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Justification and Approval (J&A) for Other Than Full and Open Competition

Was a J&A approved for the preceding acquisition? Yes No

Is this a new or amended J&A Document? New Amended (Prior to Award Only!)

Is this a Bridge Action as defined at [AFFARS 5302.101](#)? Yes No

Dollar Value of this Acquisition: ≤ \$750K > \$750K and ≤ \$15M > \$15M and ≤ \$100M > \$100M

Contracting Activity: AFLCMC/WA

Purchase Request (if available): To Be Determined

Program / Project (and PE, if applicable): Maintain N95 Respirator Industrial Expansion Capacity

Program Type (PEO, Enterprise, of Operational): PEO

Authority: 6.302-3 – 10 USC 2304(c)(3), Industrial Mobilization; Engineering, Developmental, or Research Capability; or Expert Services

Estimated Contract Cost (including options): \$ 115M J&A Type: Class Individual

!! Provide estimated cost of all contracts.

COORDINATION ([AFFARS 5306.304\(a\)](#))

Date	Project Lead / Program Mgr / Requiring Activity YOUNG-DANIEL S. ABANATHEY AFLCMC/WAB 937-713-6268	Signature ABANATHEY.YOUNG-DANIEL.SADDE.1135544236 <small>Digitally signed by ABANATHEY.YOUNG-DANIEL.SADDE.1135544236 Date: 2021.11.22 11:48:17 -05'00'</small>
Date	Contracting Officer CHLOE D. WILLIAMS AFLCMC/WNS 937-656-8914	Signature WILLIAMS.CHLOE.D.1501967218 <small>Digitally signed by WILLIAMS.CHLOE.D.1501967218 Date: 2021.11.22 11:52:39 -05'00'</small>
Date	Local Legal Reviewer JACQUELINE M. GALL AFMC/JAQ 937-257-4744	Signature GALL.JACQUELINE.MARIE.1073075153 <small>Digitally signed by GALL.JACQUELINE.MARIE.1073075153 Date: 2021.12.01 12:32:47 -05'00'</small>
Date	Chief of the Contracting Office (COCO) ROBERT D. JOHNSON AFLCMC/WA 937-681-3213	Signature JOHNSON.ROBERT.D.1230338090 <small>Digitally signed by JOHNSON.ROBERT.D.1230338090 Date: 2021.12.17 11:40:00 -05'00'</small>
Date	Competition Advocate COL ERIC D. OBERGFELL, USAF AFLCMC/PK 937-255-7429	Signature OBERGFELL.ERIC.D.1081267347 <small>Digitally signed by OBERGFELL.ERIC.D.1081267347 Date: 2021.12.17 14:40:37 -05'00'</small>
Date	Senior Contracting Official (SCO) C. ANTHONY BRASWELL AFLCMC/PK_PZ 937-255-8344	Signature BRASWELL.C.ANTHONY.1231405425 <small>Digitally signed by BRASWELL.C.ANTHONY.1231405425 Date: 2021.12.17 16:17:34 -05'00'</small>
Date	Associate Deputy Assistant Secretary (Contracting) JOHN E. CANNADAY, SES, DAF SAF/AQC 571-256-2396	Signature CANNADAY.JOHN.ELLWOOD.III.1045749777 <small>Digitally signed by CANNADAY.JOHN.ELLWOOD.III.1045749777 Date: 2022.01.26 13:35:36 -05'00'</small>

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Justification and Approval (J&A) for Other Than Full and Open Competition

APPROVAL ([AFFARS 5306.304\(a\)](#))

Date <i>4 Feb 22</i>	DARLENE J. COSTELLO Acting Assistant Secretary of the Air Force (Acquisition, Technology & Logistics)	Signature <i>Darlene Costello</i>
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I. Agency and Contracting Activity.

The United States Air Force (USAF)
Air Force Material Command (AFMC)
Air Force Life Cycle Management Center (AFLCMC)
Program Executive Office (PEO)

II. Nature and/or description of the action being approved.

This Class Justification and Approval (J&A) for Other than Full and Open Competition is intended to result in 3 (three) new Firm-Fixed-Price (FFP) contracts each with a delivery incentive to assure the maintenance of production capacity of National Institute for Occupational Safety and Health (NIOSH) approved N95 respirators domestically for use by laboratory, medical and other critical infrastructure workers. This investment is designed to ensure that domestic production is available during a time of a need such as a public health emergency. On 13 March 2020, the President of the United States declared a national emergency concerning the novel coronavirus-19 disease (COVID-19) outbreak. As COVID-19 continues to spread within our Nation's communities, it also threatens to strain our military industrial base and healthcare infrastructure. Consequently, this J&A outlines the requirement of the United States Air Force (USAF) to maintain vital domestic industrial and healthcare facilities in business production capacity of N95 respirators and to continue to make this production capacity available to the USAF, military, and intergovernmental partners during ongoing and future health emergencies. Specifically, this J&A justifies and authorizes other than full and open competition for procurements that add or sustain specialized capacity within the Defense industrial base related to healthcare equipment, supplies, and services for the COVID-19 pandemic. This J&A encompasses health-care-related services needed to maintain the industrial complex to defeat the national pandemic and to maintain availability of critical healthcare facilities, manufacturers, and suppliers for industrial mobilization during the COVID-19 national emergency.

The anticipated period of performance (PoP) for each initial contract is 3 (three) years. Any subsequent contract will require an additional J&A authorization.

III. Description of supplies/services required to meet agency needs (including the estimated value).

Department of Health and Human Services (DHHS) has a requirement to ensure access to N95 respirators in the event of health emergencies, such as the current COVID-19 pandemic. This requirement is to maintain the initial investment of production capacity of N95 respirators and to preserve capability to rapidly ramp up production in event of an emergency. The manufacturers, Owens & Minor Halyard, 3M, and Moldex-Metric, Inc. will each provide a strategic business plan that identifies required funding needed to address how their respective company will be ready to achieve the anticipated maximum N95 demand if and when, the United States Government (USG) determines the need.

The strategic business plan will include: (1) the manufacturers maximum production capacity to manufacture NIOSH-approved, surgical and/or non-surgical N95 respirators per month, (2) the schedule and associated timeline to rapidly expand respirator production and reach full production capacity within 90 or 120 days upon request, (3) the warehousing and stocking of necessary raw materials from supplier approved sources, (4) how production lines/machines will be cycled to ensure they are validated and in good working order along with the required regulatory compliance, (5) how they will guarantee and maintain their supply chain functionality and responsibilities through contracts, and (6) how they will train and staff for full manufacturing capacity should the need arise to ramp to maximum manufacturing production capacity over the next 10 years.

As part of the contract actions contemplated under this class J&A, the USG will also require and incorporate priority access to N95 respirator stocks and production capacity for a period of 10 years after initial contract completion to

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provide the DHHS opportunities for follow-on contracts in the future.

The anticipated period of performance (PoP) for each initial contract within the scope of this class J&A is 3 (three) years. Any subsequent contract will require an additional J&A authorization.

Based on analysis of preliminary information received by each of the manufacturers, the estimated ceiling for the capacity maintenance effort is \$115M.

Owens & Minor Halyard Estimated Value \$14.34M

Moldex-Metric, Inc. Estimated Value \$38.16M

3M Estimated Value \$62.50M

The combined total estimated ceiling will be \$115M.

IV. Statutory authority permitting other than full and open competition.

The statutory authority permitting other than full and open competition is 10 USC 2304(c)(3), as implemented by FAR 6.302-3, Industrial mobilization; engineering, developmental, or research capability; or expert services.

V. Demonstration that the contractor's unique qualifications or the nature of the acquisition requires use of the authority cited above (applicability of authority).

A. IAW FAR 6.302-3(a)(2)(i), full and open competition need not be provided for when it is necessary to award a contract to a particular source to maintain a facility, producer, manufacturer, or other supplier available for furnishing supplies or services in case of a national emergency or to achieve industrial mobilization.

B. In 2020, the US Government (USG) partnered with three US companies, Owens & Minor Halyard, 3M (two contracts), and Moldex-Metric, Inc, under four contracts, to increase the US domestic National Institute for Occupational Safety and Health (NIOSH)-approved N95 respirator production capacity by roughly 57.5M masks/month. These investments included roughly \$251M for rapid response in standing up new, additional production lines for domestic production capacity expansion in response to COVID-19, specifically targeted at assets that could be maintained efficiently for utilization in responding to future health emergencies such as pandemic events. As the nation began to emerge from the pandemic and the US domestic N95 respirator production was peaking, various governmental agencies and commercial entities were able to broaden their focus from daily, regular use of N95s for respiratory protection, to looking ahead at stockpiling requirements for future pandemic response. Now that demand has leveled off, there is insufficient demand to continue to fully sustain US domestic production capacity and supporting capabilities to include earlier USG investments. The USG is seeking to optimally sustain the recent gains in production capacity as well as to further advance the US domestic N95 respirator production preparedness that can provide rapid response capabilities, including surge production, in response to future pandemics. Because the severity and duration of a future pandemic event is unknown, it is likely cost-prohibitive and potentially ineffective to rely on a stockpile alone. Establishing a reserve production capacity is necessary, and offers the greatest operational flexibility, to reduce the response lead-time required to rapidly increase domestic production.

C. Pursuant to FAR 6.302-3(a)(2)(i) and FAR 6.302-3(b)(i), the manufacturers identified in Sec. III produce medical grade NIOSH-approved N95 respirators. These respirators are paramount to reducing the spread of SARS-COV-2

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virus, especially in the clinical and laboratory environments. Since 2020, each of these manufacturers have substantially expanded their domestic manufacturing capabilities and capacities to provide N95 respirators to the US public during the COVID-19 pandemic. The effort contemplated under this class J&A is to maintain that expanded domestic reserve capacity for N95respirator production in order to maintain immediate availability of American made NIOSH N95 respirators for the current COVID-19 pandemic, and maximize domestic manufactured N95 respirator availability in a future pandemic operating environment, or during some other national event requiring increased production during the next ten years. Each manufacturer identified in Sec. III will provide a strategic business plan that identifies funding needed to address how the company will be ready to achieve the anticipated maximum N95 respirator demand if and when the USG determines there is a need. As indicated in Sec. III, the plan will include: (1) the schedule and associated timeline to rapidly expand N95 respirator production in 120 days, (2) the warehousing and stocking of necessary raw materials from supplier approved sources, (3) how production lines/machines will be cycled to ensure they are validated and in good working order along with the required regulatory compliance, (4) how they will guarantee and maintain their supply chain functionality and responsibilities through contracts, and (5) how they will train and staff for full manufacturing capacity should the need arise to ramp to maximum manufacturing production capacity during the next 10 years.

D. The 3M and Moldex-Metric, Inc. production capacity expansion contracts were awarded with a J&A utilizing FAR 6.302-2, 10 USC 2304(c)(2), Unusual and Compelling Urgency, while Owens & Minor Halyard was awarded a Technology Investment Agreement (TIA) to achieve expanded production capacity. The corresponding contracts were previously awarded to expand maintenance capacity and are therefore qualified to maintain that previously acquired capacity under this current effort. With each of the companies having developed expanded production capacity, maintaining that expanded production capacity falls within the scope of FAR 6.302-3(a)(2)(i), which provides that full and open competition need not be provided for when it is necessary to award a contract to a particular source or sources to maintain a facility, producer, manufacturer, or other supplier available for furnishing supplies or services in case of a national emergency or to achieve industrial mobilization. Pursuant to FAR 6.302-2(b)(1)(i), use of the authority is appropriate when it is necessary to keep vital facilities or suppliers in business or make them available in the event of a national emergency. The manufacturers identified in this class justification, having achieved expanded production capacity since 2020, are positioned to immediately maintain their expanded production capacity at surge levels to continue meeting the USG's needs during the current COVID-19 pandemic. The USG requires all three contractors to maintain their N95 respirator production capacity moving forward as the surge capacity demand that the USG seeks cannot be met by one contractor. Contract FA8650-20-2-5518 was awarded to Owens & Minor Halyard on 15 April 2020 to provide an increased capacity by an additional 12.5M N95 respirators/month. This contract expires 10 January 2022. Contract FA8650-20-2-5519 was awarded to 3M on 17 April 2020 and expires 10 January 2022 to provide an increased capacity by an additional 14M N95 respirators/month. Contract FA8638-20-C-0046 was also awarded to 3M on 1 May 2020 and closed 10 September 2021 to provide an increased capacity by an additional 26M N95 respirators/month, for a total additional increase of 40M N95 respirators/month. Contract FA8606-20-C-0020 was awarded to Moldex-Metric, Inc. 8 May 2020 and ended 8 May 2021 to provide an increased capacity by an additional 5M N95 respirators/month. This follow on effort for N95 respirator industrial expansion capacity maintenance is being worked to establish 3-year Firm-Fixed-Price contracts with a delivery incentive. It is anticipated to award to Owens & Minor Halyard, 3M, and Moldex-Metric, Inc. Having all three contractors on contract will also fulfill the requirement of the Department of Health and Human Services (DHHS), as no one single manufacturer among the three has the capability to produce and maintain what may be anticipated to be the full requirement of the DHHS to respond to the ongoing COVID-19 pandemic and future health emergencies.

E. Furthermore, NIOSH-approved N95 respirator availability affects the ability of laboratory and clinical workers to safely perform their duties. Laboratory and clinical workers are required to wear personal protective equipment (PPE) to protect themselves from exposure to pathogens when interacting with patients and handling clinical specimens. Without maintaining reserve N95 respirator production capacity, the domestic supply of readily available N95 respirators will continue to diminish, increasing reliance on overseas capabilities with the added risk of substandard, low quality products; delaying support to our laboratory and clinical workers; and impacting national public health security. In order to address these issues and implement reporting recommendations under

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Executive Order 14001, A Sustainable Public Health Supply Chain, and with the concurrence from the DHHS Supply Chain Industrial Base Assurance Steering Committee Chair during the review on 8 July 2021, the DHHS Assistant Secretary for Preparedness and Response has a requirement to maintain domestic reserve capacity for respiratory production.

F. The manufacturers identified in Sec. III have expanded their capacity to produce masks that are NIOSH-approved and are listed on the Food and Drug Administration (FDA) device approval list. N95 respirator products with prior NIOSH approvals decrease procurement and delivery timelines to meet public health emergencies such as the recurring COVID-19 variant surges. Maintaining expanded reserve N95 respirator production capacity with these manufacturers is necessary where the PPE industry has significant barriers to entry, demand fluctuations, and skilled/trained labor shortages; shifting consumer preferences leads to supply shortages, few new manufacturers, decreased domestic capacity, and limited commercial viability.

VI. Description of efforts made to ensure that offers are solicited from as many potential sources as practicable, including whether a notice was or will be publicized as required by subpart 5.2 and, if not, which exception under FAR 5.202 applies.

A. The DHHS Supply Chain Control Tower (SCCT), a program within the DHHS Office of the Assistant Secretary for Preparedness and Response (ASPR) employing supply chain situational awareness and analysis capability, conducted Industrial Analysis between August 2021 and October 2021. The pandemic highlighted the lack of resiliency within the N95 supply chains and the need for industrial base expansion and supply sustainment. Throughout the pandemic, manufacturers transformed their supply chains to meet the needs of the U.S. At the time the Industrial Analysis was conducted, demand started to decline for N95 respirators and manufacturers started reducing capacity, via reduction in workforce and idling production lines, leading to a potential reduction in domestic production capacity and the inability to rapidly surge production for future health emergencies.

Notwithstanding the capacity expansion efforts with Owens & Minor Halyard, 3M and Moldex-Metric, Inc., the Industrial Analysis identified the barriers to entry/expansion and demand fluctuations as key challenges to rapidly increasing N95 respirator production. The most critical challenges are around obtaining and maintaining the NIOSH/FDA certifications and the fluctuating demand.

In consideration of the results of the Industrial Analysis, on 15 October 2021, DHHS decided on a two prong acquisition approach to preserve the N95 production capacity, via: 1) follow on contract awards to the three previously awarded N95 capacity vendors: Owens & Minor Halyard, 3M, and Moldex-Metric, and 2) pursuing a competitive effort, through a commercial solutions opening, for additional industrial based expansion for N95 respirators. This two-pronged effort will ensure DHHS's current and future requirements for expanded N95 production capacity are maintained, even in consideration of circumstances like fluctuating demand.

Under its Commercial Solutions Opening (CSO) No. FA810122SC001 the Air Force has issued A01-003 N95 Respirator Industrial Base Capacity Preservation. Under the CSO, the goal is to obtain solutions to contribute to domestic capability to meet a demand target of 141M N95 respirators monthly at full manufacturing capacity but maintain a minimum viable capability at 20 - 30% of that capacity, with timelines to rapidly expand production of N95 respirators should the USG need the capability. Per the two-pronged acquisition approach, the awards to be made under the CSO, along with the awards contemplated under this justification, are intended to satisfy the total demand target of 141M N95 respirators per month.

B. Per FAR 5.202(a)(10) this J&A is utilizing FAR 6.302-3(a)(2)(i), full and open competition need not be provided for when it is necessary to award a contract to a particular source to maintain a facility, producer, manufacturer, or other supplier available for furnishing supplies or services in case of a national emergency or to achieve industrial mobilization.

C. At the time of solicitation, notice will be publicized in accordance with subpart 5.2 as required.

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D. A streamlined combination synopsis solicitation will be utilized for the resulting contracts per FAR Part 12.

VII. Determination by the Contracting Officer that the anticipated cost to the Government will be fair and reasonable.

The estimated value of each individual contract was based on an analysis of preliminary information provided by each of the manufacturers, and a comparison of the current requirement to the acquisitions mentioned above in Section V; these data were used as an early indication that the total proposed price for these actions will be fair and reasonable. The Government will continually assess costs, as required, throughout the life of each contract.

The Contracting officer will solicit each contractor for pricing information as part of the proposal and negotiate favorable terms and conditions for the Government that will subsequently be used to make a fair and reasonable determination.

The anticipated awarded contracts will be Firm-Fixed-Price (FFP) each with a delivery incentive.

VIII. Description of the market research conducted and the results, or a statement of the reasons market research was not conducted.

As detailed in Sec. VI above, DHHS SCCT conducted Industrial Analysis during October 2021 which indicated that demand had started to decline for N95 respirators which is resulting in a potential reduced capacity and reduction in workforce for the N95 respirator manufacturers.

However, the USG has achieved expanded N95 respirator production capacity with Owens & Minor Halyard, 3M, and Moldex-Metric, Inc. The Air Force is aware, through award and administration of the production capacity expansion contracts with these three manufacturers, that they are currently in a position to proceed with N95 respirator production using their fully expanded capacity. Thus, the USG is in a position to maintain production capacity and continue to meet USG COVID-19 pandemic-driven needs with awards to these three manufacturers. The USG, via the current CSO and other means, will continue to conduct market research to assess future manufacturing capability.

IX. Any other facts supporting the use of Other Than Full and Open Competition.

N/A

X. List of any sources that expressed, in writing, an interest in the acquisition.

While no sources sought or request for information (RFI) were issued for this acquisition, Owens & Minor Halyard, 3M, and Moldex-Metric, Inc. have expressed interest on prior efforts identified in paragraph V of this J&A.

XI. A statement of the actions, if any, the agency may take to remove or overcome any barriers to competition before making subsequent acquisitions for the supplies or services required.

Market research will continue to be conducted for similar acquisitions in the future. Specifically, the Department of Health and Human Services (DHHS) and Joint Rapid Acquisition Cell (JRAC) intend to also qualify additional source(s) of N95 Respirators; through use of the Department of the Air Force Acquisition COVID-19 Task Force's (DAF ACT) Commercial Solutions Opening (CSO) process of soliciting for solution briefs to a publicized Area of Interest (AOI).

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XII. Certification by the Contracting Officer.

As evidenced by my signature above, I have determined this document to be both accurate and complete to the best of my knowledge and belief.

XIII. Certification by the technical/requirements personnel.

As evidenced by my (our) signature(s) above, I (we) certify that any supporting data contained herein, which is my (our) responsibility, is both accurate and complete.