

### COMBINED SYNOPSIS/SOLICITATION

- I. This is a combined synopsis/solicitation for commercial items prepared in accordance with the format in Subpart 12.6, as supplemented with additional information included in this notice. This announcement constitutes the only solicitation; proposals are being requested. and a written solicitation document will not be issued.
- II. The solicitation is 75A50122R00031- which is a Request for Proposal (RFP). Contract Type will be Firm Fixed Unit Price.
- III. The solicitation document and incorporated provisions and clauses are currently in effect through Federal Acquisition Circular 2021-07, effective 10 September 2021.  
  
This acquisition is being posted as a limited competition under the authority of Federal Acquisition Regulation (FAR) Subpart 6.302-3 Industrial mobilization; engineering, developmental, or research capability; or expert services, paragraphs (a)(2)(i) and (b)(1)(iv)(A), and is not set aside for small business. NAICS Code: 339113 (Surgical appliance and supplies manufacturing,) The size standard is 750 employees.
- IV.
  - a. The Division of Strategic National Stockpile (DSNS), of the U.S. Department of Health and Human Services (HHS), Office of the Assistant Secretary for Preparedness and Response (ASPR), has a requirement for up to 127,000,000 surgical masks, plus an optional quantity for up to 254,000,000 surgical masks. See Section B- SUPPLIES OR SERVICES AND PRICES/COSTS.
  - b. The Government intends to evaluate offers and award a contract or contracts without discussions. However, the Government may, at its sole discretion, elect to conduct discussions if determined to be in the best interest of the Government.
- V. See Sections B and C below for description of requirements.
- VI. The period of performance is anticipated to total 36 months, 31 December 2021 through 30 December 2024:
  - a. **Base Period:** 12 months  
Medical Surgical Mask quantity – 127,000,000 Anticipated Period of Performance: 31 December 2021 through 30 December 2022.
  - b. Optional ordering quantity has an ordering period of 36 months, anticipated to be 31 December 2021 through 30 December 2024:  
Medical Surgical Mask quantity – 254,000,000
- VII. The provision at FAR 52.212-1, Instructions to Offerors-Commercial Items, applies to this acquisition.
- VIII. The provision 52.212-2, Evaluation-Commercial Items, applies to this procurement. Addenda to the provision include evaluation factors and evaluation criteria.
- IX. Offerors shall include a completed copy of FAR 52.212-3, Offeror Representations and Certifications-Commercial Items, with their offers. (Note, if offerors are registered within the System for Award Management (SAM) and certs and reps are up to date, offerors shall make a statement to that effect in accordance with this clause).
- X. The clause at 52.212-4, Contract Terms and Conditions-Commercial Items, applies to this acquisition.
- XI. The clause at 52.212-5, Contract Terms and Conditions Required to Implement Statutes or Executive

Orders Commercial Items, applies to this acquisition and FAR clauses applicable include 52.219-9, 52.219-16, 52.222-3, 52.222-19, 52.222-21, 52.222-26, 52.222-35, 52.222-36, 52.222-37, 52.222-40, 52.225-13, and 52.232-33. Other applicable clauses include Health & Human Services Acquisition Regulation (HHSAR) clauses.

XII. a. There are no special contract requirements or terms and conditions related to contract financing arrangements.

b. FAR 6.302-3 Industrial mobilization; engineering, developmental, or research capability; or expert services, paragraphs (a)(2)(i) and (b)(1)(iv)(A) apply to this acquisition; see Section H for related information.

**c. Pursuant to Presidential Decision Directives 39 and 62 and Sections 311 and 319 of the Public Health Service Act, SNS storage locations are sensitive and shall not be disclosed.**

The Contractor shall sign a non-disclosure agreement (applicable and enforceable to all employees of the contractor), to not disclose any details relating to the contract, and hold all employees and/or subcontractors involved in the performance of this requirement to the same. At any time, the Government may request employees and/or subcontractors related to this performance to sign a non-disclosure agreement. HHS Non-Disclosure forms shall be released to the awardees as part of their award package.

The Contractor shall adhere to the sensitivity requirements relating to the contract whenever granted access to DSNS Sensitive But Unclassified information (SBU), and all times thereafter. The contractor shall not share the Sensitive But Unclassified information (SBU) or the HHS Non-Disclosure Agreement (NDA) without Government approval.

XIII. HHS reserves the right to exercise priorities and allocations authority with respect to this contract, to include rating this order in accordance with 45 CFR Part 101, Subpart A—Health Resources Priorities and Allocations System.

XV. Offers are due no later than December 6, 2021 on or before 1:00 PM Eastern Time, with the Subject Line “RFP 75A50122R00031,” by email to [dsnssolicitations@cdc.gov](mailto:dsnssolicitations@cdc.gov)

The offeror’s complete proposal (including all information required to be submitted as part of the offeror’s Volume A -Technical Quote, and Volume B - Price/Business Quote) must be received by the date and time specified for receipt of offers.

Electronic submissions only will be accepted and shall be submitted via email to [dsnssolicitations@cdc.gov](mailto:dsnssolicitations@cdc.gov). All submissions must include the solicitation number. Email submissions are limited to 2MB. Late submissions shall be treated in accordance with the solicitation provision at FAR 52.212-1(f)

- o All questions regarding this RFP of a contractual or technical nature must be submitted electronically by email to [dsnssolicitations@cdc.gov](mailto:dsnssolicitations@cdc.gov) no later than 1:00 p.m., ET, November 19, 2021. For proper submission of questions, include the solicitation number and the word “QUESTION” in the subject line of the email. The Government’s responses to questions will be posted as amendments to the combined synopsis/solicitation posting. Please be advised that the Government reserves the right to transmit those questions and answers of a common interest to all prospective offerors.

XVI. The point of contact for information regarding this combined synopsis/solicitation is

Akela Long, **Contract Specialist**  
Office of Resource Management (ORM)  
Assistant Secretary of Preparedness and Response (ASPR)  
U.S. Department of Health and Human Services (HHS)  
Email: [dsnssolicitations@cdc.gov](mailto:dsnssolicitations@cdc.gov)

**SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS**

**B.1 Contract Line Items**

ITEM	SUPPLIES / SERVICES	QTY/UNIT	UNIT	PRICE
1001	<p><b>Base Quantity</b></p> <p>Surgical Masks</p> <p>The required Surgical Masks are to be provided in accordance with the Statement of Work (SOW) below, Terms and Conditions contained herein, and the Contractor’s proposal dated _____ 2021.</p> <p>This is a Firm Fixed Unit Price line item.</p> <p>Anticipated Delivery Period: 31 December 2021 through 30 December 2022.</p>	127,000,000*	Each	\$ _____
2001	<p><b>Optional Ordering Quantity</b></p> <p>Surgical Masks</p> <p>The required Surgical Masks are to be provided in accordance with the Statement of Work (SOW) below, Terms and Conditions contained herein, and the Contractor’s proposal dated _____ 2021.</p> <p>This is a Firm Fixed Unit Price line item.</p> <p>Anticipated Ordering Period: 31 December 2021 through 30 December 2024.</p>	254,000,000*		\$ _____

\* NOTE: The Government reserves the right to make multiple awards under this solicitation, and different vendors are likely to propose on and may be awarded different quantities of surgical masks. The exact number of surgical masks across all awards is unlikely to equal exactly 127 million for the base quantity or 254 million for the option, and the total number (across all awards) may vary by up to 10%. Each individual vendor’s award will show only the quantity awarded to them. No one vendor is anticipated to receive the total requirement.

**B.2 Option for Increased Quantity – Separately Priced Line Items**

The Government may require the delivery of the numbered line items, identified in the schedule in Section B.1 as option items, in incremental quantities at the price stated in the award, up to the maximum quantity identified for each numbered line item, in accordance with FAR 52.217-7 Option for Increased Quantity– Separately Priced Line Items found in Section I.2. Each option line item may be exercised more than once, until the cumulative number of units to be delivered under each option is delivered. The Contractor shall not be required to make any deliveries under this contract beyond six (6) months following the end of the ordering period. The total units hereunder shall not exceed the respective line-item unit maximums over the 3-year ordering period, unless changed by formal modification to the contract. Prices applicable during the ordering period

Product Name	(Date range) 31 December 2021 through <u>date</u>	(Date range) <u>date</u> through <u>date</u>	(Date range) <u>date</u> through 30 December 2022
Surgical Masks			
Unit price is per Each.			

NOTE: The contractor may add or delete columns from the above table, if needed.

The amount of funding for each instance of exercising an option CLIN can be calculated as follows: number of units X price per unit for the CLIN being exercised = funding amount.

The Contracting Officer will exercise the option by written notice to the Contractor. The Contractor will be notified in writing, by letter or email, at least thirty (30) business days before the option to acquire more product is exercised. After that written notification, a funded, unilateral modification will be issued to formally exercise the option and order the surgical masks.

The Government may exercise option CLIN 2001 for only some of the Items, or may obtain all of them over time. The Government reserves the right not to exercise option CLIN 2001 if no additional Items are required during the entirety of this contract.

### **B.3 Increased Quantity Limitations**

In reference to FAR 52.217-6 Option for Increased Quantity found in Section I.2, the total allowable increased quantity under this clause is 20% of the total contract quantity. This option may be exercised more than once but the total number of items ordered in accordance with FAR 52.217-6 shall not exceed a cumulative total of 20% of the total contract quantity. The amount of funding for each instance of exercising this option can be calculated as follows: (number of units) X (price per unit for the ordering period applicable at the time the option is exercised) = funding amount.

This is a surge option that is included due to the unpredictability of events for which surgical masks may be required (e.g., a natural disaster or public health event), the Government cannot accurately predict the scope and timing of a need for additional surgical masks in the case of such an event.

The Contracting Officer will exercise the option by written notice to the Contractor. The Contractor will be notified in writing, by letter or email, at least fifteen (15) business days before the option to acquire more product is exercised. After that written notification, a funded, unilateral modification will be issued to formally exercise the option and order the surgical masks.

### **B.4 Volume Discount**

Vendors must provide a volume-based pricing table. Example provided below:

#### **Base CLIN 1001 Pricing Breakout:**

Volume Range	Price
1-10,000,000	\$
10,000,001 – 50,000,000	\$
50,000,001 – 100,000,000	\$
100,000,001 +	\$

#### **Option CLIN 2001 Pricing Breakout:**

Volume Range	Price
1-10,000,000	\$
10,000,001 – 50,000,000	\$
50,000,001 – 100,000,000	\$
100,000,001 +	\$

**B.5. Delivery Schedule Milestones**

**B.5.A-** Below is a sample delivery schedule for CLIN 1001. Offerors shall update this with their proposed delivery schedule and quantities. Alternate delivery schedules are encouraged. It is anticipated that SNS warehouses cannot receive more than 30M surgical masks per month from all sources.

Delivery Period: 31 December 2021 through 30 December 2022.

CLIN	Product Type	Dec-21	Jan-22	Feb-22	Mar-22	April-22	May-22	June-22	July-22	Aug-22	Sept-22	Oct-22	Nov-22	Total
1001	Surgical Mask													127M

**B.5.B – Offerors shall provide a breakout detailing the “ramp” timeframe(s) for the optional quantities, required to manufacture and deliver additional quantities. (Which table should be labeled B.5.B)**

**Example Language:** Offeror requires a 30 day period, from time of option exercise, to ramp production and delivery to XX surgical masks per month. At 60 days, production can increase to XX surgical masks per month.

## SECTION C- STATEMENT WORK STATEMENT (SOW)

### Title: **Surgical Masks Manufactured in the U.S. or its Outlying Areas**

#### **C.1 Background**

The Strategic National Stockpile (SNS) of the U.S. Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR) is a national repository of pharmaceuticals, vaccines, medical supplies, and medical equipment stored in strategic locations around the nation. These assets are designed to supplement state and local medical supplies and equipment during public health emergencies. The supplies, medicines, and devices for lifesaving care contained in the SNS can be used as a short-term, stopgap buffer when the immediate supply of these materials may not be available or sufficient.

The mission of the SNS is to ensure the availability and rapid deployment of life-saving pharmaceuticals, antidotes, other medical supplies, and equipment necessary to counter the effects of biological, chemical, radiological, natural disasters or other emerging infectious disease agents. When state, local, tribal, and territorial public health and medical authorities request federal assistance to support their response efforts, the SNS ensures that the right medicines and supplies get to those who need them most during a public health emergency or pandemic event.

Protection of healthcare workers and first responders from transmission of pathogens is essential to maintaining resilience of the U.S. healthcare system. **Surgical Masks** are one part of an infection control strategy and are examples of personal protective equipment (PPE), which are disposable devices intended for medical purposes to protect both the patient and health care personnel from transfer of microorganisms, body fluids, and particulate material. **Surgical Masks** are fluid-resistant, disposable, and loose-fitting protection devices that create a physical barrier between the mouth and nose of the wearer and the immediate environment. The Food and Drug Administration (FDA) reviews and clears **Surgical Masks** under 21 CFR 878.4040 as Class II medical devices. The appropriate use of PPE is an important component of the overall strategy of certain infection control guidelines.

#### **C.2 Purpose**

The U.S. Government is interested in establishing multiple awards for purchase of **Surgical Masks** used in healthcare settings as described in C.3 Scope of Work. In establishing multiple awards, the Government is attempting to increase the availability of domestically produced PPE. This will enable the United States to ensure sufficient domestic availability of such items during national emergencies and/or pandemic events. The Government is concerned about the risks of disruption of any manufacturing facilities or supply chains located outside of the United States.

#### **C.3 Scope of Work**

The Contractor, as an independent organization and not as an agent of the Government, shall furnish all labor, materials, supplies, facilities, equipment, transportation and travel necessary to deliver **Surgical Masks** meeting the technical requirements of this SOW. **Surgical Masks** with attached face shields, with antimicrobial coatings, labeled for laser procedure use, and masks marketed for use under the FDA's Emergency Use Authorization or enforcement policy do not meet the technical requirements of this SOW.

#### **C.4 Product Technical Requirements**

- Salient Characteristics
  - Domestically manufactured (as defined in the solicitation), commercially available and legally marketed with a cleared 510(k) Premarket Notification
  - Disposable, single use
  - Non-sterile
  - Does not contain natural rubber latex
  - Product classification is a Class II medical device with Product Code FXX per 21 CFR 878.4040
  - Firms are appropriately registered and applicable devices listed in the FDA Establishment Registration & Device Listing Database per 21 CFR Part 807 and applicable guidance
  - Be packaged in standard commercial box of not more than 50 masks per box.

- *Barrier Protection (must be covered in the cleared 510(k) premarket notification)*
  - Barrier Protection testing for **Surgical Masks** includes Bacterial Filtration Efficiency (BFE) as directed in Test Method F2101-01; Differential Pressure (Delta-P) as directed in EN 14683:2019, Annex C; Sub-Micron Particulate Filtration Efficiency (PFE) as directed by Test Method F2299; and Resistance to Penetration by Synthetic Blood as directed in Test Method F1862
  - Designated as one of the following performance properties of the materials used in the **Surgical Mask**: Level 1 barrier, Level 2 barrier, and Level 3 barrier
    - Level 1 barrier materials are evaluated for their ability to capture sub-micron particles at  $\geq 95\%$ , resistance to penetration by synthetic blood at the *minimum* velocity 80 mmHG specified in Test Method F1862, bacterial filtration efficiency  $\geq 95\%$ , and differential pressure  $< 5.0$  mm H<sub>2</sub>O/cm<sup>2</sup>
    - Level 2 barrier materials are evaluated for their ability to capture sub-micron particles at  $\geq 98\%$ , resistance to penetration by synthetic blood at the *middle* velocity 120 mmHG specified in Test Method F1862, bacterial filtration efficiency  $\geq 98\%$ , and differential pressure  $< 6.0$  mm H<sub>2</sub>O/cm<sup>2</sup>
    - Level 3 barrier materials are evaluated for resistance to penetration by synthetic blood at the *maximum* velocity 160 mmHG specified in Test Method F1862, sub-micron particulate filtration  $\geq 98\%$ , bacterial filtration efficiency  $\geq 98\%$ , and differential pressure  $< 6.0$  mm H<sub>2</sub>O/cm<sup>2</sup>
- *Flammability (must be covered in the cleared 510(k) premarket notification)*
  - Materials used in the construction of **Surgical Masks** must meet the requirements for Class I, normal flammability specified in 16 CFR Part 1610
- *Biocompatibility (must be covered in the cleared 510(k) premarket notification)*
  - The final finished **Surgical Mask** must be demonstrated to be non-cytotoxic, non-sensitizing and non-irritating in accordance with ISO/ANSI/AAMI 10993-5 and 10993-10 and FDA's Biological Evaluation of Medical Devices Part 1: Evaluation and Testing. See Final Guidance Document referenced in Section J as attachment 2. Tests selected must be appropriate for expected duration and level of contact with the device (e.g., limited contact devices including skin). Masks must be tested on a pass/fail basis with respect to cytotoxicity, sensitization, and irritation.

### **C.5 Shelf Life**

At time of delivery, product shall have no more than 20% of total shelf-life expended.

## **SECTION D-PACKAGING, MARKING AND SHIPPING**

### **D.1 PACKING**

All postage and fees related to submission of information, including forms, and reports, etc., to the Contracting Officer or Contracting Officer's Representative (COR) or other persons designated to receive, shall be paid by the Contractor.

### **D.2 MARKINGS**

All product delivered under this contract shall be packaged, marked, and shipped in accordance with Government specifications and FDA regulations. At a minimum, each deliverable shall include the following information at time of delivery:

- (1) Ordering Agency
- (2) Packing Slip with contract number
- (3) Description of product
- (4) Contract Number
- (5) Contract Name and Address
- (6) Storage Requirements shall be on all packing lists.
- (7) Lot Numbers
- (8) Quantity
- (9) Shelf life or expiry dating data
- (10) National Drug Code (NDC) or part number
- (11) For products with an issued NSN, product cases shall have applicable NSN annotated on case and inner packages' labels. NDC numbers must also be annotated on case and inner package labels. NDCs must use the 5+4+2 standard digit methodology (xxxxx-yyyy-zz). Leading zeros may be utilized on the 5-digit section and/or the 4-digit section and/or the 2-digit section within the NDC methodology.

### **D.3 DELIVERY LOCATION & SHIPPING REQUIREMENTS**

Products shall be shipped FOB Destination. The address(es) will be provided by the COR after award and will be to a Government designated location within the continental United States (CONUS).

The contractor shall adhere to the following shipping requirements:

- a. No partial case or package quantities will be accepted unless approved by SNS in advance.
- b. No mixed lot numbers per case or per packages will be accepted.
- c. No mixed sizes (e.g., smalls, mediums, or larges mixed in on one pallet) will be accepted.
- d. One lot number will be used per pallet. The last pallet may contain multiple lot numbers per order.
- e. Lots must be clearly identified.
- f. Duplicate lots should only have one expiration date (i.e., the same two lot numbers should not have different expiry dates).
- g. Contractor shall contact designated POC for the respective address items are being delivered to to schedule delivery appointments NLT 48 hours prior to shipping any product but as far in advance as possible (delivery times are Mon – Fri 8:00 AM – 3:30 PM).
- h. All pallets are to have the identical TI-HI stack pattern except for the final pallet.
- i. All product to be delivered on standard 48" by 40" pallet, not to exceed 60" in height, stretch wrapped, and secured to pallet for safe transport.



**SECTION E - INSPECTION AND ACCEPTANCE**

**No clauses included in this section.**

**SECTION F- DELIVERIES AND PERFORMANCE****52.252-2 Clauses Incorporated by Reference (Feb 1998)**

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

<http://www.acquisition.gov>

(End of Clause)

<b>FAR SOURCE</b>	<b>TITLE AND DATE</b>
52.246-16	Responsibility for Supplies (April 1984)
52.247-34	F.O.B. Destination (Nov 1991)

## SECTION G- CONTRACT ADMINISTRATION DATA

### G.1 ADMINISTRATION

This contract will be administered by the following ASPR/DSNS personnel:

#### **Contracting Officer**

Akela Long  
 Contracts and Grants Division (C&G)  
 Office of Resource Management (ORM)  
 Assistant Secretary of Preparedness and Response (ASPR)  
 U.S. Department of Health and Human Services (HHS)  
 Email: [oga1@cdc.gov](mailto:oga1@cdc.gov) 404-498-5635 office

#### **Contracting Officer**

Annette Wright, **Team Lead**  
 Contracts and Grants Division (C&G)  
 Office of Resource Management (ORM)  
 Assistant Secretary for Preparedness and Response (ASPR)  
 U.S. Department of Health and Human Services (HHS)  
 Email: [owf8@cdc.gov](mailto:owf8@cdc.gov) 404-498-0949 office

#### **Contracting Officer's Representative (COR)/Technical Point of Contact (POC)**

David Kelley  
 Division of Strategic National Stockpile (DSNS)  
 Office of Resource Management (ORM)  
 Assistant Secretary for Preparedness and Response (ASPR)  
 U.S. Department of Health and Human Services (HHS)  
 Email: [vrb7@cdc.gov](mailto:vrb7@cdc.gov) 770-488-2662 office

### G.2 PAYMENT TERMS

#### INVOICES

##### (a) Invoice Submission

- (1) The Contractor shall submit invoices within five (5) business days after each delivery.
- (2) A proper invoice, with all required back-up documentation shall be sent electronically, via email, to the COR mailbox:
  - (i) Contracting Officer's Representative(COR): David Kelley; [vrb7@cdc.gov](mailto:vrb7@cdc.gov)
- (3) A proper invoice, not including non-invoice related documents (i.e. deliverables, reports, balance statements) shall be sent electronically, via email, to:
  - (i) Contract Officer via mailbox: Akela Long; [oga1@cdc.gov](mailto:oga1@cdc.gov)
  - (ii) Financial Management Service (FMS) [viamailbox:psc\\_invoices@psc.hhs.gov](mailto:viamailbox:psc_invoices@psc.hhs.gov)
- (4) The subject line of your email invoice submission shall contain the contract number, order number (if applicable), and the number of invoices. The email may have multiple invoices for the contract. Invoices must be in the following formats: PDF, TIFF, or Word. No Excel formats will be accepted. The electronic file cannot contain multiple invoices; example, 10 invoices requires 10 separate files (PDF or TIFF or Word).
- (5) Invoices shall be submitted in accordance with the contract terms, i.e. payment schedule, progress payments, partial payments, deliverables, etc.
- (6) All calls concerning contract payment shall be directed to the COR.
- (7) Invoices will be handled in accordance with the Prompt Payment Act (31 U.S.C. 3903) and Office of Management and Budget (OMB) prompt payment regulations at 5 CFR Part 1315.

- (1) Invoice Elements.

- (2) In accordance with FAR 52.212-4, Contract Terms and Conditions-Commercial Items, the Contractor shall submit an electronic invoice to the email addresses designated in the contract to receive invoices. A proper invoice must include the following items:
- (i) Name and address of the Contractor;
  - (ii) Invoice date and number;
  - (iii) Contract number, contract line item number and, if applicable, the order number;
  - (iv) Description, quantity, unit of measure, unit price and extended price of the items delivered;
  - (v) Shipping number and date of shipment, including the bill of lading number and weight of shipment if shipped on Government bill of lading;
  - (vi) Terms of any discount for prompt payment offered;
  - (vii) Name and address of official to whom payment is to be sent;
  - (viii) Name, title, and phone number of persons to notify in event of defective invoice; and
  - (ix) Taxpayer Identification Number (TIN). The Contractor shall include its TIN on the invoice only if required elsewhere in this contract.
  - (x) Electronic funds transfer (EFT) banking information.
- (A) The Contractor shall include EFT banking information on the invoice.
- (B) In accordance with the requirements of the Debt Collection Improvement Act of 1996, all payments under this order will be made by electronic funds transfer (EFT). The Contractor shall provide financial institution information to the Finance Office designated above in accordance with FAR 52.232-33 Payment by Electronic Funds Transfer - System for Award Management.
- (3) Additionally, the Program Support Center (PSC) requires:
- (i) The invoice to break-out price/cost by contract line item number (CLIN) as specified in the pricing section of the contract
  - (ii) The invoice to include the Dun & Bradstreet Number (DUNS) of the Contractor.

## **SECTION H—SPECIAL CONTRACT REQUIREMENTS**

### **H.1 – CONTRACTING OFFICER**

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds. No person other than the Contracting Officer can make any changes to the terms, conditions, general provisions, or other stipulations of this contract.

No information, other than that which may be contained in an authorized modification to this contract, duly issued by the Contracting Officer, which may be received from any person employed by the United States Government, or otherwise, shall be considered grounds for deviation from any stipulation of this contract.

### **H.2 – CONTRACTING OFFICER’S REPRESENTATIVE**

Performance of work under this contract is subject to the technical direction of the COR identified in Section G.1, or a representative designated by the contracting officer in writing. The term “technical direction” includes, without limitation, direction to the contractor that directs or redirects the labor effort, shifts the work between work areas or locations, and/or fills in details and otherwise serves to ensure that tasks outlined in the contract are accomplished satisfactorily. Technical direction must be within the scope of the contract specification(s)/work statement. The COR does not have authority to issue technical direction that:

- i. Constitutes additional work outside the contract specification(s)/work statement;
- ii. Constitutes a change as defined in the “Changes” clause of this contract;
- iii. Causes an increase or decrease in the contract price, or the time required for contract performance;
- iv. Interferes with the contractor’s right to perform under the terms and conditions of the contract; or
- v. Directs, supervises or otherwise controls the actions of the contractor’s employees.

Technical direction may be oral or in writing. The COR must confirm oral direction in writing within five workdays, with a copy to the contracting officer. The contractor shall proceed promptly with performance resulting from the technical direction issued by the COR, if the opinion of the contractor, any direction of the COR or the designated representative falls within the limitations above, the Contractor shall immediately notify the Contracting Officer no later than the beginning of the next Government workday. Failure of the Contractor and the Contracting Officer to agree that technical direction is within the scope of the contract shall be subjected the terms of the “Disputes” clause of this contract.

### **H.3 – CONTRACTOR PUBLICITY**

The Contractor, or any entity or representative acting on behalf of the Contractor, may not refer to the equipment or services furnished pursuant to the provisions of this contract in any news release or commercial advertising, or in connection with any news release or commercial advertising, without first obtaining explicit written consent to do so from the Contracting Officer. Should any reference to such equipment or services appear in any news release or commercial advertising issued by or on behalf of the Contractor without the required consent, the Government will consider institution of all remedies available under the contract and applicable law.

#### **H.4 – NON-DISCLOSURE AGREEMENT**

All Contractor's employees that will have access to non-public and procurement-sensitive information (photos, drawings, specifications, statements of work requirements, location data, etc.) or access to non-public ASPR facilities must sign a Non-Disclosure Agreement (NDA). The NDA will be made part of the contract file. The NDA requires contractor's employees properly identify themselves as employees of a contractor when communicating or interacting with ASPR employees, employees of other governmental entities (when communication or interaction relates to the contractor's work with ASPR/SNS), and members of the public. The Federal Acquisition Regulation (FAR) 37.114 (c), states "All contractor personnel attending meetings, answering Government telephones, and working in other situations where their contractor status is not obvious to third parties are required to identify themselves as such to avoid creating an impression in the minds of members of the public or Congress that they are Government officials, unless, in the judgment of the agency, no harm can come from failing to identify themselves. They must also ensure that all documents or reports produced by contractors are suitably marked as contractor products or that contractor participation is appropriately disclosed."

- 1) The Contractor shall inform employees of the identification requirements by which they must abide and monitor employee compliance with the identification requirements.
- 2) During the contract performance period, the Contractor is responsible to ensure that all additional or replacement contractors' employees sign a NDA and it is submitted to the Contracting Officer prior to commencement of their work with ASPR/SNS.
- 3) Contractor employees in designated positions or functions that have not signed the appropriate NDA shall not have access to any non-public, procurement sensitive information or participate in government meeting where sensitive information may be discussed.
- 4) The Contractor shall prepare and maintain a current list of employees working under NDAs and submit to the Contracting Officer upon request during the contract period of performance. The list should at a minimum include: contract number, employee's name, position, date of hire and NDA requirement.

#### **H.5 – DOMESTIC MANUFACTURING**

Contractor must be a producer or manufacturer providing items manufactured in the U.S. or its outlying areas, which means items assembled in the U.S. or its territories or tribal locations, that results in an end product where the cost of domestic components must exceed 55 percent of the cost of all the components. "Component" means an article, material, or supply incorporated directly into an end product. A "domestic component" means one that is manufactured/sourced in the United States, or its territories or tribal locations.

The U.S. and its territories include;

- (1) The fifty States;
- (2) The District of Columbia;
- (3) The commonwealths of Puerto Rico and the Northern Mariana Islands;
- (4) The territories of American Samoa, Guam, and the United States Virgin Islands; and
- (5) The minor outlying islands of Baker Island, Howland Island, Jarvis Island, Johnston Atoll, Kingman Reef, Midway Islands, Navassa Island, Palmyra Atoll, and Wake Atoll.

**SECTION I – CONTRACT CLAUSES****I.1 52.252-2 Clauses Incorporated by Reference (Feb 1998)**

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

<http://www.acquisition.gov>

<https://www.hhs.gov/grants/contracts/contract-policies-regulations/hhsar/index.html>

(End of Clause)

<b>FAR SOURCE</b>	<b>TITLE AND DATE</b>
52.204-7	System for Award Management (Oct 2018)
52.204-13	System for Award Management Maintenance (Oct 2018)
52.204-16	Commercial and Government Entity Code Reporting (Aug 2020)
52.204-18	Commercial and Government Entity Code Maintenance (Aug 2020)
52.204-21	Basic Safeguarding of Covered Contractor Information Systems (June 2016)
52.209-7	Information Regarding Responsibility Matters (Oct 2018)
52.209-12	Certification Regarding Tax Matters (Oct 2020)
52.211-17	Delivery of Excess of Quantities (Sep 1989)
52.212-4	Contract Terms and Conditions-Commercial Items (Oct 2018)
52.222-56	Certification Regarding Trafficking in Person Compliance Plan (Oct 2020)
52.232-39	Unenforceability of Unauthorized Obligations (Jun 2013)
52.232-40	Providing Accelerated Payments to Small Business Subcontractors (Dec 2013)
52.242-15	Stop-Work Order (Aug 1989)
<b>HHSAR SOURCE</b>	
352.203-70	Anti-Lobbying (Dec 2015)
352.222-70	Contractor Cooperation in Equal Employment Opportunity Investigations (Dec 2015)
352.223-70	Safety and Health (Dec 2015)
352.227-70	Publications and Publicity (Dec 2015)
352.224-70	Privacy Act (Dec 2015)
352.233-71	Litigation and Claims (Dec 2015)

## I.2 Clauses Incorporated in Full Text

### Contract Terms and Conditions Required To Implement Statutes or Executive Orders—Commercial Items. (Sep 2021)

(a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses, which are incorporated in this contract by reference, to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

(1) [52.203-19](#), Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(2) [52.204-23](#), Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 115-91).

(3) [52.204-25](#), Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (Aug 2020) (Section 889(a)(1)(A) of Pub. L. 115-232).

(4) [52.209-10](#), Prohibition on Contracting with Inverted Domestic Corporations (Nov 2015).

(5) [52.233-3](#), Protest After Award (Aug 1996) ([31 U.S.C. 3553](#)).

(6) [52.233-4](#), Applicable Law for Breach of Contract Claim (Oct 2004) (Public Laws 108-77 and 108-78 ([19 U.S.C. 3805 note](#))).

(b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

[Contracting Officer check as appropriate.]

(1) [52.203-6](#), Restrictions on Subcontractor Sales to the Government (June 2020), with Alternate I (Oct 1995) ([41 U.S.C. 4704](#) and [10 U.S.C. 2402](#)).

X (2) [52.203-13](#), Contractor Code of Business Ethics and Conduct (Jun 2020) ([41 U.S.C. 3509](#)).

(3) [52.203-15](#), Whistleblower Protections under the American Recovery and Reinvestment Act of 2009 (Jun 2010) (Section 1553 of Pub. L. 111-5). (Applies to contracts funded by the American Recovery and Reinvestment Act of 2009.)

X (4) [52.204-10](#), Reporting Executive Compensation and First-Tier Subcontract Awards (Jun 2020) (Pub. L. 109-282) ([31 U.S.C. 6101 note](#)).

(5) [Reserved].

(6) [52.204-14](#), Service Contract Reporting Requirements (Oct 2016) (Pub. L. 111-117, section 743 of Div. C).

(7) [52.204-15](#), Service Contract Reporting Requirements for Indefinite-Delivery Contracts (Oct 2016) (Pub. L. 111-117, section 743 of Div. C).

X (8) [52.209-6](#), Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment. (Jun 2020) ([31 U.S.C. 6101 note](#)).

(9) [52.209-9](#), Updates of Publicly Available Information Regarding Responsibility Matters (Oct 2018) ([41 U.S.C. 2313](#)).



- \_\_ (10) [Reserved].
- \_\_ (11) (i) [52.219-3](#), Notice of HUBZone Set-Aside or Sole-Source Award (Sept 2021) ([15 U.S.C. 657a](#)).
- \_\_ (12) (i) [52.219-4](#), Notice of Price Evaluation Preference for HUBZone Small Business Concerns (Sept 2021) (if the offeror elects to waive the preference, it shall so indicate in its offer) ([15 U.S.C. 657a](#)).
- \_\_ (13) [Reserved]
- \_\_ (14) (i) [52.219-6](#), Notice of Total Small Business Set-Aside (Nov 2020) ([15 U.S.C. 644](#)).
- \_\_ (ii) Alternate I (Mar 2020) of [52.219-6](#).
- \_\_ (15) (i) [52.219-7](#), Notice of Partial Small Business Set-Aside (Nov 2020) ([15 U.S.C. 644](#)).
- \_\_ (ii) Alternate I (Mar 2020) of [52.219-7](#).
- \_\_ (16) [52.219-8](#), Utilization of Small Business Concerns (Oct 2018) ([15 U.S.C. 637\(d\)\(2\)](#)) and (3)).
- X (17) (i) [52.219-9](#), Small Business Subcontracting Plan (Sept 2021) ([15 U.S.C. 637\(d\)\(4\)](#)).
- \_\_ (ii) Alternate I (Nov 2016) of [52.219-9](#).
- X (iii) Alternate II (Nov 2016) of [52.219-9](#).
- \_\_ (iv) Alternate III (Jun 2020) of [52.219-9](#).
- \_\_ (v) Alternate IV (Sept 2021) of [52.219-9](#)
- \_\_ (18) (i) [52.219-13](#), Notice of Set-Aside of Orders (Mar 2020) ([15 U.S.C. 644\(r\)](#)).
- \_\_ (ii) Alternate I (Mar 2020) of [52.219-13](#).
- \_\_ (19) [52.219-14](#), Limitations on Subcontracting (Sept 2021) ([15 U.S.C. 637\(a\)\(14\)](#)).
- X (20) [52.219-16](#), Liquidated Damages-Subcontracting Plan (Sept 2021) ([15 U.S.C. 637\(d\)\(4\)\(F\)\(i\)](#)).
- \_\_ (21) [52.219-27](#), Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (Sept 2021) ([15 U.S.C. 657f](#)).
- x (22) (i) [52.219-28](#), Post Award Small Business Program Representation (Sept 2021) ([15 U.S.C. 632\(a\)\(2\)](#)).
- \_\_ (ii) Alternate I (MAR 2020) of [52.219-28](#).
- \_\_ (23) [52.219-29](#), Notice of Set-Aside for, or Sole Source Award to, Economically Disadvantaged Women-Owned Small Business Concerns (Sept 2021) ([15 U.S.C. 637\(m\)](#)).
- \_\_ (24) [52.219-30](#), Notice of Set-Aside for, or Sole Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (Sept 2021) ([15 U.S.C. 637\(m\)](#)).
- \_\_ (25) [52.219-32](#), Orders Issued Directly Under Small Business Reserves (Mar 2020) ([15 U.S.C. 644\(r\)](#)).
- \_\_ (26) [52.219-33](#), Nonmanufacturer Rule (Sept 2021) ([15U.S.C. 637\(a\)\(17\)](#)).
- X (27) [52.222-3](#), Convict Labor (Jun 2003) (E.O.11755).
- X (28) [52.222-19](#), Child Labor-Cooperation with Authorities and Remedies (Jan2020) (E.O.13126).
- X (29) [52.222-21](#), Prohibition of Segregated Facilities (Apr 2015).
- X (30) (i) [52.222-26](#), Equal Opportunity (Sep 2016) (E.O.11246).

- \_\_\_ (ii) Alternate I (Feb 1999) of [52.222-26](#).
- (31) (i) [52.222-35](#), Equal Opportunity for Veterans (Jun 2020) ([38 U.S.C. 4212](#)).
- \_\_\_ (ii) Alternate I (Jul 2014) of [52.222-35](#).
- (32) (i) [52.222-36](#), Equal Opportunity for Workers with Disabilities (Jun 2020) ([29 U.S.C. 793](#)).
- \_\_\_ (ii) Alternate I (Jul 2014) of [52.222-36](#).
- (33) [52.222-37](#), Employment Reports on Veterans (Jun 2020) ([38 U.S.C. 4212](#)).
- (34) [52.222-40](#), Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496).
- (35) (i) [52.222-50](#), Combating Trafficking in Persons (Oct 2020) ([22 U.S.C. chapter 78](#) and E.O. 13627).
- \_\_\_ (ii) Alternate I (Mar 2015) of [52.222-50](#) ([22 U.S.C. chapter 78](#) and E.O. 13627).
- \_\_\_ (36) [52.222-54](#), Employment Eligibility Verification (Oct 2015). (Executive Order 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial items as prescribed in [22.1803](#).)
- \_\_\_ (37) (i) [52.223-9](#), Estimate of Percentage of Recovered Material Content for EPA–Designated Items (May 2008) ([42 U.S.C. 6962\(c\)\(3\)\(A\)\(ii\)](#)). (Not applicable to the acquisition of commercially available off-the-shelf items.)
- \_\_\_ (ii) Alternate I (May 2008) of [52.223-9](#) ([42 U.S.C. 6962\(i\)\(2\)\(C\)](#)). (Not applicable to the acquisition of commercially available off-the-shelf items.)
- \_\_\_ (38) [52.223-11](#), Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (Jun 2016) (E.O. 13693).
- \_\_\_ (39) [52.223-12](#), Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (Jun 2016) (E.O. 13693).
- \_\_\_ (40) (i) [52.223-13](#), Acquisition of EPEAT®-Registered Imaging Equipment (Jun 2014) (E.O.s 13423 and 13514).
- \_\_\_ (ii) Alternate I (Oct 2015) of [52.223-13](#).
- \_\_\_ (41) (i) [52.223-14](#), Acquisition of EPEAT®-Registered Televisions (Jun 2014) (E.O.s 13423 and 13514).
- \_\_\_ (ii) Alternate I (Jun2014) of [52.223-14](#).
- (42) [52.223-15](#), Energy Efficiency in Energy-Consuming Products (May 2020) ([42 U.S.C. 8259b](#)).
- \_\_\_ (43) (i) [52.223-16](#), Acquisition of EPEAT®-Registered Personal Computer Products (Oct 2015) (E.O.s 13423 and 13514).
- \_\_\_ (ii) Alternate I (Jun 2014) of [52.223-16](#).
- (44) [52.223-18](#), Encouraging Contractor Policies to Ban Text Messaging While Driving (Jun 2020) (E.O. 13513).
- \_\_\_ (45) [52.223-20](#), Aerosols (Jun 2016) (E.O. 13693).
- (46) [52.223-21](#), Foams (Jun2016) (E.O. 13693).
- \_\_\_ (47) (i) [52.224-3](#) Privacy Training (Jan 2017) (5 U.S.C. 552 a).

\_\_\_ (ii) Alternate I (Jan 2017) of [52.224-3](#).

(48) [52.225-1](#), Buy American-Supplies (Jan2021) ([41 U.S.C. chapter 83](#)).

\_\_\_ (49) (i) [52.225-3](#), Buy American-Free Trade Agreements-Israeli Trade Act (Jan 2021)([41 U.S.C.chapter83](#), [19 U.S.C. 3301](#) note, [19 U.S.C. 2112](#) note, [19 U.S.C. 3805](#) note, [19 U.S.C. 4001](#) note, Pub. L. 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43.

\_\_\_ (ii) Alternate I (Jan 2021) of [52.225-3](#).

\_\_\_ (iii) Alternate II (Jan 2021) of [52.225-3](#).

\_\_\_ (iv) Alternate III (Jan 2021) of [52.225-3](#).

(50) [52.225-5](#), Trade Agreements (Oct 2019) ([19 U.S.C. 2501](#), et seq., [19 U.S.C. 3301](#) note).

(51) [52.225-13](#), Restrictions on Certain Foreign Purchases (Feb 2021) (E.O.'s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).

\_\_\_ (52) [52.225-26](#), Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; [10 U.S.C. 2302](#)Note).

\_\_\_ (53) [52.226-4](#), Notice of Disaster or Emergency Area Set-Aside (Nov2007) ([42 U.S.C. 5150](#)).

\_\_\_ (54) [52.226-5](#), Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov2007) ([42 U.S.C. 5150](#)).

(55) [52.229-12](#), Tax on Certain Foreign Procurements (Feb 2021).

\_\_\_ (56) [52.232-29](#), Terms for Financing of Purchases of Commercial Items (Feb 2002) ([41 U.S.C. 4505](#), [10 U.S.C. 2307\(f\)](#)).

\_\_\_ (57) [52.232-30](#), Installment Payments for Commercial Items (Jan 2017) ([41 U.S.C. 4505](#), [10 U.S.C. 2307\(f\)](#)).

(58) [52.232-33](#), Payment by Electronic Funds Transfer-System for Award Management (Oct2018) ([31 U.S.C. 3332](#)).

\_\_\_ (59) [52.232-34](#), Payment by Electronic Funds Transfer-Other than System for Award Management (Jul 2013) ([31 U.S.C. 3332](#)).

\_\_\_ (60) [52.232-36](#), Payment by Third Party (May 2014) ([31 U.S.C. 3332](#)).

\_\_\_ (61) [52.239-1](#), Privacy or Security Safeguards (Aug 1996) ([5 U.S.C. 552a](#)).

(62) [52.242-5](#), Payments to Small Business Subcontractors (Jan 2017) ([15 U.S.C. 637\(d\)\(13\)](#)).

\_\_\_ (63) (i) [52.247-64](#), Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) ([46 U.S.C. Appx. 1241\(b\)](#) and [10 U.S.C. 2631](#)).

\_\_\_ (ii) Alternate I (Apr 2003) of [52.247-64](#).

\_\_\_ (iii) Alternate II (Feb 2006) of [52.247-64](#).

(c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

[Contracting Officer check as appropriate.]

\_\_\_ (1) [52.222-41](#), Service Contract Labor Standards (Aug 2018) ([41 U.S.C. chapter 67](#)).

\_\_\_ (2) [52.222-42](#), Statement of Equivalent Rates for Federal Hires (May 2014) ([29 U.S.C. 206](#) and [41 U.S.C. chapter 67](#)).

\_\_\_ (3) [52.222-43](#), Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (Multiple Year and Option Contracts) (Aug 2018) ([29 U.S.C. 206](#) and [41 U.S.C. chapter 67](#)).

\_\_\_ (4) [52.222-44](#), Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (May 2014) ([29 U.S.C. 206](#) and [41 U.S.C. chapter 67](#)).

\_\_\_ (5) [52.222-51](#), Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May 2014) ([41 U.S.C. chapter 67](#)).

\_\_\_ (6) [52.222-53](#), Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (May 2014) ([41 U.S.C. chapter 67](#)).

\_\_\_ (7) [52.222-55](#), Minimum Wages Under Executive Order 13658 (Nov 2020).

\_\_\_ (8) [52.222-62](#), Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706).

\_\_\_ (9) [52.226-6](#), Promoting Excess Food Donation to Nonprofit Organizations (Jun 2020) ([42 U.S.C. 1792](#)).

(d) Comptroller General Examination of Record. The Contractor shall comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, as defined in FAR [2.101](#), on the date of award of this contract, and does not contain the clause at [52.215-2](#), Audit and Records-Negotiation.

(1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor's directly pertinent records involving transactions related to this contract.

(2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR subpart [4.7](#), Contractor Records Retention, of the other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.

(3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.

(e) (1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c), and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in this paragraph (e)(1) in a subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause-

(i) [52.203-13](#), Contractor Code of Business Ethics and Conduct (Jun 2020) ([41 U.S.C. 3509](#)).

(ii) [52.203-19](#), Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(iii) [52.204-23](#), Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 115-91).

(iv) [52.204-25](#), Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (Aug 2020) (Section 889(a)(1)(A) of Pub. L. 115-232).

(v) [52.219-8](#), Utilization of Small Business Concerns (Oct 2018) ([15 U.S.C. 637\(d\)\(2\)](#) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds the applicable threshold specified in FAR [19.702\(a\)](#) on the date of subcontract award, the subcontractor must include [52.219-8](#) in lower tier subcontracts that offer subcontracting opportunities.

(vi) [52.222-21](#), Prohibition of Segregated Facilities (Apr 2015).

(vii) [52.222-26](#), Equal Opportunity (Sep 2015) (E.O.11246).

(viii) [52.222-35](#), Equal Opportunity for Veterans (Jun 2020) ([38 U.S.C. 4212](#)).

(ix) [52.222-36](#), Equal Opportunity for Workers with Disabilities (Jun 2020) ([29 U.S.C. 793](#)).

(x) [52.222-37](#), Employment Reports on Veterans (Jun 2020) ([38 U.S.C. 4212](#)).

(xi) [52.222-40](#), Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause [52.222-40](#).

(xii) [52.222-41](#), Service Contract Labor Standards (Aug 2018) ([41 U.S.C. chapter 67](#)).

(xiii) (A) [52.222-50](#), Combating Trafficking in Persons (Oct 2020) ([22 U.S.C. chapter 78](#) and E.O 13627).

(B) Alternate I (Mar 2015) of [52.222-50](#) ([22 U.S.C. chapter 78 and E.O. 13627](#)).

(xiv) [52.222-51](#), Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May2014) ([41 U.S.C. chapter 67](#)).

(xv) [52.222-53](#), Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (May 2014) ([41 U.S.C. chapter 67](#)).

(xvi) [52.222-54](#), Employment Eligibility Verification (Oct 2015) (E.O. 12989).

(xvii) [52.222-55](#), Minimum Wages Under Executive Order 13658 (Nov 2020).

(xviii) [52.222-62](#), Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706).

(xix) (A) [52.224-3](#), Privacy Training (Jan 2017) ([5 U.S.C. 552a](#)).

(B) Alternate I (Jan 2017) of [52.224-3](#).

(xx) [52.225-26](#), Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; [10 U.S.C. 2302 Note](#)).

(xxi) [52.226-6](#), Promoting Excess Food Donation to Nonprofit Organizations (Jun 2020) ([42 U.S.C. 1792](#)). Flow down required in accordance with paragraph (e) of FAR clause [52.226-6](#).

(xxii) [52.247-64](#), Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) ([46 U.S.C. Appx. 1241\(b\)](#) and [10 U.S.C. 2631](#)). Flow down required in accordance with paragraph (d) of FAR clause [52.247-64](#).

(2) While not required, the Contractor may include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(End of clause)

*Alternate I* (Feb 2000). As prescribed in [12.301\(b\)\(4\)\(i\)](#), delete paragraph (d) from the basic clause, redesignate paragraph (e) as paragraph (d), and revise the reference to "paragraphs (a), (b), (c), or (d) of this clause" in the redesignated paragraph (d) to read "paragraphs (a), (b), and (c) of this clause".

*Alternate II*. (Jul 2021) As prescribed in [12.301\(b\)\(4\)\(ii\)](#), substitute the following paragraphs (d)(1) and (e)(1) for paragraphs (d)(1) and (e)(1) of the basic clause as follows:

(d)(1) The Comptroller General of the United States, an appropriate Inspector General appointed under section 3 or 8 G of the Inspector General Act of 1978 ([5 U.S.C. App.](#)), or an authorized representative of either of the foregoing officials shall have access to and right to—

(i) Examine any of the Contractor's or any subcontractors' records that pertain to, and involve transactions relating to, this contract; and

(ii) Interview any officer or employee regarding such transactions.

(e)(1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), and (c), of this clause, the Contractor is not required to flow down any FAR clause in a subcontract for commercial items, other than—

(i) *Paragraph (d) of this clause*. This paragraph flows down to all subcontracts, except the authority of the Inspector General under paragraph (d)(1)(ii) does not flow down; and

(ii) *Those clauses listed in this paragraph (e)(1)*. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause-

(A) [52.203-13](#), Contractor Code of Business Ethics and Conduct (Jun 2020) ([41 U.S.C. 3509](#)).

(B) [52.203-15](#), Whistleblower Protections Under the American Recovery and Reinvestment Act of 2009 (Jun 2010) (Section 1553 of Pub. L. 111-5).

(C) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 115-91).

(D) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (Aug 2020) (Section 889(a)(1)(A) of Pub. L. 115-232).

(E) [52.219-8](#), Utilization of Small Business Concerns (Oct 2018) ([15 U.S.C. 637\(d\)\(2\) and \(3\)](#)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds the applicable threshold specified in FAR [19.702\(a\)](#) on the date of subcontract award, the subcontractor must include [52.219-8](#) in lower tier subcontracts that offer subcontracting opportunities.

(F) [52.222-21](#), Prohibition of Segregated Facilities (Apr 2015).

(G) [52.222-26](#), Equal Opportunity (Sep 2016) (E.O. 11246).

(H) [52.222-35](#), Equal Opportunity for Veterans (Jun 2020) ([38 U.S.C. 4212](#)).

(I) [52.222-36](#), Equal Opportunity for Workers with Disabilities (Jun 2020) ([29 U.S.C. 793](#)).

(J) [52.222-40](#), Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause [52.222-40](#).

(K) [52.222-41](#), Service Contract Labor Standards (Aug 2018) ([41 U.S.C. chapter 67](#)).

(L) \_\_\_ (1) [52.222-50](#), Combating Trafficking in Persons (Oct 2020) ([22 U.S.C. chapter 78](#) and E.O. 13627).

\_\_\_ (2) Alternate I (Mar 2015) of [52.222-50](#) ([22 U.S.C. chapter 78](#) and E.O. 13627).

- (M) [52.222-51](#), Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May 2014) ([41 U.S.C. chapter 67](#)).
- (N) [52.222-53](#), Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (May 2014) ([41 U.S.C. chapter 67](#)).
- (O) [52.222-54](#), Employment Eligibility Verification (Oct 2015) (Executive Order 12989).
- (P) [52.222-55](#), Minimum Wages Under Executive Order 13658 (Nov 2020).
- (Q) [52.222-62](#), Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706).
- (R) (1) [52.224-3](#), Privacy Training (Jan 2017) ([5 U.S.C. 552a](#)).
- (2) Alternate I (Jan 2017) of [52.224-3](#).
- (S) [52.225-26](#), Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; [10 U.S.C. 2302](#) Note).
- (T) [52.226-6](#), Promoting Excess Food Donation to Nonprofit Organizations. (Jun 2020) ([42 U.S.C. 1792](#)). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.
- (U) [52.247-64](#), Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) ([46 U.S.C. 55305](#) and [10 U.S.C. 2631](#)). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.  
(End of Clause)

#### **52.217-6 Option for Increased Quantity (Mar 1989)**

The Government may increase the quantity of supplies called for in the Schedule at the unit price specified. The Contracting Officer may exercise the option by written notice to the Contractor within 15 days in which the Contracting Officer has to exercise the option. Delivery of the added items shall continue at the same rate as the like items called for under the contract, unless the parties otherwise agree.

(End of clause)

#### **52.217-7 Option for Increased Quantity-Separately Priced Line Item (Mar 1989)**

The Government may require the delivery of the numbered line item, identified in the Schedule as an option item, in the quantity and at the price stated in the Schedule. The Contracting Officer may exercise the option by written notice to the Contractor within 30 days. Delivery of added items shall continue at the same rate that like items are called for under the contract, unless the parties otherwise agree.

(End of clause)

#### **52.217-8 Option to Extend Services (Nov 1999)**

The Government may require continued performance within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 6 months. The Contracting Officer may exercise the option by written notice to the Contractor within 30 days prior to exercise of this option, which the Contracting Officer may exercise the option.

(End of clause)

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

Attachment 1 Nondisclosure Agreement

Attachment 2 Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"



**SECTION K-REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENT  
OF OFFERORS**

**K.1 52.252-1 Solicitation Provisions Incorporated by Reference (Feb 1998)**

This solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text of those provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this/these address(es): <http://www.acquisition.gov>

(End of Provision)

**FAR SOURCE TITLE AND DATE**

FAR SOURCE	TITLE AND DATE
52.212-3	Offeror Representations and Certifications – Commercial Items (Feb 2021)

## SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO BIDDERS

### L.1 SUBMISSION INSTRUCTIONS

#### **Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (FEB 1998)**

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: <http://www.acquisition.gov>.

(End of Provision)

### L.2 FAR 52.216-1 TYPE OF CONTRACT (APR 1984)

The Government contemplates award of more than one firm fixed unit price contract resulting from this solicitation.

(End of Provision)

### L.3 PROPOSAL INFORMATION

Your proposal must be prepared in two parts: **Volume A - Technical Proposal and Volume B – Price/Business Proposal**. Each part shall be separate and complete in itself so that evaluation of one may be accomplished independently of evaluation of the other. The technical proposal must not contain reference to price or cost; however, resource information, such as data concerning categories, material, subcontracts, etc., must be contained in the technical proposal so that the offeror's understanding of the Statement of Work can be evaluated. The technical proposal must disclose the offeror's technical information in sufficient detail to provide a clear and concise presentation that addresses, but is not limited to, the requirements of the technical proposal instructions.

### L.4 ADDENDUM TO FAR 52.212-1- INSTRUCTIONS TO OFFERORS- COMMERCIAL ITEMS (SEP 2021)

1. Offerors are invited to submit a proposal in response to this solicitation. All proposals received will become part of the official file. The proposal must be signed by an official authorized to bind your organization. The offeror's transmittal and cover letter for the proposal must also contain the name, phone number, and email address of the individual to be contacted concerning any matter related to the proposal.
2. The offeror shall submit an electronic copy of the **Technical Proposal** and **Price/Business Proposal** via email to [dsnsolicitations@cdc.gov](mailto:dsnsolicitations@cdc.gov) with the subject line RFP 75A50122R00031, Domestic Surgical Masks. The Technical Proposal must be submitted in Microsoft Word or Adobe Acrobat PDF format. The Price/Business Proposal must be submitted in MS Excel with formulas intact.
3. Any questions or inquiries regarding this combined synopsis/solicitation must be addressed via email to [dsnsolicitations@cdc.gov](mailto:dsnsolicitations@cdc.gov). In the subject line of your question, include in title: RFP Questions 75A50122R00031, Domestic Surgical Masks.
4. Proposals received are subject to the requirements specified in FAR 52.212-1, unless otherwise tailored in the Addendum to the solicitation.
5. The Government intends to award multiple contracts. The Government may accept any item or group of items of an offer, unless the offeror qualifies the offer by specific limitations. Any barrier level or combination thereof are acceptable. The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit prices offered.

6. Facsimile proposals are not authorized.
7. The Government will not pay any cost for the preparation and submission of a quote. All communications concerning this project prior to the award of a contract under this combined synopsis/solicitation shall be with the Contract Specialist.
8. Proposals “Received” means that the submission is in the email inbox by the time of the deadline. Please note that there may be delays in receiving these electronic submissions through the USG email server system. Please allow for this potential delay and we encourage you to send at least an hour before deadline. Furthermore, there may be file size limitations on email servers. Please be prepared to adjust accordingly. Proposals and supporting documentation must be e-mailed directly to [dsnsolicitations@cdc.gov](mailto:dsnsolicitations@cdc.gov) no later than December 6, 2021 at 1:00 PM EST. Late submissions shall be treated in accordance with the solicitation provision at FAR 52.212-1(f), Proposals
9. All proposal parts (Technical Proposal and Price/Business Proposal) must include a Cover Page.

## L.5 TECHNICAL PROPOSAL CONTENT

In order for the technical proposal to be evaluated strictly on the merit of the material, NO PRICE INFORMATION IS TO BE INCLUDED in the TECHNICAL PROPOSAL.

The technical proposal shall be no more than 10 pages in length, excluding product literature/information documents. Each page is to be numbered and labeled with the name of the offeror in the header or footer. The technical proposal must contain the following sections, in the stated order, numbered and titled to coincide with L.6 Technical Evaluation Criteria.

## L.6 TECHNICAL EVALUATION CRITERIA

The Government will perform evaluations based on the offeror’s response to the solicitation, as described in Section M, and in accordance with the Evaluation Factors for award as described in this section. The Government will conduct the evaluation based on the proposal being considered the best value to the ASPR/DSNS through the following Evaluation factors listed in descending order and will be evaluated on how it meets the requirements outlined in the SOW.

### (1) TECHNICAL EVALUATION CRITERIA

The following criteria are in descending order of importance.

#### **Factor 1: Technical Capability**

Offerors shall provide documentation that supports the below information in accordance with the appropriate type of mask being proposed.

Mandatory Criteria	Comment
<b>Subfactor 1: Manufacturer/Producer</b>	Offerors shall have and provide their currently cleared 510(k) premarket notification information that clearly states they are the manufacturer. Additionally, offers must provide documentation that indicates the offeror is appropriately registered and the proposed devices are listed in the FDA Establishment Registration & Device Listing Database per 21 CFR Part 807 and applicable guidance.
<b>Subfactor 2: Production Schedule/Manufacturing</b>	Offerors shall provide:

<b>Capability</b>	<p>A) A proposed detailed delivery schedule that aligns with the 12-month table provided in Section B. 5 and does not exceed 30M masks per month.</p> <p>B) Their maximum monthly manufacturing &amp; delivery capabilities</p> <p>C) The quantity and timeframe the Offeror could deliver the quantity proposed if/when an option is exercised. A “ramp” time shall be provided for how quickly an offeror can manufacture and begin delivering product once an option is exercised. Monthly quantities shall not exceed 30M per month. Example Language: Offeror requires a 30-day period, from time of option exercise, to ramp production and delivery to XX surgical masks per month. At 60 days, production can increase to XX surgical masks per month.</p>
<b>Subfactor 3: Labeling</b>	<p>Offerors shall provide documentation that adequately supports and confirms the below labeling requirements. This includes clear images of product/case labeling, and images of all 6 sides of outer case and inner cartons.</p>
	<p>Surgical Mask case labeling and carton labeling shall comply with the manufacturer’s 510(k), if labeling was submitted, and must meet FDA’s general device labeling requirements per 21 CFR Part 801 (e.g., a Unique Device identifier (UDI) must be present on the outer case label and inner carton; all symbols must include adjacent text or a glossary per 21 CFR Part 801.15 (c)(1)(i)(D)(3)).</p>
	<p>Product part number shall be included on the case label, at minimum, and on the Surgical Mask carton when able, (e.g., if approved as part of the 510(k)).</p>
	<p>Surgical Mask shall be packaged and labeled in inner cartons within the outer case.</p>
	<p>Product manufacturer, lot number, and date of manufacture (and/or expiration date) shall be included on the case and carton labels.</p>
	<p>European and CE markings shall not be present on the labeling for product being marketed in the United States.</p>
<b>Subfactor 4: Natural Rubber Latex</b>	<p>Manufacturer shall provide a statement that the product does not contain any natural rubber latex, if not included on the carton label. If included on the carton label, please clearly identify.</p>
<b>Subfactor 5: Catalog and Literature</b>	<p>Offerors shall provide the product catalog and specification sheets for offered items to include product description, part number, specifications, shelf life, design description, and mask image.</p>
<b>Subfactor 6: Shelf Life</b>	<p>Offerors shall be evaluated based upon the remaining shelf-life proposed for time of delivery. The Government’s overall best value determination will consider the cost of the product as it relates to the shelf-life at time of delivery and the best value determination will also consider the time, effort, and cost to sustain product with lesser shelf-life. Offerors shall provide the expected remaining shelf-life for product at time of delivery. At time of delivery, product shall have no more than 20% of total shelf-life expended.</p>

**Factor 2: Domestic End Product Criteria**

Offerors shall provide documentation supporting their claim that this product is a domestic end product. This includes all raw material supplier names and location(s) of manufacturing, as well as locations for assembly of components. For purposes of eligibility for award, items shall be manufactured in the U.S. or its outlying areas, which means items assembled in the U.S. or its territories or tribal locations, that results in an end product where the cost of domestic components must exceed 55 percent of the cost of all the components. Component means an article, material, or supply incorporated directly into an end product. A domestic component means one that is manufactured/sourced in the United States, or its territories or tribal locations. The Offerors shall provide a breakdown of the end product where the cost of domestic components must exceed 55% of the cost of all the components. For the technical proposal, this information must be expressed in terms of percentages. Validating information that contains pricing details must be provided in the business proposal only.

***(2) PAST PERFORMANCE EVALUATION CRITERIA*****Factor 3: Past Performance Evaluation Criteria**

The Offeror shall provide a description of two projects performed within the past three years that clearly demonstrate the Offeror's past performance in performing projects of similar scope, size and complexity and domestic sourcing to the requirements described in the RFP. The following information shall be provided for each project reference:

- a) Contract number, customer/agency name and contract title;
- b) Brief narrative description of the work performed for each of those contracts, including a description of how the previous work demonstrates the Offeror's capacity to successfully meet the requirements described in the RFP and a discussion of any problems encountered/corrective actions and significant accomplishments;
- c) Dollar value, contract type, period of performance, place of performance, and the number and types of items delivered in the performance of the contract;
- d) Demonstrated experience in manufacturing of surgical masks.

***(3) PRICE EVALUATION CRITERIA*****Factor 4: Price Evaluation**

The government must evaluate each Offeror's prices to determine that those prices are fair and reasonable and to determine which Offerors' overall proposal offers the best value to the agency. Risk of excessive pricing is a major concern and Offerors are advised to pay special attention to the instructions related to pricing. The government reserves the right to reject any proposals that, in its opinion, does not offer fair and reasonable prices.

The offeror's must also include in their Business Proposal each component price and the costs associated with the components to demonstrate that the 55% criteria is met for eligibility of a domestic-end product. Offeror must provide this information in order that the government may validate offerors domestic components to determine eligibility of product meeting the definition of a domestic end product. The Government recognizes that this will not be a full price or cost breakdown, as other elements such as labor and overhead will not be shown. This information regarding components is to validate eligibility; the fairness of the price proposed will be evaluated based on competition and other price analysis techniques or procedures.

The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on the capabilities of the Offeror and a response to the Government's requirements as defined in the Statement of Work in SECTION C. At minimum, Offerors must address the technical requirements/elements (detailed in SECTION C and L).

## **L.7 PRICE/BUSINESS PROPOSAL INSTRUCTIONS**

**The price/business proposal shall be comprised of the following:**

**(a) Contract Form and Representation and Certifications**

The contract form found in Section B, and the Representations and Certifications contained in Section K, of this Request for Proposal must be executed by an official authorized to bind the offeror.

This acquisition is subject to the requirements of FAR Subpart 19.7 (The Small Business Subcontracting Program). A Subcontracting Plan shall be submitted by offerors who are large business concerns. Offerors must comply with FAR 52.219-9 Small Business Subcontracting Plan (Jun 2020). This acquisition is subject to the requirements of FAR Subpart 19.7 (The Small Business Subcontracting Program).

The HHS current subcontracting goal is 33.25% for Small Business (hereafter referred to as SB), 5.00% for Small Disadvantaged Business, including 8(a) Program Participants, Alaska Native Corporations (ANC) and Indian Tribes (hereafter referred to as SDB), 5.00% for Women-Owned Small Business and Economically Disadvantaged. Offerors shall provide past experience in meeting proposed subcontracting goals along with processes that have been implemented to correct inability to meet subcontracting goals, which will also be evaluated. Past performance in meeting or exceeding SB subcontracting goals shall be demonstrated utilizing copies of Electronic Subcontracting Reporting System (eSRS) reports. Offerors shall include most recent eSRS reports covering the last three (3) years.

The eSRS reports shall include contracts of similar size and scope to this requirement. In order to be considered for award the “successful offeror”, if an other than small business, SHALL have a subcontracting plan that complies with HHS Agency subcontracting goals for each socioeconomic category. If the apparent successful other than small business offeror fails to negotiate a subcontracting plan acceptable to the contracting officer within 30 days or other time limit prescribed by the contracting officer, the offeror will be ineligible for award.

**(b ) Price/Business Proposal Cover Sheet**

The cover sheet for the Price/Business Proposal must contain the following information:

Solicitation, contract, or modification number;  
 Name and address of offeror;  
 Name and telephone number of points of contact;  
 Name, address, and telephone number of Cognizant Contract Administration Office;  
 Name, address, and telephone number of Cognizant Audit Office;  
 Total proposed price per performance/delivery/ordering period and total for all years.

## **L.8 INCURRING COSTS**

This solicitation does not commit the Government to pay any costs for the preparation and submission of a proposal. In addition, the Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed acquisition.  
 (End of Provision)

## **L.9 FAR 52.233-2 SERVICE OF PROTEST (SEP 2006)**

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the Government Accountability Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

**Contracting Officer**

Annette Wright

Team Lead, Contracting Officer

Office of Resource Management (ORM)

Assistant Secretary for Preparedness and Response (ASPR)

U.S. Department of Health and Human Services

(HHS) Email: [owf8@cdc.gov](mailto:owf8@cdc.gov) | 404-498-0949 office

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of provision)

## SECTION M - EVALUATION FACTORS FOR AWARD

### M.1 52.212-2 EVALUATION-COMMERCIAL ITEMS (OCT 2014)

(a) The Government will award a contract resulting from this solicitation to the responsible and eligible offeror whose offer demonstrates that it can meet the mandatory criteria and will be most advantageous to the Government considering both price and the other evaluation criteria. Price is the least important of the three evaluation criteria with Factor 1, subfactors 1-6, and Factor 2, being significantly more important than price. However, as proposals become more equal in technical merit, the cost/price factor will become more important.

#### (1) TECHNICAL EVALUATION CRITERIA

##### Factor 1: Technical Capability

Offerors shall provide sufficient documentation that allows the Government to verify or confirm the proposed information as it relates to the below technical evaluation criteria in accordance with the appropriate type of surgical mask being proposed.

Mandatory Criteria	Comment
<b>Subfactor 1: Manufacturer/Producer</b>	Offerors will be evaluated based upon their status as a manufacturer with a cleared 510(k) premarket notification for the offered surgical masks.
<b>Subfactor 2: Production Schedule</b>	Offerors will be evaluated on their ability to provide a detailed delivery schedule that meets the Government's desired delivery schedule of 12 months for a base quantity, their maximum monthly delivery capabilities, and how much and quickly the Offeror can deliver the quantity proposed if/when an option is exercised. A "ramp" time shall be provided for how quickly an offeror can manufacture and begin delivering product once an option is exercised. Monthly quantities shall not exceed 30M per month.
<b>Subfactor 3: Labeling</b>	Offerors will be evaluated based upon compliance with product labeling as detailed below:
	Surgical Mask case labeling and carton labeling must comply with the manufacturer's 510(k), if labeling was submitted, and must meet FDA's general device labeling requirements per 21 CFR Part 801 (e.g. a Unique Device identifier (UDI) must be present on the outer case label and inner carton; all symbols must include adjacent text or a glossary per 21 CFR Part 801.15 (c)(1)(i)(D)(3)).
	Product part number must be included on the case label, at minimum, and on the Surgical Mask carton when able (e.g. if cleared as part of the 510(k)).
	Surgical Masks must be packaged and labeled in inner cartons within the outer case.
	Product manufacturer, lot number, and date of manufacture (and/or expiration date) must be included on the case and carton labels.
	European and CE markings must not be present on the labeling for product being marketed in the United States.



<b>Subfactor 4: Natural Rubber Latex</b>	Manufacturers will be evaluated based upon the material of the product not containing natural rubber latex.
<b>Subfactor 5: Catalog and Literature</b>	Offerors will be evaluated based upon the product catalog and specification sheets for offered items being accurate and inclusive of product description, part number, specifications, shelf life, design description, and mask image.
<b>Subfactor 6: Shelf Life</b>	Offerors will be evaluated based upon the remaining shelf-life proposed at time of delivery. The Government's overall best value determination will consider the cost of the product as it relates to the shelf-life at time of delivery and the best value determination will also consider the time, effort, and cost to sustain product with lesser shelf-life. Offerors shall provide the expected remaining shelf-life for product at time of delivery. At time of delivery, product must have no more than 20% of total shelf-life expended.

**Factor 2: Domestic End product:**

Offerors must provide a domestic end product and will be evaluated on providing an end product that is manufactured in the U.S. or its outlying areas, where the cost of domestic components must exceed 55 percent of the cost of all the components; utilizing percentages of domestic components that significantly exceed 55 percent will be taken into account in the evaluation.

Offerors shall provide documentation supporting their claim that this product is a domestic end product. This includes all raw material supplier names and location(s) of manufacturing, as well as locations for assembly of components. For purposes of eligibility for award, items shall be manufactured in the U.S. or its outlying areas, which means items assembled in the U.S. or its territories or tribal locations, that results in an end product where the cost of domestic components must exceed 55 percent of the cost of all the components. Component means an article, material, or supply incorporated directly into an end product. A domestic component means one that is manufactured/sourced in the United States, or its territories or tribal locations. The Offerors shall provide a breakdown of the end product where the cost of domestic components must exceed 55% of the cost of all the components. For the technical proposal, this information must be expressed in terms of percentages. Validating information that contains pricing details must be provided in the business proposal only.

***(2) PAST PERFORMANCE EVALUATION CRITERIA***

**Factor 3: Past Performance Evaluation Criteria**

The Offeror shall provide a description of two projects performed within the past three years that clearly demonstrate the Offeror's past performance in performing projects of similar scope, size and complexity and domestic sourcing to the requirements described in the RFP. The following information shall be provided for each project reference:

- a) Contract number, customer/agency name and contract title;
- b) Brief narrative description of the work performed for each of those contracts, including a description of how the previous work demonstrates the Offeror's capacity to successfully meet the requirements described in the RFP and a discussion of any problems encountered/corrective actions and significant accomplishments;
- c) Dollar value, contract type, period of performance, place of performance, and the number and types of items delivered in the performance of the contract;
- d) Demonstrated experience in manufacturing surgical masks.

**(3) PRICE EVALUATION CRITERIA****Factor 4: Price Evaluation**

(a) The government must evaluate each Offeror's prices to determine that those prices are fair and reasonable and to determine which Offerors' overall proposal offers the best value to the agency. Risk of excessive pricing is a major concern and Offerors are advised to pay special attention to the instructions related to pricing. The government reserves the right to reject any proposal that, in its opinion, does not offer fair and reasonable prices.

(b) Options. The Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement. The Government may determine that an offer is unacceptable if the option prices are significantly unbalanced. Evaluation of options shall not obligate the Government to exercise the option(s).

(c) A written notice of award or acceptance of an offer, mailed or otherwise furnished to the successful offeror within the time for acceptance specified in the offer, shall result in a binding contract without further action by either party. Before the offer's specified expiration time, the Government may accept an offer (or part of an offer), whether or not there are negotiations after its receipt, unless a written notice of withdrawal is received before award.

(End of provision)

**M.2 NOTICE OF INTENT TO AWARD WITHOUT DISCUSSIONS AND MAKE MULTIPLE AWARDS**

It is the intention of the Government to evaluate proposals and award a contract or contracts without conducting discussions with Contractors. The Government anticipates making a split award resulting in multiple contracts as a result of this solicitation.

(End of Provision)

**M.3 52.217-5 EVALUATION OF OPTIONS (July 1990)**

Except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests, the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement. Evaluation of options will not obligate the Government to exercise the option(s).

(End of provision)

**M.4. BASIS FOR AWARD**

This is a best value acquisition conducted in accordance with Federal Acquisition Regulation (FAR) 12.301(b)(2); the Government intends to select the best overall offer, based upon an integrated assessment of Technical and Business Proposals. The Contract will be awarded to the offeror who is deemed responsible in accordance with the FAR, whose proposal conforms to the solicitation's requirements (to include all stated terms, conditions, representations, certifications, and all other information required by Section L of this solicitation); and is judged by an overall assessment of the evaluation factors and sub factors to be most advantageous to the Government. As part of making the assessment, a best value analysis will be performed determining whether or not exceeding the minimum requirements at an associated price provides the best value to the Government. Technical proposals determined to be "**Technically Unacceptable**" will not be considered for award.