

**IN THE UNITED STATES COURT OF FEDERAL CLAIMS  
BID PROTEST**

|                                   |   |                |
|-----------------------------------|---|----------------|
| AIRBOSS DEFENSE GROUP, LLC,       | ) |                |
|                                   | ) |                |
| Plaintiff,                        | ) |                |
|                                   | ) |                |
| and                               | ) |                |
|                                   | ) |                |
| STRING KING LACROSSE LLC,         | ) |                |
|                                   | ) |                |
| Plaintiff-Intervenor              | ) |                |
|                                   | ) |                |
| v.                                | ) | No. 24-365     |
|                                   | ) | (Judge Lettow) |
|                                   | ) |                |
| THE UNITED STATES,                | ) |                |
|                                   | ) |                |
| Defendant,                        | ) |                |
|                                   | ) |                |
| and                               | ) |                |
|                                   | ) |                |
| NEW YORK EMBROIDERY STUDIO, INC., | ) |                |
|                                   | ) |                |
| Defendant-Intervenor.             | ) |                |

**SECOND AMENDED COMPLAINT**

Plaintiff, AirBoss Defense Group, LLC (“ADG”), by and through its undersigned counsel, brings this pre-award bid protest action against Defendant, the United States of America, acting by and through the U.S. Department of Health and Human Services, Administration for Strategic Preparedness and Response (collectively, “HHS” or the “Government”).

On May 31, 2024, HHS released Amendment 0009 to Request for Proposal No. 75A50322R00008 for Level 2 Isolation Gowns (the “Solicitation” or “RFP”). Amendment 0009 suspends the prior solicitation in its entirety and directs offerors in the competitive range to submit new proposals by June 17, 2024. As described in detail below, Amendment 0009 includes requirements that are arbitrary, capricious, unduly restrictive of competition, an abuse of discretion, or otherwise not in accordance with law. ADG seeks permanent injunctive relief

preventing HHS from proceeding with the procurement. ADG does not seek emergency injunctive relief at this time.

### **INTRODUCTION**

1. The Solicitation seeks proposals to supply the Strategic National Stockpile (“SNS”) with ANSI/AAMI PB70 Level 2 Isolation Gowns (“Level 2 Isolation Gowns”) that are domestically manufactured with 100% domestic components.<sup>1</sup>

2. Level 2 Isolation Gowns are commercial products, and the Government issued the Solicitation under FAR Part 12’s procedures for the acquisition of commercial products.

3. ADG served as one of the primary government suppliers of personal protective equipment (“PPE”) during the declared COVID-19 Public Health Emergency. As a contractor to HHS, ADG has supplied over 150,000 powered respirators and over 3.6 million filters. In particular, ADG has a history of competing in procurements for medical gowns. In 2021, ADG first formed a coalition of small and large businesses to offer a proposal in response to HHS’s solicitation for Level 3 and Level 4 Surgical Gowns to supply the SNS. HHS publicly announced in November 2021 that the Government was entering into negotiations with ADG to supply the Level 3 and Level 4 gowns with the intent to award a contract, which HHS reaffirmed on January 14, 2022. As explained above, Level 3 and 4 gowns require higher protection ratings and thus have stricter testing criteria than the Level 2 gowns required by this procurement.

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<sup>1</sup> Isolation gowns are used in the healthcare setting to promote infection control practices and help protect patients and healthcare workers against microorganisms and bodily fluids during routine care, examinations, and medical procedures. The American National Standards Institute/Association for the Advancement of Medical Instrumentation (“ANSI/AAMI”) PB70 established a classification for isolation gowns that is based on the individual gown’s liquid barrier protection. The ANSI/AAMI PB70 incorporates four standard tests that determine the level of protection. Based on the result of the tests, an isolation gown falls within one of four categories of protection with Level 1 being the lowest level of protection and Level 4 being the highest level of protection. Here, the Solicitation calls for the provision of domestic isolation gowns with a protection rating of Level 2.

4. HHS issued Amendment 0009 only to those offerors within the competitive range, which includes ADG, and provided those offerors the opportunity to submit revised Technical and Business Proposals. As discussed below, Amendment 0009 includes requirements that are arbitrary, capricious, unduly restrictive, an abuse of discretion, or otherwise not in accordance with law. The Court should sustain this protest and enjoin HHS from proceeding with the procurement until it amends the Solicitation to comply with applicable procurement law.

### **PARTIES**

5. ADG is a limited liability company organized and existing under the laws of Maryland with its principal place of business located at 8261 Preston Court, Jessup, MD 20794.

6. ADG provides healthcare, security, and military customers around the world with an optimized mix of mission-critical consumables, durable major equipment, and deployed sustainment and service support. ADG is a recognized leader in chemical and biological PPE, rapid deployment decontamination systems, and respiratory protective solutions. ADG has successfully provided emergency response and protective solutions to HHS, the Department of Defense, the Federal Emergency Management Agency, the U.S. Department of State's Office of Strategic Medical Preparedness, Centers for Disease Control and Prevention infectious disease treatment centers, as well as numerous commercial healthcare providers in the United States and abroad. ADG has played a significant role in the U.S. COVID-19 response, supplying 150,000 Powered Air-Purifying Respirators and over three million P100 HEPA filters for urgent PPE supply initiatives and Strategic National Stockpile development.

7. Defendant is the United States of America, acting by and through the U.S. Department of Health and Human Services, Administration for Strategic Preparedness and Response, an agency of the Federal Government.

### **JURISDICTION & STANDING**

8. This Court has jurisdiction over this action pursuant to 28 U.S.C. §1491(b).

9. ADG is an interested party within the meaning of 28 U.S.C. §1491(b). ADG is a prospective bidder that HHS has found to be within the competitive range and thus ADG has a direct economic interest in the procurement. ADG will suffer a non-trivial competitive injury if the arbitrary, capricious, unduly restrictive, and unlawful terms in Amendment 0009 are not remedied.

10. This protest is timely filed prior to the deadline for submission of proposals.

### **FACTUAL BACKGROUND**

#### **A. The Solicitation**

11. HHS initially issued the Solicitation on June 28, 2022.

12. On October 31, 2022, HHS issued Amendment 0005, which included a revised Solicitation superseding the previously released RFP. AR 269.

13. On November 16, 2022, HHS issued Amendment 0007, which revised the product quantity, delivery schedule requirements, the Statement of Work, and the evaluation factors. AR 320.

14. On May 31, 2024, the Government issued Amendment 0009, which suspends the prior Solicitation in its entirety and directs offerors in the competitive range to submit new proposals by June 17, 2024. *See* Ex. 1 (Amendment 0009).

15. The commercial product Solicitation calls for up to 75,200,000 Level 2 Isolation Gowns plus an optional quantity of up to 150,400,000 Level 2 Isolation Gowns. The purpose of the procurement is to support the SNS, a national repository of pharmaceuticals, vaccines, medical supplies, and medical equipment, such as the Level 2 Isolation Gowns. The SNS is designed to supplement state and local medical supplies and equipment during public health emergencies.

16. Because of the importance of the SNS, the Solicitation emphasized that the contract awardee must have the capacity to meet increased demand. The Solicitation provides: “The Contractor must be capable of responding to unanticipated demands for increased capacity within existing capabilities covered under this SOW that may require a ‘surge’ in efforts and/or resources. If accelerated or increased quantities are required, the Government will determine the estimated need that is required.” *Id.* at 7.

17. The Solicitation includes technical requirements that set forth the requirements for non-sterile, disposable gowns, used to protect healthcare personnel and patients from the transfer of microorganisms and body fluids in routine patient care in healthcare settings.

18. Section L.4 of the Solicitation includes the instructions for the offerors’ technical proposals. Technical proposals include three factors: Factor 1: Technical Compliance Domestic End Product Criteria; Factor 2: Technical Capability; and Factor 3: Similar Experience. Factor 2 has eight Subfactors:

- a. Subfactor 1: Manufacturer/Producer
- b. Subfactor 2: Production Schedule/Manufacturing Capability
- c. Subfactor 3: Labeling and Packaging
- d. Subfactor 4: Not Made With Natural Rubber Latex
- e. Subfactor 5: Catalog and Literature
- f. Subfactor 6: Shelf Life
- g. Subfactor 7: Test Reports
- h. Subfactor 8: Biocompatibility Report/Plan.

*Id.* at 41-46.

19. Section M sets forth the Evaluation Factors for Award of the Solicitation. Section M provides:

The Government will award a contract resulting from this solicitation to the responsible 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 factors. The Government may award any resulting contract to other than the lowest priced offerors, or other than the offeror with the highest non-price rating. Price is the least important of the four (4) evaluation factors with Factor 1-

being significantly more important than price. However, as proposals become more equal in their non-price factors, the price factor will become more important.

*Id.* at 49.

20. The Solicitation emphasizes that this procurement is a “best value acquisition conducted in accordance with Federal Acquisition Regulation (FAR) 12.602; the Government intends to select the best overall offer, based upon an integrated assessment of Technical and Business Proposals.” *Id.* at 54. The Solicitation further provides that a contract will be awarded to the offeror whose proposal “is judged by an overall assessment of the evaluation factors and sub factors to be most advantageous to the Government.” *Id.*

## **B. Procurement History**

21. Offerors initially submitted proposals in November 2022. On September 25, 2023, HHS made a single contract award of Contract No. 75A50323C00013 to New York Embroidery Studio (“NYES”). AR 1347. HHS awarded NYES a base quantity of 75,200,000 gowns at \$1.98 per gown for a total price of \$148,896,000, with additional options for increased quantities.

22. On September 26 and 27, 2023, HHS sent ADG and the other offerors Unsuccessful Offeror Notices. AR 1380-1415. ADG timely requested a debriefing and, on September 29, 2023, HHS provided ADG a written debriefing explaining that HHS [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]. AR 1417.

23. ADG filed an initial protest challenging HHS’s evaluation and award decision at the U.S. Government Accountability Office (“GAO”) on October 4, 2023. GAO docketed ADG’s October 4 protest as B-420935.4. AR 1499. HHS issued NYES a Stop Work Order on October 5, 2023. AR 1437.

[REDACTED]

24. ADG filed supplemental protests at GAO identifying additional defects in HHS's evaluation and award decision on October 10, 2023 (AR 1619), and October 20, 2023 (AR 1624). GAO docketed ADG's October 10 and 20 protests as B-420935.7 and B-420935.10, respectively.

25. In addition to ADG's protests, five other contractors filed protests challenging HHS's award decision, String King Lacrosse LLC ("StringKing") (AR 1438, 1457), Atlantic Trading, Essential Safety PPE ("Essential"), Gredale, and Health Supply US. GAO docketed these other protests as B-420935.2-.3, .5-.6, and -.8-.9.

26. On October 27, 2023, prior to the filing of an administrative record in ADG's GAO protest, HHS filed a Notice of Corrective Action and Request for Dismissal. AR 1629.

27. HHS's Notice of Corrective Action stated that HHS had determined that corrective action was warranted based on the protests and stated that HHS would:

- a. Reconsider the Agency's technical evaluation of proposals, specifically relating to the findings which were challenged and, to the extent necessary, issue an amended Technical Evaluation Panel Report;
- b. After reconsidering the proposal evaluation findings, determine (within the Agency's discretion) whether discussions or additional clarifications are necessary;
- c. Make a new source selection decision; and
- d. Take other actions, as deemed necessary and appropriate by the Agency.

28. ADG did not object to HHS's proposed corrective action, and GAO dismissed all of the protests regarding the award to NYES as academic on November 3, 2023. AR 1636-1647.

29. On November 13, 2023, StringKing filed an agency-level protest arguing that HHS had failed to take the corrective action HHS had committed to in response to StringKing's GAO protest. AR 1648. Specifically, StringKing argued that HHS had failed to cancel the contract award to NYES despite having represented in HHS's Notice of Corrective Action filed at GAO that HHS would make a new source selection decision. *Id.*

**C. HHS's February 2024 Competitive Range Decision**

30. ADG heard nothing from HHS until February 16, 2024, when ADG received a letter from HHS advising ADG that HHS had completed its initial review of proposals in connection with its corrective action, had found ADG's proposal [REDACTED] [REDACTED] AR 1904. ADG timely requested a debriefing and, on February 21, 2024, HHS provided ADG with a written debriefing letter.

31. After establishing the competitive range, which included [REDACTED] [REDACTED] HHS issued Amendment 0008 only to those offerors within the competitive range. AR 1916. Amendment 0008 revised the Solicitation to removed shelf-life as a consideration for HHS when conducting its best value determination. AR 917. Amendment 0008 also permitted offerors within the competitive range to submit revised Technical Proposals.

32. HHS never issued a decision on StringKing's agency-level protests, instead dismissing it as moot on February 20, 2024, citing the issuance of Amendment 0008.

33. On February 26, 2024, StringKing filed at pre-award protest at GAO challenging the terms of Amendment 0008 and arguing that HHS had improperly modified the Solicitation by removing shelf life from the evaluation criteria for Factor 4 (Price) and from the best value determination. AR 1923.

34. On February 28, 2024, [REDACTED] submitted revised Technical Proposals. AR 1950-2013.

**D. ADG's First Complaint Before this Court**

35. ADG timely filed its initial Complaint before this Court on March 7, 2024, which it amended on March 25, 2024. ADG sought permanent declaratory and injunctive relief to remedy HHS's arbitrary and unlawful decision to [REDACTED]

36. On March 28, 2024, the Government filed a Notice of Corrective Action and Motion to Suspend Future Deadlines in this protest. ECF No. 27. The Government represented that it was:

- a. Canceling Request for Proposals No. 75A50322R00008;
- b. Terminating the award to defendant-intervenor New York Embroidery Studio, Inc. (NYES) (Contract No. 75A50323C00013), made under the agency's 2023 award decision, which has been under a stop work order since October 5, 2023;
- c. Reviewing and reconsidering the agency's requirement for isolation gowns, to include shelf-life considerations, which will likely include additional and/or updated market research;
- d. Preparing a new or revised acquisition plan for a new solicitation; and
- e. Taking other actions, as deemed necessary and appropriate by the agency.

37. HHS filed a similar notice in response to StringKing's GAO protest, leading GAO to dismiss the protest on April 9, 2024. AR 2011.

38. On April 15, 2024, the Government reversed course and determined it would not cancel the Solicitation and instead would reconsider its competitive range determination within thirty days, issue an amendment to the solicitation revising the current requirements, engage in discussions as needed, and solicit revised final proposals. ECF No. 31.

39. On April 23, 2024, Plaintiff-Intervenor StringKing filed a Complaint in this Court outlining its challenges to HHS's issuance of Amendment 0008 and HHS's competitive range determination.

40. On April 26, 2024, the Government again changed its timeline to take corrective action and informed the Court that HHS's intended corrective action schedule includes the following:

- a. By May 10, 2024, HHS will make a new competitive range determination and notify offerors who are in the competitive range.
- b. By the end of May 2024, HHS will issue an amendment to the solicitation to offerors in the competitive range. As part of the amendment, HHS intends to revise the current shelf-life requirements, further clarify the current sleeve

length and device registration requirements, allow offerors to submit solicitation questions, and allow offerors to submit revised proposals.

- c. By the end of July 2024, HHS will evaluate revised proposals and make a new award decision.

ECF No. 38.

41. On May 6, 2024, the Court issued an Order directing the Government to file the Administrative Record in this case by May 10, 2024. ECF No. 42.

42. After a request for an extension of time, which the Court granted, the Government filed the Administrative Record on May 24, 2024. ECF No. 48.

**E. Amendment 0009**

43. On May 30, 2024—twenty days after the Government said in its April 26 filing it would make a new competitive range determination—the Government finally notified ADG that the Government had revised its prior competitive range determination and that HHS [REDACTED]

44. On May 31, 2024, HHS issued Amendment 0009 to the Solicitation. *See* Ex. 1.

45. Amendment 0009 suspends the prior solicitation in its entirety and directs offerors in the competitive range to submit new technical and business proposals by June 17, 2024.

46. Amendment 0009 provides that the Solicitation is being amended to “revise the shelf-life requirements, clarify gown dimensions, clarify device registration requirements, clarify labeling requirements, delete the volume discount tables in Section B.4, make minor clarifications as needed to update language and dates and to update to the current clauses.” Ex. 1 at 2.

47. On June 4, 2024, ADG, through the undersigned counsel, alerted the Government’s counsel to several defects in, and other issues with, Amendment 0009. Ex. 2 (June 4, 2024 Email). ADG noted that Amendment 0009 (a) indicates that the Solicitation was partially set aside for small businesses; (b) is ambiguous regarding how sleeve length is to be measured;

and (c) fundamentally alters the nature of the Isolation Gowns that HHS seeks to procure by eliminating shelf-life as an evaluation criteria. *Id.* at 6-7. ADG indicated that it would file a Second Amended Complaint in this case and requested an indefinite extension of the due date for submission of proposals until the resolution of this litigation. *Id.*

48. ADG's June 4 email also noted that the administrative record indicates that HHS and NYES are currently negotiating some sort of payment by HHS to NYES that would improperly and unfairly subsidize NYES's costs for this procurement. ADG's June 4 email requested that HHS agree not to make any payment of money to any offeror in connection with this procurement until this litigation is resolved. *Id.* at 7.

49. On June 5, 2024, ADG submitted questions to HHS regarding Amendment 0009.

50. On June 6, 2024, the Government responded to ADG's June 4 email indicating that the Government would amend the Solicitation to state that it was not set aside for small businesses, and that the Government was considering "a short extension of the due date for proposal submissions to give offerors additional time to consider the agency's answers" to questions received by offerors regarding Amendment 0009. *Id.* at 1. The Government refused to agree to not make any payment to NYES during the pendency of this litigation. *Id.*

51. On June 7, 2024, HHS issued Amendment 0010 to the Solicitation, which states that the Solicitation is not set aside, in whole or in part, to small business. Ex. 3 (Amendment 0010). Amendment 0010 does not address any of the other concerns identify by ADG in its June 4 email.

## **CLAIMS FOR RELIEF**

### **COUNT I**

#### **Amendment 0009 Contains A Patent Ambiguity.**

52. ADG incorporates the foregoing paragraphs by reference as though fully restated herein.

53. Amendment 0009 provides that gown dimensions “shall be measured with the Isolation Gown laying flat with the back closed and gown dimensions reported in inches. Isolation Gown dimensions must meet the minimum to maximum ranges below.” Ex. 1 at 12. Regarding sleeve length, Amendment 0009 provides that, “[f]or large Isolation Gowns, the finished sleeve length shall be 21-24 inches. For extra-large Isolation Gowns, the finished sleeve length shall be 23-25 inches.” *Id.*

54. Amendment 0009 contains no point of reference for where sleeve length should be measured from (*e.g.*, collar to cuff, shoulder to cuff, under arm to cuff, *etc.*).

55. Previously, Amendment 0005 provided that: “Isolation Gown dimensions must meet gown length, chest width, and sleeve lengths commonly used in the commercial industry, per the specific size. Dimensions that do not meet the minimum or that significantly exceed the minimum length, chest, width, and sleeve length will not be considered.” AR 281. Regarding sleeve length, Amendment 0005 explained that “[l]arge and extra-large gown sizes should reflect dimensions currently available in the commercial market. Examples of approximate gown dimensions include chest width: large 27 inches and extra-large 30-31 inches; sleeve length: large 22-23 inches and extra-large 24 inches; and gown length 46 inches.” *Id.*

56. In revising the Solicitation, HHS removed any requirement that gown dimensions shall comply with common industry standards, despite this bring a procurement for commercial products. Further, instead of providing examples of approximate gown dimensions, Amendment 0009 mandates an arbitrary sleeve length of 21-24 inches for large gowns, and 23-25 inches for extra-large gowns. Ex. 1 at 12.

57. As is common industry practice, in ADG’s November 22, 2022 proposal, ADG [REDACTED]. AR 357.

58. In both its protest before this Court and in its previous protests before GAO, ADG provided HHS with an exhibit showing that multiple other gowns commonly sold in the commercial market [REDACTED]. ECF No. 1 at Ex. 10.

59. In both HHS's initial evaluation of ADG's proposal and in HHS's evaluation following its corrective action, HHS ignored the common industry practice and deemed ADG's proposal [REDACTED]

[REDACTED] AR 1200, 1724, 1853. HHS appeared to have been relying solely on the "examples" of sleeve lengths provided in the RFP and obtusely ignored the fact that ADG's gowns [REDACTED].

60. In fact, HHS knew that its evaluation of ADG's proposal was likely wrong because [REDACTED] [REDACTED]

[REDACTED] The Government, however, never sought that clarification from ADG.

61. When ADG protested HHS's evaluation of sleeve length at GAO, HHS elected to take corrective action and stated that it would "[r]econsider the Agency's technical evaluation of proposals, specifically relating to the findings which were challenged" by ADG. AR 1629.

62. HHS never sought dismissal of ADG's protest grounds on the basis that ADG's interpretation of the sleeve length provision was unreasonable. Instead, by representing to GAO that HHS would "reconsider" its evaluation and that HHS's reconsideration rendered ADG's protest "academic," HHS acknowledged to GAO that ADG's interpretation of these provisions was, in fact, reasonable, and that there was a reasonable possibility that ADG would be awarded a contract.

63. Yet despite HHS's acknowledgment that ADG's interpretation of the sleeve length requirement was reasonable, HHS again found [REDACTED]

AR 1724.

64. In both its Complaint and Amended Complaint filed before this Court, ADG challenged HHS's interpretation that ADG's sleeve length did not comply with the requirements of the RFP.

65. Despite representing to the Court that it would "further clarify the current sleeve length" requirements in the Solicitation, ECF No. 37 at 2, HHS has failed to address the ambiguity that ADG has identified in its protests. Amendment 0009 provides no indication of how offerors should measure the sleeve length of proposed gowns and does not identify the point of measurement for the minimum and maximum dimensions identified in Amendment 0009.

66. A patent ambiguity is "present when the contract contains facially inconsistent provisions that would place a reasonable contractor on notice and prompt the contractor to rectify the inconsistency by inquiring of the appropriate parties." *Stratos Mobile Networks USA, LLC v. United States*, 213 F.3d 1375, 1381 (Fed. Cir. 2000). When a solicitation contains a patent ambiguity, the offeror has "a duty to seek clarification from the government, and its failure to do so precludes acceptance of its interpretation" in a subsequent court action. *Blue & Gold Fleet, L.P. v. U.S.*, 492 F.3d 1308, 1313 (Fed. Cir. 2007) (quoting *Stratos Mobile Networks*, 213 F.3d at 1381).

67. On June 4, 2024, ADG alerted the Government to the ambiguity in Amendment 0009 regarding how sleeve length is measured, writing "despite the fact that ADG's protests at GAO and the Court specifically alleged that the solicitation is ambiguous regarding how sleeve length is to be measured (from the collar, shoulder, underarm, spine, etc.), Amendment 0009

attempts to impose a more narrow range of acceptable sleeve length without specifying the point of measurement. ADG therefore has no way to be certain what gowns will or will not satisfy Amendment 0009.” Ex. 2 (June 4, 2024 Email).

68. To date, Offerors have received no clarification from the Government regarding this ambiguity.

**COUNT II**  
**HHS’s Sleeve Length Requirements are Inconsistent with Customary Commercial Practice in Violation of FASA and FAR Part 12.**

69. ADG incorporates the foregoing paragraphs by reference as though fully restated herein.

70. The Federal Acquisition Streamlining Act of 1994 (“FASA”), and its implementing regulations found at FAR Part 12, require the Federal government to purchase commercial items under commercial terms to the extent practicable. 41 U.S.C. § 3307(e)(2)(B); FAR 12.301(a).

71. Specifically, FAR Part 12 requires that “contracts for the acquisition of commercial products or commercial services shall, to the maximum extent practicable, include only those clauses” required by law or “[d]etermined to be consistent with customary commercial practice.” FAR 12.301(a). It also precludes inclusion of “any additional terms or conditions in a solicitation or contract for commercial items in a manner that is inconsistent with customary commercial practice for the item being acquired unless a waiver is approved in accordance with agency procedures.” FAR 12.302(c).

72. Further, when acquiring commercial items, the agency must “[c]onduct market research to determine whether commercial products, commercial services, or nondevelopmental items are available that could meet the agency’s requirements.” FAR 12.101(a). Thus, the agency must use the market research in evaluating whether a solicitation’s terms are consistent with customary commercial practice.

73. Amendment 0009 provides “[f]or large Isolation Gowns, the finished sleeve length shall be 21-24 inches. For extra-large Isolation Gowns, the finished sleeve length shall be 23-25 inches.” Ex. 1 at 12.

74. The minimum and maximum sleeve length dimensions required by Amendment 0009 are inconsistent with customary commercial practice, and HHS’s market research, as reflected in the Administrative Record, does not support the required dimensions. Nor does the market research support HHS’s arbitrary decision not to allow for the various different points of measurement for sleeve length used in the commercial market, despite ADG raising this issue in its GAO protests and its Complaint and First Amended Complaint in this case.

75. The Administrative Record includes HHS’s Market Research Report which details the market research HHS conducted before issuing the original Solicitation, but the report does not mention product dimensions, let alone sleeve length. The Report does not include any documents or information establishing that Amendment 0009’s required sleeve lengths reflect customary commercial practice. *See* AR 11-18. Nor does the report provide any support for HHS’s decision to require offerors to guess the point of measurement for HHS’s mandatory dimensions (which have no basis in the commercial market). *Id.*

76. Specifically, the Market Research Report states that SNS “held market research discussions with FDA in an effort to understand current industry capabilities and potential vendors of domestically manufactured isolation gowns” and that “ASPR reached out to the vendors FDA indicated as showing in their pre-market database as having domestic manufacturing for medical gowns . . . requesting capabilities and location of manufacturing to further understand current industry capabilities.” AR 12. The report also states that SNS performed further research within GSAAdvantage, SAM.gov, previous contracts, the VA National Acquisition Center “for potential capable vendors and pricing information.” *Id.* The ASPR Supply Chain Control Tower and

Innovation and Industrial Expansion Branch also performed supply chain research and analysis. *Id.*

77. Nothing in the Market Research Report states that this research yielded information about gown sleeve lengths common to the commercial market or the point measurement for sleeve length that is customary commercial practice.

78. Moreover, the Market Research Report concedes that some of the information gathered may be inaccurate, explaining that “FDA did provide a disclaimer and made SNS aware that the database used to identify the[] vendors is data directly input by vendors and may be inaccurate, did not indicate the type of gown (surgical or isolation), and did not indicate at which level of protection the manufactured gowns were being made.” *Id.* at 14.

79. The Market Research Report also states that in June 2021, Contracting Officer Annette Wright issued a Request for Information for isolation and surgical gowns, which received 68 responses. *Id.* The results were reviewed by the SNS Science team, which “developed a summary of the results in both written and Excel spreadsheet form.” *Id.* at 12.

80. The SNS Science Team’s summaries are not included in the Administrative Record, and the Market Research Report does not include any indication that the summaries include conclusions about the customary commercial practice for gown sleeve lengths or points of measurement.

81. In a Notice of Corrective Action filed on March 28, 2024, Defendant explained that HHS’s corrective action “will likely include additional and/or updated market research,” but the Administrative Record demonstrates that the Government did not conduct any further market research to support the requirements in Amendment 0009. ECF No. 27.

82. Moreover, ADG has identified numerous examples of Level 2 Isolation Gowns sold in the commercial market that have sleeve lengths that differ from Amendment 0009’s

requirements and/or use different points of measurement than HHS appears to be using. For example:

- a. Gilman Gear's Disposable Isolation Gown, size XL sleeve length 27 inches measured from the shoulder to thumbhole.
- b. Medicom's Isolation Gown, size L sleeve length 65 centimeters (25.6 inches) measured from the shoulder to cuff.
- c. Safety Pure's Non Sterile Isolation Gown – Level 2, shoulder and sleeve length 33 inches.
- d. AllHeart's Urbane Essentials Unisex Medical Isolation Gown, sleeve length 34  $\frac{3}{4}$  inches.
- e. KSE Suppliers' Level II Isolation Gown, sleeve length 32 inches measured from collar to cuff; and 20 inches measured from armpit to cuff opening.

Ex. 4 (Commercially Available Gown Dimensions).

83. In addition, multiple other offerors' proposals include gowns with sleeve lengths that differ from Amendment 0009's requirements:

- a. [REDACTED]
- b. [REDACTED].

84. The Administrative Record does not contain any evidence that HHS obtained or even sought a waiver to include terms inconsistent with customary commercial practice as required by FAR 12.302(c).

85. As explained above, Amendment 0009's minimum and maximum sleeve length requirements, and failure to specify the point of measurement for sleeve length, are inconsistent with customary commercial practice and are therefore in violation of FASA and FAR Part 12.

### **COUNT III**

#### **Amendment 0009 Arbitrarily and Capriciously Eliminates the Consideration of Shelf Life.**

86. ADG incorporates the foregoing paragraphs by reference as though fully restated herein.

87. Solicitation section “C.1 Background” states that the Government is procuring isolation gowns for the Strategic National Stockpile (“SNS”), which is a national repository of pharmaceuticals, vaccines, medical supplies, and medical equipment stored in strategic locations around the United States. AR 277. Section “C.2 Purpose” originally further explained that, through this procurement, “the Government is attempting to increase the availability of domestically produced compliant PPE. This will enable the United States to ensure sufficient domestic availability of such items during national emergencies and/or pandemic events.” *Id.*

88. It is only natural that the evaluation of proposals submitted in response to the Government’s efforts to strategically stockpile gowns for future emergencies and pandemics would include consideration of the products’ shelf life. That is, the length of time for which the medical isolation gowns remain effective and usable, after which the gowns must be discarded or replaced.

89. Specifically, the Solicitation’s Factor 2, Subfactor 6: Shelf Life originally required that, for offerors making shelf-life claims, the gowns “when delivered to the SNS, shall have no more than 20% of total shelf-life expended.” AR 328. The Solicitation further stated that “[o]fferors will be evaluated based on providing appropriate data and documentation, such as accelerated aging and real-time testing reports and other validating documentation, to support their shelf-life claims.” AR 330.

90. The Solicitation also originally factored shelf life into the price and best value determination, explaining that “[t]he 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.” AR 317.

91. Despite the stockpiling of medical isolation gowns being the primary purpose of the procurement, and shelf life being among the original price and best value evaluation criteria, HHS internally questioned the value of longer shelf lives in its technical evaluations of offerors' proposals. HHS stated:

USG should consider if it is appropriate, allowable, and beneficial to stockpile a gown for over 10 years, as the industry norm for personal protective equipment (PPE) shelf life is 5 years, and, longer dated shelf life could hinder the domestic manufacturing industry

AR 1190.

92. HHS then took its devaluation of shelf life a step further in issuing Amendment 0008, which removed shelf life from the price and best value determination criteria altogether.

AR 1917.

93. Despite removing shelf life from the evaluation criteria, HHS stated that “[t]here have been no alterations to the government’s requirements in Section ‘C.1 Background’ and ‘C.2 Purpose,’” in response an offeror’s question as to whether, in connection with Amendment 0008, “there [had] been a change to the general needs of the agency found in sections ‘C.1 Background’ and ‘C.2 Purpose.’” AR 1920. In other words, HHS still sought to stockpile gowns to ensure domestic availability during future emergencies and pandemics.

94. On May 31, 2024, HHS changed the Solicitation’s requirements with respect to shelf life again with Amendment 0009, specifying for the first time that “Isolation Gowns must have a shelf life of 3 years, and, at the time of delivery to the SNS, isolation gowns shall have no

more than 3 months expended since the date of manufacture, as listed on the gown packaging labels.”<sup>2</sup> Ex. 1 at 16.

95. Amendment 0009 further explains that a “shelf life longer than 3 years will not be evaluated higher or considered to be an additional strength.” *Id.* at 53.

96. The amendment does not reinstate shelf life as part of the evaluation criteria for price and best value determination. *See id.* at 54.

97. Moreover, Amendment 0009 removed from the Solicitation’s section “C.2 Purpose” the statements that HHS was “attempting to increase the availability of domestically produced compliant PPE,” and that the procurement “will enable the United States to ensure sufficient domestic availability of such items during national emergencies and/or pandemic events.” *See* Ex. 1 at 10.

98. By establishing a specific shelf life requirement that is lower than what HHS ostensibly identified as the industry norm (5 years)<sup>3</sup>, openly questioning the value of longer shelf lives in its technical evaluations, and removing the purpose of “ensur[ing] sufficient domestic availability” of gowns for future emergencies and pandemics, HHS has effectively eliminated shelf life as an important evaluation criterion.

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<sup>2</sup> While Amendment 0007 previously included a requirement that “no more than 3 months expended since the date of manufacture, as listed on the gown packaging,” this requirement only applied to offerors who made no shelf-life claim. AR 328-30.

Read narrowly, Amendment 0009 requires all gowns to have a shelf-life of exactly three years, and would exclude as unacceptable gowns with a longer shelf life. Because such a reading would have the absurd result of rendering unacceptable nearly all of the proposals HHS received in response to previous versions of the Solicitation, ADG interprets Amendment 0009 to require a minimum shelf-life of three years. To the extent that the Government intended to impose a strict, three-year requirement, such a requirement would be all the more unreasonable and illegal, for each of the reasons discussed in this Count.

<sup>3</sup> ADG notes that this alleged industry norm is not supported by HHS’s Market Research Report, which does not discuss customary commercial practice for shelf life at all. *See* AR 11-18.

99. Doing so arbitrarily and capriciously transforms the procurement to one that is inconsistent with the Solicitation's original stated purpose, as well as the inherent purpose of the SNS, which is to stockpile supplies like medical isolation gowns that will be usable and effective during future emergencies and pandemics.

100. By effectively removing shelf life as a consideration, the Government has failed to adequately consider "life-cycle cost" as required by FAR 7.105. The FAR defines life-cycle cost as "the total cost to the Government of acquiring, operating, supporting, and (if applicable) disposing of the items being acquired." FAR 7.101. Under Amendment 0009, the Government considers a gown with three years of shelf-life to have no greater value than a gown with six or nine years of shelf-life, despite the obvious increased cost to the Government of having to replenish gowns in the SNS that expire, which cost will necessarily be higher than gowns with a shorter shelf life.

101. The Government's Acquisition Plan for this procurement dismisses life-cycle costs entirely, stating: "Life-cycle cost does not apply to this commercial medical supply acquisition." AR 105. The Government's statement is nonsense, and displays either a complete misunderstanding of (a) what life-cycle costs are, (b) the fact that shelf-life is routinely considered in the commercial marketplace by non-government customers when selecting gowns, or (c) both. As discussed above, gowns with a longer shelf-life necessarily have higher life-cycle costs, particularly where, as here, the Government's objective is to stockpile gowns for use during a future emergency.

102. Inexplicably, the Government refused to communicate to offerors its conclusion that "life-cycle cost does not apply" to isolation gowns. In response to multiple questions from offerors regarding how life-cycle costs would be considered, the Government evasively responded, "The Government intends to evaluate and make award(s) in accordance with the terms of the

Solicitation and all applicable statutes and regulations.” AR 1920 (Q&A nos. 8-10). The Government elected not to share with offerors its determination that life-cycle costs would not be considered because those costs did not “apply” to isolation gowns.

103. By effectively removing shelf life as consideration, the Government also will not meaningfully evaluate cost and price as required by 41 U.S.C. § 3306(c)(1)(B). Amendment 0009 violates this mandate by ignoring altogether the higher costs associated with gowns with a shorter shelf life, relying instead on the misleading, and illusory unit price of lower-quality gowns.

104. Finally, making such a significant change to the Solicitation’s purpose and evaluation criteria so late in the procurement process is unreasonable and ignores the substantial work that offerors have put in over the last two years to prepare and submit responsive, competitive proposals.

#### **COUNT IV**

##### **The Government Has Engaged in Disparate Treatment and Bias.**

105. ADG incorporates the foregoing paragraphs by reference as though fully restated herein.

106. As discussed above, there is no legitimate explanation for HHS’s decision not to consider shelf-life in a procurement for the SNS.

107. The only plausible explanation is that HHS seeks to make its award to NYES for NYES’s cheaper, lower-quality gowns a *fait accompli*.

108. By eliminating shelf-life from the evaluation scheme, HHS can reaffirm its award to NYES without having to consider that NYES’s gowns will expire no later than [REDACTED] from manufacture, in contrast to ADG’s gowns, which have a [REDACTED] shelf life.

109. The administrative record reveals that NYES has repeatedly complained to HHS that delays in this and other Isolation Gown procurements have placed enormous financial stress on NYES. NYES communicated to HHS that it had [REDACTED]

[REDACTED] to create the new manufacturing facility that it identified in its proposal. AR 2232. NYES complained that [REDACTED]

[REDACTED] *Id.*

110. The record also reveals that NYES has submitted a “Request for Equitable Adjustment” under the contract that was awarded to NYES in September 2023 and that this request is under consideration by HHS. AR 2257. The record indicates that this request is related to NYES’s repeated statements in the March-April 2024 timeframe that delays to this procurement have put a severe financial strain on NYES. *E.g.*, AR 2256 [REDACTED] [REDACTED]).

111. Given that performance was stayed on NYES’s contract immediately after award, NYES has no basis to seek any “Request for Equitable Adjustment” under that contract.

112. Any moneys that NYES might seek from HHS can only be a lifeline to reimburse NYES for pre-award costs and/or subsidize NYES’s overhead costs pending a new award decision.

113. That HHS is actively negotiating such a lifeline with NYES at the very same time it is tailoring its requirements to ensure that NYES receives the contract is blatant disparate treatment.

114. Like NYES, ADG has also invested [REDACTED] in production and pre-production activities to be prepared to accommodate the volumes of Level 2 Isolation Gowns contemplated by the Solicitation.

115. Unlike NYES, however, ADG does not currently hold a contract with HHS that HHS has acknowledged was improperly awarded, but that HHS is willing to use to reimburse ADG’s costs.

116. FAR 3.101 commands: “Government business shall be conducted in a manner above reproach and, except as authorized by statute or regulation, with complete impartiality and with preferential treatment for none.”

117. HHS’s actions violate FAR 3.101 because they provide preferential treatment for NYES, tailor the procurement to bolster the 2023 contract award to NYES, and provide NYES with the lifeline it has requested pending reaffirmation of its award decision.

#### **COUNT V**

#### **HHS Is Conducting a Lowest-Price, Technically Acceptable Source Selection, Contrary to the Terms of the Solicitation (Supplemental Protest Ground).**

118. ADG incorporates the foregoing paragraphs by reference as though fully restated herein.

119. The solicitation invites offerors to submit proposals that exceed the requirements of the solicitation, stating that HHS will perform a trade-off between price and non-price factors:

This is a best value acquisition conducted in accordance with Federal Acquisition Regulation (FAR) 12.602; 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, an analysis to determine whether or not exceeding the minimum requirements at an associated price premium provides the best value to the Government will be performed if necessary.

AR 318; Ex. 1 at 54.

120. Both Amendment 0005 and Amendment 0009 provide that HHS will review the technical capability of proposals and assign a rating of “outstanding,” “acceptable,” or “unacceptable.” AR 314; Ex. 1 at 50.

121. The administrative record, however, indicates that HHS never considered whether any proposal was more than “acceptable,” and the only ratings assigned by HHS during the initial

evaluation and the corrective action evaluation were “acceptable” and “unacceptable.” Although Amendment 0009 retains the same language as Amendment 0005 regarding a best-value tradeoff, the administrative record makes clear that the Government intends to make an award on a lowest-price, technically acceptable basis.

122. The use of a lowest-price, technically acceptable source selection process for the acquisition of personal protective equipment such as the gowns violates Section 880 of the John S. McCain National Defense Authorization Act for Fiscal Year 2019, Pub. L. 115-232, 41 U.S.C. 3701 Note, and FAR 15.101-2(d).

123. FAR 15.101-2 notes that LPTA procurements *shall only* be used when “[t]he agency would realize no, or minimal, value from a proposal that exceeds the minimum technical or performance requirements” and “[t]he contracting officer documents the contract file describing the circumstances that justify the use of the lowest price technically acceptable source selection process.” FAR 15.101-2(c). Here the purpose of the procurement is to provide Level 2 Isolation Gowns to support the Strategic National Stockpile, whose mission it is to “provide the right materiel at the right time to secure the nation's health.” Ex. 1 at 10. Nowhere has the Contracting Officer made the argument, nor could they reasonably do so, that proposals that exceed the requirements of the solicitation do not provide a better value to the government. Thus, HHS must perform a trade-off between price and non-price factors.

124. The Solicitation also does not advise offerors of the basis for award, as required by 41 U.S.C. § 3306(b)(1) and FAR 15.304(d).

#### **COUNT VI**

#### **Amendment 0009 Arbitrarily Precludes Level 2 Isolation Gowns Manufactured More Than Three Months Before Delivery.**

125. ADG incorporates the foregoing paragraphs by reference as though fully restated herein.

126. In issuing Amendment 0009 HHS arbitrarily restricts offerors from supplying the Government with Level 2 Isolation Gowns with a manufacture date more than three months prior to the delivery date:

Offerors shall provide a signed statement from the gown manufacturer certifying the offered Isolation Gown(s) has a shelf life of 3 years and the Isolation Gowns, at the time of delivery to the SNS, shall have no more than 3 months expended since the date of manufacture listed on the gown packaging label.

Ex.1 at 46.

127. HHS took this step at the same time it announced it would give no additional consideration to gowns with a shelf life of greater than three years.

128. Amendment 0009 arbitrarily prioritizes Level 2 Isolation Gowns with a short shelf life, but a recent manufacture date, over gowns that may have been manufactured over three months ago, but that have a far longer shelf life. For example, under Amendment 0009, HHS would accept delivery of a Level 2 Isolation Gown with a three-year shelf life that was manufactured three months prior to delivery and therefore had only thirty-three months of remaining shelf-life. By contrast, HHS would reject delivery of a gown with a ten-year shelf life that was manufactured two years ago, even though that gown has eight years of remaining shelf-life.

129. Amendment 0007 only required that Level 2 Isolation Gowns “have no more than 20% of total shelf-life expended upon delivery to the SNS.” AR 329. Under Amendment 0007, a Level 2 Isolation Gown with a 10-year shelf life would be accepted up to 2 years post manufacturing date.

130. HHS’s decision to amend the Solicitation to allow the delivery of gowns with a shorter useful life, while precluding the delivery of gowns that could be used for a much greater period of time is arbitrary and capricious. The purpose of the Solicitation is to provide Level 2 Isolation Gowns to the SNS. HHS has no justification to prioritize those gowns that could not be

used by the nation's healthcare system in three years while rejecting those gowns that would be available for use for a decade or longer.

131. Further, HHS's decision unreasonably harms those offerors who began to scale up manufacturing in response to this procurement. Offerors who began producing Level 2 Isolation Gowns so that they could be in the best position possible to meet the Government's needs in the event of contract award are unfairly harmed by this new requirement as this procurement has now dragged on far longer than the three-month manufacturing deadline the Government now imposes.

#### **COUNT VII**

##### **Amendment 0009 Arbitrarily Excludes the Most Relevant Past Performance.**

132. ADG incorporates the foregoing paragraphs by reference as though fully restated herein.

133. Amendment 0005, released on October 31, 2022, directed offerors to "provide a description of two projects performed within the past three years that clearly demonstrates the Offeror's satisfactory past performance in performing projects of similar scope, size and complexity and domestic sourcing to the requirement described in the RFP." AR 311. This lookback period gave offerors the ability to describe projects performed during the duration of the pandemic.

134. Amendment 0009 leaves the similar experience requirement unchanged. However, due to HHS's string of missteps and mismanagement that have led to multiple protests and several rounds of corrective action, this procurement has been delayed two years. Unlike Amendment 0005, which allowed offerors to list similar experience dating back to October 2019, Amendment 0009 restricts similar experiences to those performed after May 2021.

135. By prohibiting offerors from listing similar experiences performed more than three years before the due date of proposals, Amendment 0009 precludes consideration of similar

experiences that are directly relevant to the offerors' ability to perform, and which HHS had previously found relevant to its consideration of proposals.

136. HHS's decision to limit past experience is arbitrary and unreasonable as the similar experience lookback period no longer covers the full pandemic period when many offerors were supplying Isolation Gowns to the Government. In mandating that offerors list only those projects performed within the last three years, HHS unduly restricts from competition those offerors who may have directly relevant experience obtained during the pandemic, but that due to HHS's long delays, have not recently supplied Isolation Gowns.

### **PRAYER FOR RELIEF**

WHEREFORE, ADG respectfully requests this Court:

137. Declare that HHS acted arbitrarily and capriciously or otherwise contrary to law;

138. Permanently enjoin HHS from proceeding with the award of contracts under the RFP without revising the Solicitation to comply with applicable law; and

139. Grant all other relief that the Court finds to be just and proper.

Dated: June 11, 2024

Respectfully submitted,

/s/ Daniel P. Graham

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**CERTIFICATE OF SERVICE**

I hereby certify that on June 11, 2024, I caused a copy of the foregoing document to be electronically filed with the clerk using the Court's CM/ECF system. I further certify that I have served the foregoing document via Electronic Mail on the following:

United States Department of Justice  
Commercial Litigation Branch  
Civil Division, 8th Floor  
1100 L Street NW  
Washington, DC 20530  
E-mail: nationalcourts.bidprotest@usdoj.gov

Dated: June 11, 2024

s/ Daniel P. Graham  
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