RESPONSES TO QUESTIONS

RFP-HHS-BARDA-08-09-draft

1. Please explain how long the contractor is expected to maintain the 150 million pandemic dose capability under the RFP (e.g. until the end of the amortized life of the facility, as long as HHS continues to exercise yearly options, until the end of the option period, in conjunction with a specific ordering period for pandemic doses, obsolescence of the technology, etc.). Also please clarify what HHS understands or expects the amortized life of the facility to be.

   It is the expectation of the USG that the contractor will maintain a licensed facility capable of meeting contract requirements as long as option periods are in effect. The amortized life of the facility must extend through the defined options periods (20 year minimum).

2. Please define the ordering period for the pandemic doses discussed in the "Pandemic Preparedness" section on p. 9 of the draft RFP? Also clarify at what point the contractor's obligation to produce the pandemic doses upon declaration of a pandemic will end? Is it contemplated that such obligation would continue for a specific period of years? Would it cease upon delivery in response to a declared pandemic or potentially span multiple declared pandemics?

   It is the expectation of the USG that the contractor will maintain a licensed facility capable of meeting contract requirements as long as option periods are in effect. The contractor shall manufacture and provide pandemic influenza vaccine to the USG for the duration of a declared pandemic. The President or Secretary of Health and Human Services (HHS) will be the authority to declare the start and end of any pandemic influenza event. This contract will not be exclusive to a single pandemic influenza event.

3. Please clarify the following: what is meant by "Annual Warm Based Vaccine Production" in each line item (seasonal or pandemic, what strain) and also what constitutes "1 Lot", as those terms are used in the CLIN chart on page 3 of the draft RFP. The RFP states that the costs to be entered into the Option period table on pg. 3 should include "the cost of raw materials (including disposables), labor, overhead and depreciation". Will HHS also include the costs involved in changing over production to produce the 1 lot per year or high overhead costs if the facility is not at full capacity?

   The term "Annual Warm Base Manufacture" will be changed to "Pre-pandemic Influenza Vaccine Manufacturing." The pre-pandemic strain will be determined by the USG at the time an option period is executed and an order is placed. The number of doses that represents a single manufactured batch (1 Lot) is defined by the contractor, but shall in any event be at least 200,000 doses. The USG will consider change-over

costs; however, the USG will not consider costs associated with underutilization of capacity in the pricing of Option Periods.

4. If the contractor is required to manufacture a vaccine candidate for an emerging vaccine candidate as described in the "Emerging Infectious Diseases" section on page 9 of the draft RFP, will it be entitled to compensation for any business disruption expenses it may incur as a result? Will the contractor be required to manufacture the new product, or under any circumstance will it be required to surrender the facility to another manufacturer? Will contractor be required to develop vaccine candidates or solely manufacture such candidates using some other entity's process? If this is the intention of the RFP, it would be difficult for any company to make the required commitments. Is there a limit to the number of occasions this could be required in the 20 year period? Would contractor be compensated for business disruption and other expenses incurred as a result of this directed manufacture of emerging disease vaccines? What would such compensation include and exclude?

   The contractor will not be required to develop vaccine candidates for emerging infectious diseases. The contractor may be required to manufacture vaccine candidates that utilize another entity's process. The contract will not be exclusive to a single public health emergency that arises from an emerging infectious disease. All other elements of this question will be points of negotiation between the contractor and the USG under a separate procurement activity.

5. Please clarify what is meant by "doses manufactured in excess of the original 150 million doses." Does this mean doses in excess of the original 150 million within the first 6 month timeframe or does it mean in excess of 150 million manufactured at any point after the declaration of a pandemic?

   To clarify, any doses manufactured by the contractor in excess of the $150 million throughout a declared pandemic influenza event.

6. Please clarify the intent of the "Pandemic Preparedness" section on page 9 of the draft RFP. Does the USG reserve the right to direct disposition of all doses produced, or only those doses produced within the first six months after declaration of a pandemic in excess of the 150 million? How will price for doses not purchased by the USG, but directed to other buyers, be priced? Clearly, the commercial implications could have considerable impact on the Offeror's commercial and allocation/distribution commitments to other companies and countries.

   The USG reserves the right to direct disposition of any doses manufactured by the contractor in excess of the $150 million throughout a declared pandemic influenza event. The price per dose will include a negotiated ceiling price and will reflect equitable compensation to the contractor.

7. Please clarify what will occur if the costs in the last executed Option Period, referenced in the "Pandemic Preparedness" section on page 9 of the RFP, differ significantly from actual costs to produce the pandemic vaccine? Will the contractor be entitled to an

equitable adjustment for the difference if costs are higher? Will HHS expect to renegotiate price if costs are lower (possibly as a result of unique costs built into the provision of only one lot in some option years)? Clearly the variability in costs over the whole period could vary significantly and without reasonable re-imbursement provisions, Offerors would be reluctant to enter into such an open-ended commitment.

The option periods are cost-plus-fixed fee line items. Under the contract(s) awarded as a result of this RFP, costs will be reimbursed on the basis of costs actually incurred, but are subject to the conditions and limitations set forth in FAR Clause 52.232-20, Limitation of Cost.

8. Please clarify how costs already incurred, which fit within the scope of the draft RFP, will be treated under the resulting contract? Is there a time period in which pre-contract costs will be reimbursed in keeping with the cost-sharing formula? The draft RFP contains a reference to the "period covered by pre-contract cost provisions" (p 57) but no definition of that term. Further, what would be the process for negotiating and reimbursing appropriate pre-contract costs? How would the cost sharing split be applied to previously incurred costs and are these costs also subject to the goals of the Small Business Subcontracting plan?

   Pre-contract costs are not authorized. Page 57 of this RFP is a part of the billing instructions which pertain to all cost-reimbursement contracts. This section has been revised to read as follows: "…or the period covered by pre-contract cost provisions if authorized under the contract."

9. The RFP indicates that an option for a pilot scale facility may be included in the proposal to optimize the process upon an influenza strain change. Is this pilot facility intended to be used for process optimization of change in pandemic strain or both pandemic and seasonal strains? Is the pilot facility intended to handle, "wild type" strains (BSL3+)? Is the expectation that the pilot facility should have the capacity for GMP clinical material production? Would the provisions in the "emerging infectious diseases" clause be considered for pilot plant option? If the Offeror has pilot facilities for the tasks contemplated by HHS, but outside the United States such that a pilot facility in the US would be a commercially unnecessary duplication and wasteful of Offeror's resources (capital and operating costs), then would HHS consider reimbursement of a significant proportion of the pilot facility and ongoing support for operational activities? Alternatively, would HHS consider reimbursement for a pilot scale facility at a domestic site other than that producing the cell-based influenza vaccine?

   No consideration for a pilot scale manufacturing facility will be given under this contract.

10. Please clarify what assumptions regarding seed strain delivery HHS is proceeding under in requiring a capacity to deliver 150 million doses within 6 months of a declaration of a pandemic?

The USG anticipates seed strain delivery to contractors will take no more than 28 days from the declaration of a pandemic. This time shall be included in a contractor's analysis of vaccine delivery to the USG.

11. In discussing CLIN 0008, the draft RFP states that "estimates shall be revised to reflect the actual cost to manufacture influenza vaccine product and adjuvant (if applicable) as determined in Milestone 6. The actual cost of each option shall not exceed the estimated cost plus fixed fee for each line item:" (p. 3). Please clarify what is meant by this -- is the draft RFP indicating that the "Total Estimated CPFF" shall not exceed this amount? Actual costs may be difficult to estimate - particularly considering the number of option years at issue, presumably CPFF for those option years will reflect actual costs plus the fixed fee amount. Please confirm.

    Yes, the total estimated cost plus fixed fee shall not exceed this amount. Please note, however, that costs will be reimbursed based on actual costs incurred in the performance of the work, but are subject to the "Limitation of Cost (FAR 52.232-20)" clause which will be incorporated into the awarded contract(s) by reference.

12. Please indicate if there is a particular inflation index HHS is assuming will be used in estimating option year costs.

    There is no particular index. HHS does, however, use the CPI as an evaluation tool when considering what is a reasonable escalation factor in outlying contract years.

13. Please clarify what is meant by the USG-designated site for delivery referred to under item 10 on page 9.

    The contractor shall deliver the material to one or multiple sites designated by the USG. Actual site location(s) are being discussed within the USG and have not been finalized. See also D.1I.

14. In section 9 on page 9, the draft RFP requests a table outlining the cost of raw materials for the formulation and filling for a finished lot of adjuvant. Please clarify if this requirement is an indication that HHS is only interested in funding a facility that produces (and subsequently procuring) only adjuvanted product with the adjuvant separately filled and finished? If not, and it is the practice of the Offeror to typically formulate and fill antigen with adjuvant, please confirm that it would be acceptable to present costs for formulation and filling of the combined finished product. Alternatively, does the draft RFP require estimates for formulating and finishing the antigen and adjuvant separately and an estimate for formulation and filling of the combined antigen with adjuvant?

    It is a requirement of the RFP that the antigen and adjuvant cost reflect the vaccine product to be licensed by the contractor (final finished product). This includes costs associated with the formulation, filling and packaging.

15. Please confirm that contractor is only obligated to produce the lots described in CLIN 0008 for as long as HHS exercises consecutive options and that upon failure to execute a yearly option all contract obligations end.

    Confirmed.

16. Please clarify the ownership status of the facility and the equipment contained within it at the end of the contract.

    The infrastructure/equipment purchased under this contract will be the sole property of the contractor. Infrastructure/equipment procured to support requirements under other USG contracts will maintain ownership rights as specified in those contracts.

17. Are there limits to the scope of reimbursement as they relate to site infrastructure costs? For example – utility systems (GMP and non-GMP), waste treatment, warehouse, administration or office buildings, etc.

    Only infrastructure equipment required to support the manufacture of the influenza vaccine candidate will be supported by this contract. [*For example, the contract will support administrative space for personnel that will be directly involved in the production of the influenza vaccine; however, will not support space for personnel outside this scope (e.g. corporate marketing, corporate HR, R&D).*]

18. Can the Offeror's portion of cost sharing include indirect costs and can HHS provide guidance on the method preferred for determining an indirect rate for a green field site, at which the labor base would be ramping up over the first few years of operation?

    Cost-sharing should be based on CLINS 0001 - 0007. The Government cannot provide guidance to Offerors in the preparation of their proposals.

19. On pg. 10 under Surveillance and Monitoring, the RFP states that "any official notices or reports that reference or result from a Federal, State, or local agency inspection or audit of the Contractor's facility(s) shall be provided to the Contracting Officer within two (2) business days of receipt by the Contractor." Please clarify if this requirement applies to both pandemic and seasonal vaccines. Also please confirm that the use of the word "facility" refers only to the domestic facility being funded under this RFP. Further, 2 days is often insufficient time for the necessary internal review and approvals to release to an outside party. Hence it would be preferable for the RFP to provide seven business days for the notification to HHS.

    The requirement applies to both seasonal and pandemic influenza vaccine manufactured at the domestically licensed facility. The USG two (2) business day requirement will not be extended. A contractor's internal review of any official regulatory correspondence of this nature will add no value to the USG's contract administrators.

20. On pg. 8, under Milestone 5a and 5b: Contractor-defined Milestones, the RFP indicates that potential milestones could include "Within one (1) week of submission to CBER, the Contractor shall provide a copy of the Biologics License Application (BLA) to the Contracting Officer.* Please clarify if submission of a copy of a BLA is an RFP requirement. If yes, would this apply to only pandemic, or seasonal as well?

    Submission of BLA copies is a requirement of the RFP and encompasses both seasonal and pandemic influenza vaccine candidates.

21. On pg. 94, under section 2.M, the RFP states that "The proposal shall describe the extent to which the Offeror has unencumbered access to intellectual property necessary to fulfill its obligations under the contract." Please confirm that it is not HHS' intent for this statement to apply to currently unknown strains or cades and that unencumbered access to such strains or clades would be provided by the USG.

    The USG confirms that it is not the USG's intent for this statement to apply to currently unknown strains or clades of influenza. When required during a declared pandemic, the USG will provide to the contractor unencumbered access to the isolated pandemic strain for vaccine production.

22. In item 4 on pg. 84 and in item 1b on page 90-91, the draft RFP indicates that Offeror's may propose dosage ranges for the design of the facility, provided they are substantiated by clinical data. Please confirm that clinical data can be based on either cell culture- or egg-derived vaccines or both.

    The USG will accept only clinical data for the contractor's cell culture influenza vaccine candidate to be used for dose range calculations.

23. On pg. 92, item g. of the RFP states that "Preference shall be given to those Offerors that have completed Phase I clinical trials for safety, immunogenicity and cross-reactivity or cross-neutralization of antigenically drifted influenza strains using cell-based methodologies." Completion of Phase I may not alone, (even if successfully completed) be a sound basis for preferential treatment and could result in the elimination of the strongest candidate vaccine. Will HHS consider that any preferential treatment be based on the overall status of the development candidate and the estimated probability of success of the respective Offeror's programs?

    The requirement will be updated to read "Preference shall be given to those Offerors that have completed Phase I clinical trials for safety and immunogenicity of antigenically drifted influenza strains using mammalian cell-based methodologies." The USG will not give preferential treatment based on the overall status of the development candidate and the estimated probability of success of the respective Offeror's program outside the constraints of the mandatory criteria set forth in the RFP.

24. The draft RFP makes no mention of the H5N1 influenza strain as being the likely pandemic strain. Is the Offeror expected to consider all other possible candidate influenza strains in its proposal and can HHS acknowledge in the RFP that actual costs

could significantly differ from estimated costs, depending on what strains will ultimately be used for the development, registration and production of a vaccine?

The USG expects Offerors to consider all possible pandemic influenza strains in its proposal. Due to this uncertainty, the USG will not make concessions on projected costs; however, the USG will negotiate, in good faith, an equitable price per dose of pandemic vaccine.

25. Please indicate what period of notice for option exercise will be inserted into contract clause FAR 52.217-9 and what length of time will be proposed for change-over from the routine production schedule . Also please clarify the timing of the delivery of the option lot, i.e. will it coincide with seasonal flu production?

    The written notifications required by FAR 52.217-9 will not be less than 30 calendar days and 60 calendar days, respectively. Change-over and the timing of the delivery lot is dependent on the outcome of careful analysis by the contractor and the USG's review of milestone deliverables (Milestone 5). These timeframes will be a point of negotiation between the contractor and USG as the contract proceeds.

26. Would you please confirm if HHS plans to discuss responses to questions at a pre-proposal conference for this solicitation?

    Responses to questions on the draft RFP will be posted to the Federal Business Opportunities website. In the event that a pre-proposal conference is held, Offerors will be able to have additional questions addressed.

27. The requirement to maintain a facility of this complexity and size in an unpredictable market environment over such an extended period of time, as appears to be proposed in the draft RFP, creates a number of serious issues for any company. For example, if the technology is superseded or becomes obsolete, or if market conditions deteriorate in the seasonal influenza vaccine market such that it is uneconomical to continue production at the site, then the economics of such a long-term commitment could likely become untenable. As outlined in the questions and requests for clarification below, the exact obligations under the RFP are not entirely clear and we are interested in learning more. We hope that the final RFP when released will strike an appropriate balance between the Government's goals and manufacturers' business needs.

    Noted.

28. There is overlap in the deliverables required by this RFP and the deliverables required by contracts awarded in response to RFP-05-04. What are DHHS' expectations for handling this overlap with Offerors that were awarded contracts in response to RFP-05-04?

    A contractor is expected to satisfy the requirements of all contracts with the USG, individually. Any costs that are associated with duplication of work by the contractor (CLIN overlap) shall be communicated to the USG contract administrators for

consideration. However, a contractor shall not invoice the USG for a work product that was already funded under a separate USG contract (double billing).

29. Are costs incurred for filling and packaging of both pandemic and seasonal strains eligible for reimbursement?

    Yes. These costs will be a negotiation point between the contractor and the USG.

30. Are all activities and items necessary to enable the execution of the manufacturing processes mentioned on page 6 in Milestone 4, element 4 eligible for reimbursement? If not, which activities and items are not eligible for reimbursement?

    Yes. All activities and items necessary to enable the execution of the manufacturing processes mentioned on page 6 in Milestone 4, element 4 are eligible for reimbursement.

31. How does this RFP enable DHHS to mix and match antigen and adjuvants from different companies?

    The 'mix and match' program is not an element of this RFP's Statement of Work (SOW).

32. Will DHHS require the creation of contingency plans for situations in which the yield for the actual future pandemic strain will not be high enough for 150 million doses within 6 months of declaration of pandemic?

    No.

33. Could further clarification be provided to the term “pre-pandemic vaccine” in the RFP?

    An influenza vaccine with a pre-pandemic indication is intended for immunization of persons against influenza virus subtypes of pandemic potential during the period when these subtypes have not yet evolved the capacity for sustained and efficient human-to-human transmission. These vaccines will ideally stimulate sustained immunological memory to enable boosting, resulting in an adequate immune response at a much later time point.

34. The footnote in table B.2(b) on page 3 is missing. Is the only specification to manufacture and release at least one (1) lot of vaccine product per year post-licensure of the facility (to maintain cGMP compliance and licensure)?

    The double asterisk will be removed from the table. Per the contract, the USG requires the contractor to manufacture and release at least one (1) lot of vaccine product per year post-licensure of the facility to maintain cGMP compliance and licensure.

35. In regards to the cost estimates in table B.2(b): Estimates will be more accurate if provided following completion of Milestone 6 (following construction of the

manufacturing facility). How does DHHS intend to mitigate the long term pricing risk to Offerors associated with providing 20 year pricing on a contract with ceiling rates in effect and no minimum purchase commitments?

Offeror should refer to the Section B.2.(b) [pgs 2 & 3] and Milestone 6, Items 6 through 10 [pgs 8 & 9]. See also response to Question 11 above.

36. Could further clarification be provided on how the ceiling rates will be calculated and what indirect rates they will impact in section G.5. on page 16?

Ceiling rates that will be incorporated into contracts are subject to negotiation. The establishment of ceiling rates may depend upon whether or not the offeror currently has a negotiated rate or forward pricing agreement in place with its cognizant Government Agency and the terms of the negotiated agreement, previous contracts with the Government and the historical cost data that can be obtained and/or whether the offeror has ever been audited. Ceiling rates could apply to any indirect rate listed in this section although we don't ordinarily apply ceilings to fringe benefits.

37. On page 91 in criteria 1c it is stated that if the Offeror proposes the use of an antigen sparing adjuvant, then its safety and effectiveness must be proven, the formulary disclosed and the anticipated dose ranges specified. Please clarify what is meant by "proven".

The word 'proven' will be changed to 'scientifically demonstrated.'

38. What is the approximate time frame for announcing the award(s)?

We anticipate making awards by the end of the calendar year.

39. Will further clarification be provided regarding Offeror's title to and ownership of the manufacturing facility?

The infrastructure/equipment purchased under this contract will be the sole property of the contractor. Infrastructure/equipment procured to support requirements under other USG contracts will maintain ownership rights as specified in those contracts.

40. Is the government's share of costs under the RFP capped at 40% of each of the line items 0001 – 0007, or is it capped at 40% of the total cost of the project?

The cost-sharing portion of this contract pertains to CLINS 0001-0007 only. The Government's share of these costs is capped at 40%. CLINS 0008A through 0008T are cost-plus-fixed-fee CLINS. They will be fully-funded by the Government when the option is exercised, subject to the terms of the contract.

41. Will HHS consider defining differently or providing more than 40% of the Cost sharing (CLINs)? Previous RFPs, contracts (Sanofi and MedImmune) and communications have referenced HHS funding ~75%.

No.

42. Will all or some of the option years for warm based manufacturing be amended to become a firm contract commitment from HHS as consistent with previous RFPs, contracts (Sanofi and MedImmune) from HHS or recent agreements from CDC? Alternatively, can the commitment (or option) be increased to a minimum number of doses to be purchased by HHS rather than a single lot of production?

    No, the USG does not plan to convert option periods into firm contract commitments. Also see response to Question 3 above.

43. If more than one annual pandemic lot is needed for maintaining cGMP compliance, production efficiency, operator skill sets, pandemic preparedness etc., will HHS commit to purchasing these doses (or bulk) of vaccine?

    No.

44. Is the warm base portion of the contract for pre-pandemic vaccine or seasonal vaccine, or will HHS have the option for one or the other?

    Pre-pandemic. The term "Annual Warm Base Manufacture" will be changed to "Pre-pandemic Influenza Vaccine Manufacturing." The pre-pandemic strain will be determined by the USG at the time an option period is executed and an order is placed. The USG will consider change-over costs; however, the USG will not consider costs associated with underutilization of capacity in the pricing of Option Periods.

45. Does HHS intend to fund construction activities under Milestone 5, before a BLA is submitted and/or before a license is granted?

    Yes, subject to prior approval of all necessary zoning, land use and construction permits and licenses.

46. The execution of options for a defined period of time will be crucial for the business model developed by offerors. Will the final RFP define under which conditions and for which period such options will be exercised if other milestones are successfully completed?

    No.

47. In section B.2.B, if HHS does not exercise the first option (0008A first annual warm based vaccine production), does this mean no other options can or will be exercised after a facility is built? (Options appear to have to be exercised in sequence or contract automatically terminates).

    Please see response to Question 15 above.

48. Does HHS intend to declare a pandemic using a definition and criteria consistent with that already defined by WHO as " Phase 6"? If not, what are the criteria to be used.

The President or Secretary of Health and Human Services (HHS) will be the authority to declare the start and end of any pandemic influenza event in the United States.

49. Does HHS intend to have any ownership of the facility/equipment/land after it has been completed under this RFP?

No, the infrastructure/equipment purchased under this contract will be the sole property of the contractor. However, infrastructure/equipment procured to support requirements under other USG contracts will maintain ownership rights as specified in those contracts.

50. If HHS intends to hold ownership in the completed facility, will HHS amend the RFP to provide options for how HHS will purchase or alternatively divest its share of any assets?

HHS does not intend to hold ownership in the completed facility.

51. Given the national security implications and importance of this procurement, the fact that the FDA has not yet approved a cell-based influenza vaccine, and that, as currently drafted, the RFP may not allow certain potential offerors who may be well advanced in the process of developing an FDA approved cell-based influenza vaccine to participate, will the agency amend the draft RFP to allow offerors to submit alternate proposals without requiring offerors to also submit offers that strictly adhere to all of the RFPs requirements?

No.

52. The USG reserves the right to direct the Contractor to manufacture a vaccine candidate for an emerging infectious disease to address a public health emergency. There is no mention of how the USG would facilitate a technology transfer if the facility operator did not develop the candidate vaccine, how a supply agreement might be negotiated, or under what conditions the change over would have to be implemented. Can HHS please clarify?

Elements of this question will be points of negotiation between the contractor and the USG under a separate procurement activity in the event of a public health emergency that warrants the USG to exercise this right.

53. Based on the need to potentially also produce other emerging viruses, the contractor would assume that the plant should be set up as a multi-purpose facility. Can HHS please confirm?

No, this solicitation does not support the design, construction and/or licensure of a multi-purpose facility.

54. Currently, the FDA has not approved a cell-based influenza vaccine for use in the U.S. In the best interest of the program, does HHS anticipate amending the referenced September release of the RFP to a later date based on additional feedback from the FDA relative to the licensability of candidate vaccines currently under IND review?

    No.

55. If clinical data are not yet sufficiently available for FDA/HHS to confirm license and availability of either the seasonal or pandemic candidate vaccines for all applied indications, will the project officers review an acceptance of the contractor defined milestones as described in milestone 5 be amended to a later date after which such data will be available? If so, will HHS negotiate amended pricing that adjusts for inflation over the gap period of when milestone 5 is due and when the contractor defined milestones are approved?

    The USG has no intention of negotiating a potential mitigation plan prior to contract award.

56. When the proposed facility is not being used for the production of cell-based pandemic influenza vaccine, warm based production in a non-pandemic year, or an emerging infectious agent, will the awardee be allowed to produce another vaccine from the facility and/or influenza vaccine for the US or other markets?

    The facility, fully licensed for the manufacture of an influenza vaccine candidate, must remain in a state of readiness commensurate with the terms of the contract.

57. HHS is requesting considerable detailed information related to proprietary and patented material and process know-how. To what extent or under what conditions if any, does HHS intend or have the right to provide this information to any non-USG third party under this contract?

    This procurement is subject to applicable Federal laws and regulations that restrict the disclosure and release of proprietary bid and proposal information, including the provisions of the Procurement Integrity Act, 41 U.S.C. § 423, as implemented by FAR 3.104. It is the intention of the USG to abide by these mandates and not share any such proprietary information with non-USG third parties in violation of law.

58. Will HHS consider modifying the RFP to provide that, if a pandemic is declared, contractor shall have the right to sell any doses (greater than 150 million doses) not purchased by HHS on the open market at prices established by the open market?

    No. The USG will reserve the right to direct the disposition of all doses manufactured during the period of a declared pandemic, as such period is declared by the President or Secretary of HHS.

59. Will HHS consider increasing the length of the option periods from one year to five years of warm base production?

    No.

60. When will HHS notify awardees that an option will be exercised? Is it possible for HHS to commit to exercising options at least 2 years prior to the expected delivery date?

    Please see response to Question 25. No.

61. Based upon offeror's development cycle and the timing of FDA approval, is it possible to extend the period of performance for the base period beyond 60 months given that Milestones 1 through 4 have been successfully completed.

    The USG has no intention of negotiating potential mitigation plans prior to contract award.

62. FAR 52.228-1 - Bid Guarantee. Will HHS provide the insert amounts required by this clause?

    Amount will be $3M and will be included in the final RFP when released.

63. FAR 52.228-15 - Performance & Payment Bonds - We request that HHS clarify the amount and timing of bonds required that is consistent with the scope of the contract. Specifically, the P&P bonds should only be required for the construction portion of the contract; the value of which will not be determined until after the design phase and final design approval.

    Please see the clause in full text at http:// www.acquisition.gov or http://www.hhs.gov/oamp/policies/ or http://www.gpoaccess.gov/cfr/index.html

    The bonds are required for the construction portion of the contract only and should be furnished at 100% of the negotiated amount attributable to the contractor for the construction portion of the contract, as reflected in the final design plans. The bonds will be due within 10 days after final design approval but in any event before commencement of the construction work.

64. FAR 52.236-22 - Design with Funding Limitations - Please clarify that HHS will complete the inserts required by this clause after acceptance of the final design package.

    This amount will be based on the final negotiated amount for the construction portion of the contract.

65. Does the government plan to include 52.250-1 given the potential hazardous risk associated with potential severe reactions to the vaccine product to protect those parties

associated with the design, construction, prove out and production required by this contract?

FAR 52.250-1 will not be included in the contract(s) awarded as a result of this solicitation. Offerors are reminded that the Public Readiness and Emergency Preparedness Act (Pub. L. 109-148) (the "PREP Act") already provides a measure of immunity from liability claims arising from administration and use of covered countermeasures to manufacturers, distributors, program planners and qualified persons involved in the administration and use of a covered "countermeasure," as specified in a declaration by the Secretary of HHS, except in the event of willful misconduct by the covered persons.

66. Are there any qualifications regarding the type of US licensed influenza vaccine that an offeror demonstrates it is able to produce?

The intent of the RFP is to support the establishment of domestic mammalian cell-based influenza vaccine manufacturing facilities. It is essential that the efforts funded by the present RFP result in the establishment and maintenance of a domestic mammalian cell-based manufacturing facility capable of producing 150 million doses of pandemic vaccine within six months of a pandemic declaration. As a result, the likelihood of influenza vaccine licensure and utilization figures importantly in the competitiveness of the Offeror's proposal. Beyond this restatement of objectives, the proposed vaccine shall be 1) a cell-based influenza vaccine candidate; 2) manufactured using reassortant influenza virus that is produced utilizing well-characterized mammalian cell lines; and 3) based on raising immunity to the influenza hemagglutinin (HA) protein as stated in Section M.1. of the draft RFP.

67. If an offeror is able to produce a seasonal influenza vaccine that is licensed in the United States, will that ability be sufficient to meet this requirement under the solicitation?

Yes.

68. Also, how is HHS defining the "successful completion of Phase I clinical trials" for the purposes of this solicitation?

Per the RFP, successful completion of Phase I clinical trials will include safety and immunogenicity data for a mammalian, cell-based influenza vaccine candidate at the time of proposal submission. This data may be submitted as raw data in a draft report.

69. If an offeror has completed dosing subjects for a Phase I clinical trial, would that meet the definition of a "successful completion"?

Please see response to Question 68 above.