

<b>AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT</b>			1. CONTRACT ID CODE J	PAGE OF PAGES 1   35
2. AMENDMENT/MODIFICATION NO. 0004	3. EFFECTIVE DATE 09-Nov-2011	4. REQUISITION/PURCHASE REQ. NO.		5. PROJECT NO.(If applicable)
6. ISSUED BY NATICK CONTRACTING DIVISION US ARMY CONTRACTING COMMAND - APG NATICK CONTRACTING DIVISION ATTN: CCAP-SCN, KANSAS STREET NATICK MA 01760-5011	CODE W911QY	7. ADMINISTERED BY (If other than item 6) <b>See Item 6</b>		
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		X	9A. AMENDMENT OF SOLICITATION NO. W911QY-11-R-0023	
		X	9B. DATED (SEE ITEM 11) 26-Aug-2011	
			10A. MOD. OF CONTRACT/ORDER NO.	
			10B. DATED (SEE ITEM 13)	
CODE	FACILITY CODE			
11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS				
<input checked="" type="checkbox"/> The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer <input type="checkbox"/> is extended, <input checked="" type="checkbox"/> is not extended. Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning <u>1</u> copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.				
12. ACCOUNTING AND APPROPRIATION DATA (If required)				
13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.				
A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.				
B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).				
C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:				
D. OTHER (Specify type of modification and authority)				
E. IMPORTANT: Contractor <input type="checkbox"/> is not, <input type="checkbox"/> is required to sign this document and return _____ copies to the issuing office.				
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)  See Solicitation Change Log.  Within this amendment, the changes for Amendment 0004 are indicated by purple text to enable easy reference to changed areas.  This amendment MUST be acknowledged in Block 14 of the SF 33, "Solicitation, Offer, and Award."				
Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.				
15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)		
		TEL:	EMAIL:	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA		16C. DATE SIGNED
_____ (Signature of person authorized to sign)		BY _____ (Signature of Contracting Officer)		09-Nov-2011

## SECTION SF 30 BLOCK 14 CONTINUATION PAGE

**SUMMARY OF CHANGES**

## SECTION I - CONTRACT CLAUSES

The following have been added by reference:

252.225-7001	Buy American Act And Balance Of Payments Program	OCT 2011
252.225-7036	Buy American--Free Trade Agreement--Balance of Payments Program	OCT 2011

The following have been deleted:

252.225-7001	Buy American Act And Balance Of Payments Program	JAN 2009
252.225-7036	Buy American--Free Trade Agreement--Balance of Payments Program	DEC 2010

## SECTION J - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

The following have been added by full text:

GOV RESPONSES AS OF 8 NOV 2011

Government Responses to Industry Questions Posted as of:

8 Nov 2011

Q1: When is the RFP release anticipated?

A1: The RFP was released on 26 August 2011 and can be downloaded from the following sites:

[www.fbo.gov](http://www.fbo.gov) search Solicitation W911QY11R0023

<https://www3.natick.army.mil/mcmadm.html>

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Q2: Will the initial RFP release be the final?

A2: The RFP that was released on 26 August 2011 is the final RFP, although the Government reserves the right to amend it.

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Q3: Will there be an Industry Cost Share/Commercial Offset required for facilities?

A3: There is no cost share requirement.

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Q4: What were the primary drivers in the change from the five year initial contract to a 2 year structure?

A4: The effort was divided into two primary phases: establish/commission/validate the ADM, and maintenance of the capability. The two (2) year base contract mirrors the anticipated completion timeframe of the first phase of this effort. Maintenance of the capability will be in the form of 4 two-year option periods.

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Q5: What were the primary drivers in the change from the whitepaper downselect to the new RFP plan?

A5: The white paper down select process was eliminated to streamline and expedite the contract award process.

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Q6: Would this RFP also include the development of universal ventilators (broad patient type functionality by one device; non-expert use, portable, long storage times, etc)?

A6: No

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Q7: Our question is in regard to the requirement for FDA Approval/Licensure of a Biopharmaceutical Product within the Last Ten (10) Years. The Offeror's organization possesses experience in product sponsorship and advanced drug development success with FDA approval/licensure of at least one product in the past ten (10) years.

Can the Offeror utilize the experience of its subcontractor partners to satisfy this requirement?

A7: Yes. See L.3.1.a.i. which states that: "The Offeror shall describe its proposed organization that possesses experience in product sponsorship and advanced drug development success with FDA approval/licensure of at least one product in the past ten (10) years."

See also M.1.3.1. which states that: "The Offeror's organization possesses experience in product sponsorship and advanced drug development success with FDA approval/licensure of at least one product in the past ten (10) years."

The offeror's organization includes the prime contractor and all subcontractors.

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Q8: Has DoD scheduled the pre-solicitation conference for the MCM ADM initiative?

A8: No. Details will be provided on/about Friday, 2 September 2011, and will be announced via FedBizOpps under Solicitation W911QY11R0023

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Q9: RFP A.3 (pg. 2) The Government has established two (2) mandatory eligibility requirements that must be met in order for offeror's proposals to be considered responsive. These

are described in Section L.3.1 and Section M.1.3. Offerors whose proposals do not clearly show compliance with these mandatory eligibility requirements will be considered non-responsive, will not be evaluated, and will not be eligible for award.

L.3.1.c.i (pg. 164) FDA Approval/Licensure of a Biopharmaceutical Product within the Last Ten (10) Years. The Offeror shall describe its proposed organization that possesses experience in product sponsorship and advanced drug development success with FDA approval/licensure of at least one product in the past ten (10) years.

M.1.3.a (pg. 184) FDA Approval/Licensure of a Biopharmaceutical Product within the Last Ten (10) Years. The Offeror's organization possesses experience in product sponsorship and advanced drug development success with FDA approval/licensure of at least one product in the past ten (10) years.

L.3.2.h (pg. 168) Description of the offeror's relationship(s) with a pharmaceutical company that has successfully sponsored two or more drugs to FDA approval/licensure within the past ten (10) years. Emphasis should be placed on how this relationship add value to the offeror's management and process approaches.

The mandatory eligibility requirements at L.3.1.c.i and M.1.3.a require successful licensure of one product within the past ten years (underline added for emphasis) while the L.3.2.h instruction for preparation of the technical volume addresses successful licensure of two or more drugs (underline added for emphasis) in the past ten years. Would the government please clarify the relationship between these statements?

A9: Paragraph L.3.2.h erroneously states "...sponsored two or more drugs...", and the RFP will be amended to state "...sponsored one or more drugs...". Note, however, that in the evaluation methodology for Technical Factor 1, subfactor 2, the Government will place a higher emphasis on approaches that demonstrate a relationship with a pharmaceutical company that has successfully sponsored two or more drugs to FDA approval/licensure within the past ten (10) years.

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Q10: RFP A.7.1 (pg. 2) The Government's vision for this program is to establish a dedicated and enduring capability to conduct advanced development and manufacturing of MCMs that are FDA approved and ready for distribution to meet the needs of the Department of Defense for the foreseeable future.

Would the government please clarify the scope of FDA approved product categories (e.g., vaccines, vaccine components, other biologics, drugs, devices) to be addressed?

A10: The intent is to provide a capability to develop and produce FDA Approved CBRN medical countermeasures. Initially, vaccines and other biologics would be the priority in the manufacturing facility portion of this effort. The other portions of the ADM capability such as CRO, T&E and FF capabilities must be prepared to accept vaccines, other biologics and drug

product development efforts soon after of contract award. Drug manufacturing (small molecule) may be managed by the offeror through subcontract arrangements. The capability to produce drug administration combination products such as auto-injectors and inhalers as defined in 21 CFR 3.2(e) are within scope but other combination products such as diagnostics, ventilators are not part of this scope.

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Q11: RFP A.9 (pg. 3) The awardee of any contract resulting from this solicitation agrees, when requested by the Contracting Officer, to provide to the Government with negotiated direct and indirect rates and fees to be provided to all prospective offerors for MCM contracts that will utilize the MCM ADM facility as a directed subcontractor for the purpose of enabling those entities to prepare a proposal in response to a DoD solicitation for MCMs or for other work that will be performed by the MCM ADM contractor as a directed subcontractor.

Would the government please clarify the rationale for requiring the awardee to provide direct and indirect rates and fees (normally considered company proprietary) to the government for distribution to all prospective offerors of MCM contracts? May the awardee provide a sealed package containing awardee's proprietary rate data to the government and rolled-up pricing data for distribution to the prospective MCM contractors?

A11: The rationale for this requirement is to ensure fairness among all prospective offerors for MCM contracts that will utilize the MCM ADM facility as a directed subcontractor, and to ensure that the rates of the directed subcontractor are fair and reasonable. The intent is to prevent differences in rates from the directed subcontractor to become a basis for unfair competitive advantage during the source selection process of future MCM contracts.

To this end, and to protect the proprietary rate data of the MCM ADM operator, the Government will accept delivery of a sealed package containing the awardee's proprietary rate data, and rolled up pricing for distribution to prospective MCM contractors.

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Q12: RFP A.10 (pg. 3) All equipment and hardware acquired by the contractor for the execution of this contract shall become the property of the Government.

Would the government please establish a lower threshold value for government property under this article?

A12: Paragraph A.10 of the RFP will be amended to read: "The FAR clause 52.245-1(e)(3) states that the Government shall retain title to all property purchased by the Contractor for which the Contractor is entitled to be reimbursed under cost reimbursement contracts. The Government will substitute this paragraph in FAR Clause 52.245-1 with its Alternate II for a nonprofit institution of higher education or a nonprofit organization whose primary purpose is conducting scientific research allowing retention of title to tangible personnel property below a value of \$5,000."

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Q13: RFP A.14 (pg. 4) Contract award resulting from this solicitation is subject to availability of fiscal year 2012 funds.

Please provide budgeted amounts for this contract, exclusive of government management and administrative costs, for: (1) GFY 2012 and (2) each GFY 13, 14 and 15.

A13: This information will not be provided.

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Q14: RFP C.2 (pg. 43) The contractor shall perform manpower reporting as follows: The contractor shall report all contractor manpower (including subcontractor manpower) required for performance of this contract using the format provided at the following website address: <https://cmra.army.mil/>.

Please clarify this reporting requirement with respect to FFP CLINs; if required, please provide the rationale for collecting and reporting labor on fixed price work.

A14: Army policy requires the contractor to collect and report on contractor manpower for services including research and development. This policy applies to all acquisitions managed by the Army and/or for which the Army is a beneficiary, as is the case with this effort. This requirement exists for all labor, whether executed on a cost reimbursable or fixed price basis.

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Q15: RFP H.1 (pg. 86) H.1. PROHIBITION OF USE OF LABORATORY ANIMALS  
Information and guidance is provided at the following web site:  
[https://mrmc.amedd.army.mil/index.cfm?pageid=Research\\_Protections.acuro&rn=1](https://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.acuro&rn=1)

Would the government please clarify whether the contractor will submit and receive required information through the COTR? If not, please detail the process for compliance.

A15: Yes, the information will be provided through the COTR.

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Q16: RFP H.4 (pg. 87) The personnel specified in this contract are considered to be essential to the work being performed hereunder. Prior to diverting any of the specified individuals to other programs, the Contractor shall notify the Contracting Officer at 30 days in advance and shall submit justification (including proposed substitutions possessing the same or greater qualifications/experience as the individual being substituted) in sufficient detail to permit evaluation of the impact on the program. No diversion shall be made by the contractor without the written consent of the Contracting Officer;

May additional Key Personnel be proposed?

A16: Yes. However, the Offeror is cautioned to ensure that proposal page limitations are not exceeded.

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Q17: RFP H.5 (pg. 88) At present the Government only anticipates the test and evaluation associated activities to possibly involve BSAT.

This statement appears contradictory with the SOO, Article III. Scope requirement to establish BSL-3 suites. Please clarify and revise the solicitation accordingly.

A17: There is no contradiction as not all BSATs require BSL-4.

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Q18: RFP L.2.1.1 (pg. 161) Volume 1, Section 5 – Subcontracting Plan is limited to 10 pages.

Typically subcontracting plans are longer than 10 pages in order to address the requirements of FAR 52.219-9 and DFAR 252.219-7003. Would the government consider removing the page limitation for Volume 1, Section 5?

A18: The RFP will be amended to remove the page limitation for Volume 1, Section 5.

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Q19: SOO III. Scope Phase 1 (pg. 2 of 10) This contract will have up to three (3) options to incrementally increase the development and manufacturing capacity.

Please clarify this statement to quantify the incremental increase in capacity.

A19: See CLINs 6001, 6002, and 6003 in Section B of the RFP.

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Q20: SOO III. Scope Phase 2 (pg. 2 of 10) This includes transition and integration of new technologies, from pre-Investigational New Drug Application phase with readiness to support simultaneous operations, through FDA licensure.

Would the government provide the minimal Technology Readiness Level (TRL) to be considered viable for transition?

A20: TRL-4 is the minimum TRL threshold for transition and integration of new technologies.

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Q21: SOO III. Scope (pg. 3 of 10) The contractor is required to be able to provide corporate sponsorship experience (from Investigational New Drug (IND) to FDA approval to include personnel and processes) in developing and gaining FDA approval of drugs.

May the referenced corporate sponsorship experience reside within the team members, or must it be resident within the corporate entity priming the contract?

A21: See Q/A 5 above.

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Q22: SOO III. Scope (pg. 3 of 10) The contractor shall participate in up to six (6) different Government led Integrated Product Teams (IPT) with representation by Government and contractor stakeholders. These IPTs will provide the government with full insight of operations,

directly oversee the ADM operations, provide clear timely guidance, adjudicate conflicts and provide real-time feedback.

Will the government, the contractor, or both be empowered to enforce protection of proprietary information in IPT operations?

Will IPT oversight, guidance, and conflict adjudication be effected through the COTR and Contracting Officer; if not, what practices will be followed?

Would the government clearly stipulate IPT contractual authorities, limitations, and any appeal mechanisms?

A22: Proprietary information will be protected in IPT operations in accordance with the terms of the contract. Applicable United States laws will apply to government employees handling appropriately marked and recognized proprietary information.

Oversight, guidance, and conflict adjudication will be effected through the COTR by Contracting Officer and legal counsel.

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Q23: SOO IV. (pg 3 of 10) Manufacturing and warm-base capabilities to rapidly respond to CBRN events and emerging and genetically engineered infectious diseases outbreaks by producing FDA approvable products or expand (surge) manufacturing of existing products without requiring additional regulatory approvals

Would the government please clarify the expectation regarding ‘additional regulatory approvals’? Biopharmaceuticals commonly require FDA lot release, for example.

A23: The intent of the passage in question is that significant and time consuming & expensive procedures and testing should not be required to satisfy FDA requirements. For example, surge could not be met with a vertical scale up as this would involve extensive testing and process development associated with the process scaling. Horizontal scaling, wherein an approved process is replicated multiple times, is the preferred approach. Any FDA approvals required for such activities should not be of the same magnitude and so would be an acceptable result of such approaches. Likewise, FDA lot release approvals are not covered by the text in question.

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Q24: SOO IV. (pg 3 of 10) Assistance and training in the areas of drug development and manufacturing including the use of the ADM capabilities.

Q. Please clarify the phrase, drug development, in the context of this project.

A24: All aspects of drug development from IND to FDA approval/licensure.

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Q25: SOO V. (pg 6 of 10) The contractor will establish, own and operate the MCM ADM capability within the United States.

May this ownership requirement be satisfied by team members, or must the prime contractor be the owner?

A25: Please refer to the definition of “contractor” found at H.6(b) in the RFP. While the definition states that it is specifically applicable to the clause at H.6, the definition as stated applies to this question.

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Q26: The SOO (p 3 of 10) includes the following language:

“Strategies for using the ADM capability to support and facilitate transition of processes and technologies from Science and Technology - e.g., from Defense Advanced Research Projects Agency related work or the University Affiliated Research Center (UARC) associated with MCMI, currently under development. The type of requirements would include, but not limited to: Novel platform/expression systems for MCMs, Advancement in Regulatory Science, and advancements in flexible manufacturing enabling technologies for MCMs.”

Can you please clarify the current status and details of the envisioned UARC which is "currently under development"?

- 1) Has the UARC awardee institution already been selected?
  - a. If so, by what process?
  - b. If so, what institution has been selected to receive the award?
  
- 2) If the UARC awardee has not already been selected:
  - a. Will this contract be openly competed, will it be sole sourced, or what process will be employed for source (contractor) selection?
  - b. Please clarify the current stage of development of this contract award and/or RFP?
  - c. Based on the cited paragraph from the SOO, it appears that the UARC contract (rather than the awardee for W911QY11R0023) for will have primary responsibility for managing the following-
    - i. Novel platform/expression systems for MCMs
    - ii. Advancement in Regulatory Science
    - iii. Advancements in flexible manufacturing enabling technologies for MCMsPlease clarify the roles and responsibilities of the "in progress" UARC relative to the scope of RFP W911QY11R0023, with a particular emphasis on these three aspects (2.c.i. through 2.c.iii)?
  
- 3) It appears that a significant component of the DTRA ADM scope of work as described in the February 2011 briefing documents is now going to be awarded via an alternative contract vehicle other than RFP W911QY11R0023, and that alternative is to be the UARC. Please confirm and clarify?
  
- 4) If the UARC awardee has not already been selected and there will be open competition for this project, when is the SOO/SOW and RFP projected to become available?

A26: The Government strategy for the University Affiliated Research Center (UARC) is in the very early planning stages. No specific plans or timeframe for this effort exists at this time. Specific roles and division of responsibility between the MCM ADM program and the UARC have not yet been defined. With regard to Attachment J.1 (Statement of Objectives) of this RFP, the requirements stated therein are requirements for THIS acquisition.

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Q27: The solicitation specifies two manufacturing suites. What would be considered the components of the suites? Are they solely for the upstream, downstream and fill/finish, or would the suites include space for support (e.g. BSL3 process development and QC laboratories, administrative space, GMP receiving, warehousing, BSL3/GMP storage)?

A27: The solicitation calls for Offerors to propose infrastructure plans that would support simultaneous production of two biological products from starting materials to final product. Infrastructure plan proposals should include all the elements that the Offeror deems necessary to support development and production needs including process development lab space, administrative space, receiving and warehousing and cold storage capacity typical for manufacturers supporting simultaneous development of two investigational products in post IND clinical development.

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Q28: Given the relatively short Phase 1 turnover time (24 months), is this an indication that DOD would prefer a retrofit of existing facilities versus new construction?

Are there minimum or maximum footprint expectations?

A28: There is no preference toward retrofit of existing facilities or new construction. There are no expectations regarding minimum or maximum footprint.

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Q29: Given that the Candidate pipeline comprises products that would require mammalian/insect cells, microbial fermentation, and small molecule manufacturing, it would seem that a third suite would be a requirement rather than an option since the three modalities require separate facilities. Is this a correct assessment?

A29: The current contents of the candidate pipeline does not mean that all candidates will be manufactured simultaneously. It is up to the offeror to propose approaches that meet the intent of the Statement of Objectives. Regarding small molecule (chemical) see also Q/A10.

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Q30: Will the small molecule suite require LB3 or LB4 standards?

A30: The Government's assumption regarding this question is that "LB" is intended to read "BSL"; BSL is for biologic products only.

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Q31: Given that each of the candidate products will have unique dosing requirements (e.g. dosage volume/quantity, dosage route (parenteral/oral)), and the solicitation does not specify

fill/finish requirements, can it be assumed that the products to be manufactured are to be delivered as Bulk Drug Product satisfactory to the number of doses required?

Note: fill/finish is mentioned in past performance (L.3.4.1.b.), but may be interpreted as applicable to construction rather than operation.

A31: The intent is to have a capability for the production of final product. Fill/finish of final product may be outsourced to third parties.

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Q32: At the end of the ten year contract period, assuming that no additional contract work will be required, to whom does ownership of the facilities and equipment pass?

A32: At the end of the contract term, and presuming that no additional contract mechanism is in place for continued work, all ~~facilities and~~ equipment procured with program funds will become the property of the Government. See RFP paragraph A.10.

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Q33: If, during the contract period, insufficient projects occur to maintain all suites established through the contract, is it acceptable for the contractor to utilize the suites for non-Government contract projects?

A33: The Government anticipates that the MCM ADM will be fully utilized by DoD 3<sup>rd</sup> party MCM contracts, but recognizes that this may not always be the case. The Government encourages offerors to propose approaches that minimize operating costs (see L.3.2.j. L.3.2.k., M.2(Factor 1/subfactor 3 and Factor 5) of the RFP). Offerors may propose utilization of underutilized suites for non-Government contract projects. The Government will work with offerors who propose such approaches to establish appropriate contractual terms for equitable cost allocation, offsets, reimbursements or other mechanisms to enable 3<sup>rd</sup> party use of the ADM.

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Q34: Should L.3.1. Section 2, list of clauses read:

“I - 52.219-18 Notification of Competition Limited to Eligible 8(a) Concerns.”

or

“I - 52.219-28 Post-Award Small Business Program Representation.”

A34: The RFP will be amended to replace Clause 52.219-18 with 52.219-28 on page 165.

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Q35: Have looked at appropriate documents but they generally focus on development of drugs or vaccines.

Could you tell me if you are also seeking RFPs for diagnostics or medical devices?

A35: See Q/A 6 and Q/A 10.

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Q36: Governance of MCM ADM activities - The solicitation indicates MCM ADM activities will be governed by separate contracts with 3<sup>rd</sup> party entities. However, terms for governance of

MCM development and manufacturing are not included in the RFP. Since the RFP indicates that DoD plans to make a single award, it's assumed that should an Offeror receive an award, it would be obligated to enter into these third party contracts. Without an understanding of such terms well in advance of the proposal submission deadline, it may prove difficult, if not impossible, for Offerors to obtain senior management approval to respond to this RFP. So that Offerors are aware of these obligations in advance of responding to this RFP, please define all terms related to development and manufacturing of MCM under third party contracts – including, but not limited to, reimbursement for these activities and confirmation that manufacturing of an MCM would occur in the facility in which it was developed.

A36: Contracts to develop and manufacture specific MCMs will be solicited and awarded to 3rd party businesses and/or the ADM contractor if full and open competition is achievable as determined by the Government. If the MCM contract is awarded to a third party, then the ADM contractor will be a designated subcontractor. The MCM contract will be governed by the Federal Acquisition Regulations (FAR) and related specific agency regulations with the standard requirement to flow down terms and conditions to the ADM subcontractor. Governance of those 3rd party contracts will be by the respective Government Program Management Office and the prime contractor in the traditional manner. Reimbursement to the ADM contractor as a directed subcontractor will be through the prime contractor for future MCM efforts using traditional prime/subcontractor methods. Manufacturing of an MCM will generally occur in the MCM ADM suites in which the development was also conducted, except in cases where the Government determines that it is in its best interest for development and manufacturing to occur in the 3rd party's facilities. See also QAs 11, 39, 50, 56, 57.

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Q37: Third Party MCM ADM Contract Eligibility – If an organization chose not to respond to this RFP, but at some point had underutilized capacity capable of supporting MCM ADM, would it be eligible to enter into MCM ADM 3rd party contracts?

A37: It is the Government's intention to employ the MCM ADM as the primary source for the activities described in the SOW. However, the Government recognizes that situations may exist where it will be in its best interest to consider alternative sources for certain aspects of MCM development and manufacturing. Eligibility of an organization with underutilized capacity to support a future MCM contract will be considered by the Government on a case by case basis. See also Q/A 36.

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Q38: Page 3, item A9, states that, "an awardee of any contract resulting from this solicitation agrees, ... to provide to the Government with negotiated direct and indirect rates and fees to be provided to all prospective offerors for MCM contracts that will utilize the MCM ADM facility." This statement is difficult to interpret. Does the USG expect the successful offeror to provide its rates and fees to outside parties when the USG directs the selected DoD ADM contractor to be a directed subcontractor?

A38: See Q/A 11.

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Q39: Page 88-90, Section H.7. Regarding future drug/biologic development activities, would a contractor or subcontractor on this DoD ADM contract be eligible to compete for and perform work on other separate early phase or advanced development DoD drug product development contracts where the product would at some point utilize the DoD ADM capabilities?

A39: Yes, the contractor may bid on early phase or advanced development DoD drug product development contracts; however the Offeror is referred to Section A paragraph A.7.2 which states: "It is the Government's intent to maintain full and open competition to the maximum practical extent for all future DoD MCM production contracts...In order to maximize competition and to minimize any unfair competitive advantage, the awardee of THIS contract must have in place a robust Organizational Conflict of Interest (OCI) mitigation plan and an Intellectual Property (IP) Management Plan that protects the interests of both the awardee and third parties that utilize the capability.... Failure by the awardee to adequately protect the rights of third parties may result in a determination by the Government that the awardee is ineligible for participation in a future MCM contract or contracts. OCI and IP management by the awardee of third parties will be continually reassessed by the Government throughout the execution of this contract, in order to maximize fairness in future DoD MCM contracts. The Government reserves the right to prohibit the MCM ADM contractor from receiving award for future MCM production contracts on a case by case basis."

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Q40: ADM Capacity – The solicitation requires Contractors to establish 2 ADM suites, each capable of developing and manufacturing 1.5mds with capability to surge to 12mds of FDA-approved MCM – either of which to be delivered in 3 months time. Please clarify to the extent DoD requires 100% access to the 2 ADM suites or if the Contractor is able to utilize unused capacity.

A40: DoD requires 100% accessibility to the MCM ADM when necessary. Offerors may propose alternative use for unused capacity. However, if/as required, DoD requirements will take precedence. See also Q/A 33.

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Q41: Timeline to Establish ADM Capability – Please confirm that the 24 month timeline to establish ADM capability includes activities through PQ and that FDA licensure activities including PV would commence afterwards.

A41: The Offeror is referred to Milestone 4 in the Statement of Objectives which states "Complete facility validation of the ADM, within two (2) years of award and within one (1) month after completion of facility commissioning and validation the contractor shall submit for review and acceptance an equipment qualification/commissioning and facility validation summary with supporting documentation which includes, but is not limited to Installation Qualification, Operation Qualification, and Performance Qualification."

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Q42: ADM Yield Assumptions – Would you please provide the anticipated/assumed yield for MCM candidates to be used as a basis for sizing the facility and equipment?

A42: In their proposal Offerors should use past experiences and industry history to arrive at yield assumptions for developing these types of products.

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Q43: Fill Finish – Please confirm if Fill Finish operations are to be included when establishing the ADM facility or alternatively if the may be outsourced to a third party? Also, would you please confirm the required dosage method (i.e., pre-filled syringes, multi-dose or single dose vials)?

A43: See Q/A 31. Fill Finish requirements for individual MCMs will vary depending on the product and route of administration.

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Q44: Reimbursement – Are all expenses associated with each CLIN in the solicitation to be reimbursed at 100% by the DoD?

A44: The Government plans on awarding a cost reimbursement type contract with 100% reimbursement of all allowable costs by the Government. See also QAs 3, 45, 47, 69, 74.

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Q45: Facility readiness – CLINs 2001, 3001, 4001 and 5001 (ADM operations) each require Contractors to operate and sustain the ADM suites for 2 years in accordance with the SOW. In addition, the RFP indicates that Offeror's will be evaluated on their "Post-validation ADM operating process." We would like additional clarity on what is required to maintain these suites in a state of readiness (staffing, facility maintenance, warm based production, etc.) and the reimbursement for such activities.

Once validation has been completed, please clarify what is required of Contractors to maintain the ADM suites in a state of readiness in advance of the start of any MCM ADM project as governed by CLINs 2001, 3001, 4001 and 5001? For example, would these CLINs reimburse the Contractor for the cost of 100% of dedicated staff to be on hand to immediately respond to any MCM ADM project, facility maintenance costs and any type of warm base production that may be required?

A45: The Government has utilized a statement of objectives to provide maximum flexibility to Offerors so that they may propose their unique approach as documented in their proposed SOW. The RFP requires the Offeror to propose what he deems is required to maintain the ADM suites in a state of readiness. The Government will evaluate these proposals as indicated in Section M. In regards to reimbursement, the Offeror is directed to Page 97 of the RFP, clause 52.216-7 "Allowable Cost and Payment"

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Q46: Optional manufacturing suites – CLINs 6001, 6002 and 6003 are optional CLINs which allow the DoD to request the Contractor to establish one additional ADM suite with the same requirements as per CLIN 1001. Please clarify if Contractors are obligated to be able to establish additional ADM suites under these CLINs? If so, what is the required timing to establish, commission, and validate these facilities?

A46: The awardee shall be required to establish the additional ADM suite(s) if the option(s) are exercised by the Government. CLINs 6001, 6002 and 6003 will be amended to state: "For Proposal purposes, offerors shall plan for delivery of this option not later than 24 months after it is exercised. This CLIN will be re-negotiated at the time the option is exercised, based on knowledge of the MCM to be developed, and based on knowledge and experience gained by both the Awardee and the Government regarding the two (2) suites developed under CLIN 1001 and previously exercised options, if applicable."

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Q47: Contract type – The solicitation indicates the contract type as Cost Reimbursement. In addition, the solicitation proposes Cost plus fixed fee CLINs and Firm-fixed price CLINs, which are typically not included in a cost-reimbursement type contract. Please clarify the contract type expected to be awarded from this solicitation.

A47: This is a cost reimbursement type contract as described in FAR 16.301, and more specifically, as a Cost-Plus-Fixed-Fee (CPFF) type of cost reimbursement contract, as further described in FAR 16.306. Notwithstanding that the overall contract is a CPFF type, some CLINs are established as Firm Fixed Price.

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Q48: Contract term – The solicitation indicates that "The Government's vision for this program is to establish a dedicated and enduring capability to conduct advanced development and manufacturing of MCMs that are FDA approved and ready for distribution to meet the needs of the Department of Defense for the foreseeable future." Since the solicitation indicates that the maximum length of an award would be 10 years, how does the DoD envision ensuring an enduring capability to develop and manufacture MCM beyond this timeframe?

A48: Based on performance and results throughout and at the end of this contract, the Government will determine how to best ensure DoD continues to have an enduring capability to develop and manufacture MCM."

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Q49: Use – The solicitation indicates that MCMs are needed to protect and treat military and civilian populations against chemical, biological, radiological, and nuclear attacks and outbreaks of naturally occurring emerging and genetically engineered infectious diseases. Please clarify the intended access of MCM ADM (i.e. military, US public, both).

A49: This contract will provide the Department of Defense (DoD) with the Advanced Development and Manufacturing (ADM) capability to rapidly develop, approve (through Food and Drug Administration (FDA) approval), and manufacture Medical Countermeasures (MCMs).

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Q50: Place of performance – The solicitation indicates that the ADM capability will be located in one or multiple locations within the United States and its territories and may include international participation. Please clarify what is meant by "international participation." Is this meant to indicate that Contractors may be asked to enter into MCM ADM contracts with ex-US based 3rd parties?

A50: International participation in this context is with regard to offerors' team-members which may be foreign entities, although the ADM capability must be within the US and its territories.

In the context of the question, it is possible that a foreign firm may win a future MCM contract for which the ADM will be a directed subcontractor.

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Q51: The SF 33 indicates that this is a rated order under the Defense Production Act. Please explain the implications of the "DO-B9" rating and how enforcement of this provision will operate vis-à-vis the contractor's, subcontractors', and/or suppliers' obligations to other critical U.S. Government rated orders for the same or similar efforts, to include the HHS-sponsored MCM Initiative.

A51: Implementation, enforcement and conflict resolution for the Defense Priorities and Allocations System (DPAS) rating system shall be conducted in accordance with DoD-4400.1-M.

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Q52: The NAICS code assigned to this contract only covers a portion of the services required for contract performance. For example, the contract will require the contractor potentially to act as a drug sponsor for regulatory purposes. This activity is not related to pharmaceutical manufacturing. Please clarify how DOD intends to apply the assigned NAICS to this and other efforts required by the RFP that are not aligned with the assigned NAICS code.

A52: The assigned NAICS code has been selected based on the Government's assessment of the most appropriate size standard based on the overall requirement, and is for the purpose of establishing the size standard for small business determination for offerors claiming small business status at the time of proposal submission and/or award. In this case, for the assigned NAICS Code of 325412, an offeror with 750 or fewer employees will be considered a small business for this acquisition.

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Q53: The vision for the MCM ADM states that the products contemplated for manufacturing will be "FDA approved and ready for distribution." How does this vision reflect the advanced development concept embedded throughout the RFP, to include the work suggested by the sample task orders for the MCM ADM to sponsor non-FDA products for approval?

A53: The purpose of the ADM is to provide the capability to conduct advanced development and manufacturing of MCMs through FDA approval. The Sample tasks are included in the RFP to enable the Government to assess the offeror's understanding and ability to plan and execute an actual MCM effort.

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Q54: The vision for the MCM ADM anticipates "continued capability upgrade." How does DOD envision such upgrades will be contractually accomplished and funded? What process will be used to direct an upgrade of the MCM ADM (including suites supplied during the base period and options), especially upgrades that will require FDA inspection and approval following validation of the upgraded equipment and process?

A54: The Offeror is referred to the last paragraph in Section IV of the Attachment J.1 which states “Once the facility and equipment have been commissioned and validated, the ADM capability is expected to be ready to support transition and integration of new technologies from independent innovators, identify key needs for technology development, and conduct the development and manufacture of MCMs for the Government. This includes incorporating enabling science and technology (S&T) and novel platform and expression systems for delivery of products by leveraging technological and regulatory science advancements.” The Government anticipates that the awardee will maintain awareness of new and emerging technologies from Government, Academia and industry that will be necessary to maintain the ADM as state of the art facility. Upgrades may be incorporated into the contract via contractor initiated Engineering Change Proposals (ECPs), or by the Government via contract modification.

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Q55: The vision for the MCM ADM anticipates establishing this effort as a “directed subcontractor” for “all DOD MCM efforts” by 2014.

- a. Does DOD anticipate requiring all existing DOD MCM suppliers to use the MCM ADM as a “directed subcontractor?”
- b. Will the cost proposal required by the DOD MCM suppliers for use of the MCM ADM as a “directed subcontractor” be treated as if the MCM ADM was functioning as a wholly-private entity?
- c. What contract clauses does DOD anticipate will be required to be flowed-down to the MCM ADM as a “directed subcontractor” to DOD MCM contractor?
- d. What is DOD’s vision of precisely which MCM ADM capabilities will be available by 2014? What capabilities are envisioned to be used PRIOR to 2014 (but following award)?
- e. What will be the process used by DOD to determine which aspects of the “DOD MCM efforts” will be required for DOD MCM contractors to use the MCM ADM as a “directed subcontractor?”

A55: a. As specified in paragraph A.7.1. “...The DoD intends to establish the MCM ADM as a directed subcontractor for all DoD MCM efforts beginning in 2014.” To further clarify the Government’s intent in this regard, the RFP will be amended to add the following language immediately following this sentence in A.7.1: “...beginning in 2014. After that time, MCM contractors will be directed to use the ADM capability, either in its entirety, or in part, as necessary to achieve DoD MCM development requirements. MCM contractors use the services and capabilities of the MCM ADM for all CMO, CRO, T&E, and Fill/Finish activities that are not resident in the contractor’s organization. This will be assessed by the Government on a case by case basis for each MCM program prior to award, and the decision regarding the extent to which the MCM ADM is employed as a directed subcontractor will be made on the basis that provides the best value to the Government. However, anytime...”

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At this time, the Government intends to utilize FAR Clause 55.244-2 Subcontracts, in future MCM contracts, to require Government Contracting Officer approval prior to the MCM prime contractor placing any subcontract regarding CMO, CRO, T&E and/or Fill/Finish activities.

b. The ADM will be treated as a Contractor Owned Contractor Operated facility. For the purposes of cost proposal preparation by future MCM offerors beginning in 2014, the Government will provide all offerors with the established labor rates of the MCM ADM to ensure fairness among all offerors regarding the directed subcontractor (See Q/A 11). Beyond this, the Government expects the MCM prime contractor and the MCM ADM directed subcontractor to operate in a traditional prime/sub relationship, notwithstanding any redirection that may occur on the basis of the Government's assessment of the extent of MCM ADM participation in the contract as described in A55.a. above.

c. As described in A55.a. above, it is currently envisioned that FAR Clause 55.244-2 will be used to ensure Government approval as appropriate for the MCM ADM contractor as a directed subcontractor.

d. See Q/A 10.

e. As described in A55.a. above, the Government intends the ADM to evolve as a competitive and preferred choice as an MCM subcontractor for the activities for which it is being developed. Therefore, the Government anticipates that offerors' proposals for MCM prime contracts will employ the ADM as a subcontractor for CMO, CRO, T&E and Fill/Finish activities to the extent that such capabilities are not resident in the offeror's organization. Assessment of the proposals will be conducted to determine the appropriate extent of ADM employment as a subcontractor, and the Government may direct an offeror(s) to employ/increase the use of the ADM if and as determined to be in the best interest of the Government. This will be on a case by case basis.

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Q56: The RFP states that DOD wants "full and open competition" for "all future MCM production contracts," while at this same time, the RFP requires use of the MCM ADM as a directed subcontractor and requiring potential DOD MCM providers to enter into very novel and untested Intellectual Property agreements required to use the MCM ADM. Given the general lack of a robust MCM industry, and thus very limited competition, how does DOD envision it will achieve "full and open competition" while adding two mandated requirements (i.e. Use of the MCM ADM and use of novel/tested IP provision) that are likely to further restrict the willingness of the private sector to participate in the MCM industry?

A56: DoD has determined, based on historical data, that it cannot rely on free market competition to accommodate its demands for advanced development and manufacturing of MCMs. To address this problem, DoD is establishing the MCM ADM. Full and open competition as it pertains to future MCM production contracts is envisioned as providing maximum opportunity to the industry to compete for those efforts, and to direct the use of the MCM ADM for those activities that have historically been unavailable to DoD. While the DoD is sensitive to the reluctance of private industry to participate in the MCM market, the threat is

real, and the DoD has established this strategy to maximize competition for those areas where competition has been determined to exist, and to develop the necessary dedicated capabilities that for which competition has proven ineffective.

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Q57: The RFP states that the “Government reserves the right to prohibit the MCM ADM contractor from receiving award for future MCM production contracts on a case by case basis.”

- a. What would be the basis of the Government exercising this right?
- b. Would the required due process considerations mandated by the FAR for suspension and debarment apply to such an action?
- c. What is DOD’s vision for how this provision would operate with performance of non-DOD ADM efforts, to include the HHS-sponsored MCMI?
- d. Would this provision apply to subcontractors to the MCM ADM to prohibit their work on MCM production contracts?

A57:

a. The basis for exercising this right is to ensure fairness in the competitions of future MCM programs, and may be exercised by the Government if it determines that the MCM ADM operator has an inadequate OCI mitigation plan and/or Intellectual Property Protection Plan, and/or if other circumstances exist that cause the Government to believe that the MCM ADM operator would have or create an unfair competitive advantage or perception thereof.

b. The RFP statement regarding the right to prohibit the MCM ADM contractor from participating in future MCM contracts is not related to suspension and debarment proceedings. Rather, the provisions of FAR 6.202.(a) will be used to restrict the MCM ADM operator from participating in efforts for which the Government determines that exclusion of the MCM ADM operator is in the best interests of the government.

c. The Government has no desire, right or ability to limit the MCM ADM operator from participating in non-DoD (to include HHS) contracts, except to the extent where such performance interferes with the contractual obligations of the MCM ADM contractor under this contract. However, the remedies to the Government in such a case would follow the guidance prescribed by FAR Part 33.

d. The intent of the Government is generally not to restrict the ability of either the MCM ADM operator or its subcontractors from bidding/participating in other DoD MCM contracts. However, the same rationale described in A57.a above will be used by the Government to establish the acceptability of an MCM ADM subcontractor to participate in other DoD MCM programs.

Q58: Does section A.8 purport to alter or replace the standard FAR audit and inspection provisions?

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A58: No. Paragraph A.8 refers to site visits by prospective MCM offerors for the purpose of proposal preparation and is not related to audits or inspections.

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Q59: Does section A.9 purport to alter or replace the standard FAR cost accounting provisions and cost principles?

A59: No. See also Q/A 11.

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Q60: Does section A.10 purport to alter or replace the standard FAR government furnished equipment provisions?

A60: No. Paragraph A.10 refers to “contractor acquired property” purchased by the contractor with funds provided by the Government under this contract, that may reside with the contractor during contract execution. Government Furnished Property will be managed in accordance with FAR Part 45 and the clauses/provisions in the RFP and resultant contract.

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Q61: The RFP notes that award is subject to appropriation of FY 2012 funds.

- a. Does DOD anticipate using Military Construction funds for this RFP?
- b. Does DOD anticipate using Research and Development funds for this RFP?

A61: a. Military Construction (MILCON) funds will NOT be used for this acquisition.  
b. DoD anticipates utilizing RDTE funds for the contract resulting from this solicitation.

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Q62: The RFP anticipates the possible award of options for additional suites.

- a. Will these suites have to meet the same requirements as the suites awarded under the base contract, including BSL-3 manufacturing capability?

How will the costs of upgrades made to the suites awarded in the base period and desired in the suites to be acquired under the options be addressed?

A62: Yes, BSL 3. Additional costs will be handled via modification or Engineering Change Proposal (ECP).

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Q63: The RFP speaks of “Troop Equivalent Doses” but does not recognize that the manufacturing processes, yields, and validation process will differ from product to product. The RFP also draws no distinction between the processes, yields, and validations methods required for small molecule drugs as distinct from large and small biologics (including vaccines). With this lack of clarity in mind, how should the proposer determine whether its proposed suites can produce “500,000 Troop Equivalent Doses” of a wholly undefined product?

A63: For the purposes of this solicitation One Troop Equivalent dose (TED) is defined as three doses. Regarding yields see Q/A 42.

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Q64: Many small molecules will require longer than 3 months to manufacture 500,000 TED. For example, the experimental smallpox antiviral recently contracted for by HHS under Project

BioShield anticipates production of 1.7 million courses of treatment can take as long as 3 years (assuming a lower than anticipated dose is supported by FDA) using a well known and respected Contracting Manufacturing Organization with substantial output capabilities. How can an offeror prepare a meaningful proposal using only two suites when the MCM's currently contracted for by the USG would require manufacturing scale that far exceeds most current commercial manufacturing facilities?

A64: 500,000 TEDs equates to 1.5 million doses, not courses. The capability to produce previously approved products in this volume in the time frame is required.

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Q65: In Section H.3, the RFP imposes contractual implications for failure to maintain cGMP compliance, even where the contractor is actively engaged with FDA to resolve the problem.

- a. Will DOD modify this provision to ensure termination for default is not appropriate where the contractor is making best efforts to comply with FDA requirements?

A65: As stated in Section H, ". . . the contractor shall have thirty (30) calendar days from the time such material failure is identified to cure such material failure. If the contractor fails to take such an action within the thirty (30) calendar day period, then the contract may be terminated." As with any termination action, the Government will consider all aspects before proceeding with termination.

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Q66: In Section H.6, the RFP states that "At present, the Government only anticipates the test and evaluation associated activities to possibly involve BSAT," yet the RFP also appears to require manufacturing to be performed in BSL-3 conditions. Please clarify. If DOD does require manufacturing to occur in BSL-3 conditions, does this include small molecule manufacturing? The significant complexity and expense of maintaining BSL-3 does not appear to be justified for small molecule production.

A66: See Q/A 30.

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Q67: The RFP "Mandatory Responsiveness Requirements" requires an offeror to have "drug development" experience to include FDA approval/licensure in the last 10 years. The RFP draws no distinction between a drug (regulated by the Food, Drug, and Cosmetics Act) and a biologic, to include vaccines, (regulated by the Public Health Services Act).

- a. Please clarify whether experience with the FDA approval/licensure of a biologic satisfies the mandatory responsiveness criteria
- b. Please clarify whether DOD 's requirement is for both drug and biologic capabilities.

A67: a) Experience in achieving FDA approval or licensure of either a drug or biologic is acceptable. b) The requirement is for both drugs and biologics.

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Q68: The RFP describes the Statement of Work as requiring the offeror to describe its technical approach to a number of tasks that appear to contradict other portions of the RFP

- a. Will the manufacturing suites only be required to produce FDA approved products, or will they also be required to produce material used for advanced development of MCMs, with or without the MCM ADM's other participation in the MCM's development?
- b. The SOW section refers to "new facilities" yet the RFP appears to contain no provisions for Military Construction. Please clarify.
- c. The SOW section refers to the offeror's competence to "rapidly develop" MCMs. Please clarify whether the MCM ADM contractor or the MCM production contractor will be responsible for product development.
- d. The SOW section refers to assisting in the transition of products from DARPA and UARCs (which by definition will be early stage, non-FDA approved products) yet the RFP speaks to FDA approved products, which suggests late stage or approved products. Please clarify the point of development at which DOD anticipates using the MCM ADM capability and what type of funding (6.1, 6.2, 6.3, etc) will be used in this effort.
- e. The SOW section says the offeror must have experience with FDA Approval of TWO OR MORE "drugs"
  - i. Does experience with FDA approved biologics meet this requirement?
  - ii. The mandatory criteria states experience with only one such product is required. Please clarify.
- f. Please describe what DOD's vision for "agile and flexible" manufacturing in the context of small molecule drug manufacturing (as distinct from biologics manufacturing process where such concepts are well known).
- g. Early in the RFP, DOD states it is intent to award the RFP without discussions. Section L.9 states there will be negotiations. Please clarify.

A68:

(a) The ADM will be required to produce both FDA approved products AND material used for advanced development.

(b) Military Construction funds (MILCON) will not be used for this effort. See Also Q/A 61.

(c) The DoD anticipates issuing individual, competitive FAR based MCM contracts, whereby the ADM contractor will be the directed sub to develop and manufacture the product(s). The specific responsibilities for drug development will flow through the prime contractor as specified in the individual MCM contract(s).

(d) This project supports the establishment and commissioning of the MCM ADM capability and the sustainment of the capability to enable the advanced development of vaccines, and/or drugs, and the rapid response to advanced development of vaccines, and/or drugs, and the rapid

response to advanced development and manufacturing needs as they arise. Advanced Development = From 5 months prior to Investigational New Drug (IND)/Biological License Application to FDA approval as defined in the SOO.

(e) See Q/A 9.

(f) It is up to the offeror to propose a capability that it believes will provide agility and flexibility to the DOD. The DOD recognizes the capability for which it is soliciting will include use of innovative (e.g., modular, disposal, etc.) technologies, and approaches may be proposed as necessary by offerors to maximize the usefulness and efficiency of their proposed capability.

(g) These statements are correct as written. The Government intends to award without discussions, but reserves the right to conduct discussion if/necessary, and this caveat is clearly stated in various places in Section L.9.

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Q69: Page 109, item 52.232-20, Limitation of Cost. Is this a cost-sharing contract?

A69: No. This is a cost reimbursement contract. See also Q/A 3.

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Q70: Page 161, L.2.1.1. The table showing the proposal volumes lists Section 7 in Volume 1, but on page 166 there is no explanation of the content of Section 7. Will an explanation be added to describe the desired content for Section 7?

A70: Yes. Paragraph L.3.1. of the RFP will be amended to state:

“Section 7 – SETA Contractor and Foreign National Nondisclosure Agreements. The Government will utilize the contactors and subject matter experts from foreign nations listed below to provide administrative support during the evaluation of proposals submitted in response to this RFP. These contractors and foreign nationals are restricted by the “Organizational Conflict of Interest” provision of their respective contracts from participating as a contractor, sub-contractor, or consultant on the proposed program other than on a non-competitive basis under a prime contract with the Government. Each individual from these contractors and foreign nations will execute a “Certificate of Non-Disclosure” and provide a certificate of financial holdings prior to review of any proposals. Failure of an individual to execute a certificate of non-disclosure, and/or disclosure of financial holdings with any prospective Offeror or subcontractor, will render the individual ineligible for participation in this evaluation process.

By submitting a proposal, the Offeror agrees to permit the contractor(s) and foreign nationals listed below to view proposal information to the extent necessary to provide administrative support to the Government’s proposal review process.

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If specifically requested by an Offeror, the contractors and foreign nationals listed below must execute an agreement with the Offeror that states that they will protect the Offeror's information from unauthorized use or disclosure for as long as it remains proprietary, and refrain from using the information for any purpose other than that for which it was furnished. To expedite the evaluation process, each Offeror must contact the contractors to effect execution of such an agreement prior to the submission of proposals. If the offeror elects to require these contractors and/or foreign national to enter into such agreement, the Offeror shall provide copies of the agreement(s) with their proposal in this Section. The contractors and foreign nationals supporting this source selection are noted below:

**Kalman Co, Inc.**

**CIS, Inc.**

**Ken Kaitin, LLC**

**United Kingdom Ministry of Defense**

**Canada Ministry of Defense**

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Q71: Page 164, L.3.1, Section 1, item c, sub item i, states the requirement for licensure of at least one product in the last ten years. Contradicting this, on page 168, L.3.2, Section 1, item h, the offeror is asked to describe its relationship with a pharmaceutical company that has successfully sponsored two or more drugs to FDA approval/licensure. Which is the minimum product licensure requirement?

A71: See Q/A 9.

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Q72: Page 166, L.3.1, Section 4. This states that an award cannot be made until the offeror has a DCAA approved accounting system. Does this also apply to nonprofit companies and academic institutions referenced on page 171, paragraph L.3.5.1, Section 1, Introduction?

A72: Paragraph L.3.5.1 shall be amended to state: "For educational institutions and nonprofit organizations, audit cognizance will be determined according to the provisions of OMB Circular A-133, Audits of Institutions of Higher Education and Other Non-Profit Institutions as described in FAR 42."

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Q73: Page 168, L.3.2, Section 1. Can the content of paragraphs "l" [L] and paragraph "g" be combined into one item since both address the QMS program?

A73: Yes.

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Q74: Page 175, L.3.5.3.i. Cost Accounting System, states the requirement for the offeror to have an accounting system capable of handling a cost-reimbursement type of contract. Is it DoD's intention to award a cost plus award fee or a cost plus fixed fee contract?

A74: Paragraph A.1. of the RFP will be amended to include the statement: "The Government intends to award a cost plus fixed fee type contract."

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Q75: Page 168, L.3.2, Section 1, paragraph k. Requires a description of the approach to utilize the ADM during periods of no DoD demand. Can the DoD ADM suites be used for commercial production during periods without DoD demand?

A75: See QA 33 and 40.

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Q76: Page 180, Section L.9, Sequence of Events, details the steps in the source selection process. What are the estimated dates associated with each step?

A76: The Government cannot provide this information at this time, but is targeting contract award no later than March 2012.

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Q77: SOO (Draft, 20110816), page 2, Section III, Scope. The Statement of Objectives calls for the establishment and commissioning of two BSL-3 suites. Does this refer to only the upstream and downstream aspects of the suites, or does this also include the supporting process development labs, QC labs, administrative space, warehousing, etc.

A77: See Q/A 27.

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Q78: SOO, page 2, Section III, Scope. In Phase 1 it states that “this contract will have up to three (3) options to incrementally increase the development and manufacturing capacity. Under these options are there any restrictions on the approach to create additional capacity? For example, can new construction or renovation be done at a new, additional site that’s located at some distance from the location of the initial/baseline two suites?

A78: There are no restrictions on the approach to create additional capacity, other than those contained in the RFP. See also J.1. SOO paragraph V.

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Q79: Does the contract provide funding to renovate, expand or construct facilities to meet the requirements of this RFP when the capability does not already exist at the time the proposal is submitted, e.g. BSL3 capability or additional suite capacity? If yes, under which CLIN(s) would this effort be funded?

A79: Yes. These activities can be conducted under CLINs 1001, 6001, 6002, 6003.

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Q80: SOO (Draft, 20110816), page 3, Section III, states that the contractor’s organizational structure shall include all required ... personnel to include ... skilled labor (...Test and Evaluation [T&E] ...) .... Will the contractor provide T&E services or will the DoD provide that support through the separately developed T&E facility?

A80: The Contractor shall provide T&E services as described in the RFP.

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Q81: SOO (Draft, 20110816), page 6, Section IV, states that “the ADM contractor will be a directed subcontractor of these third parties.”

- a. What will be the contractual relationship between the ADM contractor (including its subcontractors) and the third parties [that will use the ADM capability] ?

- b. Will the contracts between the ADM contractor and third parties be sole source contracts?
- c. Will revenue from these subcontracts with third parties accrue to the prime contract?

A81: See Q/A 55.

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Q82: What is the pipeline and timing of products that would be processed through the ADM facility?

A82: See Q/As 28, 42, and 63.

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Q83: Attachments J3 and J4. The WBS that is provided in both attachments does not appear to have a roll-up capability. Could you add a level so that the Level 1 Activity in Attachment J.3 is called "Large Molecule Task" and the Level 1 Activity in Attachment J.4 is called "Small Molecule Task"?

A83: The Government will not revise the sample task worksheets at this time. However, offerors are referred to the "Instructions" Tab in each of the sample task workbooks, which permits the offeror to increase the number of WBS levels, add WBS items, or add entire worksheet tabs if they feel that that WBS items are missing. Such changes are permissible within other instructional constraints provided therein.

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Q84: Attachments J3 and J4. After reviewing the two Sample Task worksheets that were provided in these attachments, it appears that the two WBS numbers that were provided do not follow a consistent format. The WBS provided in attachment J.3 appears to be missing a line for WBS #11 and WBS#12 (including task headings), although there is lower level detail provided for the missing WBS #s and tasks. In addition, the WBS provided in Attachment J.4 contains WBS #9 for Regulatory activities, with lower level detail rolling up to that WBS. However, the WBS provided in Attachment J.3 contains two high level activities (#2 and #3) for BLA Preparation and BLA Submission, respectively. Could you add a high level WBS for Regulatory activities in this attachment (similar to the format in Attachment J.4) and then put the two BLA activities under that WBS number, so that the regulatory activities can be grouped together?

A84: See Q/A 83.

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Q85: Attachments J3 and J4. There is an EVM WBS (#1.2) included in Attachment J.4 but none included in Attachment J.3. Could one be added to the J.3 WBS worksheet?

A85: See Q/A 83.

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Q86: Are there any minimum or maximum footprint expectations for the two suites?

A86: No. See also Q/A 28.

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Q87: The solicitation calls for the establishment of two suites, yet there seems to be a requirement for Mammalian/Insect Cell, Microbial Fermentation and Small Molecule manufacturing capabilities based on the products mentioned in the Statement of Objectives. This seems to indicate that three suites are required. Please clarify the requirement.

A87: See Q/A 29.

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Q88: Will the Government consider an extension to the proposal due date?

A88: The Government does not anticipate consideration of an extension of the proposal due date at this time.

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Q89: Is there an incumbent?

A89: No.

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Q90: Is there a Q and A period or date to submit questions?

A90: See paragraph L.9.b.i. of the RFP for instructions regarding questions. Questions must be provided no later than the date specified in the RFP, which is currently 7 days prior to the closing date of the RFP. The RFP closes on 25 Oct, so closing date for questions is 18 October. However, the Government does not intend to extend the proposal period, so we urge you to submit questions well advance of this date to enable offerors to best respond to the answers provided.

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Q91: Would a joint venture be considered for the contractor/bidder?

A91: Yes, a joint venture is permissible, provided it is constructed within the constraints defined in the RFP.

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Q92: Is it a requirement that the manufacturing facility be based in the United States?

A92. Yes, the capability must reside in the United States and its territories, and this is a mandatory requirement for consideration.

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Q93: Will the contract require security cleared professionals on the project? What level: Secret or Top Secret?

A93: At this time, the Government does not anticipate requirements for security clearances higher than "Secret".

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Q94: We have a question on the NAIC Code: 325412 suggests a pharmaceutical small business size at 750 employees or less.

Is that true or is this open to small and large businesses?

A94: This acquisition is open to both small and large businesses (full and open competition). The NAICS code of 325412 is provided to establish the minimum size standard for a company that may bid on this contract as a small business. If a small business under this NAICS code bids on the program, then certain requirements of the RFP may not apply, particularly those regarding small business participation. See also Q/A 52.

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Q95: How will the Government address possible Organizational Conflict of Interest (OCI) issues with companies that provide SETA support to the MCM ADM program and who may bid on this contract?

A95: The Government will review potential OCI issues for any offeror that also provides contractual support to the Government (not only SETA contractors working for the program) and may prohibit those offerors from bidding on this contract if it is determined that a real or perceived OCI situation exists regarding this acquisition. This will be the case whether the contractor bids as the prime, or if the contractor is a subcontractor at any level below the prime. Offerors whose teams include SETA contractors supporting the Government must include that company's OCI mitigation plan as part of the overarching OCI Mitigation Plan which is Section 3 of Volume I of their proposal. Paragraph L.3.1 Section 3 will be amended to read: "Organizational Conflict of Interest Mitigation Plan. Offeror shall include its mitigation plan, and those of its proposed subcontractors, if applicable, in accordance with the clauses and provision listed elsewhere in the RFP."

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Q96: Regarding the statements in Section V, page 6 of RFP Attachment J.1. Statement of Objectives that states "The contractor will establish, own and operate the MCM ADM capability within the United States", and QA32 which states that equipment will become the property of the Government, and amended paragraph A.10 which emphasizes Clause 52.245-1(e)(3) relative to Government ownership of equipment purchased with Government funds: Are these statements contradictory, and if not, how not?

A96: These statements are not contradictory. The Government anticipates that the contractor will own or lease the property required to establish and operate the ADM, and therefore the facility will be contractor owned/operated. However, ownership of equipment purchased by the contractor using program funds shall rest with the Government as specified in clause 52.245-1(e)(3). In practical terms, such equipment will be installed in the contractor's facility and operated by the contractor per the terms of this contract until the program's conclusion, at which time the Government will determine the disposition of the equipment that is in the best interests of the Government.

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Q97: Can you e-mail the specs for the Butyl insulated gloves so you will potentially have another source for future bids?



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Q101: It is very difficult to fit all of the facility planning information with the other required information within the 50-page limitation for the Technical Volume. L2.1.2 states: "Exceptions to the page limitations are: cover pages, indices/tables of contents, divider pages and crosswalk matrix." Appendices are not specifically included in this exception to the page limit. Please clarify A) whether Appendices for supporting material may be included within the Technical Volume, and B) if so, whether these Appendices are excluded from the page limitations.

A101: The RFP will be amended to increase the maximum allowed pages for Section 1 of the technical volume (Volume II) from fifty (50) pages to seventy-five (75) pages.

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Q102: In RFP Section B - Supplies or Services and Prices, for CLIN 1002 Technical data, the explanation states "In accordance with CDRL List found in Section J". CLINS 1002AA through 1002AS are sub CLINS to CLIN 1002 Technical Data as shown in Section B.

What does the Government intend for the Offeror to price for CLIN 1002 Technical Data since the sub CLINS (1002AA through 1002AS) state "This CLIN is not separately priced"?

A102: The offeror should include the costs associated with the Technical Data (CLIN 1002 and its subCLINS) in CLIN 1001. The description of CLIN 1002 will be changed to state "Include the cost of all Technical Data in CLIN 1001". This wording shall also be applied to CLINs 2002, 3002, 4002, and 5002 for CLINs 2001, 3001, 4001 and 5001.

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Q103: May the offeror add contractor-defined CLINs to the proposal for capabilities that we think would be highly desirable to the USG? May the offeror submit an appendix to describe additional information contained in the contractor-defined CLIN?

A103: No. The Government is not accepting alternate proposals or proposals for capabilities as contractor defined CLINs.

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Q104: Please explain who the "contractor" should be that goes into item 1.a in the Past Performance Questionnaire (Attachment J.8) if my organization was the prime contractor for the effort, and I am providing an evaluation for a subcontractor who intends to submit a proposal in response to this RFP as the prime contractor for the ADM. Also, can I provide a questionnaire for a prior subcontractor that plans on submitting a proposal in response to this RFP if I plan on teaming with this prior sub for this acquisition?

A104: Please refer to L.3.4.2.3 in Section L of Amendment 1 to the solicitation. The organization that will be submitting the proposal in response to this RFP (or major subcontractor or predecessor organization thereof, if appropriate) should be the contractor indicated at 1.a of the Past Performance Questionnaire (PPQ), and as such, the PPQ should only contain amounts, descriptions, evaluation/comments, etc for that organization's efforts in the scope of the contract indicated at 1.b. If the evaluated organization is a major subcontractor or predecessor

organization, the form should indicate that the evaluated organization is a subcontractor or predecessor and should also indicate the name of offeror who will actually be submitting the proposal in order for the evaluating board to include the evaluation with the correct proposal.

Please note that section L.3.4.2.3 indicates that it must be an INDEPENDENT evaluation and should be sent from the client/evaluator directly to the Contract Specialist. The Government would not consider an evaluation from a teaming partner or proposed subcontractor of the offeror for this acquisition to be an independent evaluation because the evaluator would have a vested interest in the offeror receiving the award. In addition, an offeror should not submit an evaluation of past performance for its own proposed major subcontractors for this effort or predecessor organizations. Evaluations determined to be not independent will be disregarded.

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Q105: Will the Government consider an extension to the proposal due date based on the fact that we have had to work extensively with prospective subcontractors, partners, and team members to develop the organization necessary to meet this requirement, which does not leave us adequate time to respond appropriately to the requirements of the RFP?

A105: The Government will amend Section L of the RFP to change the proposal due date from 25 October 2011 to 15 November 2011. This is the maximum length of time permissible while still allowing the Government to meet its target award date.

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Q106: Please clarify RFP paragraph A.7.1. regarding utilization of the MCM ADM as a directed subcontractor in future MCM contracts. What is meant by: "This will be assessed by the Government on a case by case basis for each MCM program prior to award, and the decision regarding the extent to which the MCM ADM is employed as a directed subcontractor will be made on the basis that provides the best value to the Government."

A106: The Government intends to utilize the capabilities of the ADM to the maximum extent practicable in future MCM contracts. The decision to employ the ADM as a directed subcontractor is a function of, but not limited to: the requirements of the particular MCM acquisition; the strengths, capabilities, experience, and efficiencies (including cost, schedule and performance) of the ADM as compared to any alternative solutions that may be proposed by the offerors, if/as permitted in a particular MCM RFP; and/or other Government considerations as determined by the Government for each MCM acquisition. The decision for selection of the ADM as a subcontractor for a particular MCM will be made in accordance within statutory and regulatory parameters. In such cases where the Government directs an MCM offeror/contractor to employ the ADM as a subcontractor, such determination will be justified and documented by the Government prior to execution of such direction.

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Q107: With the extension of the due date, what is the anticipated schedule for oral presentations? Will there be any additional instructions regarding number of participants, content of presentations, etc.?

A107: Oral presentations are tentatively scheduled for the week of 29 November 2011. There are no additional instructions at this time to the instructions already found in section L of the RFP.

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Q108: It appears that the FAR clause for CAS Certification should be FAR 52.230-1, Cost Accounting Standards Notices and Certification (OCT 2008), Alt. 1 (APR 1996). Although the RFP caption indicates the same clause, it instead quotes an older version that has a \$25 million threshold for the CAS Monetary Exemption, rather than the current version which has a \$50 million threshold. Please clarify that the RFP incorporates FAR 52.230-1, Cost Accounting Standards Notices and Certification (OCT 2008), Alt. 1 (APR 1996) as it is published in the Code of Federal Regulations – with a \$50 million threshold for the CAS Monetary Exemption.

A108: The RFP shall be amended to include the current language in the FAR for FAR 52.230-1, Cost Accounting Standards Notices and Certification (OCT 2008), Alt. 1 (APR 1996)

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Q109: The RFP, at page 92, incorporates FAR 52.219-9 (JAN 2011), Alt. II (OCT 2001). Subsection (d)(1) of that FAR clause instructs offerors to express subcontracting goals as a percentage of total planned subcontracted dollars: “Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns as subcontractors.” Similarly, DOD’s Goals are published as a “Goals (% based on total planned subcontracting \$ for each SB category).” [http://www.acq.osd.mil/osbp/doing\\_business/index.htm](http://www.acq.osd.mil/osbp/doing_business/index.htm). But RFP Section L.3.6 also requests goals expressed as a percentage of “Total Contract Value,” and makes no mention of the FAR and DOD requirements expressed as percentages of total planned subcontracting dollars. Please clarify whether a deviation from FAR 52.219-9 is intended for this RFP, that will require DoD’s published percentage goals for “total planned subcontracting \$” to instead be applied, here, to the larger “Total Contract Value” figure.

A109: The structure of the breakdown requested in Section L.3.6 is pursuant to DFARS 215.304(c)(i)(B) “Proposals addressing the extent of small business and historically black college or university and minority institution performance may be separate from subcontracting plans submitted pursuant to the clause at FAR 52.219-9 and should be structured to allow for consideration of offers from small businesses.” The offeror is to complete the breakdown at L.3.6 in accordance with the instructions in the notes to that section. The breakdown is for purposes of evaluating the proposals in a manner that is applicable for both large and small business by the Source Selection Evaluation Board (SSEB) Small Business Team and is not to be interpreted as a change to the requirements of FAR 52.219-9.

## SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

The following have been added by full text:

52.230-1 COST ACCOUNTING STANDARDS NOTICES AND CERTIFICATION (OCT 2008) - ALTERNATE I (APR 1996).

Note: This notice does not apply to small businesses or foreign governments. This notice is in three parts, identified by Roman numerals I through III.

Offerors shall examine each part and provide the requested information in order to determine Cost Accounting Standards (CAS) requirements applicable to any resultant contract.

If the offeror is an educational institution, Part II does not apply unless the contemplated contract will be subject to full or modified CAS coverage pursuant to 48 CFR 9903.201-2(c)(5) or 9903.201-2(c)(6), respectively.

I. Disclosure Statement -- Cost Accounting Practices and Certification

(a) Any contract in excess of \$650,000 resulting from this solicitation will be subject to the requirements of the Cost Accounting Standards Board (48 CFR Chapter 99), except for those contracts which are exempt as specified in 48 CFR 9903.201-1.

(b) Any offeror submitting a proposal which, if accepted, will result in a contract subject to the requirements of 48 CFR Chapter 99 must, as a condition of contracting, submit a Disclosure Statement as required by 48 CFR 9903.202. When required, the Disclosure Statement must be submitted as a part of the offeror's proposal under this solicitation unless the offeror has already submitted a Disclosure Statement disclosing the practices used in connection with the pricing of this proposal. If an applicable Disclosure Statement has already been submitted, the offeror may satisfy the requirement for submission by providing the information requested in paragraph (c) of Part I of this provision.

Caution: In the absence of specific regulations or agreement, a practice disclosed in a Disclosure Statement shall not, by virtue of such disclosure, be deemed to be a proper, approved, or agreed-to practice for pricing proposals or accumulating and reporting contract performance cost data.

(c) Check the appropriate box below:

(1) *Certificate of Concurrent Submission of Disclosure Statement.* The offeror hereby certifies that, as a part of the offer, copies of the Disclosure Statement have been submitted as follows:

(i) Original and one copy to the cognizant Administrative Contracting Officer (ACO) or cognizant Federal agency official authorized to act in that capacity (Federal official), as applicable; and

(ii) One copy to the cognizant Federal auditor.

(Disclosure must be on Form No. CASB DS-1 or CASB DS-2, as applicable. Forms may be obtained from the cognizant ACO or Federal official and/or from the loose-leaf version of the Federal Acquisition Regulation.)

Date of Disclosure Statement:

\_\_\_\_\_

Name and Address of Cognizant ACO or Federal Official Where Filed:

\_\_\_\_\_

The offeror further certifies that the practices used in estimating costs in pricing this proposal are consistent with the cost accounting practices disclosed in the Disclosure Statement.

(2) *Certificate of Previously Submitted Disclosure Statement.* The offeror hereby certifies that the required Disclosure Statement was filed as follows:

Date of Disclosure Statement:

\_\_\_\_\_

Name and Address of Cognizant ACO or Federal Official Where Filed:

\_\_\_\_\_

The offeror further certifies that the practices used in estimating costs in pricing this proposal are consistent with the cost accounting practices disclosed in the applicable Disclosure Statement.

(3) *Certificate of Monetary Exemption.* The offeror hereby certifies that the offeror, together with all divisions, subsidiaries, and affiliates under common control, did not receive net awards of negotiated prime contracts and subcontracts subject to CAS totaling \$50 million or more in the cost accounting period immediately preceding the period in which this proposal was submitted. The offeror further certifies that if such status changes before an award resulting from this proposal, the offeror will advise the Contracting Officer immediately.

(4) *Certificate of Interim Exemption.* The offeror hereby certifies that

(i) the offeror first exceeded the monetary exemption for disclosure, as defined in (3) of this subsection, in the cost accounting period immediately preceding the period in which this offer was submitted and

(ii) in accordance with 48 CFR 9903.202-1, the offeror is not yet required to submit a Disclosure Statement. The offeror further certifies that if an award resulting from this proposal has not been made within 90 days after the end of that period, the offeror will immediately submit a revised certificate to the Contracting Officer, in the form specified under subparagraph (c)(1) or (c)(2) of Part I of this provision, as appropriate, to verify submission of a completed Disclosure Statement.

Caution: Offerors currently required to disclose because they were awarded a CAS-covered prime contract or subcontract of \$50 million or more in the current cost accounting period may not claim this exemption (4). Further, the exemption applies only in connection with proposals submitted before expiration of the 90-day period following the cost accounting period in which the monetary exemption was exceeded.

(5) *Certificate of Disclosure Statement Due Date by Educational Institution.* If the offeror is an educational institution that, under the transition provisions of 48 CFR 9903.202-1(f), is or will be required to submit a Disclosure Statement after receipt of this award, the offeror hereby certifies that (check one and complete):

(i) A Disclosure Statement Filing Due Date of \_\_\_\_\_ has been established with the cognizant Federal agency.

(ii) The Disclosure Statement will be submitted within the 6-month period ending \_\_\_\_\_ months after receipt of this award.

Name and Address of Cognizant ACO or Federal Official Where Disclosure Statement is to be Filed:

\_\_\_\_\_

## II. Cost Accounting Standards -- Eligibility for Modified Contract Coverage

If the offeror is eligible to use the modified provisions of 48 CFR 9903.201-2(b) and elects to do so, the offeror shall indicate by checking the box below. Checking the box below shall mean that the resultant contract is subject to the Disclosure and Consistency of Cost Accounting Practices clause in lieu of the Cost Accounting Standards clause.

The offeror hereby claims an exemption from the Cost Accounting Standards clause under the provisions of 48 CFR 9903.201-2(b) and certifies that the offeror is eligible for use of the Disclosure and Consistency of Cost Accounting Practices clause because during the cost accounting period immediately preceding the period in which this proposal was submitted, the offeror received less than \$50 million in awards of CAS-covered prime contracts

and subcontracts. The offeror further certifies that if such status changes before an award resulting from this proposal, the offeror will advise the Contracting Officer immediately.

Caution: An offeror may not claim the above eligibility for modified contract coverage if this proposal is expected to result in the award of a CAS-covered contract of \$50 million or more or if, during its current cost accounting period, the offeror has been awarded a single CAS-covered prime contract or subcontract of \$50 million or more.

### III. Additional Cost Accounting Standards Applicable to Existing Contracts

The offeror shall indicate below whether award of the contemplated contract would, in accordance with subparagraph (a)(3) of the Cost Accounting Standards clause, require a change in established cost accounting practices affecting existing contracts and subcontracts.

YES

NO

(End of Provision)

The following have been deleted:

52.230-1 Alt I      Cost Accounting Standards Notices and Certification (Oct      APR 1996  
2008) - Alternate I

(End of Summary of Changes)