

<b>SOLICITATION, OFFER AND AWARD</b>			1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)		RATING	PAGE OF PAGES 1   98	
2. CONTRACT NO.		3. SOLICITATION NO. W911QY-13-R-0012	4. TYPE OF SOLICITATION [ ] SEALED BID (IFB) [X] NEGOTIATED (RFP)	5. DATE ISSUED 18 Apr 2013	6. REQUISITION/PURCHASE NO.		
7. ISSUED BY NATICK CONTRACTING DIVISION US ARMY CONTRACTING COMMAND - APG NATICK CONTRACTING DIVISION ATTN: CCAP-SCN, KANSAS STREET NATICK MA 01760-5011			CODE W911QY	8. ADDRESS OFFER TO (If other than Item 7)  <b>See Item 7</b>		CODE	TEL: FAX:

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

### SOLICITATION

9. Sealed offers in original and 3 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 See L.1.1 until 05:00 PM local time 22 May 2013  
(Hour) (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 NATHAN JORDAN	B. TELEPHONE (Include area code) (NO COLLECT CALLS) 508-233-6169	C. E-MAIL ADDRESS nathan.c.jordan.civ@mail.mil
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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

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)	<input type="checkbox"/>	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: <input type="checkbox"/> 10 U.S.C. 2304(c)( ) <input type="checkbox"/> 41 U.S.C. 253(c)( )	23. SUBMIT INVOICES TO ADDRESS SHOWN IN	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)	27. UNITED STATES OF AMERICA	28. AWARD DATE			
TEL:	EMAIL:	(Signature of Contracting Officer)			

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

Section B - Supplies or Services and Prices

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001	<p>Formulation</p> <p>Deliver a product formulation that results from the implementation of the process provided to include improvements to that process and the required assays, release tests, and reformulations necessary to deliver the vaccine described in CLIN 0002 including all labor and materials related thereto. All efforts shall be in accordance with contractor's Statement of Work (SOW) dated (to be inserted upon award).</p> <p>CPFF Completion</p> <p>FOB: Destination</p>		Lot		
				ESTIMATED COST	
				FIXED FEE	
				TOTAL EST COST + FEE	<hr/>

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0002 OPTION	<p>cGMP Trivalent Filovirus Vaccine</p> <p>Successfully deliver a cGMP trivalent filovirus vaccine and placebo suitable for Phase 1 clinical trial including all labor and materials related thereto. Activities to include cGMP manufacture of bulk products, final vaccine, and control material; product manufacture, release testing; and 24 month stability on all products (bulk, final, and control). Efforts associated with qualifying the fill and finish process. All efforts shall be in accordance with contractor's Statement of Work (SOW) dated (to be inserted upon award). Excludes all work performed to deliver CLIN 0001.</p> <p>FFP</p> <p>FOB: Destination</p>		Lot		
				NET AMT	<hr/>

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0002AA	Final trivalent vaccine product per dosage concentration, with and without adjuvant bulk antigen concentration produced, 1.6ug to support clinical dose escalation studies. The minimum acceptable number of vials for each concentration is 2000 with adjuvant and 2000 without adjuvant. Each vial shall contain one (1) dose and sufficient overfill to enable extraction of the dose. FFP		Lot		
	FOB: Destination				

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NET AMT

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0002AB	Final trivalent vaccine product per dosage concentration, with and without adjuvant bulk antigen concentration produced, 5ug to support clinical dose escalation studies. The minimum acceptable number of vials for each concentration is 2000 with adjuvant and 2000 without adjuvant. Each vial shall contain one (1) dose and sufficient overfill to enable extraction of the dose. FFP		Lot		
	FOB: Destination				

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NET AMT

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0002AC	Final trivalent vaccine product per dosage concentration, with and without adjuvant bulk antigen concentration produced, 16ug to support clinical dose escalation studies. The minimum acceptable number of vials for each concentration is 2000 with adjuvant and 2000 without adjuvant. Each vial shall contain one (1) dose and sufficient overfill to enable extraction of the dose. FFP		Lot		
	FOB: Destination				

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NET AMT

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0002AD	Final trivalent vaccine product per dosage concentration, with and without adjuvant bulk antigen concentration produced, 50ug to support clinical dose escalation studies. The minimum acceptable number of vials for each concentration is 2000 with adjuvant and 2000 without adjuvant. Each vial shall contain one (1) dose and sufficient overfill to enable extraction of the dose. FFP		Lot		
	FOB: Destination				

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NET AMT

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0002AE	Tech Data Package FFP		Lot		
	FOB: Destination				
				NET AMT	<hr/>

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0003 OPTION	Thermo Stable Formulation		Each		
	Deliver thermo stable formulation for the final vaccine including all labor and materials related thereto. All efforts shall be in accordance with the contractor's Statement of Work (SOW) dated (to be inserted upon award). CPFF Completion				
	FOB: Destination				
				ESTIMATED COST	
				FIXED FEE	<hr/>
				TOTAL EST COST + FEE	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0004 OPTION	Expanded Stability Testing of cGMP Bulk Conduct expanded stability testing (for an additional three years beyond CLIN 0002 requirement) on cGMP bulk products produced under CLIN 0002. All efforts shall be in accordance with the contractor's Statement of Work (SOW) dated (to be inserted upon award). FFP  FOB: Destination		Lot		

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NET AMT

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0005 OPTION	Expanded Stability Testing - Tri FDP cGMP final drug product (FDP) produced under CLIN 0002 that has successfully undergone expanded stability testing (for an additional three years beyond CLIN 0002 requirement). All efforts shall be in accordance with the contractor's Statement of Work (SOW) dated (to be inserted upon award). FFP  FOB: Destination		Lot		

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NET AMT

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0006 OPTION	Technology Transfer Technology Transfer data package in accordance with CDRL Exhibit A008. All efforts shall be in accordance with the contractor's Statement of Work (SOW) dated (to be inserted upon award). FFP  FOB: Destination	1	Each		

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NET AMT

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0007 OPTION	Marburg Formulation Deliver a Marburg product formulation that results from the implementation of the process provided to include improvements to that process and the required assays, release tests, and reformulations necessary to deliver the vaccine described in CLIN 0008 including all labor and materials related thereto. Excludes all work performed to deliver CLIN 0001. All efforts shall be in accordance with contractor's Statement of Work (SOW) dated (to be inserted upon award). CPFF  FOB: Destination		Each		

ESTIMATED COST  
FIXED FEE  
TOTAL EST COST + FEE

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ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0008 OPTION	cGMP Marburg Vaccine Deliver cGMP bulk and final Marburg vaccine product suitable for Phase 1 clinical trial including all labor and materials related thereto, release testing, and 24-month stability testing. All efforts shall be in accordance with the contractor's Statement of Work (SOW) dated (to be inserted upon award). Excludes all work performed to deliver CLIN 0007. One lot consists of a final Marburg vaccine product per dosage concentration, with and without adjuvant (for four concentrations of each bulk antigen concentration produced, 1.6ug, 5ug, 16ug and 50ug) to support clinical dose escalation studies. The minimum acceptable number of vials for each concentration is 2000 with adjuvant and 2000 without adjuvant. Each vial shall contain one (1) dose and sufficient overfill to enable extraction of the dose. FFP  FOB: Destination		Each		

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NET AMT

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0008AA	Final trivalent vaccine product per dosage concentration, with and without adjuvant bulk antigen concentration produced, 1.6ug to support clinical dose escalation studies. The minimum acceptable number of vials for each concentration is 2000 with adjuvant and 2000 without adjuvant. Each vial shall contain one (1) dose and sufficient overfill to enable extraction of the dose. FFP  FOB: Destination		Lot		

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NET AMT

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0008AB	Final trivalent vaccine product per dosage concentration, with and without adjuvant bulk antigen concentration produced, 5ug to support clinical dose escalation studies. The minimum acceptable number of vials for each concentration is 2000 with adjuvant and 2000 without adjuvant. Each vial shall contain one (1) dose and sufficient overfill to enable extraction of the dose. FFP		Lot		
	FOB: Destination				

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NET AMT

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0008AC	Final trivalent vaccine product per dosage concentration, with and without adjuvant bulk antigen concentration produced, 16ug to support clinical dose escalation studies. The minimum acceptable number of vials for each concentration is 2000 with adjuvant and 2000 without adjuvant. Each vial shall contain one (1) dose and sufficient overfill to enable extraction of the dose. FFP		Lot		
	FOB: Destination				

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NET AMT

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0008AD	Final trivalent vaccine product per dosage concentration, with and without adjuvant bulk antigen concentration produced, 50ug to support clinical dose escalation studies. The minimum acceptable number of vials for each concentration is 2000 with adjuvant and 2000 without adjuvant. Each vial shall contain one (1) dose and sufficient overfill to enable extraction of the dose. FFP		Lot		
	FOB: Destination				

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NET AMT

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0008AE	Tech Data Package FFP				
	FOB: Destination				

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NET AMT

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0009 OPTION	Expanded Stability Testing - Marburg Conduct expanded stability testing (for an additional three years beyond CLIN 0002 requirement) on cGMP Marburg bulk and final products produced under CLIN 0008. All efforts shall be in accordance with the contractor's Statement of Work (SOW) dated (to be inserted upon award). FFP  FOB: Destination		Lot		

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NET AMT

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0010 OPTION	EVMS Reporting EVMS reporting as defined in Contract Data Requirement List (CDRL) at Exhibit A010 and A011. This option will be exercised only in the event that the threshold for requirement of an EVM system is met. All efforts shall be in accordance with the contractor's Statement of Work (SOW) dated (to be inserted upon award). FFP  FOB: Destination	1	Lot		

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NET AMT

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0011 OPTION	Integrated Baseline Review Integrated Baseline Review reporting requirements as defined in Contract Data Requirement List (CDRL) at Exhibit A009. This option will be exercised only in the event that the threshold for requirement of an EVM system is met. All efforts shall be in accordance with the contractor's Statement of Work (SOW) dated (to be inserted upon contract award). FFP  FOB: Destination	1	Lot		

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NET AMT

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0012	Program Reporting - Operational Official program reporting requirements included in Contract Data Requirement List (CDRL) Exhibits: A001 – Report, Record of Meetings/Minutes - Integrated Product Development Team Reports A002 - Contractor's Progress, Status and Management Report A003 - Integrated Master Schedule (IMS) A006 - Contract Work Breakdown Structure (CWBS) A007 - Quality Agreement A013 Risk Management Plan A017 – Risk Management Status Report FOB: Destination Pricing for each CDRL shall be annotated on block #18 of the DD 1423 FFP  FOB: Destination	1	Lot		

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NET AMT

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
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0013	Program Reporting - Technical Official program reporting requirements included in Contract Data Requirement List (CDRL) Exhibits:	1	Lot		
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- A004 Scientific & Technical Reports Summary
- A005 – Briefing Material – Quarterly program Review
- A012 Report, Production, or Delivery Problems
- A014 – Master Production Batch Records
- A015 – Production Batch Records
- A016 Regulatory Submissions & Communication
- A018 Stability Test Plan

Pricing for each CDRL shall be annotated on block #18 of the DD 1423 FFP

FOB: Destination

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NET AMT

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
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0014 OPTION	Shipping and storage Shipping and storage on a cost reimbursement basis for Government accepted materials. COST		Each		
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FOB: Destination

ESTIMATED COST

Section C - Descriptions and Specifications

STATEMENT OF WORK

Contractor's Statement of Work, dated (inserted upon award) incorporated upon award as attachment 1 in Section J.

## Section D - Packaging and Marking

Packaging and Marking shall be in accordance with the Contractor's Statement of Work dated (insert upon award), Attachment 1 in Section J.

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
0001	Origin	Government	Destination	Government
0002	Origin	Government	Destination	Government
0002AA	N/A	N/A	N/A	Government
0002AB	N/A	N/A	N/A	Government
0002AC	N/A	N/A	N/A	Government
0002AD	N/A	N/A	N/A	Government
0002AE	N/A	N/A	N/A	Government
0003	Origin	Government	Origin	Government
0004	Origin	Government	Origin	Government
0005	Origin	Government	Origin	Government
0006	Destination	Government	Destination	Government
0007	Origin	Government	Origin	Government
0008	Origin	Government	Destination	Government
0008AA	N/A	N/A	N/A	Government
0008AB	N/A	N/A	N/A	Government
0008AC	N/A	N/A	N/A	Government
0008AD	N/A	N/A	N/A	Government
0008AE	N/A	N/A	N/A	Government
0009	Origin	Government	Origin	Government
0010	Destination	Government	Destination	Government
0011	Destination	Government	Destination	Government
0012	Destination	Government	Destination	Government
0013	Destination	Government	Destination	Government
0014	Destination	Government	Destination	Government

CLAUSES INCORPORATED BY REFERENCE

52.246-2	Inspection Of Supplies--Fixed Price	AUG 1996
52.246-3	Inspection Of Supplies Cost-Reimbursement	MAY 2001
52.246-7	Inspection Of Research And Development Fixed Price	AUG 1996
52.246-8	Inspection Of Research And Development Cost Reimbursement	MAY 2001
52.246-16	Responsibility For Supplies	APR 1984
252.246-7000	Material Inspection And Receiving Report	MAR 2008

Section F - Deliveries or Performance

DELIVERY INFORMATION

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	UIC
0001	19 months	Lot	Ship in place	N/A
0002	30 months from exercise of option	Lot	TBD	N/A
0003	12 months from exercise of option	Each	Ship in place	N/A
0004	1155 days from exercise of option	Lot	Ship in place	N/A
0005	1155 days from exercise of option	Lot	Ship in place	N/A
0006	60 days from exercise of option	Each	CBMS- JVAP FILOVIRUS	N/A
0007	12 months from exercise of option	Each	Ship in place	N/A
0008	30 months from exercise of option	Each	TBD	N/A
0009	1155 days from exercise of option	Lot	Ship in place	N/A
0010	30 days from exercise of option	Each	CBMS- JVAP FILOVIRUS	N/A
0011	30 days from exercise of option and monthly thereafter	Lot	CBMS- JVAP FILOVIRUS	N/A
0012	180 days from exercise of option	Lot	CBMS- JVAP FILOVIRUS	N/A
0013	IAW CDRL	Lot	CBMS- JVAP FILOVIRUS	N/A
0014	IAW CDRL	Lot	CBMS- JVAP FILOVIRUS	N/A
0015	10 days of request	Each	TBD	N/A

CLAUSES INCORPORATED BY REFERENCE

52.242-15 Stop-Work Order  
 52.242-17 Government Delay Of Work

AUG 1989  
 APR 1984

52.247-29  
52.247-34

F.O.B. Origin  
F.O.B. Destination

FEB 2006  
NOV 1991



(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:

<b>Invoice Only</b>	
Pay DoDAAC	Insert Upon Award
IssueBy DoDAAC	W911QY
Admin DoDAAC	Insert Upon Award
Ship To Code	W90GXX
<b>Receiving Report (DD 250) Destination Inspection / Destination Acceptance</b>	
<b>Inspect and Accept at place of destination</b>	
<b>Invoice and Receiving Report (Combo) - Destination Inspection / Destination Acceptance</b>	
Pay DoDAAC	Insert Upon Award
IssueBy DoDAAC	W911QY
Admin DoDAAC	W911QY
InspectBy DoDAAC	W90GXX
Ship To Code	W90GXX

(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
Rebecca Kurnat	<a href="mailto:Rebecca.Kurnat.civ@mail.mil">Rebecca.Kurnat.civ@mail.mil</a>	301-619-2057	Vaccine Manager
Linda Sheffer	Linda.Sheffer.civ@mail.mil	301-619-7586	Certifying Official/ Director, Financial Management

Section H - Special Contract Requirements

H.1. PERFORMANCE BY FOREIGN NATIONALS:

a. In accordance with 8 U.S.C. 1324(a), it is unlawful to hire for employment in the U.S. an individual without verifying that individual's employment authorization. 8 C.F.R. 274(a)(2) VERIFICATION OF EMPLOYMENT ELIGIBILITY identifies the official documents that establish employment eligibility.

b. Prior to performance of work by a foreign national as a result of this contract, the employer shall provide the Contracting Officer the name of the foreign national and identify the type of forms(s) produced for verification of employment status. Should the foreign national's performance require access to DoD facilities, the employer shall coordinate with the sponsor providing access, in order to submit the following:

1. Individual's Name
2. Date of Birth
3. Citizenship
4. Date and Location of the Visit
5. Purpose of the Visit
6. Passport Number
7. Employer's Verification of Work Authorization

This information shall be forwarded to the Contracting Officer at least thirty days prior to the visit taking place. Failure to provide this information within this time frame may prevent the individual(s) from entry into the DoD facilities.

H.2. CONTRACTOR'S ORGANIZATION AND KEY PERSONNEL:

a. The contractor's organization shall be established with authority to effectively accomplish the objectives of the Statement of Work. This organization shall become effective upon award of the contract and its integrity shall be maintained for the duration of the contract effort.

b. The key personnel listed in the contractor's proposal are considered to be critical to the successful performance of this contract. Prior to replacing these key personnel, the contractor shall obtain the written consent of the contracting officer. In order to obtain such consent, the contractor shall provide advance notice of the proposed changes and shall demonstrate that the qualifications of the proposed substitute personnel are generally equivalent to or better than the qualifications of the personnel being replaced.

c. Prior to permanently reassigning any of the specified individuals to other contracts, the contractor shall provide the Contracting Officer not less than thirty (30) days advance notice and shall submit justification (including proposed substitutions) in sufficient detail to permit evaluation of the impact on the program. No reassignment shall be made by the Contractor without written consent of the Contracting Officer. The "Key Personnel" list may be amended from time to time during the course of the contract to either add or delete personnel, as appropriate.

Key Personnel: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

H.3. INSURANCE:

Pursuant to the requirements of the contract clause titled "Insurance-Work on a Government Installation", the contractor shall obtain and maintain at least the following kinds of insurance and minimum liability coverage during any period of contract performance:

a. Workmen's Compensation and occupational disease coverage as required by law except that, if this contract is to be performed in a state which does not require or permit private insurance, then compliance with the statutory or administrative requirements in any such state will be satisfactory. The required Workmen's Compensation Insurance shall extend to cover employers' liability for accidental bodily injury or death and for occupational disease with a minimum liability limit of \$100,000.

b. Comprehensive General Liability Insurance in the minimum limit of \$500,000 per occurrence for bodily injury liability.

c. Comprehensive Automotive Liability Insurance with minimum limits of \$200,000 per person and \$500,000 per occurrence for bodily injury, and a minimum limit of \$20,000 per occurrence for property damage.

#### H.4. SCIENTIFIC AND TECHNICAL REPORTS

##### 252.235-7011 FINAL SCIENTIFIC OR TECHNICAL REPORT (NOV 2004)

The Contractor shall—

(a) Submit two copies of the approved scientific or technical report delivered under this contract to the Defense Technical Information Center, Attn: DTIC-O, 8725 John J. Kingman Road, Fort Belvoir, VA 22060-6218;

(b) Include a completed Standard Form 298, Report Documentation Page, with each copy of the report; and

(c) For submission of reports in other than paper copy, contact the Defense Technical Information Center or follow the instructions at <http://www.dtic.mil>.

(End of clause)

#### CLAUSES INCORPORATED BY FULL TEXT

##### 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)

#### 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.)

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(End of clause)

## LABORATORY CLAUSES

### **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](https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.acuro)**

**<https://mrmc.amedd.army.mil/rodorpaurd.asp>**

#### **\*\* 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.

### **2. PROHIBITION OF USE OF HUMAN SUBJECTS**

**Information and guidance is provided at the following web site:**

**<https://mrmc.amedd.army.mil/rodorphrpo.asp>**

#### **\*\* PROHIBITION – READ FURTHER FOR DETAILS \*\***

Research under this award involving the use of human subjects may not begin until the U.S. Army Medical Research and Materiel Command's Office of Research Protections, Human Research Protections Office (HRPO) approves the protocol. Written approval to begin research or subcontract for the use of human subjects under the applicable protocol proposed for this award will be issued from the US Army Medical Research and Materiel Command, HRPO, under separate letter to the funded institution and the Principal Investigator. A copy of this approval will be provided to the US Army Contracting Command – Aberdeen Proving Grounds, Natick Contracting Division for the official file. Non-compliance with any provision of this clause may result in withholding of funds and or the termination of the award.

### **3. PROHIBITION OF USE OF HUMAN ANATOMICAL SUBSTANCES**

**Information and guidance is provided at the following web site:**

<https://mrmc.amedd.army.mil/rodorphrpo.asp>

#### **\*\* PROHIBITION – READ FURTHER FOR DETAILS\*\***

Research at funded institutions using human anatomical substances may not begin until the U.S. Army Medical Research and Materiel Command's Office of Research Protections, Human Research Protections Office (HRPO) approves the protocol. Written approval to begin research or subcontract for the use of human anatomical substances under the applicable protocol proposed for this award will be issued from the US Army Medical Research and Materiel Command, HRPO, under separate letter to the funded institution and the Principal Investigator. A copy of this approval will be provided to the US Army Contracting Command – Aberdeen Proving Grounds, Natick Contracting Division for the official file. Non-compliance with any provision of this clause may result in withholding of funds and or the termination of the award.

**4. The clause at FAR 52.217-7 OPTION FOR INCREASED QUANTITY--SEPARATELY PRICED LINE ITEM (MAR 1989)** provides that delivery of added items shall continue at the same rate that like items are called for under the contract, unless the parties otherwise agree. Relative to option CLIN ####, the parties hereby agree otherwise and the quantities applicable to the foregoing CLINs are as stated in said CLINs.

## Section I - Contract Clauses

### CLAUSES INCORPORATED BY REFERENCE

52.202-1	Definitions	JAN 2012
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
52.204-4	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper	MAY 2011
52.204-7	Central Contractor Registration	DEC 2012
52.204-9	Personal Identity Verification of Contractor Personnel	JAN 2011
52.209-6	Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment	DEC 2010
52.209-9	Updates of Publicly Available Information Regarding Responsibility Matters	FEB 2012
52.211-5	Material Requirements	AUG 2000
52.215-2	Audit and Records--Negotiation	OCT 2010
52.215-8	Order of Precedence--Uniform Contract Format	OCT 1997
52.215-11	Price Reduction for Defective Certified Cost or Pricing Data--Modifications	AUG 2011
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
52.215-19	Notification of Ownership Changes	OCT 1997
52.215-23	Limitations on Pass-Through Charges	OCT 2009
52.216-7	Allowable Cost And Payment	JUN 2011
52.216-11	Cost Contract--No Fee	APR 1984
52.216-16	Incentive Price Revision-Firm Target	OCT 1997
52.217-9	Option To Extend The Term Of The Contract	MAR 2000
52.219-6	Notice Of Total Small Business Set-Aside	NOV 2011
52.219-8	Utilization of Small Business Concerns	JAN 2011
52.219-14	Limitations On Subcontracting	NOV 2011
52.219-28	Post-Award Small Business Program Rerepresentation	APR 2012
52.222-19	Child Labor -- Cooperation with Authorities and Remedies	MAR 2012
52.222-20	Walsh-Healey Public Contracts Act	OCT 2010
52.222-21	Prohibition Of Segregated Facilities	FEB 1999
52.222-23	Notice of Requirement for Affirmative Action to Ensure Equal Employment Opportunity for Construction	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
52.222-40	Notification of Employee Rights Under the National Labor Relations Act	DEC 2010
52.222-50	Combating Trafficking in Persons	FEB 2009

52.222-54	Employment Eligibility Verification	JUL 2012
52.223-6	Drug-Free Workplace	MAY 2001
52.223-9	Estimate of Percentage of Recovered Material Content for EPA-Designated Items	MAY 2008
52.225-13	Restrictions on Certain Foreign Purchases	JUN 2008
52.227-1	Authorization and Consent	DEC 2007
52.227-2	Notice And Assistance Regarding Patent And Copyright Infringement	DEC 2007
52.227-11	Patent Rights--Ownership By The Contractor	DEC 2007
52.228-7	Insurance--Liability To Third Persons	MAR 1996
52.229-3	Federal, State And Local Taxes	APR 2003
52.232-1	Payments	APR 1984
52.232-8	Discounts For Prompt Payment	FEB 2002
52.232-9	Limitation On Withholding Of Payments	APR 1984
52.232-11	Extras	APR 1984
52.232-17	Interest	OCT 2010
52.232-22	Limitation Of Funds	APR 1984
52.232-23	Assignment Of Claims	JAN 1986
52.232-25	Prompt Payment	OCT 2008
52.232-33	Payment by Electronic Funds Transfer--Central Contractor Registration	OCT 2003
52.233-1	Disputes	JUL 2002
52.233-3	Protest After Award	AUG 1996
52.233-4	Applicable Law for Breach of Contract Claim	OCT 2004
52.242-13	Bankruptcy	JUL 1995
52.243-1	Changes--Fixed Price	AUG 1987
52.243-2	Changes--Cost-Reimbursement	AUG 1987
52.244-5	Competition In Subcontracting	DEC 1996
52.244-6	Subcontracts for Commercial Items	DEC 2010
52.245-1	Government Property	APR 2012
52.246-23	Limitation Of Liability	FEB 1997
52.249-2	Termination For Convenience Of The Government (Fixed-Price)	APR 2012
52.249-6	Termination (Cost Reimbursement)	MAY 2004
52.249-8	Default (Fixed-Price Supply & Service)	APR 1984
52.249-9	Default (Fixed-Priced Research And Development)	APR 1984
52.253-1	Computer Generated Forms	JAN 1991
252.203-7000	Requirements Relating to Compensation of Former DoD Officials	SEP 2011
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
252.204-7003	Control Of Government Personnel Work Product	APR 1992
252.204-7006	Billing Instructions	OCT 2005
252.209-7001	Disclosure of Ownership or Control by the Government of a Terrorist Country	JAN 2009
252.211-7000	Acquisition Streamlining	OCT 2010
252.215-7000	Pricing Adjustments	DEC 2012
252.222-7006	Restrictions on the Use of Mandatory Arbitration Agreements	DEC 2010
252.223-7001	Hazard Warning Labels	DEC 1991
252.225-7012	Preference For Certain Domestic Commodities	DEC 2012
252.225-7031	Secondary Arab Boycott Of Israel	JUN 2005
252.226-7001	Utilization of Indian Organizations and Indian-Owned Economic Enterprises, and Native Hawaiian Small Business Concerns	SEP 2004

252.227-7013	Rights in Technical Data--Noncommercial Items	FEB 2012
252.227-7016	Rights in Bid or Proposal Information	JAN 2011
252.227-7030	Technical Data--Withholding Of Payment	MAR 2000
252.227-7037	Validation of Restrictive Markings on Technical Data	JUN 2012
252.227-7039	Patents--Reporting Of Subject Inventions	APR 1990
252.231-7000	Supplemental Cost Principles	DEC 1991
252.232-7004	DOD Progress Payment Rates	OCT 2001
252.232-7007	Limitation Of Government's Obligation	MAY 2006
252.232-7010	Levies on Contract Payments	DEC 2006
252.235-7002	Animal Welfare	DEC 2011
252.235-7004	Protection of Human Subjects	JUL 2009
252.235-7010	Acknowledgment of Support and Disclaimer	MAY 1995
252.243-7001	Pricing Of Contract Modifications	DEC 1991
252.243-7002	Requests for Equitable Adjustment	DEC 2012
252.244-7000	Subcontracts for Commercial Items and Commercial Components (DoD Contracts)	JUN 2012
252.246-7001	Warranty Of Data	DEC 1991
252.247-7023	Alt III Transportation of Supplies by Sea (May 2002) Alternate III	MAY 2002
252.249-7000	Special Termination Costs	DEC 1991

#### CLAUSES INCORPORATED BY FULL TEXT

##### 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

(Contracting Officer shall insert-

(i) Appropriate agency name(s) and/or title of applicable Department of Homeland Security fraud hotline poster); and

(ii) The website(s) or other contact information for obtaining the poster(s.)

(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)

## CLAUSES INCORPORATED BY FULL TEXT

### 52.204-10 REPORTING EXECUTIVE COMPENSATION AND FIRST-TIER SUBCONTRACT AWARDS (AUG 2012)

(a) Definitions. As used in this clause:

Executive means officers, managing partners, or any other employees in management positions.

First-tier subcontract means a subcontract awarded directly by the Contractor for the purpose of acquiring supplies or services (including construction) for performance of a prime contract. It does not include the Contractor's supplier agreements with vendors, such as long-term arrangements for materials or supplies that benefit multiple contracts and/or the costs of which are normally applied to a Contractor's general and administrative expenses or indirect costs.

Month of award means the month in which a contract is signed by the Contracting Officer or the month in which a first-tier subcontract is signed by the Contractor.

Total compensation means the cash and noncash dollar value earned by the executive during the Contractor's preceding fiscal year and includes the following (for more information see 17 CFR 229.402(c)(2)):

(1) Salary and bonus.

(2) Awards of stock, stock options, and stock appreciation rights. Use the dollar amount recognized for financial statement reporting purposes with respect to the fiscal year in accordance with the Financial Accounting Standards Board's Accounting Standards Codification (FASB ASC) 718, Compensation-Stock Compensation.

(3) Earnings for services under non-equity incentive plans. This does not include group life, health, hospitalization or medical reimbursement plans that do not discriminate in favor of executives, and are available generally to all salaried employees.

(4) Change in pension value. This is the change in present value of defined benefit and actuarial pension plans.

(5) Above-market earnings on deferred compensation which is not tax-qualified.

(6) Other compensation, if the aggregate value of all such other compensation (e.g., severance, termination payments, value of life insurance paid on behalf of the employee, perquisites or property) for the executive exceeds \$10,000.

(b) Section 2(d)(2) of the Federal Funding Accountability and Transparency Act of 2006 (Pub. L. 109-282), as amended by section 6202 of the Government Funding Transparency Act of 2008 (Pub. L. 110-252), requires the Contractor to report information on subcontract awards. The law requires all reported information be made public, therefore, the Contractor is responsible for notifying its subcontractors that the required information will be made public.

(c) Nothing in this clause requires the disclosure of classified information.

(d)(1) Executive compensation of the prime contractor. As a part of its annual registration requirement in the Central Contractor Registration (CCR) database (FAR clause 52.204-7), the Contractor shall report the names and total compensation of each of the five most highly compensated executives for its preceding completed fiscal year, if—

(i) In the Contractor's preceding fiscal year, the Contractor received—

(A) 80 percent or more of its annual gross revenues from Federal contracts (and subcontracts), loans, grants (and subgrants), cooperative agreements, and other forms of Federal financial assistance; and

(B) \$25,000,000 or more in annual gross revenues from Federal contracts (and subcontracts), loans, grants (and subgrants), cooperative agreements, and other forms of Federal financial assistance; and

(ii) The public does not have access to information about the compensation of the executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. (To determine if the public has access to the compensation information, see the U.S. Security and Exchange Commission total compensation filings at <http://www.sec.gov/answers/execomp.htm>.)

(2) First-tier subcontract information. Unless otherwise directed by the contracting officer, or as provided in paragraph (g) of this clause, by the end of the month following the month of award of a first-tier subcontract with a value of \$25,000 or more, the Contractor shall report the following information at <http://www.fsr.gov> for that first-tier subcontract. (The Contractor shall follow the instructions at <http://www.fsr.gov> to report the data.)

(i) Unique identifier (DUNS Number) for the subcontractor receiving the award and for the subcontractor's parent company, if the subcontractor has a parent company.

(ii) Name of the subcontractor.

(iii) Amount of the subcontract award.

(iv) Date of the subcontract award.

(v) A description of the products or services (including construction) being provided under the subcontract, including the overall purpose and expected outcomes or results of the subcontract.

(vi) Subcontract number (the subcontract number assigned by the Contractor).

(vii) Subcontractor's physical address including street address, city, state, and country. Also include the nine-digit zip code and congressional district.

(viii) Subcontractor's primary performance location including street address, city, state, and country. Also include the nine-digit zip code and congressional district.

(ix) The prime contract number, and order number if applicable.

(x) Awarding agency name and code.

(xi) Funding agency name and code.

(xii) Government contracting office code.

(xiii) Treasury account symbol (TAS) as reported in FPDS.

(xiv) The applicable North American Industry Classification System code (NAICS).

(3) Executive compensation of the first-tier subcontractor.

Unless otherwise directed by the Contracting Officer, by the end of the month following the month of award of a first-tier subcontract with a value of \$25,000 or more, and annually thereafter (calculated from the prime contract award date), the Contractor shall report the names and total compensation of each of the five most highly compensated executives for that first-tier subcontractor for the first-tier subcontractor's preceding completed fiscal year at <http://www.fsr.gov>, if—

(i) In the subcontractor's preceding fiscal year, the subcontractor received—

(A) 80 percent or more of its annual gross revenues from Federal contracts (and subcontracts), loans, grants (and subgrants), cooperative agreements, and other forms of Federal financial assistance; and

(B) \$25,000,000 or more in annual gross revenues from Federal contracts (and subcontracts), loans, grants (and subgrants), cooperative agreements, and other forms of Federal financial assistance; and

(ii) The public does not have access to information about the compensation of the executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. (To determine if the public has access to the compensation information, see the U.S. Security and Exchange Commission total compensation filings at <http://www.sec.gov/answers/excomp.htm>.)

(e) The Contractor shall not split or break down first-tier subcontract awards to a value less than \$25,000 to avoid the reporting requirements in paragraph (d).

(f) The Contractor is required to report information on a first-tier subcontract covered by paragraph (d) when the subcontract is awarded. Continued reporting on the same subcontract is not required unless one of the reported data elements changes during the performance of the subcontract. The Contractor is not required to make further reports after the first-tier subcontract expires.

(g)(1) If the Contractor in the previous tax year had gross income, from all sources, under \$300,000, the Contractor is exempt from the requirement to report subcontractor awards.

(2) If a subcontractor in the previous tax year had gross income from all sources under \$300,000, the Contractor does not need to report awards for that subcontractor.

(h) The FSRS database at <http://www.fsrs.gov> will be prepopulated with some information from CCR and FPDS databases. If FPDS information is incorrect, the contractor should notify the contracting officer. If the CCR database information is incorrect, the contractor is responsible for correcting this information.

(End of clause)

#### CLAUSES INCORPORATED BY FULL TEXT

##### 52.216-8 FIXED FEE (JUN 2011)

(a) The Government shall pay the Contractor for performing this contract the fixed fee specified in the Schedule.

(b) Payment of the fixed fee shall be made as specified in the Schedule; provided that the Contracting Officer withholds a reserve not to exceed 15 percent of the total fixed fee or \$100,000, whichever is less, to protect the Government's interest. The Contracting Officer shall release 75 percent of all fee withholds under this contract after receipt of an adequate certified final indirect cost rate proposal covering the year of physical completion of this contract, provided the Contractor has satisfied all other contract terms and conditions, including the submission of the final patent and royalty reports, and is not delinquent in submitting final vouchers on prior years' settlements. The Contracting Officer may release up to 90 percent of the fee withholds under this contract based on the Contractor's past performance related to the submission and settlement of final indirect cost rate proposals.

(End of clause)

#### CLAUSES INCORPORATED BY FULL TEXT

##### 52.217-7 OPTION FOR INCREASED QUANTITY--SEPARATELY PRICED LINE ITEM (MAR 1989)

The Government may require the delivery of the numbered line item, identified in the Schedule as an option item, in the quantity and at the price stated in the Schedule. The Contracting Officer may exercise the option by written notice to the Contractor within **5 Calendar Days**. Delivery of added items shall continue at the same rate that like items are called for under the contract, unless the parties otherwise agree.

(End of clause)

#### CLAUSES INCORPORATED BY FULL TEXT

##### 52.219-28 POST-AWARD SMALL BUSINESS PROGRAM REREPRESENTATION (APR 2012)

(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/content/table-small-business-size-standards>.

(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 \_\_\_\_\_ - 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

### 52.228-7 INSURANCE--LIABILITY TO THIRD PERSONS (MAR 1996)

(a)(1) Except as provided in subparagraph (a)(2) of this clause, the Contractor shall provide and maintain workers' compensation, employer's liability, comprehensive general liability (bodily injury), comprehensive automobile liability (bodily injury and property damage) insurance, and such other insurance as the Contracting Officer may require under this contract.

(2) The Contractor may, with the approval of the Contracting Officer, maintain a self-insurance program; provided that, with respect to workers' compensation, the Contractor is qualified pursuant to statutory authority.

(3) All insurance required by this paragraph shall be in a form and amount and for those periods as the Contracting Officer may require or approve and with insurers approved by the Contracting Officer.

(b) The Contractor agrees to submit for the Contracting Officer's approval, to the extent and in the manner required by the Contracting Officer, any other insurance that is maintained by the Contractor in connection with the performance of this contract and for which the Contractor seeks reimbursement.

(c) The Contractor shall be reimbursed—

(1) For that portion (i) of the reasonable cost of insurance allocable to this contract, and (ii) required or approved under this clause; and

(2) For certain liabilities (and expenses incidental to such liabilities) to third persons not compensated by insurance or otherwise without regard to and as an exception to the limitation of cost or the limitation of funds clause of this contract. These liabilities must arise out of the performance of this contract, whether or not caused by the negligence of the Contractor or of the Contractor's agents, servants, or employees, and must be represented by final judgments or settlements approved in writing by the Government. These liabilities are for--

(i) Loss of or damage to property (other than property owned, occupied, or used by the Contractor, rented to the Contractor, or in the care, custody, or control of the Contractor); or

(ii) Death or bodily injury.

(d) The Government's liability under paragraph (c) of this clause is subject to the availability of appropriated funds at the time a contingency occurs. Nothing in this contract shall be construed as implying that the Congress will, at a later date, appropriate funds sufficient to meet deficiencies.

(e) The Contractor shall not be reimbursed for liabilities (and expenses incidental to such liabilities)--

(1) For which the Contractor is otherwise responsible under the express terms of any clause specified in the Schedule or elsewhere in the contract;

(2) For which the Contractor has failed to insure or to maintain insurance as required by the Contracting Officer; or

(3) That result from willful misconduct or lack of good faith on the part of any of the Contractor's directors, officers,

managers, superintendents, or other representatives who have supervision or direction of--

(i) All or substantially all of the Contractor's business;

(ii) All or substantially all of the Contractor's operations at any one plant or separate location in which this contract is being performed; or

(iii) A separate and complete major industrial operation in connection with the performance of this contract.

(f) The provisions of paragraph (e) of this clause shall not restrict the right of the Contractor to be reimbursed for the cost of insurance maintained by the Contractor in connection with the performance of this contract, other than insurance required in accordance with this clause; provided, that such cost is allowable under the Allowable Cost and Payment clause of this contract.

(g) If any suit or action is filed or any claim is made against the Contractor, the cost and expense of which may be reimbursable to the Contractor under this contract, and the risk of which is then uninsured or is insured for less than the amount claimed, the Contractor shall--

(1) Immediately notify the Contracting Officer and promptly furnish copies of all pertinent papers received;

(2) Authorize Government representatives to collaborate with counsel for the insurance carrier in settling or defending the claim when the amount of the liability claimed exceeds the amount of coverage; and

(3) Authorize Government representatives to settle or defend the claim and to represent the Contractor in or to take charge of any litigation, if required by the Government, when the liability is not insured or covered by bond. The Contractor may, at its own expense, be associated with the Government representatives in any such claim or litigation.

(End of clause)

## CLAUSES INCORPORATED BY FULL TEXT

### 52.244-2 SUBCONTRACTS (OCT 2010)

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

Approved purchasing system means a Contractor's purchasing system that has been reviewed and approved in accordance with Part 44 of the Federal Acquisition Regulation (FAR).

Consent to subcontract means the Contracting Officer's written consent for the Contractor to enter into a particular subcontract.

Subcontract means any contract, as defined in FAR Subpart 2.1, entered into by a subcontractor to furnish supplies or services for performance of the prime contract or a subcontract. It includes, but is not limited to, purchase orders, and changes and modifications to purchase orders.

(b) When this clause is included in a fixed-price type contract, consent to subcontract is required only on unpriced contract actions (including unpriced modifications or unpriced delivery orders), and only if required in accordance with paragraph (c) or (d) of this clause.

(c) If the Contractor does not have an approved purchasing system, consent to subcontract is required for any subcontract that—

(1) Is of the cost-reimbursement, time-and-materials, or labor-hour type; or

(2) Is fixed-price and exceeds—

(i) For a contract awarded by the Department of Defense, the Coast Guard, or the National Aeronautics and Space Administration, the greater of the simplified acquisition threshold or 5 percent of the total estimated cost of the contract; or

(ii) For a contract awarded by a civilian agency other than the Coast Guard and the National Aeronautics and Space Administration, either the simplified acquisition threshold or 5 percent of the total estimated cost of the contract.

(d) If the Contractor has an approved purchasing system, the Contractor nevertheless shall obtain the Contracting Officer's written consent before placing the following subcontracts:

(e)(1) The Contractor shall notify the Contracting Officer reasonably in advance of placing any subcontract or modification thereof for which consent is required under paragraph (b), (c), or (d) of this clause, including the following information:

(i) A description of the supplies or services to be subcontracted.

(ii) Identification of the type of subcontract to be used.

(iii) Identification of the proposed subcontractor.

(iv) The proposed subcontract price.

(v) The subcontractor's current, complete, and accurate certified cost or pricing data and Certificate of Current Cost or Pricing Data, if required by other contract provisions.

(vi) The subcontractor's Disclosure Statement or Certificate relating to Cost Accounting Standards when such data are required by other provisions of this contract.

(vii) A negotiation memorandum reflecting—

(A) The principal elements of the subcontract price negotiations;

(B) The most significant considerations controlling establishment of initial or revised prices;

(C) The reason certified cost or pricing data were or were not required;

(D) The extent, if any, to which the Contractor did not rely on the subcontractor's certified cost or pricing data in determining the price objective and in negotiating the final price;

(E) The extent to which it was recognized in the negotiation that the subcontractor's certified cost or pricing data were not accurate, complete, or current; the action taken by the Contractor and the subcontractor; and the effect of any such defective data on the total price negotiated;

(F) The reasons for any significant difference between the Contractor's price objective and the price negotiated; and

(G) A complete explanation of the incentive fee or profit plan when incentives are used. The explanation shall identify each critical performance element, management decisions used to quantify each incentive element, reasons for the incentives, and a summary of all trade-off possibilities considered.

(2) The Contractor is not required to notify the Contracting Officer in advance of entering into any subcontract for which consent is not required under paragraph (c), (d), or (e) of this clause.

(f) Unless the consent or approval specifically provides otherwise, neither consent by the Contracting Officer to any subcontract nor approval of the Contractor's purchasing system shall constitute a determination—

(1) Of the acceptability of any subcontract terms or conditions;

(2) Of the allowability of any cost under this contract; or

(3) To relieve the Contractor of any responsibility for performing this contract.

(g) No subcontract or modification thereof placed under this contract shall provide for payment on a cost-plus-a-percentage-of-cost basis, and any fee payable under cost-reimbursement type subcontracts shall not exceed the fee limitations in FAR 15.404-4(c)(4)(i).

(h) The Contractor shall give the Contracting Officer immediate written notice of any action or suit filed and prompt notice of any claim made against the Contractor by any subcontractor or vendor that, in the opinion of the Contractor, may result in litigation related in any way to this contract, with respect to which the Contractor may be entitled to reimbursement from the Government.

(i) The Government reserves the right to review the Contractor's purchasing system as set forth in FAR Subpart 44.3.

(j) Paragraphs (c) and (e) of this clause do not apply to the following subcontracts, which were evaluated during negotiations:

\*\*\*\* "All subcontracts not approved at the time of award shall require prior written approval of the contracting officer." \*\*\*\*

(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/>

(End of clause)

#### CLAUSES INCORPORATED BY FULL TEXT

252.204-7000 DISCLOSURE OF INFORMATION (DEC 1991)

(a) The Contractor shall not release to anyone outside the Contractor's organization any unclassified information, regardless of medium (e.g., film, tape, document), pertaining to any part of this contract or any program related to this contract, unless--

(1) The Contracting Officer has given prior written approval; or

(2) The information is otherwise in the public domain before the date of release.

(b) Requests for approval shall identify the specific information to be released, the medium to be used, and the purpose for the release. The Contractor shall submit its request to the Contracting Officer at least 45 days before the proposed date for release.

(c) The Contractor agrees to include a similar requirement in each subcontract under this contract. Subcontractors shall submit requests for authorization to release through the prime contractor to the Contracting Officer.

(End of clause)

CLAUSES INCORPORATED BY FULL TEXT

252.211-7003 ITEM IDENTIFICATION AND VALUATION (JUN 2011)

(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](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 globally unique identifier to an enterprise (e.g., Dun & Bradstreet's Data Universal Numbering System (DUNS) Number, GS1 Company Prefix, Allied Committee 135 NATO Commercial and Government Entity (NCAGE)/Commercial and Government Entity (CAGE) Code, or the Coded Representation of the North American Telecommunications Industry Manufacturers, Suppliers, and Related Service Companies (ATIS-0322000) Number), European Health Industry Business Communication Council (EHIBCC) and Health Industry Business Communication Council (HIBCC)), as indicated in the Register of Issuing Agency Codes for ISO/IEC 15459, located at <http://www.nen.nl/web/Normen-ontwikkelen/ISOIEC-15459-Issuing-Agency-Codes.htm>.

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](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  
-----

(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](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)

Section J - List of Documents, Exhibits and Other Attachments

LIST OF ATTACHMENTS

**LIST OF ATTACHMENTS**

<b>Attachment No</b>	<b>Description</b>	<b>Date</b>	<b>No. of Pages</b>
1	Contractor's Statement of Work	To be inserted upon award	
2	Summary of the Manufacturing Process	08 Apr 2011	61
*3	List of Government Furnished Material identifying materials to be provided to contract awardee	20 Jul 2011	3

Contract Data Requirements List (CDRL) DD Form 1423

<b>Data Item #</b>	<b>Description</b>
A001	Integrated Product Team Meeting Minutes
A002	Contractor's Progress, Status, and Management Report
A003	Integrated Master Schedule (IMS)
A004	Scientific and technical Reports Summary
A005	Quarterly Program Review
A006	Contract Work Breakdown Structure
A007	Quality Agreement
A008	Technical Data Package
A009	EVMS - Integrated Baseline Review (IBR)
A010	EVMS - Contract Performance Report (CPR)
A011	EVMS - Contract Funds Status Report
A012	Report, Production, or Delivery Problems
A013	Risk Management Plan
A014	Master Production Batch records
A015	Production Batch Records
A016	Regulatory Submissions and Communications

A017	Risk Management Status Report

Section K - Representations, Certifications and Other Statements of Offerors

CLAUSES INCORPORATED BY REFERENCE

52.204-5	Women-Owned Business (Other Than Small Business)	MAY 1999
52.204-8	Annual Representations and Certifications	DEC 2012
52.209-2	Prohibition on Contracting with Inverted Domestic Corporations--Representation	MAY 2011
52.219-1	Small Business Program Representations	APR 2012
52.219-8	Utilization of Small Business Concerns	JAN 2011
52.219-9 Alt II	Small Business Subcontracting Plan (JAN 2011) Alternate II	OCT 2001
52.219-16	Liquidated Damages-Subcontracting Plan	JAN 1999
52.219-22	Small Disadvantaged Business Status	OCT 1999
52.222-22	Previous Contracts And Compliance Reports	FEB 1999
52.222-25	Affirmative Action Compliance	APR 1984
252.204-7004 Alt A	Central Contractor Registration Alternate A	SEP 2007
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

CLAUSES INCORPORATED BY FULL TEXT

52.203-2 CERTIFICATE OF INDEPENDENT PRICE DETERMINATION (APR 1985)

(a) The offeror certifies that --

(1) The prices in this offer have been arrived at independently, without, for the purpose of restricting competition, any consultation, communication, or agreement with any other offeror or competitor relating to --

(i) Those prices,

(ii) The intention to submit an offer, or

(iii) The methods of factors used to calculate the prices offered:

(2) The prices in this offer have not been and will not be knowingly disclosed by the offeror, directly or indirectly, to any other offeror or competitor before bid opening (in the case of a sealed bid solicitation) or contract award (in the case of a negotiated solicitation) unless otherwise required by law; and

(3) No attempt has been made or will be made by the offeror to induce any other concern to submit or not to submit an offer for the purpose of restricting competition.

(b) Each signature on the offer is considered to be a certification by the signatory that the signatory --

(1) Is the person in the offeror's organization responsible for determining the prices offered in this bid or proposal, and that the signatory has not participated and will not participate in any action contrary to subparagraphs (a)(1) through (a)(3) of this provision; or

(2) (i) Has been authorized, in writing, to act as agent for the following principals in certifying that those principals have not participated, and will not participate in any action contrary to subparagraphs (a)(1) through (a)(3) of this provision \_\_\_\_\_ (insert full name of person(s) in the

offeror's organization responsible for determining the prices offered in this bid or proposal, and the title of his or her position in the offeror's organization);

(ii) As an authorized agent, does certify that the principals named in subdivision (b)(2)(i) above have not participated, and will not participate, in any action contrary to subparagraphs (a)(1) through (a)(3) above; and

(iii) As an agent, has not personally participated, and will not participate, in any action contrary to subparagraphs (a)(1) through (a)(3) of this provision.

(c) If the offeror deletes or modifies subparagraph (a)(2) of this provision, the offeror must furnish with its offer a signed statement setting forth in detail the circumstances of the disclosure.

(End of clause)

#### 52.203-11 CERTIFICATION AND DISCLOSURE REGARDING PAYMENTS TO INFLUENCE CERTAIN FEDERAL TRANSACTIONS (SEP 2007)

(a) Definitions. As used in this provision--"Lobbying contact" has the meaning provided at 2 U.S.C. 1602(8). The terms "agency," "influencing or attempting to influence," "officer or employee of an agency," "person," "reasonable compensation," and "regularly employed" are defined in the FAR clause of this solicitation entitled "Limitation on Payments to Influence Certain Federal Transactions" (52.203-12).

(b) Prohibition. The prohibition and exceptions contained in the FAR clause of this solicitation entitled "Limitation on Payments to Influence Certain Federal Transactions" (52.203-12) are hereby incorporated by reference in this provision.

(c) Certification. The offeror, by signing its offer, hereby certifies to the best of its knowledge and belief that no Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress on its behalf in connection with the awarding of this contract.

(d) Disclosure. If any registrants under the Lobbying Disclosure Act of 1995 have made a lobbying contact on behalf of the offeror with respect to this contract, the offeror shall complete and submit, with its offer, OMB Standard Form LLL, Disclosure of Lobbying Activities, to provide the name of the registrants. The offeror need not report regularly employed officers or employees of the offeror to whom payments of reasonable compensation were made.

(e) Penalty. Submission of this certification and disclosure is a prerequisite for making or entering into this contract imposed by 31 U.S.C. 1352. Any person who makes an expenditure prohibited under this provision or who fails to file or amend the disclosure required to be filed or amended by this provision, shall be subject to a civil penalty of not less than \$10,000, and not more than \$100,000, for each such failure.

(End of provision)

#### 52.204-3 TAXPAYER IDENTIFICATION (OCT 1998)

(a) Definitions.

Common parent, as used in this provision, means that corporate entity that owns or controls an affiliated group of corporations that files its Federal income tax returns on a consolidated basis, and of which the offeror is a member.

Taxpayer Identification Number (TIN), as used in this provision, means the number required by the Internal Revenue Service (IRS) to be used by the offeror in reporting income tax and other returns. The TIN may be either a Social Security Number or an Employer Identification Number.

(b) All offerors must submit the information required in paragraphs (d) through (f) of this provision to comply with debt collection requirements of 31 U.S.C. 7701(c) and 3325(d), reporting requirements of 26 U.S.C. 6041, 6041A, and 6050M, and implementing regulations issued by the IRS. If the resulting contract is subject to the payment reporting requirements described in Federal Acquisition Regulation (FAR) 4.904, the failure or refusal by the offeror to furnish the information may result in a 31 percent reduction of payments otherwise due under the contract.

(c) The TIN may be used by the Government to collect and report on any delinquent amounts arising out of the offeror's relationship with the Government (31 U.S.C. 7701(c)(3)). If the resulting contract is subject to the payment reporting requirements described in FAR 4.904, the TIN provided hereunder may be matched with IRS records to verify the accuracy of the offeror's TIN.

(d) Taxpayer Identification Number (TIN).

TIN:.....

TIN has been applied for.

TIN is not required because:

Offeror is a nonresident alien, foreign corporation, or foreign partnership that does not have income effectively connected with the conduct of a trade or business in the United States and does not have an office or place of business or a fiscal paying agent in the United States;

Offeror is an agency or instrumentality of a foreign government;

Offeror is an agency or instrumentality of the Federal Government.

(e) Type of organization.

Sole proprietorship;

Partnership;

Corporate entity (not tax-exempt);

Corporate entity (tax-exempt);

Government entity (Federal, State, or local);

Foreign government;

International organization per 26 CFR 1.6049-4;

Other.....

(f) Common parent.

Offeror is not owned or controlled by a common parent as defined in paragraph (a) of this provision.

Name and TIN of common parent:

Name-----

TIN-----

(End of provision)

52.204-8 ANNUAL REPRESENTATIONS AND CERTIFICATIONS (DEC 2012)

(a)(1) The North American Industry Classification System (NAICS) code for this acquisition is [insert NAICS code].

(2) The small business size standard is [insert size standard].

(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, 2010, or 2012.

(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, Alternates I, II, and III.) 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 \$77,494, the provision with its Alternate II applies.

(D) If the acquisition value is \$77,494 or more but is less than \$100,000, the provision with its Alternate III 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 Contracting with Entities Engaging in Certain Activities or Transactions Relating to Iran--Representation and Certifications. 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).

(vi) 52.227-6, Royalty Information.

(A) Basic.

(B) Alternate I.

(vii) 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 accessed through <https://www.acquisition.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
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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)

52.207-4 ECONOMIC PURCHASE QUANTITY--SUPPLIES (AUG 1987)

(a) Offerors are invited to state an opinion on whether the quantity(ies) of supplies on which bids, proposals or quotes are requested in this solicitation is (are) economically advantageous to the Government.

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Each offeror who believes that acquisitions in different quantities would be more advantageous is invited to recommend an economic purchase quantity. If different quantities are recommended, a total and a unit price must be quoted for applicable items. An economic purchase quantity is that quantity at which a significant price break occurs. If there are significant price breaks at different quantity points, this information is desired as well.

OFFEROR RECOMMENDATIONS  
PRICE

ITEM	QUANTITY	QUOTATION	TOTAL
-----	-----	-----	-----
-----	-----	-----	-----

(c) The information requested in this provision is being solicited to avoid acquisitions in disadvantageous quantities and to assist the Government in developing a data base for future acquisitions of these items. However, the Government reserves the right to amend or cancel the solicitation and resolicit with respect to any individual item in the event quotations received and the Government's requirements indicate that different quantities should be acquired.

(End of provision)

52.209-7 INFORMATION REGARDING RESPONSIBILITY MATTERS (FEB 2012)

(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 (FAPIS) 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 FAPIS as required through maintaining an active registration in the Central Contractor Registration database via <https://www.acquisition.gov> (see 52.204-7).

(End of provision)

52.215-6 PLACE OF PERFORMANCE (OCT 1997)

(a) The offeror or respondent, in the performance of any contract resulting from this solicitation, ( ) intends, ( ) does not intend (check applicable block) to use one or more plants or facilities located at a different address from the address of the offeror or respondent as indicated in this proposal or response to request for information.

(b) If the offeror or respondent checks "intends" in paragraph (a) of this provision, it shall insert in the following spaces the required information:

Place of Performance(Street Address, City, State, County, Zip Code)

Name and Address of Owner and Operator of the Plant or Facility if Other Than Offeror or Respondent

(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)

52.225-6 TRADE AGREEMENTS CERTIFICATE (JAN 2005)

(a) The offeror certifies that each end product, except those listed in paragraph (b) of this provision, is a U.S.-made or designated country end product, as defined in the clause of this solicitation entitled "Trade Agreements."

(b) The offeror shall list as other end products those supplies that are not U.S.-made or designated country end products.

Other 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. For line items covered by the WTO GPA, the Government will evaluate offers of U.S.-made or designated country end products without regard to the restrictions of the Buy American Act. The Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for those products are insufficient to fulfill the requirements of this solicitation.

(End of provision)

52.225-18 PLACE OF MANUFACTURE (SEP 2006)

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

Manufactured end product means any end product in Federal Supply Classes (FSC) 1000-9999, except--

- (1) FSC 5510, Lumber and Related Basic Wood Materials;
- (2) Federal Supply Group (FSG) 87, Agricultural Supplies;
- (3) FSG 88, Live Animals;
- (4) FSG 89, Food and Related Consumables;
- (5) FSC 9410, Crude Grades of Plant Materials;
- (6) FSC 9430, Miscellaneous Crude Animal Products, Inedible;
- (7) FSC 9440, Miscellaneous Crude Agricultural and Forestry Products;
- (8) FSC 9610, Ores;
- (9) FSC 9620, Minerals, Natural and Synthetic; and
- (10) FSC 9630, Additive Metal Materials.

Place of manufacture means the place where an end product is assembled out of components, or otherwise made or processed from raw materials into the finished product that is to be provided to the Government. If a product is disassembled and reassembled, the place of reassembly is not the place of manufacture.

(b) For statistical purposes only, the offeror shall indicate whether the place of manufacture of the end products it expects to provide in response to this solicitation is predominantly--

- (1) ( ) In the United States (Check this box if the total anticipated price of offered end products manufactured in the United States exceeds the total anticipated price of offered end products manufactured outside the United States); or
- (2) ( ) Outside the United States.

(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)

#### 252.204-7007 ALTERNATE A, ANNUAL REPRESENTATIONS AND CERTIFICATIONS (JUL 2012)

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.

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 *	Basis for Assertion **	Asserted Rights Category ***	Name of Person Asserting 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)

#### 252.247-7022 REPRESENTATION OF EXTENT OF TRANSPORTATION BY SEA (AUG 1992)

(a) The Offeror shall indicate by checking the appropriate blank in paragraph (b) of this provision whether transportation of supplies by sea is anticipated under the resultant contract. The term supplies is defined in the Transportation of Supplies by Sea clause of this solicitation.

(b) Representation. The Offeror represents that it:

\_\_\_ (1) Does anticipate that supplies will be transported by sea in the performance of any contract or subcontract resulting from this solicitation.

\_\_\_ (2) Does not anticipate that supplies will be transported by sea in the performance of any contract or subcontract resulting from this solicitation.

(c) Any contract resulting from this solicitation will include the Transportation of Supplies by Sea clause. If the Offeror represents that it will not use ocean transportation, the resulting contract will also include the Defense FAR

Supplement clause at 252.247-7024, Notification of Transportation of Supplies by Sea.

(End of provision)

52.204-99 SYSTEM FOR AWARD MANAGEMENT REGISTRATION (DEVIATION)(AUG 2012)

(a) Definitions. As used in this clause—

“Central Contractor Registration (CCR) database” means the retired primary Government repository for Contractor information required for the conduct of business with the Government.

“Commercial and Government Entity (CAGE) code” means—

(1) A code assigned by the Defense Logistics Agency (DLA) Logistics Information Service to identify a commercial or Government entity; or

(2) A code assigned by a member of the North Atlantic Treaty Organization that DLA records and maintains in the CAGE master file. This type of code is known as an “NCAGE code.”

“Data Universal Numbering System (DUNS) number” means the 9-digit number assigned by Dun and Bradstreet, Inc. (D&B) to identify unique business entities.

“Data Universal Numbering System+4 (DUNS+4) number” means the DUNS number means the number assigned by D&B plus a 4-character suffix that may be assigned by a business concern. (D&B has no affiliation with this 4-character suffix.) This 4-character suffix may be assigned at the discretion of the business concern to establish additional SAM records for identifying alternative Electronic Funds Transfer (EFT) accounts (see the FAR at Subpart 32.11) for the same concern.

“Registered in the SAM database” means that—

(1) The Contractor has entered all mandatory information, including the DUNS number or the DUNS+4 number, into the SAM database;

(2) The Contractor’s CAGE code is in the SAM database; and

(3) The Government has validated all mandatory data fields, to include validation of the Taxpayer Identification Number (TIN) with the Internal Revenue Service (IRS), and has marked the record “Active”. The Contractor will be required to provide consent for TIN validation to the Government as a part of the SAM registration process.

“System for Award Management (SAM)” means the primary Government repository for prospective federal awardee information and the centralized Government system for certain contracting, grants, and other assistance related processes. It includes—

(1) Data collected from prospective federal awardees required for the conduct of business with the Government;

(2) Prospective contractor submitted annual representations and certifications in accordance with FAR Subpart 4.12; and

(3) The list of all parties suspended, proposed for debarment, debarred, declared ineligible, or excluded or disqualified under the nonprocurement common rule by agencies, Government corporations, or by the Government Accountability Office.

(b)(1) The Contractor shall be registered in the SAM database prior to submitting an invoice and through final payment of any contract, basic agreement, basic ordering agreement, or blanket purchasing agreement resulting from this solicitation.

(2) The SAM registration shall be for the same name and address identified on the contract, with its associated CAGE code and DUNS or DUNS+4.

(3) If indicated by the Government during performance, registration in CCR may be required in lieu of SAM.

(c) If the Contractor does not have a DUNS number, it should contact Dun and Bradstreet directly to obtain one.

(1) A contractor may obtain a DUNS number—

(i) Via the internet at <http://fedgov.dnb.com/webform> or if the contractor does not have internet access, it may call Dun and Bradstreet at 1-866-705-5711 if located within the United States; or

(ii) If located outside the United States, by contacting the local Dun and Bradstreet office. The contractor should indicate that it is a contractor for a U.S. Government contract when contacting the local Dun and Bradstreet office.

(2) The Contractor should be prepared to provide the following information:

(i) Company legal business name.

(ii) Tradestyle, doing business, or other name by which your entity is commonly recognized.

(iii) Company physical street address, city, state and Zip Code.

(iv) Company mailing address, city, state and Zip Code (if separate from physical).

(v) Company telephone number.

(vi) Date the company was started.

(vii) Number of employees at your location.

(viii) Chief executive officer/key manager.

(ix) Line of business (industry).

(x) Company Headquarters name and address (reporting relationship within your entity).

(d) Reserved.

(e) Processing time for registration in SAM, which normally takes five business days, should be taken into consideration when registering. Contractors who are not already registered should consider applying for registration at least two weeks prior to invoicing.

(f) The Contractor is responsible for the accuracy and completeness of the data within the SAM database, and for any liability resulting from the Government's reliance on inaccurate or incomplete data. To remain registered in the

SAM database after the initial registration, the Contractor is required to review and update on an annual basis from the date of initial registration or subsequent updates its information in the SAM database to ensure it is current, accurate and complete. Updating information in the SAM does not alter the terms and conditions of this contract and is not a substitute for a properly executed contractual document.

(g)(1)(i) If a Contractor has legally changed its business name, “doing business as” name, or division name (whichever is shown on the contract), or has transferred the assets used in performing the contract, but has not completed the necessary requirements regarding novation and change-of-name agreements in Subpart 42.12, the Contractor shall provide the responsible Contracting Officer sufficient documentation to support the legally changed name with a minimum of one business day’s written notification of its intention to—

(A) Change the name in the SAM database;

(B) Comply with the requirements of subpart 42.12 of the FAR; and

(C) Agree in writing to the timeline and procedures specified by the responsible Contracting Officer.

(ii) If the Contractor fails to comply with the requirements of paragraph (g)(1)(i) of this clause, or fails to perform the agreement at paragraph (g)(1)(i)(C) of this clause, and, in the absence of a properly executed novation or change-of-name agreement, the SAM information that shows the Contractor to be other than the Contractor indicated in the contract will be considered to be incorrect information within the meaning of the “Suspension of Payment” paragraph of the electronic funds transfer (EFT) clause of this contract.

(2) The Contractor shall not change the name or address for EFT payments or manual payments, as appropriate, in the SAM record to reflect an assignee for the purpose of assignment of claims (see FAR Subpart 32.8, Assignment of Claims). Assignees shall be separately registered in the SAM database. Information provided to the Contractor’s SAM record that indicates payments, including those made by EFT, to an ultimate recipient other than that Contractor will be considered to be incorrect information within the meaning of the “Suspension of payment” paragraph of the EFT clause of this contract.

(h) Contractors may obtain information on registration and annual confirmation requirements via the SAM accessed through <https://www.acquisition.gov> or by calling 866-606-8220, or 334-206-7828 for international calls.

(End of Clause)

Section L - Instructions, Conditions and Notices to Bidders

GENERAL INFORMATION

**L.1 GENERAL INFORMATION**

**L.1.1 PROPOSAL SUBMISSION**

Proposals shall be delivered no later than 5:00 p.m. Eastern Time (ET) on 02 June 2013 to the address below:

Solicitation W911QY-13-R-0012

ATTN: Nathan Jordan

ACC-APG Natick Contracting Division

110 Thomas Johnson Drive

Frederick, MD 21702

Each box shall be marked with the volume and copy number(s) contained in each box. See section L.3 for formatting and submission details.

**L.1.2 PRE-AWARD SURVEY**

The Government may conduct a Pre-Award Survey prior to any contract award. The pre-award survey may examine the Offeror's and/or Key Subcontractor's records of integrity and business ethics (which includes satisfactory compliance with the law including tax, labor and employment, environmental, antitrust, and consumer protection laws), technical ability, production capacity, management structure, financial capability, accounting systems, security controls/clearances, labor resources, performance record, and ability to meet required schedules.

**L.2 DISCLOSURE OF PROPOSAL**

a. Information contained in the successful or unsuccessful Offeror's technical/management or price proposal must be released under the Freedom of Information Act (5 U.S.C. 552) upon request from the public after contract award 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 is not otherwise publicly available, and if the Offeror does and 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 legend that follows.

"This proposal, furnished in response to Solicitation No. W911QY-13-R-0012 contains 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.

#### CLAUSES INCORPORATED BY REFERENCE

52.204-6	Data Universal Numbering System Number	DEC 2012
52.207-1	Notice Of Standard Competition	MAY 2006
52.211-2	Availability of Specifications, Standards, and Data Item Descriptions Listed in the Acquisition Streamlining and Standardization Information System (ASSIST)	JAN 2006
52.215-1	Instructions to Offerors--Competitive Acquisition	JAN 2004
52.215-16	Facilities Capital Cost of Money	JUN 2003
52.215-20	Requirements for Certified Cost or Pricing Data or Information Other Than Certified Cost or Pricing Data	OCT 2010
52.222-24	Preaward On-Site Equal Opportunity Compliance Evaluation	FEB 1999
52.233-2	Service Of Protest	SEP 2006
52.247-6	Financial Statement	APR 1984
52.247-45	F.O.B. Origin And/Or Destination Evaluation	APR 1984
52.252-5	Authorized Deviations In Provisions	APR 1984
252.203-7001	Prohibition On Persons Convicted of Fraud or Other Defense-Contract-Related Felonies	DEC 2008
252.217-7026	Identification of Sources of Supply	NOV 1995
252.225-7003	Report of Intended Performance Outside the United States and Canada--Submission with Offer	OCT 2010
252.234-7001	Notice of Earned Value Management System	APR 2008

#### CLAUSES INCORPORATED BY FULL TEXT

52.203-11 CERTIFICATION AND DISCLOSURE REGARDING PAYMENTS TO INFLUENCE CERTAIN FEDERAL TRANSACTIONS (SEP 2007)

(a) Definitions. As used in this provision--"Lobbying contact" has the meaning provided at 2 U.S.C. 1602(8). The terms "agency," "influencing or attempting to influence," "officer or employee of an agency," "person," "reasonable compensation," and "regularly employed" are defined in the FAR clause of this solicitation entitled "Limitation on Payments to Influence Certain Federal Transactions" (52.203-12).

(b) Prohibition. The prohibition and exceptions contained in the FAR clause of this solicitation entitled "Limitation on Payments to Influence Certain Federal Transactions" (52.203-12) are hereby incorporated by reference in this provision.

(c) Certification. The offeror, by signing its offer, hereby certifies to the best of its knowledge and belief that no Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress on its behalf in connection with the awarding of this contract.

(d) Disclosure. If any registrants under the Lobbying Disclosure Act of 1995 have made a lobbying contact on behalf of the offeror with respect to this contract, the offeror shall complete and submit, with its offer, OMB

Standard Form LLL, Disclosure of Lobbying Activities, to provide the name of the registrants. The offeror need not report regularly employed officers or employees of the offeror to whom payments of reasonable compensation were made.

(e) Penalty. Submission of this certification and disclosure is a prerequisite for making or entering into this contract imposed by 31 U.S.C. 1352. Any person who makes an expenditure prohibited under this provision or who fails to file or amend the disclosure required to be filed or amended by this provision, shall be subject to a civil penalty of not less than \$10,000, and not more than \$100,000, for each such failure.

(End of provision)

#### 52.214-34 SUBMISSION OF OFFERS IN THE ENGLISH LANGUAGE (APR 1991)

Offers submitted in response to this solicitation shall be in the English language. Offers received in other than English shall be rejected.

(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/>

(End of provision)

#### 52.252-3 ALTERATIONS IN SOLICITATION (APR 1984)

Portions of this solicitation are altered as follows:

### **L.3 INFORMATION TO OFFERORS AND INSTRUCTIONS FOR PROPOSAL PREPARATION**

#### **L.3.1 General Instructions**

L.3.1.1 This section provides general guidance for preparation of proposals as well as specific instructions on the format and content of the proposal. The Offeror's proposal must include all data and information requested and must be submitted in accordance with these instructions. The proposal shall be compliant with requirements as stated in the Statement of Objectives (SOO), Attachment C and Contract Data Requirements List (CDRL) in Section

J. The Offeror shall include evidence (e.g., statement of intent to enter into a teaming agreement) of Subcontractor relationships. **Non-conformance with these instructions may result in an unfavorable proposal evaluation. Any Offeror who submits an incomplete package may be considered unacceptable and could be eliminated from further competition.**

L.3.1.2 The proposal shall be clear, concise, and with sufficient detail for effective evaluation and for substantiating the validity of stated claims. The proposal should not simply rephrase or restate the Government's requirements, but rather shall provide convincing rationale to address how the Offeror intends to meet these requirements. The Offeror shall assume that the Government has no prior knowledge of the Offeror's facilities and experience and will base its evaluation on the information presented in the Offeror's proposal.

L.3.1.3 Each Offeror shall submit a proposal for the optimization and manufacture of a trivalent filovirus vaccine candidate using the Virus Like Particle (VLP) system for which the license to the Intellectual property is owned by the Government. The List of Government Furnished Material is provided in Section J.

L.3.1.4 Elaborate brochures or documentation, binding, detailed art work, or other embellishments are unnecessary and not desired.

L.3.1.5 The proposal acceptance period shall be specified in block 12 of the Standard Form 33 (at least 180 days minimum).

L.3.1.6 Questions regarding this Request for Proposal (RFP) must be made in writing within 15 calendar days after issuance and directed to the sole point of contact for this acquisition, Contract Specialist, Nathan Jordan at [cbms.filorfp@amedd.army.mil](mailto:cbms.filorfp@amedd.army.mil). The Government reserves the right to decline addressing questions received more than 15 calendar days after final RFP issuance. Telephonic questions will not be accepted.

L.3.1.7 If an Offeror believes that the requirements in these instructions contain an error, omission, or are otherwise unsound, the Offeror shall immediately notify the Contract Specialist listed above in writing with supporting rationale. Offerors are reminded that the Government reserves the right to award this effort based on the initial proposal, as received, without discussion.

L.3.1.8 In accordance with (IAW) Federal Acquisition Regulation (FAR) Subpart 4.8 (Government Contract Files), the Government will retain one copy of all unsuccessful proposals. Unless the Offeror requests otherwise, the Government will destroy extra copies of such unsuccessful proposals.

L.3.1.9 In the event that revised proposals are authorized, any changed pages shall be annotated in the footer with a revision date, and changed text shall be highlighted to identify changes made from original proposals.

L.3.1.10 Debriefings. The Offeror may request debriefing by providing a written request to the Contracting Officer. If the Government elects to establish a competitive range, the Contracting Officer will promptly notify the Offeror of any decision to exclude an offer from the competitive range. Upon written request, an Offeror may receive a debriefing IAW FAR 15.505. The Offeror desiring a debriefing must make a request in writing within three (3) calendar days after receiving the Contracting Officer's notification. To the maximum extent practicable, debriefings will be conducted within five (5) working days after receipt of the Offeror's written request.

### **L.3.2 Organization of Proposals**

L.3.2.1 The Offeror shall prepare the proposal and include the number of copies set forth as shown in the table below. Each volume shall be clearly labeled. The Offeror shall clearly mark one hardcopy of each volume as "ORIGINAL" and additional hardcopies shall be clearly marked as "COPY".

VOLUME	VOLUME TITLE	COPIES	PAGE LIMIT
I	Executive Summary	7 Hard 1 CD/DVD ROMs	5
II	Technical	8 Hard 1 CD/DVD ROMs	75
III	Program Management	7 Hard 1 CD/DVD ROMs	25
IV	Past Performance	5 Hard 1 CD/DVD ROMs	No limit
V	Cost/Price and Contract Documentation  NOTE: This section V shall be submitted in binders separate from the binder(s) in which sections I through IV are submitted.	3 Hard 3 CD/DVD ROMs	30

L.3.2.2 Electronic Submission – The technical and program management volumes shall be submitted on separate CD-ROMs in PDF format except for the Cost Section, which shall be submitted as a “Read Only” Microsoft Excel file, showing all formulas and links, including:

- Offeror’s total costs including Subcontractor costs
- Offeror’s costs separate from Subcontractor costs
- Total costs of all Subcontractors, and
- Total costs of each Subcontractor individually.

The electronic submission shall be compatible with Microsoft Windows XP, Microsoft Excel 2007 and Adobe Acrobat 8.0. For the Integrated Master Schedule (IMS), in addition to a high level presentation in PDF format as part of the Program Management submission, the Offeror shall submit an electronic copy with schedule data in “Read Only” Microsoft Project file that shows all formulas and links. The files shall be virus and malware free. All passwords shall be removed.

L.3.2.3 Page Limitations - Page limitations shall be treated as maximums. If exceeded, the excess pages will not be read nor considered in the evaluation of the proposal and will be returned to the Offeror as soon as practicable. Documents referenced in the proposal but not included in the proposal will not be reviewed or considered. Page limitations exclude FDA form 483s, FDA establishment inspection report, pre-approval inspection report; Curriculum Vitae and bibliographic data for the Program Manager, Consultants, Key Personnel, Key Subcontractor Personnel, Quality Management Plan, Quality Agreement, Risk Management Plan and Subcontractor Proposals. Each subcontractor proposal cannot exceed 10 pages and the total of all subcontractor proposals cannot exceed 50 pages. The IMS to be included in Volume III, Program Management, has no page or line limit and should provide sufficient detail to facilitate Government assessment of schedule realism.

L.3.2.4 Page Size and Format - A page is defined as each face of a sheet of paper containing information. When both sides of a sheet display printed material, it shall be counted as two pages. Page size shall be 8.5 by 11 inches, not including foldouts. Pages shall be single-spaced. Except for the reproduced sections of the solicitation document, the text size shall be no less than 12 point. Tracking, kerning, and leading values shall not be changed from the default values of the word processing or page layout software. Use at least 1 inch margins on the top and bottom and ¾ -inch side margins. Pages shall be numbered sequentially by volume. These page format restrictions shall apply to responses to both electronic and hard copy proposals.

L.3.2.5 Tables, Charts, Graphs and Figures - Legible tables, charts, graphs and figures shall be used wherever practical to depict organizations, systems and layout, implementation schedules, plans, technical data, etc. These displays shall be uncomplicated, legible, and shall not exceed 11 by 17 inches in size. Foldout pages shall fold entirely within the volume, and count as a single page. Foldout pages may only be used for large tables, charts, graphs, diagrams and schematics, not for pages of text. For tables, charts, graphs and figures, the text shall be no smaller than 10 point. These limitations shall apply to both electronic and hard copy proposals.

L.3.2.6 Cross-Referencing - To the greatest extent possible, each volume shall be written on a stand-alone basis so that its contents may be evaluated with minimum cross referencing to other volumes of the proposal. Information required for proposal evaluation which is not found in its designated volume will be assumed to have been omitted from the proposal. Cross referencing within a proposal volume is not permitted.

L.3.2.7 Indexing - Each volume shall contain a more detailed table of contents to delineate the subparagraphs within that volume. Tab indexing shall be used to identify sections. Indices do not count against the page limitations for their respective volumes.

L.3.2.8 Glossary of Abbreviations or Acronyms - Each volume shall contain a glossary of all abbreviations and acronyms used. Glossaries do not count against the page limitations for their respective volumes.

L.3.2.9 Binding and Labeling – Each volume of the proposal should be separately bound in a three-ring, loose leaf binder permitting the volume to lie flat when open. Staples shall not be used. A cover page shall be bound in each book, clearly marked as to volume number, title, copy number, solicitation number, and Offeror. Be sure to apply all appropriate markings including those prescribed IAW FAR 52.215-1(e), Restriction on Disclosure and Use of Data, and FAR 3.104-4, Disclosure, Protection and Marking of Contractor Bid or Proposal Information and Source Selection Information.

L.3.2.10 Cost Information – All cost or pricing information shall be addressed ONLY in Cost/Price Proposal and Contract Documentation, Volume V (also referred to herein as Cost/Price Proposal). Labor hour estimates and material types and quantities may be used in other volumes only as appropriate for presenting rationale for alternatives or design decisions.

L.3.2.11 The information in each volume should be specific and complete. Legibility, clarity, and coherence are very important. Your responses will be evaluated against the factors, subfactors, and elements defined in Section M; Evaluation Factors for Award. Using the instructions below, provide as specifically as possible the actual methodology you would use for accomplishing/satisfying these subfactors. All the requirements specified in the

solicitation are mandatory. By your proposal submission, you are representing that your firm will be responsible for meeting the requirements specified in the solicitation performed. It is not necessary or desirable for you to tell us so in your proposal. Do not merely reiterate the objectives or reformulate the requirements specified in the solicitation.

L.3.2.12 Proposal Evaluation by Non-U.S. Government Personnel - Offerors are advised that support contractor personnel from Goldbelt-Raven, LLC may assist the Government during the evaluation of proposals. Goldbelt-Raven, LLC personnel will be authorized to access only those portions of proposal data that are necessary to enable them to provide specific technical advice on specialized matters or particular problems. All support contractor personnel will be expressly prohibited from scoring, ranking, rating, or recommending the selection of a source. The exclusive responsibility for source selection remains with the U.S. Government. All will function under a nondisclosure statement.

### **L.3.3 Volume I - Executive Summary**

L.3.3.1 Narrative Summary: The Offeror shall provide a concise narrative summary of the entire proposal, including significant risks, and a highlight of any key or unique features, excluding cost/price. The salient features should tie in with Section M Evaluation Factors/Subfactors. Any summary material presented here shall not be considered as meeting the requirements for any portions of other the volumes of the proposal.

L.3.3.2 Table of Contents: The Offeror shall provide a master table of contents of the entire proposal.

L.3.3.3 Cross-reference Matrix: The Offeror shall provide a crosswalk (Compliance Matrix) of their proposal to link the requirements of sections SOO, L, and M of this RFP.

### **L.3.4 Volume II - Technical Volume**

The Technical Section shall not contain any reference to cost or price; however, information concerning labor hours and categories, Consultant services, travel requirements, materials and equipment needed, and, if applicable, Subcontractor(s), shall be contained in the Technical Volume in sufficient detail so that the Government may adequately evaluate the Offeror's understanding of the requirements.

#### **L.3.4.1 Manufacturing Approach**

L.3.4.1.1 Offerors shall provide a manufacturing advanced development plan in sufficient detail to allow the Government to assess the fulfillment of the SOO. The formulation studies, assay development, and process development plan shall be described in sufficient detail, including go-no-go decision points complete with rationale, so that the Government may assess technical and schedule risks. The Offeror shall also discuss the potential for the scalability of the manufacturing process.

L.3.4.1.2 Offerors shall describe in sufficient detail the approach to developing a scalable manufacturing process that will meet the requirements defined in the Statement of Objectives (SOO). The manufacturing plan shall include a process development flow diagram. The manufacturing plan should include elements/approaches or philosophy of ICH Guidance Pharmaceutical Development Q8(R2)" in its application of scientific approaches and quality risk management for the development and or scale up process of the product and its manufacturing process.

L.3.4.1.3 Describe the approach to assay development. Describe in sufficient detail the proposed in-process and release testing for the bulk products and release testing of the final product. Offeror shall describe an approach to developing a potency assay for bulk product.

L.3.4.1.4 Describe the approach to the development and selection of a trivalent final vaccine formulation that meets the requirements defined in the SOO.

L.3.4.1.5 Describe an International Conference on Harmonization (ICH)-compliant stability test plan for each of the products defined in the SOO. At a minimum the stability test plan shall include a rationale of testing periodicity and the number of units to test.

L.3.4.1.6 The SOO defines the cGMP Trivalent Filovirus Vaccine lots required. Describe the specific activities required to manufacture those lots.

L.3.4.1.7 Describe the approach to the development and selection of a thermo stable trivalent final vaccine formulation that meets the requirements defined in the SOO.

#### L.3.4.2 Manufacturing Facility

L.3.4.2.1 Describe in sufficient detail the Offeror's personnel, facility, and equipment that will be used to meet the manufacturing requirements outlined in the SOO.

L.3.4.2.2 Describe provisions to insure facility systems supporting production are appropriate for product integrity (e.g., air handling, waste, automated monitoring systems, security, etc.) and include documentation to demonstrate implementation of these facility systems supporting production.

L.3.4.2.3 Describe provisions to insure systems supporting storage, packaging, handling, and distribution, are appropriate to maintain product integrity during these efforts. The Offeror shall provide documentation to demonstrate implementation of these systems.

L.3.4.2.4 Describe in sufficient detail the Offeror's safety program, including personnel and procedures, to demonstrate its success and compliance with federal, state, and local safety and environmental laws.

L.3.4.2.5 The Government reserves the right to conduct a pre-award site visit of facilities to include, subcontractor facilities to fully evaluate this Subfactor. The scope of the visit will be based on the questions after evaluation of proposals. Offerors will receive advance notification of the visit and a list of items to be reviewed.

#### L.3.4.3 Regulatory Compliance/Approach

L.3.4.3.1 The Offeror shall describe its regulatory approach for accomplishing requirements in the SOO and other sections of the RFP, including adherence to FDA regulations, guidance, the requirements related to manufacturing and testing, and preparation for regulatory submissions (i.e., CMC).

L.3.4.3.2 The Offeror shall provide an overview of its quality and regulatory systems with examples that demonstrate those systems are implemented (i.e. RA/QA roles and responsibilities). The Offeror shall provide cGMP compliance evidence for applicable Subcontractor(s).

L.3.4.3.3 The Offeror shall provide credible evidence of a FDA cGMP-compliant facility to support process development and manufacture of all clinical material (e.g., manufacture of Phase 1 material, FDA Form 483's received within the past three years, response to FDA Form 483, FDA Establishment Inspection Report, and Pre-Approval Facility Inspection). The Offeror's cGMP facility must be in good standing with the FDA at the time of proposal and award.

#### L.3.4.4 Quality Management Plan (QMP)

L.3.4.4.1 The Offeror's proposal shall include a QMP describing in sufficient detail the approach to Quality Assurance and Quality Control (QA/QC) and all Major Subcontractors, as defined in L.3.7, QA/QC to demonstrate the understanding of a sound Quality Management System. The Offeror shall demonstrate compliance with FDA quality requirements and guidances. The Offeror shall describe in sufficient detail the components of the Offeror's

QMP and its integration into the manufacturing approach. The QMP shall include, but is not limited to, quality systems in the following areas: facilities, equipment, utilities, personnel, storage, procedures for establishing quality agreements with subcontractors, vendor qualifications and technology transfer.

L.3.4.4.2 The Offeror's proposal shall include a Draft Quality Agreement that outlines the responsibilities of the Government and the Offeror with respect to quality assurance of the manufacture, testing, and release of Product in accordance with the ICH Q7 and ICH Q10 guidelines, reference to US FDA 21 CFR 210/211/600 and other regulations as applicable. The final mutually agreed upon Quality Agreement will become contractually binding and will be updated IAW CDRL A007. If the Offeror does not have a Quality Agreement template examples may be accessed at the following websites: <http://www.socma.com/assets/File/socma1/PDFfiles/bptf/Quality-Agreement-Template-4.28.10.pdf>

[http://www.apic.cefic.org/pub/Quality%20Agreement%20Guideline\\_final\\_December%202009\\_clean.pdf](http://www.apic.cefic.org/pub/Quality%20Agreement%20Guideline_final_December%202009_clean.pdf)

L.3.4.4.3 The Government reserves the right to conduct a quality audit to fully evaluate this Subfactor.

#### L.3.4.5 Statement of Work (SOW)

The Offeror shall propose a complete SOW which meets the requirements stated in the Government's SOO and the requirements of the RFP. The SOW shall be submitted using MIL-HDBK-245 as guidance (<https://www.acquisition.gov/sevensteps/library/DODhandbook.pdf>).

L.3.4.5.1 Information Required. The Offeror's proposed SOW shall define the tasks required for filovirus vaccine advanced development ensuring all minimum requirements of the Government provided SOO and preliminary Work Breakdown Structure (WBS) have been addressed, including Program Management. A list of Government required data deliverables is contained in this document as Contract Data Requirements Lists (CDRLs), however the Offeror shall tailor that list to reflect contractor unique data deliverables demonstrating understanding of manufacturing development efforts to meet first in human requirements for conduct of a Phase 1 study, identify related Data Item Descriptions (DIDs), and reference the related paragraph(s) in the SOW.

L.3.4.5.2 Organization. All SOW activities must be organized by the SOO format in a Contract Work Breakdown Structure (CWBS) and segregated by performance schedule for all tasks to be performed. The SOW shall correlate and use the same numbering system as the CWBS and Integrated Master Schedule (IMS).

L.3.4.5.3 SOW Program Management Activities and Requirements. The SOW must include the program management activities required to accomplish SOO objectives and to comply with requirements specified in the RFP. The SOW must contain every program management activity and task to be accomplished.

#### L.3.4.6 Process/Item Data Architecture

Offerors are instructed to mark their proposals in accordance with the data rights clauses included in this solicitation based on the Offeror's proposed Data Architecture which may or may not accord the Government greater data rights than otherwise applicable based upon facts and circumstances.

### **L.3.5 Volume III – Program Management Volume**

#### L.3.5.1 Contract Work Breakdown Structure (CWBS)

The Offeror shall submit a CWBS and CWBS Dictionary using the MIL-STD-881, ([http://www.acq.osd.mil/pm/currentpolicy/wbs/MIL\\_HDBK-881A/MILHDBK881A/WebHelp3/MILHDBK881A.htm](http://www.acq.osd.mil/pm/currentpolicy/wbs/MIL_HDBK-881A/MILHDBK881A/WebHelp3/MILHDBK881A.htm)). The minimum CWBS expected is Level 5. However, the Offeror shall extend CWBS elements as needed to obtain the depth and breadth required to define the contract

scope and to accurately describe the proposed effort. The CWBS shall correlate with the SOW, CLINs, and IMS. The CWBS shall not include dollar values. A template CWBS is provided in Section L, Attachment D.

#### L.3.5.2 Integrated Master Schedule (IMS)

The Offeror shall propose an IMS which documents the critical path, major milestones (including subcontractor identification and award), delivery dates, tasks/activities, duration, and schedule relationships. Details of the Offeror's integrated processes shall be addressed in the IMS. The IMS shall be directly traceable to the Offeror's SOW, CLINs, and the CWBS. The IMS is intended to be used as a tool for daily progress tracking of the program/project. Tasks/activities should roll-up to increasingly higher summary levels. All tasks/activities in the IMS shall be logically linked together showing predecessor/successor relationships. The tasks/activities shall be sufficient to account for the entire program under contract. In addition to a high level presentation in PDF format as part of the Program Management submission, the Offeror shall utilize an electronic copy of the schedule for submission (Microsoft Project) of schedule data in "Read Only" format that shows all formulas and links for review. Dates delineated in the IMS and Section F of this solicitation shall become contractually binding and will be adjusted accordingly based on actual contract award date. The IMS will reflect the proposed delivery date for the intended product. Refer to the Integrated Master Plan and Integrated Master Schedule Preparation and Use Guide ([http://www.acq.osd.mil/sse/docs/IMP\\_IMS\\_Guide\\_v9.pdf](http://www.acq.osd.mil/sse/docs/IMP_IMS_Guide_v9.pdf)) for development of the IMS. The final IMS will become contractually binding and will be updated IAW CDRL A003.

#### L.3.5.3 Risk Management System

The Offeror shall submit a Risk Management Plan that details the Offeror's integrated methods for identifying, analyzing, prioritizing, mitigating, and tracking risk drivers and includes plans for adequate resources for risk mitigation strategies to demonstrate the understanding of a sound risk management system. The Offeror shall describe tools or methodologies used in the integrated risk management and risk assessment processes. The Offeror shall identify at a minimum the top ten potential technical and quality risks, the root cause for each, the potential program impact for each, and describe the proposed risk mitigation strategies.

#### L.3.5.4 Key Personnel Qualifications

The proposal shall include a Curriculum Vitae (CV) and bibliographic data for the Program Manager and other Key Personnel such as Directors (or equivalent) of Regulatory Affairs, Quality Assurance/Quality Control (QA/QC), Manufacturing, and Risk Management detailing their qualifications to perform the work. In the case of subcontractor key personnel, the subcontract agreement shall flow down the Government Key Personnel Clause as incorporated into the awarded contract. If the Offeror does not presently employ Personnel in the positions identified as Key, the Offeror must present a description of the terms of the commitment(s). The Offeror shall provide technical, regulatory, and management staffing plans, specifically addressing vacancies and maintaining Key Personnel. The Offeror shall also provide the CVs and/or resumes and list proposed duties of key subcontractor personnel and consultants (if any) who are proposed for this effort. The Offeror shall provide specific details of all assigned personnel explaining their appropriateness, scientific qualifications, depth and breadth of expertise and credentials relative to the projects. The Offeror shall describe the proposed labor hours and labor categories relating to the performance of the SOW of Key Personnel.

#### L.3.5.5 Subcontractor Management

The Offeror shall propose a subcontracting management approach to include analysis of subcontractor selection (i.e. list selection criteria), choice of subcontract types, and the plan for incentivizing contractors and assuring subcontractors meet cost, schedule, and performance requirements. The Offeror shall describe how subcontract competition will be sought, promoted, and sustained throughout the course of the cost reimbursement component of the acquisition, identify any known barriers to increasing subcontract competition and how to overcome any such barriers. The Offeror shall propose an approach to managing subcontractors, which defines the mechanisms for interactions/communications/data access. Furthermore, the Offeror shall explain its method for avoiding

Subcontractors in financial distress and how the Offeror would rectify a situation where a Subcontractor's financial situation became problematic while under contract. The Offeror shall present mechanisms for managing and interfacing key Subcontractors/Consultants and the Government to include discussion of its techniques for communicating with its subcontractors/consultants, its plan for ensuring that performance is at the level required to ensure timely and effective contract execution. Steps planned for compliance with the Competition in Subcontracting clause (FAR 52.244-5 ) to include all CMO, CRO, T&E and Fill & Finish functions to be performed by any entity or group of entities under a subcontract shall be addressed in Volume V, the Cost Volume.

#### L.3.5.6 Earned Value Management (EVM)

Unless the total dollar value of cost type CLINs proposed is under \$15M, the Offeror shall provide a plan for adequate integration of technical performance with cost and schedule objectives via EVM System (EVMS), not to include Firm-Fixed Price efforts of the proposal. The EVM report shall include implementation plans for monitoring/reporting technical performance, cost, and schedule. The report shall address the identification of key processes and risk-planning activities related to frequency, intensity, and schedule. Key processes related to EVMS may include organizing, scheduling, work/budget authorization, accounting, indirect management, management analysis, change incorporation, material management, and Subcontractor management. The Offeror's EVMS shall be in accordance with the American National Standards Institute (ANSI)/Electronic Industries Alliance (EIA) standard 748, as well as FAR 52.234-4 and the policy letter, "Revision to DoD Earned Value Management Policy" dated march 7, 2005, provides additional guidance. The Government will consider reasonable plans and costs for establishing or improving an existing EVMS. For those Offerors requiring an upgrade to an existing management system to become fully compliant with this effort, an additional CLIN would be added to Section B for the upgrade of the system. In the event that total dollar value of the anticipated cost type CLINs is below the \$20M EVMS threshold, this requirement may be excluded or tailored at award.

#### **L.3.6 Volume IV - Past Performance**

L.3.6.1 Attachment A is to be completed and submitted by the Offeror. Attachment B is to be completed by each of the Offeror's Reference(s) provided in Attachment A.

L.3.6.2 The Offeror shall describe relevant on-going and previous (preceding three years only) Government contracts. This shall include a detailed discussion of relevant corporate experience manufacturing vaccines. The Offeror shall include the following information:

- a. Experience in assay development
- b. Experience in process development
- c. Experience in developing cGMP manufacturing processes and cGMP production of vaccines;
- d. Experience in manufacturing multivalent vaccines;
- e. Experience in producing vaccines based on virus particles, or like technology;
- f. Previous FDA submissions, inclusive of FDA response/non-response to submissions
- g. Corporate experience in timely identifying and solving challenging development efforts similar to those that may arise during the proposed effort with outcomes.
- h. Subcontract management team experience and the skill of those individuals in proposal evaluation, negotiation, and success in avoiding cost overruns.

L.3.6.3 If the Offeror, or any of its proposed Major Subcontractors, have limited Government contracting experience, a description of similar contracts with commercial entities, local and/or state governments should be included, if relevant. Information furnished concerning these efforts shall be similar to that requested of Government contracts.

L.3.6.4. The Offeror shall send Past Performance questionnaires (Attachment B) to Reference(s), who must submit the completed Past Performance questionnaire to the Government Contract Specialist listed above to be received no later than the proposal due date. It is the Offeror's responsibility to ensure that each Reference submits Attachment B to the Government by the required date.

### **L.3.7 Volume V – Cost Volume**

#### **L.3.7.1. General Information**

L.3.7.1.1 Certified cost or pricing data are not required as a result of this solicitation. ("Cost or pricing data" are data requiring certification IAW [15.406-2](#). "Cost or pricing data" are factual, not judgmental, and are verifiable). These instructions are to assist you in submitting information other than cost or pricing data that is required to evaluate the reasonableness of your proposed cost/price. Compliance with these instructions is mandatory and failure to comply may result in rejection of your proposal. Note that unrealistically low or high proposed costs or prices, initially or subsequently, may be grounds for eliminating a proposal from competition either on the basis that the Offeror does not understand the requirement or has made an unrealistic proposal. Offers should be sufficiently detailed to demonstrate their reasonableness. The burden of proof for credibility of proposed costs/prices rests with the Offeror.

IAW FAR 15.403-1(b) and 15.403-3(a), information other than cost or pricing data is required to support price reasonableness. Information shall be provided IAW FAR 15.403-5. If, after receipt of proposals, the Contracting Officer determines that there is insufficient information available to determine price reasonableness and none of the exceptions in FAR 15.403-1 apply, the Offeror shall be required to submit cost or pricing data.

L.3.7.1.2 The Cost/Price Proposal shall be an integrated and comprehensive estimate with descriptions of estimating techniques and allocation methods that correlate in sufficient depth with the SOO, SOW, CWBS, IMS, and CLINs when applicable. Estimating technique(s) used to create the proposal shall be clearly identified. When responding to the Cost/Price Proposal requirements in the solicitation, the Offeror and associated Subcontractors may use any generally accepted estimating technique, including contemporary estimating methods, commercially available parametric cost models, in-house developed parametric cost models, etc., to develop their estimates. If necessary, reasonable and supportable allocation techniques may be used to spread hours and/or costs to lower levels of the CWBS.

L.3.7.1.3 The Cost/Price Proposal shall be prepared using the Excel workbooks provided in Section L, Attachment D. Failure to use the provided workbooks may result in rejection of the Offeror's proposal. The workbooks shall be submitted in "read only" format; however, calculations, formulas, links between spreadsheets shall be clear and accessible.

L.3.7.1.4 The Cost/Price Proposal shall show proposed dollar value for each of the Milestones identified in the SOW and IMS for each CLIN and Option CLIN.

L.3.7.1.5 The Cost/Price Proposal shall include any necessary equipment to be purchased/leased or minor facility modifications necessary to execute the proposed efforts.

#### **L.3.7.2 Cost Breakdown**

L.3.7.2.1 The Cost/Price Proposal shall include a cost breakdown by Government Fiscal Year (1 Oct-30 Sep). Offeror's shall utilize the Microsoft Excel workbook templates provided in Section L, Attachment D for submission

of cost and pricing information. The Offeror shall submit a separate workbook for each CLIN. Cost/price information shall be submitted in "Read Only" format that shows all the calculations, formulas, and links for review. Option CLIN and Subcontractor efforts shall be reflected separately, but will include at a minimum, the information requested in the spreadsheet. Totals from detailed spreadsheets should track to the summary spreadsheet.

L.3.7.2.2 The Offeror shall submit an estimate by CWBS, by Government Fiscal Year (1 Oct – 30 Sep). Data for this spreadsheet will be provided at a minimum of CWBS Level 5 with subtotals provided at level 2. Add columns for additional years as required.

L.3.7.2.3 The Offeror shall address the following cost elements in sufficient detail to demonstrate reasonableness of the proposed costs.

L.3.7.2.3.1 Direct Labor. Provide estimated hours by CWBS (minimum Level 5), labor category and Government fiscal year. Explain the method used to determine the estimated hours necessary for each effort. Indicate if the proposed loaded rates are based on actual or projected rates for current employees. Indicate the escalation factor used and first month(s) for each Government fiscal year that the escalation factor is applied. Level of effort activities shall be expressed in man-hours. Define the number of man-hours that equal a man-year. Total labor costs/hours should track to summary spreadsheet. Add columns for additional years as required.

L.3.7.2.3.2 Subcontractor Costs. "Subcontractor" means any supplier, distributor, vendor, or firm that furnishes supplies or services to or for a prime contractor or another subcontractor. Provide a complete description of all Subcontractor costs, including any Teaming Arrangements/Agreements by CWBS (minimum Level 5). Submit proposals for major Subcontractors, which are those with subcontract values exceeding \$250,000 ("Major Subcontractors"). Total subcontractor costs should track to the summary spreadsheet. The Offeror shall provide the basis of selection of the subcontractor and their analysis conducted to determine price reasonableness and the steps planned for compliance with the Competition in Subcontracting clause (FAR 52.244-5 ) to include all CMO, CRO, T&E and Fill & Finish functions to be performed by any entity or group of entities under a subcontract. Numerous sources of these potential subcontract functions are or may become available for competition. Offerors shall include Subcontractor letters of commitment.

L.3.7.2.3.3 Consultants. Justify the requirement for consultant services. List proposed Consultants by name, if known. For each Consultant, describe: (1) nature of services, (2) CWBS supported (minimum Level 5), (3) fee rate, and (4) total Consultant fee and any other allowable related costs (e.g., travel, per diem). The Offeror shall provide the basis of selection of each Consultant and their analysis conducted to determine price reasonableness. Total consultant costs should track to the summary spreadsheet.

L.3.7.2.3.4 Materials and Supplies. Provide a detailed listing of materials and supplies by CWBS (minimum Level 5), quantity, unit cost, and basis of estimate (e.g., vendor quotes, catalog pricing, subcontracting estimates). Competitive historical price information of prior purchases is adequate. For all sole-sourced materials and supplies, provide a consolidated cost summary of individual material quantities included in the CWBS being proposed and the basis of estimate. Total materials and supplies costs should track to the summary spreadsheet.

L.3.7.2.3.5 Travel. Provide the purpose, origin, destination, and duration of travel. Offerors are encouraged to read FAR 31.205-46 regarding allowability of travel costs. Total travel costs should track to the summary spreadsheet.

L.3.7.2.3.6 Equipment. Contractors are ordinarily required to furnish all property necessary to perform Government contracts. The Government shall provide property to contractors or authorize contractors to purchase property under the contract only when it is clearly demonstrated-

(1) To be in the Government's best interest;

- (2) That the overall benefit to the acquisition significantly outweighs the increased cost of administration, including ultimate property disposal;
- (3) The provision of the property does not substantially increase the Government's assumption of risk; and
- (4) The Government requirements cannot otherwise be met.

The contractor's inability or unwillingness to supply its own resources is not sufficient reason for the furnishing or acquisition of property.

Provide a list of all proposed equipment to be purchased under the appropriate CLINs in support of the contract by CWBS (minimum Level 5). The list shall include equipment description, manufacturer, manufacturer's address, model and stock number, and estimated unit cost. Total equipment costs should track to the summary spreadsheet. Equipment shall be handled as a pass through cost and not have profit applied against it.

L.3.7.2.3.7 Other Costs. List direct costs not included in the above categories (i.e., special tooling, computer services, preservation, and packaging) and provide the basis of estimate.

L.3.7.2.3.8 Indirect Cost. Provide current rates for Overhead, Material Handling, General and Administrative (G&A), Facility Capital Cost of Money and any other indirect costs for all effort proposed. Provide forward pricing agreements if applicable. If forward pricing agreements are not in place, include historical trend for the last three-year period to assist in evaluating proposed rates.

L.3.7.3 Incentive Fee. The Offeror shall propose a target fee, minimum fee, and maximum, and a fee adjustment formula for base CLIN and each option CLIN separately. The Offeror shall propose milestones and incentive fees associated with each milestone.

L.3.7.4 Facilities Capital Cost of Money (FCCM). If FCCM is proposed, the Offeror must submit Form CASB-CMF and show the calculations of the proposed amount (see FAR 31.205-10).

L.3.7.5 Defense Contract Management Agency (DCMA) or the Defense Contract Audit Agency (DCAA). If the Offeror is currently under administration or audit cognizance of the DCMA or the DCAA; the name, address, and telephone number of the Government Agency's Point of Contact shall be furnished.

L.3.7.6 Estimating System. Provide a description of the estimating system or methods used. Indicate if there has been a Government review or audit of the estimating system. If the government has reviewed the estimating systems of the Offeror and the proposed Subcontractors, provide results of the review/audit (including date of review and contact numbers) or documentation of the results.

L.3.7.7 Purchasing System. Provide a summary description of the purchasing system or methods (how sources are selected, what provision is made to ensure quantity and other discounts) used. Identify any deviations from these standard procedures in preparing this cost proposal. Indicate if there has been a Government review or audit of the purchasing system. If the government has reviewed the purchasing systems of the Offeror and the proposed Subcontractors, provide results of the review/audit (including date of review and contact numbers) or documentation of the results.

L.3.7.8 Accounting System. Indicate if there has been a Government audit of the accounting system and if so, provide evidence of the accounting system's acceptability, as per DCAAP 7641.90, Section 2-301.1.a. Identify any deviations from these standard procedures in preparing this cost proposal. IAW FAR 16.301-3(a)(i), a cost reimbursement contract may only be used when the contractor's accounting system is adequate for determining cost applicable to a Government contract. The Pre-Award Survey attached at ## shall be submitted with the proposal of any Offeror that does not have an approved cost accounting system at the time of proposal submission.

L.3.7.9 Company Financial Statements. Offerors shall provide copies of their annual financial statements for the last three years.

**L.3.8 Other Information Required**

L.3.8.1. PROVIDE THE NAME, TITLE, AND TELEPHONE NUMBER OF THE COMPANY/DIVISION POINT OF CONTACT REGARDING DECISIONS MADE WITH RESPECT TO YOUR PROPOSAL AND WHO CAN OBLIGATE YOUR COMPANY CONTRACTUALLY. ALSO, IDENTIFY THOSE INDIVIDUALS AUTHORIZED TO NEGOTIATE WITH THE GOVERNMENT.

**ATTACHMENT A: PAST PERFORMANCE INFORMATION**

*WHEN FILLED IN THIS DOCUMENT IS SOURCE SELECTION SENSITIVE INFORMATION*

*IAW FAR 3.104*

Provide the information requested in this form for each contract/program being described. Provide frank, concise comments regarding your performance on the contracts you identify. Provide a separate completed form for each contract/program submitted. The number of past efforts shall be limited to six for the prime contractor and three for each subcontractor. Relevancy shall demonstrate your ability to perform the proposed effort.

A. Offeror Name (Company/Division): \_\_\_\_\_

CAGE Code: \_\_\_\_\_

DUNS Number: \_\_\_\_\_

(NOTE: If the company or division performing this effort is different than the Offeror or the relevance of this effort, or the instant acquisition is impacted by any company/corporate organizational change, note those changes. Refer to the "Organizational Structure Change History" you provided as part of your Past Performance volume.)

B. Program Title: \_\_\_\_\_

C. Contract Title: \_\_\_\_\_

**1. Contract Agency or Customer:** \_\_\_\_\_

**2. Contract Number:** \_\_\_\_\_

**3. Contract Type:** \_\_\_\_\_

**4. Period of Performance:** \_\_\_\_\_

**5. Original Contract \$ Value:** \_\_\_\_\_ (Do not include unexercised options)

**6. Current Contract \$ Value:** \_\_\_\_\_ (Do not include unexercised options)

**7. If Amounts for 5 and 6 above are different, provide a brief description of the reason:**

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(c) Brief Description of Effort as \_\_\_\_Prime or \_\_\_\_Subcontractor  
(Please indicate whether it was development and/or production, or other acquisition phase and highlight portions considered most relevant to current acquisition.)

(d) Completion Date:

**D. Original date:** \_\_\_\_\_  
**E. Current Schedule:** \_\_\_\_\_  
**F. Estimate at Completion:** \_\_\_\_\_  
**G. How Many Times Changed:** \_\_\_\_\_  
**H. Primary Causes of Change:** \_\_\_\_\_

(e) Primary Customer Points of Contact: (For Government contracts, provide current information on all three individuals. For commercial contracts, provide points of contact fulfilling these same roles.)

(f) **Program Manager:** Name \_\_\_\_\_  
Office \_\_\_\_\_  
Address \_\_\_\_\_  
\_\_\_\_\_  
Telephone \_\_\_\_\_  
Email \_\_\_\_\_

(g) **Contracting Officer:** Name \_\_\_\_\_  
Office \_\_\_\_\_  
Address \_\_\_\_\_  
\_\_\_\_\_  
Telephone \_\_\_\_\_  
Email \_\_\_\_\_

(h) **Administrative Contracting Officer:**  
Name \_\_\_\_\_

**Office** \_\_\_\_\_

**Address** \_\_\_\_\_

\_\_\_\_\_

**Telephone** \_\_\_\_\_

**Email** \_\_\_\_\_

- (i) Address any technical (or other) area about this contract/program considered unique.
- (j) Illustrate how your experience on this program applies for each of the applicable factors, subfactors, and elements in Section M.
- (k) Include relevant information concerning your compliance with FAR 52.219-8, Utilization of Small Business Concerns, on the contract you are submitting.
- (l) Identify whether a subcontracting plan was required by the contract you are submitting. If one was required, identify in percentage terms, the planned versus achieved goals during contract performance. If goals were not met, please explain.
- (m) Describe the nature or portion of the work on the proposed effort to be performed by the business entity being reported here. Also, estimate the percentage of the total proposed effort to be performed by this entity and whether this entity will be performing as the prime, subcontractor, or a corporate division related to the prime (define relationship).

**SECTION L: ATTACHMENT B**  
**ATTACHMENT B: PAST PERFORMANCE QUESTIONNAIRE**

**SOLICITATION NUMBER:**

*WHEN FILLED IN THIS DOCUMENT IS SOURCE SELECTION SENSITIVE INFORMATION*

*IAW FAR 3.104*

- (n) Please complete this questionnaire. Handwritten responses are sufficient. If you need more space than that provided, please attach additional pages or write on the back. Responses will be treated as source selection sensitive information. Scan and email or fax the completed questionnaire to:

<b>NAME:</b>	Mr. Nathan Jordan
<b>Office</b>	ATTN: ACC-APG NATICK CONTRACTING DIVISION
<b>Address</b>	110 Thomas Johnson Drive Frederick, MD 21702, USA
<b>Telephone</b>	301-619-9813 (FAX); 301-619-5069
<b>Email</b>	Lawrence.e.mize.civ@mail.mil

Explanation of codes:

CODE      PERFORMANCE LEVEL

E    EXCEPTIONAL – Performance meets contractual requirements and exceeds many requirements to the Government's benefit. The contractual performance of the elements being assessed was accomplished with few minor problems for which corrective actions taken by the contractor were highly effective.

V    VERY GOOD – Performance meets contractual requirements and exceeds some requirements to the Government's benefit. The contractual performance of the element being assessed was accomplished with some minor problems for which corrective actions taken by the contractor were effective.

S SATISFACTORY – Performance meets contractual requirements. The contractual performance of the element being assessed contains some minor problems for which corrective actions taken by the contractor appear or were satisfactory.

M MARGINAL – Performance does not meet some contractual requirements. The contractual performance of the element being assessed reflects a serious problem for which the contractor has not yet identified corrective actions or the contractor’s proposed actions appear only marginally effective or were not fully implemented.

U UNSATISFACTORY – Performance does not meet most contractual requirements and recovery is not likely in a timely manner. The contractual performance of the element being assessed contains serious problem(s) for which the contractor’s corrective actions were ineffective.

N NOT APPLICABLE – Unable to provide a score. Performance in this area is not applicable to effort assessed.

(o) Please complete the following identifying information and past performance assessment:

A. Contractor: \_\_\_\_\_

B. Contract number: \_\_\_\_\_

C. Period of Performance: \_\_\_\_\_

D. Negotiated price or cost at award: \_\_\_\_\_

E. Current estimated contract dollar amount: \_\_\_\_\_

F. Describe product acquired: \_\_\_\_\_

\_\_\_\_\_

**When Completed – Source Selection Information – See FAR 3.104**

(p) Circle the appropriate letter for each item on the questionnaire and provide supporting narrative.

ASSESSMENT ELEMENTS

(1) Contractor’s record of process development.

E                      V                      S                      M                      U                      N

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(2) Contractor’s record of pilot scale cGMP manufacturing .

E                      V                      S                      M                      U                      N

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(3) Did the contractor deliver according to the agreed-to schedule? What were the causes of any schedule variances? Did the contractor require assistance to resolve any schedule problems?

E                      V                      S                      M                      U                      N

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(4) How well did the contractor proactively manage schedule/performance/cost and risks?

E V S M U N

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(5) What is your overall rating of the contractor's performance?

E V S M U N

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(6) Contractor's cost control. Did the contractor deliver at the agreed-to cost/price? Describe the reasons for changes to contract value (e.g., scope changes, overrun/underrun, customer-imposed schedule changes, etc.)

E V S M U N

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**When Completed – Source Selection Information – See FAR 3.104**

(7) Identify the contractor's overall strengths and weaknesses.

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(8) Given the choice, would you award to this contractor again? Explain.

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(9) Are you aware of any other contracted efforts performed by this contractor similar in nature to this contract? Please identify contract/program and point of contact.

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(10) Is there anyone else we should send this questionnaire to? Please identify by name, organization, and phone number.

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(If more comment space is needed, write on back, or attach pages.)

(11) Please provide organization, name, title, address, email, and phone number of the person completing this questionnaire.

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Email \_\_\_\_\_

Phone \_\_\_\_\_ FAX \_\_\_\_\_

**SECTION L: ATTACHMENT C STATEMENT OF OBJECTIVES****STATEMENT OF OBJECTIVES****Virus-Like Particle Trivalent Filovirus Vaccine process Development, Formulation, and Manufacturing efforts****Statement of Objectives (SOO)****1. Introduction and Background:**

The requirement for a vaccine to protect against filovirus exposure is described in the Department of Defense (DoD) Joint Requirements Oversight Council (JROC) approved Joint Medical Biological Warfare Agents Prophylaxes Initial Capabilities Document (ICD), dated September 14, 2004. The ICD calls for a medical prophylaxis that will provide broad spectrum protection against a range of biological warfare agents and a range of exposure routes. The Joint Vaccine Acquisition Program Joint Product Management Office (JVAP JPMO), a subordinate organization to Chemical Biological Medical Systems Joint Project Management Office (CBMS JPMO), is responsible for the development, production, and stockpiling of Food and Drug Administration (FDA)-licensed vaccine products to protect the Warfighter against Biological Warfare agents.

A filovirus vaccine must protect against *Marburgvirus* and *Ebolavirus* (Sudan and Zaire). A vaccine(s) against the filoviruses would counter the threat of illness and death, and maintain Warfighter performance in a biological-warfare environment. To accomplish this goal, the Chemical Biological Medical Systems – Joint Vaccine Acquisition Program (CBMS-JVAP) will serve as the integrator for the Technology Development Phase by managing and coordinating the various vaccine development contracts and intergovernmental efforts through a Phase 1 clinical trial. The Office of the Surgeon General, Department of the Army will serve as the FDA regulatory sponsor through a Phase 1 clinical trial. All required efforts shall be in accordance with (IAW) FDA guidelines and requirements leading to the eventual licensure of a new filovirus vaccine.

**2. Overall Objectives**

The objective of this procurement is to deliver, after limited advanced development, a current Good Manufacturing Practices (cGMP) trivalent filovirus vaccine using the Virus-Like Particle (VLP) system that will be suitable/acceptable for release for use in humans by the Government to support non-clinical and Phase 1 clinical studies under an Investigational New Drug (IND) application. The manufacturer shall use the VLP system described in Section J, Attachment 2. The manufacturer shall develop, abide by and document cGMP and processes consistent with the International Conference on Harmonisation (ICH) Q7 and ICH Q5A- Q5E, FDA regulation 21 CFR Part 211 21 CFR Part 600, Guidance for Industry- CGMP for Phase 1 Investigational Drugs and Guidance for Industry- Characterization and Qualification of cell substrates and Other Biological Materials Used in Production of Viral vaccines for Infectious Disease Indications (February 2010). The contractor shall, pursuant to a documented scalable bulk and fill/finish manufacturing processes, develop, manufacture, test and deliver a cGMP VLP trivalent filovirus vaccine developmental candidate suitable for release for Phase 1 clinical trial use under an Investigational New Drug (IND) application. The Contractor shall, under documented scalable bulk and fill/finish manufacturing processes, develop each of the three filovirus vaccine components as monovalent products; Marburg, Ebola Sudan, and Ebola Zaire so as to formulate these antigens into a single vial formation (trivalent vaccine). In so doing, the viral glycoprotein and VP40 genes from each strain, shall be co-transfected into a GMP compliant mammalian cell line, resulting in a fully assembled Virus-Like Particle (VLP) suitable for use in Phase 1 clinical trial under an Investigational New Drug (IND) application. In addition to draft Master Product Batch Record, the Contractor will provide and the Government will test product from various stages of process development and engineering runs to assess the extent by which the product meets the 80% goal for animal efficacy threshold stipulated in the draft CDD.

The intended product is a subunit, vector-free, trivalent vaccine consisting of multiple monovalent VLPs each expressing two antigens, glycoprotein (GP) and a matrix protein (VP40) of the filovirus strains. The VLPs are spontaneously produced in cells when the two genes encoding GP and VP40 are expressed ectopically. These VLPs have a morphology that is strikingly similar to the authentic filovirus with the GP expressed on the surface, traversing the envelope and a layer of matrix protein (VP40) underneath the envelope. It is anticipated that the final product will be a trivalent vaccine consisting of separate VLPs for Marburg virus, Ebola Zaire Virus and Ebola Sudan Virus however the Offeror can propose alternate formulations to meet the requirement. Each VLP will be produced separately in mammalian cells using optimized production and purification processes and mixed before vialing in a ratio that ensures similar immunogenicity of the individual components. It is anticipated that an adjuvant will be required to elicit the desired onset and duration of protection. The final vaccine formulation will provide immunity against variants of the Zaire and Sudan species of Ebola virus (EBOV) and variants of Marburg virus (MARV). The VLP product has the potential to be used as a prophylactic and/or a post exposure vaccine.

The Contractor shall, incident to the development of a filovirus vaccine, conduct formulation studies that include exploration of adjuvants as well as analytical assay development, including in-process and release assays of cGMP bulk(s) and final product, and International Conference on Harmonization (ICH)-compliant stability testing. The small-scale manufacturing process developed must be scalable and transferrable to another facility, if necessary.

### **3. Contract Objectives**

The Contractor shall, in the development of a filovirus vaccine:

**3.1** Provide and integrate all qualified and trained personnel, facilities, equipment, supplies, materials, services, quality oversight, and related administrative and information technology necessary to accomplish all the objectives and requirements of this SOO.

**3.2** The cell line referenced in attachment J will be evaluated, as well as other proposed cell lines, in consideration of providing acceptable yields and meeting regulatory requirements. Establish and maintain cGMP Master and working cell banks to support human clinical trials.

**3.3** Develop a bulk process and bulk assays

*3.3.1 Optimize plasmid constructs and the process as needed to generate cGMP production quantities as described in Section 3.3.2 below. The Contractor shall provide a process that maximizes the level of GP expression and yield, both in the upstream and downstream processes. The developed process shall address scale up, safety, regulatory, and cost considerations. The Government will provide plasmid sequences, including the filovirus glycoprotein and VP40 sequences, as defined in Section J: List of Government Furnished Information.*

*3.3.2 Develop and optimize bulk processes (Marburg, Ebola Sudan, and Ebola Zaire) for the production and purification of VLP to be used with the VLP system described in Section J, Attachment 2. The developed process must be capable of producing 2000-2500 doses for each lot produced with the clinical dose anticipated to be, equal to or less than, 50ug per virus specific GP antigen, or 150ug total GP content. The manufacturing process must be robust, reproducible and scalable.*

*3.3.3 Complete at least two engineering runs at the same scale to be used for cGMP production of the vaccines.*

*3.3.4 Conduct two year stability testing using Government approved specifications on products generated from engineering runs.*

*3.3.5 Develop and optimize in-process and release analytical assays for all bulk products to include but not limited to purity, identity, and characterization, such as absolute concentration of GP, host protein content, and bioburden. Assays shall be compliant with cGMP or current Good Laboratory Practices (cGLP) standards as*

*applicable. In addition the Contractor shall develop an immunogenicity test or potency assay, looking at antibody levels to ensure consistency over time and across lots. The contractor's potency assay development should involve product degradation and manipulation studies capable of detecting a 50% reduction in vaccine integrity.*

**3.4** Develop a trivalent final vaccine formulation.

*3.4.1 Develop and provide a trivalent final vaccine formulation based on the monovalent bulk substances in accordance with CLIN 0002.*

*3.4.2 Formulation development efforts shall include investigation of adjuvanted products that have been previously licensed in the United States or tested in clinical trials which could boost the immune response and reduce the required vaccine concentration.*

**3.5** Develop final drug product release assays.

*3.5.1 Develop, optimize, and provide analytical assays required for release testing of final drug product. Assays shall be compliant with ICH, cGMP and/or cGLP standards as applicable.*

**3.6** Option: Manufacture cGMP final trivalent vaccine product and placebo/control article suitable for non-clinical toxicology studies and a Phase 1 clinical trial.

*3.6.1 The contractor shall produce 2000-2500 doses per lot with the clinical dose anticipated to be, equal to or less than, 50ug per virus specific GP antigen, or 150ug total GP content. The contractor shall use a manufacturing capability sufficient to produce material of each bulk antigen (Marburg, Ebola Sudan, and Ebola Zaire) to support non-clinical and clinical studies.*

*3.6.2 Manufacture and provide one (1) lot of a final trivalent vaccine product per dosage concentration, with and without adjuvant (for four concentrations of each bulk antigen concentration produced, 1.6ug, 5ug, 16ug and 50ug) to support clinical dose escalation studies. The minimum acceptable number of vials for each concentration is 2000 with adjuvant and 2000 without adjuvant. Each vial shall contain one (1) dose and sufficient overfill to enable extraction of the dose.*

*3.6.3 The contractor shall QA approve and evaluate all lots manufactured pending results from a contractor developed potency assay, and ensure sufficient material is set aside for the potential purpose of supporting a Government developed challenge based potency assay. The Government will review contractor approved batch records to determine acceptance of bulk and final product release.*

*3.6.4 Perform stability testing on the bulk and final drug product(s). Pursuant to contract options, Contractor shall conduct stability testing for a minimum of 2 years with the potential for 5 years at the Government's discretion.*

*3.6.5 Manufacture and provide 1000 doses of saline placebo/control article packaged in one (1) dose vials of a volume equal to the volume used for the vaccine.*

**3.7** Option: Provide the written/approved documents necessary to prepare the Chemistry, Manufacturing, and Controls (CMC) portion of the IND application submission in eCTD format (eCTD Module 2 and 3). The Contractor shall assist the Government with preparation for, and participation in meeting with the FDA or other regulatory agencies as requested by the Government, IAW CDRL A016.

*3.7.1 If the contractor or subcontractor has a Master File with the FDA, the Contractor shall allow the Government to review and cross-reference it during preparation of the CMC section.*

**3.8** Option: Develop a thermo-stable trivalent final vaccine formulation suitable for non-clinical studies and Phase 1 clinical trials.

*3.8.1 Develop and provide a thermo-stable trivalent final vaccine formulation that is stable for a minimum of 2 years (optimal stability 5 years) when stored at temperatures greater than or equal to -20°C, as requested by the Government.*

**3.9** Option: Manufacture cGMP final Marburg vaccine suitable for non-clinical toxicology studies and a Phase 1 clinical trial.

*3.9.1 The contractor shall produce 2000-2500 doses per lot with the clinical dose anticipated to be, equal to or less than, 50ug per virus specific GP antigen using a manufacturing capability sufficient to produce material of requested bulk antigen to support non-clinical and clinical studies.*

*3.9.2 Manufacture and provide one (1) lot of a final Marburg vaccine product per dosage concentration, with and without adjuvant (for four concentrations produced, 1.6ug, 5ug, 16ug and 50ug) to support clinical dose escalation studies. The minimum acceptable number of vials for each concentration is 2000 with adjuvant and 2000 without adjuvant. Each vial shall contain one (1) dose and sufficient overfill to enable extraction of the dose.*

*3.9.3 The contractor shall QA approve and evaluate all lots manufactured pending results from the contractor developed potency assay, and ensure sufficient material is set aside for the potential purpose of supporting a Government developed challenge based potency assay. The Government will review contractor approved batch records to determine acceptance of bulk and final product release.*

*3.9.4 Perform stability testing on the bulk and final drug product(s). Pursuant to contract options, Contractor shall conduct stability testing for a minimum of 2 years with the potential for 5 years at the Government's discretion.*

*3.9.5 Manufacture and provide 1000 doses of saline placebo/control article packaged in one (1) dose vials of a volume equal to the volume used for the vaccine.*

**3.10** General Objectives

*3.10.1 Provide access and/or a copy of records, files, and other data derived or supporting the generation of data derived from this work for the purposes of audit by the FDA and/or other DoD entities. Such information is inclusive of all activities that assure compliance with FDA guidance and regulations, which may include Standard Operating Procedures (Standard Operating Procedures (SOPs), protocol amendments, meeting minutes, audits inspections schedules, equipment logs, reagent preparation logs, and laboratory notebooks related to this effort.*

*3.10.2 The Government reserves the right and the Contractor shall accommodate a Person-in-the Plant (PIP) during all critical processes of manufacturing, including but not limited to: non-GMP process development, cGMP manufacturing runs, tech transfer, cell and virus banking, culture seeding, electroporation, bulk harvest, concentration, purification, formulation, and filling efforts. The Contractor shall provide at a minimum 30 days advanced notification to ensure Government representation is present during the conduct of identified critical processes.*

*3.10.3 Contractors shall certify they are registered in accordance with Federal, State, and local laws and regulations, including safety and environmental requirements.*

*3.10.4 Deliver product to Government specified non-clinical and clinical destinations as requested by the Government. The Contractor shall provide sufficient material from the process development, engineering, and cGMP lots to support nonclinical efficacy and safety testing. Efficacy studies need to be planned at least 12 months in advance, therefore the Contractor shall provide the Government with a delivery schedule for each lot of material requiring testing. Delivery may include Outside the Continental United States (OCOUS) shipping and distribution. All packaging, labeling, handling, storage, and transportation of the product in shall be in compliance with U.S. Pharmacopeia 1079 (Good Storage and Shipping Practices) and in accordance with FDA cGMP regulations.*

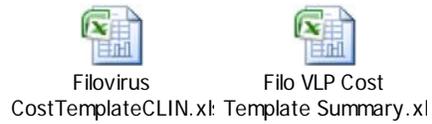
*3.10.5 Option: The Contractor shall be required to utilize an Earned Value Management System (EVMS) recognized by the cognizant Administrative Contracting Officer (ACO) as complying with the criteria provided in American National Standards Institute (ANSI)/Electronic Industries Alliance (EIA) EVMS standard (ANSI/EIA-748), FAR 52.234-4, as well as the policy letter, "Revision to DoD Earned Value Management Policy" dated March 7, 2005. Defense Contract Management Agency (DCMA) has the responsibility of validating the Contractor's EVMS. The Contractor is required to hold an Integrated Baseline Review (IBR) at their facility to assess the realism and accuracy of the integrated performance measurement baseline IAW with CDRL A009. The IBR will be initiated no later than six months from the contract award, the exercise of significant contract Options, the incorporation of major modifications or as otherwise agreed upon, per FAR 52-234-3. The Government reserves the right to require utilization of a tailored EVMS if the cost type CLIN's are less than \$20M.*

**SECTION L: ATTACHMENT D**  
**PROPOSAL TEMPLATES**

- 1) Proposal Template.



- 2) Cost Templates.



- 3) RFP Cross Walk.



- 4) CWBS Template.



- 5) Quality Agreement



## Section M - Evaluation Factors for Award

### EVALUATION CRITERIA

#### **M.1 EVALUATION CRITERIA**

##### **M.1.1 GENERAL BASIS FOR CONTRACT AWARD –**

The Government intends to award a contract for the development and manufacturing of Marburg, Ebola Sudan and Ebola Zaire filovirus vaccine(s) that will support all activities necessary to successfully complete a FDA Phase I Clinical Trial.

Contract award will be based on government's proposal evaluation and subsequent exchanges with the Offerors utilizing Evaluation Factors, and Subfactors representing the "Best Value" as described in FAR Part 15.101-1. Offeror(s) deemed responsible under the FAR Part 9 guidelines shall submit proposals conforming to the solicitation requirements. The Government's Source Selection Authority (SSA) will decide which Offeror will be awarded a contract. The Government intends to select the source whose offer is overall most advantageous to the Government. The Government reserves the right to reject any or all proposals and to award no contract at all, depending on the quality of the proposal(s) submitted and the availability of funds. Offerors are cautioned that award may not necessarily be made to the lowest-priced Offeror.

The proposals shall be complete, shall arrive by the date and time indicated in the solicitation notice, and shall be compliant with all proposal preparation instructions. Offerors shall refer to Section L (Instructions, Conditions, and Notices to Offerors), the Statement of Objectives (SOO), and other sections of the RFP for proposal preparation.

Contract Award will be based on "Best Value" to the Government.

The Government considers the non-cost "Best Value" evaluation factors of Technical, Program Management, and Past Performance to be more important than cost. Proposals will be evaluated on Technical, Program Management, Past Performance, and Cost Factors.

It is anticipated that only one award will be made as a result of this Request for Proposal (RFP).

**M.1.2 PROPOSAL EVALUATION** –The Offeror's proposal shall be compliant with the requirements of the RFP as stated in Section L, the SOO, the Contract Data Requirements List (CDRL), and other parts of this solicitation. Non-conformance with the instructions in Section L may result in submission of a deficient proposal which may receive an unfavorable proposal evaluation and lead to expulsion from the competition/source selection. Any incomplete package submitted by any Offeror may be deemed unacceptable and not considered for award. Proposals judged unsuitable in terms of technical capability, commitments, or cost may be rejected as indicating a lack of understanding of the requirements.

**M.1.3 AREAS OF EVALUATION** – The Government will review and perform an assessment of the proposal using Evaluation Factors described in Section M.3.2, Proposal Risk and Performance Confidence when making the Source Selection Decision.

**M.1.4 COMPETITIVE RANGE** – If the Contracting Officer decides that discussions with Offerors are needed, a competitive range determination will be made, if applicable. The competitive range will be comprised of the most highly rated proposals, unless the range is further reduced for purposes of efficiency. The Contracting Officer will notify Offerors promptly in writing if and when their proposals are excluded from the competitive range or

otherwise eliminated from the competition. That notice shall state the basis for the determination that a proposal revision will not be considered.

**M.1.5 CLARIFICATIONS** – In accordance with FAR 15.306, the Government may conduct limited exchanges with Offerors after receipt of proposals or award without discussions. Such exchanges shall not be used to cure proposal deficiencies or material omissions, materially alter the technical or cost elements of the proposal, and/or otherwise revise the proposal. Therefore, the Offeror's initial proposal shall contain the Offeror's best terms.

**THE GOVERNMENT RESERVES THE RIGHT TO AWARD A CONTRACT(S) BASED ON INITIAL PROPOSAL SUBMISSION, WITHOUT EXCHANGES AND/OR DISCUSSIONS.**

## **M.2 GENERAL CONSIDERATIONS**

**M.2.1 PROPOSAL RISK** – Proposal risks are those associated with the likelihood that an Offeror's proposed approach will meet the requirements of the solicitation in the RFP SOO. Proposal risk will be evaluated according to M.3.3.2 and independent from Adjectival Ratings and Performance Confidence. The Government will assign a Proposal Risk after completing Technical and Cost proposal reviews. An overall risk ranking of Low (L), Moderate (M), or High (H) will be assessed and assigned.

The assessment of risk is not intended to be a product of a mechanical or mathematical analysis, but rather the product of subjective judgment by the Government after it considers relevant information.

## **M.3 EVALUATION FOR AWARD**

**M.3.1 GENERAL** – The evaluation of proposals in response to this RFP shall be based on an independent comprehensive review and assessment of each proposal against all source selection criteria, Factors, Subfactors, Elements, Proposal Risk, and Performance Confidence as further described below. Ratings consistent with these evaluation Factors will be derived from (1) the ability of the Offeror, as demonstrated in the Technical, Program Management, and Past Performance Sections, to perform the work in accordance with all aspects of requirements outlined in this solicitation and (2) the realism of the Cost Section. Proposals that are unrealistic in terms of capability commitments in Technical, Program Management, or Cost will be deemed to reflect an inherent lack of technical competence and/or failure to comprehend the complexity and risks associated with contract requirements. Such failures, which bring into question the responsibility of the Offeror, may constitute grounds for proposal rejection.

**M.3.2 FACTORS and SUBFACTORS** – Four Factors will be used in this evaluation: Technical, Program Management, Past Performance, and Cost. The Technical and Program Management Factors are more important than the Past Performance Factor. In accordance with FAR 15.304 (e)(1), the non cost factors when combined are significantly more important than cost. The Subfactors within each Factor are of equal importance. The Elements within each Subfactor are of equal importance.

[(Technical = Program Management) > Past Performance] > Cost

#### M.3.2.1 FACTOR 1 – TECHNICAL

The Government will evaluate the completeness, feasibility, soundness, and practicality of the Offeror's proposed approach and plan for accomplishing the requirements of the SOO as proposed in the SOW. The evaluation will include analysis of the effort proposed to carry out each task, the explanations of the methods to be employed and the Offeror's regulatory compliance and approach. The Government will evaluate the Offeror's ability to meet the manufacturing requirements outlined in the SOO. The proposed technical capabilities will be evaluated using four (4) Subfactors as follows:

##### *M.3.2.1.1 SUBFACTOR 1 – MANUFACTURING APPROACH*

The Government will evaluate the feasibility of the Offeror's manufacturing advanced development plan including: process development for manufacturing clinical trial material; assay development; purification and yield; formulation development; scalability of the manufacturing process and stability testing. Analysis will also include whether the proposed manufacturing process, assay development (to include absolute quantitation of GP concentration), and formulation studies, including adjuvant, are sufficiently defined as specified in the SOO. The Government will evaluate the proposed process development flow diagram for feasibility and completeness to include decision points and quality elements. The Government will evaluate the feasibility of the Offeror's approach and knowledge and use of practices to facilitate packaging, handling, storage, and distribution of product. (L.3.4.1)

##### *M.3.2.1.2 SUBFACTOR 2- MANUFACTURING FACILITY*

The Government will evaluate the proposed facility to ensure that it meets cGMP requirements to include the schedule when the facility will be available to the requirements of the contract. The Government will evaluate the proposed key facility systems to support production, to include but not limited to: personnel, environmental controls, cleaning, proper equipment, location, security monitoring system, backup power, and procedures to protect the product. The Government will evaluate the proposed facility to ensure that adequate space and product flow exists to conduct cGMP manufacturing operations as specified in SOO. The Government will evaluate the proposed storage, packaging, handling, and distribution systems are appropriate to meet the requirements of the contract and that the Offeror has implemented these processes. The Government will evaluate the proposed safety program, including personnel and procedures, to demonstrate its success and compliance with federal, state, and local safety and environmental laws. The Government reserves the right to conduct a pre-award site visit of facilities to include key subcontractor facilities to fully evaluate this Subfactor. (L.3.4.2).

##### *M.3.2.1.3 SUBFACTOR 3 – QUALITY SYSTEM*

*The Government's evaluation will include an analysis of the following quality elements:*

##### *(a) REGULATORY COMPLIANCE/APPROACH*

The Government will evaluate whether the Offeror's proposed manufacturing facilities are adequate and compliant with FDA current Good Manufacturing Practices (cGMP; 21 CFR 210, 211) regulations for manufacturing, and applicable storage and testing. The Government's evaluation will include an analysis of the Offeror's demonstrated knowledge of the FDA guidelines and regulations related to cGMP. The Government will evaluate the feasibility of the Offeror's regulatory approach to meet the requirements defined in the SOO to include but not limited to compliance with cGMP, ICH guidelines, and preparation of the Chemistry, Manufacturing, and Control (CMC) section of the Investigation New Drug submission (IND). The Government will evaluate that the Offeror's cGMP facility is in good standing with the FDA. (L.3.4.3)

*(b) QUALITY MANAGEMENT PLAN (QMP)*

The Government will evaluate the Offeror's and Major Subcontractor's QMP for quality standards in facilities, equipment, methods, practices, records, controls, documentation supporting implemented, comprehensive cGMP compliant system, comprehensive and adequately staffed Quality Assurance Unit, established quality agreements with Subcontractors, and the approach to technology transfers of processes and assays. Evaluation will include an analysis of whether the approach to Quality is integrated into the scope of work. The Government reserves the right to conduct a quality pre-award on site audit to fully evaluate this Subfactor. The Government will evaluate the Offeror's Quality Systems which will include processes for the receipt and inspection of manufacturing components; equipment preventive maintenance program; storage of components and manufactured products (materiel management); temperature monitoring; security; and training. The Government will evaluate the Offeror's proposed Quality Agreement for completeness (L.3.4.4)

*M.3.2.1.4 SUBFACTOR 4 – STATEMENT OF WORK (SOW)*

The Government's evaluation will include analysis of whether the proposed SOW captures all requirements in the SOO, organized in SOO format using the same numbering system as the CWBS and Integrated Master Schedule (IMS), in sufficient detail and organization to demonstrate that all tasks will be executed in full compliance with all relevant statutes and regulations for the effort being executed. The Government's evaluation will include an analysis of whether the proposed SOW demonstrates an understanding and completeness for each deliverable. (L.3.4.5)

*M.3.2.1.5 SUBFACTOR 5 – Process/Item Data Architecture- Extent of Data Rights*

This solicitation includes clauses that specify Government data rights and, based upon facts and circumstances relative to each proposal, may afford the Government varying degrees of rights to data. The Government will evaluate proposals to determine the extent of the Government's entitlement to data rights under these clauses based upon each proposal received. The Government assigns greater value to proposals that afford the Government greater rights in data inasmuch as greater rights in data allow the Government to foster competition and/or broaden industry participation in future program initiatives. The Government will evaluate the Offeror's proposal regarding this Subfactor. (L.3.4.6).

### M.3.2.2 FACTOR 2 – PROGRAM MANAGEMENT

The proposed program management capabilities will be evaluated using seven (7) Subfactors as follows:

#### *M.3.2.2.1 SUBFACTOR 1 – CONTRACT WORK BREAKDOWN STRUCTURE (CWBS)*

The Government's evaluation will include analysis of whether the Offeror's CWBS is extended in detail to accurately define the complete contract scope. The Government will evaluate the CWBS dictionary for completeness. The Government will evaluate whether the CWBS accurately depicts the Offeror's proposed effort and correlates with the SOW (which follows the SOO format), IMS, and Contract Line Item Numbers (CLINs). (L.3.5.1)

#### *M.3.2.2.2 SUBFACTOR 2 – INTEGRATED MASTER SCHEDULE (IMS)*

The Government's evaluation will include analysis of the manufacturing critical path, major tasks/activities, duration, delivery dates, schedule relationships, and schedule to assess if these IMS components are reasonable, realistic, and complete. The Government will evaluate the proposed delivery date for the intended product. The Government's evaluation will include analysis of whether the IMS is directly traceable to the SOW, CLINs and the CWBS. The Government will evaluate whether the tasks/activities in the IMS link together showing predecessor/successor relationships and are sufficient to account for the entire program/project under contract. The Government's evaluation will include analysis of whether the technical approach, associated risks, and the feasibility of accomplishing these within the proposed timeline are reflected in the IMS. (L.3.5.2)

#### *M.3.2.2.3 SUBFACTOR 3 – RISK MANAGEMENT SYSTEM*

The Government's evaluation will include analysis of the proposed risk management plan identifying the process for implementing proactive risk management in an integrated and timely manner as part of the overall effort. Evaluation will also include an analysis of the proposed tools to enable integrated methodologies for the risk management process, including risk assessment, mitigation, tracking, resolution and reporting. The Government will evaluate the Offeror's proposed risks, root cause, impacts, and recommended mitigation strategies to assess the Offeror's understanding of the risk management process. (L.3.5.3)

#### *M.3.2.2.4 SUBFACTOR 4 – KEY PERSONNEL*

The Government will evaluate the Offeror's proposed technical, regulatory, and management staffing plan and the plan for addressing vacancies, replacements, and maintaining Key Personnel. The Curriculum Vitae or resume of each proposed key person and consultant (if any) to be assigned to this effort will be evaluated for their appropriateness, depth and breadth of expertise, and credentials relative to the project. The Government's evaluation will include analysis of whether the proposed labor hours and categories are inadequate, sufficient, or excessive to successfully perform the SOW. (L.3.5.4)

#### *M.3.2.2.5 SUBFACTOR 5- SUBCONTRACTOR MANAGEMENT*

The Government will evaluate the Offeror's proposed subcontracting approach, including subcontractor selection, compliance with any requirement for competition and the approach for assuring that the Subcontractor(s) meet(s) cost(s), schedule(s), and performance requirements. Among other evaluation elements, the Government will review the Offeror's standard procedures for selecting subcontract types and proposed methods of incentivizing Subcontractors (incentive-fee/award fee contracts, etc.) and approach for dealing with/avoiding risk prone subcontractors. The Government will evaluate the Offeror's proposed approach to managing subcontractors and the mechanisms for interactions/communications/data access. (L.3.5.5)

#### *M.3.2.2.6 SUBFACTOR 6 – EARNED VALUE MANAGEMENT SYSTEM (EVMS)*

The Government will evaluate the proposed EVMS for the full integration of the measurement of manufacturing performance with cost and schedule objectives. The Government will consider the Offeror's EVM understanding, and whether implementation for monitoring/reporting technical performance, accounting, cost and schedule is feasible. The Government's evaluation of the Offerors' EVMS will be measured against the American National Standards Institute (ANSI)/Electronic Industries Alliance (EIA) standard 748, FAR 52.234-4 as well as DFARS 252.234-7001 and DFARS 252.234-7002 ([http://farsite.hill.af.mil/reghtml/regs/far2afmcfars/fardfars/dfars/dfars252\\_237.htm#P720\\_44177](http://farsite.hill.af.mil/reghtml/regs/far2afmcfars/fardfars/dfars/dfars252_237.htm#P720_44177)) and the policy letter, "Revision to DoD Earned Value Management Policy" dated March 7, 2005, provides additional guidance. (L.3.5.6).

#### M.3.2.3 FACTOR 3 - PAST PERFORMANCE

Past Performance will be evaluated by assessing Past Performance Relevancy and Performance Confidence. Past Performance Relevancy will address how relevant recent efforts accomplished by the Offeror are to the effort under the solicitation. Performance Confidence Assessment will evaluate how well the Offeror performed under previous contracts and assign a confidence level based on that performance. If no past performance history exists, the Confidence Assessment will be rated as unknown/neutral. Relevancy and Confidence definitions are shown below.

##### Past Performance Relevancy Ratings

- 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.

##### Performance Confidence Assessments

- 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 any 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.

The Government's evaluation will include an analysis of the Offeror's description of relevant on-going and previous (preceding three years only) Government contracts and may include an analysis of similar contracts with commercial entities, local and/or state governments. The Government's evaluation will consider the Offeror's relevant experience:

- a) Experience in assay development;
- b) Experience in process development;
- c) Experience developing cGMP manufacturing processes and cGMP production of vaccines;
- d) Experience manufacturing vaccines, specifically multivalent vaccines;
- e) Experience producing vaccines based on virus particles, or like technology;
- f) Previous FDA submissions, inclusive of FDA response/non-response to submissions;
- g) Corporate experience solving challenging development efforts similar to those that may arise during the proposed effort with outcomes.
- h) Experience in subcontract management specifically in selecting, incentivizing contractors, and managing contractors effectively to avoid cost overruns.

The Government will also evaluate the Offeror's Past Performance Questionnaire(s) submitted to the Government by the Offeror's Reference(s). The Offeror is responsible for ensuring Reference(s) Questionnaire submission(s) are received within the stated timeline. Failure to receive these data from References will not impact past performance evaluation positively. (L.3.6.1 and L.3.6.4)

#### M.3.2.4. FACTOR 4 – COST

The Government will evaluate the estimated cost, incentive fee(s), and share ratios proposed by the Offeror for performing all requirements outlined in this RFP. Evaluation will include analysis of the proposed cost, incentive fee(s), and share ratios together with the supporting cost information. The Offeror's cost rationale will be evaluated for business judgment and protecting the taxpayers' investment. The Government will be the sole judge of validity/appropriateness of these determinations.

(a) Reasonableness: The Offeror's cost/price proposal will be evaluated using one or more of the techniques defined in FAR 15.404 to determine if it is reasonable and realistic. For a price to be reasonable, it must represent a price to the Government that a prudent person would pay in the conduct of competitive business. Normally, price and cost reasonableness are established through cost and price analysis techniques as described in FAR 15.404.

When adequate price competition exists (see FAR 15.403-1(c)(1)), generally no additional information is necessary to determine the reasonableness of price. However, if there are unusual circumstances where it is concluded that additional information is necessary to determine the reasonableness of price, the contracting officer shall, to the maximum extent practicable, obtain the additional information from sources other than the Offeror. Offerors may provide the percentage of discounts obtained from suppliers and subcontractors to demonstrate their ability to manage costs. Awardees can reasonably anticipate receiving GSA Authorization letters, therefore, Offerors may want to leverage the use of GSA contracts and related pricing. Obtaining spot discounts and price locks for a period of time from subcontractors on supplies and services will be viewed favorably by the contracting officer. In addition, the contracting officer may request information to determine the cost realism of competing offers or to evaluate competing approaches.

(b) Realism: The Government will evaluate whether the proposed Costs are realistic for the work to be performed, reflect a clear understanding of the requirements, and are consistent with the various elements of the Offeror's schedule proposal that correlate with SOW, CWBS, IMS, and CLINs when applicable, as described in FAR 15.404-1.

The Government will develop a most probable Cost of Performance for each Offeror when evaluating the Contractor Total Procurement Price projections. The most probable cost may differ from the Contractor's bid price in the Offeror's proposal. The most probable cost is determined by adjusting (for evaluation purposes only) 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.

(c) Completeness: The proposal should clearly and thoroughly document the cost/price information supporting the proposed Cost Model in sufficient detail and depth. The Government will evaluate whether the Offerors cost proposal used the provided workbook format to ensure completeness.

### **M.3.3 Scoring Criteria**

M.3.3.1. Technical, Program Management, Past Performance Factors, Subfactors and Elements will be rated using a Color/Adjectival rating scheme. Subfactor ratings will be rolled up into their corresponding Factor rating.

General definitions of ratings:

OUTSTANDING=BLUE – The proposal meets requirements and indicates an exceptional approach and understanding of the requirements. The proposal contains multiple strengths and no deficiencies.

GOOD=PURPLE – The proposal meets requirements and indicates a thorough approach and understanding of the requirements. The proposal contains at least one strength and no deficiencies.

ACCEPTABLE=GREEN – The proposal meets requirements and indicates an adequate approach and understanding of the requirements. The proposal has no strengths or deficiencies.

MARGINAL=YELLOW – The proposal does not clearly meet requirements and has not demonstrated an adequate approach and understanding of the requirements.

UNACCEPTABLE=RED – The proposal does not meet requirements and contains one or more deficiencies and is unawardable.

### **M.3.4 Proposal Risk**

A single Proposal Risk will be assigned by assessing the Evaluation Factors for Technical, Program Management, and Cost according to the definitions below:

Low Risk	Has very little potential to cause disruption of contract effort or increase in cost or diminution in performance. Government monitoring through an effective IPT with the contractor will probably be able to overcome most difficulties.
Moderate Risk	Has some potential to cause minor disruption of contract effort or increase in cost or diminution in performance. In order to overcome disruption, more involved Government monitoring, in addition to the IPT, will be required.
High Risk	Likely to cause serious disruption of contract effort or increase in cost or diminution in performance even with special Contractor emphasis and close Government monitoring. The program may be jeopardized by excessive cost overruns.

CLAUSES INCORPORATED BY REFERENCE

52.217-4

Evaluation Of Options Exercised At The Time Of Contract JUN 1988  
Award

CLAUSES INCORPORATED BY FULL TEXT

52.247-49 DESTINATION UNKNOWN (APR 1984)

For the purpose of evaluating bids (or proposals), and for no other purpose, the final destination(s) for the supplies will be considered to be as follows: Frederick, MD 21702.

(End of provision)

**CONTRACT DATA REQUIREMENTS LIST**  
(1 Data Item)

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OMB No. 0704-0188

The public reporting burden for this collection of information is estimated to average 110 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense, Executive Services and Communications Directorate (0704-0188). Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. Please do not return your form to the above organization. Send completed form to the Government Issuing Contracting Officer for the Contract/PR No. listed in Block E.

<b>A. CONTRACT LINE ITEM NO.</b> 0012	<b>B. EXHIBIT</b> A	<b>C. CATEGORY:</b> TDP _____ TM _____ OTHER _____
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<b>D. SYSTEM/ITEM</b> Filovirus Vaccine VLP Manufacturing	<b>E. CONTRACT/PR NO.</b> W911QY-13	<b>F. CONTRACTOR</b> TBD
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<b>1. DATA ITEM NO.</b> A001	<b>2. TITLE OF DATA ITEM</b> Integrated Product Team Meeting Minutes	<b>3. SUBTITLE</b>
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<b>4. AUTHORITY (Data Acquisition Document No.)</b> DI-ADMIN-81505	<b>5. CONTRACT REFERENCE</b> SOW xxx	<b>6. REQUIRING OFFICE</b> CBMS-JVAP JPMO
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<b>7. DD 250 REQ</b> LT	<b>9. DIST STATEMENT REQUIRED</b> B	<b>10. FREQUENCY</b> Weekly	<b>12. DATE OF FIRST SUBMISSION</b> see Blk 16	<b>14. DISTRIBUTION</b>			
<b>8. APP CODE</b> D		<b>11. AS OF DATE</b>	<b>13. DATE OF SUBSEQUENT SUBMISSION</b> see Blk 16	a. ADDRESSEE	b. COPIES		
					Draft	Final	
						Reg	Repro

<b>16. REMARKS</b> BLK 4. DID can be obtained from <a href="http://assist.daps.dla.mil/quicksearch">http://assist.daps.dla.mil/quicksearch</a> .  This report shall be submitted weekly to the Government. The IPT meeting minutes indicate the progress of the work for assigned tasks. They shall include all agenda items discussed, other relevant discussions including potential problem areas and proposed action to resolve the problems, and a list of meeting action items.  A draft is due to the Government three business days following the meeting. Government will review and provide comment on the draft minutes within three business days of receipt. The final minutes will be due within 1 business day of receipt from the Government.  Blk 9. Administrative or Operational Use.  Blk 12. Initial submission will be due two days following initial meeting.  Blk 14 & Blk 15. Submit via e-mail in Microsoft Office format to: Government contracting activity representatives listed in Section G of contract	see address in			
	block 16			
<b>15. TOTAL</b>	0	1	0	

<b>17. PRICE GROUP</b>
<b>18. ESTIMATED TOTAL PRICE</b>

<b>G. PREPARED BY</b> <i>[Signature]</i>	<b>H. DATE</b> 4/17/13	<b>I. APPROVED BY</b> <i>[Signature]</i>	<b>J. DATE</b> 4/17/13
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**CONTRACT DATA REQUIREMENTS LIST**  
(1 Data Item)

Form Approved  
OMB No. 0704-0188

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<b>A. CONTRACT LINE ITEM NO.</b> 0012	<b>B. EXHIBIT</b> A	<b>C. CATEGORY:</b> TDP _____ TM _____ OTHER <input checked="" type="checkbox"/>
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<b>D. SYSTEM/ITEM</b> Filovirus Vaccine	<b>E. CONTRACT/PR NO.</b> W911QY-13	<b>F. CONTRACTOR</b>
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<b>1. DATA ITEM NO.</b> A003	<b>2. TITLE OF DATA ITEM</b> Integrated Master Schedule (IMS)	<b>3. SUBTITLE</b>
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<b>4. AUTHORITY (Data Acquisition Document No.)</b> DI-MGMT-81650	<b>5. CONTRACT REFERENCE</b> Section J attachment	<b>6. REQUIRING OFFICE</b> CBMS-JVAP JPMO
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<b>7. DD 250 REQ</b> LT	<b>9. DIST STATEMENT REQUIRED</b> A	<b>10. FREQUENCY</b> Monthly	<b>12. DATE OF FIRST SUBMISSION</b> see Blk 16	<b>14. DISTRIBUTION</b>			
<b>8. APP CODE</b> N/A		<b>11. AS OF DATE</b>	<b>13. DATE OF SUBSEQUENT SUBMISSION</b> see Blk 16	<b>a. ADDRESSEE</b>	<b>b. COPIES</b>		
					Draft	Final	
						Reg	Repro

<b>16. REMARKS</b> BLK 4. DID can be obtained from <a href="http://assist.daps.dla.mil/quicksearch">http://assist.daps.dla.mil/quicksearch</a> .  The IMS shall be updated monthly to show task progress, percent completion, schedule slippage. The IMS shall include the approved baseline schedule and the actual schedule. The updated IMS is due on the first Wednesday of each month.  Blk 12. Initial submission due 30 days after contract award for Government review and approval.  Blk 13. Draft changes to the IMS, specifically program level 1 milestones or the critical path, shall be submitted to the Government for approval. The Government will respond with comments or approval 10 business days following receipt of draft changes. Approval will be signified by written acceptance from the Government and will be incorporated in a contract modification. A final IMS with incorporated changes shall be submitted 10 business days after receipt of Government comments.  Blk 14 & Blk 15. Submit via e-mail in Microsoft Office format to: Government contracting activity representatives listed in Section G of contract.	see address in	1	1		
	block 16				
	<b>15. TOTAL</b>	→	1	1	0

<b>17. PRICE GROUP</b>
<b>18. ESTIMATED TOTAL PRICE</b>

<b>G. PREPARED BY</b> Rebecca J. Kurnat	<b>H. DATE</b> 4/17/13	<b>I. APPROVED BY</b> Nancy E	<b>J. DATE</b> 4/17/13
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**CONTRACT DATA REQUIREMENTS LIST**

(1 Data Item)

Form Approved  
OMB No. 0704-0188

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<b>A. CONTRACT LINE ITEM NO.</b> 0013	<b>B. EXHIBIT</b>	<b>C. CATEGORY:</b> TDP _____ TM _____ OTHER <input checked="" type="checkbox"/>
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<b>D. SYSTEM/ITEM</b> Filovirus Vaccine	<b>E. CONTRACT/PR NO.</b> W911QY-13	<b>F. CONTRACTOR</b>
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<b>1. DATA ITEM NO.</b> A004	<b>2. TITLE OF DATA ITEM</b> Scientific and Technical Reports Summary	<b>3. SUBTITLE</b>
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<b>4. AUTHORITY (Data Acquisition Document No.)</b> DI-MISC-80048	<b>5. CONTRACT REFERENCE</b> SOW	<b>6. REQUIRING OFFICE</b> CBMS-JVAP JPMO
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<b>7. DD 250 REQ</b> LT	<b>9. DIST STATEMENT REQUIRED</b> B	<b>10. FREQUENCY</b> As required	<b>12. DATE OF FIRST SUBMISSION</b> See Blk 16	<b>14. DISTRIBUTION</b>			
<b>8. APP CODE</b> N/A		<b>11. AS OF DATE</b>	<b>13. DATE OF SUBSEQUENT SUBMISSION</b> See Blk 16	a. ADDRESSEE	b. COPIES		
					Draft	Final	
						Reg	Repro

<b>16. REMARKS</b>  BLK 4. DID can be obtained from <a href="http://assist.daps.dla.mil/quicksearch">http://assist.daps.dla.mil/quicksearch</a> .  The Contractor shall submit draft study reports within 30 days following completion of study unless otherwise stated on the approved IMS for Government review and acceptance. The Government shall provide comment or acceptance within 10 business days of receipt. The Contractor shall submit a final study report, for Government approval, within 5 business days of Government comment.  The Contractor shall submit study reports for all process and assay development efforts, formulation studies, adjuvant studies, and stability testing. Study reports shall include at a minimum the objective, methodology, raw data, interpretation, conclusion, and any final amendments.  BLK 9 Premature Dissemination  Blk 14 & Blk 15. Submit via CD and/or hard copy in Microsoft Office format to: Government contracting activity representatives listed in Section G of contract.	see address in	1	1		
	block 16				
	<b>15. TOTAL</b>	→	1	1	0

<b>17. PRICE GROUP</b>
<b>18. ESTIMATED TOTAL PRICE</b>

<b>G. PREPARED BY</b> <i>Breanna J. Kuntz</i>	<b>H. DATE</b> 4/17/13	<b>I. APPROVED BY</b> <i>Michelle L...</i>	<b>J. DATE</b> 4/17/13
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**CONTRACT DATA REQUIREMENTS LIST**  
(1 Data Item)

Form Approved  
OMB No. 0704-0188

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<b>A. CONTRACT LINE ITEM NO.</b> 0013		<b>B. EXHIBIT</b> A		<b>C. CATEGORY:</b> TDP _____ TM _____ OTHER <input checked="" type="checkbox"/>					
<b>D. SYSTEM/ITEM</b> Filovirus Vaccine			<b>E. CONTRACT/PR NO.</b> W911QY-13		<b>F. CONTRACTOR</b>				
<b>1. DATA ITEM NO.</b> A005	<b>2. TITLE OF DATA ITEM</b> Quarterly Program Review			<b>3. SUBTITLE</b>					
<b>4. AUTHORITY (Data Acquisition Document No.)</b> DI-MGMT-81605			<b>5. CONTRACT REFERENCE</b> SOW		<b>6. REQUIRING OFFICE</b> CBMS-JVAP JPMO				
<b>7. DD 250 REQ</b> LT	<b>9. DIST STATEMENT REQUIRED</b> C	<b>10. FREQUENCY</b> Quarterly		<b>12. DATE OF FIRST SUBMISSION</b> see Blk 16					
<b>8. APP CODE</b>		<b>11. AS OF DATE</b>		<b>13. DATE OF SUBSEQUENT SUBMISSION</b> see Blk 16					
<b>16. REMARKS</b> BLK 4. DID can be obtained from <a href="http://assist.daps.dla.mil/quicksearch">http://assist.daps.dla.mil/quicksearch</a> .  A draft Microsoft PowerPoint presentation in the Contractor's format shall be submitted to the Government by the Contractor or major Subcontractor ten days prior to the Quarterly Program Review. This gives the Government the opportunity to review the slides and request any changes be made prior to the review with the CBMS-JVAP JPM.  The content of the briefing shall include but not limited to the following: completed tasks with in that previous quarter, highlights of completed tasks, summary of results from completed and current studies in process, projected tasks for the next quarter, schedule updates (IMS), risks/issues, and execution rates.  BLK 9 Administrative or Operational Use  Blk 14 & Blk 15. Submit via e-mail in Microsoft Office format to: Government contracting activity representatives listed in Section G of contract.				<b>14. DISTRIBUTION</b>					
				a. ADDRESSEE		b. COPIES			
						Draft	Final		
							Reg	Repro	
				see address in block 16		1	1		
<b>15. TOTAL</b>		1	1	0					

<b>17. PRICE GROUP</b>
<b>18. ESTIMATED TOTAL PRICE</b>

<b>G. PREPARED BY</b> <i>Rebecca J. Kurnat</i>	<b>H. DATE</b> 4/17/13	<b>I. APPROVED BY</b> <i>Nancy R</i>	<b>J. DATE</b> 4/17/13
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**CONTRACT DATA REQUIREMENTS LIST**  
(1 Data Item)

Form Approved  
OMB No. 0704-0188

The public reporting burden for this collection of information is estimated to average 110 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense, Executive Services and Communications Directorate (0704-0188). Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. Please do not return your form to the above organization. Send completed form to the Government Issuing Contracting Officer for the Contract/PR No. listed in Block E.

<b>A. CONTRACT LINE ITEM NO.</b> 0012	<b>B. EXHIBIT</b> A	<b>C. CATEGORY:</b> TDP _____ TM _____ OTHER <input checked="" type="checkbox"/>
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<b>D. SYSTEM/ITEM</b> Filovirus Vaccine	<b>E. CONTRACT/PR NO.</b> W911QY-13	<b>F. CONTRACTOR</b> 3
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<b>1. DATA ITEM NO.</b> A006	<b>2. TITLE OF DATA ITEM</b> Contract Work Breakdown Structure (CWBS)	<b>3. SUBTITLE</b>
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<b>4. AUTHORITY (Data Acquisition Document No.)</b> DI-MGMT-81334C	<b>5. CONTRACT REFERENCE</b> Section J attachment	<b>6. REQUIRING OFFICE</b> CBMS-JVAP JPMO
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<b>7. DD 250 REQ</b> LT	<b>9. DIST STATEMENT REQUIRED</b> C	<b>10. FREQUENCY</b> One/R	<b>11. AS OF DATE</b> contract award	<b>12. DATE OF FIRST SUBMISSION</b> see Blk 16	<b>13. DATE OF SUBSEQUENT SUBMISSION</b> see Blk 16	<b>14. DISTRIBUTION</b>		
						<b>a. ADDRESSEE</b>		
						<b>b. COPIES</b>		
						Draft	Final	
							Reg	Repro

<b>16. REMARKS</b> BLK 4. DID can be obtained from <a href="http://assist.daps.dla.mil/quicksearch">http://assist.daps.dla.mil/quicksearch</a> .  The CWBS will be to a depth and breadth necessary to accurately describe the Offeror's proposed effort to a minimum of Level 5. The CWBS shall be structured to correlate with the Contractor's Statement of Work and Integrated Master Schedule. These documents shall be prepared in the Contractor's format.  Blk 9 Administrative or Operational Use.  Blk 14 & Blk 15. Submit via e-mail in Microsoft Office format to: Government contracting activity representatives listed in Section G of contract.	see address in	1	1		
	block 16				
		<b>15. TOTAL</b>	1	1	0

<b>17. PRICE GROUP</b>
<b>18. ESTIMATED TOTAL PRICE</b>

<b>G. PREPARED BY</b> Rebecca J. Funnat	<b>H. DATE</b> 4/17/13	<b>I. APPROVED BY</b> Nicole K	<b>J. DATE</b> 4/17/13
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**CONTRACT DATA REQUIREMENTS LIST**

(1 Data Item)

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OMB No. 0704-0188

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<b>A. CONTRACT LINE ITEM NO.</b> 0012	<b>B. EXHIBIT</b> A	<b>C. CATEGORY:</b> TDP _____ TM _____ OTHER <input checked="" type="checkbox"/>
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<b>D. SYSTEM/ITEM</b> Filovirus Vaccine	<b>E. CONTRACT/PR NO.</b> W911QY-13	<b>F. CONTRACTOR</b>
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<b>1. DATA ITEM NO.</b> A007	<b>2. TITLE OF DATA ITEM</b> Quality Agreement	<b>3. SUBTITLE</b>
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<b>4. AUTHORITY (Data Acquisition Document No.)</b>	<b>5. CONTRACT REFERENCE</b> Section J Attachment	<b>6. REQUIRING OFFICE</b> CBMS-JVAP JPMO
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<b>7. DD 250 REQ</b> DD	<b>9. DIST STATEMENT REQUIRED</b> C	<b>10. FREQUENCY</b> As required	<b>12. DATE OF FIRST SUBMISSION</b> see Blk 16	<b>14. DISTRIBUTION</b>			
<b>8. APP CODE</b>		<b>11. AS OF DATE</b> contract award	<b>13. DATE OF SUBSEQUENT SUBMISSION</b> see Blk 16	<b>a. ADDRESSEE</b>	<b>b. COPIES</b>		
					Draft	Final	
						Reg	Repro

<b>16. REMARKS</b> Blk 4. DIDs can be obtained from <a href="http://assist.daps.dla.mil/quicksearch">http://assist.daps.dla.mil/quicksearch</a> .  A final Quality Agreement will be approved at contact award. All subsequent changes to the Quality Agreement shall be submitted to the Government for acceptance. The Government will respond with comments or acceptance 10 business days following receipt of draft changes. The final agreement with incorporated changes shall be submitted 10 business days after receipt of Government comments. Approval will be signified by written acceptance for the Government and will be incorporated in a contract modification.  Blk 9 Administrative or Operational Use.  Blk 14 & Blk 15. Submit via e-mail in Microsoft Office format to: Government contracting activity representatives listed in Section G of contract.	see address in	1	1		
	block 16				
	<b>15. TOTAL</b>	→	1	1	0

<b>17. PRICE GROUP</b>
<b>18. ESTIMATED TOTAL PRICE</b>
NST

<b>G. PREPARED BY</b> <i>Rebecca J. Kuntz</i>	<b>H. DATE</b> 4/17/13	<b>I. APPROVED BY</b> <i>N. Miller</i>	<b>J. DATE</b> 4/17/13
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**CONTRACT DATA REQUIREMENTS LIST**

(1 Data Item)

Form Approved  
OMB No. 0704-0188

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<b>A. CONTRACT LINE ITEM NO.</b> 0006	<b>B. EXHIBIT</b> A	<b>C. CATEGORY:</b> TDP _____ TM _____ OTHER <input checked="" type="checkbox"/>
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<b>D. SYSTEM/ITEM</b> Filovirus Vaccine	<b>E. CONTRACT/PR NO.</b> W911QY-13	<b>F. CONTRACTOR</b>
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<b>1. DATA ITEM NO.</b> A008	<b>2. TITLE OF DATA ITEM</b> Technical Data Package (TDP)	<b>3. SUBTITLE</b> Technical Transfer Protocol
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<b>4. AUTHORITY (Data Acquisition Document No.)</b> MIL-DTL-31000C	<b>5. CONTRACT REFERENCE</b> SOW 2.5.1.8	<b>6. REQUIRING OFFICE</b> CBMS-JVAP JPMO
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<b>7. DD 250 REQ</b> DD	<b>9. DIST STATEMENT REQUIRED</b> D	<b>10. FREQUENCY</b> One Time	<b>12. DATE OF FIRST SUBMISSION</b> see Blk 16	<b>14. DISTRIBUTION</b>			
<b>8. APP CODE</b>		<b>11. AS OF DATE</b> option exercise	<b>13. DATE OF SUBSEQUENT SUBMISSION</b> see Blk 16	a. ADDRESSEE	b. COPIES		
					Draft	Final	
						Reg	Repro

<b>16. REMARKS</b> BLK 4. DID can be obtained from <a href="http://assist.daps.dla.mil/quicksearch">http://assist.daps.dla.mil/quicksearch</a> .  The Government shall direct preparation of a Technical Transfer Protocol (TTP) that includes all necessary documentation and data for the Government, or its designee, to continue the development or production of the product. The Contractor shall also assist in the technical transfer as determined by the Government. The Contractor shall use the International Society for Pharmaceutical Engineers (ISPE) Good Practice Guide: Technology Transfer. The draft TTP shall be grammatically and typographically correct. The corrected TTP with recommended changes made, is due within ten working days after receipt of the Government's comments.  Blk 9. Critical Technology.  Blk 14 & Blk 15. Submit via e-mail in Microsoft Office format to: Government POCs listed in Section G of contract.	see address in	2	2		
	block 16				
	<b>15. TOTAL</b>	→	2	2	0

<b>17. PRICE GROUP</b>
<b>18. ESTIMATED TOTAL PRICE</b>

<b>G. PREPARED BY</b> <i>Rebecca J. Gurnat</i>	<b>H. DATE</b> 4/17/13	<b>I. APPROVED BY</b> <i>Neule</i>	<b>J. DATE</b> 4/17/13
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**CONTRACT DATA REQUIREMENTS LIST**  
(1 Data Item)

Form Approved  
OMB No. 0704-0188

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<b>A. CONTRACT LINE ITEM NO.</b> 0010		<b>B. EXHIBIT</b> A		<b>C. CATEGORY:</b> TDP _____ TM _____ OTHER <input checked="" type="checkbox"/>					
<b>D. SYSTEM/ITEM</b> Filovirus Vaccine			<b>E. CONTRACT/PR NO.</b> W911QY-13		<b>F. CONTRACTOR</b>				
<b>1. DATA ITEM NO.</b> A011	<b>2. TITLE OF DATA ITEM</b> Contract Funds Status Report (CFSR)			<b>3. SUBTITLE</b>					
<b>4. AUTHORITY (Data Acquisition Document No.)</b> DI-MGMT-81468			<b>5. CONTRACT REFERENCE</b> SOW		<b>6. REQUIRING OFFICE</b> CBMS-JVAP JPMO				
<b>7. DD 250 REQ</b> DD	<b>9. DIST STATEMENT REQUIRED</b>	<b>10. FREQUENCY</b> Quarterly		<b>12. DATE OF FIRST SUBMISSION</b> see Blk 16					
<b>8. APP CODE</b>		<b>11. AS OF DATE</b> option exercise		<b>13. DATE OF SUBSEQUENT SUBMISSION</b> see Blk 16					
<b>16. REMARKS</b> BLK 4. DID can be obtained from <a href="http://assist.daps.dla.mil/quicksearch">http://assist.daps.dla.mil/quicksearch</a> .  A draft CFSR (DD Form 1568) is due on the first Wednesday of the first month of a fiscal quarter (federal fiscal year begins Oct 1).  Blk 14 & Blk 15. Submit via e-mail in Microsoft Excel format to: Government contracting activity representatives listed in Section G of contract.				<b>14. DISTRIBUTION</b>					
				<b>a. ADDRESSEE</b>		<b>b. COPIES</b>			
						Draft	Final		
						Reg	Repro		
				see address in block 16		1	1		
<b>15. TOTAL</b> →			1	1	0				

<b>17. PRICE GROUP</b>
<b>18. ESTIMATED TOTAL PRICE</b>

<b>G. PREPARED BY</b> <i>Rebecca J. Gunnat</i>		<b>H. DATE</b> 4/17/13	<b>I. APPROVED BY</b> <i>Nicole Ky</i>		<b>J. DATE</b> 4/17/2013
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**CONTRACT DATA REQUIREMENTS LIST**

(1 Data Item)

Form Approved  
OMB No. 0704-0188

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<b>A. CONTRACT LINE ITEM NO.</b> 0013	<b>B. EXHIBIT</b>	<b>C. CATEGORY:</b> TDP _____ TM _____ OTHER <input checked="" type="checkbox"/>
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<b>D. SYSTEM/ITEM</b> Filovirus Vaccine	<b>E. CONTRACT/PR NO.</b> W911QY-13	<b>F. CONTRACTOR</b>
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<b>1. DATA ITEM NO.</b> A012	<b>2. TITLE OF DATA ITEM</b> Report, Production, or Delivery Problems	<b>3. SUBTITLE</b>
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<b>4. AUTHORITY (Data Acquisition Document No.)</b> DI-MGMT-81178	<b>5. CONTRACT REFERENCE</b> SOW	<b>6. REQUIRING OFFICE</b> CBMS-JVAP JPMO
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<b>7. DD 250 REQ</b> LT	<b>9. DIST STATEMENT REQUIRED</b>	<b>10. FREQUENCY</b> see Blk 16	<b>12. DATE OF FIRST SUBMISSION</b> see Blk 16	<b>14. DISTRIBUTION</b>			
<b>8. APP CODE</b>		<b>11. AS OF DATE</b>	<b>13. DATE OF SUBSEQUENT SUBMISSION</b> see Blk 16	<b>a. ADDRESSEE</b>	<b>b. COPIES</b>		
					Draft	Final	
						Reg	Repro

<b>16. REMARKS</b> BLK 4. DID can be obtained from <a href="http://assist.daps.dla.mil/quicksearch">http://assist.daps.dla.mil/quicksearch</a> .  The contractor shall report any incident to the Government that could result in a more than two week delay in schedule, or an increase in cost Estimate at Completion. Telephonically contact the Government within one day of incident. A written summary report shall be submitted within three business days of an incident.  Blk 14 & Blk 15. Submit via email in Microsoft Office format to: Government contracting activity representatives listed in Section G of contract.	see address in	1	1		
	block 16				
	<b>15. TOTAL</b>	→	1	1	0

<b>17. PRICE GROUP</b>
<b>18. ESTIMATED TOTAL PRICE</b>

<b>G. PREPARED BY</b> <i>Rebecca J. Gurnat</i>	<b>H. DATE</b> 4/17/13	<b>I. APPROVED BY</b> <i>Mark Ky</i>	<b>J. DATE</b> 4/17/13
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**CONTRACT DATA REQUIREMENTS LIST**  
(1 Data Item)

Form Approved  
OMB No. 0704-0188

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<b>A. CONTRACT LINE ITEM NO.</b> 0012		<b>B. EXHIBIT</b>		<b>C. CATEGORY:</b> TDP _____ TM _____ OTHER <input checked="" type="checkbox"/>				
<b>D. SYSTEM/ITEM</b> Filovirus Vaccine			<b>E. CONTRACT/PR NO.</b> W911QY-13		<b>F. CONTRACTOR</b>			
<b>1. DATA ITEM NO.</b> A013	<b>2. TITLE OF DATA ITEM</b> Risk Management Plan			<b>3. SUBTITLE</b>				
<b>4. AUTHORITY (Data Acquisition Document No.)</b> DI-MGMT-81808			<b>5. CONTRACT REFERENCE</b> SOW		<b>6. REQUIRING OFFICE</b> CBMS-JVAP JPMO			
<b>7. DD 250 REQ</b> DD	<b>9. DIST STATEMENT REQUIRED</b>	<b>10. FREQUENCY</b> see Blk 16	<b>12. DATE OF FIRST SUBMISSION</b> see Blk 16		<b>14. DISTRIBUTION</b>			
<b>8. APP CODE</b> AD		<b>11. AS OF DATE</b>	<b>13. DATE OF SUBSEQUENT SUBMISSION</b> see Blk 16					
<b>16. REMARKS</b>  The Government will actively assess the contractors application of their Risk Management Plan which shall be updated annually to incorporate Government feedback. The Risk Management Plan shall include a detailed process describing the method used for identifying, analyzing, prioritizing, mitigating and tracking all risks.  A final Risk Management Plan shall be submitted within 45 days of contract award for Government review and acceptance. All subsequent changes to the Risk Management Plan shall be submitted to the Government for acceptance. The Government will respond with comments or acceptance 15 business days following receipt of draft changes. A final Risk Management Plan with incorporated changes shall be submitted 10 business days after receipt of Government comments. Approval will be signified by written acceptance from the Government and will be incorporated in a contract modification.  Blk 14 & Blk 15. Submit via e-mail in Microsoft Office format to: Government contracting activity representatives listed in Section G of contract.			see address in		b. COPIES			
			block 16		Draft	Final		
				1	1	Reg	Repro	
<b>15. TOTAL</b> →			1	1	0			

<b>17. PRICE GROUP</b>
<b>18. ESTIMATED TOTAL PRICE</b>

<b>G. PREPARED BY</b> <i>Rebecca J. Kurnat</i>	<b>H. DATE</b> 4/17/13	<b>I. APPROVED BY</b> <i>Maria K...</i>	<b>J. DATE</b> 4/17/2013
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**CONTRACT DATA REQUIREMENTS LIST**

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OMB No. 0704-0188

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<b>A. CONTRACT LINE ITEM NO.</b> 0013	<b>B. EXHIBIT</b>	<b>C. CATEGORY:</b> TDP _____ TM _____ OTHER <input checked="" type="checkbox"/>
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<b>D. SYSTEM/ITEM</b> Filovirus Vaccine	<b>E. CONTRACT/PR NO.</b> W911QY-13	<b>F. CONTRACTOR</b>
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<b>1. DATA ITEM NO.</b> A014	<b>2. TITLE OF DATA ITEM</b> Master Production Batch Records	<b>3. SUBTITLE</b>
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<b>4. AUTHORITY (Data Acquisition Document No.)</b>	<b>5. CONTRACT REFERENCE</b> SOW	<b>6. REQUIRING OFFICE</b> CBMS-JVAP JPMO
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<b>7. DD 250 REQ</b> LT	<b>9. DIST STATEMENT REQUIRED</b>	<b>10. FREQUENCY</b> As required	<b>12. DATE OF FIRST SUBMISSION</b> See Blk 16	<b>14. DISTRIBUTION</b>		
<b>8. APP CODE</b> AD	C	<b>11. AS OF DATE</b>	<b>13. DATE OF SUBSEQUENT SUBMISSION</b> See Blk 16	a. ADDRESSEE	b. COPIES	
					Draft	Final
					Reg	Repro

<b>16. REMARKS</b>  The Contractor shall submit the contractor QC approved Master Production Batch Record (MPBR) for Government review and approval prior to the initiation of the following production efforts: 1. cGMP Master and working cell banks 2. cGMP Bulk vaccine pilot lots 3. cGMP Final vaccine product  The MPBR shall include the product release testing specifications. The Government will respond with comments or approval within 15 business days following receipt. A final MPBR shall be submitted within 10 business days after receipt of the Government comment. The MPBR shall be in compliance with cGMP 21 CFR part 211 (Current Good Manufacturing Practice for finished Pharmaceuticals)  Blk 9. Critical Technology.  Blk 14 & Blk 15. Submit via CD and/or hard copy in Microsoft Office format to: Government contracting activity representatives listed in Section G of contract.	see address in	1	1		
	block 16				
	<b>15. TOTAL</b>	→	1	1	0

<b>17. PRICE GROUP</b>
<b>18. ESTIMATED TOTAL PRICE</b>

<b>G. PREPARED BY</b> <i>[Signature]</i>	<b>H. DATE</b> 4/17/13	<b>I. APPROVED BY</b> <i>[Signature]</i>	<b>J. DATE</b> 4/17/2013
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(1 Data Item)

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OMB No. 0704-0188

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<b>A. CONTRACT LINE ITEM NO.</b> 0013	<b>B. EXHIBIT</b>	<b>C. CATEGORY:</b> TDP _____ TM _____ OTHER <input checked="" type="checkbox"/>
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<b>D. SYSTEM/ITEM</b> Filovirus Vaccine	<b>E. CONTRACT/PR NO.</b> W911QY-13	<b>F. CONTRACTOR</b>
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<b>1. DATA ITEM NO.</b> A016	<b>2. TITLE OF DATA ITEM</b> Regulatory submissions and communications	<b>3. SUBTITLE</b>
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<b>4. AUTHORITY (Data Acquisition Document No.)</b>	<b>5. CONTRACT REFERENCE</b> SOW	<b>6. REQUIRING OFFICE</b> CBMS-JVAP JPMO
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<b>7. DD 250 REQ</b> LT	<b>9. DIST STATEMENT REQUIRED</b> C	<b>10. FREQUENCY</b> As required	<b>12. DATE OF FIRST SUBMISSION</b> See Blk 16	<b>14. DISTRIBUTION</b>			
<b>8. APP CODE</b>		<b>11. AS OF DATE</b> contract award	<b>13. DATE OF SUBSEQUENT SUBMISSION</b> See Blk 16	<b>a. ADDRESSEE</b>	<b>b. COPIES</b>		
					Draft	Final	
						Reg	Repro

<b>16. REMARKS</b>  The Contractor shall submit a Draft Chemical, Manufacturing, and Control section to support Investigational New Drug (IND) application submission in eCTD format to the Government within 45 days of Government request. The Government will review and provide comment within 20 days of receipt. A final documentation shall be submitted within 20 days after receipt of Government comments. All documentation shall be in accordance with FDA guidelines.  The Contractor shall assist the Government with preparation for, and participation in communications with the FDA as requested by the Government.  Blk 9. Critical Technology.  Blk 14 & Blk 15. Submit via CD and/or hard copy in Microsoft Office format to: Government contracting activity representatives listed in Section G of contract.	see address in	1	1		
	block 16				
	<b>15. TOTAL</b>		1	1	0

<b>17. PRICE GROUP</b>
<b>18. ESTIMATED TOTAL PRICE</b>

<b>G. PREPARED BY</b> <i>Rebecca J. Kurnat</i>	<b>H. DATE</b> 4/17/13	<b>I. APPROVED BY</b> <i>Michael K.</i>	<b>J. DATE</b> 4/17/2013
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