

**Consolidated NGDS Increment 1, Q&A Listing
June 8, 2012**

1. Category: Assays

1. Q. How many Biological Warfare Agent (BWA) tests must be optimized in the CP Phase?

A: Minimum of 2 – *Bacillus anthracis* (BA) (2-targets) and Viral Hemorrhagic Fevers (VHF) (3-targets, 2-Ebola & pan-Marburg). This is most likely.

A: Maximum of 6 – BA In-vitro Diagnostic (IVD), BA Environmental, VHF IVD, Tularemia (FT) IVD, Plague (YP) IVD, and Q-Fever (Q) IVD. This is less likely but will be of interest if efficiency can be gained through multiplexing. Once optimized, assay may or may not be used in that form in subsequent phases (tests may be re-optimized into a larger panel, if applicable). Pre-clinical / clinical trials may or may not be started in the next phase for all agents optimized in CP (e.g. BA IVD pre-clinical trial may be started with a BA/YP/FT multiplex assay – with the YP/FT blinded). BG optimization will be removed from CP.

2. Category: Assays

2. Q. Do all BWA test optimizations have to be done in 125 days?

A: No. Only the designated “benchmark” assay has to be done in 125 days. The benchmark” will likely be BA.

3. Category: Sample Matrices

3. Q. What sample matrices must each CP phase BWA test be optimized for?

A: See table in SOW, Section C.3.1.3.1

BA – Buffer, whole blood, NIST soil

VHF – Buffer, Whole Blood, Blood Serum

YP – Buffer and Whole Blood

FT – Buffer and whole blood

Q-Fever – Buffer and whole blood

4. Category: FDA

4 Q. Will a technology which has not yet been FDA approved be considered for Increment 1? By what date must a company have a FDA approved product to be considered?

A: No. FDA clearance/approval is required at the time of proposal submission.

5. Category: RFP Submission Constraints

5. Q. Will a technology that will meet the short and long term objectives of NGDS and will be commercially available by the end of 2012 (in a non-FDA regulated market, but will be manufactured under GMP and ISO protocols) and will be submitting for 510(k) approval and a CLIA waiver, be considered? If so, by when would the IDE meeting, 510(k) submission and request for CLIA waiver, each need to be submitted?

A. Currently No. Systems proposed must be FDA cleared at the time of proposal submission (estimated to be June-July 2012). The requirement for FDA clearance at the time of submission will only be reconsidered if there was insufficient competition and would be reflected in the Final RFP if reconsidered.

6. Category: RFP Submission Constraints

6 Q. Can a small company address the concerns regarding the capability to efficiently obtain FDA approval be satisfied by either partnering with an organization with FDA approval experience or having or hiring employees or consultants with strong FDA approval experience?

A: The system proposed must FDA cleared at the time of proposal submission. However, partnering with other companies to increase assay development and FDA clinical trials capacity is acceptable.

7. Category: Consumables

7 Q. Multiple targets are listed for each Disease/Agent assay (e.g. Bacillus Anthracis, 2-3 targets). Are the multiple targets required for redundancy to increase specificity (i.e. reduce false alarm rate), or to determine different characteristics of the Disease/Agent (e.g. speciation, drug resistance)?

A. At a minimum multiple targets are needed for specificity. Then, in addition to those targets, additional targets may be proposed to provide speciation and resistance information.

8. Category: Source Selection Question/Performance Specification

8. Q. How is the overall evaluation conducted? Is there a trades analysis between [T] and [O] specifications, or “Important” and “Desired” evaluation ratings to measure the overall system performance?

A. Refer to Section M.3.2.1.2 for the definition of Green-Acceptable with respect to Critical, Important, and desired P-Spec thresholds. Qualitatively, the number of thresholds met above the minimum and number of objectives met contribute to ratings above green.

9. Category: COTS Analyzer

9. Q. If the offeror’s current commercial product does not meet certain “Important” or “Desired” evaluation criteria, but the offeror already has under development an upgraded version of the current commercial product that meets such criteria, can project funding be used to complete the development of the upgraded product?

A: No. The intent of the NGDS Contract is not to “Build To” the NGDS P-spec after contract award. Vendor Modifications after source selection may invalidate Govt testing needed to support a fielding decision. Proposed vendor configuration changes that do not jeopardize prior FDA clearances may be proposed and adjudicated via a formal Engineering Change Proposal Process.

10. Category: RFP Submission Constraints –Number of Proposals

10. Q. Can the offeror’s proposal include different instrumentation using the same technical approach but capable of different run throughput, e.g. a mobile or hand-held product capable of testing 1 sample at a time for multiple analytes, and a man-portable “bench-top” product capable of testing multiple samples, and/or multiple analytes simultaneously?

A: See Section L.2.13. In this case, offer may submit 2 proposals

11. Category: Consumables/Performance Spec

11 Q. For the environmental sample matrices, LOD is provided in absolute units (e.g. 10 pfu) in some cases, rather than as a concentration (e.g. 10 pfu/mL). What is the expected sample volume of the matrix to achieve the absolute LOD?

A. In the Final RFP, all LODs will be expressed as a concentration:

12. Category: Source Selection Timeline

12 Q. What is the estimated proposal due date? What is the estimated award date / project start date?

A: Estimates Proposal due date is 30 days after RFP release – on or about 20 April. Estimated award date is 30 July to 30 Sept.

13. Category: Source Selection Plan

13 Q. How many awards will be issued for the CP phase?

A: Govt is estimating 3 awards dependent upon available funding and the quality of proposals received

14. Category: Contract Scope

14 Q. Is there a maximum total award, or total award per year for each proposal?

A. The estimated contract ceiling is \$200M inclusive of base period and all options. There is no specific per year total. The Ceiling includes scope for all acquisition phase of the NGDS program and optional scope for other federal agencies.

15. Category: Source Selection Scope/Contract Award

15 Q. The proposal should include that for the CP, TD, and Post MS C phases, or just the CP phase?

A. The proposal should address all requirements of the RFP, inclusive of CP, TD and PD (post MS C).

16. Category: Proposal Submission Requirements – “Bid Sample”

16 Q. A Bid Sample is required to be responsive to this solicitation. Will the Government provide compensation for the Bid Sample, or return the Bid Sample after a period of time?

A: See Section L.2.1, and L.8 A “Bid Sample” consisting of an FDA cleared/approved system and 1 of each cleared assay shall be provided at no cost to the government as Volume 6 of the proposal. Systems from offerors not selected for award will have the 1 bid sample returned at Government Expense.

A: Update: the Bid Sample will be removed as a proposal requirement. It will be replaced with a required system demonstration.

17. Category: NGDS Program Vision (Tactical Variant)

17 Q. Is it the Government's intention to replace the JBTDS identifier with NGDS?

A. Potentially. The NGDS Tactical Variant Prototype, if the options are exercised, would be one of several candidates planned to be evaluated by the JBTDS program office. Use of the NGDS Tactical Variant by the JBTDS program is not mandatory at this time.

18. Category: NGDS (Tactical Variant) Consumables-Food & Water Assays

18 Q. Will Food and Water assays be rolled into JBTDS? Is the intention to ultimately use the NGDS as the common platform for all systems (detection, ID, BWA pathogens)?

A. JBTDS questions should be directed to the JPM Biological Defense program office for definitive answers. Food and water assays are not known to be a part of the JBTDS CONOPS. It would be significant cost savings to the Government for there to be a common materiel solution between the NGDS, CALS and JBTDS programs.

19. Category: RFP SOW Content (Emphasis Area?)

19 Q. In the early draft RFP dated 26 Mar 2012, you stated "...The NGDS program will seek the development of a syndromic approach to diagnostics..." (see 2.0) How is this requirement weighted relative to other requirements and with respect to sample-type?

A. Statements in the background sections of Section C and the P-Spec are not specially weighed in the source selection. The P-Spec 3.2.3.3 addresses Simultaneous analysis. Contractors in the CP Phase are required to provide recommended assay configurations for IVD (clinical samples), and BWA and Non-BWA environmental sample assays through the conduct of various studies (SOW para C.3.1.4) to include their approach for screening/syndromic kits that would increase the clinical utility of IVD assays and reduce the burden to operators from environmental sample types. Section L.4.1 requires that the Offeror provides a narrative how Section C tasks will be addressed. Section L.4.2 requires that Offerors provide a narrative of to what degree P-Spec metrics are addressed.

20. Category: FDA IVD Kit Timeline

20 Q. How were the FDA clearance time lines derived?

A. JPM CBMS, BSV Program Experiences. The JPM BSV has cleared 7 IVD BW and Non-BW agent kit with the FDA in the last six years. Based our FDA experiences in this area, we believe the SOW IVD kit timelines of 4.5 months for assay optimization, 9 months for pre-clinical trials tests, and 6 months to complete the Clinical trial are achievable. Yes, contractor planning efforts to support the clinical trials need to start during the pre-clinical trials test efforts as outlined in SOW Enclosure A.

21. Category: NGDS Increment I, Program Vision – Technology Constraint

21 Q. NGDS as announced is nucleic –acid centric, when will protein based assays find diagnostic utility in NGDS, if at all?

A. The NGDS P-spec is intended to be technology agnostic listing only limits of detection and Clinical sensitivities that are known to be effective for the intended mission.

22. Category: NGDS Program (Increments 2 & 3)

22 Q. When will host biomarkers be addressed in the NGDS life cycle?

A. Offer's can propose any technical approach that will meet FDA guidelines for clearance as an in-vitro diagnostic. If biomarker based approaches are insufficiently mature during Increment 1 they may be proposed for NGDS Increment 2.

23. Category: RFP SOW Consumables Question-Focus

23 Q. It seems NGDS in the current format is focused on only a few targets (Ba, YP, FT, Q-Fever and VHF). When will Toxins agents be looked at in NGDS lifecycle?

A. The NGDS program does have the requirement to replace the Joint Biological Agent Identification and Diagnostic System (JBAIDS) which in turn drives the priorities for the first IVDs to be cleared on the NGDS. Toxins are included in the Section C Enclosures and there is scope in Section C to take a toxin IVD through FDA clearance when a mature technical and clinical trial approach is available. Toxin assay development is included in the NGDS SOW, Para C.3.3.3.6.2 in the PD phase.

24. Category: NGDS Program (Increments 2 & 3)

24 Q. Is there going to be NGDS Increment 2, Increment 3, etc., within the NGDS current life cycle of NGDS?

A. The JPM CBMS FY14 POM submission currently includes early development funds (MB4) for NGDS Increment 2, starting in FY14. The FY14 DoD budget, however, will not be finalized until Nov/Dec 2012 when it is submitted to OMB.

25. Category: NGDS Program (Increments 2 & 3)

25 Q. Does NGDS program find any diagnostic value for host-immune response of BWA?

A. Yes. Host response approaches will likely be required for diseases with low concentrations in the body and for Pre-symptomatic screening of large populations.

26. Category: NGDS Technology - Toxins

26 Q. What is the requirement for the capability to detect protein toxins? If the technology is incompatible with protein detection, it was mentioned that this option would not be exercised. Shouldn't this be part of the evaluation of the potential systems in the proposal review process?

A. The RFP is meant to be technology agnostic. If the candidate system can meet the performance requirements for pathogen(s) identification, and is FDA cleared for at least one diagnostic application for infectious diseases, then it can be bid by the contractor. In the contractor's proposal as noted in the SOW, the contractor needs to show that his system can meet the IVD kit development requirements in the near term for all agents in SOW para C.3.1.3.1. P-spec factors such as CLIA complexity and time to result are considered along with breadth of agent compatibility.

27. Category: Industry Day Presentation Posting

27 Q: Will the Industry day presentation be posted online?

A: Yes, by the end of this week (April 6, 2012, COB).

28. Category: FDA IVD Clearance Timeline

28 Q. How were the schedules for FDA clearance derived?

A: See Q&A No. 27 above. Also, FDA clearance schedules were derived from past examples and while keeping in mind evolving FDA guidance and what FDA allows for biological warfare agents with respect to contrived samples.

29. Category: FDA Interaction

29 Q. Is the FDA aware of the aggressive NGDS timelines? And is FDA aware that multiple companies will be approaching FDA for clearance, etc.?

A: Yes, FDA is aware. NGDS program staff has met with FDA to discuss the acquisition strategy and FDA is aware that there will be multiple pre-IDE applications and requests for meetings from vendors within the base period of performance.

30. Category: IVD Assay Development and Clinical Samples

30 Q: Is it the Government's intent that the Government will provide clinical samples for testing?

A: The Government will provide inactivated BWA materials and, if live agent testing is required, will provide access to Government facilities to perform that testing. The Government anticipates that most sample matrices will be commercially available. The Government will investigate stockpiling clinical specimens to reduce schedule risk for both the Government and the Contractor.

31. Category: IVD and Environmental Assay Development

31Q: Is the Government going to allow all spiked/contrived samples?

A: The Government expects scientifically justifiable proposal from vendor and anticipates that the contract awardee(s) will sponsor the application. The Government understands the need to share the burden of acquiring the necessary samples and will facilitate access to those samples to the extent possible. It will be the contractor's responsibility to provide the samples types as specified by the FDA in response to the contractor's Pre-IDE FDA submission package.

32. Category: Assay Consumable Screening Panels/Syndromic Panels

32 Q: The Draft RFP indicates syndromic panels should be included when possible. How are they expected to be included and what types? How would that be weighted?

A: See Q&A No. 26. This information is included in Section 2.0 (Program Scope) of the draft RFP and is, therefore, not a specific requirement. Specific requirements are listed in Section L. That being said, screening panels if applicable to the contractor's COTS analyzer design can/should be included in the contractor's assay kit design studies in SOW para C.3.1.4. (IVD, BWA Environmental, Non-BWA Environmental).

33. Category: NGDS Increment I Contract Value

33 Q: Is the \$200M ceiling just for pre-Milestone C?

A: No. The presumed \$200M contract ceiling prices includes the competitive Prototyping (CP) Phase, follow-on Technology Demonstration (TD) Phase, and Production/Deployment (PD).

34. Category: Multiple NGDS RFPs

34 Q: Has the Government considered putting out one RFP for competitive prototyping and a different RFP for post-CP phase?

A: Alternate contract approaches were considered

35. Category: RA Costing

35 Q: Will the Government pay for regulatory activities?

A: The Government contract award is intended to include payment for: development of pre-IDE; travel to FDA to conduct IDE meetings; development of clinical protocols; clinical trial sites support; equipment used in pre-clinical trials; conduct of clinical and pre-clinical trials; preparation and submission of 510K submission. Contract awardee(s) will be the sponsor of submissions to the FDA, with all attendant responsibilities.

36. Category: Consumable Sample Quantities in SOW

36 Q. For the production/deployment phase, is the number of samples listed the maximum anticipated per year or lifetime?

A: Currently the number of samples listed is for the lifetime time frame, keeping in mind that the samples are expected to be spread over 5-10 years. Quantities will be reviewed for the Final RFP.

37. Category: FDA Experience Requirements

37 Q: Would a company that has been through the FDA clearance process for a related instrument that is different than the one that would be submitted in response to this RFP be considered to have met the FDA clearance requirement?

A: While having been through the FDA clearance process reduces the company's perceived risk; it does not resolve the risk associated with having to obtain FDA clearance for the proposed instrument. To bid on the solicitation, the Offeror's candidate COTS system needs to be FDA cleared.

38. Category: "Bid Sample" Requirements

38 Q: Is an assay kit for every FDA-cleared assay for the instrument required to be delivered with the "Bid Sample"? Or a sampling of the kits?

A: The Offeror is requested to provide one each, FDA cleared IVD kit that is associated with the Contractors candidate COTS analyzer design. IF the contractor has multiple kits on the Contractors candidate COTS analyzer design, one each of these IVD kits is also requested. Again, only those IVD cleared kits associated with the contractor candidate COTS analyzer design are required.

Q: What if the kit configuration is 500 assays?

A: This issue will be worked on a case-by-case with the each contractor. The Government is not interested in obtaining consumable kits to process hundreds of samples in the same kit for the same agent/sample type. (Further Clarification on the “Bid Sample” RFP deliverable will be provided in the update RFP, Section L area.)

A: Update: the Bid Sample will be removed as a proposal requirement. It will be replaced with a required system demonstration.

39. Category: Bid Sample” Requirements

39 Q: “Bid Sample” needs to be included with CDs and binders? When does it have to be delivered and where?

A: Yes, same date deadline as proposal. Proposals should be delivered to Government Contracting Office in Natick; the shipping location for instruments/consumables/other supporting items is TBD. The “Bid Samples” needs to be delivered on the same time line, as the contactors’ paper proposals to the Government, as outlined in the final RFP.

A: Update: the Bid Sample will be removed as a proposal requirement. It will be replaced with a required system demonstration.

40. Category: CP-TD-PD Phase hardware Delivery Schedule Requirements.

40 Q: As a contractor, system delivery timeline outlined in the draft RFP will be very difficult to meet.

A. The Government plans to relook at the hardware and consumables SOW deliverables timelines. The NGDS program office will provide further clarification in the updated SOW based on feedback during Industry Day.

41. Category: JBTDS (Tactical Variant)

41 Q: Will NGDS replace JBTDS?

A: JBTDS is only under guidance to consider NGDS, but is not required to use it. JBTDS could carry competitive prototyping for identifiers into the EMD phase. NGDS intent to facilitate consideration of NGDS technology by JBTDS.

42. Category: NGDS Food and Water Assay as Part of JBTDS

42 Q: Will food and water assays be part of JBTDS?

A: See Q&A No. 25. Also, Out of our lane/scope of this RFP... but it’s in the CALS CONOPS, not JBTDS.

43. Redundant and Omitted.

44. Category: NGDS Technology Question

44. Q Is the Government only considering assay-based tests?

A: See Q&A No. 21. The proposed instrument must at match the requirements of the RFP which intended to be technology agnostic.

45. Category: NGDS RFP Consumable Agent targets

45. Q. Will final RFP include list of all targets?

A: Specific GFI relating to assay designs will only be communicated after contract award. The number of targets relating to the scope of development will be reviewed. SOW para C.3.1.3.1 provides a notional list of target assays for the CP and TP phases. The RFP Enclosure C, D, and provides a more complete listing of potential assay targets for the entire NGDS Increment I program over the next 8-10 year. As noted in the industry day briefing, the priorities for CP Phase consumable BW agent targets are Ba, and VHF. The Government, however, reserve the right to exercise options for other agents listed in the paragraph table, to include assay optimization during the CP and TD program Phases.

46. Category: NGDS SOW Deliverable Quantities (Systems & Consumables)

46 Q. The SOW contains Min and max numbers in the system and consumables delivery tables. Which number should be used for budgeting (min. or max. # of samples)?

A: An expected value will be added to aid in planning and proposing.

47. Category: NGDS RFP Content – JBTDS Spec

47. Q. When will the JBTDS performance spec available?

A: The Government program office will be provided as an attachment to final RFP.

48. Category: NGDS Technology Focus?

48 Q: How does type of technology play into how it will be assessed during the source selection?

A: The Government evaluation process is noted in Section M of the RFP. The Evaluation factors are clearly stated in RFP.

49. Category: NGDS TD Phase number of Contractors

49. Q: Your Government Industry Day briefing implies only one system will make it past the CP Phase- True?

A: Yes, only 1 system is PLANNED. Actual depends upon proposal received, final program requirements and available funding.

50. Category: NGDS - "Open Platform"

50. Q. Is an "Open Platform" a requirement on NGDS Increment 1 requirement?

A: The openness of the system design should be part of the L.4.4 narrative. It is desirable for other Government agencies to be able to develop content on the selected NGDS Increment 1 system. The NGDS program is based on teaming with potential partners outside the DoD Chem Bio defense field, like USAMRIID, WRAIR, BARDA, the CDC, etc.

51. Category- NGDS Software Requirements

51. Q. Is being DII COE compliance, Level 8, an NGDS platform requirement?

A. Not at the time of award. DII COE requirements are listed in the NGDS Performance Specification. As noted in the Industry Day briefing, and Section L and M of the RFP, a contractor's COTS systems does not have to meet all the requirements noted in the P-Spec. (The Government is purchasing an FDA cleared COTS platform, and the government has no plans to make the selected NGDS CP systems compliant with all the features in the P-Spec. Compliance with the P-Spec requirements is noted in Section M, para M.3.2.1.2. and Section L, para L.4.2. The important/ranking of various P-Spec requirements are noted in the P-Spec Table 3, para 4.0, Verification Methods: Critical, Important, and Desirable. Also, see Q&A No. 9.

52. Category: NGDS P-Spec Requirement (Who should submit?)

52. Q.: Does it make sense to submit a proposal if the system that is not field portable?

A.: The Government cannot tell a company whether or not to propose. However, the specifications for weight and size laid out in the RFP should be considered as guidelines. Furthermore, the primary intended use is with deployable combat support hospitals.

53. Category: NGDS P-Spec System Characteristics

53. Q. If weight is a potential elimination criterion, it should be considered "critical" in the P SPEC, not simply important

A. The Government will relook at the way in which this and other criteria are designated in the P-Spec table as "Critical, Important and/or Desirable."

54. Category: NGDS CP Consumables Assays

54. Q. Is the Government looking for a separate assay for each VHF or for a combined assay?

A. Several VHF targets will be required. The assay format proposed may vary based on the contractor's technical approach. If Multiple VHF targets can be combined into a single assay logistical costs would be reduced and there would be lower burden to the operator. (See SOW para C.3.1.3.1, Table: C.3.1.3.1.8/.9).

55. Category: NGDS Consumables Target Cost

55. Q. Does the Government have a target cost/test?

A. A Target Cost is not currently defined in the RFP, although lifecycle costs and sustainability are critical for the successful broad adoption of the NGDS by users and consumable costs are a key component of this. The Government will further consider this question.

56. Category: NGDS Consumables

56 Q. Do incumbents have assays already finished or in the pipeline to meet the Government's needs? Is the playing field level?

A.: There is no NGDS incumbent. The Government intends to make multiple awards in the CP Phase.

57. Category: NGDS Sample Matrices

57. Q. Different sample matrices may require an investment up-front for altering sample preparation steps; are these costs reimbursable on the CP and TD development CLINs?

A. The offerors should propose the full cost of assay optimization for the required sample types. The Government realizes that different sample type requirement may/will impact the contractor's up-front preparation steps; these costs should be reflected in the contractor's price proposal for various assays selected for development in the SOW, para C.3.1.3.1, see table.

58. Category: NGDS Increment 1 Acquisition Strategy

58. Q.: Why not just focus on having a more detailed, clearer RFP addressing just the CP phase, and then follow up with a second RFP for Post-CP activities?

A.: As previously discussed, this has been considered by the JPEO CBD/JPM CBMS team, and the Government believes the current contracting approach is appropriate.

59. Category: NGDS Cost Accounting System Requirement – EVMS

59 Q. Some companies do not have DoD military contracts, and work only in the commercial market. Being encumbered with extensive DoD funds management regulations is not desirable and could force some companies to "push away from the table," specifically EVM and cost accounting system requirements. Is this oversight mandatory for NGDS?

A. The BSV-NGDS team agrees that Earned Value Management (EVM), Section L, para L.5.4, is a burden on both contractors and the Government team, but it is currently a DoD requirement for contracts with Cost Plus CLINs that exceed a dollar threshold (over \$50M); this requirement cannot be waived. A DCMA audit may be conducted on bidders Cost Accounting Systems to determine that an adequate accounting system is in place; this audit will be arranged by the NGDS program office during the RFP source selection to ensure that each contractor in the competitive range is qualified to receive a contract award. The Government plans to have an EVM CLIN in the NGDS contract(s) to allow contractors to recover all cost associated with this DoD cost accounting system management requirement.

60. Category: Commercial Assays

60Q. Shouldn't there be wording similar to lines 935 thru 936 of the SOW inserted directly below line 507 such as: "The Contractor will provide a listing of commercially available assays, and the Government will select those commercial assays to be tested during the CP Phase as per C.3.1.2.2."

A. The issue is addressed by the statement in the SOW "The consumable sets will be selected consistent with the assay listing provided in response to Section L.4.3 of the solicitation of all commercially available clinical and environmental assays able to be run on the proposed system and according to CLIN structure proposed in response to Section L.7.1.6."

61. Category: Security

61Q. If a company does not currently hold a security clearance, can they be granted the necessary security clearances to handle GFI before a contract award if your office submits a DD-

254 and a "simple" sponsorship letter requesting that the determination be made? Would someone in the NGDS program office or the Contracting Office submit the documents?

A. Offerors must complete the DD 254 with their proposal (we will have draft with the RFP as an attachment), after which, the Government will submit the DD 254 with the Sponsor letter to DSS. DSS will issue an interim clearance based on that submission and then proceed to a final clearance. If you want more info on the process, please go to the DSS Facility Clearance website at: http://www.dss.mil/isp/fac_clear/fac_clear.html.

62. Category: EVMS

62Q. It appears that EVM is focused on the IT market, please explain its applicability to the NGDS program.

A. FAR Part 34.201 provides the federal government policy with regards to EVMS. An Earned Value Management System (EVMS) is required for major acquisitions for development, in accordance with OMB Circular A-11. The Government may also require an EVMS for other acquisitions, in accordance with agency procedures (see DFARS below). Secondly, if the offeror proposes to use a system that has not been determined to be in compliance with the American National Standards Institute/Electronics Industries Alliance (ANSI/EIA) Standard-748, Earned Value Management Systems, the offeror shall submit a comprehensive plan for compliance with these EVMS standards. Offerors shall not be eliminated from consideration for contract award because they do not have an EVMS that complies with these standards.

DFARS Part 234.201 policy requires the following: (i) For cost or incentive contracts and subcontracts valued at \$20,000,000 or more, the earned value management system shall comply with the guidelines in the American National Standards Institute/Electronic Industries Alliance Standard 748, Earned Value Management Systems (ANSI/EIA-748). (ii) For cost or incentive contracts and subcontracts valued at \$50,000,000 or more, the contractor shall have an earned value management system that has been determined by the cognizant Federal agency to be in compliance with the guidelines in ANSI/EIA-748. For DoD, this is DCMA makes this determination. Since we are requiring offerors to provide an EVMS plan as part of its proposal, the contracting officer will determine the adequacy of the proposed EVMS plan prior to contract award.

63. Category: GFI for assay optimization

63Q. Could you please clarify as to whether the targets for the subject assay will have to be those provided as GFI or will the contractor be able to use their own target sequences?

A. For the purposes of the competitive prototyping (CP) stage, vendors must adapt GFI as a demonstration of assay optimization ability. Beyond the CP stage, the vendor assays will be considered. This includes the first pre-clinical trial for BA and VHF.

64. Category: PPIP

64Q. Can we assume that per C.3.1.1.8, Program Protection Implementation Plan, that the RFP will contain the Gov't's PPP so that its guidance can be used to derive the vendor's own PPIP?

A. The Government's PPP will not be available at the time of RFP release, therefore the RFP states the PPIP will be provided to the Government 45 days after receipt of the Government's PPP following contract award.

65. Category: ACAT designation and CWBS

65Q. What ACAT designation is the NGDS? For the purpose of establishing a CWBS should the vendor use the latest MIL-STD- 881C? The current DRAFT RFP sites 881A.

A. NGDS is designated an ACAT III program. Section L in the RFP will be corrected to state MIL-STD-881C, dated 3 October 2011.

66. Category: RFP compliance matrix

66Q. Section L.3.3 in the DRAFT RFP states: L.3.3. Crosswalk Matrix: The Offeror shall provide a crosswalk (Compliance Matrix) of their proposal to link the requirements of sections SOW, Performance Specification, H, L, and M of this RFP.

And later in L.5.1: The Offeror shall submit a CWBS and CWBS Dictionary using the MIL-HDBK-881 as the guide. The minimum CWBS expected is Level 4. However, the Offeror shall extend CWBS elements as needed to provide the depth and breadth required to define the contract scope and to accurately describe the proposed effort. The CWBS shall correlate with the SOW, CLINs, IMP, and IMS.

Can you please clarify what you are requesting in terms of a complete proposal compliance matrix and versus the SOW/CWBS matrix (crosswalk) that would accompany our CWBS Dictionary.

A. The crosswalk (compliance) matrix in Section L is for the entire proposal which helps both the Government and the vendor ensure all requirements in the RFP are satisfied. The CWBS is to crosswalk the individual performance tasks proposed by the contractor to meet the requirements of the contract.

67. Category: Proposal due date

67Q. Can please define whether the reference to "days" in the quote below from the FBO is to be understood as business days i.e. Monday through Friday (5 days in a week) or Calendar days Sunday through Saturday (7 days in a week). "The Government currently estimates that the Request for Proposals (RFP) will be released within the next 20 days, and proposals will be due 45 days after the RFP is released. The proposed solicitation number is W911QY-12-R-0021".

A. The time for proposal receipt is in calendar days, not business days, so it would be Sun-Sat.

68. Category: Information Only SOW sections

68Q. There are many sections within the SOW (e.g. C.1.2.4 Concept for Maintenance, Repair Warranty, Contractor Logistics Support and Repair Services with the caveat (information only). Do these sections marked as such need to be addressed in the compliance matrix?

A. No. These sections in the SOW are provided for the vendor's information and guidance and are not applicable to specific SOW tasks which will be required for the compliance matrix.

69. Category: Information Only SOW sections

69Q. In paragraph L.2.6 it is stated: "Cross referencing within a proposal volume is not permitted". Does this mean that a diagram/chart/ or any piece of information/data called out/sited on one page within a specific volume of the proposal cannot in turn be called out/sited again (cross referenced) in a subsequent page(s) within the same volume that it was first called out/sited ?

- A. The final RFP has been corrected to delete the reference to "Cross referencing within a proposal volume is not permitted." Section L.2.6. now reads, "Cross-Referencing - To the greatest extent possible, each volume shall be written on a stand-alone basis so that its contents may be evaluated. No cross referencing to other volumes of the proposal is permitted. Information required for proposal evaluation which is not found in its designated volume will be assumed to have been omitted from the proposal

70. Category: Information Only SOW sections

70Q. The current version of the NGDS Performance Specification lists the following assays as having the same Threshold Capability for both measurements. Shouldn't the 1,000 pfu/ml LOD be designated as a Objective Capability for both assays?

Ebola	Marburg
T = 10,000 pfu/ml	T = 10,000 pfu/ml
T = 1,000 pfu/ml	T = 1,000 pfu/ml

- A. This is a typo and will be corrected for the final RFP. T = 10K, O = 1K

71. Category: RFP Release

71Q. Please confirm for me whether the subject solicitation RFP has been released formally, and if not, please advise the estimated release date. My company is very interested in submitting a proposal but I have a few more questions if the solicitation is still open. Thank you

- A. The RFP has not been formally released, currently there are draft RFP sections available for industry review and comment. Please continue to monitor FedBizOpps for updates on the program.

72. Category: NGDS Cost Accounting System Requirement - EVMS

72Q. Per the 20120509 Updated Consolidated NGDS RFP Q&As and in regard to the answer to question #59 which states in part: "The Government plans to have an EVM CLIN in the NGDS contract(s) to allow contractors to recover all cost associated with this DoD cost accounting system management requirement". Can you please be more specific with regard to a company that has no previous experience with EVMS as to how they should view the implementation of EVMS both as a start up effort and as a sustaining effort for the life of the NGDS contract? Exactly what will the government plans tell the inexperienced vendor so that vendor can adequately price out the EVM CLIN in its proposal?

A: The Government will not provide any written plans for EVMS. The RFP statement indicates that EVMS will be a contractual requirement if the anticipated dollar threshold is met. The American National Standards Institute (ANSI)/Electronic Industries Alliance (EIA) 748-A Standard provides a set of best business practices for establishing and applying an integrated

management system with coordination of work scope, schedule, and cost objectives and application of earned value methods for program or enterprise planning and control. There are several commercially available EVM software systems that assist in capturing EVM data, as well as consultants and short workshops available to assist new company's implementation.

73. Category: Pricing Structure

73Q. Will the post CP Award be a CPFF or a CPIF?

A: CPFF.

74. Category: Delivery Orders

74Q. Will each Delivery Order need to be negotiated with regard to its fee?

A: Fees should be consistent with fees proposed for similar work and the DoD weighted guidelines.