Biomedical Advanced Research and Development Authority (BARDA)

Biopharmaceutical Manufacturing Preparedness – Consortium (BioMaP-Consortium)

Request for Project Proposals (RPP)

Expansion of Domestic Manufacturing Capacity for Nitrile Gloves

RPP Identifier: 26-09-Gloves

RPP Issue Date: August 6, 2026

Proposal Due: September 8, 2026, 1 PM ET

Biomedical Advanced Research Development Authority (BARDA) Contracts Management & Acquisition (CMA)
400 7th Street, SW, Washington, DC 20024

MedicalCountermeasures.gov

Contents

1 Executive Summary

1.1 Biopharmaceutical Manufacturing Preparedness Consortium

The Biopharmaceutical Manufacturing Preparedness Consortium (BioMaP-Consortium) is a multiple-purpose acquisition vehicle comprised of industry partners across the drug and vaccine manufacturing supply chain, including, but not limited to, drug substance manufacturers of required raw materials and consumables, suppliers of fill-finish services, and developers of innovative manufacturing technologies.

The BioMaP-Consortium brings together pharmaceutical, medical, academic, and scientific organizations working toward successful development and delivery of medical countermeasure materials and products. Cooperative partnerships are maintained to ensure that there are adequate manufacturing capabilities to provide and make available requisite products and materials, so that countermeasures and therapies can be delivered to civilian populations addressing threats to the nation's public health or other security interests.

The BioMaP-Consortium is also focused on expanding the United States' domestic industrial and manufacturing base for medical countermeasures.

Advanced Technology International (ATI) has been awarded an Other Transaction Agreement (OTA) by BARDA to serve as the Consortium Management Firm (CMF) for the BioMaP-Consortium.

BioMaP-Consortium openly recruits members to join a broad and diverse biomedical consortium that includes representatives from all organizations who work within stated key domain areas. For more information on the BioMaP-Consortium mission, refer to the BioMaP-Consortium website at BioMaP-Consortium.org. For entities interested in joining the BioMaP-Consortium and responding to this solicitation, please visit www.BioMaP-Consortium.org/how-to-join.

1.2 Introduction

The importance of PPE cannot be overstated, as it serves as a critical line of defense in various contexts. In healthcare settings, PPE, including masks, gloves, face shields, and gowns, is indispensable for protecting healthcare professionals from infectious diseases, ensuring their safety while delivering essential care. Amid the unprecedented challenges brought forth by PHEs, notably underscored by the example of the COVID-19 pandemic, the importance of ensuring a resilient and robust supply chain for PPE is essential. This need goes beyond fulfilling demand during PHEs only; it emphasizes the necessity for consistently sustaining manufacturing capacities to also meet non-emergency everyday requirements. The necessity for a comprehensive and forward-thinking approach that anticipates future challenges and ensures the enduring strength of supply chain safeguards our ability to provide essential PPE.

The U.S. currently faces an estimated 15 billion nitrile glove deficit in its surge demand capacity, presenting a considerable risk in the event of another nationwide PHE. To address this gap, the USG aims to develop an agile industrial base with vertically integrated, high-capacity nitrile glove manufacturers. Ideally, these manufacturers must source and produce both the NBR rubber feedstock, and the nitrile gloves themselves, thus reducing supply chain risks for this critical PPE item. Developing this capability is crucial to closing the gap and ensuring preparedness for future PHEs.

1.3 Purpose

The Center for Industrial Base Management and Supply Chain (IBMSC), of the U.S. Department of Health and Human Services (HHS) Administration for Strategic Preparedness and Response (ASPR), has a requirement to expand the domestic manufacturing capacity of nitrile gloves. This capacity expansion is essential to ensure sufficient nitrile gloves availability in response to surge demand during future Public Health Emergencies (PHEs).

Strategic oversight for the Project Agreement(s) supported by this RPP will be provided by BARDA.

2 Administrative Overview

2.1 RPP Approach

Each response submitted to this RPP shall contain a full Technical Proposal and full Cost Proposal using the mandatory format contained in this RPP (see Attachment C), as well as additional documents detailed in Section 3 and Attachment D of this RPP. White Papers are not required for this RPP.

The Government will evaluate proposals submitted and will recommend those that best meet their current technology priorities using the criteria in Section 4 of this RPP.

The Government reserves the right to modify this process if it is determined to be in its best interest at any time during the solicitation process. In such instance, the CMF would provide additional and/or revised requests for information, clarifications, presentations, etc. and include any modified evaluation criteria to be used for the remaining portion of the selection process, if applicable.

It is expected that there will be a total of one or more qualified respondents to accomplish the statement of objectives. If an optimal team is not identified, then BARDA may direct the BioMaP-Consortium CMF to make multiple, individual awards to Offeror(s) to accomplish subset(s) of the key tasks. The Government also reserves the right to make one, multiple, or no awards as a result of this RPP.

This RPP is issued under OTA Number 75A50123D00003 between the Government and the CMF. The same provisions are contained in the BioMaP-Consortium Base Agreement. A copy of the Base Agreement can be requested from biomap-contracts@ati.org. Each

proposal selected for award under this RPP will be executed as a Project Agreement funded under OTA Number 75A50123D00003 and governed by the Base Agreement terms and conditions, unless otherwise noted in the Project Agreement.

At the time of the submission, Offerors must certify on the cover page of their proposal that, if selected for award, they will abide by the terms and conditions of the latest version of the BioMaP-Consortium Base Agreement.

Offerors are advised to check the BioMaP-Consortium website periodically during the proposal preparation period for any changes to the BioMaP-Consortium Base Agreement terms and conditions.

2.2 Period of Performance

The anticipated period of performance shall not exceed 24 months. Offerors should plan for the period of performance to begin in Quarter 2 of Government Fiscal Year 2027. Government reserves the right to change the proposed period of performance start date through negotiations via the CMF and prior to issuing a Project Agreement.

2.3 Estimated Funding

Funding of proposals submitted in response to this RPP is contingent upon the availability of federal funds for this program. The Government anticipates making one or more awards under this RPP but reserves the right to make no awards. Offerors are encouraged to propose budgets commensurate with the nature, scope and complexity of the proposed project.

2.4 Proprietary Information

The BioMaP-Consortium CMF will oversee submission of proposals submitted in response to this RPP. The BioMaP-Consortium CMF shall take the necessary steps to protect all proprietary information and shall not use such proprietary information for purposes other than proposal evaluation and agreement administration. Offerors should mark all Confidential or Proprietary Information as such. An Offeror's submission of a proposal under this RPP indicates concurrence with the aforementioned CMF responsibilities.

2.5 Minimum Eligibility Criteria

Offerors must be members of the BioMaP-Consortium prior to award of a Project Agreement. Click here to learn how to join the consortium.

To be eligible for a potential award, Offerors must include the following in their proposal, if applicable. If not applicable, the Offeror must indicate as such.

- Submit an attestation that all work on the Performer's proposed project must be performed within the continental United States and its territories; the Performer is wholly U.S. owned, U.S. operated, and has their global headquarters located within the U.S. . If circumstances change after contract award, the Performer must obtain an Agreement Officer's Authorization (AOA) approval for any proposed arrangement where the Performer will not meet the U.S.-owned and

operated and global headquarters located within the U.S. requirement.

- Submit a letter of bondability for construction-related bonding by a surety that is capable of executing the project. The letter of bondability must identify the bonding company and specify the Performer's bonding capacity, Bonding capacity is defined as the maximum dollar amount of contracts the surety will allow the Performer to take on at once. The letter must also address how much of the bonding capacity is available for the proposed project.
- Submit a maximum two-page explanation letter that identifies all of the following since March 2020: Contract terminations or settlement agreements with the U.S. Government since March 2020, bankruptcy filings, receivership and eviction history, postponements or defaults on financial obligations, default judgments from a court, adverse decisions as part of binding arbitration, and any other information that informs the risk the government is taking if the Performer is selected for an award.
- Submit a statement identifying: Contacts with the Department of Justice (DOJ) and any Office of Inspector General (OIG) for any reason in the last five years, to include names and contact information.
- Submit an attestation stating that the Performer's corporate bylaws will be amended and submitted within 90 days of a Project Agreement award to require all the following:
    - The Performer, and any successor in interest to the Performer, must remain a whole U.S. owned, U.S. operated, with global headquarters located within the U.S., domestically controlled company with corporate governance in place to prohibit foreign influence for at least ten years after a Project Agreement award.
    - In the event of a public health emergency, the Performer, any successor interest to the Performer, and any other entity that owns, operates, leases, occupies, or uses the Government funded property for any reason, must provide priority access to the Government-funded capacity for a period of ten (10) years after the period of performance ends.
    - The Performer, any successor in interest to the Performer, and any other entity that owns, operates, leases, occupies, or uses the Government-funded capacity for any reason, must not use the real property, equipment, or other assets funded by the Government as collateral or for a purpose that is not related to the production of nitrile gloves for a period of ten (10) years after the period of performance ends.
    - The Performer, any successor in interest to the Performer, and any other entity that owns, operates, leases, occupies, or uses the Government-funded capacity for any reason, must prioritize utilizing USG-funded capacity to meet U.S. market demand for nitrile gloves before meeting global market demands.

Proposals found to not meet the minimum criteria as detailed above may be removed from consideration, no further evaluation will be performed, and feedback will not be provided to these Offerors.

2.6 Special Considerations

The following are special considerations for this RPP.

Small Business Utilization. Small Businesses utilization is encouraged to the maximum extent practicable as a means to build an agile and resilient industrial and manufacturing base, which ultimately supports economic growth and development in the United States.

2.7 Cost Sharing

Cost sharing is defined as the resources expended by the Project Awardee on the proposed Statement of Work (SOW) from sources other than the federal Government.

Cost sharing is required under this RPP. Project proposals must include a minimum of 50% cost share funds from an outside source to complete the proposed project. Project awards will not be made for the full cost of proposed projects. Please see section 2.1.2.8 of Attachment A, Technical Requirements, for cost sharing requirements.

2.8 Intellectual Property and Data Rights

Intellectual Property (IP) rights for BioMaP-Consortium Project Agreements are defined in the terms of the BioMaP-Consortium Base Agreement. The BioMaP-Consortium CMF reserves the right to assist in the negotiation of IP, royalties, licensing, future development, etc., between the Government and the Project Awardees during the entire award period.

The BioMaP-Consortium Base Agreement contains general provisions regarding Data Rights. For this specific RPP, it is anticipated that anything delivered under this proposed effort would be delivered to the Government with government purpose rights, unless otherwise specified in the proposal and agreed to by the Government. All proposed data rights are subject to Government review and approval. Rights in technical data agreed to by the Government will be incorporated into the Project Agreement.

The Offeror shall complete the table provided in the RPP's Attachment A, Data Rights Appendix, identifying any Intellectual Property or Data Rights to be furnished to the Government with restrictions.

2.9 Regulatory Terms

Project Awardees are expected to comply with the relevant FDA, DEA, USP and cGMP regulatory practices.

While additional regulatory terms have not been identified at this time for this project, information on potential regulatory terms is provided in the BioMaP-Consortium Base Agreement.

2.10 Special Requirements

Offerors must be prepared to comply with the following of the BioMaP-Consortium Base Agreement:

- **Salary Rate Limitation**. Payment of the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level II is an unallowable cost under the BioMaP-Consortium OTA. See the BioMaP-Consortium Base Agreement for further details.
- **Expansion**. In accordance with the BioMaP-Consortium Base Agreement, any work for capacity expansion shall be executed within the continental United States and its Territories, whether the company is based domestically or overseas.
- **SAM.gov Registration**. Offerors are required to obtain a Unique Entity Identifier (UEI) from SAM.gov prior to award of a Project Agreement.
- **GXP (GMP, GDP, GLP) Compliance.** All facilities must be GXP (GMP, GDP, GLP) compliant and comply with all Federal, Local, and State laws and regulations, in addition to all FDA requirements.

2.11 Security Requirements

See Attachment B of this RPP for Administration for Strategic Preparedness and Response (ASPR) Deliverables and Security Requirements that will be required for any resulting projects. BioMaP-Consortium members should be prepared to include the applicable deliverables and security requirements identified in the attachment.

2.12 Preparation Cost

The cost of preparing submissions in response to this RPP is not considered a direct charge to any resulting award or any other contract.

3 Proposals

3.1 Questions

All questions regarding this RPP must be submitted via email to biomap-contracts@ati.org no later than 1:00 PM ET on August 17, 2026.

3.2 Key Dates for this RPP

Date	Event
8/6/2026	RPP Released
8/12/2026	Virtual Teaming Speed Networking Event
8/17/2026	Deadline for submitting questions to biomap-contracts@ati.org (by 1:00 PM ET)

Notification sent via email	Questions & Answers posted on the BioMaP-Consortium website
9/8/2026	Full Technical and Cost Proposals Due (by 1:00 PM ET)

3.3 General Instructions

Offerors who submit proposals in response to this RPP must submit by the date and time on the cover page of this RPP. Proposals received after the date and time specified may not be evaluated.

The template provided in this RPP is mandatory and shall reference this RPP number. Offerors are encouraged to contact the Point of Contact, identified herein up until the submission date/time to clarify requirements.

All eligible Offerors shall submit proposals for evaluation according to the criteria set forth in this RPP. The Government will evaluate proposals submitted and will select the offer(s) that best meets their current technology priorities using the criteria in Section 4 of this RPP.

Offerors are advised that only ATI, is legally authorized to contractually bind or otherwise commit funding for selected Project Awards as result of this RPP.

3.4 Submission

Proposals must be submitted online through ATI's Acquisition Management Platform (AMP) at https://identity.ati.org. Offerors will use AMP to submit proposals and review associated feedback.

Submissions will not be accepted by any other means. **Offerors are strongly encouraged to review the AMP Submitter Training, confirm access to AMP, and submit a proposal well in advance of the submission deadline. Please reach out to the POC identified in Section 3.1 of the RPP in advance of the deadline if experiencing issues.**

Neither the Government nor CMF will make allowances or exceptions for submission problems encountered by offerors using system-to-system interfaces with AMP. If an offeror encounters errors and fails to upload the complete submission before the submission deadline, the submission will not be accepted.

A receipt confirmation will be emailed upon submission of a proposal. Submissions can be made in advance of the deadline and updated up until the submission deadline.

3.5 Submission Format

Each document listed below is mandatory and must be submitted as separate files. These documents will remain valid for two years unless otherwise specified by the Offeror in the proposal. Offerors are encouraged to contact the BioMaP Consortium CMF with any questions to ensure that all aspects are clearly understood by both parties. The proposal should include the following items:

- **Technical Proposal:** A Technical Proposal is required in Word (.docx or .doc) or PDF using the mandatory template in Attachment C.
- **Cost Proposal:**
    - Section I: Cost Proposal Narrative is required in Word (.docx or .doc) or PDF using the mandatory template in Attachment C.
    - Section II: Cost Proposal Format is required in Excel (.xlsx) format, with working formulas to the maximum extent practicable.
- **Additional Required Files** (see Section 2.5 and Attachment D for full requirements):
    - **Performance Location Attestation:** One Word (.docx or .doc) or PDF file.
    - **Letter of Bondability:** One Word (.docx or .doc) or PDF file
    - **Legal and Financial History:** One Word (.docx or .doc) or PDF file, 2-page maximum. If not applicable, the Offeror must submit a letter indicating as such.
    - **DOJ and OIG Contacts:** One Word (.docx or .doc) or PDF file. If not applicable, the Offeror must submit a file indicating as such.
    - **Bylaw Amendment Attestation:** One Word (.docx or .doc) or PDF file
    - **Commercial Viability Plan:** One Word (.docx or .doc) or PDF file, 4-page maximum
    - **Regulatory Plan:** One Word (.docx or .doc) or PDF file
    - **Project Plan:** One Word (.docx or .doc) or PDF file

ZIP files and other application formats are not acceptable. All files must be print-capable and not password protected. Filenames shall contain the appropriate filename extension (.docx,.doc, or pdf). Filenames should not contain special characters. IOS users must ensure the entire filename and path are free of spaces and special characters.

3.6 Teaming Partners Identified through BioMaP-Consortium Resources

When submitting your proposal in AMP, you will be asked to identify any teaming partners/subcontractors for this proposal that were identified through the BioMaP-Consortium's **Collaboration Database on the Members-Only Website** or the **RPP Speed Networking Event**. This information is collected for informational purposes only and has no impact on the evaluation. If no teaming partners/ subcontractors were identified through either BioMaP-Consortium resource, state "None."

4 Evaluation and Selection

4.1 Compliance Screening

The BioMaP-Consortium CMF will conduct a preliminary screening of submitted Proposals to ensure compliance with the RPP requirements. As part of the preliminary screening

process, Proposals that do not meet the requirements of the RPP may be eliminated from the competition or additional information may be requested by the BioMaP-Consortium CMF. The Government reserves the right to request additional information or eliminate Proposals that do not meet these requirements from further consideration.

4.2 Evaluation Process

Following the preliminary screening, the Government sponsor will perform an evaluation of all qualified Proposals. The Government sponsor team may include a panel of subject matter experts (SMEs), to include the use of contractor consultants, who will make recommendations to the Government during the evaluation. Where appropriate, the Government will employ non-disclosure agreements to protect information. An Offeror's submission of a Proposal under this RPP indicates concurrence with the aforementioned use of contractors and SMEs.

Evaluation of Proposals will be based on a comprehensive review and assessment of the work proposed against stated source selection criteria and evaluation factors. The Government will evaluate each Proposal against the evaluation factors detailed below.

4.3 Evaluation Factors Overview

The Government will evaluate the information provided in each Offeror's Proposal to determine which Proposal(s) provide(s) the most advantageous solution to the Government. Such a determination will be based on the following criteria:

- Factor 1: Technical Approach/Solution
- Factor 2: Relevant Experience
- Factor 3: Cost/Price

4.4 Adjectival Merit Rating

Adjectival merit ratings that will be used for the non-cost/price factors.

- Technical Approach/Solution
- Relevant Experience

GENERAL MERIT RATING ASSESSMENTS	
RATING	DESCRIPTION
Outstanding	Proposal meets requirements and indicates an exceptional approach and understanding of the requirements. Strengths far outweigh any weaknesses. Risk of unsuccessful performance is very low.
Good	Proposal meets requirements and indicates a thorough approach and understanding of the requirements. Proposal contains strengths which outweigh any weaknesses. Risk of unsuccessful performance is low.
Acceptable	Proposal meets requirements and indicates an adequate approach and understanding of the requirements. Strengths and weaknesses are offsetting Risk of unsuccessful performance is no worse than moderate.

Marginal	Proposal does not clearly meet requirements and has not demonstrated an adequate approach and understanding of the requirements. The proposal has one or more weaknesses which are not offset by strengths. Risk of unsuccessful performance is high.
Unacceptable	Proposal does not meet requirements and contains one or more deficiencies. Proposal is not awardable.

4.5 Evaluation Factors

- **Factor 1 – Technical Approach/Solution (Adjectival Rating):** This factor evaluates the relevancy, thoroughness, completeness, and feasibility of the proposed approach.
- **Factor 2 – Relevant Experience (Adjectival Rating)**: This factor evaluates the Offeror's demonstrated organizational experience, as well as the technical and management experience of the proposed team to perform the proposed work. The Government may also consider information in Contractor Performance Assessment Reporting System (CPARS), and the Federal Awardee Performance and Integrity Information System (FAPIIS) or similar systems. The Government reserves the right to contact customer references to verify performance and assess quality of that performance, and to perform independent relevant experience analysis.
- **Factor 3 – Cost/Price:** The proposed cost/price will be reviewed for cost/price realism, and overall, most advantageous solution to the Government and will be given a narrative rating. Proposals will be reviewed to ascertain if the costs proposed are based on realistic assumptions, reflect a sufficient understanding of the technical goals and the objectives of the proposed work, and are consistent with the Offeror's technical approach. Quotes from proposed subcontractors and suppliers to help substantiate the project expenses are recommended. Similarly, a breakdown of significant costs in order to show realism is also recommended.

4.6 Evaluation Outcome

The Government will recommend project(s) based on an evaluation of the information provided in the applicable Proposal. Following the evaluation, the Project Agreement Evaluation Team (PAET) Chairperson may:

- Recommend proposal(s) (or some portion of the proposal) for award.
- Recommend placement of proposal(s) in the Basket if funding currently is unavailable; or
- Recommend rejection of proposal(s) (will not be considered for award and will not be placed in the Basket)

As the basis of the recommendations is completed, the Government will forward its recommendations to the BioMaP-Consortium CMF to notify the Offerors. Offerors will be notified of their results via email from the BioMaP-Consortium CMF. All Offerors will receive feedback on eligible submissions.

4.7 Basket Provision

The electronic "Basket" is an innovative acquisition tool. Proposals rated as Acceptable through Outstanding, but not immediately recommended for award, may be placed in the Basket for 2 years and are eligible for award during that time. Proposals rated as Unacceptable and Marginal will not be placed in the Basket and will not be eligible for future award. If awarding from the Basket, the Government reserves the right to award whichever proposal best meets its needs after it has received and reviewed a Full Cost Proposal and Statement of Work.

4.8 Cost/Price Estimate and Evaluation

The Cost Proposal will receive a narrative rating to determine whether costs are reasonable and complete.

If a proposal is recommended for Project Agreement award, the BioMaP-Consortium CMF will review the cost proposal submitted in response to the RPP. If necessary, the BioMaP-Consortium CMF will request an updated cost proposal for review. The BioMaP-Consortium CMF will request additional information or clarification as necessary. The BioMaP-Consortium CMF will assess the reasonableness and completeness of the cost estimates and then provide a formal assessment to the Government. The Government will review this assessment and provide concurrence to the BioMaP-Consortium CMF fair and reasonableness determination.

Cost Proposals will be evaluated using the understanding of cost reasonableness and completeness as outlined below:

a) Reasonableness: The Offeror's cost proposal will be evaluated to determine if it is reasonable. For a price to be reasonable, it must represent a price to the Government that a prudent person would pay in the conduct of competitive business. Normally, price reasonableness is established through cost and price analysis.

To be considered reasonable, the Offeror's cost estimate should be developed from applicable historic cost data. The Offeror should show that sound, rational judgment was used in deriving and applying cost methodologies. Appropriate narrative explanation and justification should be provided for critical cost elements. The overall estimate should be presented in a coherent, organized and systematic manner.

Costs provided shall be clearly attributable to activities or materials as described by the Offeror. Costs should be broken down to the level of detail outlined in the RPP.

The BioMaP-Consortium CMF will analyze and assess by directly comparing proposed costs with comparable current and historical data, evaluator experience, available estimates, etc. Proposed estimates will be compared with the corresponding technical proposals for consistency.

b) Completeness: The BioMaP-Consortium CMF will make an assessment on whether the proposal clearly and thoroughly documents the rationale supporting the proposed cost and is compliant with the requirements of the solicitation, as well as reflect a clear understanding of the requirements, and are consistent with the various elements of the Offeror's schedule proposal.

The proposal should clearly and thoroughly document the cost/price information supporting the proposed cost in sufficient detail and depth. The BioMaP-Consortium CMF will evaluate whether the Offeror's cost proposal is complete with respect to the work proposed. The BioMaP-Consortium CMF will consider substantiation of proposed cost (i.e., supporting data and estimating rationale) for all elements.

Rate and pricing information is required to properly perform the cost analysis of the proposal. If the Offeror is unwilling to provide this information in a timely manner, its proposal will be lacking information that is required to properly evaluate the proposal, and the proposal may not be eligible for further award.

4.8 Award Determination

Following final negotiations, the Government may determine award(s) based on an evaluation of the information provided in the proposal that provides the best value to the Government. After approval from the Source Selection Authority (SSA), the Government will forward their selection, if any, to the BioMaP-Consortium CMF to notify the applicable Offeror(s). The Offeror(s) will be notified of the decision and/or change in recommendation status via email from the BioMaP-Consortium CMF.

5 Points of Contact

Questions related to this RPP should be directed to Ms. Kathy Garee (biomap-contracts@ati.org)

Once an Offeror has submitted a Proposal, the Government and the BioMaP-Consortium CMF will not discuss evaluation/status until the evaluation results have been provided to the Offerors.

6 References

Manufacturing Readiness Level (MRL) definitions:
https://acqnotes.com/acqnote/careerfields/manufacturing-readiness-levelmanufact

7 Attachments

Attachment A: Technical Requirements

Attachment B: ASPR Security Requirements

Attachment C: Full Proposal Template

Attachment D: Additional Required Documentation

Attachment A: Technical Requirements

Statement of Objectives (SOO)

Project Title: Expansion of Domestic Manufacturing Capacity for Nitrile Gloves

1. SCOPE

1.1. Background:

The Center for Industrial Base Management and Supply Chain (IBMSC), of the U.S. Department of Health and Human Services (HHS) Administration for Strategic Preparedness and Response (ASPR), has a requirement to expand the domestic manufacturing capacity of nitrile gloves. This capacity expansion is essential to ensure sufficient nitrile gloves availability in response to surge demand during future Public Health Emergencies (PHEs).

The importance of PPE cannot be overstated, as it serves as a critical line of defense in various contexts. In healthcare settings, PPE, including masks, gloves, face shields, and gowns, is indispensable for protecting healthcare professionals from infectious diseases, ensuring their safety while delivering essential care. Amid the unprecedented challenges brought forth by PHEs, notably underscored by the example of the COVID-19 pandemic, the importance of ensuring a resilient and robust supply chain for PPE is essential. This need goes beyond fulfilling demand during PHEs only; it emphasizes the necessity for consistently sustaining manufacturing capacities to also meet non-emergency everyday requirements. The necessity for a comprehensive and forward-thinking approach that anticipates future challenges and ensures the enduring strength of supply chain safeguards our ability to provide essential PPE.

The U.S. currently faces an estimated 15 billion nitrile glove deficit in its surge demand capacity, presenting a considerable risk in the event of another nationwide PHE. To address this gap, the USG aims to develop an agile industrial base with vertically integrated, high-capacity nitrile glove manufacturers. Ideally, these manufacturers must source and produce both the NBR rubber feedstock, and the nitrile gloves themselves, thus reducing supply chain risks for this critical PPE item. Developing this capability is crucial to closing the gap and ensuring preparedness for future PHEs.

2. REQUIREMENTS

2.1 General Objectives

The general objective is to support manufacturing of PPE for front line workers involved in biomanufacturing, pharmaceutical production and delivery of medical

countermeasures (i.e., PPE used in a medical setting). This must be achieved as described below:

2.1.1. Project proposals must not specify a period of performance that exceeds 24 months. The objective is a not-to-exceed (NTE) 24-month effort focused on nitrile glove manufacturing to support domestic PPE production. This includes:

2.1.1.1. Manufacturing (but not limited to) production, resources, infrastructure, components, equipment and enablers utilized in the production of nitrile gloves.

2.1.1.2. Project proposals must incorporate all steps necessary for full rate production of nitrile gloves based on a Manufacturing Readiness Level (MRL) 10. MRL 10 is achieved when a system or product is in full-rate production, meeting all engineering, quality, and reliability goals; continuous process improvements and lean manufacturing operations are fully established, and; design changes are rare and mostly limited to minor cost or quality enhancements.)

2.1.1.2.1. Performers must reach MRL 10 within the time frame specified in the project proposal milestone schedule to include float and final government approval. MRL 10 means completion of installation, qualification, and commissioning of all equipment. All utilities, raw materials purchased, standard operating procedures approved, and trained staff in place. Validation runs are complete, and a USG demonstration must be scheduled for the Government to witness the successful operation of the nitrile glove plant for a significant period of operation that is representative of full scale production to the satisfaction of the Government.

2.1.1.2.2. Nitrile gloves produced during demonstrations and validation runs will become the property of the Performer and can be sold on the commercial market to support domestic nitrile glove manufacturing at the discretion/determination of the Performer.

2.1.1.3. Project proposal must describe the personnel, equipment, technology, processes, and performance metrics required to maintain scaled manufacturing of nitrile gloves, including identification of industrial partnerships and schedule requirements for each phase of manufacturing and operations.

2.1.1.4. Project proposals must specify how the Performer will provide USG access to Performer and subcontractor facilities, infrastructure, and equipment.

2.1.1.5. Project proposals must describe all industry and government standards that apply to new/expanded construction, manufacturing

line builds, and other processes related to added production.

2.1.2. In addition to the requirements in 2.1.1:

2.1.2.1. Project proposals must state the total quantity of nitrile gloves to be produced using/as a result of government funding in finished units per year. Proposals must state whether the performer can make medical gloves (such as nitrile surgical gloves or medical examination gloves), that meet FDA and industry standards for such categories of products. Proposals must also state whether the nitrile gloves produced as part of the project proposal can be produced on high-speed dipping equipment.

2.1.2.1.1. Nitrile Gloves must be no less than 4 to 5 Mils in thickness. Manufacturers must meet American Standard for Testing and Materials (ASTM) and International Organization for Standardization (ISO) standards and have the United States (U.S.) Food and Drug Administration (FDA) approval for the production and sales of nitrile medical exam gloves in the United States.

2.1.2.2. Performers must expand and/or establish new existing nitrile glove manufacturing capacity including, but not limited to, manufacturing line technology updates/upgrades; adding new manufacturing lines; automating bottleneck process steps; automating packaging and labeling; adding additional labor shifts; using other innovative approaches.

2.1.2.3. Each Performer must establish new production of a minimum of 500 million gloves to be added to their domestic annual glove manufacturing capacity.

2.1.2.4. Project proposals must include a detailed Commercial Viability Plan demonstrating the commercial viability of the nitrile glove plant for ten years after the period of performance end date without any additional USG funding for the Performer. The Commercial Viability Plan must include sections that address all of the following: 1) identification of retailer(s) or distributor(s) letters of commitment dated within the last six months that demonstrate profitability from prospective customers (with a priority for domestic U.S. sales over foreign sales); 2) proof of statements from prospective customer(s) stating that nitrile gloves to be manufactured by the Performer are suitable for commercial sale,

3) the Performer's plan to address both non-pandemic steady state demands for nitrile gloves and surge demands for nitrile gloves; 4) discussion of assumptions, risks, and likelihood of success to maintain the minimal amount of manufacturing capacity necessary to break-even, increase production to a profitable level, and ramping up to full rate production.

- A list of assumptions, risks, and mitigation plans that impact

the strategy and its implementation.

- An up-to-date market assessment.
- A description of alternative approaches to sustainment that can be considered and the introduction of innovative solutions and technologies (e.g., automation) or other methods that would enable cost-effective sustainment.
- A description of the ability to adapt to evolving requirements in the manufacturing landscape and agility in responding to changes in the pandemic response environment.
- A Risk Management Plan and Risk Register that will track, manage, and mitigate program and Program Agreement/Sub Agreement risks, including potential risks associated with the sustainment of nitrile gloves manufacturing capacity.

2.1.2.5. Project proposals must include the Performer's regulatory plan that identifies how nitrile glove production meets and maintains compliance with all regulatory requirements, industry standards, and guidelines for production of FDA-regulated PPE and how the Performer will comply with all federal, state, local and/or territorial regulations.

2.1.2.6. Project proposals must include a comprehensive project plan that demonstrates how the Performer will ensure all planning, permits, execution, and follow-through required to obtain all required certifications and validations of the nitrile glove manufacturing will occur while also ensuring that all work performed is in compliance with federal, state, and local regulations.

2.1.2.7. Project proposals must include the Performer's plans to ensure, maintain, operate, and service all equipment and tooling acquired by the Performer to produce nitrile gloves for a period of at least ten (10) years after the project period of performance end date.

2.1.2.8. Project proposals must demonstrate that the Performer has adequate facilities and infrastructure to complete the project and carry out the proposed manufacturing effort for a period of at least ten (10) years after the project period of performance end date.

2.1.2.9. Project proposals must include actual or projected cost for the Performer to purchase payment and performance bonds to ensure completion of all work necessary to meet the objective of the Performer's proposal.

2.1.2.10. Project proposals must include a detailed and accurate cost estimate and the source of funds necessary to complete the proposed project. The project proposal must also include a detailed and accurate cost estimate and source of funds to maintain the facilities and infrastructure necessary to carry out the proposed manufacturing effort for a period of at least ten (10) years after the

project period of performance end date. Project proposals must include cost share information to demonstrate that a minimum of 50% of funds to complete the proposed project are available from an outside source. Project awards will not be made for the full cost of proposed projects. Cost share funds are defined as the resources sourced by the Performer from sources other than from ASPR. Cost sharing is required for project proposals to be considered for award. Performers must provide a full Capitalization Plan that identifies all proposed cost share contributions, including the total amount, the specific sources of funding (e.g., corporate funds, third-party contributions, or non-federal governmental support), and the timing and availability of funds over the period of performance. Performers must provide supporting documentation (e.g., letters of commitment or financial statements) as appropriate. The cost sharing plan must also describe how the Performer will track, manage, and report cost share expenditures throughout project execution. Performers must propose a project milestone schedule with associated invoicing that takes the cost share into account. Work, construction, tasks, etc. completed prior to award will not be considered as a portion of the Performer's cost share for the proposed project. Performer's proposed cost share must only apply to new efforts completed under this agreement.

2.1.2.11. Detailed Project Plan

2.1.2.11.1. Plan must describe in detail the proposed plan to achieve each step in section 2.1 above.

2.1.2.11.2. Plan must include all analytical assumptions that will be employed in preparing and executing the sustainment effort.

2.1.2.11.3. Plan must include a range of assumptions/variables that can be used to assess various market conditions.

2.1.2.11.4. Plan must include metrics, variables, and milestones for gauging domestic and global market progress of required technologies and infrastructure that will be needed to sustain capacities for a minimum of 10 years after the period of performance end date.

2.1.2.11.5. Plan must include all metrics, variables and milestones that define the various gates and decision points (distinct from the bullet above).

2.1.2.11.6. Plan must include a detailed description of how sustainment will be achieved.

2.1.2.11.7. Plan must include identification of risks associated with execution of the plan and sustainment for a

minimum of 10 years after the period of performance end date.

2.1.2.12. Project proposals must include a chart or other documents and graphics that provide a summary explanation of the Performer's approach to include all aspects of engineering design, engineering review, permitting, construction, commissioning, qualification, validation, acceptance and transfer.

2.1.2.13. The agreement period of performance is 24 months. The Performer has a period of 24 months to purchase, install, and complete all necessary expansion activities to include complete initial qualification, operational qualification, and product qualification (IQ/OQ/PQ) of the new expanded manufacturing capacity, and validation of the expanded facilities and production lines.

2.2 Other Information

2.2.1. Performers must agree to source all raw materials for manufacturing the nitrile butadiene rubber gloves domestically to the maximum extent practicable.

2.3. Deliverables

Specific deliverables include the following (See also Sec 4.0 Deliverables):

2.3.1. Monthly technical progress report.

2.3.2. Updated Detailed Objective Project Plan (if applicable).

2.3.3. Configuration Management: The Performer must manage (including flow-down requirements, partnerships, sub-Performers, or other business arrangements needed to complete expanded production and qualification of the nitrile gloves to be produced). This must include commitments. The Performer must submit and implement a Configuration Management Plan within 30 days after the award that outlines their process for establishing and maintaining consistency of their products' performance, and how the Performer will measure functional, and physical attributes during their requirements, design, and operational phases of manufacturing.

2.3.4. Quality Control: The Performer must implement and maintain the proper quality management systems that meet all applicable standards, to include International Standards Organization (ISO), National Institute for Occupational Safety and Health (NIOSH), Food and Drug Administration (FDA) requirements, etc. The Performer must l also meet all applicable Federal, State and Local requirements in their quality management systems. Within 30 days of award, the Performer must develop and submit a Quality Management Plan.

3. PROGRAM MANAGEMENT

3.1. The awardee is responsible for overall management and execution of the work to achieve the objectives of the agreement. The awardee must provide the overall

management, integration, and coordination of all agreement activities to ensure the efficient planning, initiation, implementation, and direction of all agreement activities.

3.2. The awardee will be responsible for ensuring the approved project milestones are met on time and on budget. The awardee will ensure that any changes or deviations planned or incurred by the awardee in pursuing the objectives of any resulting agreement are reported to BARDA and IBMSC. While primary responsibility for management and execution of the effort resides with the awardee, HHS must have input to the milestone review process and any changes to the objectives of any resulting agreement.

4. DELIVERABLES

	Deliverable Description	Content Requirements and Instructions	Reporting Frequency
1	Kick Off Meeting	Performer to develop Agenda and host an in-person or virtual kick-off meeting to discuss overall project objectives, key personnel, deliverables, risks, schedule and funding/payment procedures. Provide meeting minutes.	Kickoff meeting conducted within two weeks of award. Minutes to be submitted to the Agreements Officer Representative (AOR) within 3 business days of meeting.
2	Ad-hoc Project Team Meetings	Performer to schedule and create an agenda. Follows Agenda mutually agreed upon in advance of meeting. Performer to provide meeting minutes within 3 business days from date of meeting.	As needed for special topics, when specifically requested by the Agreements Officer or Agreement Officer's Representative
3	Monthly Project Team Meetings	Purpose is to review monthly progress report findings, any changes since last month and any projected issues or challenges.	Virtual. Monthly, 5 business days after the monthly report deliverable. 1 hour duration, hosted by the Performer. Minutes to be submitted within 3 business days of meeting.
4	Monthly Project Progress Report	Monthly report of overall status including cost, performance and schedule progress and variance from plan. Include discussion of important considerations and milestones. Level of detail for various aspects of project may decrease or increase in detail as the project moves through the various phases. Monthly progress report should also include financial status updates and a progress dashboard that is accurate and complete.	Monthly. Due 15th of the month.

5	Quarterly In-Process Review (IPR)	Organized, scheduled and hosted by Performer. May be virtual or physical at the Performer's facilities based on USG preference. Project progress review including risks and mitigation plans.	Every 3 months from start of project. Performer to send brief 3 working days in advance of meeting.
6	Integrated Master Schedule (IMS)	Include all engineering design, procurement, construction, commissioning/qualification/start-up, manufacturing, and management activities, critical paths, and Agreement milestones. The Performer will provide the format and contents. The Performer will provide an updated IMS monthly or as requested, to the AOR. The monthly report schedule summary MUST include details of at least the upcoming six months, with no subtask more than two weeks in duration. It should also include all agreements and other milestones throughout the effort.	They are updated monthly or as needed. A summary is to be included in the monthly report. This will show delays, percent complete, and predecessors, and will not be changed (re-baselined) without approval from the USG and agreed upon change management.
7	Project Budget	Total detailed budget by month and year for the entire Project. Planned vs actual expenditures, invoiced amounts and remaining balances should be included.	Updates are submitted with monthly project progress reports, and a summary is provided during monthly meetings.
8	Project Documents and List(s)	Full listing of project documents organized by engineering discipline or other categories (e.g. drawings list, specifications list, procurement packages list, instrument index, URS/FRS, etc.). Actual document copies will be submitted as soon as available.	Submitted, uploaded and updated as required to USG specified site.
9	Project Documentation	Project design, procurement, construction, validation, regulatory, and other related project execution related documents. Documents can be copies but should include all approval signatures and inventories of products and equipment.	When specifically requested via e-mail by USG Project Manager (or designee), post latest version of requested documents to shared documents site
10	Risk Management Plan	Performer to provide a structured document that identifies, assesses, and prepares for potential project or operational risks to minimize negative impacts and includes risk identification, analysis (likelihood/impact), mitigation strategies, and assigned responsibilities. The plan is a living document monitored throughout a project's lifecycle. for categorizing risks and mitigation plans.	Initial Risk Management Plan submitted with proposal. After that, monthly, to be submitted with every other technical and programmatic progress report. Updated as required, with any changes identified/ highlighted for easy identification.
11	Project Risk Register	All project risks identified throughout the project must be tracked via a Risk Register. The Performer must identify all anticipated project risks and track them via a Risk Register. The Performer must	Updated monthly and submitted with Monthly Project Report.

		manage all project risks, and report to IBMSC any changes to all identified risks as they occur/arise. IBMSC must be permitted to participate in the risk management and mitigation processes associated with this project.	
12	Project Action Items List	Actions identified throughout the project, which are not tracked by some other project management tool, and which require follow-up and monitoring for completion, will be captured in an Action Items List. (Or similar list/tracking tool.) List should contain information regarding identification date, target completion, responsible individuals/groups, etc.	Submitted if/as required with monthly technical progress report.
13	Site Visits	Host visits from USG following agenda/schedule mutually agreed upon with USG in advance of visits. Provide visit notes within 3 business days from date of visit.	Typically, quarterly, commensurate with quarterly IPR, at the Agreements Officer's sole discretion.
14	Annual Project Progress Report	High level project progress review of overall objectives. Updated projections against project expectations, including risks and mitigation plans, should be reported with respect to the previous annual report. Summary of critical changes that took place over the year. Recommended to not exceed 20 pages.	Annually from award. To review progress over the previous 12 months. A Draft to be submitted 30 days after the completion of each year of performance. Within 15 days of receipt, the Government will provide review comments. The Performer must respond within 15 days of receipt of comments. Report format: .docx and PDF
15	Final Report	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 production improvements achieved; financial summary of project; schedule summary for project, comparing original schedule to final schedule; recommendations for path forward as applicable.	Initial submission to be submitted 30 days prior to the end of the period of performance. Within 15 days of receipt, the Government will provide review comments. The Performer must respond within 15 days of receipt of comments.
16	Quality Management Plan	The Performer must develop and submit a Quality Management Plan that details the methods/processes they will use to demonstrate the ability to produce NITRILE GLOVES under a quality system that meets all International Standards Organization (ISO), Federal, State and Local requirements.	Initial submission 30 Days after Award, updated as necessary Report format: .docx and PDF
17	Detailed Objective Project Plan	The Performer must develop and submit a detailed objective project plan that at minimal includes the following:	Initial submission 30 Days after Award, updated as necessary

		a. Plan should describe in detail the proposed plan to the objective outlined above. b. Plan should include all analytical assumptions that will be employed in preparing and executing the sustainment effort. c. Plan should include a range of assumptions/variables that can be used to assess various market conditions. d. Plan should include metrics, variables, and milestones for gauging domestic and global market progress of required technologies and infrastructure that will be needed to sustain capacities beyond the period of US Government investment. e. Plan should include all metrics, variables and milestones that define the various gates and decision points (distinct from the bullet above). f. Plan should include a detailed description of the proposed sustainment effort. Details should include the basic steps for each phase of implementation, and which includes all dependencies between phases. g. Plan should include identification of risks associated with execution of the plan.	Report format: .docx and PDF
18	Infrastructure and Management Structure Organizational Chart	The Performer must complete description of the infrastructure and management structure (organizational chart) including but not limited to addressing all elements that will accomplish the program's goals and milestones. The Performer must propose a workforce management plan, e.g., how workforce will train, maintain, etc., that reflects the ability to meet the requirements.	Initial submission 30 Days after Award, updated as necessary Report format: .docx and PDF
19	Ten-year Commercial Viability Plan	The Performer must develop, submit and implement a ten-year commercial viability plan that ensures the long-term commercial viability without relying on government funding or government purchase orders. Commercial Viability Plan will also include a financial model for the nitrile glove Plant, including Performer's capitalization assumptions, break-even analysis based on quantity produced, ten year cash flow projections, and sensitivity analysis reflecting market variability, interest	The Performer must submit a not to exceed 4-page plan to USG with the Performer's proposal. The Performer submits and updates every six months. Performer may be required to establish a relationship with a business development management company as a

		rates, demand variables, and other key inputs. The model must include a scenario analysis showing outcomes at break-even, 50%, 75%, and 100% of the design capacity. The sensitivity analysis must address, at a minimum: nitrile glove market price variance (±30%), feedstock cost variance, and interest rate variance. Based on review and feedback from the Government, Performer agrees to revise and resubmit its financial model as necessary.	condition for receiving an award.
20	Regulatory Plan	A plan that identifies how the NITRILE GLOVE production meets and maintains compliance with all regulatory requirements, industry standards, and guidelines for NITRILE GLOVES to be used in production of FDA-regulated PPE and how the Performer will comply with all federal, state, local and/or territorial regulations.	Quarterly
21	Capitalization Plan	Performers must provide a full Capitalization Plan that identifies all proposed cost share contributions, including the total amount, the specific sources of funding (e.g., corporate funds, third-party contributions, or non-federal governmental support), and the timing and availability of funds over the period of performance. Performers must provide supporting documentation (e.g., letters of commitment or financial statements) as appropriate. The cost sharing plan must also describe how the Performer will track, manage, and report cost share expenditures throughout project execution and sustainment for a period of 10 years after the period of performance end date.	Quarterly

Additional facility build/expansion Deliverables. Project proposals must include a chart or other documents that provide a summary explanation of the Performer's approach to provide each of the following Deliverables:

	Deliverable Description	Content Requirements and Instructions	Reporting Frequency
22	30% Engineering Design	Continued development and refinement of preliminary engineering designs to reach a 30% completion benchmark. Begin the identification and vetting process for potential equipment suppliers. Provide a report to the USG. Initial budget allocation for long lead equipment and acquisition. Complete Comprehensive site	As defined in the Integrated Master Schedule (Deliverable 6 above).

		geotechnical and environmental analysis. Review and approval by Vendor, Engineer of Record, and USG.	
23	30% Engineering Review	Host a review meeting with all stakeholders to discuss the progress and align the 30% design. Provide meeting minutes to the USG. Kick off the next phase of engineering, progressing towards the 60% benchmark. Site acquisition and registrations	As defined in the Integrated Master Schedule (Deliverable 6 above).
24	60% Engineering Review	Commence utilities mapping and planning, focusing on electric, water, and gas connections for site development.	As defined in the Integrated Master Schedule (Deliverable 6 above).
25	90% Engineering Review	Ensure that equipment design meets project requirements and all applicable standards. Conduct a comprehensive review of all project components to ensure that 90% of the milestones have been achieved to date. Provide a copy to the USG. Engage stakeholders in a collaborative review to identify any areas that need further attention or revision. Focusing on supporting the necessary infrastructure for power, water, sewage, and other critical utilities. Coordinate with suppliers of long-lead equipment to finalize details and ensure timely delivery. Provide meeting minutes to the USG.	As defined in the Integrated Master Schedule (Deliverable 6 above).
26	Prepare draft permits	Research and understand all necessary permits and regulations required for the project. Consult with legal experts and professionals familiar with the permitting process for guidance. Provide meeting minutes to the USG.	As defined in the Integrated Master Schedule (Deliverable 6 above).
27	Review permits	Draft initial permit applications, ensuring all requisite information and documentation are gathered and presented correctly. Permit receipt confirmation to the USG. Engage with local authorities to ensure alignment and to pre-inform them of the upcoming project. Provide meeting minutes to the USG.	As defined in the Integrated Master Schedule (Deliverable 6 above).
28	Update permits	Review the draft permits internally for any omissions or corrections. Make any necessary adjustments to the drafts based on feedback and prepare for submission.	As defined in the Integrated Master Schedule (Deliverable 6 above).

29	Submit permits	Finalize and submit all drafted permits to the relevant authorities. Provide the final permit receipt to the USG. Monitor the status of permit applications and promptly respond to any queries or requests for clarification from the authorities.	As defined in the Integrated Master Schedule (Deliverable 6 above).
30	Permits approval	Coordinate with legal and compliance teams to gather all necessary documents and data for permit applications. Submit required permit applications to local, state, or federal regulatory bodies, ensuring that all data is accurately represented. Provide permit receipts to USG. Engage in discussions, meetings, or negotiations with regulatory and permitting agencies to expedite the approval process and address any concerns they might have. Provide meeting minutes to the USG. Conduct internal reviews and risk assessments for the permits, ensuring the project is on solid legal grounds. Establish communication channels to receive real-time updates on permit status. Once permits are approved, communicate the details to all relevant stakeholders and initiate the next phase of the project. Provide USG with a copy of the approved permits.	As defined in the Integrated Master Schedule (Deliverable 6 above).
31	Construction Contracting Inspections	Conduct on-site inspections with pre-selected sub-Performers to provide them with a clearer understanding of the project scope and site conditions.	As defined in the Integrated Master Schedule (Deliverable 6 above).
32	Construction phase 1	Site preparation: Clearing the site, grading, and preparing the terrain for construction. Foundational work: Lay the foundations for reactors, storage tanks, control rooms, and other major equipment, ensuring that they are reinforced and suited for the specific loads and vibrations they will need to support. Provide approved plans for USG Underground utility conduits: Installation of underground pipelines for chemical feedstock, product lines, water, waste, and other essential utilities. Provide approved plans to USG Electrical and Control infrastructure: Laying out	As defined in the Integrated Master Schedule (Deliverable 6 above).

		the primary electrical conduits and control cables, setting up substations, and preparing for the integration of control systems. Provide approved plans to USG Safety Systems: Construct safety showers, eye-wash stations, emergency exits, and other safety infrastructure essential for a chemical plant. Provide approved plans to USG Construction of auxiliary buildings: Labs, administrative blocks, first-aid rooms, and other necessary structures. Provide approved plans to USG Initial Setup for Waste Treatment: Begin construction of effluent treatment plants or connecting to existing waste treatment facilities. Regular status updates and reviews: Coordinate with equipment vendors, especially those providing long lead items, to synchronize delivery and installation.	
33	Construction phase 2	Equipment Installation: Start with the delivery, positioning, and anchoring of major equipment, including reactors, distillation columns, heat exchangers, pumps, compressors, and storage tanks. Piping and Interconnections: Connect the primary equipment through a network of pipes. Ensure that the piping conforms to the plant's process flow diagrams (PFDs) and piping and instrumentation diagrams (P&IDs). Provide approved plans for the USG Electrical and Control System Setup: Install primary electrical systems, control panels, sensor networks, and other instrumentation required to monitor and control the plant operations. Provide approved plans to USG. Ductwork and Ventilation: Construct appropriate ductwork, especially in areas where volatile or hazardous chemicals may be released. Install ventilation systems that conform to safety and environmental standards. Provide approved plans to USG.	As defined in the Integrated Master Schedule (Deliverable 6 above).

		Safety System Enhancements: Install fire suppression systems, gas detection systems, and other safety mechanisms pertinent to the chemical processes in operation. Provide copies of the compliance reports to USG. Functional Testing: As sections of the plant get completed, start preliminary functional tests, such as dry runs, to ensure that equipment and systems function as intended. Provide the preliminary test results for USG Training and Skill Development. Begin training plant operators and technicians on the new equipment and systems.	
34	Commissioning & testing: small-scale production	Pre-commissioning Checks: Before initiating any chemical processes, conduct a series of checks on all installed equipment, piping, and control systems to ensure there are no leaks or malfunctions. Provide results with the USG Initial Startup: This involves introducing process materials and chemicals into the system and initiating the plant's operations on a smaller scale, under close monitoring. Operational Testing: During this phase, the plant's operations are continuously monitored to ensure all processes are stable and operate within specified parameters. Provide testing results to the USG. Safety and Emergency Drills: Conduct drills to simulate emergencies and ensure that all safety systems, including alarms and shutdown procedures, are operational. Provide results with the USG Quality Checks: Extract samples of the produced chemicals or products and subject them to quality control tests to verify compliance with the desired specifications. Provide results to the USG Optimization: Based on the observations from the initial runs, make any necessary adjustments to the processes to enhance efficiency and output quality.	As defined in the Integrated Master Schedule (Deliverable 6 above).
35	Commissioning & testing: large-scale production	Large-Scale Startup: This entails ramping up operations to run the plant at full capacity. Chemical input is maximized, and the system is closely monitored to ensure stability. Provide results to the USG. Continuous Operational Monitoring: Technicians and engineers will closely watch the entire	As defined in the Integrated Master Schedule (Deliverable 6 above).

		system, ensuring the processes remain within desired parameters.	
36	Performer handover	Detailed Quality Assurance: With larger batches, a more rigorous quality assurance regime will be implemented.	As defined in the Integrated Master Schedule (Deliverable 6 above).
37	Operational Calculations ability to produce proposed amount of Nitrile Gloves	Efficiency Evaluation: Calculate key performance indicators to assess the plant's efficiency at full scale. This includes evaluating material conversion rates, energy consumption, and waste production. Provide results to USG.	As defined in the Integrated Master Schedule (Deliverable 6 above).
38	Final data reporting	Safety Protocols and Drills: Reinforce safety measures, given the increased volume of materials and chemicals in use. Conduct further emergency drills at this scale. Provide results to USG Feedback Loop Implementation: Establish a feedback mechanism where observations from the large-scale operations can be looped back into the system for continuous improvement.	As defined in the Integrated Master Schedule (Deliverable 6 above).
39	Order equipment	Carry out regular quality checks and reviews throughout the fabrication process to ensure equipment quality and adherence to specifications. Provide a checklist to the USG. Plan logistics for equipment delivery upon completion of fabrication.	As defined in the Integrated Master Schedule (Deliverable 6 above).
40	Purchase Orders	For all purchases in excess of one million U.S. dollars, Performers must receive price quotes from three different vendors for Performer review and approval/selection for award. If a price quote is not able to be received from three different vendors, the Performer must provide written explanation to the Agreement Officer and AOR for authorization to proceed with the PO.	As defined in the Integrated Master Schedule (Deliverable 6 above).
41	Equipment arrival on site	Initiate the initial phase of construction, focusing on site preparation, ground-breaking and foundational work.	As defined in the Master Schedule.
42	Equipment Fabrication	Begin equipment and long lead items fabrication off-site Continuous monitoring and inspection of the equipment fabrication process to ensure quality and compliance. Engage third-party inspectors, if necessary, for quality assurance. Ensure adherence to the agreed timeline for equipment fabrication.	As defined in the Integrated Master Schedule (Deliverable 6 above).

		Address any challenges or issues that arise during the fabrication process promptly. Prepare the site to receive the equipment by ensuring necessary infrastructure and safety measures are in place. Coordinate with logistics teams to ensure smooth delivery and installation. Conduct preliminary tests on the equipment to ensure functionality.	
43	Manufacturing Capacity Confirmation	Upon completion of the validation runs a USG demonstration must be scheduled for the Government to witness the successful operation of the NITRILE GLOVE plant for a significant period of operation that is representative of full scale production and to the satisfaction of the Government.	One-time demonstration, to be performed prior to submission of Final Report.

Security Requirements Deliverables

	Deliverable Description	Content Requirements and Instructions	Reporting Frequency
44	Supply Chain Resiliency Plan	In Accordance with Attachment B	Submit within 30 calendar days of project award
45	Manufacturing Data Requirements	In Accordance with Attachment B	Submit within 30 calendar days of project award
46	Performer Locations	In Accordance with Attachment B	Submit within 5 business days of project award Submit within 30 business days after a substantive location or capabilities change Submit within 2 business days of a substantive change if the work performed supports medical countermeasure development that addresses a threat that has been declared a Public Health Emergency by the HHS Secretary or a Public Health Emergency of International Concern (PHEIC) by the WHO
47	Operational Security (OPSEC) SOP/Plan	In Accordance with Attachment B	Initial submission 90 calendar days of project award.
48	Security Plan	In Accordance with Attachment B	Initial submission within thirty (30) days after project award, updated as necessary.

5. SECURITY INTEREST AND TECHNICAL MONITORING

The Performer must propose terms for a security agreement to protect the USG interests. Payment and performance bonds may be required at the sole discretion of the Government.

The Performer, any successor interest to the Performer, and any other entity that owns, operates, leases, occupies, or uses vested Government property for any reason, must provide priority no-cost technical monitoring of that Government-funded property for a period of ten (10) years after the period of performance ends. The Performer must propose a plan for a ten-year technical monitoring program where they preserve all Government-funded property and report on the status of Government-funded property quarterly.

6. INTELLECTUAL PROPERTY

Performers must propose Intellectual Property (IP) rights arrangements that protect the interests and investments of the United States Government. The Government expects a presumption for nonexclusive, irrevocable, paid-up, worldwide license to use, reproduce, modify, prepare derivative works of, distribute, and disclose all IP first developed, generated, or delivered under this order, and to authorize others to do so on the Government's behalf.

Additionally, the Government expects s presumption that in the event of default, termination, nonperformance, or the Performer's inability or unwillingness to continue performance, the Government must have the irrevocable right to use, transfer, assign, or license to a successor performer all IP, technical data, software (including source code), and associated documentation necessary to continue, complete, or sustain the project. The Performer must, upon request, deliver or place in escrow all such materials, including source code, build instructions, and design documentation, sufficient to enable a third party to assume performance without the Performer's further involvement.

7. PRIORITY RATING

OTA Task Order and Project Agreements under this Statement of Objectives may include a priority rating pursuant to HHS' delegated Defense Production Act (DPA) Title I authorities, including the Health Resource Priorities and Allocations System (45 CFR Part 101) and Defense Priorities and Allocations System regulation (15 C.F.R, Part 700). The Performer, through the CMF may initiate a request for a DPA rating to the Agreements Officer.

Attachment B: ASPR Security Requirements

Security Reporting Requirements

The performer facility shall notify the Government Security Team within 24-72 hours of any activity or incident that is in violation of established security standards or indicates the loss or theft of government products associated with this Agreement. The facts and circumstances associated with these incidents will be documented in writing for government review.

Security Audits

Description: The partner facility agrees to formal security audits conducted at the discretion of the government. Security audits may include both Performer and sub-Performers. Minimum length of notification is 10 business days.

Supply Chain Resiliency Plan

The Performer must develop and submit within 30 calendar days of contract award, a comprehensive Supply Chain Resiliency Program that provides identification and reporting of critical components associated with the secure supply of drug substance, drug product, and work-in-process through to finished goods.

A critical component is defined as any material that is essential to the product or the manufacturing process associated with that product. Included in the definition are consumables and disposables associated with manufacturing. NOT included in the definition are facility and capital equipment.

Consideration of critical components includes the evaluation and potential impact of raw materials, excipients, active ingredients, substances, pieces, parts, software, firmware, labeling, assembly, testing, analytical and environmental componentry, reagents, or utility materials which are used in the manufacturing of a drug, cell banks, seed stocks, devices and key processing components and equipment. A clear example of a critical component is one where a sole supplier is utilized.

The Performer must identify key equipment suppliers, their locations, local resources, and the associated control processes at the time of award. This document shall address planning and scheduling for active pharmaceutical ingredients, upstream, downstream, component assembly, finished drug product and delivery events as necessary for the delivery of product.

a) Communication for these requirements shall be updated as part of an annual review, or as necessary, as part of regular contractual communications.
b) For upstream and downstream processing, both single-use and re-usable in-place processing equipment, and manufacturing disposables also shall be addressed. For finished goods, the inspection, labeling, packaging, and associated machinery shall be addressed taking into account capacity capabilities.

c) The focus on the aspects of resiliency shall be on critical components and aspects of complying with the contractual delivery schedule. Delivery methods shall be addressed, inclusive of items that are foreign-sourced, both high and low volume, which would significantly affect throughput and adherence to the contractually agreed deliveries.

The Performer must articulate in the plan, the methodology for inventory control, production planning, scheduling processes and ordering mechanisms, as part of those agreed deliveries.

a) Production rates and lead times shall be understood and communicated to the Other Transaction Agreements Officer or Project Agreement Representative (PAR) as necessary.
b) Production throughput critical constraints should be well understood by activity and by design, and communicated to contractual personnel. As necessary, communication should focus on identification, exploitation, elevation, and secondary constraints of throughput, as appropriate.

Reports for critical items should include the following information:

a) Critical Material
b) Vendor
c) Supplier, Manufacturing / Distribution Location
d) Supplier Lead Time
e) Shelf Life
f) Transportation / Shipping restrictions

The OTAO and PAR reserve the right to request un-redacted copies of technical documents, during the period of performance, for distribution within the Government. Documents shall be provided within ten (10) days after OTAO issues the request. The Performer may arrange for additional time if deemed necessary, and agreed to by the OTAO.

Manufacturing Data Requirements

The Performer must submit within 30 calendar days of contract award detailed data regarding project materials, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing, processing, and fill/finish sites; and location and nature of non-clinical and clinical studies sites. The Government may provide a table in tabular format for the Performer to be used to submit such data which would include but not be limited to the following:

- Storage/inventory of ancillary materials (vials, needles, syringes, etc.)
- Shipment of ancillary materials (vials, needles, syringes, etc.)
- Disposal of ancillary materials (vials, needles, syringes, etc.)
- Seed development or other starting material manufacturing
- Bulk drug substance and/or adjuvant production

- Fill, finish, and release of product or adjuvant
- Storage/inventory of starting materials, bulk substance, or filled/final product or adjuvant
- Stability information of bulk substance and/or finished product
- Shipment of bulk substance of final product
- Disposal of bulk substance or final product

Performer Locations

The Performer must submit detailed data regarding locations where work will be performed under this contract, including addresses, points of contact, and work performed per location, to include sub-Performers.

Performer will submit Work Locations Report:

- Within 5 business days of contract award
- Within 30 business days after a substantive location or capabilities change
- Within 2 business days of a substantive change if the work performed supports medical countermeasure development that addresses a threat that has been declared a Public Health Emergency by the HHS Secretary or a Public Health Emergency of International Concern (PHEIC) by the WHO

Operational Security (OPSEC)

The performer shall develop an OPSEC Standard Operating Procedure (SOP)/Plan within ninety (90)-calendar-days of project award to be reviewed and approved by the responsible Government OPSEC officer. This plan will be submitted to the PAR for coordination of approvals. This SOP/Plan will include identifying the critical information related to this contract, why it needs to be protected, where it is located, who is responsible for it, and how to protect it.

Security Plan

The Performer must develop a comprehensive security program that provides overall protection of personnel, information, data, and facilities associated with fulfilling the Government requirement. This plan shall establish security practices and procedures that demonstrate how the Performer will meet and adhere to the security requirements outlined below prior to the commencement of product manufacturing, and shall be delivered to the Government within 30 calendar days of award. The Performer must also ensure all sub-Performers, consultants, researchers, etc. performing work on behalf of this effort, comply with all Government security requirements and Performer security plans.

a) The Government will review in detail and submit comments within ten (10) business days to the Other Transaction Agreements Officer (OTAO) to be forwarded to the Performer. The Performer must review the Draft Security Plan comments, and, submit a Final Security Plan to the U.S. Government within ten (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 the Government.

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

At a minimum, the Final Security Plan shall address the following items:

1. Facility Security Plan Description: As part of the partner facility's overall security program, the Performer must submit a written security plan with their proposal to the Government for review and approval by Government security subject matter experts. The performance of work under the 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
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 as identified
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
2. Site Security Master Plan Description: 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.	
3. Site Threat / Vulnerability / Risk Assessment Description: 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.	
4. Physical Security Description:	
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.

	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. c) Video recordings must be maintained for a minimum of 30 days. d) CCTV surveillance system must be on emergency power backup. e) CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the contract. f) Video recordings must be maintained for a minimum of 30 days. g) 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. b) Lighting must have emergency power backup. 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. b) Must have procedures in place to control access and movement of drivers picking up or delivering shipments. c) Must identify drivers picking up Government products by government issued photo identification.
Access Control	a) Must have an electronic intrusion detection system with centralized monitoring. b) Responses to alarms must be immediate and documented in writing. 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.). d) The electronic access control should signal an alarm notification of unauthorized attempts to access restricted areas. e) Must have a system that provides a historical log of all key access transactions and kept on record for a minimum of 12 months. 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. g) Response to electronic access control alarms must be immediate and documented in writing and kept on record for a minimum of 12 months. h) Should have written procedures to prevent employee piggybacking access i) to critical infrastructure (generators, air handlers, fuel storage, etc.) should be controlled and limited to those with a legitimate need for access. j) Must have a written manual key accountability and inventory process. 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. b) Photo identification should be displayed above the waist anytime the employee is on company property. c) Visitors should be sponsored by an employee and must present government issued photo identification to enter the property. 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. b) Must have Use of Force Continuum. c) Must have communication systems available (i.e., landline on post, cell phones, handheld radio, and desktop computer). d) Must have Standing Post Orders. e) Must wear distinct uniform identifying them as security officers.
5. Security Operations Description:	
Information Sharing	a) Establish formal liaison with law enforcement. b) 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. c) Implement procedures for receiving and disseminating threat information.
Training	a) Conduct new employee security awareness training. 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. b) Ensure sub-Performer compliance with all Government security requirements.
6. Personnel Security Description:	
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. b) Off Boarding procedures should be accomplished within 24 hour of employee leaving the company. This includes termination of all network access.
7. Information Security Description:	
Physical Document Control	a) Applicable documents shall be identified and marked as procurement sensitive, proprietary, or with appropriate government markings. b) Sensitive, proprietary, and government documents should be maintained in a lockable filing cabinet/desk or other storage device and not be left unattended. 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).
8. Information Technology & Cybersecurity Description:	
Identity Management	a) Physical devices and systems within the organization are inventoried and accounted for annually.

	b) Organizational cybersecurity policy is established and communicated. c) Asset vulnerabilities are identified and documented. d) Cyber threat intelligence is received from information sharing forums and sources. e) Threats, vulnerabilities, likelihoods, and impacts are used to determine risk. f) Identities and credentials are issued, managed, verified, revoked, and audited for authorized devices, users and processes. 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	a) Limit information system access to authorized users. b) Identify information system users, processes acting on behalf of users, or devices and authenticate identities before allowing access. c) Limit physical access to information systems, equipment, and server rooms with electronic access controls. d) Limit access to/ verify access to use of external information systems.
Training	a) 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 unlawful, unauthorized, or inappropriate system activity. Records must be kept for minimum must be kept for 12 months. b) Ensure the actions of individual information system users can be uniquely traced to those users. c) Update malicious code mechanisms when new releases are available. d) Perform periodic scans of the information system and real time scans of files from external sources as files are downloaded, opened, or executed.
Configuration Management	a) Establish and enforce security configuration settings. b) Implement sub networks for publically accessible system components that are physically or logically separated from internal networks.

Contingency Planning	a) 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	a) 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. b) Limit access to information on information systems media to authorized users. c) Sanitize and destroy media no longer in use. 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. b) Intrusion detection and prevention system employed on IT networks. c) Protect the physical and support infrastructure for all information systems. d) Protect information systems against environmental hazards. e) Escort visitors and monitor visitor activity.
Network Protection	Employ intrusion prevention and detection technology with immediate analysis capabilities.
9. **Transportation Security** Description: 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 Government Personnel Security Requirements. b) Drivers must be trained on specific security and emergency procedures. c) Drivers must be equipped with backup communications. d) Driver identity must be 100 percent confirmed before the pick-up of any Government product. e) Drivers must never leave Government products unattended, and two drivers may be required for longer transport routes or critical products during times of emergency. 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. 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) Government products must be secured with tamper resistant seals during transport, and the transport trailer must be locked and sealed. • Tamper resistant seals must be verified as "secure" after the product is placed in the transport vehicle. b) Government products should be continually monitored by GPS technology while in transport, and any deviations from planned routes should be investigated and documented. c) Contingency plans should be in place to keep the product secure during emergencies such as accidents and transport vehicle breakdowns.
10. Security Reporting Requirements Description: The partner facility shall notify the Government 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.	
11. Security Audits Description: The partner facility agrees to formal security audits conducted at the discretion of the government. Security audits may include both prime and sub-Performer.	

Attachment C: Full Proposal Template (Technical and Cost)

Directions
The following pages are the mandatory Full Proposal template. The template includes required elements, including a cover page, section headings, charts, and appendices. Guidance provided in [brackets] is intended to assist the Offeror. Delete all bracketed guidance and replace it with the applicable proposal content.

Technical Proposal

Directions
The Technical Proposal must address the technical requirements described in the RPP in sufficient detail to permit evaluation from a technical perspective in accordance with the evaluation factors set forth in the RPP.

Format Requirements
The Technical Proposal shall:

- Be single-spaced and single-sided;
- Use 8.5 x 11-inch pages;
- Use a 12-point font; and
- Have margins of at least 1 inch on all sides.

Smaller font sizes may be used in figures and tables but must be clearly legible. Offerors are strongly encouraged to use pictures and graphics to succinctly represent proposed ideas, organization, and other relevant information.

Page Limitation
The Technical Proposal shall be limited to 30 pages. Sections excluded from this page count are marked with an asterisk (*) below. Pages in excess of this limitation may not be considered.

The number of pages should be commensurate with the complexity of the proposed effort. It is expected and encouraged that less complex, less expensive proposals will be significantly less than 30 pages in length.

Required Template
To ensure Technical Proposals receive proper consideration, the Technical Proposal format and all sections detailed within this template are mandatory. If an item is not applicable to a specific proposal, include the section topic with a short explanation of why it is not applicable.

The Technical Proposal shall consist of the following sections:

1. Cover Page*
2. Organization Information Sheet*
3. Executive Summary
4. Technical Approach
5. Supporting Project Information Appendix*

*Excluded from the page limitation.

Technical Proposal Cover Page

[Name of Offeror]

[Address of Offeror]

RPP Identifier: 26-09-Gloves

[Proposal Title]

[Offeror] certifies that, if selected for award, the Offeror will abide by the terms and conditions of the BioMaP-Consortium Base Agreement.

[Offeror] certifies that this Proposal is valid for two years from the close of the applicable RPP, unless otherwise stated.

[As detailed in Section 2.4 of the Request for Project Proposals, Offerors are to include a proprietary data disclosure statement/legend if proprietary data is included. Sample:

This Proposal includes data that shall not be disclosed outside the BioMaP-Consortium Management Firm and the Government. It shall not be duplicated, used, or disclosed, in whole or in part, for any purpose other than proposal evaluation and agreement administration. The data subject to this restriction is (clearly identify) and contained on pages (insert page numbers).]

Organization Information Sheet

If an item is not applicable, then that section should be listed as “not applicable.”

Offeror Name	
All Places of Performance	
Title of Proposed Effort	
UEI # (if applicable)	
CAGE Code (if applicable)	
Small Business (Yes/No)	
Small/Disadvantaged Business (Yes/No); Socioeconomic Category	
Conflict of Interest (Yes/No)	
Government Funds	
Industry Cost Share	
Total Cost of Proposal	
Proposed Period of Performance (Months)	
Preferred Payment Method (FFP, CPFF, Cost Reimbursable (CR), CR/Cost Share)	
Requested Use of Government Resources, Property, Labs, etc. (Yes/No; list if Yes)	
Proposed Use of Select Biological Agents or Toxins (Yes/No)	
Contract/Negotiation Contact (Name, Address, Phone, Email)	
Technical/Principal Investigator Contact (Name, Address, Phone, Email)	
Cognizant Rate Audit Agency Office (if known, include POC, Address, Phone, Email)	

Executive Summary

Please do not include the instructions in [brackets] in your proposal.

Executive Summary: [The Executive Summary allows Offerors to concisely present the important aspects of their proposals to evaluators. The summary should present an organized progression of the work to be accomplished, without technical details, so that the reader can understand the core concepts of the proposed project.]

Technical Approach

[If recommended for award, this section will serve as the basis for the Statement of Work, which may be further refined and negotiated. Write this section accordingly and avoid generic proposal language. Provide sufficient technical detail and analysis to fully support the proposed solution and clearly define the core approach. Do not simply list or discuss multiple potential solutions; focus on the intended strategy. The following sections are required.]

1. **Background:** [Describe the problem that the solution is addressing.]
2. **Objectives:** [Describe the goal of the project and what you are going to do to achieve the goal, including the final product(s) and/or anticipated outcome(s). Be as concise as possible.]
3. **Key Personnel and Project Team:** [Identify Key Personnel considered essential to the work to be performed. Key Personnel are defined as employees of the contractor or of any subcontractor(s), affiliates, joint venture partners, or team members, as well as consultants engaged by any of those entities. *No changes to the awarded Key Personnel are authorized without express written approval from the Agreements Officer through the CMF.* Using the summary table below, identify the proposed Key Personnel and other management and technical personnel for the project. The Principal Investigator must be identified. If you are partnering with additional organizations to execute the proposed technical and programmatic work, provide details before the table that identify the partners and clearly describe the roles and responsibilities of each organization. If you are not partnering, state that no partners are proposed.]

Key Personnel	Organization	Role and Key Contribution	Level of Effort
Name (Principal Investigator)			%

4. **General Approach:** [Summarize your overarching approach/solution and framework for addressing the requirements set forth in the RPP. Include relevant background data and

information on your platform, facilities, or solution and the current state of the solution if previous development or progress has been made.]

5. **Technical Approach**: [Provide a detailed approach, broken out by major phases/top-level tasks and gates/decision points, explaining how your organization intends to address the requirements set forth in the RPP and showing a clear course of action and the roles of organizations (if applicable).]
6. **Schedule:** [Include a Gantt chart of the project, developed to include the same level of detail as the work breakdown provided in the Technical Approach section. The Gantt chart may be rolled up to the task level for space efficiency, if necessary.]

7. Deliverables and Milestone Payments:

Instructions:

- Submitted information may change during negotiations if the Government recommends the proposal for award.
- The deliverables listed in Section 4 of Attachment A to the RPP are mandatory. Please populate the table below with all deliverables identified in Section 4 of Attachment A to the RPP, as well as any additional technical deliverables you propose to support the technical effort. The results of the technical effort are contractually binding and must be clearly identified. Offerors should carefully read the Base Agreement. Additionally, any hardware or software to be provided to the Government as a result of this project must be specified.
- The proposed milestones and deliverables should be appropriate in number relative to the project's size and duration, and they should have sufficient monetary value to justify the generation of a deliverable and any related invoices. Please note that recurring programmatic reporting will not be funded. For cost-reimbursable agreements, the Offeror is still required to assign a monetary value to each milestone. However, the total invoice amounts will be based on actual costs incurred and do not have to match the specified amounts exactly.
- List the data rights assertions using the numbers assigned in the data rights assertion table. If an assertion is not applicable to a deliverable, write "N/A."

Deliverable #	**Task #** *[For technical deliverables in Section 5 (Technical Approach), the Offeror shall reference the applicable Task # or Paragraph #. For mandatory deliverables specified in Section 4 of Attachment A to the RPP, the Offeror may indicate "N/A"]*	**Deliverable Name** *[Include all technical and mandatory deliverables specified in Section 4 of Attachment A to the RPP.]*	**Deliverable Description** *[All technical deliverables proposed by the Offeror must include a description. For mandatory deliverables outlined in Section 4 of Attachment A to the RPP, the Offeror may instead state "**the full description is outlined in the RPP**" rather than copying the entire text into the table.]*	**Due Date (Month)/ Reporting Frequency**	**Total Cost** *[Provide a breakout distinguishing Government funding from cost-share contributions for each deliverable.]*	**Assertion #**
1						
2						
3						
4						
Etc.						

Total Period of Performance: # Months

8. Intellectual Property, Data Rights, and Copy Rights

[If the Offeror intends to provide technical data that existed prior to, or was produced outside of, the proposed effort and for which the Offeror wishes to maintain additional rights, the Offeror should assert these rights by completing the table below. Note that each assertion is subject to negotiation prior to award.

Rights in such data shall be as established under the terms of the Base Agreement, unless otherwise asserted in the proposal and agreed to by the Government. The table below lists the Awardee's assertions.

Assertion #	Technical Data or Computer Software to be Furnished with Restrictions	Basis for Assertion	Asserted Rights	Name of Organization Asserting Restrictions

Supporting Project Information Appendix

1. **Cost Summary:** [This section provides technical evaluators with high-level cost data in order for the evaluators to determine if the costs proposed are realistic as compared to the scope of work proposed. This information must be consistent with the Cost Proposal. The information must be provided in this section of the Technical Proposal. Include the following table as a summary of the costs by cost element.]

Cost Summary EXAMPLE This form is to be completed by Offeror and evaluated by Technical Evaluators. Items in italics are provided as samples only. Offeror must complete table with the applicable information.		
Cost Element	**Total Proposed Cost**	**Description/Explanation**
Labor	*$XXX*	*xx hrs of senior scientist; xx hours of program management; include additional as required.*
Labor Hours	*XX*	
Subcontractors	*$XXX*	*Sub A - $xxx; xx legal advisor hours* *Sub B - $xxx; xx hours of Testing*
Subcontractor Hours	*XX*	
Consultants	*$XXX*	*Financial consultant supporting all phases*
Consultant Hours	*XX*	
Material/Equipment	*$XXX*	*pipettes, gloves, computer software*
Other Direct Costs	*$XXX*	*ship testing materials to lab*
Travel	*$XXX*	*x trips for x people for x days to xx (city), xx (state) from xx (city), xx (state) for program meetings*
Indirect Costs	*$XXX*	*approved by DHHS (provide date)*
Fee	*$XXX*	*Not applicable if cost share proposed*
Total Cost to Government	*$XXX*	
Total Project Value	*$XXX*	

2. **Risks & Mitigation:** [Identify potential problem areas (e.g., technical, schedule, cost) in the proposed approach. Describe risk mitigation methods.]

3. **Organizational Conflict of Interest:** [An Organizational Conflict of Interest can occur when an individual or an entity is unable, or potentially unable, to provide impartial advice or service to the Government or separate entity because of other business activities or relationships. Disclose any potential conflict of interest pertaining to this opportunity. If none, state as such.]

4. **Small Business Utilization:** [Complete the following subsections with as much information as currently known. In accordance with the RPP, this information is not part of the Government's technical evaluation; however, small businesses utilization is encouraged to the maximum extent practicable under the BioMaP-Consortium. To be a small business, an organization must first be a for-profit legal structure. Next, it must qualify with the Small Business Association's (SBA) size standards, which are structured by NAICS Code (see https://www.sba.gov/document/support-table-size-standards) for more details). Lastly, some small businesses participate in one or more additional programs with the Small Business Administration (see https://www.hhs.gov/grants-contracts/small-business-support/programs-supporting-small-businesses/index.html for more details).]

   4.1. Offeror's Business Status: [Select and complete the appropriate option. Delete the other two options which do not apply.]

   - Offeror qualifies a small business under NAICS code(s) _____
   - Offeror qualifies a small business under NAICS code(s) _____ and further participates in the SBA's *[select from following list as appropriate: 8(a) Business Development; HUBZone; Service-disabled-veteran-owned; small-disadvantaged-business; Women-owned-small-business]* program.
   - Offeror does not qualify as small business

   4.2. Teaming with Small Businesses: [Select and complete the appropriate option based on currently proposed teaming plan. Teaming can include subcontractors, consultants, and significant material or service providers. Delete any options with do not apply.]

   - Offeror plans to team with _____, who qualifies a small business under NAICS code(s) _____
   - Offeror plans to team with _____, who qualifies a small business under NAICS code(s) _____ and further participates in the SBA's *[select from following list as appropriate: 8(a) Business Development; HUBZone; Service-disabled-veteran-owned; small-disadvantaged-business; Women-owned-small-business]* program.
   - Offeror does not plan to partner with any small business
   - At this time, it is unknown if Offeror will be able to team with any small businesses

5. **Relevant Experience**

[Provide at least one (1) and no more than five (5) current and/or relevant experience examples of performance within the past 5 years. Copy and paste the below template as needed. While this appendix does not count towards the overall page limit of the technical proposal, each relevant experience is limited to three pages.]

<table>
<tr><td colspan="4">Respondent's Name and Contract/Example Name</td></tr>
<tr><td>Contract Number</td><td></td><td>Contract Type</td><td></td></tr>
<tr><td rowspan="2">Period of Performance</td><td rowspan="2"></td><td>Contract Value</td><td rowspan="2"></td></tr>
<tr><td>(Base and Sub-awards)</td></tr>
<tr><td>Agency</td><td></td><td colspan="2">Customer Points of Contact</td></tr>
<tr><td rowspan="6">Name & Address of Contracting Organization</td><td rowspan="6"></td><td>Project Officer</td><td></td></tr>
<tr><td>Phone</td><td></td></tr>
<tr><td>E-mail</td><td></td></tr>
<tr><td>Contracting Officer</td><td></td></tr>
<tr><td>Phone</td><td></td></tr>
<tr><td>E-mail</td><td></td></tr>
<tr><td colspan="4">Similarities to this Solicitation</td></tr>
<tr><td colspan="4"></td></tr>
<tr><td colspan="4">Brief Description of Project Scope and Customer Expectations</td></tr>
<tr><td colspan="4"></td></tr>
<tr><td colspan="4">Brief Description of Approach and Performance</td></tr>
<tr><td colspan="4"></td></tr>
</table>

Cost Proposal Template

The objective of the Cost Proposal is to provide sufficient cost information to substantiate that the proposed cost is realistic, reasonable, and complete for the proposed work. The Cost Proposal should provide enough information to ensure that a complete and fair evaluation of the reasonableness and realism of cost or price can be conducted and reflect the best estimate of the costs for the project. The Cost Proposal must be consistent with information provided in the Statement of Work and general technical approach (i.e., costs, cost share, dates, etc.). Proposals that deviate substantially from these guidelines, omit substantial parts or sections, or deviate significantly from the original Proposal Rough Order of Magnitude (ROM) estimate may be eliminated from further review and funding consideration.

To ensure Cost Proposals receive proper consideration, it is mandatory that the Cost Proposal include both Section I: Cost Proposal Narrative and Section II: Cost Proposal Format.

The Cost Proposal Narrative is used to assess various criteria. This section will be used to determine reasonableness, allowability, and allocability of costs. The Cost Proposal Narrative section should provide a more detailed breakdown of the figures that are contained in the Cost Proposal Format. The Cost Proposal Narrative section also should give substantiation and written explanation of proposed costs. Breakdowns should be as accurate and specific as possible. Ensure that any figures presented in this part are consistent with the figures in the Cost Proposal Format.

Separately, the Cost Proposal Format must be provided in Excel, with working formulas to the maximum extent practicable. Optional formats are available on the Members Only website. However, Offerors are encouraged to use their own formats so long as the required level of detail is provided.

Cost Proposal Section I: Cost Proposal Narrative

The Cost Proposal Narrative must include sufficient information to evaluate the proposed value through cost information. This information is required to properly perform the cost and/or price analysis of a proposal. All Proposals must provide the following overview information as part of the Cost Proposal Narrative:

Overall Approach. Provide an overall and succinct explanation of how this Proposal is structured.

Assumptions. Provide any assumptions. Note that assumptions should be limited to cost or pricing. Technical assumptions are better captured in the Statement of Work.

Preferred Payment Method. Identify which of the payment methods is preferred. The methods are (1) Cost Reimbursable Milestones with Ceiling, (2) Cost Reimbursable/Cost

Share with Ceiling, (3) Cost Plus Fixed Fee Milestones with Ceiling and (4) Fixed Price Milestones with Ceiling.

Detailed Cost Element Explanation: The Cost Proposal Narrative must include the following cost categories and details, at a minimum:

a. **Labor Rates**. Portions of labor information may be included in the Cost Proposal Format instead of this Cost Proposal Narrative if more practical. Identify the position title of all personnel, the labor category description, the hourly rate for each individual, and show estimated hours for each labor category proposed. If an approved organizational estimating procedure use average labor rates for specific labor categories, this would be acceptable.

   It is recognized that an organization may not be able to identify all of the personnel to be assigned to the project several years in advance. Where this cannot be done, use generic position titles such as "scientist." If direct labor costs include allocated direct costs or other direct costs in accordance with established accounting and estimating practices and systems, identify these costs separately and provide an explanation and basis for proposed costs.

   Provide an explanation for any proposed labor escalation.

   Offerors are expected to avoid overtime as much as practicable, except when lower overall costs to the Government will result or when it is necessary to meet urgent program needs. If overtime is proposed, provide an explanation as to why.

b. **Salary Rate Limitation.** Payment of the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level II is an unallowable cost under the BioMaP-Consortium OTA and shall be addressed in accordance the BioMaP-Consortium Base Agreement.

   For purposes of the salary rate limitation, the terms "direct salary," "salary," and "institutional base salary" have the same meaning and are collectively referred to as "direct salary." An individual's direct salary is the annual compensation that the entity pays for an individual's direct effort (costs). Direct salary excludes any income that an individual may be permitted to earn outside of duties to the entity. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative [F&A] costs).

   The salary rate limitation does not restrict the salary that an entity may pay an individual, it merely limits the portion of that salary that may be paid with Federal funds.

See the salaries and wages pay tables on the U.S. Office of Personnel Management Web site for Federal Executive Schedule salary levels that apply to the current period. See the BioMaP-Consortium Base Agreement for further details.

c. **Fringe Benefits.** Identify whether or not the proposed labor rates include fringe costs. If so, then identify the percentage rate. If not, then provide a statement to that effect and include the fringe costs in the indirect section instead.

d. **Travel.** Portions of travel information may be included in the Cost Proposal Format instead of this Cost Proposal Narrative if more practical. Identify the total travel amount proposed. Provide an estimate of the cost per trip; number of trips; number of days; number of persons; departure city, destination city; approximate travel time frames; and the purpose of the travel. The key is to apply best estimating techniques that are auditable. Include a brief explanation of the methodology used to estimate travel costs. If exact destination is unknown at time of proposal, for pricing purposes use a potential location using best known information. Note that BioMaP-Consortium Project Awardees are expected to be cost-conscious regarding travel (e.g., using coach rather than first class accommodations and, whenever possible, using Government per diem, or similar regulations, as a guideline for lodging and subsistence costs). If travel is estimated based on an approved methodology, then state as such.

e. **Subcontractors/Consultants.** Portions of subcontractor/consultant information may be included in the Cost Proposal Format instead of this Cost Proposal Narrative if more practical. Provide a list of all subcontractor/consultant and a total cost for each. If a cost and/or price analysis has been performed, provide a copy or summary of results.

   Support is required for each subcontractor/consultant as follows:

   - If a subcontractor/consultant is based on commercial pricing, provide an explanation of the commerciality determination and supporting documentation (e.g., website pricing, catalogue pricing, etc.)
   - For a subcontractor/consultant less than $250,000, provide a brief explanation of the work to be performed.
   - For a subcontractor/consultant greater than $250,000 and less than or equal to $2,000,000, provide a supporting quote and confirmation of compliance with the Salary Rate Limitation.
   - If a subcontractor/consultant over $2,000,000 was competitively solicited, provide the price analysis showing how the price was determined reasonable, summary of competition, and copies of the competitive quotes.

- Absent any of the above, if relying on cost data for a subcontractor/consultant greater than $2,000,000, a cost-by-cost element breakout must be provided to the same level of detail as the Offeror.

f. Material/Equipment/Other Direct Costs. Portions of the material/equipment/other direct cost information may be included in the Cost Proposal Format instead of this Cost Proposal Narrative if more practical. Provide an itemized list of the material/equipment/other direct costs, including the itemized unit cost and quantity. Identify the supplier/manufacturer and basis of cost (i.e., vendor quote, catalog pricing data, past purchase orders, etc.) for each item, if known. Additionally, a copy of the basis of cost documentation for each piece of proposed material/equipment/other direct cost with a unit cost greater than or equal to $25,000; or total cost greater than or equal to $150,000; must be provided. If material/equipment/other direct cost is estimated based on an approved methodology, then state as such.

If any sort of usage cost is determined by a rate, identify the basis and rational used to derive the rate.

Only in extraordinary circumstances will government funds be used to purchase equipment. Examples of acceptable equipment might include special test equipment, special tooling, or other specialized equipment specific to the research effort. This award is not an assistance agreement/instrument and Offerors should normally have the required equipment to perform. The value of equipment should be prorated according to the share of total use dedicated to carrying out the proposed work. Include a brief explanation of the prorating methodology used.

g. Indirect Costs. Portions of the indirect cost information may be included in the Cost Proposal Format instead of this Cost Proposal Narrative if more practical. Provide an estimate of the total indirect costs, identify each rate used in the proposal, and provide documentation to support the indirect cost rates by one of the below methods.

i. Provide a copy of certification from a Federal agency indicating these indirect rates are approved by the Federal agency; or
ii. Provide a letter from the Offeror's Administrative Agreements Officer, in lieu of a rate certificate, stating these indirect rates are approved by a Federal agency;
iii. Copy of current forward pricing rate proposal with date proposal was submitted to the Administrative Agreements Officer; or
iv. Absent Government approved rates, provide detailed supporting data to include (1) indirect rates and all pricing factors that were used; (2) methodology used for determining the rates (e.g., current experience in

the organization or the history base used); and (3) all factors, by year, applied to derive the proposed rates.

Alternately, in lieu of providing indirect rates, if the Offeror can obtain appropriate Government assistance, it may provide a letter from the cognizant Federal audit agency stating that, based upon their review of the Offeror's proposal, the indirect rates used in the proposal are approved by a Federal agency and were applied correctly in this specific proposal. If the Offeror elects to rely on these Government inputs, it is responsible for ensuring any Government agency cooperation is obtained so that the proposal is complete when submitted.

h. Fee/Profit. State the fee/profit percentage, if proposed. Fee/Profit is allowable for the effort being conducted. The fees shall be specific to the individual BioMaP-Consortium project and negotiated on a project-by-project basis.

i. Cost Share. Identify if any Cost Share is proposed. Cost Share includes any costs a reasonable person would incur to carry out (necessary to) proposed project's Statement of Work not directly paid for by the Government. If a proposal includes cost share, then it cannot include fee. Cost Share may be proposed only on cost type agreements. There are two types of cost sharing, Cash Contribution and In-Kind Contribution:

Cash Contribution:
Cash Contribution means the Project Awardee (or Awardees' lower tier subawards) financial resources expended to perform a Project Award. The cash contribution may be derived from the Project Awardee (or Awardees' subawards) funds or outside sources or from nonfederal contract or grant revenues or from profit or fee on a federal procurement contract.

An Offeror's own source of funds may include corporate retained earnings, current or prospective Independent Research and Development (IR&D) funds or any other indirect cost pool allocation. New or concurrent IR&D funds may be utilized as a cash contribution provided those funds identified by the Offeror will be spent on performance of the Statement of Work (SOW) of a Project Award or specific tasks identified within the SOW of a Project Award. Prior IR&D funds will not be considered as part of the Offeror's Cost Share.

Cash contributions include the funds the Offeror will spend for labor (including benefits and direct overhead), materials, new equipment (prorated if appropriate), awardees' subaward efforts expended on the SOW of a Project Award, and restocking the parts and material consumed.

In-Kind Contribution:
In Kind Contribution means the Offeror's non-financial resources expended to perform a Project Award such as wear-and-tear on in-place capital assets like

machinery or the prorated value of space used for performance of the Project Award, and the reasonable fair market value (appropriately prorated) of equipment, materials, IP, and other property used in the performance of the SOW of the Project Award.

Prior IR&D funds will not be considered as part of the Consortium Member's cash or In-Kind contributions, except when using the same procedures as those that authorize Pre-Award Costs, nor will fees be considered on cost share.

If cost share is proposed, the following must be provided:

- A description of each cost share item proposed;
- Proposed dollar value of each cost share item proposed; and
- The valuation technique used to derive the cost share amounts (e.g., vendor quote, historical cost, labor hours and labor rates, number of trips, etc.).

j. **Small Business Utilization.** Small businesses utilization is encouraged to the maximum extent practicable under the BioMaP-Consortium. To be a small business, an organization must first be a for-profit legal structure. Next, it must qualify with the Small Business Association's (SBA) size standards, which are structured by NAICS Code (see https://www.sba.gov/document/support-table-size-standards for more details). Lastly, some small businesses participate in one or more additional programs with the Small Business Administration (see https://www.hhs.gov/grants-contracts/small-business-support/programs-supporting-small-businesses/index.html for more details).

As part of the Cost Narrative, provide details on any significant small business utilization proposed, similar to the below chart. Participation can include the Offeror, subcontractors, consultants, material providers, service providers, etc.

Small Business Name	NAICS Code	Proposed $ Value	Task Involvement	SBA Program*

**Can include: 8(a) Business Development; HUBZone; Service-disabled-veteran-owned; small-disadvantaged-business; and/or Women-owned-small-business. Otherwise, list N/A.*

Cost Proposal Section II: Cost Proposal Format

The Cost Proposal Format must be provided as a separate Excel document. Offerors are encouraged to use their own Excel cost formats so long as the necessary cost detail is provided. Working formulas should be included to the maximum extent possible. The Cost

Proposal Formats provided on the BioMaP-Consortium Members Only Site are ***NOT*** mandatory.

The Cost Proposal Format section must include cost-by-element detail broken out by the Offeror's fiscal year. If required by the RPP, costs must also be broken out by phase to match the technical requirements and objectives. The sum of the phases must equal the total.

Supporting data and justification for labor, equipment/material, team member/subcontractor, consultants, travel, other direct costs, indirect costs, and profit used in developing the cost breakdown also must be included. The Offeror must provide sufficient details to allow a full understanding of and justification for the proposed costs. Offerors may refer to the RPP for a start date for cost estimating purposes.

Attachment D: Additional Required Documentation

[Each of the below files must be submitted as its own individual file outside of the full Technical and Cost Proposal.]

File Name	Description
Performance Location Attestation	Attestation that all work on the Performer's proposed project must be performed within the continental United States and its territories; the Performer is wholly U.S. owned, U.S. operated, and has their global headquarters located within the U.S. . If circumstances change after contract award, the Performer must obtain an Agreement Officer's Authorization (AOA) approval for any proposed arrangement where the Performer will not meet the U.S.-owned and operated and global headquarters located within the U.S. requirement.
Letter of Bondability	Letter of bondability for construction-related bonding by a surety that is capable of executing the project. The letter of bondability must identify the bonding company and specify the Performer's bonding capacity, Bonding capacity is defined as the maximum dollar amount of contracts the surety will allow the Performer to take on at once. The letter must also address how much of the bonding capacity is available for the proposed project.
Legal and Financial History	Explanation letter that identifies all of the following since March 2020: Contract terminations or settlement agreements with the U.S. Government since March 2020, bankruptcy filings, receivership and eviction history, postponements or defaults on financial obligations, default judgments from a court, adverse decisions as part of binding arbitration, and any other information that informs the risk the government is taking if the Performer is selected for an award. Letter is limited to a maximum of two pages.
DOJ and OIG Contacts	Statement identifying contacts with the Department of Justice (DOJ) and any Office of Inspector General (OIG) for any reason in the last five years, to include names and contact information.
Bylaw Amendment Attestation	Attestation stating that the Performer's corporate bylaws will be amended and submitted within 90 days of a Project Agreement award to require all the following: • The Performer, and any successor in interest to the Performer, must remain a whole U.S. owned, U.S. operated, with global headquarters located within the U.S., domestically controlled company with corporate governance in place to prohibit foreign influence for at least ten years after a Project Agreement award. • In the event of a public health emergency, the Performer, any successor interest to the Performer, and any other entity that owns, operates, leases, occupies, or uses the Government funded property for any reason, must provide priority access to the Government-funded capacity for a period of ten (10) years after the period of performance ends. • The Performer, any successor in interest to the Performer, and any other entity that owns, operates, leases, occupies, or uses the Government-funded capacity for any reason, must not use the real property, equipment, or other assets funded by the Government as collateral or for a purpose that is not related to the production of nitrile gloves for a period of ten (10) years after the period of performance ends. • The Performer, any successor in interest to the Performer, and any other entity that owns, operates, leases, occupies, or uses the

	Government-funded capacity for any reason, must prioritize utilizing USG-funded capacity to meet U.S. market demand for nitrile gloves before meeting global market demands.
Commercial Viability Plan	Commercial Viability Plan in accordance with Section 2.1.2.2 and Deliverable No. 19 of Attachment A to the RPP. Commercial Viability Plan may not exceed 4 pages.
Regulatory Plan	Regulatory Plan in accordance with Section 2.1.2.3 and Deliverable No. 20 of Attachment A to the RPP
Project Plan	Project Plan in accordance with Sections 2.1.2.4, 2.1.2.9 and Deliverable No. 17 of Attachment A to the RPP