

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT				1. CONTRACT ID CODE J	PAGE OF PAGES 1 33
2. AMENDMENT/MODIFICATION NO. 0002	3. EFFECTIVE DATE 11-Oct-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) See Item 6		
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)			<input checked="" type="checkbox"/>	9A. AMENDMENT OF SOLICITATION NO. W911QY-11-R-0023	
			<input checked="" type="checkbox"/>	9B. DATED (SEE ITEM 11) 26-Aug-2011	
			<input type="checkbox"/>	10A. MOD. OF CONTRACT/ORDER NO.	
			<input type="checkbox"/>	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 0002 are indicated by red text, to enable easy reference to the 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 _____ (Signature of person authorized to sign)		15C. DATE SIGNED	16B. UNITED STATES OF AMERICA BY _____ (Signature of Contracting Officer)		16C. DATE SIGNED 11-Oct-2011

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION A - SOLICITATION/CONTRACT FORM

The following have been modified:

IMPORTANT PROGRAM INFORMATION

A.1 This contract is being pursued as a negotiated acquisition using full and open competition that will result in a single contract award using formal source selection procedures. **The Government intends to award a Research and Development (FAR Part 35) cost plus fixed fee type contract.** Source Selection will be made on the basis of best value. The Government reserves the right to award to an offeror whose proposal is neither the lowest price nor most highly rated, but which is determined to provide the best overall value to the Government.

A.2 The Government intends to award a contract WITHOUT DISCUSSION with offerors, but reserves the right to conduct discussions if determined to be in the best interests of the Government.

A.3 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.

A.4 Offerors whose proposals are determined to be responsive will be invited to provide oral presentations. Oral presentations are intended to AUGMENT the written proposals and to familiarize the Government evaluators with the offeror's proposal. Oral presentations will be scheduled by the Government approximately one week after receipt of proposals, and will commence approximately two weeks after the proposal due date. Additional details regarding the oral presentations is provided in Section L.

A.5 The North American Industry Classification System (NAICS) code is 325412 – Pharmaceutical Preparation Manufacturing, and the size standard is 750 employees.

A.6 Contract Data Requirements List (CDRLs) are included in the individual Contract Line Item Numbers (CLINs) and shall not be separately priced in the offeror's proposal.

A.7 Government Vision for the Medical Countermeasures Advanced Development and Manufacturing (MCM ADM) Capability:

A.7.1 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. The MCM ADM will undergo continued capability upgrade based on

emerging technology advances and transition, FDA process improvements, and integration of lessons learned, making it a state of the art center of excellence for drug development and manufacturing. The DoD intends to establish the MCM ADM as a directed subcontractor for all DoD MCM efforts 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 after contract award, the Government may require the ADM contractor to be a directed subcontractor for services not involving the development/manufacturing suites - e.g., Contract Research Organization (CRO), or Test and Evaluation (T&E).

A.7.2 It is vitally important to the Government to protect intellectual property rights of third party contractors who shall be directed to use the ADM. It is the Government's intent to maintain full and open competition to the maximum practical extent for all future DoD MCM production contracts, and for the awardee of those contracts to utilize the capability established in THIS contract as a directed subcontractor for the advanced development and manufacturing of those MCMs. 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. Offerors are strongly encouraged to pay particular attention to Section L of this solicitation regarding instructions for providing their OCI Mitigation Plan and IP Management Plan. Offerors are also strongly encouraged to review Section M evaluation Factor 3 regarding the IP Management Plan. The IP Management Plan will be evaluated for adequacy in protecting the rights of third party contractors that will be directed to use the MCM ADM via a directed subcontract. 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.

A.8 The awardee of any contract resulting from this solicitation agrees, when requested by the Government Contracting Officer, to allow third party DoD contractors access to the MCM ADM facility for the purpose of site visits prior to and after award of DoD MCM contracts as necessary to provide those entities with information required, as jointly agreed between the Government Contracting Officers for this contract and for any potential future MCM contract, for potential offerors to successfully prepare a proposal in response to a DoD solicitation for MCMs and/or MCM related work.

A.9 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.

A.10 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.

A.11 Performance of this contract is subject to Earned Value Management System (EVMS) reporting. See Section H, Clause 52.234-4 and Section K, Clause 52.234-3, and Section J, CDRL A004.

A.12 This solicitation has been prepared in anticipation of, and to accommodate offers from both for-profit companies and nonprofit and/or academic institutions. Consequently, certain solicitation provisions are incorporated into this document that may not apply to all offerors. Provisions/Clauses that are pertinent to nonprofit and/or academic institutions are listed below. These items will be included or removed, as warranted, in any resulting contract. Other clauses, not currently included in this solicitation, may be added into any resulting contract as conditions warrant. Provisions applicable to nonprofit and/or academic institutions include:

- 52.226-2
- 52.227-11
- 52.230-1 Alt 1
- 52.230-5
- 52.249-5

A.13 All cost information included in the offeror's proposal shall be in 2012 dollars.

A.14 Contract award resulting from this solicitation is subject to availability of fiscal year 2012 funds.

A.15 DISCLOSURE OF UNIT PRICE INFORMATION – This constitutes notification pursuant to Executive Order 12600, Pre-Disclosure Notification Procedures for Confidential Commercial Information (June 23, 1987) of our intention to release unit prices of the awardee in response to any request under the Freedom of Information Act, 5 USC 552. Unit price is defined as the contract price per unit or item purchased. We consider any objection to be waived unless the contracting officer is notified of your objection to such release prior to submission of initial proposals.

A.16 All questions regarding this solicitation should be directed to jean.greenwood@us.army.mil, and will be posted, along with responses, to the MCM ADM website at <https://www3.natick.army.mil/mcmadm.html>

SECTION H - SPECIAL CONTRACT REQUIREMENTS

The following have been modified:

ADDITIONAL INSTRUCTIONS SEC. H

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

** PROHIBITION – READ FURTHER FOR DETAILS **

Notwithstanding any other provisions contained in this award or incorporated by reference herein, the recipient is expressly forbidden to use or subcontract for the use of laboratory animals in any manner whatsoever without the express written approval of the US Army Medical Research and Materiel Command, Animal Care and Use Office. You will receive written approval to begin research under the applicable protocol proposed for this award from the US Army Medical Research and Materiel Command, Animal Care and Use Office under separate letter to the recipient and Principal Investigator. A copy of this approval will be provided to the US Army Research, Development and Engineering Command for the official file. Non-compliance with any provision of this clause may result in the termination of the award.

H.2. INTELLECTUAL PROPERTY MANAGEMENT PLAN.

The Government anticipates future MCM contracts with third parties to use the ADM capability. Because the Government anticipates future contractors will utilize the MCM-ADM capability for MCM development and manufacturing, the ADM contractor will be a directed subcontractor of these third parties. The Government requires assurances that the ADM contractor will not use its economic leverage to obtain rights in the third party's subject inventions or technical data beyond those authorized by law in order to provide the needed service to the Government under its contract. For these reasons it is a requirement of the ADM contract that the Offeror provide a sharing plan regarding all intellectual property that is generated under the ADM contract and/or that will be required to be practiced during the performance of the third party MCM contracts.

The Government recognizes that sharing plans may vary depending on the MCM product, the nature of the resources that will be shared, the allocation of rights in intellectual property made during or as a result of the use of the ADM capability, and plans for distributing the resources. The Offeror shall be required to submit a report concerning the sharing plan intended for each use of the ADM capability to develop or produce an MCM product. The report will be submitted within 30 days of the time of an award of the MCM third party contract and will outline how that product will be handled under the Intellectual Property Management Plan.

The requirement for a sharing plan does not alter any of the FAR or DFARS requirements between the Government and the ADM contractor. The rights in data and inventions with regard to the Government will be governed by the applicable clauses in the ADM contract. Sharing plans shall not include any terms that are prohibited by the applicable statutory and regulatory structure governing data rights and inventions.

Based on the above, the Offeror, as a requirement under this solicitation, shall describe its method for protecting third party intellectual property and the licensing arrangement it intends to pursue regarding the intellectual property rights issues that may arise between the Offeror and third parties contracted by the Government. See Instructions for the Intellectual Property Management Plan in Section L.3.3.

H.3. MANUFACTURING STANDARDS

The Current Good Manufacturing Practice Regulations (cGMP) Regulations (21 CFR Parts 210-211) will be the standard to be applied for manufacturing, processing and packaging of this product. If at any time during the life of the contract, the Contractor fails to comply with cGMP in the manufacturing, processing and packaging of this product and such failure results in a material adverse effect on the safety, and purity of the product (a material failure) as identified by the FDA, 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.

H.4. KEY PERSONNEL

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; provided that the Contracting Officer may ratify in writing that such diversion and such ratification shall constitute the consent of the Contracting Officer required by this clause. The contract may be modified from time to time during the course of the contract to either add or delete personnel as appropriate.

Contractor Key Personnel:

	Name	Position
1	TBD	Program Manager (PM)
2	TBD	Chief Scientific Officer (CSO)
3	TBD	Head of Operations
4	TBD	Head of Quality Assurance
5	TBD	Head of Quality Control
6	TBD	Head of Regulatory Affairs
7	TBD	Head of Engineering

H.5. BIOLOGICAL SELECT AGENTS & TOXINS

The ADM contractor will be a directed subcontractor of future MCM contracts with third parties to use the ADM capability. As such, the contractor may be required to work with, possess, or transfer biological select agents or toxins (BSAT). At present the Government only anticipates the test and evaluation associated activities to possibly involve BSAT. Work involving BSAT shall not be conducted by the contractor until the contractor and any affected subcontractor(s) are granted a certificate of registration or are authorized to work with the applicable select agents based on compliance with Government and DoD standards imposed by those third party contracts. In that event the Code of Federal Regulations, Title 42 – Public Health, Part 73-Select Agents and Toxins applies, as well as, DoD

biological surety requirements for personnel that have access to DoD-supplied BSAT (e.g., AR 50-1, AR 190-17, DA PAM 385-69, DoDD5210.88 and DoDI5210.89).

H.6. ORGANIZATIONAL CONFLICT OF INTEREST - FAR 9.505-1

(a) In accordance with FAR 9.505-1; whereas insofar as this contract may provide for systems engineering and technical direction (SETD), the Contractor agrees not to be a supplier to the Department of Defense, a subcontract supplier, or a consultant to a supplier of any system or subsystems for which the SETD functions are performed hereunder. The prohibition relative to being a supplier, a subcontract supplier, or a consultant to a supplier of these systems or their subsystems extends for a period of three years after the term of this contract.

(b) For the purpose of this clause, the term "Contractor" means the Contractor, its subsidiaries and affiliates, joint ventures involving the Contractor, any entity with which the Contractor may hereafter merge or affiliate, and any other successor of the Contractor.

(c) The Contractor shall, within 15 days after the effective date of this contract, provide, in writing, to the Contracting Officer, a certification that all employees, agents and subcontractors involved in the performance of this contract have been informed of the provisions of this clause.

(d) Any subcontractor which performs any work relative to this contract shall be subject to this clause. The Contractor agrees to place in each subcontract affected by these provisions the necessary language contained in this clause.

(e) The prohibitions imposed by this clause may be waived by the Contracting Officer.

(f) In the event the Contractor, or any of its employees, agents or subcontractors fails to comply with the provisions of this clause, such noncompliance shall be deemed a material breach of contract for which the Government reserves the right to terminate the contract for default and/or resort to such other rights and remedies as provided for under this contract and under the Federal law of contracts. Noncompliance with the provisions of this clause may also adversely affect the determination of Contractor responsibility in future Government acquisitions.

H.7. ORGANIZATIONAL CONFLICT OF INTEREST - FAR 9.505-3

(a) In accordance with FAR 9.505-3; whereas insofar as this contract may provide for the technical evaluation of other Contractors' products or services or provides for the furnishing of management support services, the Contractor agrees that it shall not furnish to the United States Government, either as a prime contractor, as a subcontractor, or as a consultant to a prime contractor or subcontractor, any system, subsystem or component which is the subject of work under this contract, except that it may, under the circumstances stated in paragraph (e) below, participate in related Integrated Product Teams (IPT's). This prohibition is effective during the term of the contract and extends for a period of 3 years after the term of this contract.

(b) The Contractor further agrees that its employees, agents or subcontractors shall not disclose to any individual, company or Government representative* any information relating to current or proposed Government budgetary information, acquisition planning or acquisition actions, obtained either directly or indirectly as a result of the effort performed under this contract, unless so directed by the Contracting Officer. The Contractor also agrees that it shall promptly notify the Contracting Officer of any attempt by an individual, company or Government representative* to

gain access to such information. Such notification shall include the name and organization, if available, of the individual, company or Government representative seeking access to such information.

(c) For the purpose of this clause, the term "Contractor" means the Contractor, its subsidiaries and affiliates, joint ventures involving the Contractor, any entity with which the Contractor may hereafter merge or affiliate, and any other successor of the Contractor.

(d) Any subcontractor which performs any work relative to this contract shall be subject to this clause. The Contractor shall include these provisions in all subcontracts and shall substitute "subcontractor" for "contractor" where appropriate.

(e) If the contractor is tasked by the Department of Defense to participate in an IPT related to any system, subsystem or component which is the subject of work under this contract, the contractor may participate without the need for any notification to the Contracting Officer. If the contractor is tasked by some other Government office to participate in an IPT related to any system, subsystem or component which is the subject of work under this contract, the contractor may participate without advance approval but shall notify the Contracting Officer within 5 calendar days of the request. If the contractor is tasked by a non-Government entity (e.g. another contractor) to participate in an IPT related to any system, subsystem or component which is the subject of work under this contract, the contractor shall not begin work on the IPT task without obtaining authorization from the Contracting Officer of this contract. The contractor shall notify the Contracting Officer of this contract in writing, describing the IPT effort, listing the probable participants, providing a justification for the contractor's participation, and describing the safeguards which will be established to ensure the contractor's objectivity for this contract. Within 15 days of receiving the notification, the Contracting Officer will consider whether the contractor's objectivity will be affected and will issue a determination to the contractor.

(f) The Contractor certifies and warrants that to the best of its knowledge and belief the contractor does not have any organizational conflict of interest as defined in paragraph (a). The contractor shall inform all employees, subcontractors, consultants, and agents involved in the performance of this contract of the provisions of this clause.

(g) In the event the Contractor, or any of its employees, agents or subcontractors fails to comply with the provisions of this clause, such noncompliance shall be deemed a material breach of the contract for which the Government reserves the right to terminate the contract for default and/or resort to such other rights and remedies as provided for under this contract and under the Federal law of contracts. Noncompliance with the provisions of this clause may also adversely affect the determination of contractor responsibility in future Government acquisitions.

(h) If it is in the best interests of the Government, the prohibitions imposed by this clause may be waived by the contracting officer.

* Government Representative is defined as any Government employee, either military or civilian, not directly involved in the effort to be performed under this contract.

H.8. ORGANIZATIONAL CONFLICT OF INTEREST - FAR 9.505-4

(a) In accordance with FAR 9.505-4, whereas insofar as the statement of work for this contract requires access to proprietary data of other companies the Contractor must agree with the other companies to (1) protect their information from unauthorized use or disclosure for as long as it remains proprietary and (2) refrain from using the information for any purpose other than that for which it was furnished. The Contractor agrees to furnish copies of such agreements to the Contracting Officer before accepting possession of such data. The Contractor further agrees

that such proprietary data shall not be used in performing for the Department of Defense additional work in the same field as work performed under this contract if such additional work is procured competitively.

(b) For the purpose of this clause, the term "Contractor" means the Contractor, its subsidiaries and affiliates, joint ventures involving the Contractor, any entity with which the Contractor may hereafter merge or affiliate, and any other successor of the Contractor.

(c) The Contractor shall, within 15 days after the effective date of this contract, provide a written certification to the Contracting Officer that all employees, agents and subcontractors involved in the performance of this contract have been informed of the provisions of this clause.

(d) Any subcontractor which performs any work relative to this contract shall be subject to this clause. The Contractor agrees to place in each subcontract affected by these provisions the necessary language contained in this clause.

(e) The prohibitions imposed by this clause may be waived by the Contracting Officer.

(f) In the event the Contractor, or any of its employees, agents or subcontractors fails to comply with the provisions of this clause, such noncompliance shall be deemed a material breach of contract for which the Government reserves the right to terminate the contract for default and/or resort to such other rights and remedies as provided for under this contract and under the Federal law of contracts. Noncompliance with the provisions of this clause may also adversely affect the determination of Contractor responsibility in future Government acquisitions.

(g) The Government may administratively modify the contract to list agreements between the Contractor and third parties into the contract.

H.9. ETIOLOGIC AGENTS--BIOLOGICAL DEFENSE RESEARCH PROGRAM (MAR 1999)

The ADM contractor will be a directed subcontractor of future MCM contracts with third parties to use the ADM capability. As such, the contractor may be required to work with, possess, or transfer an etiologic agent--biological defense program under a third party contract. For purpose of this contract etiologic agent--biological defense program is defined as: any viable microorganism, or its toxin which causes or may cause human disease, including those agents listed in 42 CFR 723 of the Department of Health and Human Services regulations, and any agent of biological origin that poses a degree of hazard to those agents and is further identified by the DoD as a threat agent. The contractor shall comply with the following when working with etiologic agents:

1. 29 Code of Federal Regulations 1910
2. Occupational Health Standards, and the U.S. Department of Health and Human Services (DHHS)
3. DHHS Publication No. 93-8395, Biosafety in Microbiological and Biomedical Laboratories, 1993, as amended

SECTION L - INSTRUCTIONS, CONDITIONS AND NOTICES TO BIDDERS

The following have been modified:

INSTRUCTIONS TO OFFERORS

L.1 - GENERAL

In order for proposals to receive full consideration for award, the Offeror shall ensure that the information furnished in support of the proposal is factual, accurate, and complete. Failure to provide the information requested by this Request for Proposal (RFP) may render the Offeror's proposal incomplete and ineligible for further consideration for award.

L.2 PROPOSAL PREPARATION INSTRUCTIONS

L.2.1. Proposal Volumes.

L.2.1.1. Written Proposals shall be submitted in six (6)* separate volumes as follows:

Volume	Title	Page Limitation	Copies
I	Administrative Section 1 – Executive Summary Section 2 – Representation and Certification Documents Section 3 – OCI Mitigation Plan Section 4 – DCAA, DCMA Offices, Accounting System Approval Section 5 – Subcontracting Plan Section 6 – Financial Statements Section 7 – SETA Contractor and Foreign National Nondisclosure Agreements	Section 1 limited to 5 pages. No page limitation on Sections 2, 5, 6 and 7. Sections 3 and 4 limited to 10 pages each.	2 hard copies and 2 CDs
II	Technical Section 1 – Statement of Work Section 2 – Integrated Master Plan Section 3 – Sample Tasks Section 4 – Certifications	Section 1 limited to 75 pages No page limitations for Sections 2 and 4. Section 3 limited to prescribed format plus 10 pages for narrative summary for each sample task.	10 hard copies and 2 CDs
III	Intellectual Property (IP) and IP Management Plan	20 pages	2 hard copies and 2 CDs
IV	Past Performance	No Page Limit	2 hard copies and 2 CDs

V	Cost Section 1 – Introduction Section 2 – Costed Section B from RFP Section 3 – Matrix of costed WBS elements to Level 4 linked to CLINs and SubCLINs Section 4 – Basis of Estimates for costed WBS elements	No page limit	2 hard copies and 2 CDs
VI	Small Business Participation Plan	10 Pages	2 hard copies and 2 CDs
VII	Oral Presentation *	50 slides	Electronic submission

* Volume VII Oral Presentations. Volume VII, comprised of the briefing slides for oral presentations shall be delivered not later than 48 hours prior to the oral presentation, which will be scheduled by the Government and coordinated with Offerors AFTER receipt of written proposals.

L.2.1.1. Information shall be confined to the appropriate volume to facilitate independent evaluation. Missing information, or information that is referenced to a different volume than that specified in the instructions will not be evaluated. The proposal volumes shall be clear and concise, logically assembled, with all pages appropriately numbered, as well as indexed and cross-indexed to the applicable parts of the RFP as appropriate. Pages over the maximum page limitation for any volume, evaluation factor, or evaluation sub-factor will be excluded from evaluation.

L.2.1.2. All proposal volumes shall contain an offeror-completed crosswalk matrix that links the contents of the offeror’s proposal with the SOO and Sections L and M. The crosswalk matrix is at Attachment J.6 and is pre-populated with the SOO/L/M crosswalk information.

L.2.1.2. Exceptions to the page limitations are: cover pages, indices/tables of contents, divider pages and crosswalk matrix.

L.2.1.3. The CD submission for each volume shall contain one copy of the respective proposal volume in Microsoft (MS) Office 2007 Suite and one copy in Adobe Acrobat “.pdf” format. The IMS shall be provided in MS Project 2007 and PDF. Security permissions on the “.mpp”, “.xlsx,” and “.docx” files shall be set to allow the Government to select, cut, paste, and print text and graphics. The Offeror shall submit subcontractor proprietary or sensitive information on a separate CD (appropriate number of copies according to volume number) in a separate sealed envelope marked with prime and subcontractor identifying information. If a discrepancy exists between the original paper copy of the proposal and the disk copy, the original paper copy will take precedence.

L.2.1.4. Proposal Formatting. The Offeror shall mark each volume with the appropriate title at the top of each page (e.g. Volume I – Administrative). The Offeror shall number all pages of each volume and identify each page with the complete company name, date and solicitation number in the header and/or footer. The Offeror shall create a Table of Contents using the Table of Contents feature in MS Word. The Government will not include the Table of Contents with the page count for each volume. MS Word (.doc) files shall use the following page setup parameters:

Margins – Top, Bottom, Left, Right - 1”

Gutter – 0”

From Edge – Header, Footer - 0.5”

Page Size, Width – 8.5”

Page Size, Height – 11”

Printed on Single Side

Orientation- Portrait

L.2.1.5. The following additional restrictions apply:

L.2.1.5.1. Pages shall be single spaced and each paragraph shall be separated by at least one blank line. The Offeror will use a standard, 12-point minimum font size in Times New Roman font. The Offeror may use a reduced font size, not less than 8-point, and landscape orientation for Tables and illustrations. Tables or figures may be printed on foldout sheets, not to exceed 11 x 17 inches. Each foldout sheet will count as 1 page towards the maximum page count for each volume. Align all text in “Align Left.” Do not “Justify” text. Use a single column (vice double column) text format.

L.2.1.5.2. All printed pages shall contain the phrase: “SOURCE SELECTION INFORMATION” (printed or stamped) in addition to the FAR 3.104 proprietary data notice.

L.2.1.5.3. Offerors shall submit all volumes in standard size 3-ring binders that will facilitate the insertion of change pages and additional information the Offeror may be required to provide during the source selection process.

L.3. Detailed Proposal Preparation Instructions:

L.3.1. Volume I – Administrative

Section 1 – Executive Summary - A letter formally transmitting the proposal shall include:

a. Master Index. A master index that identifies the location of all major topics provided in each volume.

b. Statement of compliance with solicitation. Each offer shall include a statement indicating complete compliance with the solicitation, or detailed analysis of any objections, exceptions, contingencies, or additions. Any objection, exception, contingency, or addition shall be cross-referenced to the applicable solicitation paragraph(s).

c. Statement of compliance with mandatory responsiveness requirements. Each offer shall include a statement indicating compliance with the two (2) mandatory responsiveness requirements, and shall provide a direct reference to the volume, paragraph and page where compliance with each requirement is described. The mandatory responsiveness requirements are:

- i. 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.
- ii. U.S. Biopharmaceutical Manufacturing. The Offeror shall provide written evidence of a firm commitment that the Offeror shall initiate the establishment, and maintain, the necessary facilities in the U.S. or its territories. Written evidence may include, but is not limited to property titles, deeds, lease agreements, property plans, etc that clearly demonstrate the offeror has adequate plans in place to establish a domestic ADM operation.

d. Format and Content. Each Offeror shall describe any deviations from the specified proposal format and content. If the Offeror's proposal differs from these guidelines, state the differences, and explain the reason.

Section 2 – Solicitation Representation and Certification Documents. Each Offeror shall complete blank lines and provide signatures for the contract sections indicated below without modification to the files. An authorized official of the firm shall sign the proposal and all certifications requiring original signature. An Adobe Acrobat file, “.pdf” shall be created to capture the signatures for submission in the Administrative volume. Additionally, using the Online Representations and Certifications Application (ORCA), the Offeror shall enter their Representations and Certifications information once for use on all Federal contracts. Offerors must be registered in ORCA, and shall include a copy of their ORCA record in Section 2. Please refer to the website: <https://orca.bpn.gov/>.

The Offeror shall fill in and attach in this Section the following Fill-In-Clauses from the RFP:

RFP Section	Clause	Clause Title
I	52.219-28	Post Award Small Business Representation
I	52.223-11	Ozone Depleting Substances
I	252.225-7000	Buy American Act – Balance of Payments Program Certificate
I	252.227-7004	License Grant
I	252.247-7023	Transportation of Supplies by Sea
I	252.223-7001	Hazard Warning Labels
I	252.227-7013	Rights in Technical Data – Noncommercial Items
K	52.204-5	Woman-Owned Business (Other than Small)

K	52.209-5	Certification Regarding Responsibility Matters
K	52.209-7	Information Regarding Responsibility Matters
K	52.219-1	Small Business Program Representation (Alt 1)
K	52.219-22	Small Disadvantaged Business Status
K	52.222-22	Previous Contracts and Compliance Reports
K	52.222-25	Affirmative Action Compliance
K	52.225-2	Buy American Act Certificate
K	52.226-2	Historically Black College or University and Minority Institution Representation
K	52.230-1	Cost Accounting Standards Notices and Certification (Alt 1)
K	52.230-7	Proposal Disclosure – Cost Accounting Practice Changes
K	52.204-8	Annual Representations and Certifications
K	252.204-7007	Alt A, Annual Representations and Certifications
L	252.227-7017	Identification and Assertion of Use, Release, or Disclosure Restrictions

Section 3 – Organizational Conflict of Interest Mitigation Plan. Offerors 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.

a. NOTICE OF ORGANIZATIONAL CONFLICT OF INTEREST CLAUSE

- i. Pursuant to FAR Subpart 9.5, the Contracting Officer has included one or more clauses on organizational conflicts of interest within Section H of this solicitation, to become part of any resultant contract.
- ii. The successful contractor will be subject to the restrictions in such clause(s) for the period specified therein.
- iii. The specific language of the clauses and the applicability of FAR Subpart 9.5 to this procurement is subject to negotiation prior to submission of best and final offers. Any offeror taking exception to the terms of the clause(s), shall submit proposed revised clause(s) and shall demonstrate in its proposal how the revised clause(s) will protect the Government's interest. State clearly whether the offer is conditioned upon Government approval of the revised clause(s).

Section 4 - DCAA, DCMA Offices, accounting system approval. The Offeror shall provide the company's cognizant DCAA and DCMA offices, addresses and contact information. Additionally, the Offeror shall provide evidence of approval of its accounting system. Offeror is advised that award cannot be made until it has a DCAA approved accounting system. **For-profit Offerors are advised that award cannot be made until it has a DCAA approved accounting**

system. Non-profit offerors shall be required to comply with the provisions of OMB Circular No. A-122 or OMB Circular No. A-21. See also paragraph L.3.5.1.

Section 5 – Subcontracting Plan. The Offeror shall provide a summary describing the teaming or subcontracting arrangement established for this RFP and a signed document (format as established by Offeror) indicating a legally binding agreement (i.e., Teaming Agreements) among the parties. Identify each proposed team member by company name and address. The Offeror shall submit a subcontracting plan in accordance with FAR Clause 52.219-9 and DFARS Clause 252.219-7003 (for reference see FAR 19.704 and DFARS 219-704). The negotiation of a subcontracting plan shall not be considered as reopening of negotiations closed by a Final Proposal Revision.

Section 6 – Financial Statements. Offerors shall submit the past five (5) years of financial statements to include a Balance Statement (or Statement of Financial Position for nonprofits), Cash Flow Statement, and Income Statement (or Statement of Activities for nonprofits); Dun & Bradstreet Report; Standard & Poor's and Moody's Rating (if available). Prior to submission, a company officer or CPA will certify the statements. In accordance with FAR 9.104 and FAR 9.105, the Contracting Officer will conduct a financial responsibility determination.

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.

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

L.3.2. Volume II – Technical.

Section 1 – Statement of Work. The Offeror shall describe its technical approach to meet the goals stated in the Statement of Objectives and otherwise cited in this solicitation.

The Offeror shall provide a Statement of Work (SOW) that includes:

- a. Description of a technical approach that meets the requirements in the Statement of Objectives to establish, commission and validate, within 24 months, a streamlined ADM manufacturing capability that significantly reduces schedule and cost compared with current drug manufacturing and regulatory approval process. The Offeror demonstrates possession of the necessary knowledge, abilities and management controls to successfully develop the facility(ies) (two (2) suites) to manufacture FDA approved MCMs. This includes topics such as new facility, retrofit, commissioning and validation plans including, but not limited to: Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ), cGMP design considerations, QMS plans, biological surety plans, document management system plans. The technical approach also directly links and correlates among SOW, IMS, IMP, and WBS. The technical approach should be flexible and adaptable to rapidly accommodate advanced development and manufacturing line changes and demonstrate an ability to accommodate varied products simultaneously, within the stated objectives.
- b. Description of management approach, including the organizational structure, project management, QMS plan, regulatory compliance strategy, document management system and key personnel that is effectively organized to meet the Government's requirements.
- c. Description of proposed team, including architectural, building, equipment, regulatory strategy, quality management, internal staff and subcontractors that possess sufficient skills to establish, commission and validate the ADM.
- d. Description of the offeror's post validation organizational structure that includes certified Project Management Professionals, IPTs and a program management process that demonstrates its ability to successfully operate the MCM-ADM, in accordance with the Government's Statement of Objectives (SOO) to accommodate 3rd party products.
- e. Description of offeror's organizational core competencies to rapidly develop and manufacture FDA approved medical countermeasures, as defined in the 21 CFR to include the Animal Efficacy Rule and/or has access to such competencies when required, and 42 CFR Part 73 Public Health. In addition, the offeror shall describe a complete and thorough training program for training of Government personnel throughout the life of the program.
- f. Description of the offeror's proposed organizational structure and management processes to enable post validation operation of the ADM and description of the Offeror's access

to infrastructure and core competencies necessary to meet the full spectrum of MCM development, manufacturing through FDA approval through the life of the contract. The proposal shall contain description of 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.

- g. Description of the offeror's approach to the QMS program, document management system, quality standards related to comprehensive cGLP, cGMP, and cGCP compliant systems including but not limited to quality controls and quality assurance processes, information systems associated documentation.
- h. Description of the offeror's relationship(s) with a pharmaceutical company that has successfully [sponsored one 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.
- i. Description of the offeror's approach for post-validation operation and maintenance of the ADM in a state of readiness that meets regulatory compliance requirements, that is complete, feasible and sound. Emphasis should be placed on the manufacturing aspects of the capability that is able to support the manufacture and release of ADM developed and FDA approved MCM within three (3) months of a Government request for the following maximum doses:
 - Up to 1.5 million doses or 500,000 troop equivalent doses (TEDs)
 - Surge up to 12 million doses which is equivalent to four (4)-million TEDs
- j. Description of how the offeror, once validation is complete, will support and maintain the ADM capability in a state of readiness to support Medical Countermeasure development and manufacturing that is agile and flexible and that minimizes operating costs, and optimizes utilization during active and inactive development and manufacturing periods
- k. Description of the Offeror's approach for minimizing operating costs for post-validation operation and maintenance of the ADM during periods of no DoD demand. This shall include the proposed resources, the Offeror's assessment of associated risks, operating cost containment, the approach to effective and efficient communication between the Government and the Offeror, and the approach to managing and interfacing with its subcontractors.
- l. Description of the offeror's approach to the QMS program and document management system for quality standards related to comprehensive cGMP compliant systems including but not limited to quality controls and quality assurance processes, associated documentation.

Section 2 – Integrated Master Plan. The Offeror shall provide an Integrated Master Plan (IMP) that is comprised of:

- a. A Work Breakdown Structure (WBS) detailed to Level 5, that is fully correlated to the Offeror's SOW.
- b. An Integrated Master Schedule (IMS) that correlates to the SOW and WBS to at least Level 5, and which includes all key regulatory and quality events, all contractual Milestone driven deliverables, and contractor-defined, project-specific elements in sufficient detail to outline the full scope of the effort required to establish and

commission the ADM capability. The IMS shall show the critical path, task linkages and dependencies.

Section 3 – Sample Tasks. Two (2) sample tasks are described in Attachment J.4. The purpose of the Sample Tasks is to evaluate the offeror’s understanding of MCM manufacturing and regulatory processes for FDA approval and the offeror’s ability to plan and schedule manufacturing of MCMs in the proposed MCM ADM facility. Therefore, the Offeror’s proposed Integrated Master Plan (IMP) for each sample task shall reflect an approach that is consistent with the offeror’s proposed MCM ADM capability. Proposal information for each sample task shall be separate tabs within Section 3. For each sample task the Offeror shall provide an Integrated Master Plan (IMP) that is comprised of:

- a. The completed WBS Worksheet provided as Attachments J.3 and J.4. Instructions for completing this worksheet are at Tab 1 to Attachments J.3 and J.4.
- b. An Integrated Master Schedule (IMS) that correlates with the completed WBS worksheet to at least Level 4, shows the critical path, task linkages and dependencies.
- c. A narrative summary that discusses the following sample task attributes:
 - i. Regulatory Strategy including Quality Management System and regulatory staff requirements
 - ii. Manufacturing staff requirements
 - iii. Management and support
 - iv. Risks, risk mitigation and opportunities identified in the WBS worksheet
 - v. Organizational structure
 - vi. Lines of authority and accountability
 - vii. Surge production

Section 4 – Certifications. If the Offeror possesses any certifications associated with production and manufacturing such as ISO, CMMI, etc., a copy of the certification should be included in this Section.

L.3.3. Volume III –Intellectual Property Management Plan.

L.3.3.1. The Government anticipates future MCM contracts with third parties to use the ADM capability. Because the Government anticipates future contractors will utilize the MCM-ADM capability for MCM development and manufacturing, the ADM contractor will be a directed subcontractor of these third parties. The Government requires assurances that the ADM contractor will not use its economic leverage to obtain rights in the third party’s subject inventions or technical data beyond those authorized by law in order to provide the needed service to the Government under its contract. For these reasons it is a requirement of the ADM contract that the Offeror provide a sharing plan regarding all intellectual property that is generated under the ADM contract and/or that will be required to be practiced during the performance of the third party MCM contracts.

L.3.3.2. Because the Government anticipates possible future contracts with third parties to use the ADM for MCM development, S&T efforts supporting MCM development, and/or

production; the Offeror shall describe its intended plan vis-à-vis third party participants with regard to inventions, data rights, and other intellectual property issues that may arise between the Offeror and third parties contracting with the Government.

L.3.3.3. Based on the above, the contractor shall describe its method for protecting its own and third party intellectual property, and the licensing arrangement it intends to pursue regarding the intellectual property rights issues that may arise between the Offeror and third parties contracted by the Government. The Intellectual Property (IP) Management Plan shall address at a minimum the following:

- a. The right to practice subject inventions and data that are generated or utilized during the performance period of this contract and the third party contracts;
- b. The anticipated allocation of rights in the event of joint inventorship or authorship by ADM employees and third party employees;
- c. Licensing structure (if necessary) for intellectual property between the Offeror and all non-Government parties with which it has a contractual relationship;
- d. Allocation of rights concerning background inventions, technical data and computer software, subject inventions, and any limited rights technical data and restricted rights computer software generated or used under the ADM and MCM third party contracts;
- e. Legal and procedural protection of third party contractor trade secrets and material protected by copyright; and
- f. Handling of disputes regarding intellectual property rights and the subject matter protected thereby.

L.3.3.4. Note that the IP Management Plan is separate and distinct from any reporting requirement under DFARS 252.227-7017.

L.3.4. Volume IV - Past Performance.

L.3.4.1. The Offeror, including major subcontractors, shall provide past performance information that demonstrates:

- a. Ability and experience to fabricate and/or retrofit infrastructure through the point of facility validation.
- b. Ability and experience to establish CMO, T&E/labs, CRO, BSL3 (meeting 21 CFR), Fill/Finish.

L.3.4.2. The Offeror shall provide a table of contents describing all contracts contained in Volume IV. Each contract provided by the Offeror shall be separated by tabs into sections. For each section, the Offeror shall provide a summary for each contract (Government and non-Government), executed within the past 5 years that the Offeror considers relevant to this proposed effort. There is no limit to the number of contract summaries provided, and no page limit for each summary.

L.3.4.2.1. Each summary shall include:

- a. Contract number
- b. Government/Customer contracting agency
- c. Government/Customer Contracting Officer contact information
- d. Government/Customer Contracting Officer's technical Representative contact information
- e. Contract start and end date
- f. Initial Contract value and delivery schedule
- g. Summary of how the contract is relevant to this effort.
- h. A brief description of the scope and the tasks performed
- i. Points of Contact information for the customer

L.3.4.2.2. Relevance and performance should address and discuss the following:

- a. Experience in cGLP, cGCP, cGMP pharmaceutical processes and production
- b. Experience in producing and manufacturing vaccines
- c. Previous FDA submissions, inclusive of FDA response/non-response to submissions
- d. Corporate experience solving challenging development efforts similar to those that may arise during the proposed effort
- e. Subcontract management team experience and the skill of those individuals in proposal evaluation, negotiation, and success in avoiding cost overruns

L.3.4.2.3 Past Performance References (see Section J, attachment No. J.8). The Offeror shall prepare and submit to prior client(s) at least three (3), but no more than ten (10), Past Performance Questionnaires. This includes correspondence explaining the requirement to obtain an independent evaluation of prior contract performance, and the Past Performance Questionnaire for use in evaluating Past Performance.

L.3.4.2.3.1 Completed Performance Questionnaire shall be mailed to the address below so as to arrive **not later than 5 days prior to the closing date for receipt of proposal shown on the SF 33 "Solicitation, Offer and Award"**.

ACC-APG Natick Contracting Division
ATTN: Jean Greenwood
Kansas St., Bldg 1
Natick, MA 01760

Reference packages may also be e-mailed to jean.greenwood@us.army.mil with a courtesy copy to peter.wallace@us.army.mil. **NOTE: Offeror or subcontractor must not review the Past Performance Questionnaire prior to submission. They must be submitted by the client/evaluator directly to the Contract Specialist at the physical address or the e-mail address above.**

L.3.4.2.3.2 Offerors should follow-up and encourage references to get the questionnaires to the Contracting Officer in a timely manner. **Do not** include copies of the letters or questionnaires in the proposal. **Do include a one page statement affirming that the reference packages were sent out, date sent, and the Point of Contact to whom the questionnaire was sent.**

L.3.5. Volume V – Cost. The Offeror shall structure its cost proposal to satisfy the requirements of the RFP and to be consistent with the proposed SOW while following the format outlined below.

L.3.5.1. Section 1– Introduction. The Offeror shall include administrative information related to its cost proposals and identify points of contact for this volume. The Offeror must have an approved accounting system. For-profit companies must have a DCAA approved accounting system. For Offerors that are nonprofit or academic institutions, the cost proposal must comply with OMB Circular No A-122, Cost Principles for Nonprofit Organizations, or OMB Circular No A-21, Cost Principles for Educational Institutions, as applicable. This will include memorandum of cost negotiation from either Health and Human Services (HHS) or the Office of Naval Research (ONR).

L.3.5.2. Section 2 –Costed Section B. The Offeror shall submit a Section B with cost and fixed fee amounts for all CLINs and SubCLINs with the exception of those SubCLINs specifically indicated as not separately priced. All cost, fixed fee and total dollars for all CLINs and SubCLINs shall be in 2012 dollars. The Offeror shall complete the Offer part of the Standard Form (SF) 33 format. An official having the authority to bind the firm contractually must sign the SF33. If this individual is not an officer of the company, the proposal shall be accompanied by some form of written evidence of the individual's authority to bind the company, under contract, to a particular course of action. This might include such evidence as a written delegation of said authority, signed by an officer of the company.

L.3.5.3. Section 3 – Cost matrix for each WBS element to level 4, established in the Technical Volume Section 2, and rolled up at each successive Level, with each priced WBS element linked to its associated CLIN and SubCLIN, including roll-up at the SubCLIN and parent CLIN level that matches Section B.

The Offeror shall use the Cost Proposal Template included with the solicitation, which is available at Section J, Attachment J.7, to provide the cost element breakdown. Instructions are detailed in the Cost Proposal Template Narrative.

Major Cost Element Information:

a. Direct Labor Cost

i. Direct Labor Categories: The Offeror shall propose its direct labor categories from the labor occupations detailed in the Davis-Bacon and Service Contract Acts, where applicable. For occupations not found in the two Acts, such as Professions-Technical job descriptions, use the Bureau of Labor Statistics (BLS) 2001 National Occupational Employment and Wage Estimates. In addition, the Offeror shall provide a “crosswalk” between the proposed labor descriptions and those labor codes matching its accounting/estimating system. The two types of labor category/classification/description data are necessary to evaluate the adequacy of

proposed labor types/duties, and they provide a method (or crosswalk) for validating proposed direct labor rates from the labor position to the Offeror's accounting system.

ii. Direct Labor Hours: For all CLINs/SCLINs, the Offeror shall provide the basis of the proposed labor hours with supporting rationale, including calculations, documentation, the estimating method used, and the assumptions for the proposed estimates. The Offeror shall detail the method employed to convert the proposed staffing to direct labor hours in the proposal. There shall be a clear tracking between the Staffing Charts and the direct labor hours proposed by labor category. In addition, the Offeror shall provide and discuss the planned employee hours worked per day, week, and year, as well as proposed overtime, for. The Offeror shall discuss how leave (sick leave, vacation, etc.) impact the proposed direct labor hours (and staffing).

iii. Direct Labor Rates: The Offeror shall provide and discuss the basis for the proposed direct labor rates, for both the prime and subcontractors, such as whether the rates are current/actual (with the effective date), Forward Pricing Rate Agreement (FPRA) or Submission (FPRS), Bureau of Labor Statistics (BLS) or commercial consulting firm wage/salary survey (e.g., Watson Wyatt, etc.), or Offeror estimate. The Offeror shall provide the basis for the proposed labor categories and skill mix, and discuss the assumptions and rationale for those proposed labor categories/skill mix. Recent (within the last twelve (12) months) DCAA audits may serve as support documentation for direct labor rates. A copy of the audit may be included in the proposal. If a copy is not available to the Offeror, the Offeror may provide the DCMA and/or DCAA POC's (including office names, office addresses, name of cognizant ACO and DCAA supervisory auditor/auditor, and their phone numbers) for the Government to contact.

b. Fringe Benefits/Allowances

i. The Offeror shall provide a list of allowances/benefits by class of employee. The basis of the proposed allowances/benefits shall be provided and discussed. The allowance/benefit method of calculation shall be detailed, including its percentage or flat amount, the base for the application of percentages, and other relevant information.

ii. Overtime Premium: The Offeror shall provide the basis of any proposed overtime and shift differential/premium. The method of calculation shall be detailed, including its percentage or flat amount, the base for the application of percentages, and other relevant information.

c. Direct Material.

The Offeror shall list contractor furnished material, equipment, real property/facilities or other cost items, with unit and total costs, and the basis of the proposed costs (quote, purchase order, historic price, estimate, lease, etc.). For any facilities associated with the two (2) ADM suites, in lieu of detailed cost element buildups, Offerors may use parametric estimating tools for

developing the proposed cost plus fixed fee. Offerors shall provide the bases for the parametric estimates, including detailed drawings of the proposed facilities, the unit of measure associated with the facilities, and the parametric unit prices, along with excerpts from the authoritative reference guides from which the parametric estimates were derived (e.g., R.S Means guide for research and development and/or production facilities).

d. Indirect Costs/Overhead Rates (Material Handling, Manufacturing, Engineering), General and Administrative Expenses (G&A), and Facilities Capital Cost of Money (FCCOM).

i. The Offeror shall provide the basis of the proposed indirect cost and/or rates, such as the following: actual/current with date, Forward Pricing Rate Agreement (FPRA)/Submission (FPRS), budget, or estimate, with supporting documentation.

ii. If the proposed rates are budgetary estimates, the expense pools and bases shall be presented with a comparison to the Offeror's last two fiscal years.

iii. If current, actual, or year-to-date data were used, the Offeror shall provide support documentation (pools and bases) for the proposed figures.

iv. If a FPRA/FPRS was used, a hardcopy shall be included in the proposal. The Offeror shall also provide DCMA and DCAA Point of Contacts (office names, office addresses, name of cognizant ACO and DCAA supervisory auditor/auditor, and their phone numbers).

v. Recent (within the last twelve (12) months) DCAA audits may serve as supporting documentation for indirect rates. A copy of the audit may be included in the proposal. If a copy is not available to the Offeror, provide the DCMA and/or DCAA points of contact (including office names, office addresses, name of cognizant ACO and DCAA supervisory auditor/auditor, and their phone numbers) to allow the Government to contact the appropriate personnel.

vi. If the award of this contract will have a significant impact on the Offeror's business volume, the effects of those changes on the expense pools and bases shall be identified and disclosed.

vii. Direct/Indirect Charged Costs: The Offeror is reminded that each type of cost shall be allocated only once and on only one basis in order to preclude the "double counting" of costs. Double counting occurs when cost items are allocated directly without eliminating similar items from indirect cost pools. The accounting treatment of all costs of a similar type and nature, in like circumstances, shall be the same. The Offeror shall follow the accounting practices/procedures described in its Cost Accounting Standards (CAS) Disclosure Statement and/or established accounting/estimating system.

e. Other Direct Costs (ODCs).

i. Travel. Travel costs for activities related to the performance of the SOW shall be detailed in the proposal, and the following information shall be provided: the trip's purpose,

departure/arrival points, number of persons traveling, number of trips, trip duration, and proposed costs (airfare, car rental, per diem, and other expenses). In addition, the Offeror shall discuss the basis for the proposed costs, pricing methods, and, as applicable, its policy on travel. The Offeror shall indicate whether the proposed trips are priced to take advantage of advance booking or other discounts.

ii. Subcontracts/Interdivisional Transfers. The Offeror shall list all anticipated subcontracted effort in the format of the table below, to include: subcontractor name, total price, service provided, and applicable CLIN/SCLIN. For the major subcontractors providing labor services exceeding \$1,000,000 per year, the Offeror shall provide the subcontractor prices broken down by major cost element, in the format as required of the prime contractor, with all documentation supporting the proposed costs/prices. The Offeror shall provide a narrative describing the basis of selection; it should also discuss the cost reasonableness and realism of the subcontractors' costs and/or prices. The Offeror's price/cost evaluation of its subcontracts (and/or inter-divisional transfers) will assist the government in its evaluation of cost realism and reasonableness of the prime contractor's proposal. Copies of the subcontractors' Disclosure Statements shall also be included with their proposals.

SUBCONTRACTOR NAME	TOTAL CPFF/PRICE	SERVICE PROVIDED	APPLICABLE CLIN'S/SCLIN'S
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iii. The subcontractor names, addresses, phone numbers, and POCs shall be provided; the cognizant DCMA and DCAA offices, along with their addresses, phone numbers, and POCs, shall also be provided, as applicable.

iv. Subcontractors considering their proposal data as proprietary shall submit their proposals in secure, tamper-proof containers to the prime contractor. The Contracting Officer will not accept subcontractor proposals submitted separately to the Army Corps of Engineers, Transatlantic Program Center (CETAC).

v. The same level of cost detail, as required for the subcontracts, shall be provided for inter-organizational transfers.

f. **Fee/Profit.** The Offeror shall indicate the proposed fee for the CPFF portions of the proposed amounts and the proposed profit for the FFP portions.

g. **Economics/Escalation.** For the Direct Labor Rates, materials and equipment/supplies, ODCs, and any other costs, the Offeror shall provide the bases for any proposed/projected price changes and the assumptions used: forecast source (such as DRI/WEFA, or Economy.com), index used (index number and title), calculations (index values

used: base and projected values), and dates used (month and year for applicable index numbers). The Offeror shall provide copies of the escalation forecasts as support documentation in the proposal.

h. **Parametric Estimates.** As mentioned previously, parametric estimates may be used, particularly for the facilities associated with the ADM capability. Proposed cost items based on parametric estimation techniques shall be fully explained. The method employed, data used, calculations, and support discussion shall be included in the proposal narrative.

PLEASE NOTE: In calculating its cost and fees, the Offeror shall follow these additional instructions: fees are allowed on the Material, Equipment and Supplies costs, but are not allowed on the Facilities Capital Cost of Money (FCCM).

i. **Cost Accounting System.** The Offeror shall have an accounting system capable of handling a cost-reimbursement type of contract. The Offeror shall provide evidence that its accounting system is capable of tracking and segregating cost data in sufficient detail to administer a Cost Plus Award Fee contract. This may include a letter from either DCMA or DCAA stating that the Offeror has an adequate accounting system, with the adequacy date. In those cases where DCAA and/or DCMA do not consider the accounting system to be adequate, the Offeror shall describe the action taken to make the system adequate prior to contract award. The Offeror should discuss any reports (including Statements of Condition(s) and Recommendation(s) and/or Auditor Comments based on review of Offeror responses to Statements of Condition(s) and Recommendation(s) issued by DCAA concerning inadequacies of the accounting system, including the Offeror's planned or undertaken corrective action regarding those inadequacies, if those inadequacies have not been resolved to the satisfaction of DCAA and/or DCAA by the date of proposal submission. The Offeror should provide the information required above for each of its subcontractors (team members) to which it anticipates awarding subcontracts regardless of contract type. The Government reserves the right to coordinate with any Government Agency to obtain the current status of the Offeror's accounting and sub-systems thereof. The Offeror should provide contact information for their designated DCMA/DCAA Offices. Failure to submit the required information could result in disqualification of the proposal.

j. **Field Pricing Support.** The Defense Contract Audit Agency (DCAA) and/or Defense Contract Management Agency (DCMA) may be requested to perform proposal direct labor or indirect rate reviews, financial analyses of the Offeror's organization, or provide other pricing support, as deemed necessary. The Offeror shall provide its cognizant DCMA and DCAA offices, including addresses, telephone numbers, e-mail addresses, and POC's, for both the prime contractor and all its proposal subcontractors.

k. **Final Cost Note:** The Government reserves the right to request additional information in support of any proposed cost, as required.

L.3.5.4. Section 4 - Basis of estimates for each WBS element provide in Section 3.

Any amendments to this solicitation must be acknowledged by signature of an official having the authority to bind the Offeror contractually by the completion of the SF30 or appropriate annotation on the SF 33.

L.3.6. Volume VI – Small Business Participation Plan

- a. All Offerors are required to submit Small Business Participation Plan information in accordance with DFARS 215.304 that shall include the following:
- b. Total Contract Value (including options): \$ _____
- c. Dollar Value of your participation as a prime contractor: \$ _____
- d. Dollar Value and Percentage of Total Contract Value of Subcontracts Planned For:

	Dollar Value	Percentage of Total Contract Value
Large	\$ _____	_____
Total Small	\$ _____	_____
Small Non-Disadvantaged	\$ _____	_____
Small Disadvantaged	\$ _____	_____
Small Woman Owned	\$ _____	_____
Small HUB Zone	\$ _____	_____
Small Veteran Owned	\$ _____	_____
Small Service Disabled Veteran Owned	\$ _____	_____

Each percentage above shall be accompanied by detailed supporting documentation regarding individual commitments. Detailed explanations shall also be provided when the percentage falls short of the DOD goals.

NOTE: The sum of the dollar values and percentages of Small Non-Disadvantaged and Small Disadvantaged should equal the Total Dollar Value entry for the Total Small Business Participation category. However, the sum of all the percentages under Paragraph (4) need not equal 100% since the prime is not included and because individual subcontractors may be counted towards more than one category. All percentages should use the TOTAL CONTRACT VALUE as a baseline.

- a. List principal supplies/services (be specific) to be subcontracted to:

	Name of Company	Type of Service/Supply
Large:	_____	_____
Small Non-Disadvantaged:	_____	_____
Small Disadvantaged:	_____	_____
Small Woman Owned:	_____	_____
Small HUB Zone:	_____	_____
Small Veteran Owned:	_____	_____
Small Service Disabled Veteran Owned:	_____	_____

NOTE: For purposes of subcontracting, Historically Black Colleges and Universities/Minority Institutions (HBCUs/MIs) are considered as disadvantaged and should be broken out separately.

- b. Prior Performance Information: Provide any information substantiating the Offeror's track record of utilizing small business on past contracts. Any information concerning long-term relationships with Small Business subcontractors, such as mentor-protégé relationships should be provided.
- c. Extent of Commitment: Provide documentation regarding enforceable commitments to utilize any small business category, as defined in FAR, Part 19, as subcontractors.

L.3.7. Volume VII – Oral Presentations

L.3.7.1. The oral presentation will be considered as part of the technical proposal but will not be evaluated.

L.3.7.2. The Offeror shall provide a briefing to the Government evaluation team explaining in greater detail the key attributes of its proposed approach. The oral presentation should focus on technical and organizational aspects of the Technical Volume, but may include discussion of other volumes at the discretion of the Offeror, within the prescribed slide and time limits. There is no specific format for the oral presentation, and the information presented is solely at the discretion of the Offeror.

L.3.7.3. The primary purpose of the oral presentations is to AUGMENT the information contained in the Offeror's proposal in order to enhance the Government's understanding of the proposal and to expand upon areas of the proposal the Offeror deems most critical to the Government's understanding. The Offeror should focus the presentation on those elements of the proposal it deems most vital to meet these objectives.

L.3.7.4. The oral presentation shall be consistent with the written proposal. In the case of any inconsistencies between Volume VII and other proposal volumes, the other proposal volumes shall be presumed by the Government to be correct.

L.3.7.5. Oral presentations will not be evaluated by the Government. For evaluation purposes, the Government will only consider the contents of the written proposal volumes I-VI.

L.4. PROPOSAL SUBMISSION PROCESS

a. Electronic submission of written proposal volumes I-VI shall not be accepted. Volume VI, comprising the oral presentation briefing, shall be electronically submitted to jean.greenwood@us.army.mil NLT 48 hours prior to the scheduled oral presentation.

b. Delivery Instructions for Volumes I-VI.

i. Proposal packages are due by 1400 EST on 25 October 2011, and shall include Volumes I through VI. Proposal delivery shall be to:

Joint Product Manager, MCM-ADM
Edgewood Chemical and Biological Center
ATTN: Greg Davies
Building E3330
5183 Blackhawk Road
Edgewood, MD 21010

ii. If the Offeror intends to hand deliver the proposal and/or final proposal revision, the Offeror shall notify jean.greenwood@us.army.mil not less than four (4) WORKING DAYS in advance of its intent to hand deliver the proposal. The delivery address specified above is a secured facility, and the courier will be required to obtain a security badge to gain entrance. Entry to the facility will be denied if appropriate advance notification is not provided.

iii. For hand carried proposals, the Offeror will obtain a Proposal Receipt Form from jean.greenwood@us.army.mil and deliver the completed form with the proposal. The proposal administrative recipient will date/time stamp the original of the form, annotate the number of boxes received and sign in the "Signature of Recipient," portion of the form. This information will also be annotated on the copy that will be provided to the Offeror. The recipient's signature only denotes the receipt of the proposal and is not responsible for the proposal contents.

c. All proposals delivered in response to this solicitation shall reflect the following on the address label:

- i. RFP Number: W911QY-11-R-0023
- ii. The legend: "TO BE DELIVERED UNOPENED TO MR. GREG DAVIES"
- iii. The volume(s) and copy number(s) contained in each box

d. Offerors are encouraged NOT to wait until the last minute to submit proposals. To avoid submission of late proposals, the Government recommends that Offerors deliver their proposal package not later than 24 hours prior to the required proposal due date and time.

L.5. PERIOD FOR ACCEPTANCE OF OFFERS

The period for acceptance of offers is 180 days after closing date of solicitation.

L.6. PRE-AWARD SURVEY

Pursuant to FAR 9.103, contracts will only be placed with contractors that the Contracting Officer determines to be responsible. Offerors must be able to demonstrate that they meet the standards of responsibility set forth in FAR 9.104. The Government reserves the right to conduct a pre-award survey on any and all Offerors.

L.7. PROPOSAL PREPARATION COSTS

Offerors will not be reimbursed for any costs resulting from proposal preparation or costs associated with inquiring about or responding to this solicitation.

L.8. DISCLOSURE OF PROPOSAL

a. Information contained in the Offeror's proposal may be released under the Freedom of Information Act (5 U.S.C. 552) upon request from the public except to the extent it contains trade secrets and privileged or confidential commercial or financial information. If the Offeror's proposal contains material meeting this description which is customarily maintained in confidence in the course of the Offeror's business and which is not otherwise publicly available, and if the Offeror does not want it disclosed to the public, he shall mark the title page with the following legend:

This proposal, furnished in response to Solicitation W911QY-11-R-0023 may contain trade secrets and/or privileged or confidential commercial or financial information. This information is maintained in confidence in the course of the Offeror's business and is not otherwise publicly available. The Offeror submits this information to the Government in confidence and understands that it is received with that intent. This information shall not be released or disclosed outside the Government under the Freedom of Information Act (5 U.S.C. 552) or under any other circumstances.

b. Proposals so marked will be accepted by the Government in confidence and will not be released provided that the Offeror and/ or the Government can show, upon request under the Freedom of Information Act, that disclosure would either (1) impair the Government's ability to obtain necessary information in the future or (2) cause substantial harm to the competitive position of the Offeror.

L.9. SEQUENCE OF EVENTS

a. The Government will employ formal source selection techniques to evaluate proposals, conduct discussions and determine the successful Offeror in this acquisition. "Offer", for the purposes of this solicitation, shall be defined as a response to the solicitation that, if accepted, would bind the Offeror to perform the resultant Contract. The source selection process will follow the sequence outlined below.

- i. Issue RFP
- ii. Conduct Pre-Proposal Conference
- iii. Receive written proposals
- iv. Conduct responsive/non-responsive proposal assessment
- v. Conduct oral presentations
- vi. SSEB Evaluate proposals and establish competitive range
- vii. Present findings to SSAC and SSA
- viii. Notify Offerors of competitive range determination
- ix. Conduct negotiations (if required)
- x. Revise/Reaffirm Competitive Range (if required)
- xi. Receive Final Proposal Revisions (if required)
- xii. Conduct Final Evaluation (if required)
- xiii. Present Findings to SSAC and SSA
- xiv. SSA Decision

b. The following describes the general interaction activities that Offerors can expect during proposal evaluation and discussions:

- i. After posting of the solicitation, the Government will conduct a Pre-Proposal Conference to educate potential Offerors of the contents of the solicitation. This will be conducted approximately two (2) weeks after RFP release. This will be a presentation by the Government regarding the solicitation, and NOT an opportunity for dialog. Offerors may provide written questions to jean.greenwood@us.army.mil before or after the pre-proposal conference, and the questions and responses will be made available to all interested parties.

Offerors shall submit any questions for clarifications regarding the RFP as soon as possible after RFP release. The Government will provide responses in a timely manner. All questions and answers must be in writing. Email all questions to jean.greenwood@us.army.mil with a courtesy copy to peter.wallace@us.army.mil. Questions must be received no later than (NLT) seven (7) workdays prior to closing. Answers will be provided with questions, on a non-attribution basis to all interested parties via Federal Business Opportunities (www.fbo.gov). The Contracting Officer reserves the right to address questions received after the sixth (6) calendar day prior to solicitation closing with those offers deemed responsive and/or in the competitive range

- ii. The Government does not intend to extend the dates for proposal submissions. Therefore Offerors should take care to heed the submission dates and submit their questions in a timely manner.
- iii. Proposals must be received no later than the established date and time at the location specified. Upon receipt, the proposals will be reviewed for completeness and compliance with the instructions contained herein. Proposals that are found to be missing volumes or CDs, or are otherwise non-compliant with the instructions, will be considered non-responsive and will NOT receive further consideration. **See also Section M paragraph M.1.3. for additional mandatory responsiveness requirements.**
- iv. Within 2 business days of receipt of proposals, the Government will contact each Offeror to schedule an oral presentation. Oral presentations will be scheduled to commence not less than one (1) week after receipt of proposals. Oral presentations will be scheduled randomly and within the smallest reasonable timeframe, in an effort to promote fairness among Offerors.
- v. Upon completion of all oral presentations, the Government will apply formal source selection procedures and establish a competitive range of the Offerors with most highly rated proposals. If required, the Government will request clarifications prior to competitive range determinations. The Government will provide written notification to all Offerors within four (4) business days of completion of all evaluations regarding their inclusion in, or elimination from the competitive range.
- vi. If the number of proposals received exceeds what can reasonably be evaluated by the Government within existing resource constraints, the Contracting Officer may establish a competitive range that limits the number of proposals to the greatest number that will permit an efficient competition amongst the most highly rated proposals.
- vii. Offerors NOT included in the competitive range may request a debriefing at this time.
- viii. The Government will conduct negotiations, if necessary, with all Offerors in the competitive range.
- ix. Upon completion of negotiations, the Contracting Officer will request a Final Proposal Revision (FPR), from those Offerors in the competitive range.
- x. The Government reserves the right to reject any proposal if data specified above is not submitted with a revision or, if submitted, is inadequate to establish the acceptability of the FPR. Any revision received after the closing time and date will be considered a late Offer in accordance with this provision.

- xi. The Government will conduct final evaluation of the proposals and make an award recommendation to the SSA.
- xii. The SSA will make an award decision, and all Offerors will be notified of the decision.
- xiii. Offerors may request a debriefing at this time if they have not previously requested one.
- xiv. Written proposals submitted by Offerors that are NOT in the competitive range will be treated as unsolicited proposals and will be handled in accordance with Federal Acquisition Regulations (FAR) Part 15.6. Unsolicited proposals will not be evaluated as part of this acquisition and will not be eligible for award of a contract under this acquisition.

L.10. PARTICIPATION OF COMMERCIAL FIRMS AND FOREIGN NATIONALS IN EVALUATION PROCESS

L.10.1. The Government will utilize the contactors and subject matter experts (SMEs) 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 the proposal. By submitting a proposal, the Offeror agrees to permit the contractors and foreign nationals listed below to view proposal information to the extent necessary to provide administrative support to the Government’s proposal review process.

L.10.2. If specifically requested by an Offeror, the contractors and foreign nationals listed below must execute an agreement with each 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 these individuals to effect execution of such an agreement prior to the submission of proposals. Each Offeror shall submit copies of the agreement with their proposal. The agreements shall be attached to the Offeror’s proposal as an appendix. The list of contractors and foreign nations supporting this source selection are:

Kalman Co, Inc.

CIS, Inc.

Ken Kaitin, LLC

United Kingdom Ministry of Defense

Canada Ministry of Defense

L.11. QUESTIONS CONCERNING THIS SOLICITATION

Offeror questions and request for clarifications shall be submitted in accordance with the schedule in paragraph 10 above and shall be submitted to jean.greenwood@us.army.mil with a courtesy copy to peter.wallace@us.army.mil.

(End of Summary of Changes)