| ACRN | CLIN/SLIN | CIN | AMOUNT |
|---|---|---|---|
| AA | 000101 | GFEBS001150662800001 | (b) (4) |

Section H - Special Contract Requirements

SECTION H

**H.1 Key Personnel**

H.1.1 Pursuant to HHSAR 352.237-75 (Dec 2015), Key Personnel, any key personnel specified in this agreement 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 agreements the Contractor shall notify the Agreements 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 agreement (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 Agreements Officer. The agreement 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.1.2 Substitution of Key Personnel

H.1.2.1 The Contractor agrees to assign to the agreement those persons whose resumes/CVs were submitted with the proposal who are necessary to fill the requirements of the agreement. No substitutions shall be made except in accordance with this clause.

H.1.2.2 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 Agreements 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 Agreements Officer or authorized representative will evaluate such requests and promptly notify the contractor of his approval or disapproval thereof.

H.1.2.3 The contractor further agrees to include the substance of this clause in any subcontract, which may be awarded under this agreement.

**H.2 Disclosure of Information:**

H.2.1 Performance under this agreement 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 agreement, except authorized by Government personnel or upon written approval of the CO. The Contractor shall not use, disclose, or reproduce proprietary data that bears a restrictive legend, other than as specified in this agreement, or any information at all regarding this agency.

H.2.2 Consistent with HHS Directive 1139, the Contractor shall comply with HHS requirements for protection of non-public information. Unauthorized disclosure of nonpublic information is prohibited by the HHS's rules. Unauthorized disclosure may result in termination of the agreement, 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.

H.2.3 No information related to data obtained under this agreement 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.

**H.2.4 Publication and Publicity**

H.2.4.1 The contractor shall not release any reports, manuscripts, press releases, or abstracts about the work being performed under this agreement without written notice in advance to the Government, for additional information see HHSAR 352.227-70. Publications and Publicity (Dec 2015).

(a) Unless otherwise specified in this agreement, the contractor may publish the results of its work under this agreement. 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 AO, the contractor shall not display the HHS 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 agreement in commercial advertising, as defined in FAR 31.205-1, in any manner which states or implies HHS 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 agreement 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 Agreement No. W911SR2030004."

**H.3 Confidentiality of Information**

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

b. The Agreements Officer and the Contractor may, by mutual consent, identify elsewhere in this agreement 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 Agreements Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the agreement. Failure to agree will be settled pursuant to the "Disputes" clause.

c. If it is established elsewhere in this agreement that information to be utilized under this agreement, 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 agreement, 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 Agreements Officer prior to any release, disclosure, dissemination, or publication.

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

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

All above requirements MUST be passed to all Sub-contractors.

**H.4 Organizational Conflicts of Interest:**

H.4.1 Performance under this agreement may create an actual or potential organizational conflict of interest such as are contemplated by FAR Part 9.505-General Rules. The Contractor shall not engage in any other contractual or other activities which could create an organizational conflict of interest (OCI). This provision shall apply to the prime Contractor and all sub-Contractors. This provision shall have effect throughout the period of performance of this agreement, any extensions thereto by change order or supplemental agreement, and for two (2) years thereafter. The Government may pursue such remedies as may be permitted by law or this agreement, upon determination that an OCI has occurred.

H.4.2 The work performed under this agreement may create a significant potential for certain conflicts of interest, as set forth in FAR Parts 9.505-1, 9.505-2, 9.505-3, and 9.505-4. It is the intention of the parties hereto to prevent both the potential for bias in connection with the Contractor‘s performance of this agreement, as well as the creation of any unfair competitive advantage as a result of knowledge gained through access to any non-public data or third party proprietary information.

H.4.3 The Contractor shall notify the Agreements Officer immediately whenever it becomes aware that such access or participation may result in any actual or potential OCI. Furthermore, the Contractor shall promptly submit a plan to the Agreements Officer to either avoid or mitigate any such OCI. The Agreements Officer will have sole discretion in accepting the Contractor‘s mitigation plan. In the event the Agreements Officer unilaterally determines that any such OCI cannot be satisfactorily avoided or mitigated, other remedies may be taken to prohibit the Contractor from participating in agreement requirements related to OCI.

H.4.4 Whenever performance of this agreement provides access to another Contractor‘s proprietary information, the Contractor shall:

(1) enter into a written agreement with the other entities involved, as appropriate, in order to protect such proprietary information from unauthorized use or disclosure for as long as it remains proprietary; and refrain from using such proprietary information other than as agreed to, for example to provide assistance during technical evaluation of other Contractors’ offers or products under this agreement. An executed copy of all proprietary information agreements by individual personnel or on a corporate basis shall be furnished to the CO within fifteen (15) calendar days of execution.

**H.5 Operations Security (OPSEC)**

H.5.1 The contractor shall develop and submit an OPSEC Standing Operating Procedure (SOP)/Plan within 30 calendar days of agreement award, to be reviewed and approved by the Government OPSEC lead for this effort. The final OPSEC plan, must address the Government’s identified Critical Information List (CIL)

a) All contractors supporting this effort must complete OPSEC Computer Based Training (CBT) that can be accessed via the (Insert applicable website here).

**H.6 Security**

H.6.1 The contractor shall develop a comprehensive security plan that complies with the attached BARDA Security Requirements (Attachment C). The Recipient’s plan shall be delivered to the Government within 30 days of award. The contractor shall also ensure all subcontractors, consultants, researchers, etc. performing work on behalf of this effort, comply with all BARDA security requirements and prime contractor security plans.

a) ASPR will review in detail and submit comments within ten (10) business days to the Agreements Officer (AO) to be forwarded to the Contractor. The Contractor shall review the Draft Security Plan comments,

and, submit a Final Security Plan to the U.S. Government within thirty (10) calendar days after receipt of the comments.

b) The Security Plan shall include a timeline for compliance of all the required security measures outlined by BARDA.

c) Upon completion of initiating all security measures, the Contractor shall supply to the Agreements Officer a letter certifying compliance to the elements outlined in the Final Security Plan.

Section I - Contract Clauses

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: (b) (4)
Total Cost Share for the Agreement: (b)(4)
Total Estimated Value of the Agreem (b)(4)
Effective Date: 1 July 2020
Term of Agreement: Ten (10) Years after Date of Award

**TECHNOLOGY INVESTMENT AGREEMENT TERMS AND CONDITIONS**

ARTICLES



ATTACHMENTS

## 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)
ACC-APG, NCD
1 General Greene Avenue
Natick, MA 01760
(b) (6)

Agreements Specialist (AS)
(b) (6)
ACC-APG, ECD
8456 Brigade Street
Building E4215
Aberdeen Proving Ground, MD 21010
(b) (6)
(b) (6)

Administrative Grants Officer (AGO)
(b) (6)
Defense Contract Management Agency (DCMA) Springfield
Building 93
Picatinny Arsenal, NJ 07806-5000
(b) (6)
(b) (6)

Biomedical Advanced Research and Development Authority (BARDA) Program Manager (PM)
(b) (6)
Assistant Secretary for Preparedness and Response (ASPR)/BARDA
Room 23E07 – 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: Invoice and Receiving Report (Combo)

(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*

| ***Field Name in WAWF*** | ***Data to be entered in WA*** |
|---|---|
| Pay Official DoDAAC | HQ0337 |
| Issue By DoDAAC | W911SR |
| 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 (b)(4) 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 10th 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:**

| | |
|---|---|
| **Recipient** (b) (6) | **Government** (b) (6) (b) (6) |
| **Signature** (b) (6) | **Signature** (b) (6) |
| **Printed Name** (b) (6) | **Printed Name** Agreements Officer |
| **Title** 7/1/2020 | **Title** |
| **Date** | **Date** |

**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 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).

**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 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 (anticipated June 2020) through June 30, 2021. Incremental capacity may become available quarterly beginning in 2021. However, more rapid acceleration is highly desired by the Government in order to meet critical COVID-19 response needs. As acceleration opportunities are identified, the recipient is encouraged to work with USG BARDA to make optional incremental funding to realize these opportunities. As incremental capabilities become available from different component facilities, they 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.9.1. Monthly Progress Reports. Submitted monthly no later than the 10th 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 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.

CI.9.2. Quarterly In Process Reviews. 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.9.3. Annual Financial Status Report. (37.880)

C.9.4. 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 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.

## BARDA Security Requirements

The following paragraphs are the minimum-security requirements for any partner facility receiving a BARDA contract / agreement where the USG purchases product or technologies.

| Table 1: BARDA Security Requirements | |
|---|---|
| **1. Security Administration** | |
| Security Program | The partner facility shall have a comprehensive security program that provides a security plan for the overall protection of personnel, information, data, and facilities associated with fulfilling the BARDA requirement. The proposal submitted shall include a security plan which establishes security practices and procedures that demonstrate how the Offeror will meet and adhere to the security requirements outlined below prior to the commencement of product manufacturing. The Offeror shall also ensure that other entities (sub-contractors, consultants, etc.) performing work on behalf of the Offeror establishes and manages a security program that complies with all BARDA security requirements. |
| **2. Facility Security Plan** | |
| As part of the partner facility's overall security program, the Offeror shall submit a written security plan with their proposal to BARDA for review and approval by BARDA security subject matter experts. The performance of work under the BARDA contract will be in accordance with the approved security plan. The security plan will include the following processes and procedures at a minimum: | |
| Security Administration | Organization chart and responsibilities; written security risk assessment for site; threat levels with identification matrix (High, Medium, or Low); enhanced security procedures during elevated threats; liaison procedures with law enforcement; annual employee security education and training program. |
| Personnel Security Policies and Procedures | Candidate recruitment process; background investigations process; employment suitability policy; employee access determination; rules of behavior/ conduct; termination procedures; non-disclosure agreements. |

| Table 1: BARDA Security Requirements | |
|---|---|
| Physical Security Policies and Procedures | Internal/external access control; protective services; identification/badging; employee and visitor access controls; parking areas and access control; perimeter fencing/barriers; product shipping, receiving and transport security procedures; facility security lighting; restricted areas; signage; intrusion detection systems; alarm monitoring/response; closed circuit television; product storage security; other control measures. |
| Information Security | Identification and marking of sensitive information; access control; storage of information; document control procedures; retention/ destruction requirements. |
| Information Technology/Cyber Security Policies and Procedures | Intrusion detection and prevention systems; threat identification; employee training (initial and annual); encryption systems; identification of sensitive information/media; password policy (max days 90); lock screen time out policy (minimum time 20 minutes); removable media policy; laptop policy; removal of IT assets for domestic/foreign travel; access control and determination; VPN procedures; WiFi and Bluetooth disabled when not in use; system document control; system backup; system disaster recovery; incident response; system audit procedures; property accountability. |
| **3. Site Security Master Plan** | |
| | The partner facility shall provide a site schematic for security systems which includes: main access points; security cameras; electronic access points; IT Server Room; Product Storage Freezer/Room; and bio-containment laboratories. |
| **4. Site Threat / Vulnerability / Risk Assessment** | |
| | The partner facility shall provide a written risk assessment for the facility addressing: criminal threat, including crime data; foreign/domestic terrorist threat; industrial espionage; insider threats; natural disasters; and potential loss of critical infrastructure (power/water/natural gas, etc.) This assessment shall include recent data obtained from local law enforcement agencies. The assessment should be updated annually. |
| **5. Physical Security** | |
| Closed Circuit Television (CCTV) Monitoring | (a) Layered (internal/external) CCTV coverage with time-lapse video recording for buildings and areas where critical assets are processed or stored. |

| Table 1: BARDA Security Requirements | |
|---|---|
| | (b) CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the contract.<br><br>(c) Video recordings must be maintained for a minimum of 30 days.<br><br>(d) CCTV surveillance system must be on emergency power backup. |
| Facility Lighting | (a) Lighting must cover facility perimeter, parking areas, critical infrastructure, and entrances and exits to buildings.<br><br>(b) Lighting must have emergency power backup.<br><br>(c) Lighting must be sufficient for the effective operation of the CCTV surveillance system during hours of darkness. |
| Shipping and Receiving | (a) Must have CCTV coverage and an electronic access control system.<br><br>(b) Must have procedures in place to control access and movement of drivers picking up or delivering shipments.<br><br>(c) Must identify drivers picking up BARDA products by government issued photo identification. |
| Access Control | (a) Must have an electronic intrusion detection system with centralized monitoring.<br><br>(b) Responses to alarms must be immediate and documented in writing.<br><br>(c) Employ an electronic system (i.e., card key) to control access to areas where assets critical to the contract are located (facilities, laboratories, clean rooms, production facilities, warehouses, server rooms, records storage, etc.).<br><br>(d) The electronic access control should signal an alarm notification of unauthorized attempts to access restricted areas.<br><br>(e) Must have a system that provides a historical log of all key access transactions and kept on record for a minimum of12 months.<br><br>(f) Must have procedures in place to track issuance of access cards to employees and the ability to deactivate cards when they are lost or an employee leaves the company.<br><br>(g) Response to electronic access control alarms must be immediate and documented in writing and kept on record for a minimum of 12 months. |

| Table 1: BARDA Security Requirements | |
|---|---|
| | (h) Should have written procedures to prevent employee piggybacking.<br><br>(i) Access to critical infrastructure (generators, air handlers, fuel storage, etc.) should be controlled and limited to those with a legitimate need for access.<br><br>(j) Must have a written manual key accountability and inventory process.<br><br>(k) Physical access controls should present a layered approach to critical assets within the facility. |
| Employee/Visitor Identification | (a) Should issue company photo identification to all employees.<br><br>(b) Photo identification should be displayed above the waist anytime the employee is on company property.<br><br>(c) Visitors should be sponsored by an employee and must present government issued photo identification to enter the property.<br><br>(d) Visitors should be logged in and out of the facility and should be escorted by an employee while on the premises at all times. |
| Security Fencing | Requirements for security fencing will be determined by the criticality of the program, review of the security plan, threat assessment, and onsite security assessment. |
| Protective Security Forces | Requirements for security officers will be determined by the criticality of the program, review of the security plan, threat assessment, and onsite security assessment. |
| Protective Security Forces Operations | (a) Must have in-service training program.<br><br>(b) Must have Use of Force Continuum.<br><br>(c) Must have communication systems available (i.e., landline on post, cell phones, handheld radio, and desktop computer).<br><br>(d) Must have Standing Post Orders.<br><br>(e) Must wear distinct uniform identifying them as security officers. |
| **6. Security Operations** | |

| Table 1: BARDA Security Requirements | |
|---|---|
| Information Sharing | Establish formal liaison with law enforcement.<br><br>(a) Meet in person at a minimum annually. Document meeting notes and keep them on file for a, minimum of 12 months. POC information for LE Officer that attended the meeting must be documented.<br><br>(b) Implement procedures for receiving and disseminating threat information. |
| Training | (a) Conduct new employee security awareness training.<br><br>(b) Conduct and maintain records of annual security awareness training. |
| Security Management | (a) Designate a knowledgeable security professional to manage the security of the facility.<br><br>(b) Ensure subcontractor compliance with all BARDA security requirements. |
| **7. Personnel Security** | |
| Records Checks | Verification of social security number, date of birth, citizenship, education credentials, five-year previous employment history, five-year previous residence history, FDA disbarment, sex offender registry, credit check based upon position within the company; motor vehicle records check as appropriate; and local/national criminal history search. |
| Hiring and Retention Standards | (a) Detailed policies and procedures concerning hiring and retention of employees, employee conduct, and off boarding procedures.<br><br>(b) Off Boarding procedures should be accomplished within 24 hour of employee leaving the company. This includes termination of all network access. |
| **8. Information Security** | |
| Physical Document Control | (a) Applicable documents shall be identified and marked as procurement sensitive, proprietary, or with appropriate government markings.<br><br>(b) Sensitive, proprietary, and government documents should be maintained in a lockable filing cabinet/desk or other storage device and not be left unattended. |

| Table 1: BARDA Security Requirements | |
|---|---|
| | (c) Access to sensitive information should be restricted to those with a need to know. |
| Document Destruction | Documents must be destroyed using approved destruction measures (i.e, shredders/approved third party vendors / pulverizing / incinerating). |
| **9. Information Technology & Cybersecurity** | |
| Identity Management | (a) Physical devices and systems within the organization are inventoried and accounted for annually.<br><br>(b) Organizational cybersecurity policy is established and communicated.<br><br>(c) Asset vulnerabilities are identified and documented.<br><br>(d) Cyber threat intelligence is received from information sharing forums and sources.<br><br>(e) Threats, vulnerabilities, likelihoods, and impacts are used to determine risk.<br><br>(f) Identities and credentials are issued, managed, verified, revoked, and audited for authorized devices, users and processes.<br><br>(g) Users, devices, and other assets are authenticated (e.g., single-factor, multifactor) commensurate with the risk of the transaction (e.g., individuals' security and privacy risks and other organizational risks) |
| Access Control | (h) Limit information system access to authorized users.<br><br>(i) Identify information system users, processes acting on behalf of users, or devices and authenticate identities before allowing access.<br><br>(j) Limit physical access to information systems, equipment, and server rooms with electronic access controls. |
| Training | Ensure that personnel are trained and are made aware of the security risks associated with their activities and of the applicable laws, policies, standards, regulations, or procedures related to information technology systems. |
| Audit and Accountability | (a) Create, protect, and retain information system audit records to the extent needed to enable the monitoring, analysis, investigation, and reporting of |

| Table 1: BARDA Security Requirements | |
|---|---|
| | unlawful, unauthorized, or inappropriate system activity. Records must be kept for minimum must be kept for 12 months.<br><br>(b) Ensure the actions of individual information system users can be uniquely traced to those users. |
| Configuration Management | Establish and enforce security configuration settings. |
| Contingency Planning | Establish, implement, and maintain plans for emergency response, backup operations, and post-disaster recovery for information systems to ensure the availability of critical information resources at all times. |
| Incident Response | Establish an operational incident handling capability for information systems that includes adequate preparation, detection, analysis, containment, and recovery of cybersecurity incidents. Exercise this capability annually. |
| Media and Information Protection | (a) Protect information system media, both paper and digital.<br><br>(b) Limit access to information on information systems media to authorized users.<br><br>(c) Sanitize and destroy media no longer in use.<br><br>(d) Control the use of removable media through technology or policy. |
| Physical and Environmental Protection | (a) Limit access to information systems, equipment, and the respective operating environments to authorized individuals.<br><br>(b) Intrusion detection and prevention system employed on IT networks.<br><br>(c) Protect the physical and support infrastructure for all information systems.<br><br>(d) Protect information systems against environmental hazards. |
| Network Protection | Employ intrusion prevention and detection technology with immediate analysis capabilities. |

| Table 1: BARDA Security Requirements | |
|---|---|
| **10. Transportation Security** | |
| Adequate security controls must be implemented to protect materials while in transit from theft, destruction, manipulation, or damage. | |
| Drivers | (a) Drivers must be vetted in accordance with BARDA Personnel Security Requirements.<br><br>(b) Drivers must be trained on specific security and emergency procedures.<br><br>(c) Drivers must be equipped with backup communications.<br><br>(d) Driver identity must be 100 percent confirmed before the pick-up of any BARDA product.<br><br>(e) Drivers must never leave BARDA products unattended, and two drivers may be required for longer transport routes or critical products during times of emergency.<br><br>(f) Truck pickup and deliveries must be logged and kept on record for a minimum of 12 months. |
| Transport Routes | (a) Transport routes should be pre-planned and never deviated from except when approved or in the event of an emergency.<br><br>(b) Transport routes should be continuously evaluated based upon new threats, significant planned events, weather, and other situations that may delay or disrupt transport. |
| Product Security | (a) BARDA products must be secured with tamper resistant seals during transport, and the transport trailer must be locked and sealed.<br><br>(b) Tamper resistant seals must be verified as “secure” after the product is placed in the transport vehicle.<br><br>(a) BARDA products should be continually monitored by GPS technology while in transport, and any deviations from planned routes should be investigated and documented.<br><br>(b) Contingency plans should be in place to keep the product secure during emergencies such as accidents and transport vehicle breakdowns. |

| Table 1: BARDA Security Requirements | |
|---|---|
| **11. Security Reporting Requirements** | |
| | The partner facility shall notify the BARDA Security Team within 24 hours of any activity or incident that is in violation of established security standards or indicates the loss or theft of government products. The facts and circumstances associated with these incidents will be documented in writing for government review. |
| **12. Security Audits** | |
| | The partner facility agrees to formal security audits conducted at the discretion of the government. Security audits may include both prime and subcontractor locations. Minimum length of notification is 10 business day. |

**VOLUME I – TECHNICAL**

BAA Number: MSC-BAA-17-01-W911QY-17-S-0001 Amendment 0003
Topic Area: Expanding Domestic Production of Needles & Syringes

**BD/BARDA Partnership for a National Vaccination Campaign in response to COVID-19 Pandemic**

Submitted: May 29, 2020

Becton, Dickinson and Company ("BD")
1 Becton Drive
Franklin Lakes, NJ 07417

DUNS: 001292192 CAGE: 06531
Large Business

**Administrative Points of Contact:**


**Technical Points of Contact:**

**Executive Summary:**

**In support of Section VII.C.2 of BAA# W911QY-17-S-0001, BD requests an investment of (b) (4) to add three manufacturing lines to the company's existing operations in Columbus, Nebraska, which would increase US supply of safety injection devices (b) (4)**

As the largest manufacturer of needles and syringes in the world, BD is the only company that can supply injection products at the scale needed to enable COVID-19 vaccination efforts. In support of the goals of Operation Warp Speed, BD has communicated that the company can (b) (4) These devices are manufactured at BD's facilities in Nebraska and Connecticut, and leverage BD's global manufacturing footprint.

BD is collaborating with BARDA to supply existing availability of needles and syringes to increase immediate stockpiles. However, additional capacity is needed in the US to ensure long term pandemic planning and sustainable supply of needles and syringes, in particular safety injection devices. With the requested investment, capacity for (b) (4) to support near-term vaccination goals as well as add long-term domestic capacity for these critical products.

BD is steadfast in its commitment to support COVID-19 vaccination efforts in the US and has a proven track record for meeting the needs of the government. BD was selected by the Biomedical Advanced Research and Development Authority (BARDA) as the primary provider for needles and syringes used in the 2009 H1N1 vaccination campaign. Our Nebraska presence was also established at the request of the federal government for strategic public health benefits and is a primary reason BD has continued to invest in these facilities for more than 60 years.

**Statement of Work:**

Introduction

BARDA is tasked with securing enough injection devices to vaccinate the country's entire population and has communicated a target of ~700 million dose units to prepare for a two-dose vaccine. In order to fulfill this goal, contracts have been initiated with BD and two additional industry partners to leverage all available capacity both in the US and globally. However, these plans must be expanded to include additional capacity for safety injection devices to meet the country's goals.

Based on current US market availability, the total incremental volume required for 2020-2023 is expected to be greater than 800 million dose units of safety injection devices. This represents an increase of 57% to current market supply (GHX Market Data Calendar 2019) for safety injection needles and syringes used for vaccination delivery alone. Without addressing manufacturing capacity for injection products, BD anticipates that routine patient care would be significantly impacted due to a lack of adequate supply of these devices. The absence of safety injection devices could increase risk to healthcare workers for sharps injuries and exposure to bloodborne pathogens.

Overarching Objectives

In support of Operation Warp Speed, BD seeks strategic support to add US-based manufacturing capacity in Columbus, Nebraska for an additional (b) (4) units of safety injection devices for the COVID-19 response in the first operational year. This investment would not only address the following pandemic preparedness needs in the US, but also protect essential delivery of care:

- **Effective immunization in the short term will require adequate and ongoing supply of needles and syringes**: Needle and syringe manufacturing is critical to enable delivery of vaccines and other medications. For successful, full-scale vaccination of the US population against COVID-19, these injection solutions are essential and support national defense priorities. The proposed incremental investment would support products needed to vaccinate the entire US population.
- **Expanding US capacity for needles and syringes supports an "America First" strategy to increase US manufacturing**. The investment would also ensure the timely availability of essential domestic industrial resources to expand capabilities to address reserve capacity and ramp-up production as needed for pandemic requirements.

Technical Approach

To achieve the total doses required for a national vaccination campaign and ongoing pandemic preparedness, BD will leverage the requested investment to procure and install three new equipment lines, one line dedicated to Eclipse™ Safety needle production and two lines dedicated to 3ml syringe production. Target production for syringes would begin within 8 months and safety needles within 12 months of an award. Upon completion of the agreed-upon capital investment, the US Government, through BARDA, would have priority access to facilitate procurement from this expanded capacity, (b) (4)

The proposed products, deliverables and milestones outlined below serve to fill the gap between the current volume of safety injection devices that are available and those that are required with new domestic manufacturing capacity.

Products

For the US, BD annually produces (b) (4)

BD proposes the following market leading products to be manufactured. These devices represent some of the most frequently used products in US healthcare and are familiar to end-users.

- **Eclipse™ Safety Needle:** BD provides (b) (4) (b) (4)

- **3mL Luer-Lok Syringe**: BD produces (b) (4) (b) (4)

Timeline to Success

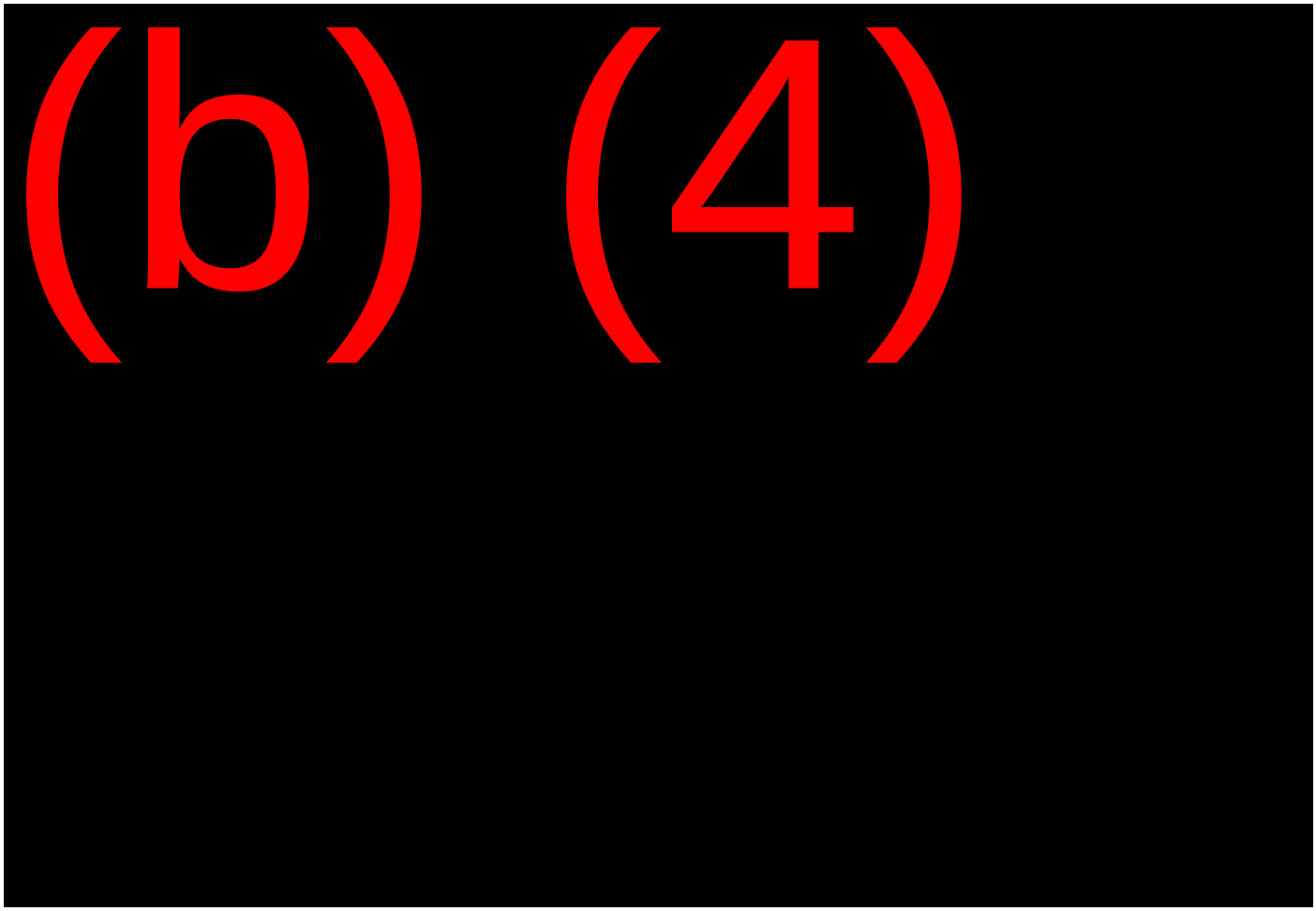
Upon award of investment, BD will operationalize 3 manufacturing lines, along with ancillary support equipment, within 12 months, with the first syringe line up and running at an estimated 8 months into the project. While we add capacity in Columbus, BD will accelerate production by leveraging our existing manufacturing footprint across the US.

BD will oversee management, integration, and coordination of all project milestones, including technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, and direction of all project tasks.

BD will also seek opportunities to address efficiencies that could impact timeline to production. For example, we will leverage existing orders for capital equipment for similar capacity expansions of our commercial lines that could be prioritized to increase the cadence of the project. BD has used these equipment costs as the basis of costs for this project.

The following milestones will be carefully monitored, and progress will be reported on a monthly basis as outlined in the tables below. Only major milestones are shown in the chart below. Please reference "Project Cost Worksheet in RFFP Final 29May2020" for a detailed breakout.

(b) (4)




Deliverables

The following deliverables will be provided as part of the anticipated public-private partnership:

- **Monthly Progress Reports:** No later than the 10th of each month, BD will provide a summary of project performance. Reports will contain the following components:
  - 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.

- **Quarterly Process Review:** BD will schedule quarterly reviews which would be scheduled in person and/or virtually. Quarterly engagements will aim to be informative in nature to keep BARDA apprised of project progress and to discuss issues that may

require joint resolution, such as milestone changes related to objectives, schedule, and funding.

- **Annual Financial Status Report:** BD will provide and annual financial report that provides a full summary of the project costs and expenditures as well as project milestone status.

- **Final Report:** BD will provide a 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 **(final report will not be marked proprietary)**.

- **Project Transparency:** BD shall identify all anticipated project risks categorized as moderate or high and report them to BARDA in accordance with reporting requirements outlined in deliverables.

Manufacturing Excellence and Facilities Description

In addition to manufacturing the market leading products proposed for production, BD's Columbus operations hold the proud distinction of being the first manufacturing plant for BD outside of the company's headquarters in New Jersey. BD's Columbus facility was established in 1949 at the request of the federal government to geographically diversify and support domestic manufacturing. Over the past 69 years, these operations have expanded to address various public health needs in the US and globally. BD now employs approximately (b) (4) in Columbus.

The strong Nebraska workforce and expertise BD associates bring to the table in terms of science, technology and engineering is a key reason why BD has continued to expand across the state and why BD can bring this capacity on board and to scale so quickly to address the COVID-19 response.

| | |
|---|---|
| BD Medical<br>1852 10th Avenue<br>Columbus, NE<br>68601 |   |

Capital and Commercial Equipment:

BD works with a dedicated group of suppliers to ensure the continuity of our operations and to meet customer needs. The equipment, components and services that our partners provide are more critical than ever to support our ability to manufacture necessary medical technology. Lead times for equipment vary, but historical purchases give BD valuable insight to the process. We have a proposed schedule in the attachment "Project Cost Worksheet in RFFP Final 29May2020" which details the equipment below.

| Equipment | Qty | Manufacturer | Place of Manufacture |
|---|---|---|---|
| (b) (4) | | | |

| Equipment | Qty | Manufacturer | Place of Manufacture |
|---|---|---|---|
| (b) (4) | | | |

Direct Labor Hours:

Direct labor hours attributed to this project include both pre- and post-operational labor. These hours and costs are broken out in the "Project Cost Worksheet in RFFP Final 29May2020" on the tab titled "Generic Cost breakout".

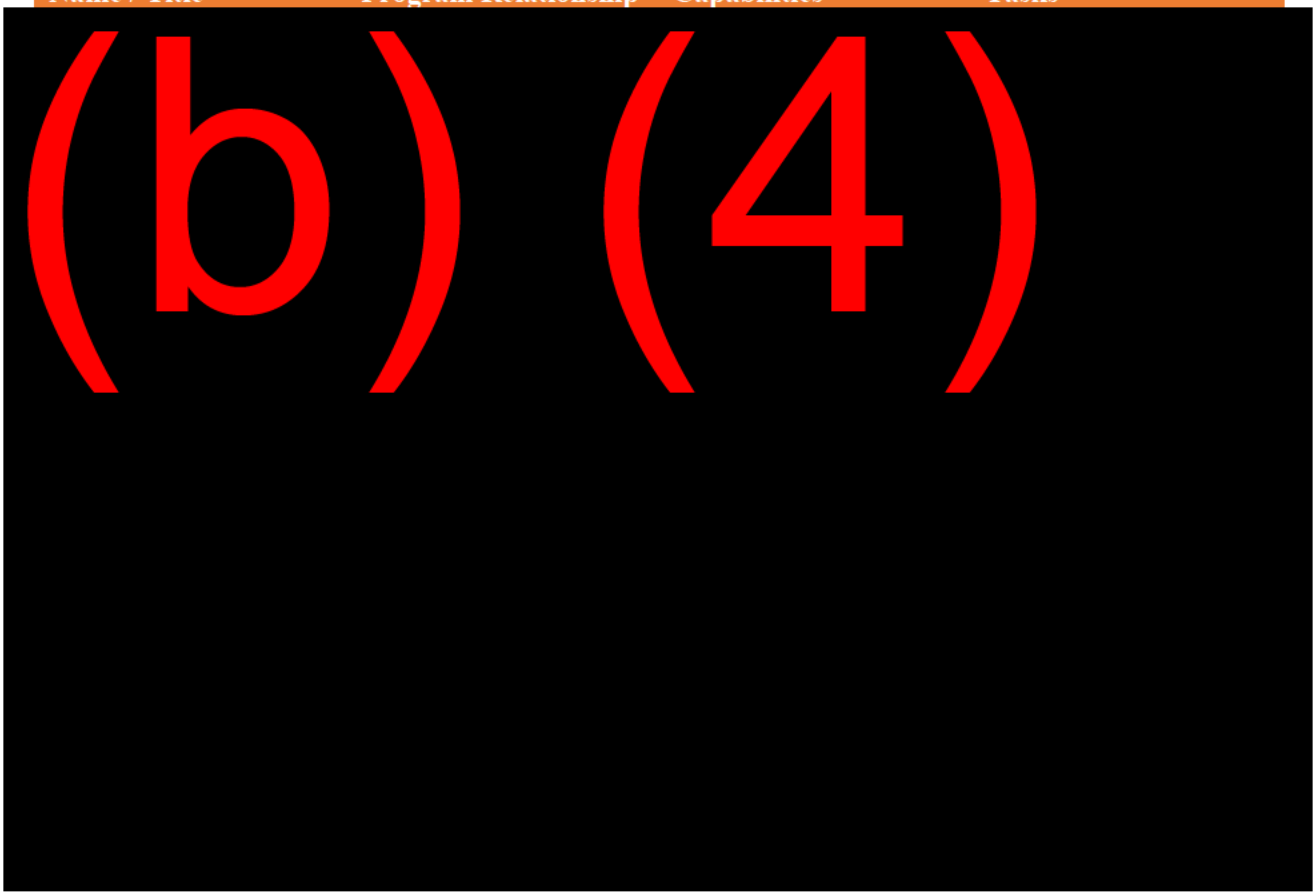
**Pre-operational labor** is defined as the personnel necessary to implement the equipment buildout, installation and validation of all equipment coming into the manufacturing plant. These rates are not included in the installation or equipment costs. (b) (4) The following titles are used in the calculation and are also listed in the cost section below:

| Position | Qty | Total Hours |
|---|---|---|
| (b) (4) | | |

**Post-operational labor** is defined as personnel required to staff and maintain the equipment once it is online to ensure full capacity under this project requirement. (b) (4) [redacted] The following staffing requirements listed below are based on historical needs for similar manufacturing lines:


Key Personnel - BD Responsibility Matrix

| Name / Title | Program Relationship | Capabilities | Tasks |
|---|---|---|---|



Volume II – Financial Aspects

BAA Number: MSC-BAA-17-01-W911QY-17-S-0001 Amendment 0003

Topic Area: Expanding Domestic Production of Needles & Syringes

BD/BARDA Partnership for a National Vaccination Campaign
in response to COVID-19 Pandemic

Submitted: May 29, 2020
Becton, Dickinson and Company ("BD")
1 Becton Drive
Franklin Lakes, NJ 07417

DUNS: 001292192 CAGE: 06531
Large Business

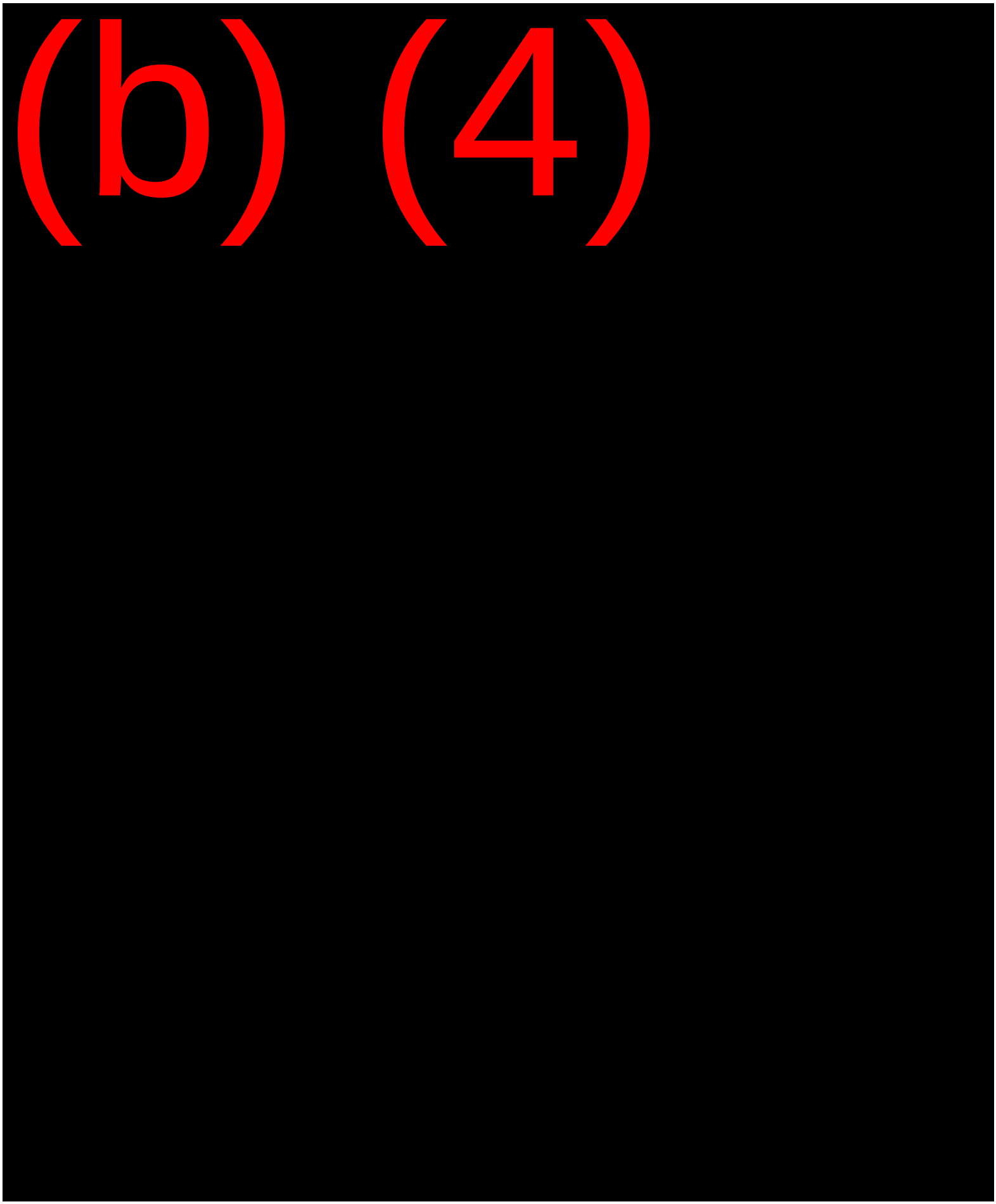
Administrative Points of Contact:

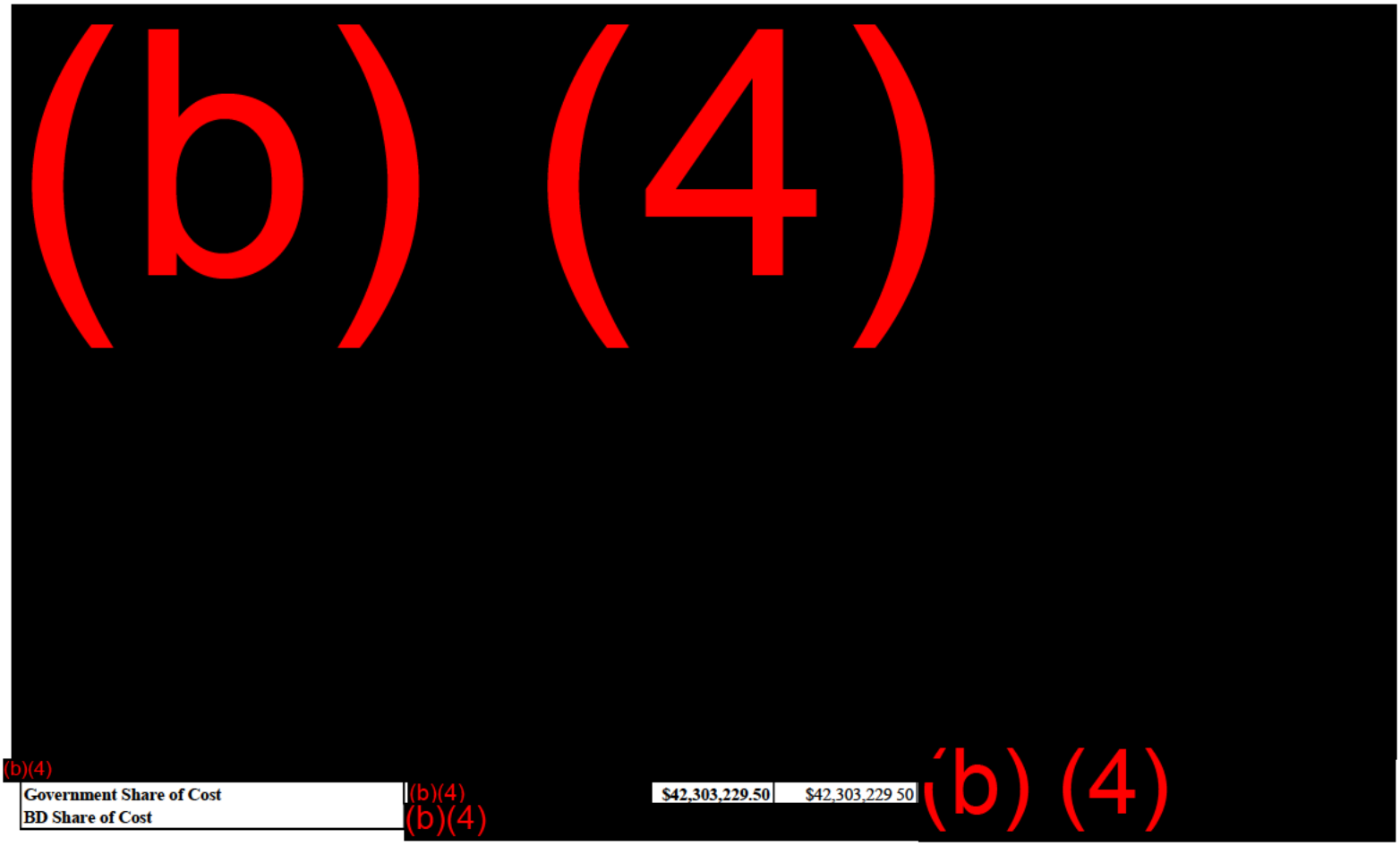

As a Commercial Item manufacturer as defined in FAR 2.101, BD is exempt from Cost Accounting System requirements. As such, BD does not have an approved Cost Accounting System, DCAA office, nor DCAA contact to provide. This proposal is consistent with BD's established estimating and accounting practices and procedures.

| Milestone | Description | Milestone Completion Criteria | Months | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |

(b) (4)


(b) (4)


(b) (4)




| | | | |
|---|---|---|---|
| **Government Share of Cost** | **$42,303,229.50** | $42,303,229 50 |
| **BD Share of Cost** | | |

BARDA Capacity
Investment Spend Schedule

27-May-2020

(b) (4)

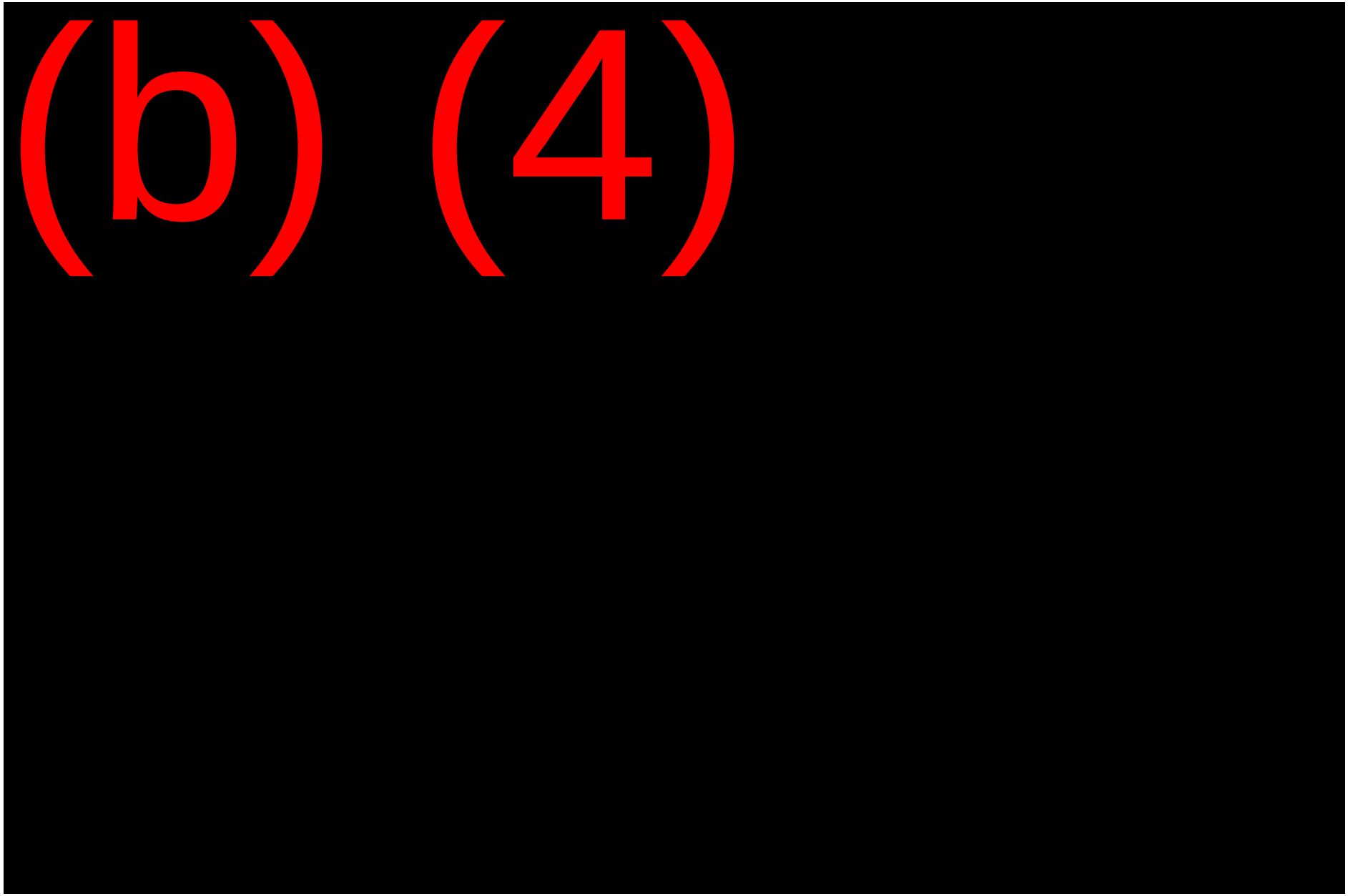
| | | | |
|---|---|---|---|
| Contingency: | | | $ - |
| Grand Total incl. Contingency: | | | #REF! |

| Payment Terms | Month 1 | Month 2 | Month 3 | Month 4 | Month 5 | Month 6 | Month 7 | Month 8 | Month 9 | Month 10 | Month 11 | Month 12 | Check |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|

(b) (4)

| Category | Item | Rate | QTY | Payment by Month | | | | | | | | | | | | Total Cost |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Month 1 | Month 2 | Month 3 | Month 4 | Month 5 | Month 6 | Month 7 | Month 8 | Month 9 | Month 10 | Month 11 | Month 12 | |
| (b) (4) | | | | | | | | | | | | | | | | |

| Name / Title | Program Relationship | Capabilities | Tasks |
| --- | --- | --- | --- |
| (b) (6) | | | |


(b) (4)

# AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

| 1 CONTRACT ID CODE | PAGE OF PAGES |
|---|---|
| | 1 \| 14 |

| 2 AMENDMENT/MODIFICATION NO | 3 EFFECTIVE DATE | 4 REQUISITION/PURCHASE REQ NO | 5 PROJECT NO (If applicable) |
|---|---|---|---|
| P00001 | 29-Sep-2020 | 0011506628-0002 | |

| 6 ISSUED BY | CODE | 7 ADMINISTERED BY (If other than item 6) | CODE |
|---|---|---|---|
| USA CONTRACTING CMD-APG. - W911SR<br>EDGEWOOD CONTRACTING DIVISION<br>8456 BRIGADE STREET<br>BLDG E4215<br>ABERDEEN PROVING GROUND MD 21010-5401 | W911SR | DCMA SPRINGFIELD - S3101A<br>BLDG. 93<br>PICAT NNY NJ 07806-5000 | S3101A |

| 8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) | | |
|---|---|---|
| BECTON, DICKNSON AND COMPANY<br>1 BECTON DR<br>FRANKLN LAKES NJ 07417-1880 | | 9A. AMENDMENT OF SOLICITATION NO. |
| | | 9B. DATED (SEE ITEM 11) |
| | X | 10A. MOD. OF CONTRACT/ORDER NO.<br>W911SR2030001 |
| | X | 10B. DATED (SEE ITEM 13)<br>01-Jul-2020 |
| CODE 06531 | FACILITY CODE | |

## 11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

## 12. ACCOUNTING AND APPROPRIATION DATA (If required)

## 13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

☐ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

☐ C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

X D. OTHER (Specify type of modification and authority)
Unilateral IAW Terms & Conditions Para. 17.3

E. IMPORTANT: Contractor ☒ is not, ☐ is required to sign this document and return _____ copies to the issuing office.

## 14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Modification Control Number: [redacted]20675

See 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)<br>TEL: (b) (6) EMAIL: (b) (6) |

| 15B. CONTRACTOR/OFFEROR | 15C. DATE SIGNED | 16B. (b) (6) | 16C. DATE SIGNED |
|---|---|---|---|
| (Signature of person authorized to sign) | | BY (b) (6)<br>(Signature of Contracting Officer) | 29-Sep-2020 |

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 P00001

1. The purpose of this modification is to make the following administrative changes:

   a. Correct e-mail addresses for the Agreements Officer and Agreements Specialist in Paragraph 4.2 of the Terms and Conditions.

   b. Change the Administrative Grants Officer from (b) (6) in Paragraphs 4.2 and 5.3.4 of the Terms and Conditions.

   c. Change the required WAWF Document Type in Paragraph 5.3.4 of the Terms and Conditions.

2. There is no change to the cost or price of this Agreement as a result of this Modification. 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: (b) (4)
Total Cost Share for the Agreement: (b) (4)
Total Estimated Value of the Agreement: (b) (4)
Effective Date: 1 July 2020
Term of Agreement: Ten (10) Years after Date of Award

**TECHNOLOGY INVESTMENT AGREEMENT TERMS AND CONDITIONS**

ARTICLES

18. Miscellaneous

ATTACHMENTS

A. Recipient's Proposal

B. Statement of Objectives [SOO]

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)
ACC-APG, NCD
1 General Greene Avenue
Natick, MA 01760
(b) (6)

Agreements Specialist (AS)
(b) (6)
ACC-APG, ECD
8456 Brigade Street
Building E4215
Aberdeen Proving Ground, MD 21010
(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
Room 23E07 – O'Neill House Office Building
Washington, DC 20515
(b) (6)

4.3 Recipients Representatives

(b) (6), PhD – Business POC
VP, Injection Systems
1 Becton Drive
Franklin Lakes, NJ 07417
(b) (6)
(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)
(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*

| ***Field Name in WAWF*** | ***Data to be entered in WA*** |
|---|---|
| Pay Official DoDAAC | HQ0337 |
| Issue By DoDAAC | W911SR |
| 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 10th 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:**

| **Recipient** | **Government** |
|---|---|
| **Signature** | **Signature** (b) (6) |
| [redacted] | **Printed Name** Agreements Officer |
| **Title** | **Title** |
| **Date** | **Date** |

(End of Summary of Changes)