Redacted Version

IN THE UNITED STATES COURT OF FEDERAL CLAIMS
BID PROTEST

AIRBOSS DEFENSE GROUP, LLC, *Plaintiff*, and STRING KING LACROSSE LLC, *Plaintiff-Intervenor*, v. THE UNITED STATES, *Defendant*.	Case No. 24-365 Judge Charles F. Lettow [redacted]

FIRST AMENDED BID PROTEST COMPLAINT

Plaintiff-Intervenor String King Lacrosse LLC ("StringKing" or "Plaintiff-Intervenor"), by and through undersigned counsel, submits this amended bid protest Complaint against the United States of America, acting through the U.S. Department of Health and Human Services, Administration for Strategic Preparedness and Response ("HHS" or the "Agency"). StringKing seeks permanent declaratory and injunctive relief to remedy the Agency's arbitrary and capricious issuance of Amendments 0008 and 0009, which unlawfully modified Request for Proposals No. 75A50322R00008 (the "RPF" or the "Solicitation"). StringKing alleges as follows:

SUMMARY OF THE CASE

1. The Agency's actions in issuing Amendments 0008 and 0009 have materially changed the procurement and reflect that the Agency is attempting to unlawfully utilize the current procurement to solicit what is, at bottom, a new requirement. These unlawful changes reflect nothing more than a Hail Mary attempt by the Agency to redirect award to the Agency's preferred

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vendor (and current awardee) New York Embroidery Studio, Inc. ("NYES"). It appears to be a blatant attempt by the Agency to rewrite the Solicitation's requirements in a manner that favors NYES by emphasizing NYES's strengths [redacted] in comparison to StringKing's product, which has [redacted]. Notably, the record is devoid of any rational explanation to support the Agency's arbitrary and capricious actions.

2. Amendment 0008 and Amendment 0009 come on the heels of StringKing's Government Accountability Office ("GAO") protest in October 2023 (and the Agency's subsequent corrective action) and an agency-level protest in November 2023.

3. StringKing challenged the Agency's issuance of Amendment 0008 in a pre-award protest before GAO in February 2024. The Agency took corrective action for a second time and appears again to attempt to redirect the award to NYES. In taking corrective action in response to StringKing's February 2024 protest, the Agency first issued a notice of corrective action on March 26, 2024, that stated (among other things) an intent to terminate award to NYES and cancel the procurement overall. Less than two weeks later, on April 9, 2024, the Agency issued a revised notice of corrective action that reflected an inherently different planned course of action, including not cancelling the award to NYES and not cancelling the procurement.

4. On May 31, 2024, the Agency issued Amendment 0009 during pendency of this bid protest action before the Court as a supposed corrective action that purported to, among other things, add a three-year shelf-life in the procurement as an evaluation factor under Factor 2 (Technical Capability). As will be demonstrated below, the actual result of this change is a *de*

[redacted]

facto elimination of shelf-life as an evaluation factor as well as the competitive elimination of any offeror with a longer shelf life, [redacted] given the material changes in the Solicitation.[1]

5. It is unclear what the Agency actually plans to do with this procurement and its conduct and the record before the Court reflects internal agency disagreement and unsupported arbitrary decisions. The Agency now apparently seeks a completely new requirement and is unlawfully attempting to utilize the current procurement instead of properly cancelling the procurement given its material changes to the Solicitation's purpose and elimination of shelf life and life cycle costs from the evaluation criteria overall.

6. Regardless, offerors—including StringKing—have expended and invested enormous resources to develop a product in response to the Solicitation's stated requirements as initially solicited for the purpose of awarding multiple awards to create a national stockpile of disposable medical gowns for future national emergencies. The Solicitation, as originally issued, included evaluation criteria that prioritized an offeror's ability to provide the Agency a product with long shelf life as part of the best value evaluation criteria. The Agency's Amendments 0008 and 0009 show that the Agency now seeks to instead simply procure "disposable medical Isolation Gowns used in healthcare settings" rather than "attempting to increase the availability of domestically produced compliant PPE . . . to ensure sufficient domestic availability of such items during national emergencies and/or pandemic events." (*Compare* AR 277 (Amend. 0005) *with* Exhibit A (Amend. 0009) at 11.)

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[1] The Agency subsequently issued Amendment 0010 clarifying that this procurement is not partially being set-aside for small businesses after errantly checking a box indicating that it would be. StringKing is not protesting Amendment 0010.

[redacted]

7. Specifically, Amendments 0008 and 0009: (a) materially change the stated purpose of the Solicitation; (b) materially change the shelf life evaluation requirements under Factor 2 (Technical Capability); (c) remove shelf life from the evaluation criteria for Factor 4 (Price); and (d) remove shelf life from the evaluation criteria for the best value determination for the procurement. Further, the Agency's actions reflect disparate treatment, have unduly restricted competition in this procurement, and have unlawfully converted this from a best value procurement to a lowest price technically acceptable ("LPTA") procurement.

8. The Agency cannot arbitrarily and capriciously at this late hour change the evaluation criteria and/or Solicitation requirements in such a fundamental, material way to the prejudice of StringKing and other offerors with longer shelf life.

9. StringKing, accordingly, requests that the Court, *inter alia*: (1) declare (a) HHS's issuance of Amendments 0008 and 0009 to be arbitrary and capricious, an abuse of its discretion, and contrary to law, or (b) alternatively declare HHS's issuance of Amendment 0008 and Amendment 0009 to reflect material changes to the Solicitation's requirements that mandates cancellation of the procurement overall; (2) permanently enjoin HHS from removing shelf life and life cycle costs from the Solicitation's evaluation criteria because shelf life is fundamental to the evaluation of products that will be kept for a period of time in a national stockpile; (3) permanently enjoin HHS from proceeding with the award of NYES without first evaluating StringKing's proposal in a manner consistent with the Solicitation and applicable law; (4) direct the Agency to re-evaluate proposals in accordance with the terms of the Solicitation evaluation criteria to include consideration of shelf life as originally contemplated; and (5) grant StringKing such other relief as the Court may deem just and proper including its attorneys' fees and costs.

[redacted]

PARTIES

10. Plaintiff-Intervenor, StringKing, is a U.S. company based in California that qualifies as a small business under the Solicitation's applicable North American Industry Classification System ("NAICS") Code No. 339113. StringKing is an experienced, well-performing supplier of personal protective equipment ("PPE") to the federal government, such as the disposable medical isolation gowns being solicited in the procurement at issue.

11. Defendant is the United States of America, acting through HHS.

JURISDICTION &VENUE

12. The Court has jurisdiction over this bid protest under the Tucker Act, 28 U.S.C. § 1491(b).

13. Venue is appropriate in this Court pursuant to 28 U.S.C. § 1491(b).

STANDING

14. StringKing is an interested party and has standing in this matter as "an actual or prospective bidder or offeror whose direct economic interest would be affected by the award of the contract or by failure to award the contract." *Myers Investigative and Sec. Servs., Inc. v. United States*, 275 F.3d 1366, 1370 (Fed. Cir. 2002) (citations omitted). StringKing timely submitted its proposal in response to the Solicitation and the Agency determined [redacted]. StringKing also submitted a revised proposal [redacted]. Finally, StringKing intends to file a revised proposal in response to Amendment 0009.

[redacted]

15. The Agency's actions have prejudiced StringKing and but for the Agency's errors, StringKing has a substantial chance to receive award of a contract resulting from the Solicitation. *See Banknote Corp. of Am. v. United States*, 365 F.3d 1345, 1352 (Fed. Cir. 2004) (finding that an "interested party" is "an actual or prospective bidder or offeror whose direct economic interest would be affected by the award of the contract or by failure to award the contract").

STATEMENT OF FACTS

A. The Solicitation

16. On June 28, 2022, the Agency issued the RFP for "ANSI [American National Standards Institute]/AAMI [Association for the Advancement of Medical Instrumentation] Level 2 Disposable Isolation Gowns Manufactured in the U.S. or its Outlying Areas." (AR 277.) The Solicitation provided that the products procured would be utilized in the Strategic National Stockpile ("SNS"), which is managed by HHS, and is a national repository of pharmaceuticals, vaccines, medical supplies, and medical equipment stored in strategic locations around the United States. (*Id.*)

17. The Agency issued the Solicitation as a best value acquisition for the stated purpose of creating a stockpile of disposable medical isolation gowns to be used in healthcare settings in preparation for future national emergencies, including pandemic events. Specifically, the Solicitation stated its purpose as follows:

> The U.S. Government is interested in establishing multiple awards for the purchase of domestically manufactured ANSI/AAMI PB70 Level 2 disposable medical Isolation Gowns used in healthcare settings. In establishing multiple awards for such medical isolation gowns, ***the Government is attempting to increase the availability of domestically produced compliant PPE***. <u>***This will enable the United States to ensure sufficient domestic availability of such items during national emergencies and/or pandemic events***</u>.

[redacted]

(AR 277.[2]) Inherent in the Agency's procurement of these disposable medical isolation gowns is evaluation of the products' shelf-life and consideration of related life cycle costs given the stated intent and purpose of the procurement is to stockpile the gowns in preparation for future national emergencies.

18. The Agency conducted the best value procurement in accordance with Federal Acquisition Regulation ("FAR") 12.602 in conjunction with FAR Part 15 procedures. (AR 318.) The RFP informed offerors that the Agency intended to establish multiple awards "to increase the availability of domestically produced compliant PPE" to "enable the United States to ensure sufficient domestic availability of such items during national emergencies and/or pandemic events." (AR 277; *see also* AR 270 (providing the Agency intended "award of more than one firm fixed price contract resulting from this solicitation"); AR 318, § M.2 (Notice of Intent to . . . Make Multiple Awards); AR 306, § L.3 ("The Government intends to award multiple contracts.").) The RFP provided that the Agency contemplated that each award would have a 24-month base period of performance with one additional 12-month option period. (AR 270, 306.)

1. Proposal Instructions

19. The Solicitation provided the Agency will evaluate offerors' proposals based on four factors and eight subfactors:

Factor 1: Technically [*sic*] **Compliance Go/No-Go**
Factor 2: Technical Capability
Subfactor 1: Manufacturer/Producer

[2] There are ten amendments to the Solicitation, which are briefly summarized *infra*. Amendments 0001 to 0007 were issued by the Agency prior to receipt of initial proposals. Amendment 5, issued October 31, 2022, amended the RFP "in its entirety." (AR 269.) All references to the RFP are to Amendment 5, unless stated otherwise.

[redacted]

Subfactor 2: Production Schedule/Manufacturing Capability
Subfactor 3: Labeling and Packaging
Subfactor 4: Natural Rubber Latex
Subfactor 5: Catalog and Literature
Subfactor 6: Shelf Life
Subfactor 7: Test Reports
Subfactor 7 [*sic*]: Biocompatibility Report Plan
Factor 3: Similar Experience
Factor 4: Price Evaluation

(AR 313 (emphasis in original.)

20. The Solicitation required offerors to "provide documentation that support[ed]" the requirements for each subfactor. (AR 308.)

2. Evaluation and Award Criteria

21. The Solicitation, as originally issued, advised offerors that in conducting the best value procurement:

> 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-[3] [sic] being significantly more important than price. However, as proposals become more equal in their non-price factors, the price factor will become more important.

(AR 313 (emphasis added).)

a. Factor 2: Technical Capability

22. Under Factor 2 (Technical Capability), the Government was required to "evaluate whether an offeror's proposal demonstrates its understanding of the isolation gowns requirement and the objectives set forth in Section C of this Solicitation." (*Id.*)

[redacted]

23. In conducting its evaluation, the Solicitation required the Agency to utilize the following adjectival ratings in assessing a subfactor rating for each offeror under Factor 2:

The rating scale for subfactor criteria is defined below: **Factor 2 Ratings**	
Ratings	Definition
Outstanding	Proposal meets and exceeds contractual requirements to the Government's benefit in Section C of the solicitation. Limited risk to the Government.
Acceptable	Proposal meets contractual requirements in Section C of the solicitation. Moderate risk to the Government.
Unacceptable	Proposal does not meet contractual requirements. High risk to the Government.

(AR 314.)

24. Under Factor 2 (Technical Capability), the Solicitation required the Agency to evaluate proposals under Subfactors 6 and 7 as follows:

Factor 2, Subfactor	**Solicitation Evaluation Requirements**
Subfactor 6: Shelf Life	"If the Offeror is making a shelf-life claim (a statement in the proposal, on the technical specification sheet, an expiration date listed on the isolation gown packaging, etc.) then the product, when delivered to the SNS, shall have no more than 20% of total shelf-life expended. Offerors will be evaluated based on providing the appropriate data and documentation, such as accelerated aging and real-time testing reports and other validating documentation, to support their shelf-life claims." (AR 331.) "Offerors will be evaluated based on providing a statement verifying that the Isolation Gowns will have no more than 20% of total shelf-life expended upon delivery to the SNS. If the Offeror is not making a shelf-life claim (no statements made or expiration date listed on the isolation gown packaging), the product, when delivered to the SNS, shall have no more than 3 months expended since the date of manufacture, as listed on the gown packaging. Offerors will be evaluated based on no shelf-life claims being made and a statement provided verifying that at time of delivery to the SNS the Isolation Gowns will have no more than 3 months expended since the date of manufacture." (*Id.*)
Subfactor 7: Test Reports	"***Offerors' proposals will be evaluated to determine whether their proposed products have the appropriate test reports that meet the testing criteria, gowns sampling size, and passing result requirements***. Test reports must be in English and include a description of the test device and components tested (including the manufacturer part/model and lot numbers), sample preparation, test procedure and/or the standard followed result values, averages, and appropriate sampling size to meet the specific standard." (AR 316 (emphasis added.))

[redacted]

	"Test reports shall include: A. Barrier Protection (AATCC 42 and AATCC 127) B. Flammability (CPSC Standard 16 CFR Part 1610) C. Seam Strength (ASTMD1683/D1683M) D. Tensile Strength (ASTMD5034) E. Tear Strength (ASTM D5587 or D5733)." (*Id.*) "Offerors' proposals will be evaluated ***to determine whether the gowns were tested at an independent ISO 17025 laboratory and documentation provided supporting the laboratory's ISO 17025 accreditation*** and illustrating that each test performed at the laboratory is within their scope of accreditation." (*Id.* (emphasis added).) "Offerors' proposals will be evaluated based upon their ability to comply with ANSI/AAMI PB70 4% AQL." (*Id.*)

(AR 316.)

b. Factor 3: Similar Experience

25. Under Factor 3 (Similar Experience), the Solicitation required the Agency to evaluate whether offerors met the proposal instruction requirements. (AR 317 (stating the "Government will evaluate . . . ." and then copying and pasting the Instructions to offerors for Factor 3).)

c. Factor 4: Price

26. Under Factor 4 (Price), the Solicitation required the Government to "evaluate each Offeror's prices to determine that those prices are fair and reasonable and to determine which Offerors' proposals offer the best value to the agency." (AR 317.) The Solicitation stated that "[r]isk of excessive pricing is a major concern and Offerors are advised to pay special attention to the instructions related to pricing" and advised offerors that the Agency reserved "the right to reject any proposals that, in its opinion, does not offer fair and reasonable prices." (*Id.*)

27. The Solicitation also provided the Agency would "evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement" and

[redacted]

cautioned that the Agency may determine "determine that an offer is unacceptable if the option prices are significantly unbalanced." (*Id.*)

28. As will be discussed further below, the Agency also stated it would consider the cost of sustaining a product with "a lesser shelf-life." (*Id.*)

29. Finally, the Solicitation also required the Agency to utilize FAR 15.401-1 in evaluating price and required the Agency to specifically evaluate whether offerors' proposals had "unbalanced pricing when performing the price evaluation." (*Id.*)

d. Best Value Evaluation

30. The Solicitation specifically required the Agency to utilize, in its best value determination, the cost of offerors' products as it related to shelf-life of the product in two ways. Specifically, the Solicitation provided that:

> The Government's overall best value determination ***<u>will consider the cost</u>*** of the product as it relates to the ***<u>shelf-life at time of delivery</u>*** and the best value determination will also consider the time, effort, and ***<u>cost to sustain product with lesser shelf-life</u>***.

(AR 317 (emphasis added).) That is, the Solicitation required the Agency to specifically evaluate offerors' price by analyzing (a) the cost of the product relating to shelf-life at the time of delivery; and (b) the cost to sustain an offerors' product that offered the Agency lesser shelf-life than products offered by other offerors. (*See id.*)

31. The Solicitation provided the Agency would make a best value award determination and make award to the "***best overall offer, based upon an <u>integrated assessment</u> of Technical and Business Proposals***." (AR 318 (emphasis added).)

32. The Solicitation required the Agency to award to offeror(s) who were deemed:

[redacted]

> [R]esponsible 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. Technical proposals determined to be*** **"Technically Unacceptable"** ***will not be considered for award.***

(*Id*. (emphasis added).)

3. Amendments 0001 to 0007 to the Solicitation

33. During the course of the procurement, the Agency issued eight amendments to the Solicitation. The first seven amendments were issued prior to the receipt of initial proposals and the eighth amendment was issued as a corrective action taken in response to StringKing's GAO protest in October 2023 (which are both discussed below). The first seven amendments are briefly summarized below.

a. Amendment 00001: extended the offer date of proposals to July 29, 2022. (AR 171.)

b. Amendment 00002: revised various terms of the Solicitation and issued a set of Questions and Answers. (AR 172-242.)

c. Amendment 00003: extended the offer due date to August 3, 2022, revised various terms of the Solicitation and issued a revised set of Questions and Answers. (AR 243-265.)

d. Amendment 00004: changed the due date of the Biocompatibility Report to be due within 30 days of award and prior to first delivery. (AR 266-268.)

[redacted]

e. Amendment 00005: revised various terms of the Solicitation to ensure its compliance with the Infrastructure Investment and Jobs Act ("IIJA")/Make PPE In America. (AR 269-318.)

f. Amendment 00006: extended the offer due date for proposals to November 22, 2022. (AR 319.)

g. Finally, Amendment 00007 revised line items 2001, 2002, and 2003, and notations B.2, B.2.1, B.5, B.5.A. (AR 320-340.) Notably, Amendment 00007 also updated the Statement of Work as it related to Shelf-Life as follows:

> If the Offeror is making a shelf-life claim (a statement in the proposal, on the technical specification sheet, an expiration date listed on the isolation gown packaging, etc.) then the product, at time of delivery to the SNS, shall have no more than 20% of total shelf-life expended. Offerors shall provide data and documentation, such as accelerated aging and real-time testing reports and other validating documentation, to support their shelf-life claims. Offerors shall provide a statement verifying that the Isolation Gowns will have no more than 20% of total shelf-life expended upon delivery to the SNS.
>
> * * *
>
> If the Offeror is not making a shelf-life claim (no statements made or expiration date listed on the isolation gown packaging, etc.), the product, at the time of delivery to the SNS, shall have no more than 3 months expended since the date of manufacture, as listed on the gown packaging. Offerors shall provide a statement verifying that the Isolation Gowns will have no more than 3 months expended since the date of manufacture.

(AR 326.)

[redacted]

B. Agency's Questions and Answers

34. During the procurement's question and answer ("Q&A") period, HHS engaged in two rounds of Q&A with offerors.

C. StringKing's Offer and Agency's Initial Award Decision

35. In accordance with the Solicitation, StringKing invested substantial resources both in money and time to create a product responsive to the Agency's specific Solicitation requirements, which emphasized the need for the selected awardee to provide a best value product that would have sufficient shelf life for stockpiling in preparation for future national emergencies including pandemics.

36. On November 22, 2022, StringKing timely submitted its initial proposal including price. The Agency did not engage in discussions with StringKing or allow StringKing to revise its business/price proposal during the procurement.

37. On September 18, 2023, the Technical Evaluation Panel ("TEP") issued its report. (AR 1162.)

38. In the TEP Report, the TEP found that [redacted] out of [redacted] were acceptable: [redacted] (AR 1163-64.)

39. [redacted] (AR 1172-200.)

40. In its evaluation of NYES's proposal, the [redacted] (AR 1181.)

[redacted]

41. Further, the TEP Report found that [redacted] (*Id.*)

42. Additionally, according to the TEP Report, NYES's proposed gowns had a shelf-life of [redacted]. (*Id.*)

43. Comparatively, StringKing had a recognized shelf life of [redacted], with the TEP also observing that StringKing's shelf life could [redacted]. (AR 1190.)

44. However, in contravention of the solicitation's stated evaluation criteria, the TEP Report said, in reference to StringKing's proposal, "[redacted]." (*Id.*)

45. On September 22, 2023, the Agency issued its Award Decision Memo. (AR 1308.)

46. In its Memo, the Agency largely copied the TEP's findings, beginning by noting that only [redacted] were found acceptable [redacted] and then repeating the TEP's conclusions about the offerors' proposals. (AR 1313-28.)

47. Importantly, the Memo also noted that [redacted] (AR 1319.)

48. The Memo also noted the same domestic manufacturing concern as the TEP Report, parroting, "[redacted]." (AR 1342.)

[redacted]

49. After reciting the TEP's findings, for each of the acceptable offerors, the Award Memo found that [redacted] technical proposals "meet[] the requirements and indicates an adequate approach and understanding of the requirements and increases the likelihood of successful performance." (AR 1341-42.)

50. The Award Memo then found that, after comparing the prices of the offerors, NYES's price of [redacted] was fair and reasonable. (AR 1343.) The Award Memo did not discuss whether [redacted] prices were fair and reasonable.

51. The Award Memo then discussed the Contracting Officer's best value determination.

52. The Contracting Officer first found that all the acceptable offerors' proposals "[redacted]" and that [redacted]." (AR 1344.) This conclusory discussion did not have any actual comparison between the offerors' proposals—as it was required to have under the terms of the Solicitation.

53. [redacted] did note that [redacted] but rather than actually compare the proposals, [redacted] simply said that she "[redacted]." (*Id.*) Therefore, despite concern for the domestic manufacturing industry and the industry norm for shelf life not appearing anywhere in the evaluation factors, [redacted] summarily concluded, without any actual discussion of the

[redacted]

merits of this conclusion, "[redacted]." (*Id.*) Such a decision is clearly in conflict with the Solicitation's terms 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.)

54. Because [redacted] did not consider [redacted] in her decision, the Agency held that [redacted]." (AR 1344.) [redacted], therefore, determined that NYES, [redacted], would be awarded the contract. (AR 1345.)

55. [redacted], however, made no mention of [redacted] (*See id.*)

56. On September 27, 2023, the Agency issued a notice of unsuccessful offer to StringKing and informed StringKing that the Contract had been awarded to NYES. StringKing timely requested a debriefing by e-mail the same day.

57. On September 29, 2023, the Agency conducted an oral debriefing for StringKing via video conference during which counsel for StringKing was present. During the oral debriefing, the Agency stated that because it determined that the awardee, NYES, and StringKing were [redacted] the Agency had made award to NYES because [redacted] (Compl. Ex. B, Decl. of [redacted].) The CO also stated that the Agency did not review StringKing's [redacted] during its evaluation of StringKing's proposal because the Agency evaluators were not "experts on shelf life." (*Id.* at ¶ 14.)

[redacted]

D. StringKing's First GAO Protest and the Agency's Corrective Action

58. On October 4, 2023, StringKing filed a protest with GAO alleging the Agency improperly evaluated offerors by improperly: (a) utilizing a *de facto* lowest-price, technically acceptable scheme; (b) failing to evaluate proposals equally and fairly under Factors 2, 3, and 4; (c) engaging in unequal and improper discussions with NYES, allowing NYES to amend its proposal, and not engaging in discussions with StringKing or allowing StringKing to amend its proposal; (d) failing to consider StringKing's product's shelf life in evaluating price; (e) failing to adequately document its award decision; and (f) failing to consider StringKing's product's shelf life in making its award determination. (*See generally* AR 1438.)

59. On October 27, 2023, the Agency issued its Notice of Corrective Action, which StringKing objected to on October 31, 2023, as failing to remedy the concerns in StringKing's protest.

60. On November 3, 2023, GAO dismissed the protest and issued a Public Decision, which read the Agency's Notice of Corrective Action as encompassing StringKing's protest allegations.

E. StringKing's November 2023 Agency-Level Protest

61. On November 13, 2023, StringKing filed an agency-level protest with the CO, which requested review above the contracting officer level. StringKing's agency-level protest sought an acknowledgment from the Agency that proposals would be evaluated in alignment with the criteria outlined in the Solicitation and that the Agency's corrective action would resolve StringKing's previous protest grounds at GAO in an equitable manner, including its concerns with the Agency's evaluation of offerors' products' shelf life.

[redacted]

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62. StringKing never received a decision on the merits from the Agency on its agency-level protest despite the FAR's mandate for agencies to "make their best efforts to resolve agency protests within 35 days after the protest is filed[,]" FAR 33.103(g), and despite StringKing's counsel following up with the Agency eight times. (*See* Compl. Ex. C, Agency Protest E-mails to CO at 1-7 (showing requests for a decision or status of the Agency's review on December 20, 2023; December 22, 2023; December 29, 2023; January 11, 2024; January 18, 2024; January 22, 2024; January 29, 2024; and February 9, 2024).) The CO acknowledged receipt of StringKing's agency-level protest and its counsel's follow-up emails on several occasions. (*See id.*) The CO also indicated StringKing would receive a decision on January 16, 2024, which it never did.

63. ***After the Agency issued Amendment 0008,*** on February 20, 2024, the Agency dismissed StringKing's agency-level protest as being moot. (AR 2308.) In its notification of dismissal, the Agency mischaracterized StringKing's agency-level protest and ignored several elements of the protest, failed to confirm whether the protest was received or reviewed a level above the CO as StringKing reasonably requested, and provided that the protest was moot due to the Agency's issuance of Amendment 0008. (*See id.*)

F. The Agency's Corrective Action Reevaluation

64. On January 3, 2024, the TEP issued a new report. (AR 1680.)

65. The TEP Report, again, found that only [redacted] submitted acceptable proposals and that each offeror was rated as [redacted] (AR 1682, 1693-721.)

66. Largely, the newest TEP Report, with minimal changes, repeated the findings and conclusions of the previous TEP Report and Award Decision Memo. (*Compare* Tab 42 *with* Tabs 25-26.) In fact, the TEP Report reiterated that [redacted]

[redacted]

[redacted].

(AR 1703.) Then, on February 16, 2024, the Agency issued a Competitive Range Memo, determining a competitive range for the procurement. (AR 1835.)

67. The Competitive Range Memo, again, largely followed the newest TEP Report's and the previous Award Decision Memo's findings, resulting in [redacted] being found as the only acceptable proposals and being rated as [redacted] (AR 1840-52.)

68. The Agency then performed a price assessment and found that all [redacted] acceptable offerors had a [redacted], resulting in the Agency establishing a competitive range of those [redacted] offerors. (AR 1900-03.)

69. The Agency would then issue Amendment 0008 for the submission of revised proposals and stated that "[d]iscussions will be conducted with [redacted] offerors that have been determined to be in the competitive range for this solicitation" (AR 1903.)

G. The Agency Issues Amendment 0008 to the Solicitation

70. On February 16, 2024,[3] at 10:27 p.m. EDT,[4] the Agency e-mailed "offerors in the competitive range" to issue Amendment 0008, which extended the discussion period until 1 p.m. EDT on Wednesday, February 28, 2024; invited offerors to submit a revised proposal based on

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[3] We note that while the Amendment is dated February 14, 2024, and the CO's text says February 15, 2024, offerors did not receive Amendment 0008 until the Agency issued the Amendment post-business hours on a Friday before a holiday weekend. (*See* AR 1916-18, AR 2305-06.) Offerors therefore did not receive the amendment for business purposes until Tuesday, February 20, 2024 because Monday, February 19, 2024, was a federal holiday.

[4] Please note that while the e-mail says 7:27 p.m., this time was PST as StringKing is located in California and so the e-mail was received by StringKing at 10:27 p.m. EST.

[redacted]

Amendment 0008; and informed offerors that questions regarding Amendment 0008 should be submitted to the Agency by 1 p.m. EDT on February 21, 2024. (AR 1916-18, AR 2305-06.)

71. Amendment 0008 drastically changed the requirements of the Solicitation by removing shelf-life from the Agency's evaluation criteria for Factor 4 (Price) and the Agency's best value determination. Specifically, Amendment 0008 stated:

> **4. Factor 4: *Price Evaluation is hereby revised to remove paragraph (a)*, and to read as follows:**
>
> **REMOVED: a) 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.**
>
> **Factor 4: Price Evaluation**
>
> The government will evaluate each Offeror's prices to determine that those prices are fair and reasonable and to determine which Offerors' proposals offer the best value to the agency. Risk of excessive pricing is a 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.
>
> a) 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).
>
> b) In accordance with FAR 15.401-1 Proposal Analysis techniques, the Government will consider unbalanced pricing when performing the price evaluation.
>
> 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

[redacted]

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)

(AR 1917-18 (emphasis added).)

72. Amendment 0008 also allowed offerors to submit revised Technical Proposals and Business Proposals. (AR 1917.) However, offerors' Technical Proposal revisions were limited to a maximum of five (5) pages as an addendum to the Technical Proposal (i.e., proposals cannot be revised in their entirety in their prior full length). (*Id.*)

73. Pursuant to Amendment 0008, offerors were given only seven business days to submit revised proposals in response to these objectively large changes to the Agency's evaluation criteria (and product requirements) by removing shelf life from the evaluation for Factor 4 and the best value determination. (AR 1916-18.)

H. Agency's Questions and Answers Post-Amendment 00008

74. On February 21, 2024, StringKing timely filed questions in response to the Agency's Amendment 0008. (AR 2309-10.)

75. On February 23, 2024, the Agency issued a compilation of questions the Agency received from offerors within the competitive range and the Agency's responses. (AR 1919-21.)

76. StringKing's questions and the Agency's answers are below.

No.	Question	Answer
7	Has there been a change to the general needs of the agency found in sections "C.1. Background" and "C.2 Purpose"? (If yes, then how?) Examples of the solicitation's stated needs: • "[T]o ensure sufficient domestic availability of [Level 2 Isolation Gowns]	There have been no alterations to the government's requirements in Section "C.1 Background" and "C.2 Purpose"

[redacted]

	during national emergencies and/or pandemic events.” • “[T]he SNS ensures medical countermeasures are available and can be rapidly deployed to counter the effects of chemical, biological, radiological, nuclear and explosive threats as well as pandemics, emerging infectious diseases and natural disasters.”	
8	Are life-cycle costs (sustainment costs) still being considered? If not, then why?	The Government intends to evaluate and make award(s) in accordance with the terms of the Solicitation and all applicable statutes and regulations.
9	If life-cycle costs (sustainment costs) are being considered, then please provide details on how they will be evaluated, and the cost model used.	The Government intends to evaluate and make award(s) in accordance with the terms of the Solicitation and all applicable statutes and regulations.
10	If life-cycle costs (sustainment costs) are not being considered, is this an SNS wide change to procurements or just specific to this solicitation?	The Government intends to evaluate and make award(s) in accordance with the terms of the Solicitation and all applicable statutes and regulations. The Government is not making any determination as to an SNS wide change to its future procurements.
11	Is there any preference for longer shelf-life gowns? If yes, where is this evaluation factor located and how is the shelf life valued? If not, can the agency explain why?	The Government intends to evaluate and make award(s) in accordance with the terms of the Solicitation and all applicable statutes and regulations. There is no evaluation factor providing a preference for longer or shorter shelf-life gowns.
12	Is there any preference for a 100-year shelf-life gown vs. a 3-month shelf life gown? If not, can the agency explain why?	See Response on #11
13	Are contractors liable for gowns meeting performance requirements after shelf life is expired?	No contractors are not held liable once gowns are expired.
14	What does SNS plan to do with expired/and or otherwise defective gowns that no longer meet technical requirements?	SNS will dispose any expired or defective gowns.
15	Is the agency willing to accept recently expired gowns if the price is compelling enough? For example, would the government be willingly to purchase gowns for $0.10 which expired the day before delivery?	No
16	Is the agency willingly to accept gowns that don’t meet the stated seam strength requirements if the price is compelling enough? For example, would the government be willing to purchase gowns for $0.10 which had a seam strength 5% below the technical requirement?	No.

[redacted]

17	Does the agency see any value in these gowns lasting until the next pandemic? If yes, then how is this reflected in changing the price evaluation from cost of sustainment to lowest unit price? If not, then what is the purpose of this procurement?	The purpose of this procurement is to purchase domestically manufactured ANSI/AAMI PB70 **Level 2 disposable medical Isolation Gowns** used in healthcare settings to ensure sufficient domestic availability of such items during national emergencies and/or pandemic events. It cannot be determined when the next pandemic or natural disaster will occur. See SECTION C.2 – Purpose in Amendment 0005 of the solicitation.
18	Is there stiff funding available for a new gown award(s)? There is concern that the funds for NYES award were appropriated for 2023 and cannot be re appropriated.	Funding is available for this Isolation Gowns procurement.
19	Is the agency's current requirement for 75,200,000 gowns or ~132,500,000 gowns, which is how many gowns were previously purchased from NYES?	The quantity for this procurement is identified in Sections B.1 and B.2 of the Solicitation, to include base quantities of 75,200,000 gowns, optional quantities of up to 150,400,000, and surge capacity not to exceed 20% of CLIN 2001 and 2002.
20	The solicitation states, "The Government intends to award multiple contracts." and " The U.S. Government is interested in establishing multiple awards." Does the government still intend to make multiple awards?	See response on question 1.
21	What are the main reasons the government would decide to make a single award instead of multiple awards?	See response on question 1.

(*See* AR 1919-21.)

I. StringKing's Second GAO Protest, the Agency's Notice of Corrective Action, and the Agency's Amended Notice of Corrective Action

77. On February 26, 2024, StringKing timely filed a second GAO protest challenging the Agency's unreasonable issuance of Amendment 0008 and improper modification of the Solicitation in removing shelf life from the evaluation criteria for Factor 4 (Price) and in the best value determination for the procurement.

78. On March 26, 2024, the Agency filed a Notice of Corrective Action and Request for Dismissal of StringKing's protest. (AR 2253.) The Agency announced its intention to

[redacted]

terminate the contract award to NYES; cancel the Solicitation in full; review and reconsider the Agency's requirement for isolation gowns, to include shelf-life considerations, which may include additional or updated market research and a new or revised acquisition plan for a new solicitation; and take other actions deemed necessary and appropriate by the Agency. (*Id.*)

79. On March 28, 2024, StringKing filed an Objection to the Agency's Notice of Corrective Action and Request for Dismissal of StringKing's protest. (Compl. Ex. D.)

80. On April 9, 2024, GAO dismissed StringKing's protest as academic.

81. Within a few hours after GAO dismissed StringKing's protest on April 9, 2024, the Agency filed a Revised Notice of Corrective Action and Request for Dismissal of StringKing's protest. (Compl. Ex. E.) HHS's revised corrective action completely changed the Agency's course of action. Specifically, HHS determined not to cancel the Solicitation and instead stated it would review and reconsider the Agency's requirement for isolation gowns, including shelf-life considerations, and fully document the Agency's conclusions; reconsider its competitive range determination; issue an Amendment to the Solicitation to companies in the competitive range revising the current shelf-life requirements, engaging in discussions as needed, and soliciting complete revised final proposal revisions; withdraw the cancellation of the contract to NYES and instead maintain the stop work order for Contract No. 75A50323C00013, the award made under the prior award decision, which has been under a stop work order since October 2023; make a new award decision; and take other actions, as deemed necessary and appropriate by the Agency. (*Id.*)

82. StringKing then intervened into this action and filed a complaint challenging the issuance of Amendment 0008 and the subsequent corrective action.

J. The Agency Issues Amendment 0009

83. On May 31, 2024, the Agency then issued Amendment 0009 purporting to, among other things, add shelf-life back into the requirements by requiring a three-year shelf-life. Notably, none of the technically acceptable offerors had [redacted] This Amendment requires a proposal date of June 17, 2024, despite the Agency significantly altering the shelf-life requirement, materially changing the overall purpose of the Solicitation, and removing shelf life from the evaluation criteria for Factor 2, Factor 4, and the overall best value determination—which requires offerors to design a new product in response to the Agency's new requirement.

84. Altering the shelf-life requirement means that potential bidders can use much cheaper materials, but those cheaper materials must be procured and tested at a substantial cost; that is not something that can realistically be accomplished within a few months, let alone a few weeks.

85. More specifically, procuring a new gown design includes the following steps (to be in compliance with FDA's required manufacturing processes):

a. Plan gown design
b. Procure raw materials (generally not off the shelf)
c. Test biocompatibility of raw materials
d. Create samples (this requires extensive research and development to understand interactions of ultrasonic welding machines with the raw material to optimize seam strength)
e. Send samples to an independent lab for testing
f. Make final samples including five production lots
g. Properly age gowns through an independent lab to enable certified shelf life claims
h. Conduct pre-aging testing on gowns
i. Conduct post-aging testing on gowns which must occur once aging tests are completed
j. Prepare final bid

[redacted]

86. In addition, Amendment 0009 continues to require companies to have an FDA-registered facility when submitting their bids, substantially raising the bid and proposal costs for offerors.

87. Other changes include a change to the "Purpose" section of the Solicitation to delete: "In establishing multiple awards for such medical isolation gowns, 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. The Government is concerned about the risks of disruption of any manufacturing facilities or supply chains located outside of the United States. Thus, offerors are advised to pay special attention to the requirement regarding location of manufacturing."

88. Amendment 0009 also deleted information about the National Stockpile in the "Background" section:

> The Strategic National Stockpile (SNS) — managed by the U.S. Department of Health and Human Services' Administration for Strategic Preparedness and Response — 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

[redacted]

> 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.

(*See* AR 277.)

89. Amendment 0009 also changed the flammability requirements. While the Agency previously allowed for Class II intermediate flammability, it now only permits Class I normal flammability under 16 CFR 1610. Under Class II, the burn time is 4.0 to 7.0 seconds whereas the burn time under Class I is more than 7.0 seconds.

90. Test reports also no longer require testing for biocompatibility under ISO 10993-5 and ISO 10993-10, though it is listed in Subfactor 8.

91. Under Section C.4, the Agency now requires a three year shelf-life: "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." (*See* Amendment 0009 at 17.)

92. Under Section D.2, the Agency deleted a requirement in the "Markings" section: "Product name, lot number, part number, UDI, quantity, gown size, AAMI level, date of manufacture, and expiration dating/use by date (if applicable) included on both the outer case and the inner gowns packaging label." (*Compare* AR 286 *with* Amendment 0009 *at* 18.)

93. The Technical Proposal is now limited to 20 pages, instead of 41 pages. (*Compare* AR 307 *with* Amendment 0009 at 41.)

94. Amendment 0009 also added requirements to Subfactor 5, Catalog and Literature:

[redacted]

> Offerors will be evaluated on their ability to provide non-sterile, single-use, disposable Level 2 Isolation Gowns that are blue or yellow; made of woven, non-woven or composite materials; with elastic wrists or knitted cuffs; meets PB70 testing requirements to claim gown as Level 2; and meets ASTM F3352-19 and other applicable standards as identified in the solicitation.
>
> Offeror's proposals will be evaluated based on:
> 1) having included a technical drawing for each offered Isolation Gown model and each offered size illustrating the points of measures used for the gown length, sleeve length, and chest width;
> 2) having provided front and back photographs of each offered Isolation Gown model and size being worn on an appropriate height male (accordingly to the gown size) with arms to the side and arms extended from sides- height of person was provided; and
> 3) gown dimensions for length, sleeve length, and chest width within the minimum maximum range provided in Section C of the solicitation; and
> 4) each gown model and size offered providing 360-degree protection to the wearer, that at a minimum, ensures both arms, front, back, and sides of the body from the knees up to but not including the neck are fully covered during movement and use when the correct gown size is worn (per Section C and ASTM F3352-19).

(*Compare* AR 316 *with* Amendment 0009 at 53.)

95. Under Subfactor 6, Shelf Life, Amendment 0009 adds that: "A shelf life longer than 3 years will not be evaluated higher or considered to be an additional strength." (Amendment 0009 at 54.)

96. Under Factor 4, Price Evaluation, the Agency deleted: "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." (*Compare* AR 317 with Amendment 0009 at 55.)

97. As noted above, the Agency subsequently issued Amendment 0010 to include clarification that there is no small business set-aside.

[redacted]

98. This Amended Complaint follows.

COUNT I[5]

The Agency Arbitrarily and Capriciously Issued Amendment 0008 and Amendment 0009 to the Solicitation to Remove Shelf Life From its Evaluation Criteria.

99. StringKing incorporates by reference the allegations set forth above and in the foregoing paragraphs as if fully stated herein.

100. "As a general rule, offerors must be given sufficient detail in an RFP to allow them to compete intelligently and on a relatively equal basis[,]" *Glenn Def. Marine (Asia) PTE Ltd. v. United States*, 97 Fed.Cl. 568, 578 (Fed. Cl. 2011) (internal quotation omitted), and "[i]t is beyond peradventure that a contracting agency must treat all offerors equally, evaluating proposals evenhandedly against common requirements and evaluation criteria." *Banknote Corp. of Am. v. United States*, 56 Fed.Cl. 377, 383 (2003), *aff'd*, 365 F.3d 1345 (Fed. Cir. 2004).

101. Likewise, it is "hornbook law that agencies must evaluate proposals and make awards based on the criteria stated in the solicitation. This requirement is firmly rooted in the Competition in Contracting Act (CICA) . . . which indicate[s] that an agency shall evaluate competitive proposals and assess their qualities solely on the factors and subfactors specified in the solicitation." *Banknote Corp. of Am., Inc. v. United States*, 56 Fed.Cl. 377, 386 (2003); *see also, e.g.*, *FirstLine Transp. Sec., Inc. v. United States*, 100 Fed.Cl. at 388 ("It is a fundamental principle of procurement law that an agency must conduct its best-value analysis using the

[5] StringKing maintains its arguments related to Amendment 0008 to preserve the arguments in the event the Government and/or Agency rely on or revert back to Amendment 0008.

[redacted]

evaluation factors and subfactors specified in the solicitation.") (citing 48 C.F.R. § 15.101–1(b)(1); 48 C.F.R. § 15.305(a)).

102. Here, the Agency has unreasonably changed the Solicitation's requirements by issuing Amendment 0008 and Amendment 0009 to remove evaluation of shelf life from the Agency's evaluation criteria for Factor 2 (Technical Capability), Factor 4 (Price), and the best value determination. This action is contrary to the fundamental requirement for offerors to compete on an equal basis and reflects arbitrary and capricious conduct by the Agency.

103. The Agency's issuance of Amendment 0008 is also inconsistent with policies and market conditions that are directly applicable to the procurement.[6]

104. The Agency has conflated its discretion to determine its needs and has revised the Solicitation in a manner that is inconsistent with the Solicitation's actual stated requirements and fails to meet its obligation to provide a meaningful basis to evaluate proposals. Amendment 0008 and Amendment 0009 also adopt a price evaluation method that produces a misleading result in analyzing whether one proposal is more competitive than another.

105. Additionally, to make such a drastic change to the Solicitation's evaluation criteria this late in the procurement process is fundamentally unfair and ignores the investment of time and

[6] Stockpiles are prepared for national emergencies, and the only national emergency that requires significant volumes of isolation gowns is a pandemic. (Compl. Ex. B, [redacted] Decl. ¶ 20; AR 277 ("[T]he 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.") Over the past 120 years, there have only been five national pandemics, of which only two would require large volumes of isolation gowns: the Spanish flu and Covid-19. (Comp. Ex. B, [redacted] Decl. ¶ 20.) This gap between national pandemics is normally about 26.5 years, and the gap between pandemics requiring large volumes of isolation gowns is about 100 years. (*Id.*) Superior shelf life, therefore, is necessary to consider to ensure stockpiles remain viable for the next national emergency. (*Id.*)

[redacted]

resources companies, like StringKing, have invested to create the best product to respond to the Agency's requirements.

106. Finally, the Agency's issuance of Amendment 0008 and Amendment 0009 shows the Agency failed to take meaningful corrective action in response to StringKing's prior protest.

107. Each of the Agency's actions prejudiced StringKing.

108. StringKing's protest should be sustained on each of these grounds. The Agency cannot manipulate the protest process to fundamentally change evaluation requirements to circumvent its obligation to conduct a fair and unbiased procurement.

COUNT II

The Agency's Issuance of Amendment 0008 and Amendment 0009 Is Arbitrary and Capricious and an Abuse of the Discretion Afforded to it Under Procurement Regulations Because It Fails to Provide a Meaningful Basis to Evaluate Price and Make a Reasonable Best Value Determination.

109. StringKing incorporates by reference the allegations set forth above and in the foregoing paragraphs as if fully stated herein.

110. Agencies may not conflate the discretion afforded to it in crafting a solicitation by failing to provide a meaningful basis to evaluate proposals.

111. Here, the Agency's issuance of Amendment 00008 and Amendment 0009 has eliminated the consideration of shelf life in evaluating offerors' proposed prices under Factor 2 (Technical Capability), Factor 4 (Price), and in making the Agency's overall best value determination. The revised evaluation methodologies fail to provide for a reasonable comparison of the price of performance under competing quotations.

112. The Agency cannot reasonably evaluate price without consideration of shelf life. This is a procurement for disposable medical gowns with the express stated purpose to "ensure

[redacted]

sufficient domestic availability" of these crucial personal protective equipment "during national emergencies and/or pandemic events[.]" (AR 277.) And while the Agency changed the purpose of the Solicitation through Amendment 0009 from "ensur[ing] sufficient domestic availability of such items during national emergencies and/or pandemic events" to "disposable medical Isolation Gowns used in healthcare settings[,]" this is in direct contravention from the Agency's statement during questions and answers that the purpose of the procurement has not changed. (AR 1920 ("There have been no alterations to the government's requirements in Section "C.1 Background" and "C.2 Purpose").) The Agency further confirmed that it "cannot be determined when the next pandemic or natural disaster will occur" and that it intends to dispose of the isolation gowns once they are expired, which comes at considerable additional cost. (AR 1919-22.)

113. It is illogical that the Agency could evaluate price or make a best value determination on disposable gowns being procured to stockpile for an unknown future pandemic or natural disaster without consideration of shelf life. Any evaluation of price without considering shelf life given the stated purpose of the procurement fails to provide for a reasonable comparison of the price of performance under competing quotations or lifecycle costs (as the Agency is required to consider pursuant to FAR 7.105). Without any comparative assessment of prices and lifecycle costs, any best value determination will be made without a weighing of the true cost value and benefits associated with an offeror's approach against its associated cost to the government.

114. The Agency's elimination of shelf life from the evaluation requirements is arbitrary and capricious and an abuse of the discretion afforded to it under procurement regulations.

115. Each of the Agency's actions prejudiced StringKing.

116. StringKing's protest on this count should be sustained.

[redacted]

COUNT III

Amendment 0008 and Amendment 0009 Improperly Convert the Solicitation into an LPTA Procurement.

117. StringKing incorporates by reference the allegations set forth above and in the foregoing paragraphs as if fully stated herein.

118. Amendment 0008's elimination of shelf life from consideration of Factor 4 (Price) and the overall best value determination and Amendment 0009's *de facto* elimination of shelf life from Factor 2 (Technical Capability) improperly convert this procurement from a best value procurement to a lowest price technically acceptable ("LPTA") procurement. By eliminating shelf life, the only difference between offerors' proposals is price once technical acceptability is determined by the Agency. The record confirms the Agency failed to consider whether any proposal was more than "acceptable" in its previous evaluations (as it was required to do, *see, e.g.*, AR 314). Nothing in the record shows the Agency is engaging in any different evaluation currently.

119. The Agency cannot maintain this is a best value procurement when it has eliminated shelf life and life cycle costs from the evaluation criteria for the procurement. That is, the Agency cannot claim this is a best value procurement by merely including the best value language in the Solicitation but have price evaluation that lacks any meaningful way to compare offerors' prices (as discussed above). Further, this violates FAR 15.101-2(d), which specifically finds that COs "shall avoid, to the maximum extent practicable, using the lowest price technically acceptable source selection process in the case of a procurement that is predominantly for the acquisition of . . . [p]ersonal protective equipment."

[redacted]

120. Finally, the extensive revisions to the Solicitation via Amendment 0008 and Amendment 0009 have rendered the Agency's evaluation requirements obsolete, and the Solicitation fails to advise offerors of the basis for award, as it is required to do pursuant to 41 U.S.C. § 3306(b)(1) and FAR 15.304(d). Each of the Agency's actions prejudiced StringKing.

121. StringKing's protest on this ground should be sustained.

COUNT IV

The Agency Has Engaged in Unequal and Disparate Treatment.

122. StringKing incorporates by reference the allegations set forth above and in the foregoing paragraphs as if fully stated herein.

123. The Agency's revisions to the evaluation criteria in the Solicitation related to shelf life under Factor 2, Factor 4, and in the overall best value determination lack a rational basis, are arbitrary and capricious, and reflect disparate treatment as the Agency has materially changed the requirements it is procuring and has revised the Solicitation to favor the prior awardee, NYES, and other offerors [redacted], which reflects disparate treatment.

124. First, since taking its first corrective action in October 2023, the Agency has communicated repeatedly with the other offerors that remain in the competitive range for the procurement and has not communicated with StringKing in the same manner. Specifically, the Agency has had phone calls and exchanged text messages with NYES [redacted] regarding the ongoing procurement and these offerors' proposals and products but has not engaged in the same communications with StringKing. (Comp. Ex. B, Decl. of [redacted] at ¶¶ 22-24.) For example, [redacted], has stated he has had "at least fifty to sixty" phone conversations with the CO throughout the

[redacted]

procurement process, including many in the last few months alone. (*Id*. at ¶ 22-23.) Additionally, NYES's CEO, [redacted], has had several private conversations through both text message and phone calls with the contracting officer, [redacted], while proposals were being previously evaluated. (*Id*.)

125. These communications constitute improper exchanges and/or discussions after the receipt of proposals, in violation of FAR 15.306(d) and/or FAR 15.306(e), and further reflect disparate and unequal treatment by the Agency. Here, although the Solicitation did not require the Agency to hold discussions with offerors, it is axiomatic that, in a negotiated procurement, once an agency chooses to conduct discussions, it must do so with all offerors in the competitive range, and that, when holding discussions, agencies may not engage in conduct that favors one offeror over another. FAR 15.306(d)(1). Further, in conducting exchanges with offerors, agency personnel may not "engage in conduct that . . .[f]avors one offeror over another[.]" FAR 15.306(e); in particular, agencies may not engage in what amounts to disparate treatment of the competing offerors.

126. The Agency's failure to do so here and its subsequent discussions with only NYES and [redacted] and not with StringKing are improper and show preferential treatment for these offerors over StringKing. Further, the Agency's discussions with NYES and [redacted] were a motivating factor in the Agency's decision to remove shelf life from the Solicitation's evaluation criteria for Factor 4 (Price) and in the overall best value determination because the removal of shelf life favors the products offered by NYES and [redacted] (and disfavors the product offered by StringKing).

[redacted]

127. Further, the record reflects an inherent preferential treatment in favor of NYES because the Agency is currently negotiating a request for equitable adjustment ("REA") from NYES at the same time it is supposedly neutrally re-evaluating proposals. This comes after it has revised its Solicitation requirements and evaluation criteria to favor NYES's offered product with lesser shelf life. *See* FAR 3.101. The REA is related to NYES's complaints that delays to this procurement [redacted] that "[redacted]." (*See, e.g.*, AR 2256.) StringKing has also invested [redacted] into this procurement but is not receiving the same preferential treatment from the Agency that the Agency is extending to NYES. StringKing also questions the Agency's evaluation of NYES's responsibility if NYES is seemingly going to lose its business if it does not maintain its prior award. Regardless, the record shows the Agency is not acting impartially and is engaging in disparate treatment (and perhaps even bias) as it appears NYES will be maintaining its award despite the fact the Agency is supposedly re-evaluating proposals including NYES' (as it must, given the materially different evaluation criteria changes the Agency has made to the Solicitation).[7]

128. Each of the Agency's actions prejudiced StringKing.

129. StringKing's protest should be sustained.

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[7] The disparate treatment carried throughout the previous evaluation by the Agency. For instance, NYES was a subcontractor under a DLA contract and used that as a basis for its past performance in this procurement. (*See* AR 924.) NYES, however, was never listed as a place of performance for these contracts even though it was required to be under FAR 52.215-6. If they had been, NYES would be listed in this database: https://www.dibbs.bsm.dla.mil//awards/awdrecs.aspx?scope=all. Either NYES did not perform the contracts as stated or the Government was never informed that it was a manufacturer under a government contract despite a requirement that it be listed. The Agency, in evaluating the proposals, did not conduct basic due diligence on this prior to relying on this past performance when awarding the contract to NYES.

[redacted]

COUNT V

The Agency Has Failed to Implement Corrective Action in Response to StringKing's Prior Protest Allegations Concerning the Agency's Failure to Consider Shelf Life in Its Evaluation.

130. StringKing incorporates by reference the allegations set forth above and in the foregoing paragraphs as if fully stated herein.

131. The Agency has failed to implement the corrective action it took in response to StringKing's GAO protest filed on October 13, 2023, and has failed to enact effective corrective action despite a number of attempts to do so, including here. In fact, instead of implementing corrective action, the Agency continues to try and slant the procurement in favor of its chosen awardee.

132. Where an agency fails to implement the promised corrective action, or implements corrective action that fails to address a meritorious issue raised in the protest that prompted the corrective action, such that the protester is put to the expense of subsequently protesting the very same procurement deficiency, the agency's action has precluded the timely, economical resolution of the protest. *See, e.g.*, *Oak Grove Tech., LLC v. United States*, 155 Fed. Cl. 84, 120-21 (2021) (granting an injunction "where the government apparently failed to implement the corrective action to which it had committed before the GAO.").

133. Here, the record indicates the Agency has not implement its proposed corrective action and has not resolved the issues raised in StringKing's protests. The main crux of StringKing's protests is that the Agency (a) failed to evaluate proposals in accordance with the Solicitation as the Agency did not evaluate offerors' prices by considering shelf life under Factor 4 (Price) and in the best value determination as the Solicitation required the Agency to do; and (b) has arbitrarily and capriciously eliminated shelf life in its evaluation criteria under Factor 2, Factor

[redacted]

4, and in the overall best value determination through its issuance of Amendment 0008 and Amendment 0009.

134. Instead of re-evaluating proposals in accordance with the express language in the Solicitation, the Agency issued Amendment 0008 and Amendment 0009 to change the entire evaluation landscape for the procurement and seeks to unreasonably eliminate shelf life from the evaluation criteria for Factor 2 (Technical Capability), Factor 4 (Price), and the overall best value determination. That is, the Agency objectively intends to not re-evaluate offerors' prices and technical proposals and make a best value determination that considers shelf life pursuant to StringKing's prior protest and instead has arbitrarily and capriciously eliminated shelf life from the Agency's consideration for award altogether.

135. StringKing's protest on this ground should be sustained and StringKing is entitled to reimbursement of protest costs relating to this protest under the Equal Access to Justice Act and the Court's inherent power to award attorneys' fees.

136. StringKing has been put to the expense of protesting ***a fourth time*** (i.e., two GAO protests, an agency-level protest, and now before the Court) to ensure that shelf life for offerors' proposals (and products) are evaluated under Factor 2 (Technical Capability), Factor 4 (Price), and in the best value determination as contemplated by the Solicitation prior to the Agency's unreasonable issuance of Amendment 0008 and Amendment 0009.

<u>COUNT VI</u>

The Agency Arbitrarily and Capriciously Issued Amendment 0009 to the Solicitation as a Corrective Action.

137. StringKing incorporates by reference the allegations set forth above and in the foregoing paragraphs as if fully stated herein.

[redacted]

138. Here, the Agency has unreasonably changed the Solicitation's requirements as part of the Agency's corrective action by issuing Amendment 0009, which places a ceiling on the value the Agency may assess to the shelf life of offerors' products under Factor 2, Technical Capability. Specifically, Amendment 0009 states 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." (Amend. 0009 at 53 (emphasis added).) Amendment 0009 further states that "***[a] shelf life longer than 3 years will not be evaluated higher or considered to be an additional strength.***" (*Id*. at 53 (emphasis added).)

139. It is well-established that "an agency has broad discretion to take necessary corrective action" where there has been an error in the procurement process. *See Sys. Application & Techs., Inc., v. United States*, 100 Fed.Cl. 687, 716 (2011). Given the broad discretion afforded to agencies, the great weight of authority is that to survive review, an agency's corrective action must be "'reasonable under the circumstances and appropriate to remedy the impropriety.'" *Amazon Web Servs., Inc., v. United States*, 113 Fed.Cl. 102, 115 (2013) (quoting *Reema Consulting Servs., Inc. v. United States*, 107 Fed.Cl. 519, 527 (2012)); *see also, e.g., Sheridan Corp. v. United States*, 95 Fed.Cl. 141, 145 (2010) (stating that "[t]o be reasonable, the agency's corrective action must be rationally related to the defect to be corrected" and "the reason for the corrective action must be supported by the evidence in the record"). When an agency amends a solicitation as part of a corrective action, "in order to survive review under the arbitrary and capricious standard, 'a reasoned explanation is needed for disregarding facts and circumstances that underlay . . . the prior policy[.]'" *See, e.g., Prof'l Servs. Indus., Inc. v. United States*, 129 Fed.Cl. 190, 206 (2016) (internal citation omitted).

[redacted]

140. Here, the Agency's issuance of Amendment 0009 and decision to amend the evaluation criteria for Factor 2 to state that "[a] shelf life longer than 3 years will not be evaluated higher or considered to be an additional strength" is not rationally related to a defect the Agency presumably is fixing through corrective action in response to StringKing's protest. Further, no reasoned explanation is apparent or can be inferred on the basis of the present administrative record and the Court should be disinclined to infer that the Agency examined its needs and engaged in reasoned decision-making when it amended the requirements of the Solicitation in such a material way—especially given the history of this procurement.

141. "Presumably, the agency had good reasons for assigning" the evaluation criteria and product requirements related to shelf life under Factor 2 in the original Solicitation. *See Prof'l Servs. Indus.*, 129 Fed.Cl. at 206. The record is devoid of evidence that the Agency reviewed its needs, reasonably assessed them, and had a rational basis for deciding that the original solicitation did not meet them. Accordingly, HHS's decision to amend the solicitation to shorten the material value of an offerors' products' shelf life under Factor 2 through Amendment 0009 is arbitrary and capricious and must be set aside.

142. Each of the Agency's actions prejudiced StringKing.

143. StringKing's protest should be sustained.

COUNT VII

The Agency's Issuance of Amendment 0009 is Arbitrary and Capricious and Effectively Eliminates Product Shelf-Life as a Consideration in this Procurement.

144. StringKing incorporates by reference the allegations set forth above and in the foregoing paragraphs as if fully stated herein.

[redacted]

145. The Agency's issuance of Amendment 0009 fundamentally changes the Solicitation's requirements by effectively eliminating the Agency's consideration of shelf life under Factor 2, Technical Capability. Specifically, Amendment 0009 states 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." (Amend. 0009 at 53 (emphasis added).) Additionally, Amendment 0009 states that "***[a] shelf life longer than 3 years will not be evaluated higher or considered to be an additional strength***." (*Id*. at 53 (emphasis added).) Amendment 0009, together with Amendment 0008 (which StringKing protested in its original complaint), effectively removes the evaluation of shelf life from the Agency's evaluation criteria. This is markedly different than the requirement originally solicited by the Agency, which prioritized and placed emphasis and strength in an offeror's ability to provide a product with longer shelf life. Offerors that have products with longer shelf life (which in turn, have a higher price) [redacted] are no longer competitive in this procurement due to the Agency's materially changed requirement. This action is contrary to the fundamental requirement for offerors to compete on an equal basis and reflects arbitrary and capricious conduct by the Agency.

146. Further, it is unduly burdensome to expect offerors [redacted], which proposed a gown with a relatively long shelf-life in response to prior iterations of the Solicitation, to prepare and submit a proposal for gowns with a relatively short shelf-life by June 17, 2024, as offerors are required to do by Amendment 0009. The materials utilized for a short shelf-life gown are completely different than the materials needed for a long shelf-life gown. This abrupt, material change by the Agency requires offerors that designed products with longer shelf life to meet the

[redacted]

Agency's requirements as originally solicited, [redacted], to procure a completely different product. This, in turn, requires offerors to re-engage in the research and design process and to comply with FDA's required manufacturing process, which requires (at minimum) that an offeror:

a. Plan gown design
b. Procure raw materials (generally not off the shelf)
c. Test biocompatibility of raw materials
d. Create samples (this requires extensive research and development to understand interactions of ultrasonic welding machines with the raw material to optimize seam strength)
e. Send samples to an independent lab for testing
f. Make final samples including five production lots
g. Properly age gowns through an independent lab to enable certified shelf life claims
h. Conduct pre-aging testing on gowns
i. Conduct post-aging testing on gowns which must occur once aging tests are completed
j. Prepare final bid

147. Further, the Agency's removal of shelf life from the Agency's material evaluation requirements violates FAR 7.105, which requires the Agency to adequately consider "life-cycle cost." Amendment 0008 and Amendment 0009 have changed the Solicitation to eliminate any distinction between a medical gown with three years of shelf life and a medical gown with twenty years of shelf life—despite the concrete fact that the Agency will be required to reprocure gowns that expire.

148. Each of the Agency's actions has prejudiced StringKing.

149. StringKing's protest should be sustained.

<u>COUNT VIII</u>

Amendment 0009 Unduly Restricts Competition.

150. StringKing incorporates by reference the allegations set forth above and in the foregoing paragraphs as if fully stated herein.

[redacted]

151. Amendment 0009 renders the Solicitation unduly restrictive because it is unnecessary, eliminates the competitiveness of offerors whose products have longer shelf life, and effectively allows only offerors with shorter shelf life [redacted] to compete for award.

152. The Competition in Contracting Act ("CICA") imposes a duty on the Agency to "obtain full and open competition." 41 U.S.C. § 253(a)(1)(A) (1994); 10 U.S.C. § 2304(a)(1)(A). A consequence of this duty is that Solicitation provisions that restrict competition may be used only "to the extent necessary to satisfy the needs of the agency or as authorized by law." 48 C.F.R. § 11.002(a)(1)(ii); 41 U.S.C. § 253a(a)(2)(B); 10 U.S.C. § 2305(a)(1)(B)(ii). "Unnecessarily restrictive specifications or requirements that might unduly limit the number of bidders are prohibited." 48 C.F.R. § 14.101(a).

153. The Agency's decision to issue Amendment 0009 is entitled to a "presumption of regularity," *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415, 91 S.Ct. 814, 823, 28 L.Ed.2d 136 (1971), although that presumption does not shield it from a "***thorough, probing, in-depth review.***" *Id.* (emphasis added). While courts "recognize the relevant agency's technical expertise and experience, and defer[s] to its analysis unless it is without substantial basis in fact," *Fed' Power Comm'n v. Florida Power & Light Co.*, 404 U.S. 453, 463, 92 S.Ct. 637, 644, 30 L.Ed.2d 600 (1972), the Court must also perform an informed review of even technical decisions in order to meaningfully exercise its jurisdiction. *Prineville Sawmill Co., Inc. v. United States*, 859 F.2d 905, 910–11 (Fed. Cir. 1988). Furthermore, "[e]xpertise is a rational process and ***a rational process implies expressed reasons for judgment***." *Redland Genstar, Inc. v. United States*, 39 Fed.Cl. 220, 231 (1997) (emphasis added) (internal citations omitted). The Court must therefore "ensure that the agency has 'examin[ed] the relevant data ***and articulat[ed] a satisfactory***

[redacted]

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explanation for its action including a rational connection between the facts found and the choice made.'" *Id*. (emphasis added) (internal citations omitted).

154. Here, the Agency has arbitrarily and capriciously changed the Solicitation's requirements by issuing Amendment 0009, which unduly restricts competition by materially changing the procurement two years into the competition. Specifically, Amendment 0009 states 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." (Amend. 0009 at 53 (emphasis added).) Amendment 0009 further provides that "***[a] shelf life longer than 3 years will not be evaluated higher or considered to be an additional strength.***" (*Id*. at 53 (emphasis added).) Amendment 0009 does not otherwise reinstate shelf life as part of the evaluation criteria for Factor 4 (Price) or as a requirement for the Agency's overall best value determination. Moreover, Amendment 0009 changes the purpose of the procurement from "ensur[ing] sufficient domestic availability" of gowns for future emergencies and pandemics to merely "Isolation Gowns used in healthcare settings."

155. The resulting impact of the Agency's issuance of Amendment 0009 is to unduly restrict competition. First, offerors that have products with longer shelf life (which in turn, have a higher price) [redacted] are no longer competitive in this procurement due to the Agency's materially changed requirement, which places a ceiling on the value the Agency may assess to the shelf life of offerors' products under Factor 2. Amendment 0009's short turnaround time for revised proposals artificially eliminates competitors that have invested the last few years and significant research and development dollars into developing long shelf-life gowns under the Agency's previous evaluation scheme that both credited gowns with a longer life-cycle and

[redacted]

emphasized the Agency's need for medical gowns with a long shelf life for the purpose of creating a national stockpile of PPE. Second, a plain reading of Amendment 0009 shows the Agency is irrationally requiring all gowns to have a shelf life of exactly three years or else risk being eliminated as unacceptable. Such a requirement is arbitrary and capricious and lacks a rational basis in restricting competition.

156. The record shows the Agency lacks a rational basis for making these changes to the Solicitation. For example, the Agency includes a Market Research Report in support of its amendment but that report fails to discuss customary commercial practice for shelf life in any way and as such does not support the Agency's unsupported statement that the industry norm for shelf life is five years. (*See* AR 11-18.) Further, the Agency's Acquisition Plan for the procurement arbitrarily and capriciously dismisses life-cycle costs entirely. (AR 105 ("Life-cycle cost does not apply to this commercial medical supply acquisition.") Gowns with a longer shelf-life inherently have lower life-cycle costs and the Agency's statement shows a flawed misunderstanding of both lifecycle costs and the PPE marketplace (as shelf life is standardly considered in the commercial marketplace and has been considered by HHS itself in other similar procurements).

157. In short, nothing in the record demonstrates a rational connection between the Agency's needs as originally solicited (and appropriated through federal funding) and its late hour decision to eliminate the evaluation of shelf life in any meaningful way under Factor 2 through Amendment 0009 and Factor 4 and the overall best value determination through Amendment 0008. *See, e.g.*, *Redland Genstar*, 39 Fed.Cl. at 234-25 (finding the agency failed to articulate the required rational connection between its needs and its departure from previous practice, which had a restrictive effect on competition, and that changes to bid specifications made following filing of

[redacted]

the protest were arbitrary and did not retroactively rationalize the agency's choice of bid specifications); *see also, e.g., U.S. Foodservice, Inc. v. United States*, 100 Fed.Cl. 659 (2011) (holding the MFC clause crafted by the agency exceeded the bounds of rationality and amounted to an arbitrary and capricious requirement in granting an injunction in favor of plaintiffs).

158. This is especially true here since the departure from prioritizing shelf life under Factor 2 restricts competition, reflects a materially changed requirement (that likely justifies cancellation of the procurement overall), and reflects disparate treatment and bias in favor of certain competitors in the procurement [redacted]. Since the record does not reveal a rational connection between the facts associated with the Agency's decision to place a ceiling on the value the Agency may assess to the shelf life of offerors' products under Factor 2, the Agency's issuance of Amendment 0009 is invalid because it is arbitrary and capricious and an abuse of discretion.

159. Amendment 0009 also shows the Agency failed to take meaningful corrective action in response to StringKing's prior protests.

160. Each of the Agency's actions prejudiced StringKing.

161. StringKing's protest should be sustained. The Agency cannot abuse the discretion afforded to it and fundamentally change evaluation requirements to restrict competition and circumvent its obligation to conduct a fair and unbiased procurement. StringKing is entitled to a declaration that the Agency's issuance of Amendment 0009 lacks a rational basis and that, as a result, the Solicitation unduly restricts competition in violation of CICA.

COUNT IX

Alternatively, the Agency's Issuance of Amendment 0008 and Amendment 0009 Reflects Cardinal Changes to the Solicitation that Violate CICA and FAR 15.206(e).

[redacted]

162. StringKing incorporates by reference the allegations set forth above and in the foregoing paragraphs as if fully stated herein.

163. Amendment 0009 (and Amendment 0008) materially changes the Solicitation requirements in such a substantial way that exceeds what offerors could have reasonably anticipated.

164. CICA requires executive agencies, when procuring property or services, to “obtain full and open competition through the use of competitive procedures,” unless certain specified exceptions apply. 41 U.S.C. § 3301(a)(1). This statutory imperative for full and open competition is violated if a procuring agency makes a cardinal change to a contract requirement after accepting bids in response to a solicitation. *See AT & T Comm., Inc. v. Wiltel, Inc.*, 1 F.3d 1201, 1205 (Fed. Cir. 1993) (“[M]odifications outside the scope of the original competed contract fall under the statutory competition requirement.”). “In other words, a cardinal change to a proposed contract during the course of a procurement, or after the contract has been awarded, disguises the essential nature of the competed contract and frustrates full and open competition.” *Golden Mfg. Co. v. United States*, 107 Fed.Cl. 264, 275 (2012).

165. This principle is carried forth in FAR 15.206(e), which provides:

> If, in the judgment of the contracting officer, based on market research or otherwise, ***an amendment proposed for issuance after offers have been received is so <u>substantial as to exceed what prospective offerors reasonably could have anticipated</u>***, so that additional sources likely would have submitted offers had the substance of the amendment been known to them, ***the contracting officer shall cancel the original solicitation and issue a new one, regardless of the stage of the acquisition***.

48 C.F.R. § 15.206(e) (emphasis added). “A cardinal change to a solicitation may thus constitute a violation of CICA and a violation of FAR 15.206(e), unless the agency takes steps to re-open the

[redacted]

competition and disclose its changed contract requirements to potential offerors." *Golden Mfg. Co.*, 107 Fed.Cl. at 275.

166. Here, the Agency's issuance of Amendment 0008 and Amendment 0009 reflects cardinal changes to the Solicitation that violate CICA and FAR 15.206(e) because the Agency's amendments have "substantially changed a solicitation or contract requirement that was previously determinative of the elimination of offerors, thus rendering that elimination process arbitrary and capricious[.]" *Golden Mfg. Co.*, 107 Fed.Cl. at 276. These changes materially change the procurement in such a way that the Agency is required to cancel the procurement and resolicit its new requirement.

167. Shelf life is integral to any evaluation and assessment of disposable medical isolation gowns being procured because the stated ***original*** purpose of the procurement was to stockpile the gowns in preparation for future national emergencies and pandemic events. That is, Agency funding was appropriated for the express purpose of stockpiling medical gowns. The Solicitation as originally issued prioritized the ability of the Agency to procure disposable medical gowns with a long shelf life because the Agency's stated (and required) evaluation criteria emphasized the Agency's need for a product with long shelf life in three evaluation factors: Factor 2 (Technical Capability); Factor 4 (Price); and in the Agency's overall best value determination.

168. A simple comparison of the plain language of the Solicitation as originally issued to the Solicitation post-issuance of Amendment Nos. 0008 and 0009 demonstrates the materiality of the Agency's changes.

Original Solicitation	**Current Language via Amendment 0009 or Amendment 0008**

[redacted]

Original Solicitation **C.2 <u>Purpose</u>**: The U.S. Government is interested in establishing multiple awards for the purchase of domestically manufactured ANSI/AAMI PB70 Level 2 disposable medical Isolation Gowns used in healthcare settings. In establishing multiple awards for such medical isolation gowns, ***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***. The Government is concerned about the risks of disruption of any manufacturing facilities or supply chains located outside of the United States. Thus, offerors are advised to pay special attention to the requirement regarding location of manufacturing. Medical gowns promote infection control practices and help protect patients and healthcare workers against microorganisms and body fluids during routine care, examinations, and medical procedures. The choice of medical gown(s) is dependent on the level of risk of contamination. The American National Standards Institute/Association for the Advancement of Medical Instrumentation (ANSI/AAMI) PB70 establishes a system of classification for surgical and isolation gowns used in healthcare facilities, based on their liquid barrier performance. The ANSI/AAMI PB70 standard includes four standard tests to evaluate the barrier effectiveness of surgical gowns, isolation gowns, and surgical drapes. Based on the results of these standardized tests, four levels of barrier performance are defined, with Level 1 being the lowest level of protection and Level 4 being the highest level of protection.	***Via Amendment 0009*** **C.2 <u>Purpose</u>** The U.S. Government has a requirement for domestically manufactured ANSI/AAMI PB70 Level 2 disposable medical Isolation Gowns used in healthcare settings. Medical gowns promote infection control practices and help protect patients and healthcare workers against microorganisms and body fluids during routine care, examinations, and medical procedures. The choice of medical gown(s) is dependent on the level of risk of contamination. The American National Standards Institute/Association for the Advancement of Medical Instrumentation (ANSI/AAMI) PB70 establishes a system of classification for surgical and isolation gowns used in healthcare facilities, based on their liquid barrier performance. The ANSI/AAMI PB70 standard includes four standard tests to evaluate the barrier effectiveness of surgical gowns, isolation gowns, and surgical drapes. Based on the results of these standardized tests, four levels of barrier performance are defined, with Level 1 being the lowest level of protection and Level 4 being the highest level of protection.
Original Solicitation **<u>Factor 2: Technical Capability</u>** **Subfactor 6: Shelf Life** ***Offerors' proposals will be evaluated to determine whether the product meets the shelf life requirements of this solicitation***. 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. Offerors shall provide data and documentation to support any shelf claim.	***Via Amendment 0009*** **<u>Factor 2: Technical Capability</u>** **Subfactor 6: Shelf Life** Offeror's proposals will be evaluated based on providing the signed certified manufacturer statement in the format provided in Section L: Subfactor 6: Shelf Life. A shelf life longer than 3 years will not be evaluated higher or considered to be an additional strength.
Original Solicitation **<u>Factor 4: Price</u>**	***Via Amendment 0008*** **<u>Factor 4: Price</u>**

[redacted]

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The government will evaluate each Offeror's prices to determine that those prices are fair and reasonable and to determine which Offerors' proposals offer 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. a) ***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.*** 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) In accordance with FAR 15.401-1 Proposal Analysis techniques, the Government will consider unbalanced pricing when performing the price evaluation.	The government will evaluate each Offeror's prices to determine that those prices are fair and reasonable. 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. a) 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). b) In accordance with FAR 15.401-1 Proposal Analysis techniques, the Government will consider unbalanced pricing when performing the price evaluation. 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

169. By way of summary, the Agency has: (a) changed the purpose of the procurement from creating a stockpile of medical gowns "to ensure sufficient domestic availability of such items during national emergencies and/or pandemic events" to simply soliciting medical gowns to be used in "healthcare settings", (*compare* AR 277 *with* Amendment 0009 at 11); (b) eliminated the evaluation of shelf life in any substantive way under Factor 2, Subfactor 6 (Shelf Life) to merely requiring offerors to submit a "signed certified manufacturer statement" and expressly stating that products with shelf life that exceeds three years "will not be evaluated higher or considered to be an additional strength", (*compare* AR 316 *with* Amendment 0009 at 54); (c) eliminated the consideration of shelf life in evaluating offerors' prices under Factor 4 (Price),

[redacted]

(*compare* AR 317 *with* Amendment 0009 at 55); and (d) eliminated the consideration of shelf life in making the Agency's best value determination by removing the requirement for the Agency to "consider the cost of the product as it relates to the shelf-life at time of delivery" and "also consider the time, effort, and cost to sustain product with lesser shelf-life." (*compare* AR 318 *with* Amendment 0009 at 55).

170. These changes to the Solicitation show the Agency now seeks to procure a new requirement—medical gowns without a long shelf life that are cheaper for only the next three years. Because the Agency's needs have apparently materially changed, the Agency is required under the law and applicable regulations to cancel the Solicitation and competitively procure its new requirements in accordance with CICA and FAR 15.206(e).[8]

171. StringKing has been prejudiced by the Agency's failure to cancel the Solicitation and resolicit the Agency's new requirements in accordance with CICA and the FAR. As amended, the Solicitation unfairly skews the competition in favor of products with lesser shelf life and essentially eliminates StringKing from consideration for award under the Agency's new evaluation criteria.

172. StringKing's protest must be sustained.

PREJUDICE

173. StringKing incorporates by reference the allegations set forth above.

[8] If the Agency's requirements have not materially changed, the Agency should be estopped from eliminating shelf life from the evaluation criteria for Factors 2 and 4 and in the overall best value determination as well as changing the stated purpose of the procurement.

[redacted]

174. At bottom, the Solicitation was issued by the Agency to procure medical gowns to create a stockpile and prepare for future national emergencies and pandemics in response to the COVID-19 pandemic, which saw dangerous shortages of personal protective equipment for medical personnel throughout the country and world. The Agency has completely changed the requirement it is soliciting through a series of arbitrary and capricious amendments, to the extreme detriment of StringKing and other offerors that have products with longer shelf life.

175. HHS's actions have harmed StringKing specifically. StringKing has spent millions of dollars to prepare for this procurement, which includes creating a new product with long shelf life to specifically meet the Agency's requirements, securing and equipping a specialized manufacturing facility, and undergoing lengthy and expensive shelf life testing to meet the Agency's requirements and emphasis on shelf life as originally stated in the Solicitation.

176. Among other things, as an offeror with surgical gowns with a long shelf life, StringKing has been harmed by Amendment 0008, which was specifically aimed at eliminating shelf life as a factor for the Agency's price evaluation and overall best value determination, and Amendment 0009, which has resulted in an arbitrary and capricious *de facto* elimination of shelf life from the evaluation criteria for the procurement overall by arbitrarily and capriciously revising Factor 2 to state that "Isolation Gowns must have a shelf life of 3 years" and that "shelf life longer than 3 years will not be evaluated higher or considered to be an additional strength a ceiling value on shelf life."

177. These amendments, both individually and collectively, have resulted in a *de facto* elimination of shelf life from the evaluation criteria for the Solicitation, which is inconsistent with the Solicitation's original stated purpose (as well as the purpose of SNS, which is to create a

[redacted]

stockpile of PPE). The entirety of StringKing's extensive preparations over the last few years have been focused on providing the Agency with a product that has as long a shelf life as possible in response to the Agency's emphasis on shelf life in the evaluation criteria under Factors 2 and 4 and in the overall best value determination. And now, at the very last minute, the Agency has sought to change course in a material way that harms StringKing and makes StringKing's proposal noncompetitive (especially from a price standpoint).

PRAYER FOR RELIEF

178. Accordingly, StringKing respectfully requests that this Court enter judgment for Plaintiff-Intervenor and further requests that the Court:

a. Declare HHS's issuance of Amendment 0008 to be:

i. arbitrary and capricious, an abuse of its discretion, and contrary to law; or

ii. alternatively, declare HHS's issuance of Amendment 0008 to be a material change to the Solicitation's requirements that mandates cancellation of the procurement overall;

b. Declare HHS's issuance of Amendment 0009 to be:

i. arbitrary and capricious, an abuse of its discretion, and contrary to law; or

ii. alternatively declare HHS's issuance of Amendment 0009 to be a material change to the Solicitation's requirements that mandates cancellation of the procurement overall;

[redacted]

c. Permanently enjoin HHS from removing shelf life from the Solicitation's evaluation criteria;

d. Permanently enjoin HHS from proceeding with the award of NYES's under the RFP without first evaluating StringKing's proposal in a manner consistent with the Solicitation and applicable law;

e. Direct the Agency to re-evaluate proposals in accordance with the terms of the Solicitation evaluation criteria to include consideration of shelf life as originally contemplated;

f. Award StringKing its reasonable attorney's fees and costs; and,

g. Provide such other and further relief as the Court deems just and proper.

[redacted]

Dated: June 12, 2024

Respectfully submitted,

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