SOLICITATION, OFFER AND AWARD

1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE	OF	PAGES
	DO-B9	1		230

2. CONTRACT NO.	3. SOLICITATION NO.	4. TYPE OF SOLICITATION	5. DATE ISSUED	6. REQUISITION/PURCHASE NO.
	W911QY-11-R-0023	[ ] SEALED BID (IFB) [X] NEGOTIATED (RFP)	26 Aug 2011	

7. ISSUED BY CODE W911QY
NATICK CONTRACTING DIVISION
ATTN: CCRD-NA BUILDING 1, KANSAS STREET
NATICK MA 01760-5011
TEL:
FAX:

8. ADDRESS OFFER TO (If other than Item 7) CODE
See Item 7
TEL:
FAX:

NOTE: In sealed bid solicitations "offer" and "offeror" mean "bid" and "bidder".

SOLICITATION

9. Sealed offers in original and _____ copies for furnishing the supplies or services in the Schedule will be received at the place specified in Item 8, or if handcarried, in the depository located in _____ until _____ (Hour) local time _____ (Date)

CAUTION - LATE Submissions, Modifications, and Withdrawals: See Section L, Provision No. 52.214-7 or 52.215-1. All offers are subject to all terms and conditions contained in this solicitation.

10. FOR INFORMATION CALL:	A. NAME	B. TELEPHONE (Include area code) (NO COLLECT CALLS)	C. E-MAIL ADDRESS
	PETER WALLACE	508-233-4370	peter.wallace@us.army.mil

11. TABLE OF CONTENTS

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OFFER (Must be fully completed by offeror)

NOTE: Item 12 does not apply if the solicitation includes the provisions at 52.214-16, Minimum Bid Acceptance Period.

12. In compliance with the above, the undersigned agrees, if this offer is accepted within _____ calendar days (60 calendar days unless a different period is inserted by the offeror) from the date for receipt of offers specified above, to furnish any or all items upon which prices are offered at the price set opposite each item, delivered at the designated point(s), within the time specified in the schedule.

13. DISCOUNT FOR PROMPT PAYMENT (See Section I, Clause No. 52.232-8)

14. ACKNOWLEDGMENT OF AMENDMENTS (The offeror acknowledges receipt of amendments to the SOLICITATION for offerors and related documents numbered and dated):

AMENDMENT NO.	DATE	AMENDMENT NO.	DATE

15A. NAME AND ADDRESS OF OFFEROR CODE _____ FACILITY _____

16. NAME AND TITLE OF PERSON AUTHORIZED TO SIGN OFFER (Type or print)

15B. TELEPHONE NO (Include area code)

15C. CHECK IF REMITTANCE ADDRESS IS DIFFERENT FROM ABOVE - ENTER SUCH ADDRESS IN SCHEDULE.

17. SIGNATURE

18. OFFER DATE

AWARD (To be completed by Government)

19. ACCEPTED AS TO ITEMS NUMBERED

20. AMOUNT

21. ACCOUNTING AND APPROPRIATION

22. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION:
[ ] 10 U.S.C. 2304(c)( ) [ ] 41 U.S.C. 253(c)( )

23. SUBMIT INVOICES TO ADDRESS SHOWN IN (4 copies unless otherwise specified) ITEM

24. ADMINISTERED BY (If other than Item 7) CODE

25. PAYMENT WILL BE MADE BY CODE

26. NAME OF CONTRACTING OFFICER (Type or print)
TEL: EMAIL:

27. UNITED STATES OF AMERICA
(Signature of Contracting Officer)

28. AWARD DATE

IMPORTANT - Award will be made on this Form, or on Standard Form 26, or by other authorized official written notice.

Section A - Solicitation/Contract Form

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 intellectial 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 B - Supplies or Services and Prices

SUMMARY CLIN STRUCTURE

The following depiction of the CLIN structure is for clarity only:

TITLE	BASE	OPTION 1	OPTION 2	OPTION 3	OPTION 4
	1-24 mos	25-48 ms	49-72 mos	58-97 mos	97-120 mos
Establish/Commission/Validate and sustain 2 ADM Suites for 1.5M doses with surge capability to 12M doses per SOO	1001	2001	3001	4001	5001
Technical Data	1002	2002	3002	4002	5002
Training	1003	2003	3003	4003	5003

		25-120 mos
Optional Suite #1 Add'l capacity for 1.5M doses	OPTION 5	6001
Optional Suite #2 Add'l capacity for 1.5M doses	OPTION 6	6002
Optional Suite #3 Add'l capacity for 1.5M doses	OPTION 7	6003

Note: CLINs 6001, 6002 and 6003 are optional CLINs for increased capacity that may be exercised by the Government only once per CLIN at any point from 25 to 120 months after contract award.

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1001					

ADM Establishment & Commissioning

CPFF

Completion of the establishment, commissioning and validation of the ADM facilities and equipment comprising two (2) ADM suites, each capable of developing and manufacturing 1.5 M doses (500 K Total Equivalent Doses (TED)) with capability to surge to 12M doses (4M TED) of FDA approved MCM, as evidenced by inspection and acceptance of the capability infrastructure and of the ADM Final Technical Closeout Report detailing that the Advanced Development and Manufacturing Capability (ADM) achieved all milestones and requirements, in accordance with the Contractor's Statement of Work, including all program reporting requirements.

FOB: Destination

ESTIMATED COST

FIXED FEE

TOTAL EST COST + FEE

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1002					
	Technical Data FFP In accordance with CDRL List found in Section J. Include the cost of all Technical Data in CLIN 1001. FOB: Destination				
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1002AA		2	Each		
	Integrated Master Plan FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination				
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1002AB		8	Each		
	Integrated Master Schedule FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination				
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1002AC		5	Each		
	Contract Work Breakdown Structure FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination				
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1002AD		24	Each		
	EVMS Contract Performance Report FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination				
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1002AE		1	Each		
	Detailed Manufacturing Capability Plan FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination				
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1002AF		1	Each		
	Facility Operation Feasibility Plan FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination				
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1002AG		1	Each		
	Equip Qual/Facility Validation Summary FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination				
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1002AH		24	Each		
	Monthly Progress, Status & Mgmt Report FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination				
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1002AJ		8	Each		
	Contract Funds Status Report FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination				
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1002AK		24	Each		
	Training Report FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination				
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1002AL		4	Each		
	Miscellaneous Data Submissions FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination				
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1002AM		2	Each		

Patents – Reporting of Subject Invention
FFP
In accordance with CDRL List found in Section J

This CLIN is not separately priced.
FOB: Destination

NET AMT

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1002AN		100	Each		

Regulatory Approvals and FDA Submissions
FFP
In accordance with CDRL List found in Section J

Quantity is estimated. Actual number of deliveries is dependent upon FDA submissions as required. Period of performance to be inserted at time of award.

This CLIN is not separately priced.
FOB: Destination

NET AMT

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1002AP		2	Each		

Intellectual Property Plan - Updates
FFP
In accordance with CDRL List found in Section J

Quantity is estimated. Actual number of deliveries is dependent upon Government request.

This CLIN is not separately priced.
FOB: Destination

NET AMT

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1002AQ		23	Each		

Master Government Property List
FFP
In accordance with CDRL List found in Section J

Quantity is estimated. Actual number of deliveries is dependent upon Government request.

This CLIN is not separately priced.
FOB: Destination

NET AMT

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1002AR		2	Each		
	Master Gov't Property–Physical Inventory FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination				
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1002AS		2	Each		
	Contractor Manpower Reporting FFP In accordance with CDRL List found in Section J FOB: Destination				
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1003 OPTION	Training CPFF Training to the Government and to other Contractors, as ordered, including workshops, seminars, and training courses on best business practices, processes, and standard operating procedures. FOB: Destination				
				ESTIMATED COST	
				FIXED FEE	
				TOTAL EST COST + FEE	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
2001 OPTION	ADM Operations CPFF Operate and sustain the ADM for two (2) years in accordance with the Statement of Work FOB: Destination				
				ESTIMATED COST	
				FIXED FEE	
				TOTAL EST COST + FEE	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
2002 OPTION	Technical Data FFP In accordance with CDRL List found in Section J Include the cost of all Technical Data in CLIN 2001. FOB: Destination				
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
2002AA OPTION	Integrated Master Plan FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination	2	Each		
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
2002AB OPTION	Integrated Master Schedule FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination	8	Each		
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
2002AC OPTION	Contract Work Breakdown Structure FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination	4	Each		
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
2002AD OPTION	EVMS Contract Performance Report FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination	24	Each		
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
2002AH OPTION	Monthly Progress, Status & Mgmt Report FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination	24	Each		
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
2002AJ OPTION	Contract Funds Status Report FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination	8	Each		
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
2002AK OPTION	Training Report FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination	24	Each		
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
2002AL OPTION	Miscellaneous Data Submissions FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination	4	Each		
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
2002AM OPTION	Patents – Reporting of Subject Invention FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination	2	Each		
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
2002AN OPTION	Regulatory Approvals and FDA Submissions FFP In accordance with CDRL List found in Section J Quantity is estimated. Actual number of deliveries is dependent upon FDA submissions as required. Period of performance to be inserted at time of award. This CLIN is not separately priced. FOB: Destination	100	Each		
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
2002AS OPTION	Contractor Manpower Reporting FFP In accordance with CDRL List found in Section J FOB: Destination	2	Each		
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
2003 OPTION	Training CPFF Training to the Government and to other Contractors, as ordered, including workshops, seminars, and training courses on best business practices, processes, and standard operating procedures. FOB: Destination				
				ESTIMATED COST	
				FIXED FEE	
				TOTAL EST COST + FEE	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
3001 OPTION	ADM Operations CPFF Operate and sustain the ADM for two (2) years in accordance with the Statement of Work FOB: Destination				
				ESTIMATED COST	
				FIXED FEE	
				TOTAL EST COST + FEE	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
3002 OPTION	Technical Data FFP In accordance with CDRL List found in Section J Include the cost of all Technical Data in CLIN 3001. FOB: Destination				
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
3002AA OPTION	Integrated Master Plan FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination	2	Each		
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
3002AB OPTION	Integrated Master Schedule FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination	8	Each		
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
3002AC OPTION	Contract Work Breakdown Structure FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination	4	Each		
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
3002AD OPTION	EVMS Contract Performance Report FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination	24	Each		
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
3002AH OPTION	Monthly Progress, Status & Mgmt Report FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination	24	Each		
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
3002AJ OPTION	Contract Funds Status Report FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination	8	Each		
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
3002AK OPTION	Training Report FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination	24	Each		
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
3002AL OPTION	Miscellaneous Data Submissions FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination	4	Each		
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
3002AM OPTION	Patents – Reporting of Subject Invention FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination	2	Each		
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
3002AN OPTION		100	Each		
	Regulatory Approvals and FDA Submissions FFP In accordance with CDRL List found in Section J Quantity is estimated. Actual number of deliveries is dependent upon FDA submissions as required. Period of performance to be inserted at time of award. This CLIN is not separately priced. FOB: Destination				
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
3002AS OPTION		2	Each		
	Contractor Manpower Reporting FFP In accordance with CDRL List found in Section J FOB: Destination				
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
3003 OPTION	Training CPFF Training to the Government and to other Contractors, as ordered, including workshops, seminars, and training courses on best business practices, processes, and standard operating procedures. FOB: Destination				
				ESTIMATED COST	
				FIXED FEE	_____
				TOTAL EST COST + FEE	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
4001 OPTION	ADM Operations CPFF Operate and sustain the ADM for two (2) years in accordance with the Statement of Work FOB: Destination				
				ESTIMATED COST	
				FIXED FEE	_____
				TOTAL EST COST + FEE	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
4002 OPTION	Technical Data FFP In accordance with CDRL List found in Section J Include the cost of all Technical Data in CLIN 4001. FOB: Destination				
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
4002AA OPTION	Integrated Master Plan FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination	2	Each		
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
4002AB OPTION	Integrated Master Schedule FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination	8	Each		
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
4002AC OPTION	Contract Work Breakdown Structure FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination	4	Each		
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
4002AD OPTION	EVMS Contract Performance Report FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination	24	Each		
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
4002AH OPTION	Monthly Progress, Status & Mgmt Report FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination	24	Each		
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
4002AJ OPTION	Contract Funds Status Report FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination	8	Each		
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
4002AK OPTION	Training Report FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination	24	Each		
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
4002AL OPTION	Miscellaneous Data Submissions FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination	4	Each		
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
4002AM OPTION	Patents – Reporting of Subject Invention FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination	2	Each		
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
4002AN OPTION		100	Each		
	Regulatory Approvals and FDA Submissions FFP In accordance with CDRL List found in Section J Quantity is estimated. Actual number of deliveries is dependent upon FDA submissions as required. Period of performance to be inserted at time of award. This CLIN is not separately priced. FOB: Destination				
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
4002AS OPTION		2	Each		
	Contractor Manpower Reporting FFP In accordance with CDRL List found in Section J FOB: Destination				
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
4003 OPTION	Training CPFF Training to the Government and to other Contractors, as ordered, including workshops, seminars, and training courses on best business practices, processes, and standard operating procedures. FOB: Destination				
				ESTIMATED COST	
				FIXED FEE	_____
				TOTAL EST COST + FEE	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
5001 OPTION	ADM Operations CPFF Operate and sustain the ADM for two (2) years in accordance with the Statement of Work FOB: Destination				
				ESTIMATED COST	
				FIXED FEE	_____
				TOTAL EST COST + FEE	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
5002 OPTION	Technical Data FFP In accordance with CDRL List found in Section J Include the cost of all Technical Data in CLIN 5001. FOB: Destination				
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
5002AA OPTION	Integrated Master Plan FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination	3	Each		
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
5002AB OPTION	Integrated Master Schedule FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination	8	Each		
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
5002AC OPTION	Contract Work Breakdown Structure FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination	4	Each		
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
5002AD OPTION	EVMS Contract Performance Report FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination	24	Each		
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
5002AH OPTION	Monthly Progress, Status & Mgmt Report FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination	24	Each		
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
5002AJ OPTION	Contract Funds Status Report FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination	8	Each		
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
5002AK OPTION	Training Report FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination	24	Each		
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
5002AL OPTION	Miscellaneous Data Submissions FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination	4	Each		
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
5002AM OPTION	Patents – Reporting of Subject Invention FFP In accordance with CDRL List found in Section J This CLIN is not separately priced. FOB: Destination	2	Each		
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
5002AN OPTION		100	Each		
	Regulatory Approvals and FDA Submissions FFP In accordance with CDRL List found in Section J Quantity is estimated. Actual number of deliveries is dependent upon FDA submissions as required. Period of performance to be inserted at time of award. This CLIN is not separately priced. FOB: Destination				
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
5002AS OPTION		2	Each		
	Contractor Manpower Reporting FFP In accordance with CDRL List found in Section J FOB: Destination				
				NET AMT	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
5003 OPTION	Training CPFF Training to the Government and to other Contractors, as ordered, including workshops, seminars, and training courses on best business practices, processes, and standard operating procedures. FOB: Destination				
				ESTIMATED COST	
				FIXED FEE	
				TOTAL EST COST + FEE	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
6001 OPTION	Optional Manufacturing Suite #1 CPFF Establish one (1) additional ADM Suite as described in the Contractor's SOW : Increase manufacturing capability by establishing, commissioning and validating one (1) additional ADM suite capable of manufacturing 1.5M doses (500K TED) of ADM developed and FDA approved MCM within 3 months of Government request. This optional CLIN may be exercised at the Government's discretion at any time after 25 months ADC in order to establish additional needed capacity. 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. FOB: Destination				
				ESTIMATED COST	
				FIXED FEE	
				TOTAL EST COST + FEE	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
6002 OPTION	Optional Manufacturing Suite #2 CPFF Establish one (1) additional ADM Suite as described in the Contractor's SOW : Increase manufacturing capability by establishing, commissioning and validating one (1) additional ADM suite capable of manufacturing 1.5M doses (500K TED) of ADM developed and FDA approved MCM within 3 months of Government request. This optional CLIN may be exercised at the Government's discretion at any time after 25 months ADC in order to establish additional needed capacity. 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. FOB: Destination				
				ESTIMATED COST	
				FIXED FEE	
				TOTAL EST COST + FEE	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
6003 OPTION	Optional Manufacturing Suite #3 CPFF Establish one (1) additional ADM Suite as described in the Contractor's SOW : Increase manufacturing capability by establishing, commissioning and validating one (1) additional ADM suite capable of manufacturing 1.5M doses (500K TED) of ADM developed and FDA approved MCM within 3 months of Government request. This optional CLIN may be exercised at the Government's discretion at any time after 25 months ADC in order to establish additional needed capacity. 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. FOB: Destination				
				ESTIMATED COST	
				FIXED FEE	
				TOTAL EST COST + FEE	

Section C - Descriptions and Specifications

OFFEROR'S STATEMENT OF WORK
To be insterted upon award.

NOTE: Offeror is to include the Contract Data Requirements Lists (CDRL) as an intergral part of the Statement of Work (SOW). See Section J.

CONTRACTOR MANPOWER REPORTING
C.2. 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/. The contractor shall report the following:

a. Contracting Office
Contracting Officer
Contracting Officer's Technical Representative
b. Contract number
c. Beginning and ending dates covered by the reporting period
d. Contractor name, address, phone number, email address, and name of contractor employee entering data
e. Estimated total contract direct labor hours (including subcontractors)
f. Estimated direct contract labor hours paid this reporting period (including subcontractors)
g. Total payments (including subcontractors)
h. Predominant Federal Service Code (FSC)-
i. Estimated data collection cost
j. Organizational title associated with the Unique Identification Code (UIC) for the Army Requiring Activity. UIC for this contract is W911QY.
k. Locations where contractor and subcontractors perform the work (specified by zip code in the US and, for overseas addresses, the nearest city and country
l. Presence of deployment or contingency contract language
m. Number of contractor and subcontractor employees deployed in-theater this reporting period, by country.

The contractor shall also provide the estimated total cost (if any) incurred in order to comply with this reporting requirement (item i above). The reporting period shall be the period of performance not to exceed 12 months ending 30 September of each Government fiscal year and must be reported by 3 October of each calendar year.

The contractor may use a direct XML data transfer to the database server or fill in the fields on the website. The XML direct transfer is a format for transferring files from the contractor's system to a secure web site without the need for separate data entries for each required data

element. The specific formats for XML direct transfer may be downloaded per instructions on the site.

Section D - Packaging and Marking

PACKAGING

D.1 The Government anticipates that all hardware and equipment deliveries will be made to the contractor's facility in accordance with the contractor's packaging and markings.

D.2 All technical data shall be delivered to the following addresses:

JPM MCM
ATTN: Peter Bureau
50 Tech Parkway, Suite 301
Stafford, VA 22556

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

Section E - Inspection and Acceptance

INSPECTION AND ACCEPTANCE TERMS

Supplies/services will be inspected/accepted at:

CLIN	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
1001	Origin	Government	Origin	Government
1002	Origin	Government	Origin	Government
1002AA	N/A	N/A	N/A	Government
1002AB	N/A	N/A	N/A	Government
1002AC	N/A	N/A	N/A	Government
1002AD	N/A	N/A	N/A	Government
1002AE	N/A	N/A	N/A	Government
1002AF	N/A	N/A	N/A	Government
1002AG	N/A	N/A	N/A	Government
1002AH	N/A	N/A	N/A	Government
1002AJ	N/A	N/A	N/A	Government
1002AK	N/A	N/A	N/A	Government
1002AL	N/A	N/A	N/A	Government
1002AM	N/A	N/A	N/A	Government
1002AN	N/A	N/A	N/A	Government
1002AP	N/A	N/A	N/A	Government
1002AQ	N/A	N/A	N/A	Government
1002AR	N/A	N/A	N/A	Government
1002AS	N/A	N/A	N/A	Government
1003	N/A	N/A	N/A	Government
2001	Origin	Government	Origin	Government
2002	Origin	Government	Origin	Government
2002AA	N/A	N/A	N/A	Government
2002AB	N/A	N/A	N/A	Government
2002AC	N/A	N/A	N/A	Government
2002AD	N/A	N/A	N/A	Government
2002AH	N/A	N/A	N/A	Government
2002AJ	N/A	N/A	N/A	Government
2002AK	N/A	N/A	N/A	Government
2002AL	N/A	N/A	N/A	Government
2002AM	N/A	N/A	N/A	Government
2002AN	N/A	N/A	N/A	Government
2002AS	N/A	N/A	N/A	Government
2003	N/A	N/A	N/A	Government
3001	Origin	Government	Destination	Government
3002	Origin	Government	Origin	Government
3002AA	N/A	N/A	N/A	Government
3002AB	N/A	N/A	N/A	Government
3002AC	N/A	N/A	N/A	Government
3002AD	N/A	N/A	N/A	Government
3002AH	N/A	N/A	N/A	Government
3002AJ	N/A	N/A	N/A	Government
3002AK	N/A	N/A	N/A	Government
3002AL	N/A	N/A	N/A	Government

3002AM	N/A	N/A	N/A	Government
3002AN	N/A	N/A	N/A	Government
3002AS	N/A	N/A	N/A	Government
3003	N/A	N/A	N/A	Government
4001	Origin	Government	Origin	Government
4002	Origin	Government	Origin	Government
4002AA	N/A	N/A	N/A	Government
4002AB	N/A	N/A	N/A	Government
4002AC	N/A	N/A	N/A	Government
4002AD	N/A	N/A	N/A	Government
4002AH	N/A	N/A	N/A	Government
4002AJ	N/A	N/A	N/A	Government
4002AK	N/A	N/A	N/A	Government
4002AL	N/A	N/A	N/A	Government
4002AM	N/A	N/A	N/A	Government
4002AN	N/A	N/A	N/A	Government
4002AS	N/A	N/A	N/A	Government
4003	Origin	Government	Origin	Government
5001	Origin	Government	Origin	Government
5002	Origin	Government	Origin	Government
5002AA	N/A	N/A	N/A	Government
5002AB	N/A	N/A	N/A	Government
5002AC	N/A	N/A	N/A	Government
5002AD	N/A	N/A	N/A	Government
5002AH	N/A	N/A	N/A	Government
5002AJ	N/A	N/A	N/A	Government
5002AK	N/A	N/A	N/A	Government
5002AL	N/A	N/A	N/A	Government
5002AM	N/A	N/A	N/A	Government
5002AN	N/A	N/A	N/A	Government
5002AS	N/A	N/A	N/A	Government
5003	Origin	Government	Origin	Government
6001	Origin	Government	Origin	Government
6002	Origin	Government	Origin	Government
6003	Origin	Government	Origin	Government

CLAUSES INCORPORATED BY REFERENCE

52.246-8 Alt I	Inspection Of Research And Development-Cost Reimbursement (May 2001) - Alternate I	APR 1984
252.246-7000	Material Inspection And Receiving Report	MAR 2008
252.246-7001	Warranty Of Data	DEC 1991

CLAUSES INCORPORATED BY FULL TEXT

52.246-11 HIGHER-LEVEL CONTRACT QUALITY (FEB 1999)

The Contractor shall comply with the higher-level quality standard selected below. (If more than one standard is listed, the offeror shall indicate its selection by checking the appropriate block.)

Title	Number	Date	Tailoring
FDA Current Good Manufacturing Practice Regulations (cGMP) Regulations (21 CFR Parts 210-211)			

(End of clause)

Section F - Deliveries or Performance

DELIVERY INFORMATION

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	UIC
1001	24 mths. ADC		N/A FOB: Destination	
1002	N/A	N/A	N/A	N/A
1002AA	30 dys. ADC	1	N/A FOB: Destination	
1002AA	13 mths. ADC	1	N/A FOB: Destination	
1002AB	3 mths. ADC	1	N/A FOB: Destination	
1002AB	6 mths. ADC	1	N/A FOB: Destination	
1002AB	9 mths. ADC	1	N/A FOB: Destination	
1002AB	12 mths. ADC	1	N/A FOB: Destination	
1002AB	15 mths. ADC	1	N/A FOB: Destination	
1002AB	18 mths. ADC	1	N/A FOB: Destination	
1002AB	21 mths. ADC	1	N/A FOB: Destination	
1002AB	24 mths. ADC	1	N/A FOB: Destination	
1002AC	30 dys. ADC	1	N/A FOB: Destination	
1002AC	6 mths. ADC	1	N/A FOB: Destination	
1002AC	12 mths. ADC	1	N/A FOB: Destination	

1002AC 18 mths. ADC	1	N/A FOB: Destination
1002AC 24 mths. ADC	1	N/A FOB: Destination
1002AD 1 mth. ADC	1	N/A FOB: Destination
1002AD 2 mths. ADC	1	N/A FOB: Destination
1002AD 3 mths. ADC	1	N/A FOB: Destination
1002AD 4 mths. ADC	1	N/A FOB: Destination
1002AD 5 mths. ADC	1	N/A FOB: Destination
1002AD 6 mths. ADC	1	N/A FOB: Destination
1002AD 7 mths. ADC	1	N/A FOB: Destination
1002AD 8 mths. ADC	1	N/A FOB: Destination
1002AD 9 mths. ADC	1	N/A FOB: Destination
1002AD 10 mths. ADC	1	N/A FOB: Destination
1002AD 11 mths. ADC	1	N/A FOB: Destination
1002AD 12 mths. ADC	1	N/A FOB: Destination
1002AD 13 mths. ADC	1	N/A FOB: Destination
1002AD 14 mths. ADC	1	N/A FOB: Destination
1002AD 15 mths. ADC	1	N/A FOB: Destination
1002AD 16 mths. ADC	1	N/A FOB: Destination

1002AD 17 mths. ADC	1	N/A FOB: Destination
1002AD 18 mths. ADC	1	N/A FOB: Destination
1002AD 19 mths. ADC	1	N/A FOB: Destination
1002AD 20 mths. ADC	1	N/A FOB: Destination
1002AD 21 mths. ADC	1	N/A FOB: Destination
1002AD 22 mths. ADC	1	N/A FOB: Destination
1002AD 23 mths. ADC	1	N/A FOB: Destination
1002AD 24 mths. ADC	1	N/A FOB: Destination
1002AE 90 dys. ADC	1	N/A FOB: Destination
1002AF 365 dys. ADC	1	N/A FOB: Destination
1002AG 24 mths. ADC	1	N/A FOB: Destination
1002AH 1 mth. ADC	1	N/A FOB: Destination
1002AH 2 mths. ADC	1	N/A FOB: Destination
1002AH 3 mths. ADC	1	N/A FOB: Destination
1002AH 4 mths. ADC	1	N/A FOB: Destination
1002AH 5 mths. ADC	1	N/A FOB: Destination
1002AH 6 mths. ADC	1	N/A FOB: Destination
1002AH 7 mths. ADC	1	N/A FOB: Destination

1002AH 8 mths. ADC	1	N/A FOB: Destination
1002AH 9 mths. ADC	1	N/A FOB: Destination
1002AH 10 mths. ADC	1	N/A FOB: Destination
1002AH 11 mths. ADC	1	N/A FOB: Destination
1002AH 12 mths. ADC	1	N/A FOB: Destination
1002AH 13 mths. ADC	1	N/A FOB: Destination
1002AH 14 mths. ADC	1	N/A FOB: Destination
1002AH 15 mths. ADC	1	N/A FOB: Destination
1002AH 16 mths. ADC	1	N/A FOB: Destination
1002AH 17 mths. ADC	1	N/A FOB: Destination
1002AH 18 mths. ADC	1	N/A FOB: Destination
1002AH 19 mths. ADC	1	N/A FOB: Destination
1002AH 20 mths. ADC	1	N/A FOB: Destination
1002AH 21 mths. ADC	1	N/A FOB: Destination
1002AH 22 mths. ADC	1	N/A FOB: Destination
1002AH 23 mths. ADC	1	N/A FOB: Destination
1002AH 24 mths. ADC	1	N/A FOB: Destination
1002AJ 3 mths. ADC	1	N/A FOB: Destination

1002AJ	6 mths. ADC	1	N/A FOB: Destination
1002AJ	9 mths. ADC	1	N/A FOB: Destination
1002AJ	12 mths. ADC	1	N/A FOB: Destination
1002AJ	15 mths. ADC	1	N/A FOB: Destination
1002AJ	18 mths. ADC	1	N/A FOB: Destination
1002AJ	21 mths. ADC	1	N/A FOB: Destination
1002AJ	24 mths. ADC	1	N/A FOB: Destination
1002AK	1 mth. ADC	1	N/A FOB: Destination
1002AK	2 mths. ADC	1	N/A FOB: Destination
1002AK	3 mths. ADC	1	N/A FOB: Destination
1002AK	4 mths. ADC	1	N/A FOB: Destination
1002AK	5 mths. ADC	1	N/A FOB: Destination
1002AK	6 mths. ADC	1	N/A FOB: Destination
1002AK	7 mths. ADC	1	N/A FOB: Destination
1002AK	8 mths. ADC	1	N/A FOB: Destination
1002AK	9 mths. ADC	1	N/A FOB: Destination
1002AK	10 mths. ADC	1	N/A FOB: Destination
1002AK	11 mths. ADC	1	N/A FOB: Destination

1002AK 12 mths. ADC	1	N/A FOB: Destination
1002AK 13 mths. ADC	1	N/A FOB: Destination
1002AK 14 mths. ADC	1	N/A FOB: Destination
1002AK 15 mths. ADC	1	N/A FOB: Destination
1002AK 16 mths. ADC	1	N/A FOB: Destination
1002AK 17 mths. ADC	1	N/A FOB: Destination
1002AK 18 mths. ADC	1	N/A FOB: Destination
1002AK 19 mths. ADC	1	N/A FOB: Destination
1002AK 20 mths. ADC	1	N/A FOB: Destination
1002AK 21 mths. ADC	1	N/A FOB: Destination
1002AK 22 mths. ADC	1	N/A FOB: Destination
1002AK 23 mths. ADC	1	N/A FOB: Destination
1002AK 24 mths. ADC	1	N/A FOB: Destination
1002AL 6 mths. ADC	1	N/A FOB: Destination
1002AL 12 mths. ADC	1	N/A FOB: Destination
1002AL 18 mths. ADC	1	N/A FOB: Destination
1002AL 24 mths. ADC	1	N/A FOB: Destination
1002AM 1 yr. ADC	1	N/A FOB: Destination

1002AM 2 yrs. ADC	1	N/A FOB: Destination
1002AN 24 mths. ADC	100	N/A FOB: Destination
1002AP 24 mths. ADC	2	N/A FOB: Destination
1002AQ 45 dys. ADC	1	N/A FOB: Destination
1002AQ 2 mths. ADC	1	N/A FOB: Destination
1002AQ 3 mths. ADC	1	N/A FOB: Destination
1002AQ 4 mths. ADC	1	N/A FOB: Destination
1002AQ 5 mths. ADC	1	N/A FOB: Destination
1002AQ 6 mths. ADC	1	N/A FOB: Destination
1002AQ 7 mths. ADC	1	N/A FOB: Destination
1002AQ 8 mths. ADC	1	N/A FOB: Destination
1002AQ 9 mths. ADC	1	N/A FOB: Destination
1002AQ 10 mths. ADC	1	N/A FOB: Destination
1002AQ 11 mths. ADC	1	N/A FOB: Destination
1002AQ 12 mths. ADC	1	N/A FOB: Destination
1002AQ 13 mths. ADC	1	N/A FOB: Destination
1002AQ 14 mths. ADC	1	N/A FOB: Destination
1002AQ 15 mths. ADC	1	N/A FOB: Destination

1002AQ	16 mths. ADC	1	N/A FOB: Destination	
1002AQ	18 mths. ADC	1	N/A FOB: Destination	
1002AQ	19 mths. ADC	1	N/A FOB: Destination	
1002AQ	20 mths. ADC	1	N/A FOB: Destination	
1002AQ	21 mths. ADC	1	N/A FOB: Destination	
1002AQ	22 mths. ADC	1	N/A FOB: Destination	
1002AQ	23 mths. ADC	1	N/A FOB: Destination	
1002AQ	24 mths. ADC	1	N/A FOB: Destination	
1002AR	1 yr. ADC	1	N/A FOB: Destination	
1002AR	2 yrs. ADC	1	N/A FOB: Destination	
1002AS	03-OCT-2012	1	N/A FOB: Destination	
1002AS	03-OCT-2013	1	N/A FOB: Destination	
1003	24 mths. ADC		N/A FOB: Destination	
2001	48 mths. ADC		N/A FOB: Destination	
2002	N/A	N/A	N/A	N/A
2002AA	25 mths. ADC	1	N/A FOB: Destination	
2002AA	33 mths. ADC	1	N/A FOB: Destination	
2002AB	27 mths. ADC	1	N/A FOB: Destination	

2002AB 30 mths. ADC	1	N/A FOB: Destination
2002AB 33 mths. ADC	1	N/A FOB: Destination
2002AB 36 mths. ADC	1	N/A FOB: Destination
2002AB 39 mths. ADC	1	N/A FOB: Destination
2002AB 42 mths. ADC	1	N/A FOB: Destination
2002AB 45 mths. ADC	1	N/A FOB: Destination
2002AB 48 mths. ADC	1	N/A FOB: Destination
2002AC 30 mths. ADC	1	N/A FOB: Destination
2002AC 36 mths. ADC	1	N/A FOB: Destination
2002AC 42 mths. ADC	1	N/A FOB: Destination
2002AC 48 mths. ADC	1	N/A FOB: Destination
2002AD 25 mths. ADC	1	N/A FOB: Destination
2002AD 26 mths. ADC	1	N/A FOB: Destination
2002AD 27 mths. ADC	1	N/A FOB: Destination
2002AD 28 mths. ADC	1	N/A FOB: Destination
2002AD 29 mths. ADC	1	N/A FOB: Destination
2002AD 30 mths. ADC	1	N/A FOB: Destination
2002AD 31 mths. ADC	1	N/A FOB: Destination

2002AD 32 mths. ADC	1	N/A FOB: Destination
2002AD 33 mths. ADC	1	N/A FOB: Destination
2002AD 34 mths. ADC	1	N/A FOB: Destination
2002AD 35 mths. ADC	1	N/A FOB: Destination
2002AD 36 mths. ADC	1	N/A FOB: Destination
2002AD 37 mths. ADC	1	N/A FOB: Destination
2002AD 38 mths. ADC	1	N/A FOB: Destination
2002AD 39 mths. ADC	1	N/A FOB: Destination
2002AD 40 mths. ADC	1	N/A FOB: Destination
2002AD 41 mths. ADC	1	N/A FOB: Destination
2002AD 42 mths. ADC	1	N/A FOB: Destination
2002AD 43 mths. ADC	1	N/A FOB: Destination
2002AD 44 mths. ADC	1	N/A FOB: Destination
2002AD 45 mths. ADC	1	N/A FOB: Destination
2002AD 46 mths. ADC	1	N/A FOB: Destination
2002AD 47 mths. ADC	1	N/A FOB: Destination
2002AD 48 mths. ADC	1	N/A FOB: Destination
2002AH 25 mths. ADC	1	N/A FOB: Destination

2002AH 26 mths. ADC	1	N/A FOB: Destination
2002AH 27 mths. ADC	1	N/A FOB: Destination
2002AH 28 mths. ADC	1	N/A FOB: Destination
2002AH 29 mths. ADC	1	N/A FOB: Destination
2002AH 30 mths. ADC	1	N/A FOB: Destination
2002AH 31 mths. ADC	1	N/A FOB: Destination
2002AH 32 mths. ADC	1	N/A FOB: Destination
2002AH 33 mths. ADC	1	N/A FOB: Destination
2002AH 34 mths. ADC	1	N/A FOB: Destination
2002AH 35 mths. ADC	1	N/A FOB: Destination
2002AH 36 mths. ADC	1	N/A FOB: Destination
2002AH 37 mths. ADC	1	N/A FOB: Destination
2002AH 38 mths. ADC	1	N/A FOB: Destination
2002AH 39 mths. ADC	1	N/A FOB: Destination
2002AH 40 mths. ADC	1	N/A FOB: Destination
2002AH 41 mths. ADC	1	N/A FOB: Destination
2002AH 42 mths. ADC	1	N/A FOB: Destination
2002AH 43 mths. ADC	1	N/A FOB: Destination

2002AH 44 mths. ADC	1	N/A FOB: Destination
2002AH 45 mths. ADC	1	N/A FOB: Destination
2002AH 46 mths. ADC	1	N/A FOB: Destination
2002AH 47 mths. ADC	1	N/A FOB: Destination
2002AH 48 mths. ADC	1	N/A FOB: Destination
2002AJ 27 mths. ADC	1	N/A FOB: Destination
2002AJ 30 mths. ADC	1	N/A FOB: Destination
2002AJ 33 mths. ADC	1	N/A FOB: Destination
2002AJ 36 mths. ADC	1	N/A FOB: Destination
2002AJ 39 mths. ADC	1	N/A FOB: Destination
2002AJ 42 mths. ADC	1	N/A FOB: Destination
2002AJ 45 mths. ADC	1	N/A FOB: Destination
2002AJ 48 mths. ADC	1	N/A FOB: Destination
2002AK 25 mths. ADC	1	N/A FOB: Destination
2002AK 26 mths. ADC	1	N/A FOB: Destination
2002AK 27 mths. ADC	1	N/A FOB: Destination
2002AK 28 mths. ADC	1	N/A FOB: Destination
2002AK 29 mths. ADC	1	N/A FOB: Destination

2002AK 30 mths. ADC	1	N/A FOB: Destination
2002AK 31 mths. ADC	1	N/A FOB: Destination
2002AK 32 mths. ADC	1	N/A FOB: Destination
2002AK 33 mths. ADC	1	N/A FOB: Destination
2002AK 34 mths. ADC	1	N/A FOB: Destination
2002AK 35 mths. ADC	1	N/A FOB: Destination
2002AK 36 mths. ADC	1	N/A FOB: Destination
2002AK 37 mths. ADC	1	N/A FOB: Destination
2002AK 38 mths. ADC	1	N/A FOB: Destination
2002AK 39 mths. ADC	1	N/A FOB: Destination
2002AK 40 mths. ADC	1	N/A FOB: Destination
2002AK 41 mths. ADC	1	N/A FOB: Destination
2002AK 42 mths. ADC	1	N/A FOB: Destination
2002AK 43 mths. ADC	1	N/A FOB: Destination
2002AK 44 mths. ADC	1	N/A FOB: Destination
2002AK 45 mths. ADC	1	N/A FOB: Destination
2002AK 46 mths. ADC	1	N/A FOB: Destination
2002AK 47 mths. ADC	1	N/A FOB: Destination

2002AK	48 mths. ADC	1	N/A FOB: Destination	
2002AL	30 mths. ADC	1	N/A FOB: Destination	
2002AL	36 mths. ADC	1	N/A FOB: Destination	
2002AL	42 mths. ADC	1	N/A FOB: Destination	
2002AL	48 mths. ADC	1	N/A FOB: Destination	
2002AM	3 yrs. ADC	1	N/A FOB: Destination	
2002AM	4 yrs. ADC	1	N/A FOB: Destination	
2002AN	48 mths. ADC	100	N/A FOB: Destination	
2002AS	03-OCT-2014	1	N/A FOB: Destination	
2002AS	03-OCT-2015	1	N/A FOB: Destination	
2003	48 mths. ADC		N/A FOB: Destination	
3001	72 mths. ADC		N/A FOB: Destination	
3002	N/A	N/A	N/A	N/A
3002AA	49 mths. ADC	1	N/A FOB: Destination	
3002AA	61 mths. ADC	1	N/A FOB: Destination	
3002AB	51 mths. ADC	1	N/A FOB: Destination	
3002AB	54 mths. ADC	1	N/A FOB: Destination	
3002AB	57 mths. ADC	1	N/A FOB: Destination	

3002AB 60 mths. ADC	1	N/A FOB: Destination
3002AB 63 mths. ADC	1	N/A FOB: Destination
3002AB 66 mths. ADC	1	N/A FOB: Destination
3002AB 69 mths. ADC	1	N/A FOB: Destination
3002AB 72 mths. ADC	1	N/A FOB: Destination
3002AC 54 mths. ADC	1	N/A FOB: Destination
3002AC 60 mths. ADC	1	N/A FOB: Destination
3002AC 66 mths. ADC	1	N/A FOB: Destination
3002AC 72 mths. ADC	1	N/A FOB: Destination
3002AD 49 mths. ADC	1	N/A FOB: Destination
3002AD 50 mths. ADC	1	N/A FOB: Destination
3002AD 51 mths. ADC	1	N/A FOB: Destination
3002AD 52 mths. ADC	1	N/A FOB: Destination
3002AD 53 mths. ADC	1	N/A FOB: Destination
3002AD 54 mths. ADC	1	N/A FOB: Destination
3002AD 55 mths. ADC	1	N/A FOB: Destination
3002AD 56 mths. ADC	1	N/A FOB: Destination
3002AD 57 mths. ADC	1	N/A FOB: Destination

3002AD 58 mths. ADC	1	N/A FOB: Destination
3002AD 59 mths. ADC	1	N/A FOB: Destination
3002AD 60 mths. ADC	1	N/A FOB: Destination
3002AD 61 mths. ADC	1	N/A FOB: Destination
3002AD 62 mths. ADC	1	N/A FOB: Destination
3002AD 63 mths. ADC	1	N/A FOB: Destination
3002AD 64 mths. ADC	1	N/A FOB: Destination
3002AD 65 mths. ADC	1	N/A FOB: Destination
3002AD 66 mths. ADC	1	N/A FOB: Destination
3002AD 67 mths. ADC	1	N/A FOB: Destination
3002AD 68 mths. ADC	1	N/A FOB: Destination
3002AD 69 mths. ADC	1	N/A FOB: Destination
3002AD 70 mths. ADC	1	N/A FOB: Destination
3002AD 71 mths. ADC	1	N/A FOB: Destination
3002AD 72 mths. ADC	1	N/A FOB: Destination
3002AH 49 mths. ADC	1	N/A FOB: Destination
3002AH 50 mths. ADC	1	N/A FOB: Destination
3002AH 51 mths. ADC	1	N/A FOB: Destination

3002AH 52 mths. ADC	1	N/A FOB: Destination
3002AH 53 mths. ADC	1	N/A FOB: Destination
3002AH 54 mths. ADC	1	N/A FOB: Destination
3002AH 55 mths. ADC	1	N/A FOB: Destination
3002AH 56 mths. ADC	1	N/A FOB: Destination
3002AH 57 mths. ADC	1	N/A FOB: Destination
3002AH 58 mths. ADC	1	N/A FOB: Destination
3002AH 59 mths. ADC	1	N/A FOB: Destination
3002AH 60 mths. ADC	1	N/A FOB: Destination
3002AH 61 mths. ADC	1	N/A FOB: Destination
3002AH 62 mths. ADC	1	N/A FOB: Destination
3002AH 63 mths. ADC	1	N/A FOB: Destination
3002AH 64 mths. ADC	1	N/A FOB: Destination
3002AH 65 mths. ADC	1	N/A FOB: Destination
3002AH 66 mths. ADC	1	N/A FOB: Destination
3002AH 67 mths. ADC	1	N/A FOB: Destination
3002AH 68 mths. ADC	1	N/A FOB: Destination
3002AH 69 mths. ADC	1	N/A FOB: Destination

3002AH 70 mths. ADC	1	N/A FOB: Destination
3002AH 71 mths. ADC	1	N/A FOB: Destination
3002AH 72 mths. ADC	1	N/A FOB: Destination
3002AJ 51 mths. ADC	1	N/A FOB: Destination
3002AJ 54 mths. ADC	1	N/A FOB: Destination
3002AJ 57 mths. ADC	1	N/A FOB: Destination
3002AJ 60 mths. ADC	1	N/A FOB: Destination
3002AJ 63 mths. ADC	1	N/A FOB: Destination
3002AJ 66 mths. ADC	1	N/A FOB: Destination
3002AJ 69 mths. ADC	1	N/A FOB: Destination
3002AJ 72 mths. ADC	1	N/A FOB: Destination
3002AK 49 mths. ADC	1	N/A FOB: Destination
3002AK 50 mths. ADC	1	N/A FOB: Destination
3002AK 51 mths. ADC	1	N/A FOB: Destination
3002AK 52 mths. ADC	1	N/A FOB: Destination
3002AK 53 mths. ADC	1	N/A FOB: Destination
3002AK 54 mths. ADC	1	N/A FOB: Destination
3002AK 55 mths. ADC	1	N/A FOB: Destination

3002AK 56 mths. ADC	1	N/A FOB: Destination
3002AK 57 mths. ADC	1	N/A FOB: Destination
3002AK 58 mths. ADC	1	N/A FOB: Destination
3002AK 59 mths. ADC	1	N/A FOB: Destination
3002AK 60 mths. ADC	1	N/A FOB: Destination
3002AK 61 mths. ADC	1	N/A FOB: Destination
3002AK 62 mths. ADC	1	N/A FOB: Destination
3002AK 63 mths. ADC	1	N/A FOB: Destination
3002AK 64 mths. ADC	1	N/A FOB: Destination
3002AK 65 mths. ADC	1	N/A FOB: Destination
3002AK 66 mths. ADC	1	N/A FOB: Destination
3002AK 67 mths. ADC	1	N/A FOB: Destination
3002AK 68 mths. ADC	1	N/A FOB: Destination
3002AK 69 mths. ADC	1	N/A FOB: Destination
3002AK 70 mths. ADC	1	N/A FOB: Destination
3002AK 71 mths. ADC	1	N/A FOB: Destination
3002AK 72 mths. ADC	1	N/A FOB: Destination
3002AL 54 mths. ADC	1	N/A FOB: Destination

3002AL	60 mths. ADC	1	N/A FOB: Destination	
3002AL	66 mths. ADC	1	N/A FOB: Destination	
3002AL	72 mths. ADC	1	N/A FOB: Destination	
3002AM	5 yrs. ADC	1	N/A FOB: Destination	
3002AM	6 yrs. ADC	1	N/A FOB: Destination	
3002AN	72 mths. ADC	100	N/A FOB: Destination	
3002AS	03-OCT-2016	1	N/A FOB: Destination	
3002AS	03-OCT-2017	1	N/A FOB: Destination	
3003	72 mths. ADC		N/A FOB: Destination	
4001	96 mths. ADC		N/A FOB: Destination	
4002	N/A	N/A	N/A	N/A
4002AA	73 mths. ADC	1	N/A FOB: Destination	
4002AA	85 mths. ADC	1	N/A FOB: Destination	
4002AB	75 mths. ADC	1	N/A FOB: Destination	
4002AB	78 mths. ADC	1	N/A FOB: Destination	
4002AB	81 mths. ADC	1	N/A FOB: Destination	
4002AB	84 mths. ADC	1	N/A FOB: Destination	
4002AB	87 mths. ADC	1	N/A FOB: Destination	

4002AB 90 mths. ADC	1	N/A FOB: Destination
4002AB 93 mths. ADC	1	N/A FOB: Destination
4002AB 96 mths. ADC	1	N/A FOB: Destination
4002AC 78 mths. ADC	1	N/A FOB: Destination
4002AC 84 mths. ADC	1	N/A FOB: Destination
4002AC 90 mths. ADC	1	N/A FOB: Destination
4002AC 96 mths. ADC	1	N/A FOB: Destination
4002AD 73 mths. ADC	1	N/A FOB: Destination
4002AD 74 mths. ADC	1	N/A FOB: Destination
4002AD 75 mths. ADC	1	N/A FOB: Destination
4002AD 76 mths. ADC	1	N/A FOB: Destination
4002AD 77 mths. ADC	1	N/A FOB: Destination
4002AD 78 mths. ADC	1	N/A FOB: Destination
4002AD 79 mths. ADC	1	N/A FOB: Destination
4002AD 80 mths. ADC	1	N/A FOB: Destination
4002AD 81 mths. ADC	1	N/A FOB: Destination
4002AD 82 mths. ADC	1	N/A FOB: Destination
4002AD 83 mths. ADC	1	N/A FOB: Destination

4002AD 84 mths. ADC	1	N/A FOB: Destination
4002AD 85 mths. ADC	1	N/A FOB: Destination
4002AD 86 mths. ADC	1	N/A FOB: Destination
4002AD 87 mths. ADC	1	N/A FOB: Destination
4002AD 88 mths. ADC	1	N/A FOB: Destination
4002AD 89 mths. ADC	1	N/A FOB: Destination
4002AD 90 mths. ADC	1	N/A FOB: Destination
4002AD 91 mths. ADC	1	N/A FOB: Destination
4002AD 92 mths. ADC	1	N/A FOB: Destination
4002AD 93 mths. ADC	1	N/A FOB: Destination
4002AD 94 mths. ADC	1	N/A FOB: Destination
4002AD 95 mths. ADC	1	N/A FOB: Destination
4002AD 96 mths. ADC	1	N/A FOB: Destination
4002AH 73 mths. ADC	1	N/A FOB: Destination
4002AH 74 mths. ADC	1	N/A FOB: Destination
4002AH 75 mths. ADC	1	N/A FOB: Destination
4002AH 76 mths. ADC	1	N/A FOB: Destination
4002AH 77 mths. ADC	1	N/A FOB: Destination

4002AH 78 mths. ADC	1	N/A FOB: Destination
4002AH 79 mths. ADC	1	N/A FOB: Destination
4002AH 80 mths. ADC	1	N/A FOB: Destination
4002AH 81 mths. ADC	1	N/A FOB: Destination
4002AH 82 mths. ADC	1	N/A FOB: Destination
4002AH 83 mths. ADC	1	N/A FOB: Destination
4002AH 84 mths. ADC	1	N/A FOB: Destination
4002AH 85 mths. ADC	1	N/A FOB: Destination
4002AH 86 mths. ADC	1	N/A FOB: Destination
4002AH 87 mths. ADC	1	N/A FOB: Destination
4002AH 88 mths. ADC	1	N/A FOB: Destination
4002AH 89 mths. ADC	1	N/A FOB: Destination
4002AH 90 mths. ADC	1	N/A FOB: Destination
4002AH 91 mths. ADC	1	N/A FOB: Destination
4002AH 92 mths. ADC	1	N/A FOB: Destination
4002AH 93 mths. ADC	1	N/A FOB: Destination
4002AH 94 mths. ADC	1	N/A FOB: Destination
4002AH 95 mths. ADC	1	N/A FOB: Destination

4002AH	96 mths. ADC	1	N/A FOB: Destination
4002AJ	75 mths. ADC	1	N/A FOB: Destination
4002AJ	78 mths. ADC	1	N/A FOB: Destination
4002AJ	81 mths. ADC	1	N/A FOB: Destination
4002AJ	84 mths. ADC	1	N/A FOB: Destination
4002AJ	87 mths. ADC	1	N/A FOB: Destination
4002AJ	90 mths. ADC	1	N/A FOB: Destination
4002AJ	93 mths. ADC	1	N/A FOB: Destination
4002AJ	96 mths. ADC	1	N/A FOB: Destination
4002AK	73 mths. ADC	1	N/A FOB: Destination
4002AK	74 mths. ADC	1	N/A FOB: Destination
4002AK	75 mths. ADC	1	N/A FOB: Destination
4002AK	76 mths. ADC	1	N/A FOB: Destination
4002AK	77 mths. ADC	1	N/A FOB: Destination
4002AK	78 mths. ADC	1	N/A FOB: Destination
4002AK	79 mths. ADC	1	N/A FOB: Destination
4002AK	80 mths. ADC	1	N/A FOB: Destination
4002AK	81 mths. ADC	1	N/A FOB: Destination

4002AK 82 mths. ADC	1	N/A FOB: Destination
4002AK 83 mths. ADC	1	N/A FOB: Destination
4002AK 84 mths. ADC	1	N/A FOB: Destination
4002AK 85 mths. ADC	1	N/A FOB: Destination
4002AK 86 mths. ADC	1	N/A FOB: Destination
4002AK 87 mths. ADC	1	N/A FOB: Destination
4002AK 88 mths. ADC	1	N/A FOB: Destination
4002AK 89 mths. ADC	1	N/A FOB: Destination
4002AK 90 mths. ADC	1	N/A FOB: Destination
4002AK 91 mths. ADC	1	N/A FOB: Destination
4002AK 92 mths. ADC	1	N/A FOB: Destination
4002AK 93 mths. ADC	1	N/A FOB: Destination
4002AK 94 mths. ADC	1	N/A FOB: Destination
4002AK 95 mths. ADC	1	N/A FOB: Destination
4002AK 96 mths. ADC	1	N/A FOB: Destination
4002AL 78 mths. ADC	1	N/A FOB: Destination
4002AL 84 mths. ADC	1	N/A FOB: Destination
4002AL 90 mths. ADC	1	N/A FOB: Destination

4002AL	96 mths. ADC	1	N/A FOB: Destination	
4002AM	7 yrs. ADC	1	N/A FOB: Destination	
4002AM	8 yrs. ADC	1	N/A FOB: Destination	
4002AN	96 mths. ADC	100	N/A FOB: Destination	
4002AS	03-OCT-2018	1	N/A FOB: Destination	
4002AS	03-OCT-2019	1	N/A FOB: Destination	
4003	96 mths. ADC		N/A FOB: Destination	
5001	120 mths. ADC		N/A FOB: Destination	
5002	N/A	N/A	N/A	N/A
5002AA	97 mths. ADC	1	N/A FOB: Destination	
5002AA	109 mths. ADC	1	N/A FOB: Destination	
5002AA	120 mths. ADC	1	N/A FOB: Destination	
5002AB	99 mths. ADC	1	N/A FOB: Destination	
5002AB	102 mths. ADC	1	N/A FOB: Destination	
5002AB	105 mths. ADC	1	N/A FOB: Destination	
5002AB	108 mths. ADC	1	N/A FOB: Destination	
5002AB	111 mths. ADC	1	N/A FOB: Destination	
5002AB	114 mths. ADC	1	N/A FOB: Destination	

5002AB 117 mths. ADC	1	N/A FOB: Destination
5002AB 120 mths. ADC	1	N/A FOB: Destination
5002AC 102 mths. ADC	1	N/A FOB: Destination
5002AC 108 mths. ADC	1	N/A FOB: Destination
5002AC 114 mths. ADC	1	N/A FOB: Destination
5002AC 120 mths. ADC	1	N/A FOB: Destination
5002AD 97 mths. ADC	1	N/A FOB: Destination
5002AD 98 mths. ADC	1	N/A FOB: Destination
5002AD 99 mths. ADC	1	N/A FOB: Destination
5002AD 100 mths. ADC	1	N/A FOB: Destination
5002AD 101 mths. ADC	1	N/A FOB: Destination
5002AD 102 mths. ADC	1	N/A FOB: Destination
5002AD 103 mths. ADC	1	N/A FOB: Destination
5002AD 104 mths. ADC	1	N/A FOB: Destination
5002AD 105 mths. ADC	1	N/A FOB: Destination
5002AD 106 mths. ADC	1	N/A FOB: Destination
5002AD 107 mths. ADC	1	N/A FOB: Destination
5002AD 108 mths. ADC	1	N/A FOB: Destination

5002AD 109 mths. ADC	1	N/A FOB: Destination
5002AD 110 mths. ADC	1	N/A FOB: Destination
5002AD 111 mths. ADC	1	N/A FOB: Destination
5002AD 112 mths. ADC	1	N/A FOB: Destination
5002AD 113 mths. ADC	1	N/A FOB: Destination
5002AD 114 mths. ADC	1	N/A FOB: Destination
5002AD 115 mths. ADC	1	N/A FOB: Destination
5002AD 116 mths. ADC	1	N/A FOB: Destination
5002AD 117 mths. ADC	1	N/A FOB: Destination
5002AD 118 mths. ADC	1	N/A FOB: Destination
5002AD 119 mths. ADC	1	N/A FOB: Destination
5002AD 120 mths. ADC	1	N/A FOB: Destination
5002AH 97 mths. ADC	1	N/A FOB: Destination
5002AH 98 mths. ADC	1	N/A FOB: Destination
5002AH 99 mths. ADC	1	N/A FOB: Destination
5002AH 100 mths. ADC	1	N/A FOB: Destination
5002AH 101 mths. ADC	1	N/A FOB: Destination
5002AH 102 mths. ADC	1	N/A FOB: Destination

5002AH 103 mths. ADC	1	N/A FOB: Destination
5002AH 104 mths. ADC	1	N/A FOB: Destination
5002AH 105 mths. ADC	1	N/A FOB: Destination
5002AH 106 mths. ADC	1	N/A FOB: Destination
5002AH 107 mths. ADC	1	N/A FOB: Destination
5002AH 108 mths. ADC	1	N/A FOB: Destination
5002AH 109 mths. ADC	1	N/A FOB: Destination
5002AH 110 mths. ADC	1	N/A FOB: Destination
5002AH 111 mths. ADC	1	N/A FOB: Destination
5002AH 112 mths. ADC	1	N/A FOB: Destination
5002AH 113 mths. ADC	1	N/A FOB: Destination
5002AH 114 mths. ADC	1	N/A FOB: Destination
5002AH 115 mths. ADC	1	N/A FOB: Destination
5002AH 116 mths. ADC	1	N/A FOB: Destination
5002AH 117 mths. ADC	1	N/A FOB: Destination
5002AH 118 mths. ADC	1	N/A FOB: Destination
5002AH 119 mths. ADC	1	N/A FOB: Destination
5002AH 120 mths. ADC	1	N/A FOB: Destination

5002AJ	99 mths. ADC	1	N/A FOB: Destination
5002AJ	102 mths. ADC	1	N/A FOB: Destination
5002AJ	105 mths. ADC	1	N/A FOB: Destination
5002AJ	108 mths. ADC	1	N/A FOB: Destination
5002AJ	111 mths. ADC	1	N/A FOB: Destination
5002AJ	114 mths. ADC	1	N/A FOB: Destination
5002AJ	117 mths. ADC	1	N/A FOB: Destination
5002AJ	120 mths. ADC	1	N/A FOB: Destination
5002AK	97 mths. ADC	1	N/A FOB: Destination
5002AK	98 mths. ADC	1	N/A FOB: Destination
5002AK	99 mths. ADC	1	N/A FOB: Destination
5002AK	100 mths. ADC	1	N/A FOB: Destination
5002AK	101 mths. ADC	1	N/A FOB: Destination
5002AK	102 mths. ADC	1	N/A FOB: Destination
5002AK	103 mths. ADC	1	N/A FOB: Destination
5002AK	104 mths. ADC	1	N/A FOB: Destination
5002AK	105 mths. ADC	1	N/A FOB: Destination
5002AK	106 mths. ADC	1	N/A FOB: Destination

5002AK 107 mths. ADC	1	N/A FOB: Destination
5002AK 108 mths. ADC	1	N/A FOB: Destination
5002AK 109 mths. ADC	1	N/A FOB: Destination
5002AK 110 mths. ADC	1	N/A FOB: Destination
5002AK 111 mths. ADC	1	N/A FOB: Destination
5002AK 112 mths. ADC	1	N/A FOB: Destination
5002AK 113 mths. ADC	1	N/A FOB: Destination
5002AK 114 mths. ADC	1	N/A FOB: Destination
5002AK 115 mths. ADC	1	N/A FOB: Destination
5002AK 116 mths. ADC	1	N/A FOB: Destination
5002AK 117 mths. ADC	1	N/A FOB: Destination
5002AK 118 mths. ADC	1	N/A FOB: Destination
5002AK 119 mths. ADC	1	N/A FOB: Destination
5002AK 120 mths. ADC	1	N/A FOB: Destination
5002AL 102 mths. ADC	1	N/A FOB: Destination
5002AL 108 mths. ADC	1	N/A FOB: Destination
5002AL 114 mths. ADC	1	N/A FOB: Destination
5002AL 120 mths. ADC	1	N/A FOB: Destination

5002AM	9 yrs. ADC	1	N/A FOB: Destination
5002AM	10 yrs. ADC	1	N/A FOB: Destination
5002AN	120 mths. ADC	100	N/A FOB: Destination
5002AS	03-OCT-2020	1	N/A FOB: Destination
5002AS	03-OCT-2021	1	N/A FOB: Destination
5003	120 mths. ADC		N/A FOB: Destination
6001	25 mths. ADC		N/A FOB: Destination
6002	25 mths. ADC		N/A FOB: Destination
6003	25 mths. ADC		N/A FOB: Destination

CLAUSES INCORPORATED BY REFERENCE

52.242-15 Alt I	Stop-Work Order (Aug 1989) - Alternate I	APR 1984

Section G - Contract Administration Data

SECTION G
Payments:

A detailed Copy of all payment requests will be provided electronically to each of the Government points of contact listed below at the same time of submission to WAWF:

Contracting Office:
ACC-APG NATICK CONTRACTING DIVISION
ATTN: Peter Wallace
Kansas Street
Natick, MA 01760
Telephone: 508 233-6139
Email: peter.wallace@us.army.mil

Contract Specialist:
Jean Greenwood
Telephone: 508 233-6187
Email: jean.greenwood@us.army.mil

Contracting Officer's Representative (COR):

JPEO-CBD JPM MCM ADM
ATTN: Peter Bureau
50 Tech Parkway, Suite 301
Stafford, VA 22556

Administrative Contracting Officer (ACO):

DCMA – Details to be inserted upon award.

CLAUSES INCORPORATED BY FULL TEXT

5152.232-7003 INVOICING INSTRUCTIONS AND PAYMENT (WAWF INSTRUCTIONS) (NCD) (AUG 2009)

(a) Invoices for goods received or services rendered under this contract shall be submitted electronically through Wide Area Work Flow – Receipt and Acceptance (WAWF):

(1) The vendor shall self-register at the web site https://wawf.eb.mil. Vendor training is available on the Internet at http://www.wawftraining.com.

(2) Select the invoice type within WAWF as specified below. Back up documentation (such as timesheets, etc.) can be included and attached to the invoice in WAWF. Attachments created in any Microsoft Office product are attachable to the invoice in WAWF. Total limit for the size of files per invoice is 5 megabytes.

(b) The following information, regarding invoice routing DODAAC's, must be entered for completion of the invoice in WAWF:

Invoice Only	
Pay DoDAAC	Insert Upon Award
IssueBy DoDAAC	W911QY
Admin DoDAAC	Insert Upon Award
Ship To Code	
Receiving Report (DD 250) Destination Inspection / Destination Acceptance Inspect and Accept at place of destination Invoice and Receiving Report (Combo) - Destination Inspection / Destination Acceptance	
Pay DoDAAC	Insert Upon Award
IssueBy DoDAAC	W911QY
Admin DoDAAC	W911QY
InspectBy DoDAAC	W81XAG
Ship To Code	W81XAG

(c) The contractor shall submit invoices / cost vouchers for payment per contract terms.

(d) The Government shall process invoices / cost vouchers for payment per contract terms.

(e) For each invoice / cost voucher submitted for payment, the contractor shall also email the WAWF automated invoice notice directly to the following points of contact:

Name	Email	Phone	Job Title
Peter Bureau	peter.bureau@usmc.mil	410 617 2401	Contracting Officer's Representative
Peter Wallace	peter.wallace@us.army.mil	508 233 6139	Contracting Officer
Jean Greenwood	jean.greenwood@us.army.mil	508 233 6187	Contract Specialist

Section H - Special Contract Requirements

CLAUSES INCORPORATED BY FULL TEXT

52.234-4 EARNED VALUE MANAGEMENT SYSTEM (JUL 2006)

(a) The Contractor shall use an earned value management system (EVMS) that has been determined by the Cognizant Federal Agency (CFA) to be compliant with the guidelines in ANSI/EIA Standard - 748 (current version at the time of award) to manage this contract. If the Contractor's current EVMS has not been determined compliant at the time of award, see paragraph (b) of this clause. The Contractor shall submit reports in accordance with the requirements of this contract.

(b) If, at the time of award, the Contractor's EVM System has not been determined by the CFA as complying with EVMS guidelines or the Contractor does not have an existing cost/schedule control system that is compliant with the guidelines in ANSI/EIA Standard - 748 (current version at time of award), the Contractor shall--

(1) Apply the current system to the contract; and

(2) Take necessary actions to meet the milestones in the Contractor's EVMS plan approved by the Contracting Officer.

(c) The Government will conduct an Integrated Baseline Review (IBR). If a pre-award IBR has not been conducted, a post award IBR shall be conducted as early as practicable after contract award.

(d) The Contracting Officer may require an IBR at--

(1) Exercise of significant options; or

(2) Incorporation of major modifications.

(e) Unless a waiver is granted by the CFA, Contractor proposed EVMS changes require approval of the CFA prior to implementation. The CFA will advise the Contractor of the acceptability of such changes within 30 calendar days after receipt of the notice of proposed changes from the Contractor. If the advance approval requirements are waived by the CFA, the Contractor shall disclose EVMS changes to the CFA at least 14 calendar days prior to the effective date of implementation.

(f) The Contractor shall provide access to all pertinent records and data requested by the Contracting Officer or a duly authorized representative as necessary to permit Government surveillance to ensure that the EVMS conforms, and continues to conform, with the performance criteria referenced in paragraph (a) of this clause.

(g) The Contractor shall require the subcontractors specified below to comply with the requirements of this clause: (Insert list of applicable subcontractors.)

To be filled-in at time of award.

(End of clause)

CLAUSES INCORPORATED BY FULL TEXT

252.234-7002 EARNED VALUE MANAGEMENT SYSTEM (MAY 2011)

(a) Definitions. As used in this clause--

Acceptable earned value management system means an earned value management system that generally complies with system criteria in paragraph (b) of this clause.

Earned value management system means an earned value management system that complies with the earned value management system guidelines in the ANSI/EIA-748.

Significant deficiency means a shortcoming in the system that materially affects the ability of officials of the Department of Defense to rely upon information produced by the system that is needed for management purposes.

(b) System criteria. In the performance of this contract, the Contractor shall use--

(1) An Earned Value Management System (EVMS) that complies with the EVMS guidelines in the American National Standards Institute/Electronic Industries Alliance Standard 748, Earned Value Management Systems (ANSI/EIA-748); and

(2) Management procedures that provide for generation of timely, reliable, and verifiable information for the Contract Performance Report (CPR) and the Integrated Master Schedule (IMS) required by the CPR and IMS data items of this contract.

(c) If this contract has a value of $50 million or more, the Contractor shall use an EVMS that has been determined to be acceptable by the Cognizant Federal Agency (CFA). If, at the time of award, the Contractor's EVMS has not been determined by the CFA to be in compliance with the EVMS guidelines as stated in paragraph (b)(1) of this clause, the Contractor shall apply its current system to the contract and shall take necessary actions to meet the milestones in the Contractor's EVMS plan.

(d) If this contract has a value of less than $50 million, the Government will not make a formal determination that the Contractor's EVMS complies with the EVMS guidelines in ANSI/EIA-748 with respect to the contract. The use of the Contractor's EVMS for this contract does not imply a Government determination of the Contractor's compliance with the EVMS guidelines in ANSI/EIA-748 for application to future contracts. The Government will allow the use of a Contractor's EVMS that has been formally reviewed and determined by the CFA to be in compliance with the EVMS guidelines in ANSI/EIA-748.

(e) The Contractor shall submit notification of any proposed substantive changes to the EVMS procedures and the impact of those changes to the CFA. If this contract has a value of $50 million or more, unless a waiver is granted by the CFA, any EVMS changes proposed by the Contractor require approval of the CFA prior to implementation. The CFA will advise the Contractor of the acceptability of such changes as soon as practicable (generally within 30 calendar days) after receipt of the Contractor's notice of proposed changes. If the CFA waives the advance approval requirements, the Contractor shall disclose EVMS changes to the CFA at least 14 calendar days prior to the effective date of implementation.

(f) The Government will schedule integrated baseline reviews as early as practicable, and the review process will be conducted not later than 180 calendar days after--

(1) Contract award;

(2) The exercise of significant contract options; and

(3) The incorporation of major modifications.

During such reviews, the Government and the Contractor will jointly assess the Contractor's baseline to be used for performance measurement to ensure complete coverage of the statement of work, logical scheduling of the work activities, adequate resourcing, and identification of inherent risks.

(g) The Contractor shall provide access to all pertinent records and data requested by the Contracting Officer or duly authorized representative as necessary to permit Government surveillance to ensure that the EVMS complies, and continues to comply, with the performance criteria referenced in paragraph (b) of this clause.

(h) When indicated by contract performance, the Contractor shall submit a request for approval to initiate an over-target baseline or over-target schedule to the Contracting Officer. The request shall include a top-level projection of cost and/or schedule growth, a determination of whether or not performance variances will be retained, and a schedule of implementation for the rebaselining. The Government will acknowledge receipt of the request in a timely manner (generally within 30 calendar days).

(i) Significant deficiencies.

(1) The Contracting Officer will provide an initial determination to the contractor, in writing, on any significant deficiencies. The initial determination will describe the deficiency in sufficient detail to allow the Contractor to understand the deficiency.

(2) The Contractor shall respond within 30 days to a written initial determination from the Contracting Officer that identifies significant deficiencies in the Contractor's EVMS. If the Contractor disagrees with the initial determination, the Contractor shall state, in writing, its rationale for disagreeing.

(3) The Contracting Officer will evaluate the Contractor's response and notify the Contractor, in writing, of the Contracting Officer's final determination concerning--

(i) Remaining significant deficiencies;

(ii) The adequacy of any proposed or completed corrective action;

(iii) System noncompliance, when the Contractor's existing EVMS fails to comply with the earned value management system guidelines in the ANSI/EIA-748; and

(iv) System disapproval, if initial EVMS validation is not successfully completed within the timeframe approved by the Contracting Officer, or if the Contracting Officer determines that the Contractor's earned value management system contains one or more significant deficiencies in high-risk guidelines in ANSI/EIA-748 standards (guidelines 1, 3, 6, 7, 8, 9, 10, 12, 16, 21, 23, 26, 27, 28, 30, or 32). When the Contracting Officer determines that the existing earned value management system contains one or more
significant deficiencies in one or more of the remaining 16 guidelines in ANSI/EIA-748 standards, the contracting officer will use discretion to disapprove the system based on input received from functional specialists and the auditor.

(4) If the Contractor receives the Contracting Officer's final determination of significant deficiencies, the Contractor shall, within 45 days of receipt of the final determination, either correct the significant deficiencies or submit an acceptable corrective action plan showing milestones and actions to eliminate the
significant deficiencies.

(j) Withholding payments. If the Contracting Officer makes a final determination to disapprove the Contractor's EVMS, and the contract includes the clause at 252.242-7005, Contractor Business Systems, the Contracting Officer will withhold payments in accordance with that clause.

(k) With the exception of paragraphs (i) and (j) of this clause, the Contractor shall require its ubcontractors to comply with EVMS requirements as follows:

(1) For subcontracts valued at $50 million or more, the following subcontractors shall comply with the requirements of this clause:

[Contracting Officer to insert names of subcontractors (or subcontracted effort if subcontractors have not been selected) designated for application of the EVMS requirements of this clause.]

To be filled-in at time of award.

(2) For subcontracts valued at less than $50 million, the following subcontractors shall comply with the requirements of this clause, excluding the requirements of paragraph (c) of this clause:

[Contracting Officer to insert names of subcontractors (or subcontracted effort if subcontractors have not been selected) designated for application of the EVMS requirements of this clause.]

To be filled-in at time of award.

(End of clause)

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, posses, 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, posses, 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 I - Contract Clauses

CLAUSES INCORPORATED BY REFERENCE

252.225-7036	Buy American--Free Trade Agreement--Balance of Payments Program	OCT 2011
252.225-7001	Buy American Act And Balance Of Payments Program	OCT 2011
252.219-7003	Small Business Subcontracting Plan (DOD Contracts)	OCT 2010
52.202-1	Definitions	JUL 2004
52.203-3	Gratuities	APR 1984
52.203-5	Covenant Against Contingent Fees	APR 1984
52.203-6	Restrictions On Subcontractor Sales To The Government	SEP 2006
52.203-7	Anti-Kickback Procedures	OCT 2010
52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity	JAN 1997
52.203-10	Price Or Fee Adjustment For Illegal Or Improper Activity	JAN 1997
52.203-12	Limitation On Payments To Influence Certain Federal Transactions	OCT 2010
52.203-13	Contractor Code of Business Ethics and Conduct	APR 2010
52.204-2	Security Requirements	AUG 1996
52.204-4	Printed or Copied Double-Sided on Recycled Paper	AUG 2000
52.204-7	Central Contractor Registration	APR 2008
52.204-9	Personal Identity Verification of Contractor Personnel	JAN 2011
52.204-10	Reporting Executive Compensation and First-Tier Subcontract Awards	JUL 2010
52.209-6	Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment	DEC 2010
52.210-1	Market Research	APR 2011
52.215-2	Audit and Records--Negotiation	OCT 2010
52.215-8	Order of Precedence--Uniform Contract Format	OCT 1997
52.215-10	Price Reduction for Defective Certified Cost or Pricing Data	OCT 2010
52.215-11	Price Reduction for Defective Certified Cost or Pricing Data--Modifications	OCT 2010
52.215-12	Subcontractor Certified Cost or Pricing Data	OCT 2010
52.215-13	Subcontractor Certified Cost or Pricing Data--Modifications	OCT 2010
52.215-14	Integrity of Unit Prices	OCT 2010
52.215-15	Pension Adjustments and Asset Reversions	OCT 2010
52.215-18	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) Other than Pensions	JUL 2005
52.215-19	Notification of Ownership Changes	OCT 1997
52.215-21 Alt III	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data--Modifications (Oct 2010) - Alternate III	OCT 1997
52.215-23 Alt I	Limitations on Pass-Through Charges	OCT 2009
52.216-8	Fixed Fee	JUN 2011
52.216-15	Predetermined Indirect Cost Rates	APR 1998
52.219-4	Notice of Price Evaluation Preference for HUBZone Small Business Concerns	JAN 2011
52.219-8	Utilization of Small Business Concerns	JAN 2011
52.219-9 Alt II	(INVALID EFF_DT) Small Business Subcontracting Plan (JAN 2011) Alternate II	DEC 1900
52.219-16	Liquidated Damages-Subcontracting Plan	JAN 1999

52.219-24	Small Disadvantaged Business Participation Program--Targets	OCT 2000
52.219-24	Small Disadvantaged Business Participation Program--Targets	OCT 2000
52.219-25	Small Disadvantaged Business Participation Program--Disadvantaged Status and Reporting	DEC 2010
52.222-1	Notice To The Government Of Labor Disputes	FEB 1997
52.222-20	Walsh-Healey Public Contracts Act	OCT 2010
52.222-21	Prohibition Of Segregated Facilities	FEB 1999
52.222-26	Equal Opportunity	MAR 2007
52.222-35	Equal Opportunity for Veterans	SEP 2010
52.222-36	Affirmative Action For Workers With Disabilities	OCT 2010
52.222-37	Employment Reports on Veterans	SEP 2010
52.222-50	Combating Trafficking in Persons	FEB 2009
52.222-54	Employment Eligibility Verification	JAN 2009
52.223-3	Hazardous Material Identification And Material Safety Data	JAN 1997
52.223-6	Drug-Free Workplace	MAY 2001
52.223-15	Energy Efficiency in Energy-Consuming Products	DEC 2007
52.223-17	Affirmative Procurement of EPA-Designated Items in Service and Construction Contracts	MAY 2008
52.223-18	Contractor Policy to Ban Text Messaging While Driving	SEP 2010
52.225-1	Buy American Act--Supplies	FEB 2009
52.225-13	Restrictions on Certain Foreign Purchases	JUN 2008
52.225-25	Prohibition on Engaging in Sanctioned Activities Relating to Iran--Certification.	SEP 2010
52.226-1	Utilization Of Indian Organizations And Indian-Owned Economic Enterprises	JUN 2000
52.227-1 Alt I	Authorization And Consent (Dec 2007) - Alternate I	APR 1984
52.227-2	Notice And Assistance Regarding Patent And Copyright Infringement	DEC 2007
52.227-10	Filing Of Patent Applications--Classified Subject Matter	DEC 2007
52.228-7	Insurance--Liability To Third Persons	MAR 1996
52.229-3	Federal, State And Local Taxes	APR 2003
52.230-2	Cost Accounting Standards	OCT 2010
52.230-5	Cost Accounting Standards--Educational Institutions	OCT 2010
52.230-6	Administration of Cost Accounting Standards	JUN 2010
52.232-17	Interest	OCT 2010
52.232-18	Availability Of Funds	APR 1984
52.232-22	Limitation Of Funds	APR 1984
52.232-23	Assignment Of Claims	JAN 1986
52.232-25 Alt I	Prompt Payment (Oct 2008) Alternate I	FEB 2002
52.232-33	Payment by Electronic Funds Transfer--Central Contractor Registration	OCT 2003
52.233-1 Alt I	Disputes (Jul 2002) - Alternate I	DEC 1991
52.233-3 Alt I	Protest After Award (Aug 1996) - Alternate I	JUN 1985
52.233-4	Applicable Law for Breach of Contract Claim	OCT 2004
52.237-3	Continuity Of Services	JAN 1991
52.242-1	Notice of Intent to Disallow Costs	APR 1984
52.242-2	Production Progress Reports	APR 1991
52.242-3	Penalties for Unallowable Costs	MAY 2001
52.242-4	Certification of Final Indirect Costs	JAN 1997
52.242-13	Bankruptcy	JUL 1995
52.243-6	Change Order Accounting	APR 1984
52.244-5	Competition In Subcontracting	DEC 1996

52.244-6	Subcontracts for Commercial Items	DEC 2010
52.245-1	Government Property	AUG 2010
52.246-23	Limitation Of Liability	FEB 1997
52.246-25	Limitation Of Liability--Services	FEB 1997
52.247-63	Preference For U.S. Flag Air Carriers	JUN 2003
52.247-64	Preference for Privately Owned U.S. - Flag Commercial Vessels	FEB 2006
52.249-5	Termination For Convenience Of The Government (Educational And Other Nonprofit Institutions)	SEP 1996
52.249-6	Termination (Cost Reimbursement)	MAY 2004
52.249-14	Excusable Delays	APR 1984
52.253-1	Computer Generated Forms	JAN 1991
252.201-7000	Contracting Officer's Representative	DEC 1991
252.203-7000	Requirements Relating to Compensation of Former DoD Officials	JAN 2009
252.203-7001	Prohibition On Persons Convicted of Fraud or Other Defense-Contract-Related Felonies	DEC 2008
252.203-7002	Requirement to Inform Employees of Whistleblower Rights	JAN 2009
252.203-7003	Agency Office of the Inspector General	SEP 2010
252.204-0002	Line Item Specific: Sequential ACRN Order	SEP 2009
252.204-0005	Line Item Specific: by Cancellation Date	SEP 2009
252.204-7000	Disclosure Of Information	DEC 1991
252.204-7003	Control Of Government Personnel Work Product	APR 1992
252.204-7004 Alt A	Central Contractor Registration (52.204-7) Alternate A	SEP 2007
252.204-7008	Export-Controlled Items	APR 2010
252.209-7001	Disclosure of Ownership or Control by the Government of a Terrorist Country	JAN 2009
252.209-7002	Disclosure Of Ownership Or Control By A Foreign Government	JUN 2010
252.209-7004	Subcontracting With Firms That Are Owned or Controlled By The Government of a Terrorist Country	DEC 2006
252.209-7005	Reserve Officer Training Corps and Military Recruiting on Campus	JAN 2000
252.209-7009	Organizational Conflict of Interest--Major Defense Acquisition Program	DEC 2010
252.211-7007	Reporting of Government-Furnished Equipment in the DoD Item Unique Identification (IUID) Registry	NOV 2008
252.211-7008	Use of Government-Assigned Serial Numbers	SEP 2010
252.215-7000	Pricing Adjustments	DEC 1991
252.215-7002	Cost Estimating System Requirements	DEC 2006
252.223-7004	Drug Free Work Force	SEP 1988
252.223-7008	Prohibition of Hexavalent Chromium	MAY 2011
252.225-7003	Report of Intended Performance Outside the United States and Canada--Submission with Offer	OCT 2010
252.225-7004	Report of Intended Performance Outside the United States and Canada--Submission after Award	OCT 2010
252.225-7006	Quarterly Reporting of Actual Contract Performance Outside the United States	OCT 2010
252.225-7012	Preference For Certain Domestic Commodities	JUN 2010
252.225-7013	Duty-Free Entry	DEC 2009
252.225-7031	Secondary Arab Boycott Of Israel	JUN 2005
252.225-7032	Waiver Of United Kingdom Levies--Evaluation of Offers	APR 2003
252.225-7033	Waiver of United Kingdom Levies	APR 2003

252.226-7001	Utilization of Indian Organizations and Indian-Owned Economic Enterprises, and Native Hawaiian Small Business Concerns	SEP 2004
252.227-7000	Non-estoppel	OCT 1966
252.227-7016	Rights in Bid or Proposal Information	JAN 2011
252.227-7020	Rights In Special Works	JUN 1995
252.227-7024	Notice and Approval of Restricted Designs	APR 1984
252.227-7025	Limitations on the Use or Disclosure of Government-Furnished Information Marked with Restrictive Legends	MAR 2011
252.227-7027	Deferred Ordering Of Technical Data Or Computer Software	APR 1988
252.227-7037	Validation of Restrictive Markings on Technical Data	SEP 1999
252.227-7038	Patent Rights--Ownership by the Contractor (Large Business)	DEC 2007
252.227-7039	Patents--Reporting Of Subject Inventions	APR 1990
252.231-7000	Supplemental Cost Principles	DEC 1991
252.232-7003	Electronic Submission of Payment Requests and Receiving Reports	MAR 2008
252.232-7010	Levies on Contract Payments	DEC 2006
252.235-7002	Animal Welfare	DEC 1991
252.235-7004	Protection of Human Subjects	JUL 2009
252.235-7010	Acknowledgment of Support and Disclaimer	MAY 1995
252.235-7011	Final Scientific or Technical Report	NOV 2004
252.236-7000	Modification Proposals-Price Breakdown	DEC 1991
252.242-7004	Material Management And Accounting System	MAY 2011
252.242-7005	Contractor Business Systems	MAY 2011
252.242-7006	Accounting System Administration	MAY 2011
252.243-7002	Requests for Equitable Adjustment	MAR 1998
252.244-7000	Subcontracts for Commercial Items and Commercial Components (DoD Contracts)	NOV 2010
252.245-7001	Tagging, Labeling, and Marking of Government-Furnished Property	FEB 2011
252.245-7002	Reporting Loss of Government Property	FEB 2011
252.245-7003	Contractor Property Management System Administration	MAY 2011
252.247-7015 Alt I	Requirements Alternate I	DEC 1991
252.247-7024	Notification Of Transportation Of Supplies By Sea	MAR 2000

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52.203-14 DISPLAY OF HOTLINE POSTER(S) (DEC 2007)

(a) Definition.

United States, as used in this clause, means the 50 States, the District of Columbia, and outlying areas.

(b) Display of fraud hotline poster(s). Except as provided in paragraph (c)--

(1) During contract performance in the United States, the Contractor shall prominently display in common work areas within business segments performing work under this contract and at contract work sites--

(i) Any agency fraud hotline poster or Department of Homeland Security (DHS) fraud hotline poster identified in paragraph (b)(3) of this clause; and

(ii) Any DHS fraud hotline poster subsequently identified by the Contracting Officer.

(2) Additionally, if the Contractor maintains a company website as a method of providing information to employees, the Contractor shall display an electronic version of the poster(s) at the website.

(3) Any required posters may be obtained as follows:

Poster(s) Obtain from:

DoD Inspector General
ATTN: Defense Hotline
400 Army Navy Drive, Arlington, VA 22202-4704

(c) If the Contractor has implemented a business ethics and conduct awareness program, including a reporting mechanism, such as a hotline poster, then the Contractor need not display any agency fraud hotline posters as required in paragraph (b) of this clause, other than any required DHS posters.

(d) Subcontracts. The Contractor shall include the substance of this clause, including this paragraph (d), in all subcontracts that exceed $5,000,000, except when the subcontract--

(1) Is for the acquisition of a commercial item; or

(2) Is performed entirely outside the United States.

(End of clause)

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52.209-9 Updates of Publicly Available Information Regarding Responsibility Matters (JAN 2011)
(a) The Contractor shall update the information in the Federal Awardee Performance and Integrity Information System (FAPIIS) on a semi-annual basis, throughout the life of the contract, by posting the required information in the Central Contractor Registration database at http://www.ccr.gov.

(b)(1) The Contractor will receive notification when the Government posts new information to the Contractor's record.

(2) The Contractor will have an opportunity to post comments regarding information that has been posted by the Government. The comments will be retained as long as the associated information is retained, i.e., for a total period of 6 years. Contractor comments will remain a part of the record unless the Contractor revises them.

(3)(i) Public requests for system information posted prior to April 15, 2011, will be handled under Freedom of Information Act procedures, including, where appropriate, procedures promulgated under E.O. 12600.

(ii) As required by section 3010 of Public Law 111-212, all information posted in FAPIIS on or after April 15, 2011, except past performance reviews, will be publicly available.

(End of clause)

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52.211-14 NOTICE OF PRIORITY RATING FOR NATIONAL DEFENSE, EMERGENCY PREPAREDNESS, AND ENERGY PROGRAM USE (APR 2008)

Any contract awarded as a result of this solicitation will be [ ] DX rated order; [X] DO rated order certified for national defense, emergency preparedness, and energy program use under the Defense Priorities and Allocations System (DPAS) (15 CFR 700), and the Contractor will be required to follow all of the requirements of this regulation.

(End of provision)

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52.216-7 ALLOWABLE COST AND PAYMENT (JUN 2011)

(a) Invoicing.

(1) The Government will make payments to the Contractor when requested as work progresses, but (except for small business concerns) not more often than once every 2 weeks, in amounts determined to be allowable by the Contracting Officer in accordance with Federal Acquisition Regulation (FAR) subpart 31.2 in effect on the date of this contract and the terms of this contract. The Contractor may submit to an authorized representative of the Contracting Officer, in such form and reasonable detail as the representative may require, an invoice or voucher supported by a statement of the claimed allowable cost for performing this contract.

(2) Contract financing payments are not subject to the interest penalty provisions of the Prompt Payment Act. Interim payments made prior to the final payment under the contract are contract financing payments, except interim payments if this contract contains Alternate I to the clause at 52.232-25.

(3) The designated payment office will make interim payments for contract financing on the 30th day after the designated billing office receives a proper payment request.

In the event that the Government requires an audit or other review of a specific payment request to ensure compliance with the terms and conditions of the contract, the designated payment office is not compelled to make payment by the specified due date.

(b) Reimbursing costs. (1) For the purpose of reimbursing allowable costs (except as provided in subparagraph (b)(2) of the clause, with respect to pension, deferred profit sharing, and employee stock ownership plan contributions), the term "costs" includes only--

(i) Those recorded costs that, at the time of the request for reimbursement, the Contractor has paid by cash, check, or other form of actual payment for items or services purchased directly for the contract;

(ii) When the Contractor is not delinquent in paying costs of contract performance in the ordinary course of business, costs incurred, but not necessarily paid, for--

(A) Supplies and services purchased directly for the contract and associated financing payments to subcontractors, provided payments determined due will be made--

(1) In accordance with the terms and conditions of a subcontract or invoice; and

(2) Ordinarily within 30 days of the submission of the Contractor's payment request to the Government;

(B) Materials issued from the Contractor's inventory and placed in the production process for use on the contract;

(C) Direct labor;

(D) Direct travel;

(E) Other direct in-house costs; and

(F) Properly allocable and allowable indirect costs, as shown in the records maintained by the Contractor for purposes of obtaining reimbursement under Government contracts; and

(iii) The amount of financing payments that have been paid by cash, check, or other forms of payment to subcontractors.

(2) Accrued costs of Contractor contributions under employee pension plans shall be excluded until actually paid unless--

(i) The Contractor's practice is to make contributions to the retirement fund quarterly or more frequently; and

(ii) The contribution does not remain unpaid 30 days after the end of the applicable quarter or shorter payment period (any contribution remaining unpaid shall be excluded from the Contractor's indirect costs for payment purposes).

(3) Notwithstanding the audit and adjustment of invoices or vouchers under paragraph (g) of this clause, allowable indirect costs under this contract shall be obtained by applying indirect cost rates established in accordance with paragraph (d) of this clause.

(4) Any statements in specifications or other documents incorporated in this contract by reference designating performance of services or furnishing of materials at the Contractor's expense or at no cost to the Government shall be disregarded for purposes of cost-reimbursement under this clause.

(c) Small business concerns. A small business concern may receive more frequent payments than every 2 weeks.

(d) Final indirect cost rates. (1) Final annual indirect cost rates and the appropriate bases shall be established in accordance with Subpart 42.7 of the Federal Acquisition Regulation (FAR) in effect for the period covered by the indirect cost rate proposal.

(2)(i) The Contractor shall submit an adequate final indirect cost rate proposal to the Contracting Officer (or cognizant Federal agency official) and auditor within the 6-month period following the expiration of each of its fiscal years. Reasonable extensions, for exceptional circumstances only, may be requested in writing by the Contractor and granted in writing by the Contracting Officer. The Contractor shall support its proposal with adequate supporting data.

(ii) The proposed rates shall be based on the Contractor's actual cost experience for that period. The appropriate Government representative and the Contractor shall establish the final indirect cost rates as promptly as practical after receipt of the Contractor's proposal.

(iii) An adequate indirect cost rate proposal shall include the following data unless otherwise specified by the cognizant Federal agency official:

(A) Summary of all claimed indirect expense rates, including pool, base, and calculated indirect rate.

(B) General and Administrative expenses (final indirect cost pool). Schedule of claimed expenses by element of cost as identified in accounting records (Chart of Accounts).

(C) Overhead expenses (final indirect cost pool). Schedule of claimed expenses by element of cost as identified in accounting records (Chart of Accounts) for each final indirect cost pool.

(D) Occupancy expenses (intermediate indirect cost pool). Schedule of claimed expenses by element of cost as identified in accounting records (Chart of Accounts) and expense reallocation to final indirect cost pools.

(E) Claimed allocation bases, by element of cost, used to distribute indirect costs.

(F) Facilities capital cost of money factors computation.

(G) Reconciliation of books of account (i.e., General Ledger) and claimed direct costs by major cost element.

(H) Schedule of direct costs by contract and subcontract and indirect expense applied at claimed rates, as well as a subsidiary schedule of Government participation percentages in each of the allocation base amounts.

(I) Schedule of cumulative direct and indirect costs claimed and billed by contract and subcontract.

(J) Subcontract information. Listing of subcontracts awarded to companies for which the contractor is the prime or upper-tier contractor (include prime and subcontract numbers; subcontract value and award type; amount claimed during the fiscal year; and the subcontractor name, address, and point of contact information).

(K) Summary of each time-and-materials and labor-hour contract information, including labor ategories, labor rates, hours, and amounts; direct materials; other direct costs; and, indirect expense applied at claimed rates.

(L) Reconciliation of total payroll per IRS form 941 to total labor costs distribution.

(M) Listing of decisions/agreements/approvals and description of accounting/organizational changes.

(N) Certificate of final indirect costs (see 52.242-4,
Certification of Final Indirect Costs).

(O) Contract closing information for contracts physically completed in this fiscal year (include contract number, period of performance, contract ceiling amounts, contract fee computations, level of effort, and indicate if the contract is ready to close).

(iv) The following supplemental information is not required to determine if a proposal is adequate, but may be required during the audit process:

(A) Comparative analysis of indirect expense pools detailed by account to prior fiscal year and budgetary data.

(B) General Organizational information and Executive compensation for the five most highly compensated executives. See 31.205-6(p). Additional salary reference information is available at http://www.whitehouse.gov/omb/procurement_index_exec_comp/.

(C) Identification of prime contracts under which the contractor performs as a subcontractor.

(D) Description of accounting system (excludes contractors required to submit a CAS Disclosure Statement or contractors where the description of the accounting system has not changed from the previous year's submission).

(E) Procedures for identifying and excluding unallowable costs from the costs claimed and billed (excludes contractors where the procedures have not changed from the previous year's submission).

(F) Certified financial statements and other financial data (e.g., trial balance, compilation, review, etc.).

(G) Management letter from outside CPAs concerning any internal control weaknesses.

(H) Actions that have been and/or will be implemented to correct the weaknesses described in the management letter from subparagraph G) of this section.

(I) List of all internal audit reports issued since the last disclosure of internal audit reports to the Government.

(J) Annual internal audit plan of scheduled audits to be performed in the fiscal year when the final indirect cost rate submission is made.

(K) Federal and State income tax returns.

(L) Securities and Exchange Commission 10-K annual report.

(M) Minutes from board of directors meetings.

(N) Listing of delay claims and termination claims submitted which contain costs relating to the subject fiscal year.

(O) Contract briefings, which generally include a synopsis of all pertinent contract provisions, such as: Contract type, contract amount, product or service(s) to be provided, contract performance period, rate ceilings, advance approval requirements, pre-contract cost allowability limitations, and billing limitations.

(v) The Contractor shall update the billings on all contracts to reflect the final settled rates and update the schedule of cumulative direct and indirect costs claimed and billed, as required in paragraph (d)(2)(iii)(I) of this section, within 60 days after settlement of final indirect cost rates.

(3) The Contractor and the appropriate Government representative shall execute a written understanding setting forth the final indirect cost rates. The understanding shall specify (i) the agreed-upon final annual indirect cost rates, (ii) the bases to which the rates apply, (iii) the periods for which the rates apply, (iv) any specific indirect cost items treated as direct costs in the settlement, and (v) the affected contract and/or subcontract, identifying any with advance agreements or special terms and the applicable rates. The understanding shall not change any monetary ceiling, contract obligation, or specific cost allowance or disallowance provided for in this contract. The understanding is incorporated into this contract upon execution.

(4) Failure by the parties to agree on a final annual indirect cost rate shall be a dispute within the meaning of the Disputes clause.

(5) Within 120 days (or longer period if approved in writing by the Contracting Officer) after settlement of the final annual indirect cost rates for all years of a physically complete contract, the Contractor shall submit a completion invoice or voucher to reflect the settled amounts and rates. The completion invoice or voucher shall include settled subcontract amounts and rates. The prime contractor is responsible for settling subcontractor amounts and rates included in the completion invoice or voucher and providing status of subcontractor audits to the contracting officer upon request.

(6)(i) If the Contractor fails to submit a completion invoice or voucher within the time specified in paragraph (d)(5) of this clause, the Contracting Officer may--

(A) Determine the amounts due to the Contractor under the contract; and

(B) Record this determination in a unilateral modification to the contract.

(ii) This determination constitutes the final decision of the Contracting Officer in accordance with the Disputes clause.

(e) Billing rates. Until final annual indirect cost rates are established for any period, the Government shall reimburse the Contractor at billing rates established by the Contracting Officer or by an authorized representative (the cognizant auditor), subject to adjustment when the final rates are established. These billing rates--

(1) Shall be the anticipated final rates; and

(2) May be prospectively or retroactively revised by mutual agreement, at either party's request, to prevent substantial overpayment or underpayment.

(f) Quick-closeout procedures. Quick-closeout procedures are applicable when the conditions in FAR 42.708(a) are satisfied.

(g) Audit. At any time or times before final payment, the Contracting Officer may have the Contractor's invoices or vouchers and statements of cost audited. Any payment may be (1) Reduced by amounts found by the Contracting Officer not to constitute allowable costs or (2) Adjusted for prior overpayments or underpayments.

(h) Final payment. (1) Upon approval of a completion invoice or voucher submitted by the Contractor in accordance with paragraph (d)(4) of this clause, and upon the Contractor's compliance with all terms of this contract, the Government shall promptly pay any balance of allowable costs and that part of the fee (if any) not previously paid.

(2) The Contractor shall pay to the Government any refunds, rebates, credits, or other amounts (including interest, if any) accruing to or received by the Contractor or any assignee under this contract, to the extent that those amounts are properly allocable to costs for which the Contractor has been reimbursed by the Government. Reasonable expenses incurred by the Contractor for securing refunds, rebates, credits, or other amounts shall be allowable costs if approved by the Contracting Officer. Before final payment under this contract, the Contractor and each assignee whose assignment is in effect at the time of final payment shall execute and deliver--

(i) An assignment to the Government, in form and substance satisfactory to the Contracting Officer, of refunds, rebates, credits, or other amounts (including interest, if any) properly allocable to costs for which the Contractor has been reimbursed by the Government under this contract; and

(ii) A release discharging the Government, its officers, agents, and employees from all liabilities, obligations, and claims arising out of or under this contract, except--

(A) Specified claims stated in exact amounts, or in estimated amounts when the exact amounts are not known;

(B) Claims (including reasonable incidental expenses) based upon liabilities of the Contractor to third parties arising out of the performance of this contract; provided, that the claims are not known to the Contractor on the date of the execution of the release, and that the Contractor gives notice of the claims in writing to the Contracting Officer within 6 years following the release date or notice of final payment date, whichever is earlier; and

(C) Claims for reimbursement of costs, including reasonable incidental expenses, incurred by the Contractor under the patent clauses of this contract, excluding, however, any expenses arising from the Contractor's indemnification of the Government against patent liability.

(End of clause)

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52.219-28 POST-AWARD SMALL BUSINESS PROGRAM REREPRESENTATION (APR 2009)

(a) Definitions. As used in this clause--

Long-term contract means a contract of more than five years in duration, including options. However, the term does not include contracts that exceed five years in duration because the period of performance has been extended for a cumulative period not to exceed six months under the clause at 52.217-8, Option to Extend Services, or other appropriate authority.

Small business concern means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR part 121 and the size standard in paragraph (c) of this clause. Such a concern is ``not dominant in its field of operation'' when it does not exercise a controlling or major influence on a national basis in a kind of business activity in which a number of business concerns are primarily engaged. In determining whether dominance exists, consideration shall be given to all appropriate factors, including volume of business, number of employees, financial resources, competitive status or position, ownership or control of materials, processes, patents, license agreements, facilities, sales territory, and nature of business activity.

(b) If the Contractor represented that it was a small business concern prior to award of this contract, the Contractor shall rerepresent its size status according to paragraph (e) of this clause or, if applicable, paragraph (g) of this clause, upon the occurrence of any of the following:

(1) Within 30 days after execution of a novation agreement or within 30 days after modification of the contract to include this clause, if the novation agreement was executed prior to inclusion of this clause in the contract.

(2) Within 30 days after a merger or acquisition that does not require a novation or within 30 days after modification of the contract to include this clause, if the merger or acquisition occurred prior to inclusion of this clause in the contract.

(3) For long-term contracts--

(i) Within 60 to 120 days prior to the end of the fifth year of the contract; and

(ii) Within 60 to 120 days prior to the date specified in the contract for exercising any option thereafter.

(c) The Contractor shall rerepresent its size status in accordance with the size standard in effect at the time of this rerepresentation that corresponds to the North American Industry Classification System (NAICS) code assigned to this contract. The small business size standard corresponding to this NAICS code can be found at http://www.sba.gov/services/contractingopportunities/sizestandardstopics/.

(d) The small business size standard for a Contractor providing a product which it does not manufacture itself, for a contract other than a construction or service contract, is 500 employees.

(e) Except as provided in paragraph (g) of this clause, the Contractor shall make the rerepresentation required by paragraph (b) of this clause by validating or updating all its representations in the Online Representations and Certifications Application and its data in the Central Contractor Registration, as necessary, to ensure that they reflect the Contractor's current status. The Contractor shall notify the contracting office in writing within the timeframes specified in paragraph (b) of this clause that the data have been validated or updated, and provide the date of the validation or update.

(f) If the Contractor represented that it was other than a small business concern prior to award of this contract, the Contractor may, but is not required to, take the actions required by paragraphs (e) or (g) of this clause.

(g) If the Contractor does not have representations and certifications in ORCA, or does not have a representation in ORCA for the NAICS code applicable to this contract, the Contractor is required to complete the following rerepresentation and submit it to the contracting office, along with the contract number and the date on which the rerepresentation was completed:

The Contractor represents that it ( ) is, ( ) is not a small business concern under NAICS Code 325412- assigned to contract number .

(Contractor to sign and date and insert authorized signer's name and title).

(End of clause)

CLAUSES INCORPORATED BY FULL TEXT

52.222-2 PAYMENT FOR OVERTIME PREMIUMS (JUL 1990)

(a) The use of overtime is authorized under this contract if the overtime premium cost does not exceed ZERO or the overtime premium is paid for work --

(1) Necessary to cope with emergencies such as those resulting from accidents, natural disasters, breakdowns of production equipment, or occasional production bottlenecks of a sporadic nature;

(2) By indirect-labor employees such as those performing duties in connection with administration, protection, transportation, maintenance, standby plant protection, operation of utilities, or accounting;

(3) To perform tests, industrial processes, laboratory procedures, loading or unloading of transportation conveyances, and operations in flight or afloat that are continuous in nature and cannot reasonably be interrupted or completed otherwise; or

(4) That will result in lower overall costs to the Government.

(b) Any request for estimated overtime premiums that exceeds the amount specified above shall include all estimated overtime for contract completion and shall--

(1) Identify the work unit; e.g., department or section in which the requested overtime will be used, together with present workload, staffing, and other data of the affected unit sufficient to permit the Contracting Officer to evaluate the necessity for the overtime;

(2) Demonstrate the effect that denial of the request will have on the contract delivery or performance schedule;

(3) Identify the extent to which approval of overtime would affect the performance or payments in connection with other Government contracts, together with identification of each affected contract; and

(4) Provide reasons why the required work cannot be performed by using multishift operations or by employing additional personnel.

(End of clause)

CLAUSES INCORPORATED BY FULL TEXT

52.223-7 NOTICE OF RADIOACTIVE MATERIALS (JAN 1997)

(a) The Contractor shall notify the Contracting Officer or designee, in writing, fourteen (14) days prior to the delivery of, or prior to completion of any servicing required by this contract of, items containing either (1) radioactive material requiring specific licensing under the regulations issued pursuant to the Atomic Energy Act of 1954, as amended, as set forth in Title 10 of the Code of Federal Regulations, in effect on the date of this contract, or (2) other radioactive material not requiring specific licensing in which the specific activity is greater than 0.002 microcuries per gram or the activity per item equals or exceeds 0.01 microcuries. Such notice shall specify the part or parts of the items which contain radioactive materials, a description of the materials, the name and activity of the isotope, the manufacturer of the materials, and any other information known to the Contractor which will put users of the items on notice as to the hazards involved (OMB No. 9000-0107).

* The Contracting Officer shall insert the number of days required in advance of delivery of the item or completion of the servicing to assure that required licenses are obtained and appropriate personnel are notified to institute any necessary safety and health precautions. See FAR 23.601(d).

(b) If there has been no change affecting the quantity of activity, or the characteristics and composition of the radioactive material from deliveries under this contract or prior contracts, the Contractor may request that the Contracting Officer or designee waive the notice requirement in paragraph (a) of this clause. Any such request shall-

(1) Be submitted in writing;

(2) State that the quantity of activity, characteristics, and composition of the radioactive material have not changed; and

(3) Cite the contract number on which the prior notification was submitted and the contracting office to which it was submitted.

(c) All items, parts, or subassemblies which contain radioactive materials in which the specific activity is greater than 0.002 microcuries per gram or activity per item equals or exceeds 0.01 microcuries, and all containers in which such items, parts or subassemblies are delivered to the Government shall be clearly marked and labeled as required by the latest revision of MIL-STD 129 in effect on the date of the contract.

(d) This clause, including this paragraph (d), shall be inserted in all subcontracts for radioactive materials meeting the criteria in paragraph (a) of this clause.

(End of clause)

CLAUSES INCORPORATED BY FULL TEXT

52.223-11 OZONE-DEPLETING SUBSTANCES (MAY 2001)

(a) Definition. Ozone-depleting substance, as used in this clause, means any substance the Environmental Protection Agency designates in 40 CFR part 82 as--

(1) Class I, including, but not limited to, chlorofluorocarbons, halons, carbon tetrachloride, and methyl chloroform; or

(2) Class II, including, but not limited to, hydrochlorofluorocarbons.

(b) The Contractor shall label products which contain or are manufactured with ozone-depleting substances in the manner and to the extent required by 42 U.S.C. 7671j (b), (c), and (d) and 40 CFR Part 82, Subpart E, as follows:

“WARNING: Contains (or manufactured with, if applicable), a substance(s) which harm(s) public health and environment by destroying ozone in the upper atmosphere.”----------

The Contractor shall insert the name of the substance(s).

(End of clause)

CLAUSES INCORPORATED BY FULL TEXT

52.227-11 PATENT RIGHTS--OWNERSHIP BY THE CONTRACTOR (DEC 2007)

(a) As used in this clause--

Invention means any invention or discovery that is or may be patentable or otherwise protectable under title 35 of the U.S. Code, or any variety of plant that is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321, et seq.)

Made means--

(1) When used in relation to any invention other than a plant variety, the conception or first actual reduction to practice of the invention; or

(2) When used in relation to a plant variety, that the Contractor has at least tentatively determined that the variety has been reproduced with recognized characteristics.

Nonprofit organization means a university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)), or any nonprofit scientific or educational organization qualified under a State nonprofit organization statute.

Practical application means to manufacture, in the case of a composition of product; to practice, in the case of a process or method; or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

Subject invention means any invention of the Contractor made in the performance of work under this contract.

(b) Contractor's rights. (1) Ownership. The Contractor may retain ownership of each subject invention throughout the world in accordance with the provisions of this clause.

(2) License. (i) The Contractor shall retain a nonexclusive royalty-free license throughout the world in each subject invention to which the Government obtains title, unless the Contractor fails to disclose the invention within the times specified in paragraph (c) of this clause. The Contractor's license extends to any domestic subsidiaries and

affiliates within the corporate structure of which the Contractor is a part, and includes the right to grant sublicenses to the extent the Contractor was legally obligated to do so at contract award. The license is transferable only with the written approval of the agency, except when transferred to the successor of that part of the Contractor's business to which the invention pertains.

(ii) The Contractor's license may be revoked or modified by the agency to the extent necessary to achieve expeditious practical application of the subject invention in a particular country in accordance with the procedures in FAR 27.302(i)(2) and 27.304-1(f).

(c) Contractor's obligations. (1) The Contractor shall disclose in writing each subject invention to the Contracting Officer within 2 months after the inventor discloses it in writing to Contractor personnel responsible for patent matters. The disclosure shall identify the inventor(s) and this contract under which the subject invention was made. It shall be sufficiently complete in technical detail to convey a clear understanding of the subject invention. The disclosure shall also identify any publication, on sale (i.e., sale or offer for sale), or public use of the subject invention, or whether a manuscript describing the subject invention has been submitted for publication and, if so, whether it has been accepted for publication. In addition, after disclosure to the agency, the Contractor shall promptly notify the Contracting Officer of the acceptance of any manuscript describing the subject invention for publication and any on sale or public use.

(2) The Contractor shall elect in writing whether or not to retain ownership of any subject invention by notifying the Contracting Officer within 2 years of disclosure to the agency. However, in any case where publication, on sale, or public use has initiated the 1-year statutory period during which valid patent protection can be obtained in the United States, the period for election of title may be shortened by the agency to a date that is no more than 60 days prior to the end of the statutory period.

(3) The Contractor shall file either a provisional or a nonprovisional patent application or a Plant Variety Protection Application on an elected subject invention within 1 year after election. However, in any case where a publication, on sale, or public use has initiated the 1-year statutory period during which valid patent protection can be obtained in the United States, the Contractor shall file the application prior to the end of that statutory period. If the Contractor files a provisional application, it shall file a nonprovisional application within 10 months of the filing of the provisional application. The Contractor shall file patent applications in additional countries or international patent offices within either 10 months of the first filed patent application (whether provisional or nonprovisional) or 6 months from the date permission is granted by the Commissioner of Patents to file foreign patent applications where such filing has been prohibited by a Secrecy Order.

(4) The Contractor may request extensions of time for disclosure, election, or filing under paragraphs (c)(1), (c)(2), and (c)(3) of this clause.

(d) Government's rights--(1) Ownership. The Contractor shall assign to the agency, on written request, title to any subject invention--

(i) If the Contractor fails to disclose or elect ownership to the subject invention within the times specified in paragraph (c) of this clause, or elects not to retain ownership; provided, that the agency may request title only within 60 days after learning of the Contractor's failure to disclose or elect within the specified times.

(ii) In those countries in which the Contractor fails to file patent applications within the times specified in paragraph (c) of this clause; provided, however, that if the Contractor has filed a patent application in a country after the times specified in paragraph (c) of this clause, but prior to its receipt of the written request of the agency, the Contractor shall continue to retain ownership in that country.

(iii) In any country in which the Contractor decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceeding on, a patent on a subject invention.

(2) License. If the Contractor retains ownership of any subject invention, the Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice, or have practiced for or on its behalf, the subject invention throughout the world.

(e) Contractor action to protect the Government's interest. (1) The Contractor shall execute or have executed and promptly deliver to the agency all instruments necessary to--

(i) Establish or confirm the rights the Government has throughout the world in those subject inventions in which the Contractor elects to retain ownership; and

(ii) Assign title to the agency when requested under paragraph (d) of this clause and to enable the Government to obtain patent protection and plant variety protection for that subject invention in any country.

(2) The Contractor shall require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in the Contractor's format, each subject invention in order that the Contractor can comply with the disclosure provisions of paragraph (c) of this clause, and to execute all papers necessary to file patent applications on subject inventions and to establish the Government's rights in the subject inventions. The disclosure format should require, as a minimum, the information required by paragraph (c)(1) of this clause. The Contractor shall instruct such employees, through employee agreements or other suitable educational programs, as to the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(3) The Contractor shall notify the Contracting Officer of any decisions not to file a nonprovisional patent application, continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceeding on a patent, in any country, not less than 30 days before the expiration of the response or filing period required by the relevant patent office.

(4) The Contractor shall include, within the specification of any United States nonprovisional patent or plant variety protection application and any patent or plant variety protection certificate issuing thereon covering a subject invention, the following statement, “This invention was made with Government support under (identify the contract) awarded by (identify the agency). The Government has certain rights in the invention.”

(f) Reporting on utilization of subject inventions. The Contractor shall submit, on request, periodic reports no more frequently than annually on the utilization of a subject invention or on efforts at obtaining utilization of the subject invention that are being made by the Contractor or its licensees or assignees. The reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the Contractor, and other data and information as the agency may reasonably specify. The Contractor also shall provide additional reports as may be requested by the agency in connection with any march-in proceeding undertaken by the agency in accordance with paragraph (h) of this clause. The Contractor also shall mark any utilization report as confidential/proprietary to help prevent inadvertent release outside the Government. As required by 35 U.S.C. 202(c)(5), the agency will not disclose that information to persons outside the Government without the Contractor's permission.

(g) Preference for United States industry. Notwithstanding any other provision of this clause, neither the Contractor nor any assignee shall grant to any person the exclusive right to use or sell any subject invention in the United States unless the person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for an agreement may be waived by the agency upon a showing by the Contractor or its assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States, or that under the circumstances domestic manufacture is not commercially feasible.

(h) March-in rights. The Contractor acknowledges that, with respect to any subject invention in which it has retained ownership, the agency has the right to require licensing pursuant to 35 U.S.C. 203 and 210(c), and in accordance with the procedures in 37 CFR 401.6 and any supplemental regulations of the agency in effect on the date of contract award.

(i) Special provisions for contracts with nonprofit organizations. If the Contractor is a nonprofit organization, it shall--

(1) Not assign rights to a subject invention in the United States without the written approval of the agency, except where an assignment is made to an organization that has as one of its primary functions the management of inventions, provided, that the assignee shall be subject to the same provisions as the Contractor;

(2) Share royalties collected on a subject invention with the inventor, including Federal employee co-inventors (but through their agency if the agency deems it appropriate) when the subject invention is assigned in accordance with 35 U.S.C. 202(e) and 37 CFR 401.10;

(3) Use the balance of any royalties or income earned by the Contractor with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to the administration of subject inventions for the support of scientific research or education; and

(4) Make efforts that are reasonable under the circumstances to attract licensees of subject inventions that are small business concerns, and give a preference to a small business concern when licensing a subject invention if the Contractor determines that the small business concern has a plan or proposal for marketing the invention which, if executed, is equally as likely to bring the invention to practical application as any plans or proposals from applicants that are not small business concerns; provided, that the Contractor is also satisfied that the small business concern has the capability and resources to carry out its plan or proposal. The decision whether to give a preference in any specific case will be at the discretion of the Contractor.

(5) Allow the Secretary of Commerce to review the Contractor's licensing program and decisions regarding small business applicants, and negotiate changes to its licensing policies, procedures, or practices with the Secretary of Commerce when the Secretary's review discloses that the Contractor could take reasonable steps to more effectively implement the requirements of paragraph (i)(4) of this clause.

(j) Communications. Communications shall be made to the Contracting Officer:

ACC-APG NATICK CONTRACTING DIVISION
ATTN: Peter Wallace
Kansas Street
Natick, MA 01760
Email: peter.wallace@us.army.mil

(k) Subcontracts. (1) The Contractor shall include the substance of this clause, including this paragraph (k), in all subcontracts for experimental, developmental, or research work to be performed by a small business concern or nonprofit organization.

(2) The Contractor shall include in all other subcontracts for experimental, developmental, or research work the substance of the patent rights clause required by FAR Subpart 27.3.

(3) At all tiers, the patent rights clause must be modified to identify the parties as follows: references to the Government are not changed, and the subcontractor has all rights and obligations of the Contractor in the clause. The Contractor shall not, as part of the consideration for awarding the subcontract, obtain rights in the subcontractor's subject inventions.

(4) In subcontracts, at any tier, the agency, the subcontractor, and the Contractor agree that the mutual obligations of the parties created by this clause constitute a contract between the subcontractor and the agency with respect to the matters covered by the clause; provided, however, that nothing in this paragraph is ntended to confer any jurisdiction under the Contract Disputes Act in connection with proceedings under paragraph (h) of this clause.

(End of clause)

CLAUSES INCORPORATED BY FULL TEXT

52.232-20 LIMITATION OF COST (APR 1984)

(a) The parties estimate that performance of this contract, exclusive of any fee, will not cost the Government more than (1) the estimated cost specified in the Schedule or, (2) if this is a cost-sharing contract, the Government's share of the estimated cost specified in the Schedule. The Contractor agrees to use its best efforts to perform the work specified in the Schedule and all obligations under this contract within the estimated cost, which, if this is a cost-sharing contract, includes both the Government's and the Contractor's share of the cost.

(b) The Contractor shall notify the Contracting Officer in writing whenever it has reason to believe that--

(1) The costs the Contractor expects to incur under this contract in the next 60 days, when added to all costs previously incurred, will exceed 75 percent of the estimated cost specified in the Schedule; or

(2) The total cost for the performance of this contract, exclusive of any fee, will be either greater or substantially less than had been previously estimated.

(c) As part of the notification, the Contractor shall provide the Contracting Officer a revised estimate of the total cost of performing this contract.

(d) Except as required by other provisions of this contract, specifically citing and stated to be an exception to this clause--

(1) The Government is not obligated to reimburse the Contractor for costs incurred in excess of (i) the estimated cost specified in the Schedule or, (ii) if this is a cost-sharing contract, the estimated cost to the Government specified in the Schedule; and

(2) The Contractor is not obligated to continue performance under this contract (including actions under the Termination clause of this contract) or otherwise incur costs in excess of the estimated cost specified in the Schedule, until the Contracting Officer (i) notifies the Contractor in writing that the estimated cost has been increased and (ii) provides a revised estimated total cost of performing this contract. If this is a cost-sharing contract, the increase shall be allocated in accordance with the formula specified in the Schedule.

(e) No notice, communication, or representation in any form other than that specified in subparagraph (d)(2) above, or from any person other than the Contracting Officer, shall affect this contract's estimated cost to the Government. In the absence of the specified notice, the Government is not obligated to reimburse the Contractor for any costs in excess of the estimated cost or, if this is a cost-sharing contract, for any costs in excess of the estimated cost to the Government specified in the Schedule, whether those excess costs were incurred during the course of the contract or as a result of termination.

(f) If the estimated cost specified in the Schedule is increased, any costs the Contractor incurs before the increase that are in excess of the previously estimated cost shall be allowable to the same extent as if incurred afterward, unless the Contracting Officer issues a termination or other notice directing that the increase is solely to cover

termination or other specified expenses.

(g) Change orders shall not be considered an authorization to exceed the estimated cost to the Government specified in the Schedule, unless they contain a statement increasing the estimated cost.

(h) If this contract is terminated or the estimated cost is not increased, the Government and the Contractor shall negotiate an equitable distribution of all property produced or purchased under the contract, based upon the share of costs incurred by each.

(End of clause)

CLAUSES INCORPORATED BY FULL TEXT

52.234-1 INDUSTRIAL RESOURCES DEVELOPED UNDER DEFENSE PRODUCTION ACT TITLE III (DEC 1994)

(a) Definitions.

"Title III industrial resource" means materials, services, processes, or manufacturing equipment (including the processes, technologies, and ancillary services for the use of such equipment) established or maintained under the authority of Title III, Defense Production Act (50 U.S.C. App. 2091-2093)..

"Title III project contractor" means a contractor that has received assistance for the development or manufacture of an industrial resource under 50 U.S.C. App. 2091-2093, Defense Production Act.

(b) The Contractor shall refer any request from a Title III project contractor for testing and qualification of a Title III industrial resource to the Contracting Officer.

(c) Upon the direction of the Contracting Officer, the Contractor shall test Title III industrial resources for qualification. The Contractor shall provide the test results to the Defense Production Act Office, Title III Program, located at Wright Patterson Air Force Base, Ohio 45433-7739.

(d) When the Contracting Officer modifies the contract to direct testing pursuant to this clause, the Government will provide the Title III industrial resource to be tested and will make an equitable adjustment in the contract for the costs of testing and qualification of the Title III industrial resource.

(e) The Contractor agrees to insert the substance of this clause, including paragraph (e), in every subcontract issued in performance of this contract.

(End of clause)

CLAUSES INCORPORATED BY FULL TEXT

52.243-2 CHANGES--COST-REIMBURSEMENT (AUG 1987) - ALTERNATE V (APR 1984)

(a) The Contracting Officer may at any time, by written order, and without notice to the sureties, if any, make changes within the general scope of this contract in any one or more of the following:

(1) Drawings, designs, or specifications.

(2) Method of shipment or packing.

(3) Place of inspection, delivery, or acceptance.

(b) If any such change causes an increase or decrease in the estimated cost of, or the time required for, performance of any part of the work under this contract, whether or not changed by the order, or otherwise affects any other terms and conditions of this contract, the Contracting Officer shall make an equitable adjustment in the (1) estimated cost, delivery or completion schedule, or both; (2) amount of any fixed fee; and (3) other affected terms and shall modify the contract accordingly.

(c) The Contractor must assert its right to an adjustment under this clause within 30 days from the date of receipt of the written order. However, if the Contracting Officer decides that the facts justify it, the Contracting Officer may receive and act upon a proposal submitted before final payment of the contract.

(d) Failure to agree to any adjustment shall be a dispute under the Disputes clause. However, nothing in this clause shall excuse the Contractor from proceeding with the contract as changed.

(e) Notwithstanding the terms and conditions of paragraphs (a) and (b) above, the estimated cost of this contract and, if this contract is incrementally funded, the funds allotted for the performance of this contract, shall not be increased or considered to be increased except by specific written modification of the contract indicating the new contract estimated cost and, if this contract is incrementally funded, the new amount allotted to the contract. Until this modification is made, the Contractor shall not be obligated to continue performance or incur costs beyond the point established in the Limitation of Cost or Limitation of Funds clause of this contract.

(End of clause)

CLAUSES INCORPORATED BY FULL TEXT

52.243-7 NOTIFICATION OF CHANGES (APR 1984)

(a) Definitions.

"Contracting Officer," as used in this clause, does not include any representative of the Contracting Officer.

"Specifically authorized representative (SAR)," as used in this clause, means any person the Contracting Officer has so designated by written notice (a copy of which shall be provided to the Contractor) which shall refer to this subparagraph and shall be issued to the designated representative before the SAR exercises such authority.

(b) Notice. The primary purpose of this clause is to obtain prompt reporting of Government conduct that the Contractor considers to constitute a change to this contract. Except for changes identified as such in writing and signed by the Contracting Officer, the Contractor shall notify the Administrative Contracting Officer in writing, within one (1) calendar days from the date that the Contractor identifies any Government conduct (including actions, inactions, and written or oral communications) that the Contractor regards as a change to the contract terms and conditions. On the basis of the most accurate information available to the Contractor, the notice shall state--

(1) The date, nature, and circumstances of the conduct regarded as a change;

(2) The name, function, and activity of each Government individual and Contractor official or employee involved in or knowledgeable about such conduct;

(3) The identification of any documents and the substance of any oral communication involved in such conduct;

(4) In the instance of alleged acceleration of scheduled performance or delivery, the basis upon which it arose;

(5) The particular elements of contract performance for which the Contractor may seek an equitable adjustment under this clause, including--

(i) What contract line items have been or may be affected by the alleged change;

(ii) What labor or materials or both have been or may be added, deleted, or wasted by the alleged change;

(iii) To the extent practicable, what delay and disruption in the manner and sequence of performance and effect on continued performance have been or may be caused by the alleged change;

(iv) What adjustments to contract price, delivery schedule, and other provisions affected by the alleged change are estimated; and

(6) The Contractor's estimate of the time by which the Government must respond to the Contractor's notice to minimize cost, delay or disruption of performance.

(c) Continued performance. Following submission of the notice required by (b) above, the Contractor shall diligently continue performance of this contract to the maximum extent possible in accordance with its terms and conditions as construed by the Contractor, unless the notice reports a direction of the Contracting Officer or a communication from a SAR of the Contracting Officer, in either of which events the Contractor shall continue performance; provided, however, that if the Contractor regards the direction or communication as a change as described in (b) above, notice shall be given in the manner provided. All directions, communications, interpretations, orders and similar actions of the SAR shall be reduced to writing and copies furnished to the Contractor and to the Contracting Officer. The Contracting Officer shall countermand any action which exceeds the authority of the SAR.

(d) Government response. The Contracting Officer shall promptly, within seven (7) calendar days after receipt of notice, respond to the notice in writing. In responding, the Contracting Officer shall either--

(1) Confirm that the conduct of which the Contractor gave notice constitutes a change and when necessary direct the mode of further performance;

(2) Countermand any communication regarded as a change;

(3) Deny that the conduct of which the Contractor gave notice constitutes a change and when necessary direct the mode of further performance; or

(4) In the event the Contractor's notice information is inadequate to make a decision under (1), (2), or (3) above, advise the Contractor what additional information is required, and establish the date by which it should be furnished and the date thereafter by which the Government will respond.

(e) Equitable adjustments.

(1) If the Contracting Officer confirms that Government conduct effected a change as alleged by the Contractor, and the conduct causes an increase or decrease in the Contractor's cost of, or the time required for, performance of any part of the work under this contract, whether changed or not changed by such conduct, an equitable adjustment shall be made--

(i) In the contract price or delivery schedule or both; and

(ii) In such other provisions of the contract as may be affected.

(2) The contract shall be modified in writing accordingly. In the case of drawings, designs or specifications which are defective and for which the Government is responsible, the equitable adjustment shall include the cost and time extension for delay reasonably incurred by the Contractor in attempting to comply with the defective drawings, designs or specifications before the Contractor identified, or reasonably should have identified, such defect. When the cost of property made obsolete or excess as a result of a change confirmed by the Contracting Officer under this clause is included in the equitable adjustment, the Contracting Officer shall have the right to prescribe the manner of disposition of the property. The equitable adjustment shall not include increased costs or time extensions for delay resulting from the Contractor's failure to provide notice or to continue performance as provided, respectively, in (b) and (c) above.

Note: The phrases “contract price” and “cost” wherever they appear in the clause, may be appropriately modified to apply to cost-reimbursement or incentive contracts, or to combinations thereof.

(End of clause)

CLAUSES INCORPORATED BY FULL TEXT

52.247-66 RETURNABLE CYLINDERS (MAY 1994)

(a) Cylinder, referred to in this clause, is a pressure vessel designed for pressures higher than 40 psia and having a circular cross section excluding a portable tank, multi-tank car tank, cargo tank, or tank car.

(b) Returnable cylinders shall remain the Contractor's property but shall be loaned without charge to the Government for a period of __**__days (hereafter refereed to as loan period) following the day of delivery to the f.o.b. point specified in the contract. Any cylinder not returned within the loan period shall be charged a daily rental beginning with the first day after the loan period expires, to and including the day the cylinders are delivered to the Contractor (if the original delivery was f.o.b. origin) or are delivered or made available for delivery to the Contractor's designated carrier) if the original delivery was f.o.b. destination). The Government shall pay the Contractor a rental of $ __**__ per cylinder, per day, computed separately for cylinders by type, size and capacity and for each point of delivery named in the contract. No rental shall accrue to the Contractor in excess of replacement value per cylinder specified in paragraph (c) of this clause.

(c) For each cylinder lost or damaged beyond repair while in the Government's possession, the Government shall pay to the Contractor the replacement value, less the allocable rental paid for that cylinder as follows:__**__ These cylinders shall become Government property.

(d) If any lost cylinder is located within __**__ calendar days after payment by the Government, it may be returned to the Contractor by the Government, and the Contractor shall pay to the Government an amount equal to the replacement value , less rental computed in accordance with paragraph (b) of this clause, beginning at the expiration of the loan period specified in paragraph (b) of this clause, and continuing to the date on which cylinder was delivered to the contractor.

** To be negotiated, if applicable.

(End of clause)

CLAUSES INCORPORATED BY FULL TEXT

52.247-67 SUBMISSION OF TRANSPORTATION DOCUMENTS FOR AUDIT (FEB 2006)

(a) The Contractor shall submit to the address identified below, for prepayment audit, transportation documents on which the United States will assume freight charges that were paid--

(1) By the Contractor under a cost-reimbursement contract; and

(2) By a first-tier subcontractor under a cost-reimbursement subcontract thereunder.

(b) Cost-reimbursement Contractors shall only submit for audit those bills of lading with freight shipment charges exceeding $100. Bills under $100 shall be retained on-site by the Contractor and made available for on-site audits. This exception only applies to freight shipment bills and is not intended to apply to bills and invoices for any other transportation services.

(c) Contractors shall submit the above referenced transportation documents to--

This information will be provided at time of award.

(End of clause)

CLAUSES INCORPORATED BY FULL TEXT

52.248-1 VALUE ENGINEERING (OCT 2010)

(a) General. The Contractor is encouraged to develop, prepare, and submit value engineering change proposals (VECP's) voluntarily. The Contractor shall share in any net acquisition savings realized from accepted VECP's, in accordance with the incentive sharing rates in paragraph (f) below.

(b) Definitions. "Acquisition savings," as used in this clause, means savings resulting from the application of a VECP to contracts awarded by the same contracting office or its successor for essentially the same unit. Acquisition savings include--

(1) Instant contract savings, which are the net cost reductions on this, the instant contract, and which are equal to the instant unit cost reduction multiplied by the number of instant contract units affected by the VECP, less the Contractor's allowable development and implementation costs;

(2) Concurrent contract savings, which are net reductions in the prices of other contracts that are definitized and ongoing at the time the VECP is accepted; and

(3) Future contract savings, which are the product of the future unit cost reduction multiplied by the number of future contract units in the sharing base. On an instant contract, future contract savings include savings on increases in quantities after VECP acceptance that are due to contract modifications, exercise of options, additional orders, and funding of subsequent year requirements on a multiyear contract.

"Collateral costs," as used in this clause, means agency cost of operation, maintenance, logistic support, or Government-furnished property.

"Collateral savings," as used in this clause, means those measurable net reductions resulting from a VECP in the agency's overall projected collateral costs, exclusive of acquisition savings, whether or not the acquisition cost changes.

"Contracting office" includes any contracting office that the acquisition is transferred to, such as another branch of the agency or another agency's office that is performing a joint acquisition action.

"Contractor's development and implementation costs," as used in this clause, means those costs the Contractor incurs on a VECP specifically in developing, testing, preparing, and submitting the VECP, as well as those costs the Contractor incurs to make the contractual changes required by Government acceptance of a VECP.

"Future unit cost reduction," as used in this clause, means the instant unit cost reduction adjusted as the Contracting Officer considers necessary for projected learning or changes in quantity during the sharing period. It is calculated at the time the VECP is accepted and applies either (1) throughout the sharing period, unless the Contracting Officer decides that recalculation is necessary because conditions are significantly different from those previously anticipated or (2) to the calculation of a lump-sum payment, which cannot later be revised.

"Government costs," as used in this clause, means those agency costs that result directly from developing and implementing the VECP, such as any net increases in the cost of testing, operations, maintenance, and logistics support. The term does not include the normal administrative costs of processing the VECP or any increase in this contract's cost or price resulting from negative instant contract savings.

"Instant contract," as used in this clause, means this contract, under which the VECP is submitted. It does not include increases in quantities after acceptance of the VECP that are due to contract modifications, exercise of options, or additional orders. If this is a multiyear contract, the term does not include quantities funded after VECP acceptance. If this contract is a fixed-price contract with prospective price redetermination, the term refers to the period for which firm prices have been established.

"Instant unit cost reduction" means the amount of the decrease in unit cost of performance (without deducting any Contractor's development or implementation costs) resulting from using the VECP on this, the instant contract. If this is a service contract, the instant unit cost reduction is normally equal to the number of hours per line-item task saved by using the VECP on this contract, multiplied by the appropriate contract labor rate.

"Negative instant contract savings" means the increase in the cost or price of this contract when the acceptance of a VECP results in an excess of the Contractor's allowable development and implementation costs over the product of the instant unit cost reduction multiplied by the number of instant contract units affected.

"Net acquisition savings" means total acquisition savings, including instant, concurrent, and future contract savings, less Government costs.

"Sharing base," as used in this clause, means the number of affected end items on contracts of the contracting office accepting the VECP.

Sharing period, as used in this clause, means the period beginning with acceptance of the first unit incorporating the VECP and ending at a calendar date or event determined by the contracting officer for each VECP.

"Unit," as used in this clause, means the item or task to which the Contracting Officer and the Contractor agree the VECP applies.

"Value engineering change proposal (VECP)" means a proposal that--

(1) Requires a change to this, the instant contract, to implement; and

(2) Results in reducing the overall projected cost to the agency without impairing essential functions or characteristics; provided, that it does not involve a change--

(i) In deliverable end item quantities only;

(ii) In research and development (R&D) end items or R&D test quantities that is due solely to results of previous testing under this contract; or

(iii) To the contract type only.

(c) VECP preparation. As a minimum, the Contractor shall include in each VECP the information described in subparagraphs (1) through (8) below. If the proposed change is affected by contractually required configuration management or similar procedures, the instructions in those procedures relating to format, identification, and priority assignment shall govern VECP preparation. The VECP shall include the following:

(1) A description of the difference between the existing contract requirement and the proposed requirement, the comparative advantages and disadvantages of each, a justification when an item's function or characteristics are being altered, the effect of the change on the end item's performance, and any pertinent objective test data.

(2) A list and analysis of the contract requirements that must be changed if the VECP is accepted, including any suggested specification revisions.

(3) Identification of the unit to which the VECP applies.

(4) A separate, detailed cost estimate for (i) the affected portions of the existing contract requirement and (ii) the VECP. The cost reduction associated with the VECP shall take into account the Contractor's allowable development and implementation costs, including any amount attributable to subcontracts under the Subcontracts paragraph of this clause, below.

(5) A description and estimate of costs the Government may incur in implementing the VECP, such as test and evaluation and operating and support costs.

(6) A prediction of any effects the proposed change would have on collateral costs to the agency.

(7) A statement of the time by which a contract modification accepting the VECP must be issued in order to achieve the maximum cost reduction, noting any effect on the contract completion time or delivery schedule.

(8) Identification of any previous submissions of the VECP, including the dates submitted, the agencies and contract numbers involved, and previous Government actions, if known.

(d) Submission. The Contractor shall submit VECP's to the Contracting Officer, unless this contract states otherwise. If this contract is administered by other than the contracting office, the Contractor shall submit a copy of the VECP simultaneously to the Contracting Officer and to the Administrative Contracting Officer.

(e) Government action. (1) The Contracting Officer will notify the Contractor of the status of the VECP within 45 calendar days after the contracting office receives it. If additional time is required, the Contracting Officer will notify the Contractor within the 45-day period and provide the reason for the delay and the expected date of the decision. The Government will process VECP's expeditiously; however, it shall not be liable for any delay in acting upon a VECP.

(2) If the VECP is not accepted, the Contracting Officer will notify the Contractor in writing, explaining the reasons for rejection. The Contractor may withdraw any VECP, in whole or in part, at any time before it is accepted by the Government. The Contracting Officer may require that the Contractor provide written notification before undertaking significant expenditures for VECP effort.

(3) Any VECP may be accepted, in whole or in part, by the Contracting Officer's award of a modification to this contract citing this clause and made either before or within a reasonable time after contract performance is completed. Until such a contract modification applies a VECP to this contract, the Contractor shall perform in accordance with the existing contract. The decision to accept or reject all or part of any VECP is a unilateral decision made solely at the discretion of the Contracting Officer.

(f) Sharing rates. If a VECP is accepted, the Contractor shall share in net acquisition savings according to the percentages shown in the table below. The percentage paid the Contractor depends upon (1) this contract's type (fixed-price, incentive, or cost-reimbursement), (2) the sharing arrangement specified in paragraph (a) above (incentive, program requirement, or a combination as delineated in the Schedule), and (3) the source of the savings (the instant contract, or concurrent and future contracts), as follows:

CONTRACTOR'S SHARE OF NET ACQUISITION SAVINGS
(Figures in percent)

Contract Type	Incentive (Voluntary)		Program Requirement (Mandatory)	
	Instant Contract Rate	Concurrent and Future Contract Rate	Instant Contract Rate	Concurrent and Future Contract Rate
Cost-reimbursement (includes cost-plus-award-fee; excludes other cost-type incentive Contracts)	25	25	15	15

(g) Calculating net acquisition savings.

(1) Acquisition savings are realized when (i) the cost or price is reduced on the instant contract, (ii) reductions are negotiated in concurrent contracts, (iii) future contracts are awarded, or (iv) agreement is reached on a lump-sum payment for future contract savings (see subparagraph (i)(4) below). Net acquisition savings are first realized, and the Contractor shall be paid a share, when Government costs and any negative instant contract savings have been fully offset against acquisition savings.

(2) Except in incentive contracts, Government costs and any price or cost increases resulting from negative instant contract savings shall be offset against acquisition savings each time such savings are realized until they are fully offset. Then, the Contractor's share is calculated by multiplying net acquisition savings by the appropriate Contractor's percentage sharing rate (see paragraph (f) above). Additional Contractor shares of net acquisition savings shall be paid to the Contractor at the time realized.

(3) If this is an incentive contract, recovery of Government costs on the instant contract shall be deferred and offset against concurrent and future contract savings. The Contractor shall share through the contract incentive structure in savings on the instant contract items affected. Any negative instant contract savings shall be added to the target cost or to the target price and ceiling price, and the amount shall be offset against concurrent and future contract savings.

(4) If the Government does not receive and accept all items on which it paid the Contractor's share, the Contractor shall reimburse the Government for the proportionate share of these payments.

(h) Contract adjustment. The modification accepting the VECP (or a subsequent modification issued as soon as possible after any negotiations are completed) shall--

(1) Reduce the contract price or estimated cost by the amount of instant contract savings, unless this is an incentive contract;

(2) When the amount of instant contract savings is negative, increase the contract price, target price and ceiling price, target cost, or estimated cost by that amount;

(3) Specify the Contractor's dollar share per unit on future contracts, or provide the lump-sum payment;

(4) Specify the amount of any Government costs or negative instant contract savings to be offset in determining net acquisition savings realized from concurrent or future contract savings; and

(5) Provide the Contractor's share of any net acquisition savings under the instant contract in accordance with the following:

(i) Fixed-price contracts--add to contract price.

(ii) Cost-reimbursement contracts--add to contract fee.

(i) Concurrent and future contract savings.

(1) Payments of the Contractor's share of concurrent and future contract savings shall be made by a modification to the instant contract in accordance with subparagraph (h)(5) above. For incentive contracts, shares shall be added as a separate firm-fixed-price line item on the instant contract. The Contractor shall maintain records adequate to identify the first delivered unit for 3 years after final payment under this contract.

(2) The Contracting Officer shall calculate the Contractor's share of concurrent contract savings by (i) subtracting from the reduction in price negotiated on the concurrent contract any Government costs or negative instant contract savings not yet offset and (ii) multiplying the result by the Contractor's sharing rate.

(3) The Contracting Officer shall calculate the Contractor's share of future contract savings by (i) multiplying the future unit cost reduction by the number of future contract units scheduled for delivery during the sharing period, (ii) subtracting any Government costs or negative instant contract savings not yet offset, and (iii) multiplying the result by the Contractor's sharing rate.

(4) When the Government wishes and the Contractor agrees, the Contractor's share of future contract savings may be paid in a single lump sum rather than in a series of payments over time as future contracts are awarded. Under this alternate procedure, the future contract savings may be calculated when the VECP is accepted, on the basis of the Contracting Officer's forecast of the number of units that will be delivered during the sharing period. The Contractor's share shall be included in a modification to this contract (see subparagraph (h)(3) above) and shall not be subject to subsequent adjustment.

(5) Alternate no-cost settlement method. When, in accordance with subsection 48.104-4 of the Federal Acquisition Regulation, the Government and the Contractor mutually agree to use the no-cost settlement method, the following applies:

(i) The Contractor will keep all the savings on the instant contract and on its concurrent contracts only.

(ii) The Government will keep all the savings resulting from concurrent contracts placed on other sources, savings from all future contracts, and all collateral savings.

(j) Collateral savings. If a VECP is accepted, the Contracting Officer will increase the instant contract amount, as specified in paragraph (h)(5) of this clause, by a rate from 20 to 100 percent, as determined by the Contracting Officer, of any projected collateral savings determined to be realized in a typical year of use after subtracting any

Government costs not previously offset. However, the Contractor's share of collateral savings will not exceed the contract's firm-fixed-price, target price, target cost, or estimated cost, at the time the VECP is accepted, or $100,000, whichever is greater. The Contracting Officer will be the sole determiner of the amount of collateral savings.

(k) Relationship to other incentives. Only those benefits of an accepted VECP not rewardable under performance, design-to-cost (production unit cost, operating and support costs, reliability and maintainability), or similar incentives shall be rewarded under this clause. However, the targets of such incentives affected by the VECP shall not be adjusted because of VECP acceptance. If this contract specifies targets but provides no incentive to surpass them, the value engineering sharing shall apply only to the amount of achievement better than target.

(l) Subcontracts. The Contractor shall include an appropriate value engineering clause in any subcontract of $150,000 or more and may include one in subcontracts of lesser value. In calculating any adjustment in this contract's price for instant contract savings (or negative instant contract savings), the Contractor's allowable development and implementation costs shall include any subcontractor's allowable development and implementation costs, and any value engineering incentive payments to a subcontractor, clearly resulting from a VECP accepted by the Government under this contract. The Contractor may choose any arrangement for subcontractor value engineering incentive payments; provided, that the payments shall not reduce the Government's share of concurrent or future contract savings or collateral savings.

(m) Data. The Contractor may restrict the Government's right to use any part of a VECP or the supporting data by marking the following legend on the affected parts:

"These data, furnished under the Value Engineering clause of contract . . . . . , shall not be disclosed outside the Government or duplicated, used, or disclosed, in whole or in part, for any purpose other than to evaluate a value engineering change proposal submitted under the clause. This restriction does not limit the Government's right to use information contained in these data if it has been obtained or is otherwise available from the Contractor or from another source without limitations."

If a VECP is accepted, the Contractor hereby grants the Government unlimited rights in the VECP and supporting data, except that, with respect to data qualifying and submitted as limited rights technical data, the Government shall have the rights specified in the contract modification implementing the VECP and shall appropriately mark the data. (The terms "unlimited rights" and "limited rights" are defined in Part 27 of the Federal Acquisition Regulation.)

(End of clause)

CLAUSES INCORPORATED BY FULL TEXT

52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es):

http://farsite.hill.af.mil/

https://www.acquisition.gov/far/index.html

(End of clause)

CLAUSES INCORPORATED BY FULL TEXT

252.204-7006 BILLING INSTRUCTIONS (OCT 2005)

When submitting a request for payment, the Contractor shall--

(a) Identify the contract line item(s) on the payment request that reasonably reflect contract work performance; and

(b) Separately identify a payment amount for each contract line item included in the payment request.

(End of clause)

CLAUSES INCORPORATED BY FULL TEXT

252.211-7003 ITEM IDENTIFICATION AND VALUATION (AUG 2008)

(a) Definitions. As used in this clause'

Automatic identification device means a device, such as a reader or interrogator, used to retrieve data encoded on machine-readable media.

Concatenated unique item identifier means--

(1) For items that are serialized within the enterprise identifier, the linking together of the unique identifier data elements in order of the issuing agency code, enterprise identifier, and unique serial number within the enterprise identifier; or

(2) For items that are serialized within the original part, lot, or batch number, the linking together of the unique identifier data elements in order of the issuing agency code; enterprise identifier; original part, lot, or batch number; and serial number within the original part, lot, or batch number.

Data qualifier means a specified character (or string of characters) that immediately precedes a data field that defines the general category or intended use of the data that follows.

DoD recognized unique identification equivalent” means a unique identification method that is in commercial use and has been recognized by DoD. All DoD recognized unique identification equivalents are listed at http://www.acq.osd.mil/dpap/pdi/uid/iuid_equivalents.html.

DoD unique item identification means a system of marking items delivered to DoD with unique item identifiers that have machine-readable data elements to distinguish an item from all other like and unlike items. For items that are serialized within the enterprise identifier, the unique item identifier shall include the data elements of the enterprise identifier and a unique serial number. For items that are serialized within the part, lot, or batch number within the enterprise identifier, the unique item identifier shall include the data elements of the enterprise identifier; the original part, lot, or batch number; and the serial number.

Enterprise means the entity (e.g., a manufacturer or vendor) responsible for assigning unique item identifiers to items.

Enterprise identifier means a code that is uniquely assigned to an enterprise by an issuing agency.

Government's unit acquisition cost means--

(1) For fixed-price type line, subline, or exhibit line items, the unit price identified in the contract at the time of delivery;

(2) For cost-type or undefinitized line, subline, or exhibit line items, the Contractor's estimated fully burdened unit cost to the Government at the time of delivery; and

(3) For items produced under a time-and-materials contract, the Contractor's estimated fully burdened unit cost to the Government at the time of delivery.

Issuing agency means an organization responsible for assigning a non-repeatable identifier to an enterprise (i.e., Dun & Bradstreet's Data Universal Numbering System (DUNS) Number, GS1 Company Prefix, or Defense Logistics Information System (DLIS) Commercial and Government Entity (CAGE) Code).

Issuing agency code means a code that designates the registration (or controlling) authority for the enterprise identifier.

Item means a single hardware article or a single unit formed by a grouping of subassemblies, components, or constituent parts.

Lot or batch number means an identifying number assigned by the enterprise to a designated group of items, usually referred to as either a lot or a batch, all of which were manufactured under identical conditions.

Machine-readable means an automatic identification technology media, such as bar codes, contact memory buttons, radio frequency identification, or optical memory cards.

Original part number means a combination of numbers or letters assigned by the enterprise at item creation to a class of items with the same form, fit, function, and interface.

Parent item means the item assembly, intermediate component, or subassembly that has an embedded item with a unique item identifier or DoD recognized unique identification equivalent.

Serial number within the enterprise identifier means a combination of numbers, letters, or symbols assigned by the enterprise to an item that provides for the differentiation of that item from any other like and unlike item and is never used again within the enterprise.

Serial number within the part, lot, or batch number means a combination of numbers or letters assigned by the enterprise to an item that provides for the differentiation of that item from any other like item within a part, lot, or batch number assignment.

Serialization within the enterprise identifier means each item produced is assigned a serial number that is unique among all the tangible items produced by the enterprise and is never used again. The enterprise is responsible for ensuring unique serialization within the enterprise identifier.

Serialization within the part, lot, or batch number means each item of a particular part, lot, or batch number is assigned a unique serial number within that part, lot, or batch number assignment. The enterprise is responsible for ensuring unique serialization within the part, lot, or batch number within the enterprise identifier.

Unique item identifier means a set of data elements marked on items that is globally unique and unambiguous. The term includes a concatenated unique item identifier or a DoD recognized unique identification equivalent.

Unique item identifier type means a designator to indicate which method of uniquely identifying a part has been used. The current list of accepted unique item identifier types is maintained at http://www.acq.osd.mil/dpap/pdi/uid/uii_types.html.

(b) The Contractor shall deliver all items under a contract line, subline, or exhibit line item.

(c) Unique item identifier.

(1) The Contractor shall provide a unique item identifier for the following:

(i) All delivered items for which the Government's unit acquisition cost is $5,000 or more.

(ii) The following items for which the Government's unit acquisition cost is less than $5,000:

Contract line, subline, or exhibit line item No.	Item description

To be filled in at time of award, if applicable.

(iii) Subassemblies, components, and parts embedded within delivered items as specified in Attachment Number ----.

(2) The unique item identifier and the component data elements of the DoD unique item identification shall not change over the life of the item.

(3) Data syntax and semantics of unique item identifiers. The Contractor shall ensure that--

(i) The encoded data elements (except issuing agency code) of the unique item identifier are marked on the item using one of the following three types of data qualifiers, as determined by the Contractor:

(A) Application Identifiers (AIs) (Format Indicator 05 of ISO/IEC International Standard 15434), in accordance with ISO/IEC International Standard 15418, Information Technology--EAN/UCC Application Identifiers and Fact Data Identifiers and Maintenance and ANSI MH 10.8.2 Data Identifier and Application Identifier Standard.

(B) Data Identifiers (DIs) (Format Indicator 06 of ISO/IEC International Standard 15434), in accordance with ISO/IEC International Standard 15418, Information Technology--EAN/UCC Application Identifiers and Fact Data Identifiers and Maintenance and ANSI MH 10.8.2 Data Identifier and Application Identifier Standard.

(C) Text Element Identifiers (TEIs) (Format Indicator 12 of ISO/IEC International Standard 15434), in accordance with the Air Transport Association Common Support Data Dictionary; and

(ii) The encoded data elements of the unique item identifier conform to the transfer structure, syntax, and coding of messages and data formats specified for Format Indicators 05, 06, and 12 in ISO/IEC International Standard 15434, Information Technology--Transfer Syntax for High Capacity Automatic Data Capture Media.

(4) Unique item identifier.

(i) The Contractor shall--

(A) Determine whether to--

(1) Serialize within the enterprise identifier;

(2) Serialize within the part, lot, or batch number; or

(3) Use a DoD recognized unique identification equivalent; and

(B) Place the data elements of the unique item identifier (enterprise identifier; serial number; DoD recognized unique identification equivalent; and for serialization within the part, lot, or batch number only: original part, lot, or batch number) on items requiring marking by paragraph (c)(1) of this clause, based on the criteria provided in the version of MIL-STD-130, Identification Marking of U.S. Military Property, cited in the contract Schedule.

(ii) The issuing agency code--

(A) Shall not be placed on the item; and

(B) Shall be derived from the data qualifier for the enterprise identifier.

(d) For each item that requires unique item identification under paragraph (c)(1)(i) or (ii) of this clause, in addition to the information provided as part of the Material Inspection and Receiving Report specified elsewhere in this contract, the Contractor shall report at the time of delivery, either as part of, or associated with, the Material Inspection and Receiving Report, the following information:

(1) Unique item identifier.

(2) Unique item identifier type.

(3) Issuing agency code (if concatenated unique item identifier is used).

(4) Enterprise identifier (if concatenated unique item identifier is used).

(5) Original part number (if there is serialization within the original part number).

(6) Lot or batch number (if there is serialization within the lot or batch number).

(7) Current part number (optional and only if not the same as the original part number).

(8) Current part number effective date (optional and only if current part number is used).

(9) Serial number (if concatenated unique item identifier is used).

(10) Government's unit acquisition cost.

(11) Unit of measure.

(e) For embedded subassemblies, components, and parts that require DoD unique item identification under paragraph (c)(1)(iii) of this clause, the Contractor shall report as part of, or associated with, the Material Inspection and Receiving Report specified elsewhere in this contract, the following information:

(1) Unique item identifier of the parent item under paragraph (c)(1) of this clause that contains the embedded subassembly, component, or part.

(2) Unique item identifier of the embedded subassembly, component, or part.

(3) Unique item identifier type.**

(4) Issuing agency code (if concatenated unique item identifier is used).**

(5) Enterprise identifier (if concatenated unique item identifier is used).**

(6) Original part number (if there is serialization within the original part number).**

(7) Lot or batch number (if there is serialization within the lot or batch number).**

(8) Current part number (optional and only if not the same as the original part number).**

(9) Current part number effective date (optional and only if current part number is used).**

(10) Serial number (if concatenated unique item identifier is used).**

(11) Description.

** Once per item.

(f) The Contractor shall submit the information required by paragraphs (d) and (e) of this clause in accordance with the data submission procedures at http://www.acq.osd.mil/dpap/pdi/uid/data_ submission_information.html.

(g) Subcontracts. If the Contractor acquires by subcontract, any item(s) for which unique item identification is required in accordance with paragraph (c)(1) of this clause, the Contractor shall include this clause, including this paragraph (g), in the applicable subcontract(s).

(End of clause)

CLAUSES INCORPORATED BY FULL TEXT

252.223-7001 HAZARD WARNING LABELS (DEC 1991)

(a) "Hazardous material," as used in this clause, is defined in the Hazardous Material Identification and Material Safety Data clause of this contract.

(b) The Contractor shall label the item package (unit container) of any hazardous material to be delivered under this contract in accordance with the Hazard Communication Standard (29 CFR 1910.1200 et seq). The Standard requires that the hazard warning label conform to the requirements of the standard unless the material is otherwise subject to the labeling requirements of one of the following statutes:

(1) Federal Insecticide, Fungicide and Rodenticide Act;

(2) Federal Food, Drug and Cosmetics Act;

(3) Consumer Product Safety Act;

(4) Federal Hazardous Substances Act; or

(5) Federal Alcohol Administration Act.

(c) The Offeror shall list which hazardous material listed in the Hazardous Material Identification and Material Safety Data clause of this contract will be labeled in accordance with one of the Acts in paragraphs (b)(1) through (5) of this clause instead of the Hazard Communication Standard. Any hazardous material not listed will be interpreted to mean that a label is required in accordance with the Hazard Communication Standard.

MATERIAL (If None, Insert "None.")	ACT
_____	_____
_____	_____

(d) The apparently successful Offeror agrees to submit, before award, a copy of the hazard warning label for all hazardous materials not listed in paragraph (c) of this clause. The Offeror shall submit the label with the Material Safety Data Sheet being furnished under the Hazardous Material Identification and Material Safety Data clause of this contract.

(e) The Contractor shall also comply with MIL-STD-129, Marking for Shipment and Storage (including revisions adopted during the term of this contract).

(End of clause)

CLAUSES INCORPORATED BY FULL TEXT

252.225-7000 BUY AMERICAN ACT--BALANCE OF PAYMENTS PROGRAM CERTIFICATE (DEC 2009)

(a) Definitions. “Commercially available off-the-shelf (COTS) item,” “component,” “domestic end product,” “foreign end product,” “qualifying country,” “qualifying country end product,” and “United States” have the meanings given in the Buy American Act and Balance of Payments Program clause of this solicitation.

(b) Evaluation. The Government--

(1) Will evaluate offers in accordance with the policies and procedures of Part 225 of the Defense Federal Acquisition Regulation Supplement; and

(2) Will evaluate offers of qualifying country end products without regard to the restrictions of the Buy American Act or the Balance of Payments Program.

(c) Certifications and identification of country of origin.

(1) For all line items subject to the Buy American Act and Balance of Payments Program clause of this solicitation, the offeror certifies that--

(i) Each end product, except those listed in paragraph (c)(2) or (3) of this provision, is a domestic end product; and

(ii) For end products other than COTS items, components of unknown origin are considered to have been mined, produced, or manufactured outside the United States or a qualifying country.

(2) The offeror certifies that the following end products are qualifying country end products:

(Line Item Number Country of Origin)

(Country of Origin)

(3) The following end products are other foreign end products, including end products manufactured in the United States that do not qualify as domestic end products, i.e., an end product that is not a COTS item and does not meet the component test in paragraph (ii) of the definition of ``domestic end product'':

(Line Item Number)----------

(Country of Origin (If known))----------

(End of provision)

CLAUSES INCORPORATED BY FULL TEXT

252.227-7004 LICENSE GRANT (AUG 1984)

(a) The Contractor hereby grants to the Government an irrevocable, nonexclusive, nontransferable, and paid up license under the following patents, applications for patent, and any patents granted on such applications, and under any patents which may issue as the result of any reissue, division or continuation thereof, to practice by or cause to be practiced for the Government throughout the world, any and all of the inventions thereunder, in the manufacture and use of any article or material, in the use of any method or process, and in the disposition of any article or material in accordance with law:

U.S. Patent No.

Date

Application Serial No.

Filing Date

together with corresponding foreign patents and foreign applications for patents, insofar as the Contractor has the right to grant licenses thereunder without incurring an obligation to pay royalties or other compensation to others solely on account of such grant.

(b) No rights are granted or implied by the agreement under any other patents other than as provided above or by operation of law.

(c) Nothing contained herein shall limit any rights which the Government may have obtained by virtue of prior contracts or by operation of law or otherwise.

(End of clause)

CLAUSES INCORPORATED BY FULL TEXT

252.227-7010 LICENSE TO OTHER GOVERNMENT AGENCIES (AUG 1984)

The Contractor hereby agrees to grant a separate license under the patents, applications for patents, and improvements referred to in the "License Grant" clause of this contract, on the same terms and conditions as appear

in this license contract, to any other department or agency of the Government at any time on receipt of a written request for such a license from such department or agency; Provided, however, that as to royalties which accrue under such separate licenses, reports and payments shall be made directly to the Contractor by each such other department or agency pursuant to the terms of such separate licenses. The Contractor shall notify the Licensee hereunder promptly upon receipt of any request for license hereunder.

(End of clause)

CLAUSES INCORPORATED BY FULL TEXT

252.227-7013 RIGHTS IN TECHNICAL DATA--NONCOMMERCIAL ITEMS. (MAR 2011)

(a) Definitions. As used in this clause--

(1) Computer data base means a collection of data recorded in a form capable of being processed by a computer. The term does not include computer software.

(2) Computer program means a set of instructions, rules, or routines recorded in a form that is capable of causing a computer to perform a specific operation or series of operations.

(3) Computer software means computer programs, source code, source code listings, object code listings, design details, algorithms, processes, flow charts, formulae and related material that would enable the software to be reproduced, recreated, or recompiled. Computer software does not include computer data bases or computer software documentation.

(4) Computer software documentation means owner's manuals, user's manuals, installation instructions, operating instructions, and other similar items, regardless of storage medium, that explain the capabilities of the computer software or provide instructions for using the software.

(5) Covered Government support contractor means a contractor under a contract, the primary purpose of which is to furnish independent and impartial advice or technical assistance directly to the Government in support of the Government's management and oversight of a program or effort (rather than to directly furnish an end item or service to accomplish a program or effort), provided that the contractor--

(i) Is not affiliated with the prime contractor or a first-tier subcontractor on the program or effort, or with any direct competitor of such prime contractor or any such first-tier subcontractor in furnishing end items or services of the type developed or produced on the program or effort; and

(ii) Receives access to technical data or computer software for performance of a Government contract that contains the clause at 252.227-7025, Limitations on the Use or Disclosure of Government-Furnished Information Marked with Restrictive Legends.

(6) Detailed manufacturing or process data means technical data that describe the steps, sequences, and conditions of manufacturing, processing or assembly used by the manufacturer to produce an item or component or to perform a process.

(7) Developed means that an item, component, or process exists and is workable. Thus, the item or component must have been constructed or the process practiced. Workability is generally established when the item, component, or process has been analyzed or tested sufficiently to demonstrate to reasonable people skilled in the applicable art that there is a high probability that it will operate as intended. Whether, how much, and what type of analysis or testing is required to establish workability depends on the nature of the item, component, or process, and the state of the art.

To be considered "developed," the item, component, or process need not be at the stage where it could be offered for sale or sold on the commercial market, nor must the item, component, or process be actually reduced to practice within the meaning of Title 35 of the United States Code.

(8) Developed exclusively at private expense means development was accomplished entirely with costs charged to indirect cost pools, costs not allocated to a government contract, or any combination thereof.

(i) Private expense determinations should be made at the lowest practicable level.

(ii) Under fixed-price contracts, when total costs are greater than the firm-fixed-price or ceiling price of the contract, the additional development costs necessary to complete development shall not be considered when determining whether development was at government, private, or mixed expense.

(9) Developed exclusively with government funds means development was not accomplished exclusively or partially at private expense.

(10) Developed with mixed funding means development was accomplished partially with costs charged to indirect cost pools and/or costs not allocated to a government contract, and partially with costs charged directly to a government contract.

(11) Form, fit, and function data means technical data that describes the required overall physical, functional, and performance characteristics (along with the qualification requirements, if applicable) of an item, component, or process to the extent necessary to permit identification of physically and functionally interchangeable items.

(12) Government purpose means any activity in which the United States Government is a party, including cooperative agreements with international or multi-national defense organizations, or sales or transfers by the United States Government to foreign governments or international organizations. Government purposes include competitive procurement, but do not include the rights to use, modify, reproduce, release, perform, display, or disclose technical data for commercial purposes or authorize others to do so.

(13) Government purpose rights means the rights to--

(i) Use, modify, reproduce, release, perform, display, or disclose technical data within the Government without restriction; and

(ii) Release or disclose technical data outside the Government and authorize persons to whom release or disclosure has been made to use, modify, reproduce, release, perform, display, or disclose that data for United States government purposes.

(14) Limited rights means the rights to use, modify, reproduce, release, perform, display, or disclose technical data, in whole or in part, within the Government. The Government may not, without the written permission of the party asserting limited rights, release or disclose the technical data outside the Government, use the technical data for manufacture, or authorize the technical data to be used by another party, except that the Government may reproduce, release, or disclose such data or authorize the use or reproduction of the data by persons outside the Government if--

(i) The reproduction, release, disclosure, or use is--

(A) Necessary for emergency repair and overhaul; or

(B) A release or disclosure to--

(1) A covered Government support contractor, for use, modification, reproduction, performance, display, or release or disclosure to authorized person(s) in performance of a Government contract; or

(2) A foreign government, of technical data other than detailed manufacturing or process data, when use of such databy the foreign government is in the interest of the Government and is required for evaluational or informational purposes;

(ii) The recipient of the technical data is subject to a prohibition on the further reproduction, release, disclosure, or use of the technical data; and

(iii) The contractor or subcontractor asserting the restriction is notified of such reproduction, release, disclosure, or use.

(15) Technical data means recorded information, regardless of the form or method of the recording, of a scientific or technical nature (including computer software documentation). The term does not include computer software or data incidental to contract administration, such as financial and/or management information.

(16) Unlimited rights means rights to use, modify, reproduce, perform, display, release, or disclose technical data in whole or in part, in any manner, and for any purpose whatsoever, and to have or authorize others to do so.

(b) Rights in technical data. The Contractor grants or shall obtain for the Government the following royalty free, world-wide, nonexclusive, irrevocable license rights in technical data other than computer software documentation (see the Rights in Noncommercial Computer Software and Noncommercial Computer Software Documentation clause of this contract for rights in computer software documentation):

(1) Unlimited rights.

The Government shall have unlimited rights in technical data that are--

(i) Data pertaining to an item, component, or process which has been or will be developed exclusively with Government funds;

(ii) Studies, analyses, test data, or similar data produced for this contract, when the study, analysis, test, or similar work was specified as an element of performance;

(iii) Created exclusively with Government funds in the performance of a contract that does not require the development, manufacture, construction, or production of items, components, or processes;

(iv) Form, fit, and function data;

(v) Necessary for installation, operation, maintenance, or training purposes (other than detailed manufacturing or process data);

(vi) Corrections or changes to technical data furnished to the Contractor by the Government;

(vii) Otherwise publicly available or have been released or disclosed by the Contractor or subcontractor without restrictions on further use, release or disclosure, other than a release or disclosure resulting from the sale, transfer, or other assignment of interest in the technical data to another party or the sale or transfer of some or all of a business entity or its assets to another party;

(viii) Data in which the Government has obtained unlimited rights under another Government contract or as a result of negotiations; or

(ix) Data furnished to the Government, under this or any other Government contract or subcontract thereunder, with--

(A) Government purpose license rights or limited rights and the restrictive condition(s) has/have expired; or

(B) Government purpose rights and the Contractor's exclusive right to use such data for commercial purposes has expired.

(2) Government purpose rights.

(i) The Government shall have government purpose rights for a five-year period, or such other period as may be negotiated, in technical data--

(A) That pertain to items, components, or processes developed with mixed funding except when the Government is entitled to unlimited rights in such data as provided in paragraphs (b)(ii) and (b)(iv) through (b)(ix) of this clause; or

(B) Created with mixed funding in the performance of a contract that does not require the development, manufacture, construction, or production of items, components, or processes.

(ii) The five-year period, or such other period as may have been negotiated, shall commence upon execution of the contract, subcontract, letter contract (or similar contractual instrument), contract modification, or option exercise that required development of the items, components, or processes or creation of the data described in paragraph (b)(2)(i)(B) of this clause. Upon expiration of the five-year or other negotiated period, the Government shall have unlimited rights in the technical data.

(iii) The Government shall not release or disclose technical data in which it has government purpose rights unless-

(A) Prior to release or disclosure, the intended recipient is subject to the non-disclosure agreement at 227.7103-7 of the Defense Federal Acquisition Regulation Supplement (DFARS); or

(B) The recipient is a Government contractor receiving access to the data for performance of a Government contract that contains the clause at DFARS 252.227-7025, Limitations on the Use or Disclosure of Government-Furnished Information Marked with Restrictive Legends.

(iv) The Contractor has the exclusive right, including the right to license others, to use technical data in which the Government has obtained government purpose rights under this contract for any commercial purpose during the time period specified in the government purpose rights legend prescribed in paragraph (f)(2) of this clause.

(3) Limited rights.

(i) Except as provided in paragraphs (b)(1)(ii) and (b)(1)(iv) through (b)(1)(ix) of this clause, the Government shall have limited rights in technical data--

(A) Pertaining to items, components, or processes developed exclusively at private expense and marked with the limited rights legend prescribed in paragraph (f) of this clause; or

(B) Created exclusively at private expense in the performance of a contract that does not require the development, manufacture, construction, or production of items, components, or processes.

(ii) The Government shall require a recipient of limited rights data for emergency repair or overhaul to destroy the data and all copies in its possession promptly following completion of the emergency repair/overhaul and to notify the Contractor that the data have been destroyed.

(iii) The Contractor, its subcontractors, and suppliers are not required to provide the Government additional rights to use, modify, reproduce, release, perform, display, or disclose technical data furnished to the Government with limited rights. However, if the Government desires to obtain additional rights in technical data in which it has limited rights, the Contractor agrees to promptly enter into negotiations with the Contracting Officer to determine

whether there are acceptable terms for transferring such rights. All technical data in which the Contractor has granted the Government additional rights shall be listed or described in a license agreement made part of the contract. The license shall enumerate the additional rights granted the Government in such data.

(iv) The Contractor acknowledges that--

(A) Limited rights data is authorized to be released or disclosed to covered Government support contractors;

(B) The Contractor will be notified of such release or disclosure;

(C) The Contractor (or the party asserting restrictions as identified in the limited rights legend) may require each such covered Government support contractor to enter into a non-disclosure agreement directly with the Contractor (or the party asserting restrictions) regarding the covered Government support contractor's use of such data, or alternatively, that the Contractor (or party asserting restrictions) may waive in writing the requirement for a non-disclosure agreement;

(D) Any such non-disclosure agreement shall address the restrictions on the covered Government support contractor's use of the limited rights data as set forth in the clause at 252.227-7025, and shall not include any additional terms and conditions unless mutually agreed to by the parties to the non-disclosure agreement; and

(E) The Contractor shall provide a copy of any such non-disclosure agreement or waiver to the Contracting Officer, upon request.

(4) Specifically negotiated license rights.

The standard license rights granted to the Government under paragraphs (b)(1) through (b)(3) of this clause, including the period during which the Government shall have government purpose rights in technical data, may be modified by mutual agreement to provide such rights as the parties consider appropriate but shall not provide the Government lesser rights than are enumerated in paragraph (a)(13) of this clause. Any rights so negotiated shall be identified in a license agreement made part of this contract.

(5) Prior government rights.

Technical data that will be delivered, furnished, or otherwise provided to the Government under this contract, in which the Government has previously obtained rights shall be delivered, furnished, or provided with the pre-existing rights, unless--

(i) The parties have agreed otherwise; or

(ii) Any restrictions on the Government's rights to use, modify, reproduce, release, perform, display, or disclose the data have expired or no longer apply.

(6) Release from liability.

The Contractor agrees to release the Government from liability for any release or disclosure of technical data made in accordance with paragraph (a)(13) or (b)(2)(iii) of this clause, in accordance with the terms of a license negotiated under paragraph (b)(4) of this clause, or by others to whom the recipient has released or disclosed the data and to seek relief solely from the party who has improperly used, modified, reproduced, released, performed, displayed, or disclosed Contractor data marked with restrictive legends.

(c) Contractor rights in technical data. All rights not granted to the Government are retained by the Contractor.

(d) Third party copyrighted data. The Contractor shall not, without the written approval of the Contracting Officer, incorporate any copyrighted data in the technical data to be delivered under this contract unless the Contractor is the

copyright owner or has obtained for the Government the license rights necessary to perfect a license or licenses in the deliverable data of the appropriate scope set forth in paragraph (b) of this clause, and has affixed a statement of the license or licenses obtained on behalf of the Government and other persons to the data transmittal document.

(e) Identification and delivery of data to be furnished with restrictions on use, release, or disclosure. (1) This paragraph does not apply to restrictions based solely on copyright.

(2) Except as provided in paragraph (e)(3) of this clause, technical data that the Contractor asserts should be furnished to the Government with restrictions on use, release, or disclosure are identified in an attachment to this contract (the Attachment). The Contractor shall not deliver any data with restrictive markings unless the data are listed on the Attachment.

(3) In addition to the assertions made in the Attachment, other assertions may be identified after award when based on new information or inadvertent omissions unless the inadvertent omissions would have materially affected the source selection decision. Such identification and assertion shall be submitted to the Contracting Officer as soon as practicable prior to the scheduled date for delivery of the data, in the following format, and signed by an official authorized to contractually obligate the Contractor: Identification and Assertion of Restrictions on the Government's Use, Release, or Disclosure of Technical Data.

The Contractor asserts for itself, or the persons identified below, that the Government's rights to use, release, or disclose the following technical data should be restricted--

Technical data to be Furnished With Restrictions \1/	Asserted Basis for Assertion \2/	Name of Person Asserting Category \3/	Restrictions \4/
(LIST)	(LIST)	(LIST)	(LIST)

\1/ If the assertion is applicable to items, components or processes developed at private expense, identify both the data and each such items, component, or process.

\2/ Generally, the development of an item, component, or process at private expense, either exclusively or partially, is the only basis for asserting restrictions on the Government's rights to use, release, or disclose technical data pertaining to such items, components, or processes. Indicate whether development was exclusively or partially at private expense. If development was not at private expense, enter the specific reason for asserting that the Government's rights should be restricted.

\3/ Enter asserted rights category (e.g., government purpose license rights from a prior contract, rights in SBIR data generated under another contract, limited or government purpose rights under this or a prior contract, or specifically negotiated licenses).

\4/ Corporation, individual, or other person, as appropriate.
Date _____

Printed Name and Title _____

_____

Signature _____

(End of identification and assertion)

(4) When requested by the Contracting Officer, the Contractor shall provide sufficient information to enable the Contracting Officer to evaluate the Contractor's assertions. The Contracting Officer reserves the right to add the Contractor's assertions to the Attachment and validate any listed assertion, at a later date, in accordance with the procedures of the Validation of Restrictive Markings on Technical Data clause of this contract.

(f) Marking requirements. The Contractor, and its subcontractors or suppliers, may only assert restrictions on the Government's rights to use, modify, reproduce, release, perform, display, or disclose technical data to be delivered under this contract by marking the deliverable data subject to restriction. Except as provided in paragraph (f)(5) of this clause, only the following legends are authorized under this contract: the government purpose rights legend at paragraph (f)(2) of this clause; the limited rights legend at paragraph (f)(3) of this clause; or the special license rights legend at paragraph (f)(4) of this clause; and/or a notice of copyright as prescribed under 17 U.S.C. 401 or 402.

(1) General marking instructions. The Contractor, or its subcontractors or suppliers, shall conspicuously and legibly mark the appropriate legend on all technical data that qualify for such markings. The authorized legends shall be placed on the transmittal document or storage container and, for printed material, each page of the printed material containing technical data for which restrictions are asserted. When only portions of a page of printed material are subject to the asserted restrictions, such portions shall be identified by circling, underscoring, with a note, or other appropriate identifier. Technical data transmitted directly from one computer or computer terminal to another shall contain a notice of asserted restrictions. Reproductions of technical data or any portions thereof subject to asserted restrictions shall also reproduce the asserted restrictions.

(2) Government purpose rights markings. Data delivered or otherwise furnished to the Government purpose rights shall be marked as follows:

Government Purpose Rights

Contract No. _____

Contractor Name _____

Contractor Address _____

_____

Expiration Date _____

The Government's rights to use, modify, reproduce, release, perform, display, or disclose these technical data are restricted by paragraph (b)(2) of the Rights in Technical Data--Noncommercial Items clause contained in the above identified contract. No restrictions apply after the expiration date shown above. Any reproduction of technical data or portions thereof marked with this legend must also reproduce the markings.

(End of legend)

(3) Limited rights markings. Data delivered or otherwise furnished to the Government with limited rights shall be marked with the following legend:

Limited Rights

Contract No. _____

Contractor Name _____

Contractor Address _____

The Government's rights to use, modify, reproduce, release, perform, display, or disclose these technical data are restricted by paragraph (b)(3) of the Rights in Technical Data--Noncommercial Items clause contained in the above identified contract. Any reproduction of technical data or portions thereof marked with this legend must also reproduce the markings. Any person, other than the Government, who has been provided access to such data must promptly notify the above named Contractor.

(End of legend)

(4) Special license rights markings. (i) Data in which the Government's rights stem from a specifically negotiated license shall be marked with the following legend:

Special License Rights

The Government's rights to use, modify, reproduce, release, perform, display, or disclose these data are restricted by Contract No. _____ (Insert contract number) _____, License No. _____ (Insert license identifier) _____. Any reproduction of technical data or portions thereof marked with this legend must also reproduce the markings.

(End of legend)

(ii) For purposes of this clause, special licenses do not include government purpose license rights acquired under a prior contract (see paragraph (b)(5) of this clause).

(5) Pre-existing data markings. If the terms of a prior contract or license permitted the Contractor to restrict the Government's rights to use, modify, reproduce, release, perform, display, or disclose technical data deliverable under this contract, and those restrictions are still applicable, the Contractor may mark such data with the appropriate restrictive legend for which the data qualified under the prior contract or license. The marking procedures in paragraph (f)(1) of this clause shall be followed.

(g) Contractor procedures and records. Throughout performance of this contract, the Contractor and its subcontractors or suppliersthat will deliver technical data with other than unlimited rights, shall--

(1) Have, maintain, and follow written procedures sufficient to assure that restrictive markings are used only when authorized by the terms of this clause; and

(2) Maintain records sufficient to justify the validity of any restrictive markings on technical data delivered under this contract.

(h) Removal of unjustified and nonconforming markings. (1) Unjustified technical data markings. The rights and obligations of the parties regarding the validation of restrictive markings on technical data furnished or to be furnished under this contract are contained in the Validation of Restrictive Markings on Technical Data clause of this contract. Notwithstanding any provision of this contract concerning inspection and acceptance, the Government may ignore or, at the Contractor's expense, correct or strike a marking if, in accordance with the procedures in the Validation of Restrictive Markings on Technical Data clause of this contract, a restrictive marking is determined to be unjustified.

(2) Nonconforming technical data markings. A nonconforming marking is a marking placed on technical data delivered or otherwise furnished to the Government under this contract that is not in the format authorized by this contract. Correction of nonconforming markings is not subject to the validation of Restrictive Markings on Technical Data clause of this contract. If the Contracting Officer notifies the Contractor of a nonconforming

marking and the Contractor fails to remove or correct such marking within sixty (60) days, the Government may ignore or, at the Contractor's expense, remove or correct any nonconforming marking.

(i) Relation to patents. Nothing contained in this clause shall imply a license to the Government under any patent or be construed as affecting the scope of any license or other right otherwise granted to the Government under any patent.

(j) Limitation on charges for rights in technical data. (1) The Contractor shall not charge to this contract any cost, including, but not limited to, license fees, royalties, or similar charges, for rights in technical data to be delivered under this contract when--

(i) The Government has acquired, by any means, the same or greater rights in the data; or

(ii) The data are available to the public without restrictions.

(2) The limitation in paragraph (j)(1) of this clause--

(i) Includes costs charged by a subcontractor or supplier, at any tier, or costs incurred by the Contractor to acquire rights in subcontractor or supplier technical data, if the subcontractor or supplier has been paid for such rights under any other Government contract or under a license conveying the rights to the Government; and

(ii) Does not include the reasonable costs of reproducing, handling, or mailing the documents or other media in which the technical data will be delivered.

(k) Applicability to subcontractors or suppliers. (1) The Contractor shall ensure that the rights afforded its subcontractors and suppliers under 10 U.S.C. 2320, 10 U.S.C. 2321, and the identification, assertion, and delivery processes of paragraph (e) of this clause are recognized and protected.

(2) Whenever any technical data for noncommercial items is to be obtained from a subcontractor or supplier for delivery to the Government under this contract, the Contractor shall use this same clause in the subcontract or other contractual instrument, and require its subcontractors or suppliers to do so, without alteration, except to identify the parties. No other clause shall be used to enlarge or diminish the Government's, the Contractor's, or a higher-tier subcontractor's or supplier's rights in a subcontractor's or supplier's technical data.

(3) Technical data required to be delivered by a subcontractor or supplier shall normally be delivered to the next higher-tier contractor, subcontractor, or supplier. However, when there is a requirement in the prime contract for data which may be submitted with other than unlimited rights by a subcontractor or supplier, then said subcontractor or supplier may fulfill its requirement by submitting such data directly to the Government, rather than through a higher-tier contractor, subcontractor, or supplier.

(4) The Contractor and higher-tier subcontractors or suppliers shall not use their power to award contracts as economic leverage to obtain rights in technical data from their subcontractors or suppliers. (5) In no event shall the Contractor use its obligation to recognize and protect subcontractor or supplier rights in technical data as an excuse for failing to satisfy its contractual obligations to the Government.

(End of clause)

CLAUSES INCORPORATED BY FULL TEXT

252.247-7023 Transportation of Supplies by Sea (MAY 2002)

(a) Definitions. As used in this clause --

(1) "Components" means articles, materials, and supplies incorporated directly into end products at any level of manufacture, fabrication, or assembly by the Contractor or any subcontractor.

(2) "Department of Defense" (DoD) means the Army, Navy, Air Force, Marine Corps, and defense agencies.

(3) "Foreign flag vessel" means any vessel that is not a U.S.-flag vessel.

(4) "Ocean transportation" means any transportation aboard a ship, vessel, boat, barge, or ferry through international waters.

(5) "Subcontractor" means a supplier, materialman, distributor, or vendor at any level below the prime contractor whose contractual obligation to perform results from, or is conditioned upon, award of the prime contract and who is performing any part of the work or other requirement of the prime contract.

(6) "Supplies" means all property, except land and interests in land, that is clearly identifiable for eventual use by or owned by the DoD at the time of transportation by sea.

(i) An item is clearly identifiable for eventual use by the DoD if, for example, the contract documentation contains a reference to a DoD contract number or a military destination.

(ii) "Supplies" includes (but is not limited to) public works; buildings and facilities; ships; floating equipment and vessels of every character, type, and description, with parts, subassemblies, accessories, and equipment; machine tools; material; equipment; stores of all kinds; end items; construction materials; and components of the foregoing.

(7) "U.S.-flag vessel" means a vessel of the United States or belonging to the United States, including any vessel registered or having national status under the laws of the United States.

(b)(1) The Contractor shall use U.S.-flag vessels when transporting any supplies by sea under this contract.

(2) A subcontractor transporting supplies by sea under this contract shall use U.S.-flag vessels if--

(i) This contract is a construction contract; or

(ii) The supplies being transported are--

(A) Noncommercial items; or

(B) Commercial items that--

(1) The Contractor is reselling or distributing to the Government without adding value (generally, the Contractor does not add value to items that it contracts for f.o.b. destination shipment);

(2) Are shipped in direct support of U.S. military contingency operations, exercises, or forces deployed in humanitarian or peacekeeping operations; or

(3) Are commissary or exchange cargoes transported outside of the Defense Transportation System in accordance with 10 U.S.C. 2643.

(c) The Contractor and its subcontractors may request that the Contracting Officer authorize shipment in foreign-flag vessels, or designate available U.S.-flag vessels, if the Contractor or a subcontractor believes that --

(1) U.S.-flag vessels are not available for timely shipment;

(2) The freight charges are inordinately excessive or unreasonable; or

(3) Freight charges are higher than charges to private persons for transportation of like goods.

(d) The Contractor must submit any request for use of other than U.S.-flag vessels in writing to the Contracting Officer at least 45 days prior to the sailing date necessary to meet its delivery schedules. The Contracting Officer will process requests submitted after such date(s) as expeditiously as possible, but the Contracting Officer's failure to grant approvals to meet the shipper's sailing date will not of itself constitute a compensable delay under this or any other clause of this contract. Requests shall contain at a minimum --

(1) Type, weight, and cube of cargo;

(2) Required shipping date;

(3) Special handling and discharge requirements;

(4) Loading and discharge points;

(5) Name of shipper and consignee;

(6) Prime contract number; and

(7) A documented description of efforts made to secure U.S.-flag vessels, including points of contact (with names and telephone numbers) with at least two U.S.-flag carriers contacted. Copies of telephone notes, telegraphic and facsimile message or letters will be sufficient for this purpose.

(e) The Contractor shall, within 30 days after each shipment covered by this clause, provide the Contracting Officer and the Maritime Administration, Office of Cargo Preference, U.S. Department of Transportation, 400 Seventh Street SW., Washington, DC 20590, one copy of the rated on board vessel operating carrier's ocean bill of lading, which shall contain the following information:

(1) Prime contract number;

(2) Name of vessel;

(3) Vessel flag of registry;

(4) Date of loading;

(5) Port of loading;

(6) Port of final discharge;

(7) Description of commodity;

(8) Gross weight in pounds and cubic feet if available;

(9) Total ocean freight in U.S. dollars; and

(10) Name of the steamship company.

(f) The Contractor shall provide with its final invoice under this contract a representation that to the best of its knowledge and belief--

(1) No ocean transportation was used in the performance of this contract;

(2) Ocean transportation was used and only U.S.-flag vessels were used for all ocean shipments under the contract;

(3) Ocean transportation was used, and the Contractor had the written consent of the Contracting Officer for all non-U.S.-flag ocean transportation; or

(4) Ocean transportation was used and some or all of the shipments were made on non-U.S.-flag vessels without the written consent of the Contracting Officer. The Contractor shall describe these shipments in the following format:

ITEM DESCRIPTION	CONTRACT LINE ITEMS	QUANTITY
TOTAL		

(g) If the final invoice does not include the required representation, the Government will reject and return it to the Contractor as an improper invoice for the purposes of the Prompt Payment clause of this contract. In the event there has been unauthorized use of non-U.S.-flag vessels in the performance of this contract, the Contracting Officer is entitled to equitably adjust the contract, based on the unauthorized use.

(h) In the award of subcontracts for the types of supplies described in paragraph (b)(2) of this clause, the Contractor shall flow down the requirements of this clause as follows:

(1) The Contractor shall insert the substance of this clause, including this paragraph (h), in subcontracts that exceed the simplified acquisition threshold in part 2 of the Federal Acquisition Regulation.

(2) The Contractor shall insert the substance of paragraphs (a) through (e) of this clause, and this paragraph (h), in subcontracts that are at or below the simplified acquisition threshold in part 2 of the Federal Acquisition Regulation.

(End of clause)

Section J - List of Documents, Exhibits and Other Attachments

ATTACHMENTS

List of Attachments

Attachment No	Description	Document
J.1	Statement of Objectives (SOO)	**J1 MCM ADM SOO.pdf**
J.2	Sample Tasks for Notional Products	**J2 Sample Tasks for Notional Products.pdf**
J.3	Sample Task 1 WBS Worksheet	**J3 Sample Task 1 WBS Worksheet.xlsx**
J.4	Sample Task 2 WBS Worksheet	**J4 Sample Task 2 WBS Worksheet .xlsx**
J.5	Sample Task Evaluation Criteria	**J5 Sample Task Evaluation Criteria.pdf**
J.6	Crosswalk Matrix	**J6 Crosswalk Matrix.xlsx**
J.7	Cost Proposal Spreadsheet Template	**J7 Cost Proposal Spreadsheet Template.xlsx**
J.8	Past Performance Questionnaire	**J8 Past Performance Questionnaire.doc**

CDRLS

List of Contract Data Requirements List (CDRLs)

Item Number	Description	Format
A001	Integrated Master Plan	DI-MGMT-80004
A002	Integrated Master Schedule	DI-MGMT-81650
A003	Contract Work Breakdown Structure	DI-MGMT-81334c
A004	EVMS – Contract Performance Report (CPR)	DI-MGMT-81466A
A005	Manufacturing Capability Plan (CLIN 1002AE)	contractor
A006	Facility Operation Feasibility Plan (CLIN 1002AF)	contractor
A007	Equipment Qualification/Commissioning and Facility Validation Summary (CLIN 1002AG)	contractor
A008	Monthly Contractor Progress, Status, & Management Report	contractor
A009	Contract Funds Status Report	DI-MGT-81468
A010	Training Report	contractor

A011	Miscellaneous Data Submissions	contractor
A012	Patents – Reporting of Subject Inventions	contractor
A013	Regulatory Approval and FDA Submissions	contractor
A014	Intellectual Property Plan - Update	contractor
A015	Master Government Property List	DI-MGT-80269
A016	Master Government Property – Physical Inventory	DI-MGT-80441
A017	Contractor Manpower Reporting	See Section C.2

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 search Solicitation W911QY11R0023

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

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.

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

A3: There is no cost share requirement.

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.

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.

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

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.

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

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 <u>at least one product</u> 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 <u>at least one product</u> 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.

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.

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.

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."

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.

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.

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

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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 MCMs
Please 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.

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.

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.

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.

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.

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.

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.

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 3rd 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 3rd party use of the ADM.

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.

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.

Q36: Governance of MCM ADM activities - The solicitation indicates MCM ADM activities will be governed by separate contracts with 3rd 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.

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.

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.

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."

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.

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."

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.

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.

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.

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"

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."

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.

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."

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).

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.

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.

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.

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.

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.

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…"

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.

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.

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?

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.

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.

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.

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.

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).

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.

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.

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.

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.

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.

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.

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.

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.

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 sto 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

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.

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."

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.

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."

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

Q86: Are there any minimum or maximum footprint expectations for the two suites?
A86: No. See also Q/A 28.

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.

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.

Q89: Is there an incumbent?

A89: No.

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.

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.

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.

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”.

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.

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.

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.

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

A97: This program is not responsible for items such as butyl insulated gloves and we will not provide information pertaining to items or requirements that are not part of this program.

Q98: IAW with FAR 15.404-4, states: The contracting officer shall not negotiate a price or fee that exceeds the following statutory limitations, imposed by 10 U.S.C. 2306(d) http://uscode.house.gov/uscode-cgi/fastweb.exe?getdoc+uscview+t09t12+37+408++%2810%29%20%252 and 41 U.S.C. 254(b) http://uscode.house.gov/uscode-cgi/fastweb.exe?getdoc+uscview+t41t42+2+13++%2841%29%20%20AND%20%28%2841%29%20ADJ%20USC%29%3ACITE%20%20%20%20%20%20%20%20%20 :

(A) For experimental, developmental, or research work performed under a cost-plus-fixed-fee contract, the fee shall not exceed 15 percent of the contract's estimated cost, excluding fee.

(B) For architect-engineer services for public works or utilities, the contract price or the estimated cost and fee for production and delivery of designs, plans, drawings, and specifications shall not exceed 6 percent of the estimated cost of construction of the public work or utility, excluding fees.

(C) For other cost-plus-fixed-fee contracts, the fee shall not exceed 10 percent of the contract's estimated cost, excluding fee.

For pricing purposes, we are assuming that all of the work to be bid and performed under the MCM ADM contract, Solicitation Number W911QY-11-R-0023, falls under (A) above, which seems most consistent with the (NAICS) code 325412 - Pharmaceutical Preparation Manufacturing. Is this correct?

A98: Yes, the action is RDTE with a 15% maximum allowable fee. Paragraph A.1 will be amended to include the following: “Research and Development (FAR Part 35).

Q99: Please clarify the definition of "Procurement" as it relates to Task Order 1, WBS elements 12.8 and 12.12; and Task Order 2, WBS elements 2.5, 2.9, and 10.0. Does this refer to the Offeror's procurement of supplies and materials (other than equipment) or to DoD's procurement of final products from the Offeror? If the latter, is this intended to be just the summation of the costs in the WBS or the Offeror's total cost plus fixed fee?

A99: For the referenced WBS elements listed above, “Procurement” refers to the work of the contractor to fabricate and deliver the specified doses. In this context, it is “procurement by the Government from the contractor” for the specified quantities.

Q100: Please clarify the expected roles of the Key Personnel, particularly distinguishing between the Chief Scientific Officer and the Principle Investigator.

A100: Paragraph H.4. of the RFP will be amended to remove Principal Investigator as a "key personnel".

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.

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.

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.

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 indicated 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.

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.

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.

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.

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)

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. 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 clarity 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

CLAUSES INCORPORATED BY REFERENCE

52.203-11	Certification And Disclosure Regarding Payments To Influence Certain Federal Transactions	SEP 2007
52.222-38	Compliance With Veterans' Employment Reporting Requirements	SEP 2010
52.223-4	Recovered Material Certification	MAY 2008
252.227-7030	Technical Data--Withholding Of Payment	MAR 2000
252.227-7033	Rights in Shop Drawings	APR 1966
252.234-7001	Notice of Earned Value Management System	APR 2008

CLAUSES INCORPORATED BY FULL TEXT

52.204-5 WOMEN-OWNED BUSINESS (OTHER THAN SMALL BUSINESS) (MAY 1999)

(a) Definition. Women-owned business concern, as used in this provision, means a concern that is at least 51 percent owned by one or more women; or in the case of any publicly owned business, at least 51 percent of its stock is owned by one or more women; and whose management and daily business operations are controlled by one or more women.

(b) Representation. [Complete only if the offeror is a women-owned business concern and has not represented itself as a small business concern in paragraph (b)(1) of FAR 52.219-1, Small Business Program Representations, of this solicitation.] The offeror represents that it ( ) is a women-owned business concern.

(End of provision)

CLAUSES INCORPORATED BY FULL TEXT

52.204-8 ANNUAL REPRESENTATIONS AND CERTIFICATIONS (MAY 2011)

(a)(1) The North American Industry Classification System (NAICS) code for this acquisition is ---------- 325412.

(2) The small business size standard is ---------- 750 in average number of employees.

(3) The small business size standard for a concern which submits an offer in its own name, other than on a construction or service contract, but which proposes to furnish a product which it did not itself manufacture, is 500 employees.

(b)(1) If the clause at 52.204-7, Central Contractor Registration, is included in this solicitation, paragraph (d) of this provision applies.

(2) If the clause at 52.204-7 is not included in this solicitation, and the offeror is currently registered in CCR, and has completed the ORCA electronically, the offeror may choose to use paragraph (d) of this provision instead of

completing the corresponding individual representations and certifications in the solicitation. The offeror shall indicate which option applies by checking one of the following boxes:

(__) Paragraph (d) applies.

(__) Paragraph (d) does not apply and the offeror has completed the individual representations and certifications in the solicitation.

(c)(1) The following representations or certifications in ORCA are applicable to this solicitation as indicated:

(i) 52.203-2, Certificate of Independent Price Determination. This provision applies to solicitations when a firm-fixed-price contract or fixed-price contract with economic price adjustment is contemplated, unless--

(A) The acquisition is to be made under the simplified acquisition procedures in Part 13;

(B) The solicitation is a request for technical proposals under two-step sealed bidding procedures; or

(C) The solicitation is for utility services for which rates are set by law or regulation.

(ii) 52.203-11, Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions. This provision applies to solicitations expected to exceed $150,000.

(iii) 52.204-3, Taxpayer Identification. This provision applies to solicitations that do not include the clause at 52.204-7, Central Contractor Registration.

(iv) 52.204-5, Women-Owned Business (Other Than Small Business).This provision applies to solicitations that--

(A) Are not set aside for small business concerns;

(B) Exceed the simplified acquisition threshold; and

(C) Are for contracts that will be performed in the United States or its outlying areas.

(v) 52.209-2, Prohibition on Contracting with Inverted Domestic Corporations--Representation. This provision applies to solicitations using funds appropriated in fiscal years 2008, 2009, or 2010.

(vi) 52.209-5, Certification Regarding Responsibility Matters. This provision applies to solicitations where the contract value is expected to exceed the simplified acquisition threshold.

(vii) 52.223-5, Pollution Prevention and Right-to-Know Information (May 2011) (E.O. 13423) (Applies to services performed on Federal facilities).

(viii) 52.215-6, Place of Performance. This provision applies to solicitations unless the place of performance is specified by the Government.

(ix) 52.219-1, Small Business Program Representations (Basic & Alternate I). This provision applies to solicitations when the contract will be performed in the United States or its outlying areas.

(A) The basic provision applies when the solicitations are issued by other than DoD, NASA, and the Coast Guard.

(B) The provision with its Alternate I applies to solicitations issued by DoD, NASA, or the Coast Guard.

(x) 52.219-2, Equal Low Bids. This provision applies to solicitations when contracting by sealed bidding and the contract will be performed in the United States or its outlying areas.

(xi) 52.222-22, Previous Contracts and Compliance Reports. This provision applies to solicitations that include the clause at 52.222-26, Equal Opportunity.

(xii) 52.222-25, Affirmative Action Compliance. This provision applies to solicitations, other than those for construction, when the solicitation includes the clause at 52.222-26, Equal Opportunity.

(xiii) 52.222-38, Compliance with Veterans' Employment Reporting Requirements. This provision applies to solicitations when it is anticipated the contract award will exceed the simplified acquisition threshold and the contract is not for acquisition of commercial items.

(xiv) 52.223-1, Biobased Product Certification. This provision applies to solicitations that require the delivery or specify the use of USDA-designated items; or include the clause at 52.223-2, Affirmative Procurement of Biobased Products Under Service and Construction Contracts.

(xv) 52.223-4, Recovered Material Certification. This provision applies to solicitations that are for, or specify the use of, EPA-designated items.

(xvi) 52.225-2, Buy American Act Certificate. This provision applies to solicitations containing the clause at 52.225-1.

(xvii) 52.225-4, Buy American Act--Free Trade Agreements—Israeli Trade Act Certificate. (Basic, Alternate I, and Alternate II) This provision applies to solicitations containing the clause at 52.225-3.

(A) If the acquisition value is less than $25,000, the basic provision applies.

(B) If the acquisition value is $25,000 or more but is less than $50,000, the provision with its Alternate I applies.

(C) If the acquisition value is $50,000 or more but is less than $67,826, the provision with its Alternate II applies.

(xviii) 52.225-6, Trade Agreements Certificate. This provision applies to solicitations containing the clause at 52.225-5.

(xix) 52.225-20, Prohibition on Conducting Restricted Business Operations in Sudan--Certification. This provision applies to all solicitations.

(xx) 52.225-25, Prohibition on Engaging in Sanctioned Activities Relating to Iran--Certification. This provision applies to all solicitations.

(xxi) 52.226-2, Historically Black College or University and Minority Institution Representation. This provision applies to--

(A) Solicitations for research, studies, supplies, or services of the type normally acquired from higher educational institutions; and

(B) For DoD, NASA, and Coast Guard acquisitions, solicitations that contain the clause at 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns.

(2) The following certifications are applicable as indicated by the Contracting Officer:

(Contracting Officer check as appropriate.)

------(i) 52.219-22, Small Disadvantaged Business Status.

------(A) Basic.

------(B) Alternate I.

------(ii) 52.222-18, Certification Regarding Knowledge of Child Labor for Listed End Products.

------(iii) 52.222-48, Exemption from Application of the Service Contract Act to Contracts for Maintenance, Calibration, or Repair of Certain Equipment Certification.

------(iv) 52.222-52 Exemption from Application of the Service Contract Act to Contracts for Certain Services--Certification.

------(v) 52.223-9, with its Alternate I, Estimate of Percentage of Recovered Material Content for EPA-Designated Products (Alternate I only).

X ------(vi) 52.223-13, Certification of Toxic Chemical Release Reporting.

------(vii) 52.227-6, Royalty Information.

------ (A) Basic.

------ (B) Alternate I.

------(viii) 52.227-15, Representation of Limited Rights Data and Restricted Computer Software.

(d) The offeror has completed the annual representations and certifications electronically via the Online Representations and Certifications Application (ORCA) website at http://orca.bpn.gov. After reviewing the ORCA database information, the offeror verifies by submission of the offer that the representations and certifications currently posted electronically that apply to this solicitation as indicated in paragraph (c) of this provision have been entered or updated within the last 12 months, are current, accurate, complete, and applicable to this solicitation (including the business size standard applicable to the NAICS code referenced for this solicitation), as of the date of this offer and are incorporated in this offer by reference (see FAR 4.1201); except for the changes identified below (offeror to insert changes, identifying change by clause number, title, date). These amended representation(s) and/or certification(s) are also incorporated in this offer and are current, accurate, and complete as of the date of this offer.

FAR Clause	Title	Date	Change

Any changes provided by the offeror are applicable to this solicitation only, and do not result in an update to the representations and certifications posted on ORCA.

(End of Provision)

CLAUSES INCORPORATED BY FULL TEXT

52.209-5 CERTIFICATION REGARDING RESPONSIBILITY MATTERS (APR 2010)

(a)(1) The Offeror certifies, to the best of its knowledge and belief, that-

(i) The Offeror and/or any of its Principals-

(A) Are ( ) are not ( ) presently debarred, suspended, proposed for debarment, or declared ineligible for the award of contracts by any Federal agency;

(B) Have ( ) have not ( ), within a three-year period preceding this offer, been convicted of or had a civil judgment rendered against them for: commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) contract or subcontract; violation of Federal or State antitrust statutes relating to the submission of offers; or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, violating Federal criminal tax laws, or receiving stolen property (if offeror checks “have”, the offeror shall also see 52.209-7, if included in this solicitation); and

(C) Are ( ) are not ( ) presently indicted for, or otherwise criminally or civilly charged by a governmental entity with, commission of any of the offenses enumerated in paragraph (a)(1)(i)(B) of this provision.; and

(D) Have [ballot], have not [ballot], within a three-year period preceding this offer, been notified of any delinquent Federal taxes in an amount that exceeds $3,000 for which the liability remains unsatisfied.

(1) Federal taxes are considered delinquent if both of the following criteria apply:

(i) The tax liability is finally determined. The liability is finally determined if it has been assessed. A liability is not finally determined if there is a pending administrative or judicial challenge. In the case of a judicial challenge to the liability, the liability is not finally determined until all judicial appeal rights have been exhausted.

(ii) The taxpayer is delinquent in making payment. A taxpayer is delinquent if the taxpayer has failed to pay the tax liability when full payment was due and required. A taxpayer is not delinquent in cases where enforced collection action is precluded.

(2) Examples. (i) The taxpayer has received a statutory notice of deficiency, under I.R.C. Sec. 6212, which entitles the taxpayer to seek Tax Court review of a proposed tax deficiency. This is not a delinquent tax because it is not a final tax liability. Should the taxpayer seek Tax Court review, this will not be a final tax liability until the taxpayer has exercised all judicial appeal rights.

(ii) The IRS has filed a notice of Federal tax lien with respect to an assessed tax liability, and the taxpayer has been issued a notice under I.R.C. Sec. 6320 entitling the taxpayer to request a hearing with the IRS Office of Appeals contesting the lien filing, and to further appeal to the Tax Court if the IRS determines to sustain the lien filing. In the course of the hearing, the taxpayer is entitled to contest the underlying tax liability because the taxpayer has had no prior opportunity to contest the liability. This is not a delinquent tax because it is not a final tax liability. Should the taxpayer seek tax court review, this will not be a final tax liability until the taxpayer has exercised all judicial appeal rights.

(iii) The taxpayer has entered into an installment agreement pursuant to I.R.C. Sec. 6159. The taxpayer is making timely payments and is in full compliance with the agreement terms. The taxpayer is not delinquent because the taxpayer is not currently required to make full payment.

(iv) The taxpayer has filed for bankruptcy protection. The taxpayer is not delinquent because enforced collection action is stayed under 11 U.S.C. 362 (the Bankruptcy Code).

(ii) The Offeror has ( ) has not ( ), within a three-year period preceding this offer, had one or more contracts terminated for default by any Federal agency.

(2) Principal, for the purposes of this certification, means an officer, director, owner, partner, or a person having primary management or supervisory responsibilities within a business entity (e.g., general manager; plant manager; head of a division or business segment; and similar positions).

(b) The Offeror shall provide immediate written notice to the Contracting Officer if, at any time prior to contract award, the Offeror learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.

(c) A certification that any of the items in paragraph (a) of this provision exists will not necessarily result in withholding of an award under this solicitation. However, the certification will be considered in connection with a determination of the Offeror's responsibility. Failure of the Offeror to furnish a certification or provide such additional information as requested by the Contracting Officer may render the Offeror nonresponsible.

(d) Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render, in good faith, the certification required by paragraph (a) of this provision. The knowledge and information of an Offeror is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

(e) The certification in paragraph (a) of this provision is a material representation of fact upon which reliance was placed when making award. If it is later determined that the Offeror knowingly rendered an erroneous certification, in addition to other remedies available to the Government, the Contracting Officer may terminate the contract resulting from this solicitation for default.

(End of provision)

CLAUSES INCORPORATED BY FULL TEXT

52.209-7 INFORMATION REGARDING RESPONSIBILITY MATTERS (JAN 2011)

(a) Definitions. As used in this provision--

Administrative proceeding means a non-judicial process that is adjudicatory in nature in order to make a determination of fault or liability (e.g., Securities and Exchange Commission Administrative Proceedings, Civilian Board of Contract Appeals Proceedings, and Armed Services Board of Contract Appeals Proceedings). This includes administrative proceedings at the Federal and State level but only in connection with performance of a Federal contract or grant. It does not include agency actions such as contract audits, site visits, corrective plans, or inspection of deliverables.

Federal contracts and grants with total value greater than $10,000,000 means--

(1) The total value of all current, active contracts and grants, including all priced options; and

(2) The total value of all current, active orders including all priced options under indefinite-delivery, indefinite-quantity, 8(a), or requirements contracts (including task and delivery and multiple-award Schedules).

Principal means an officer, director, owner, partner, or a person having primary management or supervisory responsibilities within a business entity (e.g., general manager; plant manager; head of a division or business segment; and similar positions).

(b) The offeror ( ) has ( ) does not have current active Federal contracts and grants with total value greater than $10,000,000.

(c) If the offeror checked “has” in paragraph (b) of this provision, the offeror represents, by submission of this offer, that the information it has entered in the Federal Awardee Performance and Integrity Information System (FAPIIS) is current, accurate, and complete as of the date of submission of this offer with regard to the following information:

(1) Whether the offeror, and/or any of its principals, has or has not, within the last five years, in connection with the award to or performance by the offeror of a Federal contract or grant, been the subject of a proceeding, at the Federal or State level that resulted in any of the following dispositions:

(i) In a criminal proceeding, a conviction.

(ii) In a civil proceeding, a finding of fault and liability that results in the payment of a monetary fine, penalty, reimbursement, restitution, or damages of $5,000 or more.

(iii) In an administrative proceeding, a finding of fault and liability that results in--

(A) The payment of a monetary fine or penalty of $5,000 or more; or

(B) The payment of a reimbursement, restitution, or damages in excess of $100,000.

(iv) In a criminal, civil, or administrative proceeding, a disposition of the matter by consent or compromise with an acknowledgment of fault by the Contractor if the proceeding could have led to any of the outcomes specified in paragraphs (c)(1)(i), (c)(1)(ii), or (c)(1)(iii) of this provision.

(2) If the offeror has been involved in the last five years in any of the occurrences listed in (c)(1) of this provision, whether the offeror has provided the requested information with regard to each occurrence.

(d) The offeror shall post the information in paragraphs (c)(1)(i) through (c)(1)(iv) of this provision in FAPIIS as required through maintaining an active registration in the Central Contractor Registration database at http://www.ccr.gov (see 52.204-7).

(End of provision)

52.219-1 SMALL BUSINESS PROGRAM REPRESENTATIONS (APR 2011) - ALTERNATE I (APR 2011)

(a)(1) The North American Industry Classification System (NAICS) code for this acquisition is 325412.

(2) The small business size standard is 750 in average number of employees.

(3) The small business size standard for a concern which submits an offer in its own name, other than on a construction or service contract, but which proposes to furnish a product which it did not itself manufacture, is 500 employees.

(b) Representations. (1) The offeror represents as part of its offer that it ( ) is, ( ) is not a small business concern.

(2) (Complete only if the offeror represented itself as a small business concern in paragraph (b)(1) of this provision.) The offeror represents, for general statistical purposes, that it ( ) is, ( ) is not a small disadvantaged business concern as defined in 13 CFR 124.1002.

(3) (Complete only if the offeror represented itself as a small business concern in paragraph (b)(1) of this provision.) The offeror represents as part of its offer that it ( ) is, ( ) is not a women-owned small business concern.

(4) Women-owned small business (WOSB) concern eligible under the WOSB Program. [Complete only if the offeror represented itself as a women-owned small business concern in paragraph (b)(3) of this provision.] The offeror represents as part of its offer that--

(i) It * is, * is not a WOSB concern eligible under the WOSB Program, has provided all the required documents to the WOSB Repository, and no change in circumstances or adverse decisions have been issued that affects its eligibility; and

(ii) It * is, * is not a joint venture that complies with the requirements of 13 CFR part 127, and the representation in paragraph (b)(4)(i) of this provision is accurate in reference to the WOSB concern or concerns that are participating in the joint venture. [The offeror shall enter the name or names of the WOSB concern or concerns that are participating in the joint venture: -----.] Each WOSB concern participating in the joint venture shall submit a separate signed copy of the WOSB representation.

(5) Economically disadvantaged women-owned small business (EDWOSB) concern. [Complete only if the offeror represented itself as a women-owned small business concern eligible under the WOSB Program in (b)(4) of this provision.] The offeror represents as part of its offer that--

(i) It * is, * is not an EDWOSB concern eligible under the WOSB Program, has provided all the required documents to the WOSB Repository, and no change in circumstances or adverse decisions have been issued that affects its eligibility; and

(ii) It * is, * is not a joint venture that complies with the requirements of 13 CFR part 127, and the representation in paragraph (b)(5)(i) of this provision is accurate in reference to the EDWOSB concern or concerns that are participating in the joint venture. [The offeror shall enter the name or names of the EDWOSB concern or concerns that are participating in the joint venture: ----------.] Each EDWOSB concern participating in the joint venture shall submit a separate signed copy of the EDWOSB representation.

(6) (Complete only if the offeror represented itself as a small business concern in paragraph (b)(1) of this provision.) The offeror represents as part of its offer that it ( ) is, ( ) is not a veteran-owned small business concern.

(7) (Complete only if the offeror represented itself as a veteran-owned small business concern in paragraph (b)(6) of this provision.) The offeror represents as part of its offer that it ( ) is, ( ) is not a service-disabled veteran-owned small business concern.

(8) [Complete only if the offeror represented itself as a small business concern in paragraph (b)(1) of this provision.] The offeror represents, as part of its offer, that--

(i) It ( ) is, ( ) is not a HUBZone small business concern listed, on the date of this representation, on the List of Qualified HUBZone Small Business Concerns maintained by the Small Business Administration, and no material change in ownership and control, principal office, or HUBZone employee percentage has occurred since it was certified by the Small Business Administration in accordance with 13 CFR part 126; and

(ii) It ( ) is, ( ) is not a joint venture that complies with the requirements of 13 CFR part 126, and the representation in paragraph (b)(8)(i) of this provision is accurate for the HUBZone small business concern or concerns that are participating in the joint venture. (The offeror shall enter the name or names of the HUBZone small business concern or concerns that are participating in the joint venture:_____.) Each HUBZone small business concern participating in the joint venture shall submit a separate signed copy of the HUBZone representation.

(9) (Complete if offeror represented itself as disadvantaged in paragraph (b)(2) of this provision.) The offeror shall check the category in which its ownership falls:

____ Black American.

____ Hispanic American.

____ Native American (American Indians, Eskimos, Aleuts, or Native Hawaiians).

____ Asian-Pacific American (persons with origins from Burma, Thailand, Malaysia, Indonesia, Singapore, Brunei, Japan, China, Taiwan, Laos, Cambodia (Kampuchea), Vietnam, Korea, The Philippines, U.S. Trust Territory of the Pacific Islands (Republic of Palau), Republic of the Marshall Islands, Federated States of Micronesia, the Commonwealth of the Northern Mariana Islands, Guam, Samoa, Macao, Hong Kong, Fiji, Tonga, Kiribati, Tuvalu, or Nauru).

____ Subcontinent Asian (Asian-Indian) American (persons with origins from India, Pakistan, Bangladesh, Sri Lanka, Bhutan, the Maldives Islands, or Nepal).

____ Individual/concern, other than one of the preceding.

(c) Definitions. As used in this provision--

Service-disabled veteran-owned small business concern--

(1) Means a small business concern--

(i) Not less than 51 percent of which is owned by one or more service-disabled veterans or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more service-disabled veterans; and

(ii) The management and daily business operations of which are controlled by one or more service-disabled veterans or, in the case of a service-disabled veteran with permanent and severe disability, the spouse or permanent caregiver of such veteran.

(2) Service-disabled veteran means a veteran, as defined in 38 U.S.C. 101(2), with a disability that is service-connected, as defined in 38 U.S.C. 101(16).

"Small business concern," means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR Part 121 and the size standard in paragraph (a) of this provision.

Veteran-owned small business concern means a small business concern--

(1) Not less than 51 percent of which is owned by one or more veterans (as defined at 38 U.S.C. 101(2)) or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more veterans; and

(2) The management and daily business operations of which are controlled by one or more veterans.

"Women-owned small business concern," means a small business concern --

(1) That is at least 51 percent owned by one or more women or, in the case of any publicly owned business, at least 51 percent of the stock of which is owned by one or more women; or

(2) Whose management and daily business operations are controlled by one or more women.

(d) Notice.

(1) If this solicitation is for supplies and has been set aside, in whole or in part, for small business concerns, then the clause in this solicitation providing notice of the set-aside contains restrictions on the source of the end items to be furnished.

(2) Under 15 U.S.C. 645(d), any person who misrepresents a firm's status as a small, HUBZone small, small disadvantaged, or women-owned small business concern in order to obtain a contract to be awarded under the preference programs established pursuant to section 8(a), 8(d), 9, or 15 of the Small Business Act or any other provision of Federal law that specifically references section 8(d) for a definition of program eligibility, shall--

(i) Be punished by imposition of fine, imprisonment, or both;

(ii) Be subject to administrative remedies, including suspension and debarment; and

(iii) Be ineligible for participation in programs conducted under the authority of the Act.

(End of provision)

52.219-22 SMALL DISADVANTAGED BUSINESS STATUS (OCT 1999)

(a) General. This provision is used to assess an offeror's small disadvantaged business status for the purpose of obtaining a benefit on this solicitation. Status as a small business and status as a small disadvantaged business for general statistical purposes is covered by the provision at FAR 52.219-1, Small Business Program Representation.

(b) Representations.

(1) General. The offeror represents, as part of its offer, that it is a small business under the size standard applicable to this acquisition; and either--

___ (i) It has received certification by the Small Business Administration as a small disadvantaged business concern consistent with 13 CFR 124, Subpart B; and

(A) No material change in disadvantaged ownership and control has occurred since its certification;

(B) Where the concern is owned by one or more disadvantaged individuals, the net worth of each individual upon whom the certification is based does not exceed $750,000 after taking into account the applicable exclusions set forth at 13 CFR 124.104(c)(2); and

(C) It is identified, on the date of this representation, as a certified small disadvantaged business concern in the database maintained by the Small Business Administration(PRO0Net); or

___ (ii) It has submitted a completed application to the Small Business Administration or a Private Certifier to be certified as a small disadvantaged business concern in accordance with 13 CFR 124, Subpart B, and a decision on that application is pending, and that no material change in disadvantaged ownership and control has occurred since its application was submitted.

(2)___ For Joint Ventures. The offeror represents, as part of its offer, that it is a joint venture that complies with the requirements at 13 CFR 124.1002(f) and that the representation in paragraph (b)(1) of this provision is accurate for the small disadvantaged business concern that is participating in the joint venture. [The offeror shall enter the name of the small disadvantaged business concern that is participating in the joint venture: _____.]

(c) Penalties and Remedies. Anyone who misrepresents any aspects of the disadvantaged status of a concern for the purposes of securing a contract or subcontract shall:

(1) Be punished by imposition of a fine, imprisonment, or both;

(2) Be subject to administrative remedies, including suspension and debarment; and

(3) Be ineligible for participation in programs conducted under the authority of the Small Business Act.

(End of provision)

52.222-22 PREVIOUS CONTRACTS AND COMPLIANCE REPORTS (FEB 1999)

The offeror represents that --

(a) ( ) It has, ( ) has not participated in a previous contract or subcontract subject to the Equal Opportunity clause of this solicitation;

(b) ( ) It has, ( ) has not, filed all required compliance reports; and

(c) Representations indicating submission of required compliance reports, signed by proposed subcontractors, will be obtained before subcontract awards.

(End of provision)

52.222-25 AFFIRMATIVE ACTION COMPLIANCE (APR 1984)

The offeror represents that

(a) [ ] it has developed and has on file, [ ] has not developed and does not have on file, at each establishment, affirmative action programs required by the rules and regulations of the Secretary of Labor (41 CFR 60-1 and 60-2), or

(b) [ ] has not previously had contracts subject to the written affirmative action programs requirement of the rules and regulations of the Secretary of Labor.

(End of provision)

52.225-2 BUY AMERICAN ACT CERTIFICATE (FEB 2009)

(a) The offeror certifies that each end product, except those listed in paragraph (b) of this provision, is a domestic end product and that for other than COTS items, the offeror has considered components of unknown origin to have been mined, produced, or manufactured outside the United States. The offeror shall list as foreign end products those end products manufactured in the United States that do not qualify as domestic end products, i.e., an end product that is not a COTS item and does not meet the component test in paragraph (2) of the definition of “domestic end product.” The terms “commercially available off-the-shelf (COTS) item, “ “component,” “domestic end product,” “end product,” “foreign end product,” and “United States” are defined in the clause of this solicitation entitled “Buy American Act--Supplies.”

(b) Foreign End Products:

Line Item No.:----------

Country of Origin:----------

(List as necessary)

(c) The Government will evaluate offers in accordance with the policies and procedures of Part 25 of the Federal Acquisition Regulation.

(End of provision)

52.225-20 PROHIBITION ON CONDUCTING RESTRICTED BUSINESS OPERATIONS IN SUDAN--CERTIFICATION (AUG 2009)

(a) Definitions. As used in this provision--

Business operations means engaging in commerce in any form, including by acquiring, developing, maintaining, owning, selling, possessing, leasing, or operating equipment, facilities, personnel, products, services, personal property, real property, or any other apparatus of business or commerce.

Marginalized populations of Sudan means--

(1) Adversely affected groups in regions authorized to receive assistance under section 8(c) of the Darfur Peace and Accountability Act (Pub. L. 109-344) (50 U.S.C. 1701 note); and

(2) Marginalized areas in Northern Sudan described in section 4(9) of such Act.

Restricted business operations means business operations in Sudan that include power production activities, mineral extraction activities, oil-related activities, or the production of military equipment, as those terms are defined in the Sudan Accountability and Divestment Act of 2007 (Pub. L. 110-174). Restricted business operations do not include business operations that the person (as that term is defined in Section 2 of the Sudan Accountability and Divestment Act of 2007) conducting the business can demonstrate--

(1) Are conducted under contract directly and exclusively with the regional government of southern Sudan;

(2) Are conducted pursuant to specific authorization from the Office of Foreign Assets Control in the Department of the Treasury, or are expressly exempted under Federal law from the requirement to be conducted under such authorization;

(3) Consist of providing goods or services to marginalized populations of Sudan;

(4) Consist of providing goods or services to an internationally recognized peacekeeping force or humanitarian organization;

(5) Consist of providing goods or services that are used only to promote health or education; or

(6) Have been voluntarily suspended.

(b) Certification. By submission of its offer, the offeror certifies that the offeror does not conduct any restricted business operations in Sudan.

(End of provision)

52.226-2 HISTORICALLY BLACK COLLEGE OR UNIVERSITY AND MINORITY INSTITUTION REPRESENTATION (OCT 2008)

(a) Definitions. As used in this provision--

Historically black college or university means an institution determined by the Secretary of Education to meet the requirements of 34 CFR 608.2. For the Department of Defense, the National Aeronautics and Space Administration, and the Coast Guard, the term also includes any nonprofit research institution that was an integral part of such a college or university before November 14, 1986.

Minority institution means an institution of higher education meeting the requirements of Section 365(3) of the Higher Education Act of 1965 (20 U.S.C. 1067k), including a Hispanic-serving institution of higher education, as defined in Section 502(a) of the Act (20 U.S.C. 1101a).

(b) Representation. The offeror represents that it--

( ) is ( ) is not a historically black college or university;

( ) is ( ) is not a minority institution.

(End of provision)

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)

CLAUSES INCORPORATED BY FULL TEXT

52.230-7 PROPOSAL DISCLOSURE--COST ACCOUNTING PRACTICE CHANGES (APR 2005)

The offeror shall check ``yes" below if the contract award will result in a required or unilateral change in cost accounting practice, including unilateral changes requested to be desirable changes.

( ) Yes ( ) No

If the offeror checked ``Yes" above, the offeror shall--

(1) Prepare the price proposal in response to the solicitation using the changed practice for the period of performance for which the practice will be used; and

(2) Submit a description of the changed cost accounting practice to the Contracting Officer and the Cognizant Federal Agency Official as pricing support for the proposal.

(End of provision)

52.234-3 NOTICE OF EARNED VALUE MANAGEMENT SYSTEM -POST AWARD IBR (JUL 2006)

(a) The offeror shall provide documentation that the Cognizant Federal Agency has determined that the proposed earned value management system (EVMS) complies with the EVMS guidelines in ANSI/EIA Standard -748 (current version at time of solicitation).

(b) If the offeror proposes to use a system that has not been determined to be in compliance with the requirements of paragraph (a) of this provision, the offeror shall submit a comprehensive plan for compliance with the EVMS guidelines.

(1) The plan shall--

(i) Describe the EVMS the offeror intends to use in performance of the contracts;

(ii) Distinguish between the offeror's existing management system and modifications proposed to meet the guidelines;

(iii) Describe the management system and its application in terms of the EVMS guidelines;

(iv) Describe the proposed procedure for administration of the guidelines, as applied to subcontractors; and

(v) Provide documentation describing the process and results of any third-party or self-evaluation of the system's compliance with the EVMS guidelines.

(2) The offeror shall provide information and assistance as required by the Contracting Officer to support review of the plan.

(3) The Government will review and approve the offeror's plan for an EVMS before contract award.

(4) The offeror's EVMS plan must provide milestones that indicate when the offeror anticipates that the EVM system will be compliant with the ANSI/EIA Standard -748 guidelines.

(c) Offerors shall identify the major subcontractors, or major subcontracted effort if major subcontractors have not been selected, planned for application of the guidelines. The prime Contractor and the Government shall agree to subcontractors selected for application of the EVMS guidelines.

(End of provision)

252.204-7007 ALTERNATE A, ANNUAL REPRESENTATIONS AND CERTIFICATIONS (MAY 2010)

As prescribed in 204.1202, substitute the following paragraph (d) for paragraph (d) of the provision at FAR 52.204-8:

(d) The offeror has completed the annual representations and certifications electronically via the Online Representations and Certifications Application (ORCA) website at https://orca.bpn.gov/. After reviewing the ORCA database information, the offeror verifies by submission of the offer that the representations and

certifications currently posted electronically have been entered or updated within the last 12 months, are current, accurate, complete, and applicable to this solicitation (including the business size standard applicable to the NAICS code referenced for this solicitation), as of the date of this offer, and are incorporated in this offer by reference (see FAR 4.1201); except for the changes identified below [offeror to insert changes, identifying change by clause number, title, date]. These amended representation(s) and/or certification(s) are also incorporated in this offer and are current, accurate, and complete as of the date of this offer.

FAR/DFARS Clause #	Title	Date	Change

Any changes provided by the offeror are applicable to this solicitation only, and do not result in an update to the representations and certifications posted on ORCA.

Section L - Instructions, Conditions and Notices to Bidders

CLAUSES INCORPORATED BY REFERENCE

52.215-1	Instructions to Offerors--Competitive Acquisition	JAN 2004
52.215-16	Facilities Capital Cost of Money	JUN 2003
52.215-22	Limitations on Pass-Through Charges--Identification of Subcontract Effort	OCT 2009
52.222-24	Preaward On-Site Equal Opportunity Compliance Evaluation	FEB 1999
52.252-3	Alterations in Solicitation	APR 1984
252.209-7008	Notice of Prohibition Relating to Organizational Conflict of Interest--Major Defense Acquisition Program	DEC 2010
252.227-7028	Technical Data or Computer Software Previously Delivered to the Government	JUN 1995

CLAUSES INCORPORATED BY FULL TEXT

52.215-20 REQUIREMENTS FOR CERTIFIED COST OR PRICING DATA OR INFORMATION OTHER THAN CERTIFIED COST OR PRICING DATA (OCT 2010)—ALTERNATE IV (OCT 2010)

(a) Submission of certified cost or pricing data is not required.

(b) Provide data described below:

Direct Labor Hours, Direct Labor Dollars, Direct Materials, Subcontracting, Overhead, G&A and Profit. Offeror to is refer to the requirements listed in Sections L and M for Factor 5 – Cost, and to utilize the template described in Section J document J.7.

(End of provision)

52.216-1 TYPE OF CONTRACT (APR 1984)

The Government contemplates award of a Cost Plus Fixed Fee contract resulting from this solicitation.

(End of provision)

52.219-24 SMALL DISADVANTAGED BUSINESS PARTICIPATION PROGRAM--TARGETS (OCT 2000)

(a) This solicitation contains a source selection factor or subfactor related to the participation of small disadvantaged business (SDB) concerns in the contract. Credit under that evaluation factor or subfactor is not available to an SDB concern that qualifies for a price evaluation adjustment under the clause at FAR 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns, unless the SDB concern specifically waives the price evaluation adjustment.

(b) In order to receive credit under the source selection factor or subfactor, the offeror must provide, with its offer, targets, expressed as dollars and percentages of total contract value, for SDB participation in any of the North American Industry Classification System (NAICS Industry Subsectors as determined by the Department of

Commerce. The targets may provide for participation by a prime contractor, joint venture partner, teaming arrangement member, or subcontractor; however, the targets for subcontractors must be listed separately.

(End of provision)

52.233-2 SERVICE OF PROTEST (SEP 2006)

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the Government Accountability Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from

ACC-APG NATICK CONTRACTING DIVISION
ATTN: MR. PETER WALLACE
BLDG. 1, KANSAS STREET
NATICK, MA 01760

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of provision)

52.252-1 SOLICITATION PROVISIONS INCORPORATED BY REFERENCE (FEB 1998)

This solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text of those provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this/these address(es):

http://farsite.hill.af.mil/

https://www.acquisition.gov/far/index.html

(End of provision)

252.227-7017 IDENTIFICATION AND ASSERTION OF USE, RELEASE, OR DISCLOSURE RESTRICTIONS. (JAN 2011)

(a) The terms used in this provision are defined in following clause or clauses contained in this solicitation--

(1) If a successful offeror will be required to deliver technical data, the Rights in Technical Data--Noncommercial Items clause, or, if this solicitation contemplates a contract under the Small Business Innovation Research Program, the Rights in Noncommercial Technical Data and Computer Software--Small Business Innovation Research (SBIR) Program clause.

(2) If a successful offeror will not be required to deliver technical data, the Rights in Noncommercial Computer Software and Noncommercial Computer Software Documentation clause, or, if this solicitation contemplates a

contract under the Small Business Innovation Research Program, the Rights in Noncommercial Technical Data and Computer Software--Small Business Innovation Research (SBIR) Program clause.

(b) The identification and assertion requirements in this provision apply only to technical data, including computer software documents, or computer software to be delivered with other than unlimited rights. For contracts to be awarded under the Small Business Innovation Research Program, the notification requirements do not apply to technical data or computer software that will be generated under the resulting contract. Notification and identification is not required for restrictions based solely on copyright.

(c) Offers submitted in response to this solicitation shall identify, to the extent known at the time an offer is submitted to the Government, the technical data or computer software that the Offeror, its subcontractors or suppliers, or potential subcontractors or suppliers, assert should be furnished to the Government with restrictions on use, release, or disclosure.

(d) The Offeror's assertions, including the assertions of its subcontractors or suppliers or potential subcontractors or suppliers shall be submitted as an attachment to its offer in the following format, dated and signed by an official authorized to contractually obligate the Offeror:

Identification and Assertion of Restrictions on the Government's Use, Release, or Disclosure of Technical Data or Computer Software.

The Offeror asserts for itself, or the persons identified below, that the Government's rights to use, release, or disclose the following technical data or computer software should be restricted:

Technical Data or Computer Software to be Furnished With Restrictions *	Name of Person Asserting Basis for Assertion **	Asserted Rights Category ***	Restrictions ****
(LIST) *****	(LIST)	(LIST)	(LIST)

*For technical data (other than computer software documentation) pertaining to items, components, or processes developed at private expense, identify both the deliverable technical data and each such items, component, or process. For computer software or computer software documentation identify the software or documentation.

**Generally, development at private expense, either exclusively or partially, is the only basis for asserting restrictions. For technical data, other than computer software documentation, development refers to development of the item, component, or process to which the data pertain. The Government's rights in computer software documentation generally may not be restricted. For computer software, development refers to the software. Indicate whether development was accomplished exclusively or partially at private expense. If development was not accomplished at private expense, or for computer software documentation, enter the specific basis for asserting restrictions.

***Enter asserted rights category (e.g., government purpose license rights from a prior contract, rights in SBIR data generated under another contract, limited, restricted, or government purpose rights under this or a prior contract, or specially negotiated licenses).

****Corporation, individual, or other person, as appropriate.

*****Enter "none" when all data or software will be submitted without restrictions.

Date _____

Printed Name and Title _____

Signature _____

(End of identification and assertion)

(e) An offeror's failure to submit, complete, or sign the notification and identification required by paragraph (d) of this provision with its offer may render the offer ineligible for award.

(f) If the Offeror is awarded a contract, the assertions identified in paragraph (d) of this provision shall be listed in an attachment to that contract. Upon request by the Contracting Officer, the Offeror shall provide sufficient information to enable the Contracting Officer to evaluate any listed assertion.

(End of provision)

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 1 limited to 75 pages No page limitations for Sections 2 and 4. Section 3 limited to	10 hard copies and 2 CDs

	Section 4 – Certifications	prescribed format plus 10 pages for narrative summary for each sample task.	
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.

L2.1.2. Exceptions to the page limitations are: cover pages, indices/tables of contents, divider pages and crosswalk matrix.

L2.1.3. 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 sto 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 Offerors 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	TOTAL CPFF/PRICE	SERVICE PROVIDED	APPLICABLE CLIN'S/SCLIN'S

NAME			

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 <u>not</u> 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

L3.7.1. 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 15 November 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.

Section M - Evaluation Factors for Award

CLAUSES INCORPORATED BY REFERENCE

52.217-5 Evaluation Of Options JUL 1990

EVALUATION FACTORS FOR AWARD

M.1. BASIS FOR CONTRACT AWARD

M.1.1. Award will be made to the Offeror whose proposal offers the best overall value to the Government based on an integrated assessment of the non-cost and cost factors.

M.1.2. The Government intends to make a single award. The Government intends to award without discussions; however, the Government reserve the right to enter into discussions if necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

M.1.3. Mandatory Responsiveness Requirements.

M.1.3.1. The mandatory responsiveness criteria must be met at time of proposal submission. Proposals that do not meet the mandatory responsiveness criteria shall be determined to be NONRESPONSIVE and will be immediately eliminated from further consideration. The mandatory responsiveness criteria are:

a. 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.

b. U.S. Biopharmaceutical Manufacturing. The Offeror demonstrates a firm commitment to initiate the establishment, and maintain, the necessary facilities in the U.S. or its territories, as described by 8 USC 1101(a)(36).

M.1.4. Contract award will be made to that Offeror(s) whose proposal offers the best overall value to the Government based on an integrated assessment of the non-price and price factors. Evaluation factors other than cost, when combined, are significantly more important than cost. The evaluation factors and subfactors are defined below. There are six (6) factors, each of which are described further in paragraph M.2. below, with relative weighting as follows:

Technical Factor 1 = Technical Factor 2 > IP/IP Management Plan > Past Performance > Cost >> Small Business Participation

- Technical Factor 1: Establishment through post validation, maintenance and operation of the ADM (all subfactors are of equal value)
  - Subfactor 1: Establishing/commissioning and validation of ADM facility(ies)
  - Subfactor 2: Post-validation ADM organization for development and manufacturing
  - Subfactor 3: Post-validation ADM operating process
- Technical Factor 2: Sample Tasks (subfactor 1 is of greater value than subfactor 2)
  - Subfactor 1: Large Molecule sample task including surge production
  - Subfactor 2: Small Molecule sample task including surge production
- Intellectual Property (IP)/IP Management Plan Factor 3.
- Past Performance Factor 4 (both subfactors rolled into single performance confidence assessment)
  - Subfactor 1: Relevance
  - Subfactor 2: Past Performance History
- Cost Factor 5. Narrative assessment of cost reasonableness, realism and completeness for:
  - Establishing, commissioning and validation of the ADM
  - Operating the ADM after validation
- Small Business Participation Factor 6. One adjectival rating based on consideration of the following attributes:
  - Extent of small business participation at the component level
  - Extent of small business participation at the dollar level
  - Risk assessment of past performance with small business participation
  - Past compliance with the requirements of FAR 52.219-8 and FAR 52.219-9

M.1.5. Any proposal that is evaluated as UNACCEPTABLE in any evaluation factor or subfactor may be rejected for such reasons. Furthermore, any significant inconsistency among the evaluated factors and subfactors, if unexplained, may be grounds for rejection of the proposal due to an Offeror's misunderstanding of the work required or an inability to perform any resultant work in the contract. The Government will evaluate each proposal strictly in accordance with its content and will not assume that performance will include areas not specified in the Offeror's proposal.

M.1.6. The Government may render any proposal UNACCEPTABLE that:

a. Merely offers to perform work according to the terms of the Request for Proposals (RFP) or fails to present more than a statement indicating its capability to comply with the terms without support and elaboration as specified in the instructions.

b. Reflects an inherent lack of technical competence or a failure to comprehend the complexity and risks required to perform the terms of the RFP due to submission of a proposal that is unrealistically high or low in price and/or unrealistic in terms of technical approach.

M.1.7. The Government reserves the right to make an award to other than the Offeror who submits the lowest total cost or highest rated proposal. Each proposal will be evaluated in

accordance with the evaluation criteria set forth herein. In order to be eligible for award, an Offeror's evaluated proposal must receive the following minimum ratings:

- Technical Factor 1: ACCEPTABLE
- Technical Factor 2: ACCEPTABLE
- IP/IP Management Plan Factor 3: ACCEPTABLE
- Past Performance Factor 4: SATISFACTORY CONFIDENCE
- Cost Factor 5: REALISTIC, REASONABLE and COMPLETE
- Small Business Participation Factor 6: ACCEPTABLE

M.1.8. The Government reserves the right to make no award if no Offerors are found to meet the minimum acceptable standards for award as described in paragraph M.1.7 above.

M.2. EVALUATION FACTOR STANDARDS

Technical Factor 1: Establishment through post validation, maintenance and operation of the ADM. All subfactors will be of an equal weight.

Technical Factor 1 will employ a combined technical/risk rating that includes consideration of risk in conjunction with the strengths, weaknesses, and deficiencies in determining technical ratings. Combined technical/risk evaluations shall utilize the combined technical/risk ratings as described in Table 1 below. All subfactors will be evaluated individually and then rolled up into a single factor rating.

STANDARD: The Offeror provides a flexible, disposable and single use technical approach to establish, commission, validate, maintain and operate the ADM capability that meets the requirements of the SOO. The Offeror's SOW and IMP (WBS and IMS) are comprehensive, logical, feasible, effective, efficient and appropriately linked. Plans are well organized to meet the Government's requirements. The Offeror's proposed organization to establish, commission, validate, maintain and operate the ADM capability is appropriately established to perform the work, and possesses the correct competencies, skills and abilities. The proposal contains acceptable strategies for using the ADM capability to support and facilitate transition of processes and technologies from the technology base, such as DARPA, T&E Facility, and UARC currently under development. The Offeror's proposed operating plans are appropriate, effective and efficient to maintain the ADM in a state of readiness, and include plans for training of Government personnel.

ASSESSMENT METHODOLOGY: The Offeror's approach for this factor and each subfactor will be considered holistically to determine if the Offeror's overall technical approach to establish, operate and maintain the ADM is feasible and achievable within the context of the Offeror's proposal. The following adjectival rating system will be used to evaluate this factor and each subfactor:

Table 1. Combined Technical/Risk Ratings		
Color	Rating	Description
Blue	Outstanding	Proposal meets requirements and indicates an exceptional approach and understanding of the requirements. Strengths far outweigh any weaknesses. Risk of unsuccessful performance is very low.
Purple	Good	Proposal meets requirements and indicates a thorough approach and understanding of the requirements. Proposal contains strengths which outweigh any weaknesses. Risk of unsuccessful performance is low.
Green	Acceptable	Proposal meets requirements and indicates an adequate approach and understanding of the requirements. Strengths and weaknesses are offsetting or will have little or no impact on contract performance. Risk of unsuccessful performance is no worse than moderate.
Yellow	Marginal	Proposal does not clearly meet requirements and has not demonstrated an adequate approach and understanding of the requirements. The proposal has one or more weaknesses which are not offset by strengths. Risk of unsuccessful performance is high.
Red	Unacceptable	Proposal does not meet requirements and contains one or more deficiencies. Proposal is unawardable.

Subfactor 1: Establishing, commissioning and validation of ADM facility(ies).

STANDARD: The Offeror describes a technical approach that meets the requirements in the Statement of Objectives (SOO) to establish, commission and validate, within 24 months, the streamlined ADM manufacturing capability in that significantly reduces schedule and cost compared with the 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/licensed MCMs. This includes topics such as facility design, 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, and document management system plans. The technical approach also directly links and correlates among SOW, IMS, IMP, and WBS.

ASSESSMENT METHODOLOGY: The Offeror's technical approach as described in the SOW will be evaluated to determine that it is sound and achievable in meeting the Government's objectives to establish, commission and validate two (2) suites within 24 months of award. The Offeror's SOW, WBS, IMP and IMS will be evaluated to determine if they are cohesive, relate to each other, and clearly describe the Offeror's planned approach. The Government will place higher value on approaches that demonstrate greater flexibility and adaptability in rapidly accommodating advanced development and manufacturing line changes and ability to accommodate varied products simultaneously, within the stated objectives. The Offeror's proposed management approach, including the organizational structure, project management,

QMS plan, regulatory compliance strategy, document management system and key personnel will be evaluated to determine if they are effectively organized to meet the Government's requirements. The Offeror's proposed team, including architectural, building, equipment, regulatory strategy, quality management,, internal staff and subcontractors will be evaluated to determine if they possess sufficient skills to establish, commission and validate the ADM.

Subfactor 2: Post-validation organization for ADM development and manufacturing

STANDARD: The Offeror describes a post validation organizational structure that includes certified Project Management Professionals, IPTs, and program management processes that demonstrates its ability to successfully operate the MCM ADM, in accordance with the Government's Statement of Objectives (SOO) to accommodate third party products. The organization possesses core competencies to rapidly develop and manufacture FDA approved medical countermeasures, as defined in the CFR Title 21(to include the Animal Efficacy Rule) and CFR 42 Public Health Part 73, or has access to such competencies when required. The offeror describes a complete and thorough training program for training of Government personnel throughout the life of the program.

ASSESSMENT METHODOLOGY: The Government will evaluate that the Offeror's proposed organizational structure and management processes to enable post- validation facility operation of the ADM and that the Offeror has access to infrastructure and core competencies necessary to meet the full spectrum of MCM development, manufacturing through FDA approval. 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 Government will place higher value on approaches that demonstrate robust and well placed management and oversight expertise from within the Offeror's team. The Government will evaluate the Offeror's ability to provide these capabilities through the life of the contract. The Government will evaluate the 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. The Government will place higher value 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.

Subfactor 3: Post-validation ADM operating process

STANDARD: The Offeror's approach for post-validation operation and maintenance of the ADM in a state of readiness meets regulatory compliance requirements, is complete, feasible and sound. Emphasis will be placed on the manufacturing aspects of the capability to include simultaneous accommodation of various third party products. Once validated, the Offeror will support and maintain the ADM capability in a state of readiness to support Medical Countermeasure development and manufacturing. The proposal describes a streamlined, agile and flexible manufacturing approach that minimizes operating costs, and optimizes utilization during active and inactive development and manufacturing periods and 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

ASSESSMENT METHODOLOGY: The Government will evaluate the Offerors approach for post-validation operation and maintenance of the ADM during periods of no DoD demand for minimizing operating costs, with emphasis on the manufacturing aspects of the capability. The Government will evaluate 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. The Government will evaluate the 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, quality assurance processes, and associated documentation.

Technical Factor 2: Sample Tasks. Subfactor 1 is of greater importance than Subfactor 2

Technical Factor 2 will employ a combined technical/risk rating that includes consideration of risk in conjunction with the strengths, weaknesses, and deficiencies in determining technical ratings. Combined technical /risk evaluations shall utilize the combined technical/risk ratings as described in Table 1 above. Both subfactors will be evaluated individually and then rolled up into a single factor rating.

STANDARD (same for both subfactors): The Offeror's Integrated Master Plan (IMP) for each sample task reflects an approach that is consistent with the offeror's proposed MCM ADM capability and provides a realistic schedule including all major milestones, critical path, decision points and reflects the Offeror-completed WBS template provided by the Government. The Offeror describes a regulatory strategy under the Animal Rule with all major risks with mitigations, and opportunities identified by the Offeror in the WBS template. Most Likely, Best Case, and Worst Case schedule estimates and cycle times, are reasonable and supported. Proposed Cost estimates are appropriate, reasonable and supported. The Offeror identifies appropriate number and skills/ qualifications of personnel. The Government will evaluate the realism and completeness of the surge production plan. The Offeror identifies types of facilities and equipment used that will enable manufacturing innovation, and use of innovative technologies supporting modular flexible manufacturing that can be incorporated to upgrade the facilities

ASSESSMENT METHODOLOGY (same for both subfactors): The Government will evaluate the submitted responses to the Sample Tasks in accordance with Attachment J.5.

Subfactor 1: Large Molecule Sample Task including surge production: Development of a vaccine effective against a gram negative bacterium, using recombinant technology based on a microbial expression system.

Subfactor 2: Small Molecule Sample Task including surge production: Development of a bifunctional acetylcholinesterase reactivator for treatment of nerve agent exposure. "Development" for this task is to include assembly and submission of the IND (ADM will be holder of the IND) through FDA approval/licensure.

Factor 3: Intellectual Property (IP) Management Plan. The IP Management Plan will be evaluated to assess whether the offeror has adequate protections for IP for potential third party contractors who may utilize the ADM as a directed subcontractor.

STANDARD: The offeror describes a method for protecting its own, and third party intellectual property and any 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 plan describes acceptable methods that address:

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.

ASSESSMENT METHODOLOGY. Factor 3, the Intellectual Property Management Plan will be evaluated using the adjectival rating scale in Table 1, after review of the plan considering compliance with the regulatory framework established by the Bayh-Dole Act; measures for assuring the right to practice background intellectual property and data; and a dispute resolution strategy regarding intellectual property. The IP Management Plan is distinct from any Government rights under the contract, which is governed by the contract clauses included in this solicitation. The IP Management Plan will not receive a rating less than "acceptable" based on any limitations that the offeror desires on technical data or information that has been developed exclusively at private expense.

Factor 4: Past Performance.

Past Performance, contains two (2) subfactors of equal weight: Subfactor 1 Relevance is equal to Subfactor 2 Past Performance History. Both subfactors will be evaluated separately and rolled up into a single Performance Confidence Assessment rating.

Subfactor 1. Relevancy

STANDARD: The Offeror's, and/or its major subcontractor's past performance to fabricate and/or retrofit facilities and to establish CMO, T&E/labs, CRO, BSL3, Fill/Finish capabilities, including past performance data submitted by the Offeror and its subcontractors, as well as past performance information independently obtained by the Government indicates that the Offeror, possesses a performance history that is relevant and considered to provide a satisfactory performance confidence assessment rating.

ASSESSMENT METHODOLOGY The Offeror's past performance, for both Government and non-Government contracts, will be evaluated to determine how relevant the Offeror's recent efforts, conducted or completed within the last five (5) years, are to this acquisition and to ensuring an enduring capability for the duration of this contract. This includes the efforts of major subcontractors relative to their role within the Offeror's organization to meet the requirements of the program. Relevancy evaluations shall utilize the ratings as described in Table 2 below, and will comprise evaluation of the Offeror's:

i. Experience in cGLP, cGCP, cGMP pharmaceutical processes and production
ii. Experience in manufacturing vaccines
iii. Experience producing vaccines based on virus particles, or like technology
iv. Previous FDA submissions, inclusive of FDA response/non-response to submissions
v. Corporate experience solving challenging development efforts similar to those that may arise during the proposed effort
vi. Subcontract management team experience and the skill of those individuals in proposal evaluation, negotiation, and success in avoiding cost overruns.

Relevance for efforts with a low level of completion may receive a lower relevance rating than for efforts at a higher level of completion. Offerors lacking relevant past performance experience may submit information regarding predecessor entities, key personnel who have relevant experience or subcontractors that will perform major or critical aspects of the requirement if such information is relevant to this acquisition. In this case, Offerors shall provide relevant information to allow the Government evaluators to conduct a Past Performance evaluation on the predecessor entities, key personnel and/or subcontractors. Such information shall, as a minimum, include: Name(s) of Predecessor Subcontractor and/or Key Personnel and include complete address and point of contact information and a synopsis of the experience and relevancy to this project.

Table 2. Past Performance Relevancy Ratings	
Rating	Definition
Very Relevant	Present/past performance effort involved essentially the same scope and magnitude of effort and complexities this solicitation requires.
Relevant	Present/past performance effort involved similar scope and magnitude of effort and complexities this solicitation requires.
Somewhat Relevant	Present/past performance effort involved some of the scope and magnitude of effort and complexities this solicitation requires.
Not Relevant	Present/past performance effort involved little or none of the scope and magnitude of effort and complexities this solicitation requires.

Subfactor 2: Past Performance History. The Offeror's past performance history will be evaluated to determine how well the Offeror, including major subcontractors, performed on ongoing and completed contracts within the past five (5) years. Past performance information will be gathered by sources including, but not limited to:

i. Past performance information may be provided by the Offeror, as solicited.
ii. Past performance information may be obtained from questionnaires tailored to the circumstances of the acquisition.
iii. Past performance information obtained from any other sources available to the Government, to include, but not limited to, the Past Performance Information Retrieval System (PPIRS), Federal Awardee Performance and Integrity Information System (FAPIIS), Electronic Subcontract Reporting System (eSRS), or other databases; interviews with Program Managers, Contracting Officers, and Fee Determining Officials; and the Defense Contract Management Agency.

c. The overall Performance Confidence Assessment rollup shall employ the ratings as described in Table 3 below. Adjectival ratings for subfactor 2 shall not be used. Rather, the evaluators will document the findings in narrative form and roll this information up with the subfactor 1 relevance rating to obtain the Performance Confidence Assessment rating.

Table 3. Performance Confidence Assessments	
Rating	Description
Substantial Confidence	Based on the offeror's recent/relevant performance record, the Government has a high expectation that the offeror will successfully perform the required effort.
Satisfactory Confidence	Based on the offeror's recent/relevant performance record, the Government has a reasonable expectation that the offeror will successfully perform the required effort.
Limited Confidence	Based on the offeror's recent/relevant performance record, the Government has a low expectation that the offeror will successfully perform the required effort.
No Confidence	Based on the offeror's recent/relevant performance record, the Government has no expectation that the offeror will be able to successfully perform the required effort.
Unknown Confidence (Neutral)	No recent/relevant performance record is available or the offeror's performance record is so sparse that no meaningful confidence assessment rating can be reasonably assigned.

Factor 5: Cost. The proposed CPFF CLINs will be evaluated for realism, reasonableness, and completeness. Cost will not be evaluated using an adjectival rating system, but rather will be evaluated with a narrative of the evaluation findings. The proposed FFP CLINs will be evaluated for reasonableness.

a. The Government will perform cost analyses for the cost-plus-fixed-fee (CPFF) portions of the proposal to establish the reasonableness and realism of the estimated cost proposed by the Offeror for the following areas:

i. Establishing, commissioning and validating the ADM capability
ii. Technical operations to maintain the ADM capability in a state of readiness (no throughput)
iii. Minimizing operating costs

b. The evaluation will include analysis of the proposed cost together with the supporting cost information. The Offeror's cost rationale for building the Basis of Estimate will be evaluated.

The following cost attributes will be assessed:

i. Reasonableness. Acceptable estimating technique(s) may be Cost-to-Cost and Cost-to-non-Cost estimating relationships, commercially available parametric cost models, and in-house developed parametric cost models. Proposals may be rejected if there is no indication of the rationale used to determine estimates. Costs shall be provided to WBS Level 4 as provided by the Offeror in the IMP.

ii. Realism. IAW FAR 15.305(1). The Government will evaluate the realism of the Offeror's proposed costs on CPFF prices in relation to the Offeror's specific technical approach. Any proposal that is evaluated by the Government and found to be significantly unrealistic in price may be considered by the Government to reflect either a lack of technical competence to accomplish the Government's requirements or a failure to understand the Government's requirements, or both. The Government will develop a most probable Cost of Performance for each Offeror and proposed Subcontractor when evaluating the contractor Total Procurement CPFF projections. The most probable cost may differ from the Offeror's proposal. The most probable cost is determined by adjusting each Offeror's proposed cost, when appropriate, to reflect any changes (unnecessary additions or omissions by the Offeror) in cost elements to realistic levels based on the cost realism analysis.

iii. Completeness. The proposal clearly and thoroughly documents the rationale supporting the proposed cost and be compliant with the specified content and format requirements of the solicitation.

Factor 6: Small Business Participation Plan

STANDARD: The Offeror proposes a cumulative small business participation goal of 32% of the total contract value, with subordinate goals of 5% attributed to contributions from Small Disadvantaged Businesses, 5% attributed to Women-Owned Small Businesses, 3% attributed to HUBZone certified small businesses, and 3% attributed to Service-Disabled Veteran Owned Small Businesses. All of these subordinate goals are included in the overall small business participation goal. The Offeror describes an approach for achieving its proposed small business participation and subcontracting goals. The approach describes the nature of the work relative to the proposed SOW that small firms are anticipated to perform. Factor 6 will employ a combined technical/risk rating that includes consideration of risk in conjunction with the strengths, weaknesses, and deficiencies in determining the ratings. Combined technical /risk evaluations shall utilize the combined technical/risk ratings as described in Table 1 above. If the offeror's proposal does not meet the goals stated above, the offeror provides sound rationale in the proposal describing why the goals cannot be achieved.

ASSESSMENT METHODOLOGY: The Government will evaluate the extent to which the Offeror identifies and commits to utilizing, SBs, VOSBs, SDVOSBs, HUBZone SBs, SDBs, WOSBs and HBCUs/MIs in the performance of the contract in the offerors attempt to achieve the DoD published Small Business Participation Goals stated above. Such utilization may be as the prime contractor or a subcontractor, or as a member of a joint venture or teaming arrangement. The Government will evaluate rationale, if applicable, regarding small business goals that cannot be achieved. The Government will also evaluate the extent of the Offeror's past compliance with FAR 52.219-8, Utilization of Small Business Concerns, and FAR 52.219-9, and Small Business Subcontracting Plan. Evaluation will consider the following:

a. The extent to which the proposal specifically identifies SBs, VOSBs, SDVOSBs, HUBZone SBs, SDBs, WOSBs and HBCUs/MIs, identifying specific components and/or labor to be produced by them

b. The extent of participation of such Small Business Concerns in terms of the value of the total contract amount; and

c. An assessment of the risk, based upon past performance, of the Offeror actually achieving the involvement of Small Business Concerns as proposed. Such assessment will include:

- For all Offerors, an evaluation of performance over the past three calendar years in complying with the requirements of FAR 52.219-8, Utilization of Small Business Concerns;

- For Offeror's who are large businesses as defined by the North American Industry Classification System (NAICS) Code applicable to this solicitation, an additional evaluation of past performance over the last three calendar years in complying with the requirements of FAR 52.219-9, Small Business Subcontracting Plan. Where a large business has not held a contract that included 52.219-9, its prior performance will be evaluated against 52.219-8 only.

d. The extent of substantive evidence indicating the level of past compliance with the requirements of FAR 52.219-8 and FAR 52.219-9.

M.3. EVALUATION METHODOLOGY

M.3.1. All proposals shall be evaluated by a team of Government employees using the formal source selection procedures described herein. Systems Engineering and Technical Assistance (SETA) and support contractors listed in paragraph M.4 below may be used throughout the source selection process as Subject Matter Experts (SMEs), providing technical analysis and comments during the evaluation process. SETA contractors serve only in an advisory.

M.3.2. The Government will evaluate proposals in accordance with the processes and criteria contained herein to determine compliance with all requirements of the RFP, including any attachments and exhibits. The Government will evaluate proposals for soundness, creative and innovative methods, processes, and/or solutions that are beneficial to the Government and demonstrate responsiveness to the stated requirements. The Government will evaluate each proposal strictly in accordance with its content. The Government will caution Offerors that in order for proposals to be eligible for award, the proposals shall be in compliance with the terms and conditions set forth in the RFP. The Government will not evaluate multiple proposal submissions from the same Offeror.

M.3.3. Definitions used in assessing evaluation factors and subfactors.

a) CLARIFICATION: A request by the Government, and/or a response by the Offeror, to resolve an uncertainty in the offeror's proposal.

b) DEFICIENCY. A material failure of a proposal to meet a Government requirement or a combination of significant weaknesses in a proposal that increases the risk of unsuccessful Contract performance to an unacceptable level. Examples of deficiencies include a statement by the Offeror that it cannot or will not meet a requirement, an approach that clearly does not meet a requirement, or omission of data required to assess compliance with the requirement.

c) STRENGTH. An aspect of a proposal that, when judged against a stated evaluation criterion, enhances the merit of the proposal or increases the probability of successful performance of the Contract. A "significant strength" appreciably enhances the merit of a proposal or appreciably increases the probability of successful Contract performance.

d) WEAKNESS. A flaw in the proposal that increases the risk of unsuccessful Contract performance. A "significant weakness" in the proposal is a flaw that appreciably increases the risk of unsuccessful Contract performance.

e) UNCERTAINTY. Any aspect of the proposal for which the intent of the Offeror is unclear because there may be more than one way to interpret the offer or because inconsistencies in the offer indicate that there may be an error, omission or mistake. Examples include a mistake in calculation or measurement and contradictory statements.

M.4. PARTICIPATION OF COMMERCIAL FIRMS AND FOREIGN NATIONALS IN EVALUATION PROCESS

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 nationals 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 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 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 DefensCon