

SOLICITATION, OFFER AND AWARD				1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)		RATING		PAGE OF PAGES 1 80			
2. CONTRACT NO.		3. SOLICITATION NO. W81XWH-12-R-0001		4. TYPE OF SOLICITATION <input type="checkbox"/> SEALED BID (IFB) <input checked="" type="checkbox"/> NEGOTIATED (RFP)		5. DATE ISSUED 09 Jan 2012		6. REQUISITION/PURCHASE NO. W74MYF1160N813			
7. ISSUED BY USA MED RESEARCH ACQ ACTIVITY 820 CHANDLER ST FORT DETRICK MD 21702-5014				CODE W81XWH		8. ADDRESS OFFER TO (If other than Item 7) See Item 7					
TEL: FAX:						TEL: FAX:					
NOTE: In sealed bid solicitations "offer" and "offeror" mean "bid" and "bidder".											
SOLICITATION											
9. Sealed offers in original and <u>3</u> copies for furnishing the supplies or services in the Schedule will be received at the place specified in Item 8, or if handcarried, in the depository located in _____ until <u>03:00 PM</u> local time <u>24 Feb 2012</u> (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 JENNIFER JACKSON		B. TELEPHONE (Include area code) (NO COLLECT CALLS) 301-619-2054		C. E-MAIL ADDRESS jennifer.jackson1@us.army.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		AMENDMENT NO.		DATE	
15A. NAME AND ADDRESS OF OFFEROR		CODE		FACILITY		16. NAME AND TITLE OF PERSON AUTHORIZED TO SIGN OFFER (Type or print)					
15B. TELEPHONE NO (Include area code)		15C. CHECK IF REMITTANCE ADDRESS IS DIFFERENT FROM ABOVE - ENTER SUCH ADDRESS IN SCHEDULE. <input type="checkbox"/>				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		
						(4 copies unless otherwise specified)					
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	Base Year Non-Personal Services FFP Technical and administrative operational support services for the Pilot Bioproduction Facility at the Walter Reed Army Institute of Research (WRAIR), Silver Spring, MD to be performed in accordance with the Performance Work Statement (PWS). FOB: Destination PURCHASE REQUEST NUMBER: W74MYF1160N813	12	Months		

NET AMT

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0002	Other Direct Cost CPFF Other Direct Cost for Materials, Supplies, Training and Travel in support of operational support services for the Pilot Bioproduction Facility. FOB: Destination PURCHASE REQUEST NUMBER: W74MYF1160N813		Dollars, U.S.		

ESTIMATED COST
FIXED FEE
TOTAL EST COST + FEE

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0003	Base Year Contractor Manpower Reporting FFP	1	Lot		
	Provide information for the duration of Phase I performance associated with the input of the Accounting for Contract Services information in the web site operated and maintained by the Assistant Secretary of the Army (Manpower & Reserve Affairs). See the "Contractor Manpower Reporting" paragraph in Section C for specific reporting information. The Unit Identification Code for the Walter Reed Army Institute of Research (WRAIR) is W30KAA. FOB: Destination PURCHASE REQUEST NUMBER: W74MYF1160N813				

NET AMT

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1001 OPTION	Option Year 1 Non-Personal Services FFP	12	Months		
	Technical and administrative operational support services for the Pilot Bioproduction Facility at the Walter Reed Army Institute of Research (WRAIR), Silver Spring, MD to be performed in accordance with the Performance Work Statement (PWS). FOB: Destination				

NET AMT

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1002			Dollars, U.S.		
OPTION	Option Year 1 Other Direct Cost CPFF Other Direct Cost for Materials, Supplies, Training and Travel in support of operational support services for the Pilot Bioproduction Facility. FOB: Destination				
				ESTIMATED COST	
				FIXED FEE	
				TOTAL EST COST + FEE	<hr/>

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1003		1	Lot		
OPTION	Opt Yr 1 Contractor Manpower Reporting FFP Provide information for the duration of Phase I performance associated with the input of the Accounting for Contract Services information in the web site operated and maintained by the Assistant Secretary of the Army (Manpower & Reserve Affairs). See the "Contractor Manpower Reporting" paragraph in Section C for specific reporting information. The Unit Identification Code for the Walter Reed Army Institute of Research (WRAIR) is W30KAA. FOB: Destination				
				NET AMT	<hr/>

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
2001		12	Months		
OPTION	Option Year 2 Non-Personal Services FFP Technical and administrative operational support services for the Pilot Bioproduction Facility at the Walter Reed Army Institute of Research (WRAIR), Silver Spring, MD to be performed in accordance with the Performance Work Statement (PWS). FOB: Destination				

NET AMT

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
2002			Dollars, U.S.		
OPTION	Option Year 2 Other Direct Cost CPFF Other Direct Cost for Materials, Supplies, Training and Travel in support of operational support services for the Pilot Bioproduction Facility. FOB: Destination				

ESTIMATED COST
FIXED FEE
TOTAL EST COST + FEE

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
2003 OPTION	Opt Yr 2 Contractor Manpower Reporting FFP	1	Lot		
	Provide information for the duration of Phase I performance associated with the input of the Accounting for Contract Services information in the web site operated and maintained by the Assistant Secretary of the Army (Manpower & Reserve Affairs). See the "Contractor Manpower Reporting" paragraph in Section C for specific reporting information. The Unit Identification Code for the Walter Reed Army Institute of Research (WRAIR) is W30KAA. FOB: Destination				

NET AMT

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
3001 OPTION	Option Year 3 Non-Personal Services FFP	12	Months		
	Technical and administrative operational support services for the Pilot Bioproduction Facility at the Walter Reed Army Institute of Research (WRAIR), Silver Spring, MD to be performed in accordance with the Performance Work Statement (PWS). FOB: Destination				

NET AMT

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
3002			Dollars, U.S.		
OPTION	Option Year 3 Other Direct Cost CPFF Other Direct Cost for Materials, Supplies, Training and Travel in support of operational support services for the Pilot Bioproduction Facility. FOB: Destination				
				ESTIMATED COST	
				FIXED FEE	
				TOTAL EST COST + FEE	<hr/>

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
3003		1	Lot		
OPTION	Opt Yr 3 Contractor Manpower Reporting FFP Provide information for the duration of Phase I performance associated with the input of the Accounting for Contract Services information in the web site operated and maintained by the Assistant Secretary of the Army (Manpower & Reserve Affairs). See the "Contractor Manpower Reporting" paragraph in Section C for specific reporting information. The Unit Identification Code for the Walter Reed Army Institute of Research (WRAIR) is W30KAA. FOB: Destination				
				NET AMT	<hr/>

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
4001		12	Months		
OPTION	Option Year 4 Non-Personal Services FFP Technical and administrative operational support services for the Pilot Bioproduction Facility at the Walter Reed Army Institute of Research (WRAIR), Silver Spring, MD to be performed in accordance with the Performance Work Statement (PWS). FOB: Destination				

NET AMT

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
4002			Dollars, U.S.		
OPTION	Option Year 4 Other Direct Cost CPFF Other Direct Cost for Materials, Supplies, Training and Travel in support of operational support services for the Pilot Bioproduction Facility. FOB: Destination				

ESTIMATED COST
FIXED FEE
TOTAL EST COST + FEE

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
4003		1	Lot		
OPTION	Opt Yr 4 Contractor Manpower Reporting FFP				

Provide information for the duration of Phase I performance associated with the input of the Accounting for Contract Services information in the web site operated and maintained by the Assistant Secretary of the Army (Manpower & Reserve Affairs). See the "Contractor Manpower Reporting" paragraph in Section C for specific reporting information. The Unit Identification Code for the Walter Reed Army Institute of Research (WRAIR) is W30KAA.
FOB: Destination

NET AMT

NOTES:

For proposal and evaluation purposes annual estimates for other direct costs are as follows:

Materials/Supplies: - \$1,000,000

Training and Travel - \$15,000

Indirect Costs and Fee may be applied to these amounts.

Attached are the following documents in Section J.

Attachment 1 – Historical Staffing (FOR INFORMATIONAL PURPOSES ONLY)

Attachment 2 – PBF Historical Vaccine Manufacturing (broken down in parts) (FOR INFORMATIONAL PURPOSES ONLY)

Attachment 3 – Past Performance Questionnaire

Attachment 4 – Wage Determination which is applicable to any Service Contract Act service employee proposed.

ADDITIONAL INFORMATION

The Incumbent Contractor is:

Clinical Research Management (CRM)
1265 Ridge Road, Suite A
Hinckley, OH 44233-801

Previous Contract Number: DAMD17-02-C-0002

Total contract was estimated at \$39,931,063.58

Section C - Descriptions and Specifications

PERFORMANCE WORK STATEMENT

1. GENERAL INFORMATION

1.1 BACKGROUND

1.1.1 Walter Reed Army Institute of Research (WRAIR). The WRAIR is the largest and most diverse medical laboratory within the U.S. Army Medical Research and Materiel Command. It is also the Department of Defense's lead agency for infectious disease research. WRAIR's mission is to conduct biomedical research focused on soldier health and readiness.

1.1.2 Pilot Bioproduction Facility (PBF). The Department of PBF, Division of Regulated Activities, is part of the WRAIR. It is located within the WRAIR, Forest Glen Annex, Silver Spring, Maryland. The PBF conducts research, development, production, and testing of vaccines and other biological products. Vaccine production is performed following and products are tested in compliance with current Good Manufacturing Practices (cGMP). Production is pilot-scale: 1,000 – 10,000 doses per finished lot of product. Products are released for use in Phase I – II clinical studies under Investigational New Drug applications (INDs). Vaccines being produced include, but are not limited to, those for prophylaxis against shigellosis, meningitis, malaria, and dengue fever. Conventional as well as recombinant and other genetically engineered vaccines are undergoing development and production. Other types of biological products (i.e. therapeutics) are capable of being produced as well under the right circumstances.

1.2 Objective. The primary objective defined by this Performance Work Statement (PWS) is for a contractor to provide the specialized technical and administrative personnel support required to operate the WRAIR PBF. The contractor who meets this objective must be familiar with and have prior experience in providing and overseeing personnel who have GMP manufacturing and testing experience. In support of the primary objective and the PBF itself, there exist two secondary objectives:

1.2.1 Purchasing Activities. Provide purchasing activities for all raw materials and other materials as allowed by the Federal government in a timely manner in support of production and administrative activities at the WRAIR PBF. This is a mandatory objective.

1.2.2 Marketing Activities. Provide marketing activities designed to increase potential business for the WRAIR PBF. This would include submitting proposals to RFPs for appropriate potential Phase 1 manufacturing activities.

1.3 Scope of Work. Except as otherwise specified in the contract, the Contractor shall furnish all supervision, personnel, transportation and materials to provide technical and administrative personnel to operate the PBF in accordance with the terms stated herein.

1.4 Contracting Officer. The Contracting Officer (CO) or other designated official will be responsible for the execution and administration of this contract on behalf of the Government.

1.5 Contracting Officer's Representative. The Contracting Officer's Representative (COR) will be responsible for monitoring and assessing the technical performance of the Contractor on a day-to-day basis.

1.6 Period of Performance. Base Period: April 1, 2012 – March 31, 2013. The contract includes four one-year option periods. The contract period of performance shall not exceed 5 years.

1.7 Place of Performance. The main duty location is the PBF, building 501, of the WRAIR, Forest Glen Annex, Silver Spring, Maryland, 20910.

1.8 Travel. Minimal travel may be required in support of this contract. When such travel is required, the Contractor shall travel at the Government-approved rate in accordance with the Federal Travel Regulation. The CO will be the approving authority for all remote travel.

1.9 Personal Requirements.

1.9.1 Safety. The Contractor shall ensure its employees are familiar with, and observe, all safety guidelines established to cover work within the laboratory, and that its employees shall receive all safety training required by the Government. Some projects may require vaccination. By regulation WRAIR will offer the vaccine. The contractor will take the vaccine voluntarily (i.e. WRAIR will not force a contractor to take the vaccine). Vaccine inoculations are on a case-by-case and project-by-project basis.

1.9.2 Certification(s). Contractor employees will be provided Government training and demonstrate competence in current Good Manufacturing Practices (cGMP) as required by their duties. **Contractors must participate in, at minimum, yearly current Good Manufacturing Practices (cGMP) refresher training and demonstrate competence in cGMP as required by their duties.**

1.9.3 Minimum Qualifications. The Contractor shall hire/assign qualified technical and administrative personnel to operate the PBF. Attachment 1 contains a listing of Key Personnel and a historical staffing list.

1.10 Reporting Requirements. The Contractor shall submit quarterly progress reports of all work accomplished during contract performance. Reports shall be in tabular form, brief, and informal in content. The Contractor shall submit each quarterly progress report to the COR within thirty days after the end of the quarter being reported. The reports shall contain:

1.10.1 Quantitative description of overall progress;

1.10.2 Description of any performance problems and the proposed corrective action(s);

1.10.3 Discussion of the work to be performed during the next quarterly reporting period, including estimated completion dates for associated milestones and deliverables; and

1.10.4 The financial status to date relative to the original plan, including information on cost incurred vs. planned cost and labor hours spent vs. projected effort.

1.11 Training.

1.11.1 General Requirements. The Government may provide /require other on-going training related to operating on government premises during the course of this contract. Government training shall be conducted at the PBF or off-site at designated facilities.

ACRONYMS

BPR. Batch Production Record
BSL. Biological Safety Level
CDR. Contract Discrepancy Report
CFR. Code of Federal Regulation
CO. Contracting Officer
COR. Contracting Officer's Representative
CRADA. Cooperative Research and Development Agreement
FDA. Food and Drug Administration
FFU. Formulation and Filling Unit
GLP. Good Laboratory Practices
cGMP. Current Good Manufacturing Practices
GSA. General Services Administration
HIV. Human Immunodeficiency Virus
IND. Investigational New Drug application

LIDS. Laboratory Integrated Delivery System
PBF. Pilot Bioproduction Facility
PRS. Performance Requirements Summary
PU. Purification Unit
PWS. Performance Work Statement
QA. Quality Assurance
QAM. Quality Assurance Manager
QASP. Quality Assurance Surveillance Plan
QAU. Quality Assurance Unit
QCU. Quality Control Unit
SOP. Standard Operational Procedures
SPFU. Seed Preparation and Fermentation Unit
TBD. To Be Determined
VPU. Viral Products Unit
VDADU. Viral Development and Diagnostics Unit
WIP. Work In Process
WMIS. Walter Reed Army Institute of Research Management Information System
WRAIR. Walter Reed Army Institute of Research

SECTION 2 – Government Furnished Property.

For all work performed on Government premises, the Government will furnish, to the extent needed to perform the required tasks under this contract, the following items:

- 2.1 Office and laboratory space
- 2.2 Computer and laboratory equipment

SECTION 3 - Contractor Responsibility.

The Contractor shall be responsible for:

- 3.1 Identifying and purchasing the materials/supplies to fulfill the contract requirements made with clients for GMP production;
- 3.2 Identify and provide other services (such as calibration/validation) as required/recommended by FDA guidelines on equipment maintenance and performance as per the Code of Federal Regulations (CFR) for vaccine and biologics production to WRAIR PBF management in order to fulfill GMP requirements.
- 3.3 The Contractor shall designate one key personnel as an on-site supervisor for day-to-day communications and responsibility for Contractor personnel.
- 3.4 Compliance with all procedures for the protection of life, property and cGMP.

SECTION 4 – Contractor Service Unit

Documents, data and reports must be generated by personnel in all functional units in order to meet GMP requirements; and conduct of personnel while performing manufacturing and testing processes must meet current Food and Drug Association (FDA) requirements/guidelines. The contractor shall furnish personnel and materials to operate the following PBF units to perform, at a minimum, the following tasks:

4.1 Quality Assurance Unit (QAU). The Contractor shall provide a Quality Assurance Unit (QAU) that performs, at a minimum, the following:

4.1.1 Receives, logs in, quarantines, and releases raw materials used for production;

4.1.2 Writes, reviews, and approves BPRs prior to production; reviews, approves and releases BPRs and products after production;

4.1.3 Writes, reviews, and releases SOPs used for manufacturing and testing of products;

4.1.4 Audits production and testing on a regular basis;

4.1.5 Monitors validation and calibration of equipment;

4.1.6 Reviews preventive maintenance records on manufacturing equipment;

4.1.7 Keeps current with cGMP and related regulations.

4.2 Quality Control Unit (QCU). The Contractor shall provide a Quality Control Unit (QCU) that furnishes microbiological, and chemical analytical services in support of biological and vaccine production. The QCU shall perform, at a minimum, the following:

4.2.1 Analyzes water and steam used in production for purity levels and compares the results to published standards;

4.2.2 Analyzes in-process and final products for composition, sterility, purity, homogeneity, viability and potency;

4.2.3 Performs environmental monitoring of clean rooms used for production;

4.2.4 Analyzes raw materials for identification and purity;

4.2.5 Writes and reviews SOPs for production and testing of biological products and vaccines;

4.2.6 Reviews BPRs for sampling and testing content prior to issuance;

4.2.7 Keeps current with all cGMP and other relevant regulations;

4.2.8 Co-ordinates shipment of samples for products requiring testing by outside vendors and receipt of testing results from these tests; and

4.2.9 Develops, coordinates, and executes stability protocols with PBF CRADA partners.

4.3 Viral Diagnostic and Development Unit (VDADU). The Contractor shall provide a Viral Diagnostic and Development Unit (VDADU) that furnishes viral analytical services in support of biological and vaccine production. The VDADU shall perform, at a minimum, the following:

4.3.1 Analyzes in-process and final products for composition, purity, homogeneity, viability and potency;

4.3.2 Writes, reviews, and releases SOPs used for testing of products;

4.3.3 Develops, coordinates, and executes stability protocols with PBF CRADA partners;

4.3.4 Analyzes raw materials for identification and purity;

4.3.5 Reviews BPRs for sampling and testing content prior to issuance;

4.3.6 Keeps current with all cGMP and other relevant regulations;

4.3.7 Develops, coordinates, and executes stability protocols with PBF CRADA partners; and

4.3.8 Performs assay qualifications as needed in coordination with PBF CRADA partners.

4.4 Production Unit. The Contractor shall provide four (4) production units that are responsible for manufacturing vaccines. The four units are listed below:

4.4.1 Seed Preparation and Fermentation Unit

4.4.2 Purification Unit

4.4.3 Viral Production Unit

4.4.4 Formulation and Filling Unit

SECTION 5 - SPECIFIC TASKS.

The contractor shall furnish personnel and materials to perform, at a minimum, the following tasks while following FDA regulations and guidelines for cGMP:

5.1 QUALITY ASSURANCE UNIT (QAU) TASKS

5.1.1 Task 1. The Contractor shall designate a Quality Assurance Manager (QAM) as the responsible Head of the QAU. The QAM shall oversee QAU operations.

5.1.2 Task 2. The QAU shall maintain a filing system for all incoming raw materials used for production and quality control. Incoming materials shall be logged processed according to established GMP procedures. Update all documentation and tracking information periodically (spreadsheets, database, logs, etc.) to accurately reflect physical inventory of materials following cGMP's. The QAU shall store retention samples for reference and analysis, as needed.

5.1.3 Task 3. Following production, the QAU shall ensure the proper storage of quarantined WIP and final products. The QAU shall release these products following review of documents and release criteria. Storage may be off-site for some quarantined and released products.

5.1.4 Task 4. The QAU shall write (when appropriate), review, and release BPRs and SOPs required for PBF operations.

5.1.5 Task 5. The QAU shall monitor the preventive maintenance program that includes the building(s) as well as utilities and equipment located in the PBF.

5.1.6 Task 6. The QAU shall monitor the calibration and validation program for all equipment and processes used in the manufacture and quality control of products.

5.1.7 Task 7. The QAU shall monitor training for all personnel involved with production and quality control in the facility.

5.1.8 Task 8. The QAU shall audit internal production units, external suppliers, and interface with

business partners for compliance audits.

5.1.9 Task 9. The QAU shall report inventory discrepancies, assist in resolving, documenting and performing corrective action.

5.1.10 Task 10. The QAU shall verify that all labeling of materials is correct, generate and apply labels reflecting material information and status.

5.1.11 Task 9. The QAU shall arrange for a yearly GMP refresher course for PBF personnel.

5.2 QUALITY CONTROL UNIT (QCU) TASKS

5.2.1 Task 1. The QCU shall perform or arrange for microbiological, chemical, and other testing required for the analysis of raw materials, in-process production material, and final products to verify the safety, homogeneity, and potency of these products.

5.2.2 Task 2. The QCU will document and review testing results and will submit them to QA for incorporation into executed BPRs.

5.2.3 Task 3. The QCU shall, on a regular basis, analyze purified water and steam generated in the production facility for quality and suitability for use in products.

5.2.4 Task 4. The QCU shall routinely perform environmental monitoring of clean rooms used for production.

5.2.5 Task 5. The QCU shall write and review SOPs for vaccine testing; the QCU will review draft BPRs for proper sampling and testing documentation.

5.2.6 Task 6. The QCU shall develop and/or modify existing assays that can be applied to the analysis of products manufactured in the facility.

5.2.7 Task 7. The QCU shall write stability and administer protocols and execute testing or arrange for testing as dictated by the approved protocols.

5.2.8 Task 8. The QCU shall perform services in accordance with cGMP, Code of Federal Regulations 24 CFR 58, and Good Laboratory Practices GLP.

5.2.9 Task 9. The QCU shall maintain a validated and calibrated laboratory that will generate data used for Investigational New Drug Submissions to FDA.

5.3 SEED PREPARATION AND FERMENTATION UNIT (SPFU) TASKS

5.3.1 Task 1. The SPFU shall expand research-grade seed preparations by culture to prepare Master and Production (Working) Seeds. The SPFU shall vial and store the seeds for future manufacture.

5.3.2 Task 2. The SPFU shall expand seeds by fermentation so that up to 300L batches of seed organisms can be grown under optimal conditions and harvested for optimal yields.

5.3.3 Task 3. The SPFU shall record all production and processing data in BPRs. The data shall be available for IND submissions.

5.3.4 Task 4. The SPFU shall write BPRs using information obtained from the Principal Investigator or

from other sources in the scientific literature. The BPR shall describe, in detail, the procedures to follow for specified purifications.

5.3.5 Outcomes.

5.3.5.1 The SPFU must be able to complete up to 44 seed preparations and up to 22 fermentations over a one-year period. (Minimum requirements cannot be set because the procurement of business/CRADA partners and scheduling of product is beyond the contractor's control).

5.3.5.2 The SPFU must execute protocol development, ordering of raw materials, preparation of materials and completion of training in order to complete seeds and fermentation according to production scheduling 95% of the time.

5.4 PURIFICATION UNIT (PU) TASKS

5.4.1 Task 1. Provided with concentrated bacteria or soluble, crude antigen as starting materials, the PU shall purify the material using all available technologies including chromatography, centrifugation, chemical extraction, or other methodologies. The final, bulk material shall meet all purity specifications set by the Principal Investigator.

5.4.2 Task 2. The PU will perform conjugation, bulk formulation, and other procedures that are within the capabilities of the unit.

5.4.3 Task 3. The PU shall write BPRs using information obtained from the Principal Investigator or from other sources in the scientific literature. The BPR shall describe, in detail, the procedures to follow for specified purifications.

5.4.4 Task 4. The SPFU shall record all production and processing data in BPRs. The data shall be available for IND submissions.

5.4.5 Outcomes. Performance of the required tasks shall result in the following outcomes:

5.4.5.1. The PU must be able to complete up to 22 purifications over a one-year period. The purifications may include non-GMP "practice" purifications. (Minimum requirements cannot be set because the procurement of business/CRADA partners and scheduling of product is beyond the contractor's control).

5.4.5.2. The PU must execute protocol development, ordering of raw materials, preparation of materials and completion of training in order to complete purification according to production scheduling 95% of the time.

5.5 PRODUCTION - VIRAL PRODUCTS UNIT (VPU) TASKS

5.5.1 Task 1. The VPU shall inoculate various viral agents into large-scale cell cultures and harvest these agents for filling into a vaccine vial or for further purification and formulation and fill. Agents shall not exceed the Biological Safety Level (BSL)-2 classification for the designated clean room where they will be processed. **5.5.2 Task 2.** The VPU shall prepare, under cGMP conditions, seeds (Master and Production) for all candidate vaccine viruses. The VPU shall perform amplification passages of a research seed as needed.

5.5.3 Task 3. The VPU shall write BPRs using information obtained from the Principal Investigator or from other sources in the scientific literature. The BPR shall describe, in detail, the procedures to follow for specified purifications.

5.5.4 Task 4. The VPU shall record all production and processing data in BPRs. The data shall be available for IND submissions.

5.5.5 Outcomes. Performance of the required tasks shall result in the following outcomes:

5.5.5.1 Over a one-year period, the VPU shall prepare vaccine lots so that 1,000 – 10,000 doses may be filled for clinical use.

5.5.5.2 The VPU must be able to produce up to 16 viral products (seed preparation or a final vaccine bulk lot) over a one-year period. (Minimum requirements cannot be set because the procurement of business/CRADA partners and scheduling of product is beyond the contractor's control).

5.5.5.3 The VPU must execute protocol development, ordering of raw materials, preparation of materials and completion of training in order to complete viral product manufacture according to production scheduling 95% of the time.

5.6 FORMULATION AND FILLING UNIT (FFU) TASKS.

5.6.1 Task 1. The FFU shall formulate and fill bulk lots of vaccine as specified in BPRs.

5.6.2. Task 2. The FFU shall write BPRs using information obtained from the Principal Investigator or from other sources in the scientific literature. The BPR shall describe, in detail, the procedures to follow for specified purifications.

5.6.3. Task 3. The FFU shall record all production and processing data in BPRs. The data shall be available for IND submissions

5.6.4 Special Requirements.

5.6.4.1. All products shall be handled aseptically. All safeguards shall be in place for sterile filling of products.

5.6.4.2. All personnel must participate in annual aseptic fill re-validations.

5.6.5 Outcomes. Task performance shall result in the following outcomes:

5.6.5.1 The FFU shall fill lot sizes of up to 2,000 vials either as single or multiple dose vials.

5.6.5.2 The FFU shall fill up to 44 separate lots of final container product in a one-year period. (Minimum requirements cannot be set because the procurement of business/CRADA partners and scheduling of product is beyond the contractor's control).

5.6.5.3 The FFU must execute protocol development, ordering of raw materials, preparation of materials and completion of training in order to complete product fills according to production scheduling 95% of the time.

5.6.3.4. Aseptic fill re-validations must be successful.

5.7 VIRAL DIAGNOSTICS AND DEVELOPMENT UNIT (VDADU) TASKS.

5.7.1. Task 1. The VDADU shall perform various viral testing assays when required by clients and product specifications.

5.7.2 Task 2. The VDADU shall write and review SOPs for vaccine testing; the VDADU will review draft BPRs for proper sampling and testing documentation.

5.7.3 Task 3. The VDADU shall develop and/or modify (and qualify, when required) existing assays that can be applied to the analysis of products manufactured in the facility.

5.7.4 Task 4. The VDADU will document and review testing results and will submit them to QA for incorporation into executed BPRs.

5.7.5 Task 5. The VDADU shall write stability and administer protocols and execute testing or arrange for testing as dictated by the approved protocols.

5.8 Business Administration and Coordination. The contractor shall provide business administration and coordination for the daily operation of the PBF for the following specific tasks:

5.8.1 Provide managerial and administrative support for the PBF determines priorities for actions and assures that suspense dates are met.

5.8.2 Maintains the budget for the PBF and reconciles funding sites as required.

5.8.3 Prepares correspondence, memoranda, reports, and manuscripts; maintains office files for scientific and non-scientific data.

5.8.4 Annotates and updates the office calendar daily; arranges meetings between the Chief and members of the Department staff and persons outside of the Department;

5.8.5 Processes documents for all purchasing requirements for the PBF.

5.8.6 Utilizes internal WRAIR and other government information systems. (WIMIS, LIDS and GSA)

SECTION 6 - MILESTONE/DELIVERABLE SCHEDULE. The milestone/deliverable schedule will be established by the COR. Any change(s) to the schedule will be implemented via a modification.

Task/Activity	Milestone/Deliverable	Due Date
Reporting Requirements (1.10)	Quarterly Progress Reports	Within thirty days after the end of the quarter being reported.
Reporting Requirements (1.10)	Monthly Status Meetings	Within 15 working days after the end of each month

SECTION 7 PERFORMANCE-BASED CONTRACTING

7.1 GENERAL INFORMATION. Performance-based contracting emphasizes that all aspects of an acquisition be structured around the purpose of the work to be performed as opposed to the manner in which the work is to be performed or broad, imprecise statements of work which preclude an objective assessment of Contractor performance. It is designed to ensure that Contractors are given freedom to determine how to meet the Government's objectives that appropriate quality levels are achieved, and that payment is made only for products/services that meet these levels. The PBF has developed the performance metrics specified for the contract Schedule, which will be used to evaluate Contractor performance.

7.2 PERFORMANCE REQUIREMENTS SUMMARY (PRS). The PRS (Technical Exhibit A) lists the performance requirements under the contract that are to be evaluated by the Government, performance indicators for these requirements, performance standards for these requirements, and surveillance methods to be used to determine if performance standards are met.

7.3 QUALITY ASSURANCE SURVEILLANCE PLAN (QASP). Further details regarding the surveillance methods used by the Government to evaluate Contractor performance are contained in the QASP (Technical Exhibit B), which is the Government's plan to assure the quality and timeliness of services performed under the contract.

7.4 DISCREPANCIES. When discrepancies occur in contract performance, the COR will issue a Contract Discrepancy Report (CDR) to the Contractor, and a meeting will be held at the discretion of the contracting representative to discuss the issues. The written meeting minutes will be prepared by the COR, forwarded to the CO for concurrence, and distribution by the CO to all concerned within 15 calendar days of the meeting. The written minutes shall be signed by the Contractor, the Contractor's Contract Manager, the COR, and the CO. Should the Contractor not concur with the minutes, its company representative shall state so in writing within the time required by the CDR or notice to the CO.

Technical Exhibit A: Performance Requirements Summary (PRS) Table

Performance Requirement	Performance Indicator	Performance Standard	Surveillance Methods
Supporting Documentation (progress reports, standard operating procedures, BPRs, etc.) QAU (5.1), QCU (5.2), and VDADU (5.7)	Contractor provides supporting documentation in accordance with (IAW) the PWS.	Supporting documentation is accurate, free of grammatical errors, matches operational procedures/processes and meets identified standards. Documentation is delivered within established timeframes.	Periodic inspection (to confirm adherence to established standards and delivery dates) conducted on an ongoing basis.
Seed Preparation and Fermentation (5.3)	Contractor performs the required tasks IAW the PWS.	Contractor produces as scheduled and meets batch production record specifications.	≥95% yearly compliance to production schedule- quarterly performance review
Purification (5.4)	Contractor performs the required tasks IAW the PWS.	Contractor produces as scheduled and meets batch production record specifications.	≥95% yearly compliance to production schedule- quarterly performance review
Viral Products (5.5)	Contractor performs the required tasks IAW the PWS.	Contractor produces as scheduled and meets batch production record specifications.	≥95% yearly compliance to production schedule- quarterly performance review
Formulation and Filling (5.6)	Contractor performs the required task IAW the PWS.	Contractor produces as scheduled and meets batch production record specifications.	≥95% yearly compliance to production schedule- quarterly performance review

Technical Exhibit B: Quality Assurance Surveillance Plan

A. Introduction. This Quality Assurance Surveillance Plan (QASP) has been developed to set forth procedures and guidelines that will be used to evaluate the technical performance of the Contractor.

B. Purpose. The QASP is intended to accomplish the following:

Define the role and responsibilities of participating Government inspection/surveillance officials.

Refer to the types of work to be performed (i.e., specialized technical and administrative operational support for the Walter Reed Army Institute of Research (WRAIR) Pilot Bioproduction Facility (PBF)).

Describe the evaluation methods that will be employed by the Government in assessing the Contractor's performance.

Provide copies of any quality assurance (QA) monitoring forms that will be used by the Government in documenting and evaluating the Contractor's performance.

Describe the process of performance documentation.

C. Roles and Responsibilities. The following Government officials will participate in assessing the quality of the Contractor's performance. The roles and responsibilities are:

Contracting Officer's Representative (COR). The COR will be responsible for monitoring, assessing, recording, and reporting on the technical performance of the Contractor on a day-to-day basis. The COR will have primary responsibility for documenting the inspection and evaluation of the Contractor's work performance.

Contracting Officer (CO). The CO will be responsible for the execution and administration of this contract on behalf of the Government. The CO is the only official that can bind the Government contractually.

D. Types of Work Performed. This work statement requires specialized technical and administrative personnel to operate the PBF. Specifically, the Contractor shall provide specialized services for vaccine production.

E. Methods of Surveillance. The Government will use the following methods of surveillance to monitor the Contractor's performance:

100% Periodic Inspection (including on-site
observation of performance)

F. Quality Assurance Documentation. The Contract Discrepancy Report (CDR) is a required form. With the exception of the CDR, the COR may document surveillance results in any format. The COR will forward copies of QA documentation to the Contractor as needed (i.e., the documentation contains negative findings on the Contractor's performance), or upon request by the Contractor.

G. Progress Reports. The Contractor shall provide quarterly progress reports to the COR in accordance with the PWS. The Contractor shall provide a copy of each progress report at the same time to the CO.

KEY PERSONNEL

1. The following individuals under this requirement are Key Personnel:

a. Fermentation Specialist, Head

- b. Purification Manager, Head
- c. Filling and Formulation Manager, Head
- d. Viral Products, Head
- e. Quality Assurance Manager, Head
- f. Quality Control Manager, Head
- g. Viral Diagnostics and Assay Development, Head

2. These individual shall have the following taskings and qualifications:

a. Fermentation Specialist, Head

General: Serves as Head, Fermentation Section in Pilot Bioproduction Facility, Walter Reed Army Institute of Research. Performs duties associated with the design, start-up, evaluation, validation, and maintenance of fermentation systems as they are applied to the fermentation of prokaryotic and eukaryotic cells. Fermentation harvests will be processed and purified so that end products can be used for human vaccines and biological products.

Specific Duties: Plans schedules for fermentation of desired materials; makes recommendations for production of desired products based on research data received from research personnel; responsible for all levels of fermentation, from bench scale to 400 liters; responsible for process development when this is necessary prior to full-scale production; responsible for optimizing growth of various prokaryotic and eukaryotic cells so that optimal yields are available for processing. Depending on the desired product, will harvest cells intact, or when desired, process cells through various stages of downstream processing using various types of equipment to accomplish this. Responsible for writing Standard Operating Procedures, Batch Production Records, and any other documents that are required to maintain documentation and compliance with current Good Manufacturing Procedures. Ensures that all data is entered in records to be maintained on file for each product.

Knowledge required: Professional knowledge of the principles and practices applicable to fermentation and downstream processing. Knowledge of operation of fermenters from bench capacity to 400 liters. Knowledge of operation of centrifuges, ultrafiltration, and cell disruption equipment. Familiarity with related fields such as microbial physiology, general microbiology, microbial fermentation, mammalian cell culture, physical chemistry, and biochemistry. This knowledge could be acquired through formal course work or by experience in the field. Extensive knowledge of Good Manufacturing Practices as applied to biological products.

Education and Training: BS degree in Engineering or the Life Sciences; 10 years experience operating fermentation under GMP; 15 total years experience in the biotechnology field

b. Purification Manager, Head

General: Serves as manager and Head, Purification Section in the Pilot Bioproduction Facility, Walter Reed Army Institute of Research. Performs duties associated with the downstream processing and purification of cells and cell products for use in human vaccines and biological products.

Specific Duties: As a Section manager, directs the planning and scheduling of purification of desired products; makes recommendations for purification of desired products based on research data received from research personnel. If necessary, will advise on further research to be conducted by appropriate personnel and/or work with the personnel to perfect purification processes. Purification Section is responsible for all types of purification and downstream processing and the use of various equipment to meet these goals. Responsible for perfecting purification procedures that will result in optimal recoveries. Starting materials will be concentrated suspensions of bacteria, yeast, mammalian cells, or insect cells. Depending on the desired product, will harvest cells intact, or when desired, process cells through various stages of downstream processing using appropriate equipment to accomplish this. Section personnel are responsible for writing Standard Operating Procedures, Batch Production Records, and any other documents that are required to maintain documentation and compliance with current Good Manufacturing Procedures.

Knowledge Required: Professional knowledge of the principles and practices applicable to purification and downstream processing of materials for vaccines destined for clinical testing. Knowledge of operation of centrifuges (large and small-scale), ultrafiltration, and cell disruption equipment. Knowledge of column chromatography and other purification methodologies. Knowledge of facility support equipment such as water for injection, RODI water, and Hepa filtration HVAC systems. Familiarity with related fields such as general microbiology, physical chemistry, and biochemistry. Extensive knowledge of Good Manufacturing Practices as applied to biological products.

Education and Training: MS degree in Biochemistry or the Life Sciences with at least 10 years experience in scaled purification. Recent certification of training in GMP regulations.

c. Filling and Formulation Manager, Head

General: Responsible for all filling operations for the, Pilot Bioproduction Facility, Walter Reed Army Institute of Research. All bulk vaccines will be scheduled for filling in vials using either an automatic filling machine or by semiautomatic/manual filling protocols. Products may also require freeze-drying as part of the protocol. The filling room is a certified Class 100 clean room that requires decontamination and environmental monitoring on a routine basis. The Manager must ensure that all products that are filled into final containers for use in humans meet all specifications for safety, potency, and efficacy.

Specific Duties: Responsible for scheduling of products that require filling and freeze-drying; operation and non-contract maintenance of the filling machines, freeze-dryer, and sterilization equipment; preparation of all glassware, reagents, and materials that are used for a filling operation; preparation of a Batch Production Record (BPR) for each fill (and listed as the Principal Investigator on this record); procurement of labels for the product being filled; and completion of all data required for the fill. Develops freeze-drying processes by experimentally determining optimal parameters for particular products.

Knowledge Required: Microbiology laboratory experience with knowledge of freeze-drying of bacteria and viruses. Knowledge of GMP regulations pertaining to vaccines.

Education and Training: A minimum of five years experience in filling of parenteral products under GMP conditions.

d. Viral Products, Head

General: Head, Viral Vaccine Section, Pilot Bioproduction Facility, Walter Reed Army Institute of Research. The virologist is responsible for the process development and manufacture of viral vaccines for human use. Current vaccine projects include dengue, Japanese encephalitis, and HIV. Vaccine candidates may be whole virus-inactivated, live-attenuated, recombinant sub-unit or live-vectored immunogens.

Specific Duties: Responsible for all viral vaccine candidate development and production. Research discoveries will be implemented for this process. Optimizes growth of virus in cell cultures and scale these processes to the desired level of production; prepares master and production seeds; develops any processes such as concentration and purification required for the desired product; writes Standard Operating Procedures and Batch Production Records for full GMP documentation of production; directs the appropriate safety tests required for the product and provide documents for FDA submission.

Knowledge Required: Knowledge and implementation of Good Manufacturing Practices (GMP) and manufacture of vaccines are desirable. Specific knowledge and experience in cell culture husbandry, virus seed preparation, and aseptic procedures. Experienced in the use of laboratory equipment including centrifuges, tangential flow filters, autoclaves, and other standard equipment. Knowledge and use of viral plaque assays, hemagglutination, ELISA, and other standard viral assays.

Education and Training: BS/MS in microbiology. At least 10 years experience in virology and cell culture technology. Experience may substitute for formal education. Recent certification in GMP regulations.

e. Quality Assurance Manager, Head

General: Provides leadership and accurate information based on current Good Manufacturing Practices (cGMP) and other governing regulatory documentation to Pilot Bioproduction Facility staff. Directs work and manages the Quality Assurance, Inventory and Calibration staff. Makes continuous improvements to the Pilot Bioproduction Facility (PBF) and Quality Systems to execute and implement cGMP and increase system efficiency. Designs (if required) and implements the following cGMP systems: Internal Training, Deviation, Failure Investigation, Critical Change Control, Corrective Action, Internal Auditing, and External Auditing. Coordinates the following programs: calibration, inventory, documentation, preventative maintenance, equipment, validation and cleaning. Provides guidance and training to all Biologics staff and Principal Investigators on compliance (cGMPs) and Quality Systems. Directs the work of all outside contractors performing work for the Quality Assurance (QA) Dept and as directed by the Dept Chief. Assists with supplying regulatory information (IND submissions, etc.) as directed by the Dept Chief. Supports Principal Investigators and CRADA Partners as required with compliance and regulatory concerns. Provides back-up support to Dept Chief and coordinates to meet the facility quality goals. Provides assistance to all Facility Section Heads on cGMP issues. Note: the Dept Chief, as required, will assign other duties.

Specific Duties: Writes, reviews and edits Batch Production Records (BPRs), Validation Reports, Protocols, Forms, and Standard Operating Procedures (SOPs). Has signature authority for disposition of final and in-process products; has review and signature authority for Product Certificates of Analysis. Interfaces with Program Manager, Human Resources (HR), Payroll Dept Chief, etc. to provide information to staff and address staff concerns. Provides assistance with review and resolution of deviations, failure investigations, and critical change and validation documents. Collects, reviews, rectifies, and trends data (QC, Calibration, Water, BPR, Environmental, etc.). Performs and trains and directs QA staff to perform internal and external audits and assist in correcting audit deficiencies. Manages the updating of all documentation and tracking information periodically (spreadsheets, database, logs, etc.). Assists in resolving, documenting and performing corrective actions for failures that occur at or are related to the PBF, including facility repairs, utilities, equipment and instruments. Trains QA staff on cGMPs and Quality Systems. Verifies labels as required. Interacts with building monitoring system to ensure equipment remains in proper state of operation. Notifies Section Heads if production equipment fails. Provides service to Production Personnel, CRADA partners, and Principal Investigators to ensure their quality compliance needs are met. Assists Dept Chief with budgeting for the QA section. Backs up other QA staff members as needed.

Knowledge Required: GMP and regulatory training and a full understanding of inventory control or material management from a Biotechnology, Pharmaceutical or related facility. Familiarity with Microsoft Excel 5.0, WordPerfect 8.0 and Access 2000 (or higher versions). Ability to follow directions, written policies, and procedures for all work responsibilities.

Education and Training: A BS/BA degree in Biology or related field. At least six years employment at a Biotechnology, Pharmaceutical or related facility. At least four years experience in QA in the areas of documentation control, raw material management, instrument calibration, validation, repair, facility system controls, internal and external audit competency and compliance training expertise. Experience in GMP production and cGMP/GLP.

f. Quality Control, Manager, Head

General: Directs and develops testing for microbiological, serological, environmental, in-house facility system and chemical analysis services, as it relates to the products manufactured at the Pilot Bioproduction Facility, Walter Reed Army Institute of Research.

Specific Duties: Oversees a group of qualified analysts and is responsible for all aspects of quality control testing and data generation. Specific duties include raw material testing, water and air analysis, environmental monitoring and data trending, as well as upstream, intermediate and final product analysis in accordance with current Good Manufacturing Practices (cGMP) and the Code of Federal Regulations 21 CFR 58, Good Laboratory Practices

(GLP). Maintains a validated and calibrated laboratory that will generate data used for Investigational New Drug submissions to the FDA. Will be directly involved in the generation of product testing summary reports and Certificates of Analyses generation in conjunction with the QA unit.

Knowledge Required: At least six years of experience in quality control relating to testing biological material and documented GLP and GMP experience. Must possess skills using various types of analytical and laboratory equipment, as well as proficiency with IBM compatible software including spreadsheet programs and word processing programs. Must also have two years managerial/supervisory experience.

Education and Training: A BA/BS in Engineering or Science and at least six years of experience in quality control relating to testing biological material.

g. Viral Diagnostics and Assay Development, Head

General: Directs testing and develops assays for viral products manufactured at the Pilot Bioproduction Facility, Walter Reed Army Institute of Research.

Specific Duties: Oversees a group of qualified technicians that is responsible for all aspects of testing for quality and safety of viral products that are required in the development process. Testing may include assay of infectivity, protein and antigen content, potency, purity and other characterization assays required for complete analysis of final products or intermediates. Some assays may require custom development for new products and writing of standard operating procedures. Assays may also need qualification or validation depending on the level of regulatory scrutiny that is anticipated. Assay results will be used for regulatory support of potency and safety of products intended for human use. Maintains a validated and calibrated laboratory that will generate data used for Investigational New Drug submissions to the FDA. Will be directly involved in the generation of product testing summary reports and Certificates of Analyses.

Knowledge Required: At least six years of experience in viral assay development and testing of viral products documented GLP and GMP experience. Must possess skills using various types of analytical and laboratory equipment, as well as proficiency with IBM compatible software including spreadsheet programs and word processing programs. Must also have four years of managerial/supervisory experience.

Education and Training: A MS degree in biology or related science and at least six years of experience in viral testing.

SECURITY REQUIREMENTS

All proposed personnel to perform services contractor must verify employment eligibility (E-Verify) and also obtain a favorable National Agency Check (NACI).

CLAUSES INCORPORATED BY FULL TEXT**CONTRACTOR MANPOWER REPORTING (CMR) - (ACCOUNTING FOR CONTRACT SERVICES) (APR 2011) (USAMRAA)**

The Office of the Assistant Secretary of the Army (Manpower & Reserve Affairs) operates and maintains a secure Army data collection site where the contractor will report ALL contractor manpower (including sub-contractor manpower) required for performance of this contract. The contractor is required to completely fill in all the information in the format using the following web address: <https://cmra.army.mil>. The required information includes: (1) Contract Number; (2) Delivery Order Number (If applicable); (3) Task Order Number (If applicable); (4) Requiring Activity Unit Identification Code (UIC); (5) Command; (6) Contractor Contact Information; (7) Federal Service Code (FSC); (8) Direct Labor Hours; (9) Direct Labor Dollars; and, (10) Location. In the event the Contracting Officer's Representative (COR)/Contracting Officer's Technical Representative (COTR) has not entered their data requirements first, the contractor must also enter the COR/COTR required data with the exception of fund cite, obligations, and disbursement data. The CMRA help desk can be reach at 703-695-5103 or 703-695-5058 for any technical questions. The help desk can also be contacted via email: contractormanpower@hqda.army.mil. As part of its quote or offer, the contractor will also provide the estimated total cost (if any) incurred to comply with this reporting requirement. The reporting period will be the period of performance not to exceed 12 months ending 30 September of each government fiscal year and must be reported by 31 October of each calendar year.

ORGANIZATIONAL AND CONSULTANT CONFLICTS OF INTEREST (MAR 1999) (USAMRAA)

- a. It is recognized by the parties hereto that the effort performed by the contractor under this contract is of a nature that it creates a potential organizational conflict of interest as is contemplated under the FAR Subpart 9.5.
- b. In the performance of this contract, the contractor may have access to data which is procurement sensitive or is proprietary to other companies, Government consultants or advisors, or the Government. The contractor agrees that he will not utilize such procurement sensitive or proprietary data in performance of future competitive contracts, for studies in the same field, procured either through sealed bids or competitive negotiations. The contractor further agrees not to act as a subcontractor or consultant to any other prime contractor or subcontractor seeking to utilize such data.
- c. The contractor will include the provisions of paragraphs a and b in every first tier subcontract for performance of any portion of this requirement.
- d. This clause shall have effect from **Date of Award** to **Final Date of Performance**.

SAFEGUARDING PROPRIETARY INFORMATION (MAY 1999) (USAMRAA)

- a. "Proprietary information" shall mean all information, whether disclosed orally, in writings, by drawings, or otherwise relating to the work to be performed under this contract, whether proprietary to the Government or one of its collaborating partners. Proprietary information includes, but is not limited to, information regarding properties, formulae, structures, manufacturing processes, and test results. Information ceases to be proprietary when it is generally available to the public or is available from sources other than the Department of the Army. All information submitted to the contractor under this contract shall be presumed to be proprietary to the Department of the Army or one of its collaborating partners until the Department of the Army announces to the contrary.
- b. The contractor shall safeguard proprietary information both during and after the term of this contract, and shall neither appropriate, nor disclose, nor make unauthorized use of the proprietary information received under this contract. The requirements of this paragraph include, but are not limited to, the following:
- (1) Maintenance of a high degree of physical security over proprietary information at all times;
 - (2) Discussion of proprietary information only among contractor's employees whose duties and responsibilities require knowledge of that information; and,
 - (3) Elimination of proprietary information in open publications by the contractor and its personnel.
- c. The contractor shall require all personnel who receive proprietary information to execute the statement in paragraph d below when this contract becomes effective or when first employed (if employed after the contract becomes effective). All statements executed pursuant to this paragraph shall be forwarded to the U.S. Army Medical Research Acquisition Activity when this contract terminates, when the employment ends, or upon request of the Contracting Officer.
- d. The following statement shall be executed pursuant to paragraph c above:

I hereby acknowledge that I have been informed that my duties may require that I have access to proprietary information. I understand this proprietary information which I will receive includes, but is not limited to, properties, formulae, structures, protocols, manufacturing processes, and test results.

I agree that I will neither appropriate nor disclose nor make unauthorized use of proprietary information both during and after my employment. I further agree that I will neither include nor draw upon proprietary information received under this contract in open publication. This agreement is executed with the intention that collaborating partners of the United States Government who have submitted information to the Government under non-disclosure obligations shall be third party beneficiary hereunder, and shall have the right to enforce the obligations undertaken herein.

Name:

Date:

e. The contractor shall insert the substance of paragraphs a through d above in each subcontract hereunder. Compliance with the provisions of this clause shall be the responsibility of the contractor.

GOOD LABORATORY PRACTICES (DEC 2006) (USAMRAA)

The conduct of studies on investigational new drugs or devices shall comply with the GOOD LABORATORY PRACTICE (GLP) FOR NONCLINICAL LABORATORY STUDIES regulations 21 CFR 58. The contractor shall notify the Administrative Contracting Officer by telephone immediately upon announcement by a representative of the Food and Drug Administration (FDA) of an inspection of studies performed under this contract. In addition to the FDA representative, the Contracting Officer's Representative (COR) shall have access to the contractor's records and specimens. With reference to paragraph 58.195(h) of the GLP regulations, the contractor shall notify the COR in writing in addition to the FDA, should the contractor go out of business and/or transfer the records during the periods prescribed in paragraph 58.195. On expiration or termination of the contract, the contractor shall notify the COR of any remaining unused test articles.

CURRENT GOOD MANUFACTURING PRACTICES (DEC 2006) (USAMRAA)

The drug or biological drug products required by this contract shall be developed and produced in compliance with the CURRENT GOOD MANUFACTURING PRACTICE (CGMP) FOR FINISHED PHARMACEUTICALS regulations for parenteral products, 21 CFR, Part 211. Results of routine FDA inspections for licensed facilities as recorded on Form FDA 482 shall be supplied to the Contracting Officer's Representative and become part of the contract file.

USE OF TECHNICAL REFERENCE FACILITY (APR 2005) (USAMRAA)

The contractor agrees to use, to the extent practical, the technical reference facilities of the Defense Technical Information Center (DTIC) for the purpose of surveying existing knowledge and avoiding needless duplication of scientific and engineering effort and the expenditure thereby represented. The DTIC headquarters office is located at 8725 John J. Kingman Road, Fort Belvoir, VA 22060-6218. Information can also be obtained via the Internet at <http://www.dtic.mil> or via the toll-free number for the DTIC help desk, 1-800-225-3842. To the extent practical, all other sources, whether or not Government controlled, should be consulted for the same purpose.

INVESTIGATING AND REPORTING POSSIBLE SCIENTIFIC MISCONDUCT (MAR 1999) (USAMRAA)

- a. "Misconduct" or "Misconduct in Science" is defined as fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.
- b. Contractors shall foster a research environment that prevents misconduct in all research and that deals forthrightly with possible misconduct associated with research for which U.S. Army Medical Research and Materiel Command funds have been provided or requested.
- c. The contractor agrees to:
- (1) Establish and keep current an administrative process to review, investigate, and report allegations of misconduct in science in connection with research conducted by the contractor;
 - (2) Comply with its own administrative process;
 - (3) Inform its scientific and administrative staff of the policies and procedures and the importance of compliance with those policies and procedures;
 - (4) Take immediate and appropriate action as soon as misconduct on the part of employees or persons within the organization's control is suspected or alleged; and
 - (5) Report to the Administrative Contracting Officer (ACO) a decision to initiate an investigation into possible scientific misconduct.
- d. The contractor is responsible for notifying the ACO of appropriate action taken if at any stage of an inquiry or investigation any of the following conditions exist:
- (1) An immediate health hazard is involved;
 - (2) There is an immediate need to protect Federal funds or equipment;
 - (3) A probability exists that the alleged incident will be reported publicly; or
 - (4) There is a reasonable indication of possible criminal violation.

52.035-4030 CONTRACTOR SAFETY AND REPORTING (NON-BDRP) (DEC 2006) (USAMRAA)

- a. The contractor shall operate under established safety programs for all biosafety levels of work as identified in the Safety Program Plan, which is incorporated in this contract. The safety programs shall ensure that personnel, facilities, and the environment are protected from accidents and hazardous exposures.
- b. The contractor shall conduct this contract work under established operating procedures which ensure that all individuals who have access to areas for storage, handling, and disposal of etiologic agents are trained and are thoroughly familiar with safety requirements. Such procedures shall assure full compliance with the regulatory standards cited above.
- c. The contractor shall conduct an inspection and report the results of all required biosafety inspections for all Research, Development, Test, or Evaluation work in accordance with the below listed timeframes. As a minimum the safety inspections shall address those factors identified in the Safety Program Plan.

1. For Biosafety Level (BL) 1 and 2:

Time	Inspector
Preaward	Government designated Biosafety Officer
Quarterly	Contractor safety personnel
Weekly	First line supervisor

2. For Biosafety Level (BL) 3:

Time	Inspector
Preaward	Government designated Biosafety Officer
Monthly	Contractor safety personnel
Annual	Government designated Biosafety Officer
Weekly	First line supervisor

3. For Biosafety Level (BL) 4:

Time	Inspector
Preaward	Government designated Biosafety Officer
Monthly	Contractor safety personnel
Annual	Government designated Biosafety Officer
Weekly	First line supervisor

4. Copies of all biosafety inspection reports will be distributed as follows:

Original: In the contractor's records

One copy to the following:

- a. US Army Medical Research and Materiel Command
ATTN: MCMR-ZC-SSE
504 Scott Street
Fort Detrick, Maryland 21702-5012
- b. US Army Medical Research and Materiel Command
ATTN: MCMR-ZB-DRI
504 Scott Street
Fort Detrick, Maryland 21702-5012
- c. US Army Medical Research Acquisition Activity
ATTN: MCMR-AAA-W
820 Chandler Street
Fort Detrick, Maryland 21702-5014

REPORTS, MANUSCRIPTS AND PUBLIC RELEASES (DEC 2006) (USAMRAA)

- a. Contractors are encouraged to publish results of research supported by the US Army Medical Research and Materiel Command (USAMRMC) in appropriate media forum. Any publication, report or public release, which may create a statutory bar to the issuance of a patent on any subject invention, shall be coordinated with appropriate patent counsel.
- b. Manuscripts intended for publication in any media shall be submitted to the Contracting Officer and Contracting Officer's Representative (COR), simultaneously with submission for publication. Review of such manuscripts is for comment to the Principal Investigator, not for approval or disapproval. Courtesy copies of the reprint shall be forwarded to the Contracting Officer and COR, even though publication may be subsequent to the expiration of the contract.

c. The Contractor shall notify the Contracting Officer of planned news releases, planned publicity, advertising material concerning contract work, and planned presentations to scientific meetings, prior to public release. This is not intended to restrict dissemination of research information but to allow USAMRMC advance notice in order to adequately respond to inquiries.

d. Manuscripts, reports, public releases and abstracts, which appear in professional journals, media and programs, shall include the following statements:

(1) "This work is supported by the US Army Medical Research and Materiel Command under Contract No. **TBD.**"

(2) "The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation."

(3) As applicable, if the research involves the use of animals, the Contractor must include the following statement: "In conducting research using animals, the investigator(s) adhered to the Animal Welfare Act Regulations and other Federal statutes relating to animals and experiments involving animals and the principles set forth in the current version of the Guide for Care and Use of Laboratory Animals, National Research Council."

(4) As applicable, if the research involves human use, the Contractor must include the following statement: "In the conduct of research where humans are the subjects, the investigator(s) adhered to the policies regarding the protection of human subjects as prescribed by Code of Federal Regulations (CFR) Title 45, Volume 1, Part 46; Title 32, Chapter 1, Part 219; and Title 21, Chapter 1, Part 50 (Protection of Human Subjects)."

(5) As applicable, if the research involves the use of recombinant DNA, the Contractor must include the following statement: "In conducting work involving the use of recombinant DNA the investigator(s) adhered to the current version of the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules."

KEY PERSONNEL (MAR 1999) (USAMRAA)

a. The Contractor agrees to utilize the following Key Personnel on this contract:

Fermentation Specialist, Head
Purification Manager, Head
Filling and Formulation Manager, Head
Viral Products, Head
Quality Assurance Manager, Head
Quality Control Manager, Head
Viral Diagnostics and Assay Development, Head

b. The above Key Personnel shall be utilized as necessary to fulfill the requirements of this contract.

c. The offerer must provide thorough and detailed documentation of the experience, abilities, and background for Key Personnel under this contract in the form of resumes or equivalent statements of qualifications. Such documentation should include but not be limited to: name, curriculum vitae, type and description of experience.

d. The contractor agrees that during the contract performance period substitution for Key Personnel shall not be permitted unless such substitution is necessitated by sudden illness, death, or termination of employment. In any of these events, the contractor shall promptly notify the Contracting Officer and provide the information required by paragraph (e) below.

e. All requests for substitutions must provide a detailed

explanation of the circumstances necessitating the proposed substitution(s), a complete resume for the proposed substitute(s), and any other information requested by the Contracting Officer needed to approve or disapprove the proposed substitution(s). All proposed substitutes shall have qualifications that are equal to or higher than the qualifications of the person to be replaced. The Contracting Officer or his authorized representative will evaluate such requests and promptly notify the contractor of his approval or disapproval thereof.

f. If any of the listed Key Personnel are subcontractor personnel, the contractor shall include the substance of this clause in any subcontract which he awards under this contract.

Section D - Packaging and Marking

Packaging shall be standard commercial to ensure acceptance by common carrier for safe delivery to destination unless other specified in the work statement. All items shall be **MARKED FOR TBD.**

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	Destination	Government	N/A	Government
0002	N/A	N/A	N/A	Government
0003	Destination	Government	N/A	Government
1001	Destination	Government	N/A	Government
1002	N/A	N/A	N/A	Government
1003	Destination	Government	N/A	Government
2001	Destination	Government	N/A	Government
2002	N/A	N/A	N/A	Government
2003	Destination	Government	N/A	Government
3001	Destination	Government	N/A	Government
3002	N/A	N/A	N/A	Government
3003	Destination	Government	N/A	Government
4001	Destination	Government	N/A	Government
4002	N/A	N/A	N/A	Government
4003	Destination	Government	N/A	Government

CLAUSES INCORPORATED BY FULL TEXT

52.246-4 INSPECTION OF SERVICES--FIXED-PRICE (AUG 1996)

(a) Definitions. "Services," as used in this clause, includes services performed, workmanship, and material furnished or utilized in the performance of services.

(b) The Contractor shall provide and maintain an inspection system acceptable to the Government covering the services under this contract. Complete records of all inspection work performed by the Contractor shall be maintained and made available to the Government during contract performance and for as long afterwards as the contract requires.

(c) The Government has the right to inspect and test all services called for by the contract, to the extent practicable at all times and places during the term of the contract. The Government shall perform inspections and tests in a manner that will not unduly delay the work.

(d) If the Government performs inspections or tests on the premises of the Contractor or a subcontractor, the Contractor shall furnish, and shall require subcontractors to furnish, at no increase in contract price, all reasonable facilities and assistance for the safe and convenient performance of these duties.

(e) If any of the services do not conform with contract requirements, the Government may require the Contractor to perform the services again in conformity with contract requirements, at no increase in contract amount. When the defects in services cannot be corrected by reperformance, the Government may (1) require the Contractor to take necessary action to ensure that future performance conforms to contract requirements and (2) reduce the contract

price to reflect the reduced value of the services performed.

(f) If the Contractor fails to promptly perform the services again or to take the necessary action to ensure future performance in conformity with contract requirements, the Government may (1) by contract or otherwise, perform the services and charge to the Contractor any cost incurred by the Government that is directly related to the performance of such service or (2) terminate the contract for default.

(End of clause)

Section F - Deliveries or Performance

DELIVERY INFORMATION

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	UIC
0001	POP 01-APR-2012 TO 31-MAR-2013	N/A	WALTER REED ARMY INSTITUTE OF RESEARCH ROBERT GRANT AVENUE BLDG 503 SILVER SPRING MD 20910-7500 FOB: Destination	W74MYF
0002	POP 01-APR-2012 TO 31-MAR-2013	N/A	WALTER REED ARMY INSTITUTE OF RESEARCH . ROBERT GRANT AVENUE BLDG 503 SILVER SPRING MD 20910-7500 FOB: Destination	W74MYF
0003	31-OCT-2012	1	WALTER REED ARMY INSTITUTE OF RESEARCH ROBERT GRANT AVENUE BLDG 503 SILVER SPRING MD 20910-7500 FOB: Destination	W74MYF
1001	POP 01-APR-2013 TO 31-MAR-2014	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W74MYF
1002	POP 01-APR-2013 TO 31-MAR-2014	N/A	WALTER REED ARMY INSTITUTE OF RESEARCH . ROBERT GRANT AVENUE BLDG 503 SILVER SPRING MD 20910-7500 FOB: Destination	W74MYF
1003	31-OCT-2013	1	WALTER REED ARMY INSTITUTE OF RESEARCH ROBERT GRANT AVENUE BLDG 503 SILVER SPRING MD 20910-7500 FOB: Destination	W74MYF
2001	POP 01-APR-2014 TO 31-MAR-2015	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W74MYF

2002	POP 01-APR-2014 TO 31-MAR-2015	N/A	WALTER REED ARMY INSTITUTE OF RESEARCH . ROBERT GRANT AVENUE BLDG 503 SILVER SPRING MD 20910-7500 FOB: Destination	W74MYF
2003	31-OCT-2014	1	WALTER REED ARMY INSTITUTE OF RESEARCH ROBERT GRANT AVENUE BLDG 503 SILVER SPRING MD 20910-7500 FOB: Destination	W74MYF
3001	POP 01-APR-2015 TO 31-MAR-2016	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W74MYF
3002	POP 01-APR-2015 TO 31-MAR-2016	N/A	WALTER REED ARMY INSTITUTE OF RESEARCH . ROBERT GRANT AVENUE BLDG 503 SILVER SPRING MD 20910-7500 FOB: Destination	W74MYF
3003	31-OCT-2015	1	WALTER REED ARMY INSTITUTE OF RESEARCH ROBERT GRANT AVENUE BLDG 503 SILVER SPRING MD 20910-7500 FOB: Destination	W74MYF
4001	POP 01-APR-2016 TO 31-MAR-2017	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W74MYF
4002	POP 01-APR-2016 TO 31-MAR-2017	N/A	WALTER REED ARMY INSTITUTE OF RESEARCH . ROBERT GRANT AVENUE BLDG 503 SILVER SPRING MD 20910-7500 FOB: Destination	W74MYF
4003	31-MAR-2017	1	WALTER REED ARMY INSTITUTE OF RESEARCH ROBERT GRANT AVENUE BLDG 503 SILVER SPRING MD 20910-7500 FOB: Destination	W74MYF

CLAUSES INCORPORATED BY REFERENCE

52.242-15 Alt I	Stop-Work Order (Aug 1989) - Alternate I
52.247-34	F.O.B. Destination

APR 1984
NOV 1991

Section G - Contract Administration Data

CLAUSES INCORPORATED BY FULL TEXT

ARMY ELECTRONIC INVOICING INSTRUCTIONS (FEB 2006)

Contractor shall submit payment request using the following method(s) as mutually agreed to by the Contractor, the Contracting Officer, the contract administration office, and the payment office.

Wide Area Workflow (WAWF) (see instructions below)

Web Invoicing System (WInS)(<https://ecweb.dfas.mil>)

American National Standards Institute (ANSI) X.12 electronic data interchange (EDI) formats (<http://www.X12.org> and <http://www.dfas.mil/ecedi>)

Other (please specify) _____
DFAS POC and Phone: _____

WAWF is the preferred method to electronically process vendor request for payment. This application allows DOD vendors to submit and track Invoices and Receipt/Acceptance documents electronically. Contractors electing to use WAWF shall (i) register to use WAWF at <https://wawf.eb.mil> and (ii) ensure an electronic business point of contact (POC) is designated in the Central Contractor Registration site at <http://www.ccr.gov> within ten (10) calendar days after award of this contract/order.

WAWF Instructions

*Questions concerning payments should be directed to the Defense Finance and Accounting Service (DFAS) [Contracting Office **fill in DFAS location here as indicated on your purchase order/contract**] at [Contracting Office **fill in DFAS vendor pay phone number here**] or faxed to [Contracting Office **fill in DFAS vendor pay fax phone number here**]. Please have your purchase order/contract number ready when calling about payments.*

You can easily access payment and receipt information using the DFAS web site at <http://www.dfas.mil/money/vendor>. Your purchase order/contract number or invoice number will be required to inquire about the status of your payment.

The following codes and information will be required to assure successful flow of WAWF documents. TYPE OF DOCUMENT [Check the appropriate type]

Commercial Item Financing

Construction Invoice (Contractor Only)

Invoice (Contractor Only)

(Invoice and Receiving Report COMBO)

Invoice as 2-in-1 (Services Only)

Performance Based Payment (Government Only)

_____ *Progress Payment (Government Only)*

_____ *Cost Voucher (Government Only)*

_____ *Receiving Report (Government Only)*

_____ *Receiving Report With Unique Identification (UID) Data (Government Only)*

UID is a new globally unique "part identifier" containing data elements used to track DoD parts through their life cycle.

_____ *Summary Cost Voucher (Government Only)*

CAGE CODE: [TBD]

ISSUE BY DODAAC: W81XWH

ADMIN BY DODAAC: W81XWH

INSPECT BY DODAAC: [TBD]

ACCEPT BY DODAAC: [TBD]

SHIP TO DODAAC: [Enter Ship to DODAAC(s) here]

LOCAL PROCESSING OFFICE DODDAC: [Enter LPO DODAAC here if applicable]

PAYMENT OFFICE FISCAL STATION CODE: [TBD]

EMAIL POINTS OF CONTACT LISTING: (Use Group e-mail accounts if applicable)

INSPECTOR: [TBD]

ACCEPTOR: [TBD]

RECEIVING OFFICE POC: [TBD]

CONTRACT ADMINISTRATOR: *jennifer.jackson1@us.army.mil*

CONTRACTING OFFICER: *wanda.harper@amedd.army.mil*

ADDITIONAL CONTACT: [TBD]

For more information contact Jennifer Jackson, Contract Specialist, 301-619-2054 or Wanda Harper, Contracting Officer, 301-619-8094.

TRAVEL (JULY 2007) (USAMRAA)

a. Approval of Foreign Travel. The cost of foreign travel is allowable only when the specific written approval of the Contracting Officer is obtained prior to commencing the trip. Approval shall be requested at least 90 calendar days before the scheduled departure date in order that all necessary clearances may be processed. Each

individual trip must be approved separately, even though it may have been included in a previously approved budget. Foreign travel under this contract is defined as any travel outside of the United States and its territories and possessions.

b. Costs incurred by contractor personnel on official company business, whether foreign travel and/or domestic/local travel, are allowable, subject to the limitations contained in the Federal Acquisition Regulation (FAR) clause at 52.216-7, Allowable Cost and Payment, incorporated into this contract.

PROPERTY REPORTING (COMMERCIAL) (MAR 1999) (USAMRAA)

The designated property administrator for Government property acquired for use under this contract is the Contract Specialist, US Army Medical Research Acquisition Activity, Fort Detrick, MD 21702-5014. The contractor shall furnish the designated property administrator report, (i.e. DD FORM 1662, DOD Property in the Custody of Contractors).

- a. Interim Inventories - Annually, as of 30 September, report due 10 October, each year.
- b. Final Inventory - When the contract expires.

Section I - Contract Clauses

CLAUSES INCORPORATED BY REFERENCE

52.202-1	Definitions	JUL 2004
52.203-3	Gratuities	APR 1984
52.203-5	Covenant Against Contingent Fees	APR 1984
52.203-6	Restrictions On Subcontractor Sales To The Government	SEP 2006
52.203-7	Anti-Kickback Procedures	OCT 2010
52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity	JAN 1997
52.203-10	Price Or Fee Adjustment For Illegal Or Improper Activity	JAN 1997
52.203-12	Limitation On Payments To Influence Certain Federal Transactions	OCT 2010
52.204-4	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper	MAY 2011
52.204-10	Reporting Executive Compensation and First-Tier Subcontract Awards	JUL 2010
52.208-9	Contractor Use of Mandatory Sources of Supply or Services	OCT 2008
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	JAN 2011
52.209-10	Prohibition on Contracting With Inverted Domestic Corporations	MAY 2011
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
52.215-13	Subcontractor Certified Cost or Pricing Data--Modifications	OCT 2010
52.215-15	Pension Adjustments and Asset Reversions	OCT 2010
52.215-16	Facilities Capital Cost of Money	JUN 2003
52.215-17	Waiver of Facilities Capital Cost of Money	OCT 1997
52.215-19	Notification of Ownership Changes	OCT 1997
52.215-21	Requirements for Certified Cost or Pricing Data or Information Other Than Certified Cost or Pricing Data-- Modifications	OCT 2010
52.215-23	Limitations on Pass-Through Charges	OCT 2009
52.216-7	Allowable Cost And Payment	JUN 2011
52.216-8	Fixed Fee	JUN 2011
52.219-6	Notice Of Total Small Business Set-Aside	JUN 2003
52.219-8	Utilization of Small Business Concerns	JAN 2011
52.219-9	Small Business Subcontracting Plan	JAN 2011
52.219-14	Limitations On Subcontracting	DEC 1996
52.219-16	Liquidated Damages-Subcontracting Plan	JAN 1999
52.222-1	Notice To The Government Of Labor Disputes	FEB 1997
52.222-3	Convict Labor	JUN 2003
52.222-21	Prohibition Of Segregated Facilities	FEB 1999
52.222-26	Equal Opportunity	MAR 2007
52.222-35	Equal Opportunity for Veterans	SEP 2010
52.222-36	Affirmative Action For Workers With Disabilities	OCT 2010
52.222-37	Employment Reports on Veterans	SEP 2010

52.222-41	Service Contract Act Of 1965	NOV 2007
52.222-46	Evaluation Of Compensation For Professional Employees	FEB 1993
52.222-50	Combating Trafficking in Persons	FEB 2009
52.222-54	Employment Eligibility Verification	JAN 2009
52.223-5	Pollution Prevention and Right-to-Know Information	MAY 2011
52.223-6	Drug-Free Workplace	MAY 2001
52.223-10	Waste Reduction Program	MAY 2011
52.223-16 Alt I	IEEE 1680 Standard for the Environmental Assessment of Personal Computer Products (Dec 200&0 Alternate I	DEC 2007
52.223-18	Encouraging Contractor Policies To Ban Text Messaging While Driving	AUG 2011
52.223-19	Compliance with Environmental Management Systems	MAY 2011
52.225-13	Restrictions on Certain Foreign Purchases	JUN 2008
52.225-14	Inconsistency Between English Version And Translation Of Contract	FEB 2000
52.225-25	Prohibition on Engaging in Sanctioned Activities Relating to Iran--Certification.	SEP 2010
52.227-2	Notice And Assistance Regarding Patent And Copyright Infringement	DEC 2007
52.228-7	Insurance--Liability To Third Persons	MAR 1996
52.229-3	Federal, State And Local Taxes	APR 2003
52.232-9	Limitation On Withholding Of Payments	APR 1984
52.232-20	Limitation Of Cost	APR 1984
52.232-22	Limitation Of Funds	APR 1984
52.232-23 Alt I	Assignment of Claims (Jan 1986) - Alternate I	APR 1984
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 Alt I	Protest After Award (Aug 1996) - Alternate I	JUN 1985
52.233-4	Applicable Law for Breach of Contract Claim	OCT 2004
52.237-2	Protection Of Government Buildings, Equipment, And Vegetation	APR 1984
52.237-3	Continuity Of Services	JAN 1991
52.239-1	Privacy or Security Safeguards	AUG 1996
52.242-1	Notice of Intent to Disallow Costs	APR 1984
52.242-3	Penalties for Unallowable Costs	MAY 2001
52.242-4	Certification of Final Indirect Costs	JAN 1997
52.242-13	Bankruptcy	JUL 1995
52.243-1 Alt I	Changes--Fixed Price (Aug 1987) - Alternate I	APR 1984
52.243-2	Changes--Cost-Reimbursement	AUG 1987
52.244-2 Alt I	Subcontracts (Oct 2010) - Alternate I	JUN 2007
52.244-5	Competition In Subcontracting	DEC 1996
52.244-6	Subcontracts for Commercial Items	DEC 2010
52.245-1	Government Property	AUG 2010
52.245-9	Use And Charges	AUG 2010
52.246-25	Limitation Of Liability--Services	FEB 1997
52.249-2	Termination For Convenience Of The Government (Fixed-Price)	MAY 2004
52.249-8	Default (Fixed-Price Supply & Service)	APR 1984
52.249-14	Excusable Delays	APR 1984
52.251-1	Government Supply Sources	AUG 2010
52.253-1	Computer Generated Forms	JAN 1991
252.201-7000	Contracting Officer's Representative	DEC 1991

252.203-7000	Requirements Relating to Compensation of Former DoD Officials	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
252.204-7000	Disclosure Of Information	DEC 1991
252.204-7003	Control Of Government Personnel Work Product	APR 1992
252.204-7004 Alt A	Central Contractor Registration Alternate A	SEP 2007
252.204-7008	Export-Controlled Items	APR 2010
252.205-7000	Provision Of Information To Cooperative Agreement Holders	DEC 1991
252.209-7001	Disclosure of Ownership or Control by the Government of a Terrorist Country	JAN 2009
252.209-7002	Disclosure Of Ownership Or Control By A Foreign Government	JUN 2010
252.209-7004	Subcontracting With Firms That Are Owned or Controlled By The Government of a Terrorist Country	DEC 2006
252.211-7007	Reporting of Government-Furnished Equipment in the DoD Item Unique Identification (IUID) Registry	NOV 2008
252.215-7000	Pricing Adjustments	DEC 1991
252.219-7003	Small Business Subcontracting Plan (DOD Contracts)	SEP 2011
252.222-7000	Restriction On Employment Of Personnel	MAR 2000
252.223-7004	Drug Free Work Force	SEP 1988
252.223-7006	Prohibition On Storage And Disposal Of Toxic And Hazardous Materials	APR 1993
252.225-7001	Buy American Act And Balance Of Payments Program	OCT 2011
252.225-7002	Qualifying Country Sources As Subcontractors	APR 2003
252.225-7012	Preference For Certain Domestic Commodities	JUN 2010
252.225-7026	Acquisition Restricted to Products or Services	APR 2010
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	SEP 2011
252.227-7014	Rights in Noncommercial Computer Software and Noncommercial Computer Software Documentation	MAR 2011
252.227-7016	Rights in Bid or Proposal Information	JAN 2011
252.227-7017	Identification and Assertion of Use, Release, or Disclosure Restrictions	JAN 2011
252.227-7019	Validation of Asserted Restrictions--Computer Software	SEP 2011
252.227-7030	Technical Data--Withholding Of Payment	MAR 2000
252.231-7000	Supplemental Cost Principles	DEC 1991
252.232-7003	Electronic Submission of Payment Requests and Receiving Reports	MAR 2008
252.232-7010	Levies on Contract Payments	DEC 2006
252.239-7001	Information Assurance Contractor Training and Certification	JAN 2008
252.243-7002	Requests for Equitable Adjustment	MAR 1998
252.244-7000	Subcontracts for Commercial Items and Commercial Components (DoD Contracts)	SEP 2011
252.245-7001	Tagging, Labeling, and Marking of Government-Furnished Property	FEB 2011
252.245-7002	Reporting Loss of Government Property	FEB 2011
252.245-7003	Contractor Property Management System Administration	MAY 2011
252.247-7023	Transportation of Supplies by Sea	MAY 2002
252.247-7024	Notification Of Transportation Of Supplies By Sea	MAR 2000

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EXPORT CONTRACT ACT COMPLIANCE (DEC 2006) (USAMRAA)

The contractor shall assess the work to be performed in this effort to assure that all actions are in compliance with the Export Administration Regulations, 15 CFR Part 730 (EAR), of the Export Administration Act of 1979, 50 U.S.C. app. 2401-2420 (EAA). Technology listed in the Commerce Control List (CCL), 15 CFR Part 774, of the EAR shall not be exported or exposed to foreign nationals without the written consent of the U.S. Department of Commerce.

CLAUSES INCORPORATED BY FULL TEXT

52.203-16 Preventing Personal Conflicts of Interest (DEC 2011)

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

Acquisition function closely associated with inherently governmental functions means supporting or providing advice or recommendations with regard to the following activities of a Federal agency:

- (1) Planning acquisitions.
- (2) Determining what supplies or services are to be acquired by the Government, including developing statements of work.
- (3) Developing or approving any contractual documents, to include documents defining requirements, incentive plans, and evaluation criteria.
- (4) Evaluating contract proposals.
- (5) Awarding Government contracts.
- (6) Administering contracts (including ordering changes or giving technical direction in contract performance or contract quantities, evaluating contractor performance, and accepting or rejecting contractor products or services).
- (7) Terminating contracts.
- (8) Determining whether contract costs are reasonable, allocable, and allowable.

Covered employee means an individual who performs an acquisition function closely associated with inherently governmental functions and is--

- (1) An employee of the contractor; or
- (2) A subcontractor that is a self-employed individual treated as a covered employee of the contractor because there is no employer to whom such an individual could submit the required disclosures.

Non-public information means any Government or third-party information that--

- (1) Is exempt from disclosure under the Freedom of Information Act (5 U.S.C. 552) or otherwise protected from disclosure by statute, Executive order, or regulation; or
- (2) Has not been disseminated to the general public and the Government has not yet determined whether the information can or will be made available to the public.

Personal conflict of interest means a situation in which a covered employee has a financial interest, personal activity, or relationship that could impair the employee's ability to act impartially and in the best interest of the Government when performing under the contract. (A de minimis interest that would not "impair the employee's ability to act impartially and in the best interest of the Government" is not covered under this definition.)

(1) Among the sources of personal conflicts of interest are--

- (i) Financial interests of the covered employee, of close family members, or of other members of the covered employee's household;
- (ii) Other employment or financial relationships (including seeking or negotiating for prospective employment or business); and
- (iii) Gifts, including travel.

(2) For example, financial interests referred to in paragraph (1) of this definition may arise from--

- (i) Compensation, including wages, salaries, commissions, professional fees, or fees for business referrals;
- (ii) Consulting relationships (including commercial and professional consulting and service arrangements, scientific and technical advisory board memberships, or serving as an expert witness in litigation);
- (iii) Services provided in exchange for honorariums or travel expense reimbursements;
- (iv) Research funding or other forms of research support;
- (v) Investment in the form of stock or bond ownership or partnership interest (excluding diversified mutual fund investments);
- (vi) Real estate investments;
- (vii) Patents, copyrights, and other intellectual property interests; or
- (viii) Business ownership and investment interests.

(b) Requirements. The Contractor shall--

(1) Have procedures in place to screen covered employees for potential personal conflicts of interest, by--

(i) Obtaining and maintaining from each covered employee, when the employee is initially assigned to the task under the contract, a disclosure of interests that might be affected by the task to which the employee has been assigned, as follows:

(A) Financial interests of the covered employee, of close family members, or of other members of the covered employee's household.

(B) Other employment or financial relationships of the covered employee (including seeking or negotiating for prospective employment or business).

(C) Gifts, including travel; and

(ii) Requiring each covered employee to update the disclosure statement whenever the employee's personal or financial circumstances change in such a way that a new personal conflict of interest might occur because of the task the covered employee is performing.

(2) For each covered employee--

(i) Prevent personal conflicts of interest, including not assigning or allowing a covered employee to perform any task under the contract for which the Contractor has identified a personal conflict of interest for the employee that the Contractor or employee cannot satisfactorily prevent or mitigate in consultation with the contracting agency;

(ii) Prohibit use of non-public information accessed through performance of a Government contract for personal gain; and

(iii) Obtain a signed non-disclosure agreement to prohibit disclosure of non-public information accessed through performance of a Government contract.

(3) Inform covered employees of their obligation--

(i) To disclose and prevent personal conflicts of interest;

(ii) Not to use non-public information accessed through performance of a Government contract for personal gain; and

(iii) To avoid even the appearance of personal conflicts of interest;

(4) Maintain effective oversight to verify compliance with personal conflict-of-interest safeguards;

(5) Take appropriate disciplinary action in the case of covered employees who fail to comply with policies established pursuant to this clause; and

(6) Report to the Contracting Officer any personal conflict-of-interest violation by a covered employee as soon as it is identified. This report shall include a description of the violation and the proposed actions to be taken by the Contractor in response to the violation. Provide follow-up reports of corrective actions taken, as necessary. Personal conflict-of-interest violations include--

(i) Failure by a covered employee to disclose a personal conflict of interest;

(ii) Use by a covered employee of non-public information accessed through performance of a Government contract for personal gain; and

(iii) Failure of a covered employee to comply with the terms of a non-disclosure agreement.

(c) Mitigation or waiver. (1) In exceptional circumstances, if the Contractor cannot satisfactorily prevent a personal conflict of interest as required by paragraph (b)(2)(i) of this clause, the Contractor may submit a request through the Contracting Officer to the Head of the Contracting Activity for--

(i) Agreement to a plan to mitigate the personal conflict of interest; or

(ii) A waiver of the requirement.

(2) The Contractor shall include in the request any proposed mitigation of the personal conflict of interest.

(3) The Contractor shall--

(i) Comply, and require compliance by the covered employee, with any conditions imposed by the Government as necessary to mitigate the personal conflict of interest; or

(ii) Remove the Contractor employee or subcontractor employee from performance of the contract or terminate the applicable subcontract.

(d) Subcontract flowdown. The Contractor shall include the substance of this clause, including this paragraph (d), in subcontracts--

(1) That exceed \$150,000; and

(2) In which subcontractor employees will perform acquisition functions closely associated with inherently governmental functions (i.e., instead of performance only by a self-employed individual).

(End of clause)

52.204-9 PERSONAL IDENTITY VERIFICATION OF CONTRACTOR PERSONNEL (JAN 2011)

(a) The Contractor shall comply with agency personal identity verification procedures identified in the contract that implement Homeland Security Presidential Directive-12 (HSPD-12), Office of Management and Budget (OMB) guidance M-05-24, and Federal Information Processing Standards Publication (FIPS PUB) Number 201.

(b) The Contractor shall account for all forms of Government-provided identification issued to the Contractor employees in connection with performance under this contract. The Contractor shall return such identification to the issuing agency at the earliest of any of the following, unless otherwise determined by the Government:

(1) When no longer needed for contract performance.

(2) Upon completion of the Contractor employee's employment.

(3) Upon contract completion or termination.

(c) The Contracting Officer may delay final payment under a contract if the Contractor fails to comply with these requirements.

(d) The Contractor shall insert the substance of this clause, including this paragraph (d), in all subcontracts when the subcontractor's employees are required to have routine physical access to a Federally-controlled facility and/or routine access to a Federally-controlled information system. It shall be the responsibility of the prime Contractor to return such identification to the issuing agency in accordance with the terms set forth in paragraph (b) of this section, unless otherwise approved in writing by the Contracting Officer.

(End of Clause)

CLAUSES INCORPORATED BY FULL TEXT

52.217-8 OPTION TO EXTEND SERVICES (NOV 1999)

The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 6 months. The Contracting Officer may exercise the option by written notice to the Contractor within 30 days.

(End of clause)

CLAUSES INCORPORATED BY FULL TEXT

52.217-9 OPTION TO EXTEND THE TERM OF THE CONTRACT (MAR 2000)

(a) The Government may extend the term of this contract by written notice to the Contractor within 30 days; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 60 days before the contract expires. The preliminary notice does not commit the Government to an extension.

(b) If the Government exercises this option, the extended contract shall be considered to include this option clause.

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 5 years.

(End of clause)

CLAUSES INCORPORATED BY FULL TEXT

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

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

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

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

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

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

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

(3) For long-term contracts--

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

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

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

(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 541712- assigned to contract number W81XWH-12-X-XXX.

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

(End of clause)

52.222-42 STATEMENT OF EQUIVALENT RATES FOR FEDERAL HIRES (MAY 1989)

In compliance with the Service Contract Act of 1965, as amended, and the regulations of the Secretary of Labor (29 CFR Part 4), this clause identifies the classes of service employees expected to be employed under the contract and

states the wages and fringe benefits payable to each if they were employed by the contracting agency subject to the provisions of 5 U.S.C. 5341 or 5332.

THIS STATEMENT IS FOR INFORMATION ONLY: IT IS NOT A WAGE DETERMINATION

Employee Class	Monetary Wage-Fringe Benefits
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Administrative Assistant	\$20.29
Administrative Coordinator	\$27.34

(End of clause)

52.232-20 LIMITATION OF COST (APR 1984)

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

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

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

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

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

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

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

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

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

(f) If the estimated cost specified in the Schedule is increased, any costs the Contractor incurs before the increase that are in excess of the previously estimated cost shall be allowable to the same extent as if incurred afterward,

unless the Contracting Officer issues a termination or other notice directing that the increase is solely to cover termination or other specified expenses.

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

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

(End of clause)

52.233-4 APPLICABLE LAW FOR BREACH OF CONTRACT CLAIM (OCT 2004)

United States law will apply to resolve any claim of breach of this contract.

(End of clause)

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):

www.usamraa.army.mil
www.acquisition.gov

(End of provision)

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):

www.usamraa.army.mil
www.acquisition.gov

(End of clause)

52.252-6 AUTHORIZED DEVIATIONS IN CLAUSES (APR 1984)

(a) The use in this solicitation or contract of any Federal Acquisition Regulation (48 CFR Chapter 1) clause with an authorized deviation is indicated by the addition of "(DEVIATION)" after the date of the clause.

(b) The use in this solicitation or contract of any Defense Federal Acquisition Regulation (48 CFR 2) clause with an authorized deviation is indicated by the addition of "(DEVIATION)" after the name of the regulation.

(End of clause)

252.245-7004 REPORTING, REUTILIZATION, AND DISPOSAL (AUG 2011)

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

(1) Demilitarization means the act of eliminating the functional capabilities and inherent military design features from DoD personal property. Methods and degree range from removal and destruction of critical features to total destruction by cutting, tearing, crushing, mangling, shredding, melting, burning, etc.

(2) Export-controlled items means items subject to the Export Administration Regulations (EAR) (15 CFR parts 730-774) or the International Traffic in Arms Regulations (ITAR) (22 CFR parts 120-130). The term includes--

(i) Defense items, defined in the Arms Export Control Act, 22 U.S.C. 2778(j)(4)(A), as defense articles, defense services, and related technical data, etc.; and

(ii) Items, defined in the EAR as ``commodities," ``software," and ``technology," terms that are also defined in the EAR, 15 CFR 772.1.

(3) Ineligible transferees means individuals, entities, or countries--

(i) Excluded from Federal programs by the General Services Administration as identified in the Excluded Parties Listing System (EPLS) (<https://www.epls.gov/>);

(ii) Delinquent on obligations to the U.S. Government under surplus sales contracts;

(iii) Designated by the Department of Defense as ineligible, debarred, or suspended from defense contracts; or

(iv) Subject to denial, debarment, or other sanctions under export control laws and related laws and regulations, and orders

administered by the Department of State, the Department of Commerce, the Department of Homeland Security, or the Department of the Treasury.

(4) Scrap means property that has no value except for its basic material content. For purposes of demilitarization, scrap is defined as recyclable waste and discarded materials derived from items that have been rendered useless beyond repair, rehabilitation, or restoration such that the item's original identity, utility, form, fit, and function have been destroyed. Items can be classified as scrap if processed by cutting, tearing, crushing, mangling, shredding, or melting. Intact or recognizable components and parts are not ``scrap."

(5) Serviceable or usable property means property with potential for reutilization or sale ``as is" or with minor repairs or alterations.

(b) Inventory disposal schedules. Unless disposition instructions are otherwise included in this contract, the Contractor shall complete SF 1428, Inventory Schedule B, within the Plant Clearance Automated Reutilization Screening System (PCARSS). Information on PCARSS can be obtained from the plant clearance officer and at <http://www.dema.mil/ITCSO/CBT/PCARSS/index.cfm>.

(1) The SF 1428 shall contain the following:

(i) If known, the applicable Federal Supply Code (FSC) for all items, except items in scrap condition.

(ii) If known, the manufacturer name for all aircraft components under Federal Supply Group (FSG) 16 or 17 and FSCs 2620, 2810, 2915, 2925, 2935, 2945, 2995, 4920, 5821, 5826, 5841, 6340, and 6615.

(iii) The manufacturer name, make, model number, model year, and serial number for all aircraft under FSCs 1510 and 1520.

(iv) Appropriate Federal Condition Codes. See Appendix 2 of DoD 4000.25-2, Military Standard Transaction Reporting and Accounting Procedures manual, edition in effect as of the date of this contract. Information on Federal Condition Codes can be obtained at http://www.DLA.Mil/J-6/DLMSO/Elibrary/Manuals/Milstrap/AP2_Index.asp.

(2) If the schedules are acceptable, the plant clearance officer shall complete and send the Contractor a DD Form 1637, Notice of Acceptance of Inventory.

(c) Proceeds from sales of surplus property. Unless otherwise provided in the contract, the proceeds of any sale, purchase, or retention shall be--

(1) Forwarded to the Contracting Officer;

(2) Credited to the Government as part of the settlement agreement;

(3) Credited to the price or cost of the contract; or

(4) Applied as otherwise directed by the Contracting Officer.

(d) Demilitarization, mutilation, and destruction. If demilitarization, mutilation, or destruction of contractor inventory is required, the Contractor shall demilitarize, mutilate, or destroy contractor inventory, in accordance with the terms and conditions of the contract and consistent with Defense Demilitarization Manual, DoDM 4160.28-M, edition in effect as of the date of this contract. The plant clearance officer may authorize the purchaser to demilitarize, mutilate, or destroy as a condition of sale provided the property is not inherently dangerous to public health and safety.

(e) Classified Contractor inventory. The Contractor shall dispose of classified contractor inventory in accordance with applicable security guides and regulations or as directed by the Contracting Officer.

(f) Inherently dangerous Contractor inventory. Contractor inventory dangerous to public health or safety shall not be disposed of unless rendered innocuous or until adequate safeguards are provided.

(g) Contractor inventory located in foreign countries. Consistent with contract terms and conditions, property disposition shall be in accordance with foreign and U.S. laws and regulations, including laws and regulations involving export controls, host nation requirements, Final Governing Standards, and Government-to-Government agreements. The Contractor's responsibility to comply with all applicable laws and regulations regarding export-controlled items exists independent of, and is not established or limited by, the information provided by this clause.

(h) Disposal of scrap.

(1) Contractor with scrap procedures.

(i) The Contractor shall include within its property management procedure, a process for the accountability and management of Government-owned scrap. The process shall, at a minimum, provide for the effective and efficient

disposition of scrap, including sales to scrap dealers, so as to minimize costs, maximize sales proceeds, and, contain the necessary internal controls for mitigating the improper release of non-scrap property.

(ii) The Contractor may commingle Government and contractor-owned scrap and provide routine disposal of scrap, with plant clearance officer concurrence, when determined to be effective and efficient.

(2) Scrap warranty. The plant clearance officer may require the Contractor to secure from scrap buyers a DD Form 1639, Scrap Warranty.

(i) Sale of surplus Contractor inventory.

(1) The Contractor shall conduct sales of contractor inventory (both useable property and scrap) in accordance with the requirements of this contract and plant clearance officer direction.

(2) Any sales contracts or other documents transferring title shall include the following statement:

“The Purchaser certifies that the property covered by this contract will be used in (name of country). In the event of resale or export by the Purchaser of any of the property, the Purchaser agrees to obtain the appropriate U.S. and foreign export or re-export license approval.”

(j) Restrictions on purchase or retention of Contractor inventory. (1) The Contractor may not knowingly sell the inventory to any person or that person's agent, employee, or household member if that person--

(i) Is a civilian employee of the DoD or the U.S. Coast Guard;

(ii) Is a member of the armed forces of the United States, including the U.S. Coast Guard; or

(iii) Has any functional or supervisory responsibilities for or within the DoD's property disposal/disposition or plant clearance programs or for the disposal of contractor inventory.

(2) The Contractor may conduct Internet-based sales, to include use of a third party.

(3) If the Contractor wishes to bid on the sale, the Contractor or its employees shall submit bids to the plant clearance officer prior to soliciting bids from other prospective bidders.

(4) The Contractor shall solicit a sufficient number of bidders to obtain adequate competition. Informal bid procedures shall be used, unless the plant clearance officer directs otherwise. The Contractor shall include in its invitation for bids, the sales terms and conditions provided by the plant clearance officer.

(5) The Contractor shall solicit bids at least 15 calendar days before bid opening to allow adequate opportunity to inspect the property and prepare bids.

(6) For large sales, the Contractor may use summary lists of items offered as bid sheets with detailed descriptions attached.

(7) In addition to mailing or delivering notice of the proposed sale to prospective bidders, the Contractor may (when the results are expected to justify the additional expense) display a notice of the proposed sale in appropriate public places, e.g., publish a sales notice on the Internet in appropriate trade journals or magazines and local newspapers.

(8) The plant clearance officer or representative will witness the bid opening. The Contractor shall submit, either electronically or manually, two copies of the bid abstract.

(9) The following terms and conditions shall be included in sales contracts involving the demilitarization, mutilation, or destruction of property:

(i) Demilitarization, mutilation, or destruction on Contractor or subcontractor premises. Item(s) ---- require demilitarization, mutilation, or destruction by the Purchaser. Insert item number(s) and specific demilitarization, mutilation, or destruction requirements for item(s) shown in Defense Demilitarization Manual, DoDM 4160.28-M, edition in effect as of the date of this contract. Demilitarization shall be witnessed and verified by a Government representative using DRMS Form 145 or equivalent.

(ii) Demilitarization, mutilation, or destruction off Contractor or subcontractor premises.

(A) Item(s) ---- require demilitarization, mutilation, or destruction by the Purchaser. Insert item number(s) and specific demilitarization, mutilation, or destruction requirements for item(s) shown in Defense Demilitarization Manual, DoDM 4160.28-M, edition in effect as of the date of this contract. Demilitarization shall be witnessed and verified by a Government representative using DRMS Form 145 or equivalent.

(B) Property requiring demilitarization shall not be removed, and title shall not pass to the Purchaser, until demilitarization has been accomplished and verified by a Government representative. Demilitarization will be accomplished as specified in the sales contract. Demilitarization shall be witnessed and verified by a Government representative using DRMS Form 145 or equivalent.

(C) The Purchaser agrees to assume all costs incident to the demilitarization and to restore the working area to its present condition after removing the demilitarized property.

(iii) Failure to demilitarize. If the Purchaser fails to demilitarize, mutilate, or destroy the property as specified in the contract, the Contractor may, upon giving 10 days written notice from date of mailing to the Purchaser--

(A) Repossess, demilitarize, and return the property to the Purchaser, in which case the Purchaser hereby agrees to pay to the Contractor, prior to the return of the property, all costs incurred by the Contractor in repossessing, demilitarizing, and returning the property;

(B) Repossess, demilitarize, and resell the property, and charge the defaulting Purchaser with all costs incurred by the Contractor. The Contractor shall deduct these costs from the purchase price and refund the balance of the purchase price, if any, to the Purchaser. In the event the costs exceed the purchase price, the defaulting Purchaser hereby agrees to pay these costs to the Contractor; or

(C) Repossess and resell the property under similar terms and conditions. In the event this option is exercised, the Contractor shall charge the defaulting Purchaser with all costs incurred by the Contractor. The Contractor shall deduct these costs from the original purchase price and refund the balance of the purchase price, if any, to the defaulting Purchaser. Should the excess costs to the Contractor exceed the purchase price, the defaulting Purchaser hereby agrees to pay these costs to the Contractor.

(End of clause)

PROHIBITION OF HUMAN RESEARCH (JAN 2007) (USAMRAA)

**** PROHIBITION – READ FURTHER FOR DETAILS ****

Research under this award involving the use of human subjects, to include the use of human anatomical substances and/or human data, may not begin until the US 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 Contractor. A copy of the approval will be provided to the US Army Medical Research Acquisition Activity for the official file. Non-compliance with any provisions of this clause may result in withholding of funds and or the termination of the award.

PROHIBITION OF USE OF LABORATORY ANIMALS (JAN 2007)(USAMRAA)

PROHIBITION – READ FURTHER FOR DETAILS

Notwithstanding any other provisions contained in the award or incorporated by reference herein, the Contractor 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's Office of Research Protections, Animal Care and Use Office (ACURO). The Contractor will receive written approval to begin research under the applicable protocol proposed for this award from the US Army Medical Research and Materiel Command, Acquisition Activity for the official file. Non-compliance with any provision of this clause may result in the termination of the award.

CONTRACTOR IDENTIFICATION (DEC 2005) (USAMRAA)

When contractor personnel perform the services required in this contract on a Government installation they are required to possess and wear an identification badge that displays his or her name and the name of the Company. The contractor shall ensure that contractor personnel identify themselves as contractors when attending meetings, answering Government telephones, providing any type of written correspondence, or working in situations where their actions could be construed as official Government acts.

While performing in a contractor capacity, contractor personnel shall refrain from using their retired or reserve component military rank or title in all written or verbal communications.

Section J - List of Documents, Exhibits and Other Attachments

Exhibit/Attachment Table of Contents

DOCUMENT TYPE	DESCRIPTION	PAGES	DATE
Attachment 1	Attachment 1 Historical Staffing		
Attachment 2	Attachment 2 PBF Historical Production Levels		
Attachment 3	Attachment 3 Past Performance Questionnaire		
Attachment 4	Attachment 4 Wage Determination		

Section K - Representations, Certifications and Other Statements of Offerors

CLAUSES INCORPORATED BY REFERENCE

52.203-11	Certification And Disclosure Regarding Payments To Influence Certain Federal Transactions	SEP 2007
52.209-7	Information Regarding Responsibility Matters	JAN 2011
52.215-22	Limitations on Pass-Through Charges--Identification of Subcontract Effort	OCT 2009
52.222-38	Compliance With Veterans' Employment Reporting Requirements	SEP 2010
52.225-18	Place of Manufacture	SEP 2006
52.225-20	Prohibition on Conducting Restricted Business Operations in Sudan--Certification	AUG 2009
252.209-7001	Disclosure of Ownership or Control by the Government of a Terrorist Country	JAN 2009
252.227-7028	Technical Data or Computer Software Previously Delivered to the Government	JUN 1995
252.247-7022	Representation Of Extent Of Transportation Of Supplies By Sea	AUG 1992

CLAUSES INCORPORATED BY FULL TEXT

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)

52.209-5 CERTIFICATION REGARDING RESPONSIBILITY MATTERS (APR 2010)

(a)(1) The Offeror certifies, to the best of its knowledge and belief, that-

(i) The Offeror and/or any of its Principals-

(A) Are () are not () presently debarred, suspended, proposed for debarment, or declared ineligible for the award of contracts by any Federal agency;

(B) Have () have not (), within a three-year period preceding this offer, been convicted of or had a civil judgment rendered against them for: commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) contract or subcontract; violation of Federal or State antitrust

statutes relating to the submission of offers; or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, violating Federal criminal tax laws, or receiving stolen property (if offeror checks "have", the offeror shall also see 52.209-7, if included in this solicitation); and

(C) Are () are not () presently indicted for, or otherwise criminally or civilly charged by a governmental entity with, commission of any of the offenses enumerated in paragraph (a)(1)(i)(B) of this provision.; and

(D) Have [ballot], have not [ballot], within a three-year period preceding this offer, been notified of any delinquent Federal taxes in an amount that exceeds \$3,000 for which the liability remains unsatisfied.

(1) Federal taxes are considered delinquent if both of the following criteria apply:

(i) The tax liability is finally determined. The liability is finally determined if it has been assessed. A liability is not finally determined if there is a pending administrative or judicial challenge. In the case of a judicial challenge to the liability, the liability is not finally determined until all judicial appeal rights have been exhausted.

(ii) The taxpayer is delinquent in making payment. A taxpayer is delinquent if the taxpayer has failed to pay the tax liability when full payment was due and required. A taxpayer is not delinquent in cases where enforced collection action is precluded.

(2) Examples. (i) The taxpayer has received a statutory notice of deficiency, under I.R.C. Sec. 6212, which entitles the taxpayer to seek Tax Court review of a proposed tax deficiency. This is not a delinquent tax because it is not a final tax liability. Should the taxpayer seek Tax Court review, this will not be a final tax liability until the taxpayer has exercised all judicial appeal rights.

(ii) The IRS has filed a notice of Federal tax lien with respect to an assessed tax liability, and the taxpayer has been issued a notice under I.R.C. Sec. 6320 entitling the taxpayer to request a hearing with the IRS Office of Appeals contesting the lien filing, and to further appeal to the Tax Court if the IRS determines to sustain the lien filing. In the course of the hearing, the taxpayer is entitled to contest the underlying tax liability because the taxpayer has had no prior opportunity to contest the liability. This is not a delinquent tax because it is not a final tax liability. Should the taxpayer seek tax court review, this will not be a final tax liability until the taxpayer has exercised all judicial appeal rights.

(iii) The taxpayer has entered into an installment agreement pursuant to I.R.C. Sec. 6159. The taxpayer is making timely payments and is in full compliance with the agreement terms. The taxpayer is not delinquent because the taxpayer is not currently required to make full payment.

(iv) The taxpayer has filed for bankruptcy protection. The taxpayer is not delinquent because enforced collection action is stayed under 11 U.S.C. 362 (the Bankruptcy Code).

(ii) The Offeror has () has not (), within a three-year period preceding this offer, had one or more contracts terminated for default by any Federal agency.

(2) Principal, for the purposes of this certification, means an officer, director, owner, partner, or a person having primary management or supervisory responsibilities within a business entity (e.g., general manager; plant manager; head of a division or business segment; and similar positions).

(b) The Offeror shall provide immediate written notice to the Contracting Officer if, at any time prior to contract award, the Offeror learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.

(c) A certification that any of the items in paragraph (a) of this provision exists will not necessarily result in withholding of an award under this solicitation. However, the certification will be considered in connection with a

determination of the Offeror's responsibility. Failure of the Offeror to furnish a certification or provide such additional information as requested by the Contracting Officer may render the Offeror nonresponsible.

(d) Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render, in good faith, the certification required by paragraph (a) of this provision. The knowledge and information of an Offeror is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

(e) The certification in paragraph (a) of this provision is a material representation of fact upon which reliance was placed when making award. If it is later determined that the Offeror knowingly rendered an erroneous certification, in addition to other remedies available to the Government, the Contracting Officer may terminate the contract resulting from this solicitation for default.

(End of provision)

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)

52.219-1 SMALL BUSINESS PROGRAM REPRESENTATIONS (APR 2011) - ALTERNATE I (APR 2011)

(a)(1) The North American Industry Classification System (NAICS) code for this acquisition is 541712.

(2) The small business size standard is 500 employees.

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

(b) Representations. (1) The offeror represents as part of its offer that it () is, () is not a small business concern.

(2) (Complete only if the offeror represented itself as a small business concern in paragraph (b)(1) of this provision.) The offeror represents, for general statistical purposes, that it () is, () is not a small disadvantaged business concern as defined in 13 CFR 124.1002.

(3) (Complete only if the offeror represented itself as a small business concern in paragraph (b)(1) of this provision.) The offeror represents as part of its offer that it () is, () is not a women-owned small business concern.

(4) Women-owned small business (WOSB) concern eligible under the WOSB Program. [Complete only if the offeror represented itself as a women-owned small business concern in paragraph (b)(3) of this provision.] The offeror represents as part of its offer that--

(i) It * is, * is not a WOSB concern eligible under the WOSB Program, has provided all the required documents to the WOSB Repository, and no change in circumstances or adverse decisions have been issued that affects its eligibility; and

(ii) It * is, * is not a joint venture that complies with the requirements of 13 CFR part 127, and the representation in paragraph (b)(4)(i) of this provision is accurate in reference to the WOSB concern or concerns that are participating in the joint venture. [The offeror shall enter the name or names of the WOSB concern or concerns that are participating in the joint venture: ----.] Each WOSB concern participating in the joint venture shall submit a separate signed copy of the WOSB representation.

(5) Economically disadvantaged women-owned small business (EDWOSB) concern. [Complete only if the offeror represented itself as a women-owned small business concern eligible under the WOSB Program in (b)(4) of this provision.] The offeror represents as part of its offer that--

(i) It * is, * is not an EDWOSB concern eligible under the WOSB Program, has provided all the required documents to the WOSB Repository, and no change in circumstances or adverse decisions have been issued that affects its eligibility; and

(ii) It * is, * is not a joint venture that complies with the requirements of 13 CFR part 127, and the representation in paragraph (b)(5)(i) of this provision is accurate in reference to the EDWOSB concern or concerns that are participating in the joint venture. [The offeror shall enter the name or names of the EDWOSB concern or concerns that are participating in the joint venture: -----.] Each EDWOSB concern participating in the joint venture shall submit a separate signed copy of the EDWOSB representation.

(6) (Complete only if the offeror represented itself as a small business concern in paragraph (b)(1) of this provision.) The offeror represents as part of its offer that it () is, () is not a veteran-owned small business concern.

(7) (Complete only if the offeror represented itself as a veteran-owned small business concern in paragraph (b)(6) of this provision.) The offeror represents as part of its offer that it () is, () is not a service-disabled veteran-owned small business concern.

(8) [Complete only if the offeror represented itself as a small business concern in paragraph (b)(1) of this provision.] The offeror represents, as part of its offer, that--

(i) It () is, () is not a HUBZone small business concern listed, on the date of this representation, on the List of Qualified HUBZone Small Business Concerns maintained by the Small Business Administration, and no material change in ownership and control, principal office, or HUBZone employee percentage has occurred since it was certified by the Small Business Administration in accordance with 13 CFR part 126; and

(ii) It () is, () is not a joint venture that complies with the requirements of 13 CFR part 126, and the representation in paragraph (b)(8)(i) of this provision is accurate for the HUBZone small business concern or concerns that are participating in the joint venture. (The offeror shall enter the name or names of the HUBZone small business concern or concerns that are participating in the joint venture: _____.) Each HUBZone small business concern participating in the joint venture shall submit a separate signed copy of the HUBZone representation.

(9) (Complete if offeror represented itself as disadvantaged in paragraph (b)(2) of this provision.) The offeror shall check the category in which its ownership falls:

___ Black American.

___ Hispanic American.

___ Native American (American Indians, Eskimos, Aleuts, or Native Hawaiians).

___ Asian-Pacific American (persons with origins from Burma, Thailand, Malaysia, Indonesia, Singapore, Brunei, Japan, China, Taiwan, Laos, Cambodia (Kampuchea), Vietnam, Korea, The Philippines, U.S. Trust Territory of the Pacific Islands (Republic of Palau), Republic of the Marshall Islands, Federated States of Micronesia, the Commonwealth of the Northern Mariana Islands, Guam, Samoa, Macao, Hong Kong, Fiji, Tonga, Kiribati, Tuvalu, or Nauru).

___ Subcontinent Asian (Asian-Indian) American (persons with origins from India, Pakistan, Bangladesh, Sri Lanka, Bhutan, the Maldives Islands, or Nepal).

___ Individual/concern, other than one of the preceding.

(c) Definitions. As used in this provision--

Service-disabled veteran-owned small business concern--

(1) Means a small business concern--

(i) Not less than 51 percent of which is owned by one or more service-disabled veterans or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more service-disabled veterans; and

(ii) The management and daily business operations of which are controlled by one or more service-disabled veterans or, in the case of a service-disabled veteran with permanent and severe disability, the spouse or permanent caregiver of such veteran.

(2) Service-disabled veteran means a veteran, as defined in 38 U.S.C. 101(2), with a disability that is service-connected, as defined in 38 U.S.C. 101(16).

"Small business concern," means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR Part 121 and the size standard in paragraph (a) of this provision.

Veteran-owned small business concern means a small business concern--

(1) Not less than 51 percent of which is owned by one or more veterans (as defined at 38 U.S.C. 101(2)) or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more veterans; and

(2) The management and daily business operations of which are controlled by one or more veterans.

"Women-owned small business concern," means a small business concern --

(1) That is at least 51 percent owned by one or more women or, in the case of any publicly owned business, at least 51 percent of the stock of which is owned by one or more women; or

(2) Whose management and daily business operations are controlled by one or more women.

(d) Notice.

(1) If this solicitation is for supplies and has been set aside, in whole or in part, for small business concerns, then the clause in this solicitation providing notice of the set-aside contains restrictions on the source of the end items to be furnished.

(2) Under 15 U.S.C. 645(d), any person who misrepresents a firm's status as a small, HUBZone small, small disadvantaged, or women-owned small business concern in order to obtain a contract to be awarded under the preference programs established pursuant to section 8(a), 8(d), 9, or 15 of the Small Business Act or any other provision of Federal law that specifically references section 8(d) for a definition of program eligibility, shall--

- (i) Be punished by imposition of fine, imprisonment, or both;
- (ii) Be subject to administrative remedies, including suspension and debarment; and
- (iii) Be ineligible for participation in programs conducted under the authority of the Act.

(End of provision)

52.222-22 PREVIOUS CONTRACTS AND COMPLIANCE REPORTS (FEB 1999)

The offeror represents that --

- (a) It has, has not participated in a previous contract or subcontract subject to the Equal Opportunity clause of this solicitation;
- (b) It has, has not, filed all required compliance reports; and
- (c) Representations indicating submission of required compliance reports, signed by proposed subcontractors, will be obtained before subcontract awards.

(End of provision)

52.222-25 AFFIRMATIVE ACTION COMPLIANCE (APR 1984)

The offeror represents that

- (a) it has developed and has on file, has not developed and does not have on file, at each establishment, affirmative action programs required by the rules and regulations of the Secretary of Labor (41 CFR 60-1 and 60-2), or
- (b) has not previously had contracts subject to the written affirmative action programs requirement of the rules and regulations of the Secretary of Labor.

(End of provision)

252.204-7007 ALTERNATE A, ANNUAL REPRESENTATIONS AND CERTIFICATIONS (SEP 2011)

Substitute the following paragraphs (d) and (e) for paragraph (d) of the provision at FAR 52.204-8:

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

(i) 252.209-7001, Disclosure of Ownership or Control by the Government of a Terrorist Country. Applies to all solicitations expected to result in contracts of \$150,000 or more.

(ii) 252.209-7005, Reserve Officer Training Corps and Military Recruiting on Campus. Applies to all solicitations and contracts with institutions of higher education.

(iii) 252.216-7003, Economic Price Adjustment-Wage Rates or Material Prices Controlled by a Foreign Government. Applies to fixed-price supply and service contracts when the contract is to be performed wholly or in part in a foreign country, and a foreign government controls wage rates or material prices and may during contract performance impose a mandatory change in wages or prices of materials.

(iv) 252.225-7042, Authorization to Perform. Applies to all solicitations when performance will be wholly or in part in a foreign country.

(v) 252.229-7003, Tax Exemptions (Italy). Applies to solicitations and contracts when contract performance will be in Italy.

(vi) 252.229-7005, Tax Exemptions (Spain). Applies to solicitations and contracts when contract performance will be in Spain.

(vii) 252.247-7022, Representation of Extent of Transportation by Sea. Applies to all solicitations except those for direct purchase of ocean transportation services or those with an anticipated value at or below the simplified acquisition threshold.

(2) The following representations or certifications in ORCA are applicable to this solicitation as indicated by the Contracting Officer: [Contracting Officer check as appropriate.]

___ (i) 252.209-7002, Disclosure of Ownership or Control by a Foreign Government.

___ (ii) 252.225-7000, Buy American Act--Balance of Payments Program Certificate.

___ (iii) 252.225-7020, Trade Agreements Certificate.

___ Use with Alternate I.

___ (iv) 252.225-7022, Trade Agreements Certificate--Inclusion of Iraqi End Products.

___ (v) 252.225-7031, Secondary Arab Boycott of Israel.

___ (vi) 252.225-7035, Buy American Act--Free Trade Agreements--Balance of Payments Program Certificate.

___ Use with Alternate I.

___ Use with Alternate II.

___ Use with Alternate III.

(e) The offeror has completed the annual representations and certifications electronically via the Online Representations and Certifications Application (ORCA) Web site 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 that apply to this solicitation as indicated in FAR 52.204-8(c) and paragraph (d) 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 provision 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.

(End of provision)

Section L - Instructions, Conditions and Notices to Bidders

INSTRUCTIONS TO OFFERORS

L.1. Proposal General Information

This is a re-compete requirement, current award DAMD17-02-C-0002, incumbent Clinical Management Research (CMR).

This is a 100% Small Business Set-Aside acquisition for the award of non-personnel services Firm Fixed Price (FFP). Award will be made to the best overall proposal, which is determined to be the most beneficial to the Government. This will be accomplished using the best value approach of subjectively evaluating non-priced factors, price analysis, and possibly selecting for award other than the lowest-priced offer utilizing the trade-off process.

The Government intends to evaluate proposals and award a contract without discussions with Offerors, except clarifications. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary; the Contracting Offer will provide proposal revision instructions to the Offeror, as required. Therefore, the Offeror's initial proposal should contain the Offeror's best terms from a technical and cost/price standpoint. All proposals shall be subject to evaluation by a team of Government personnel who will evaluate only one proposal from each prime Offeror.

Contract Specialist

The Contract Specialist (CS) is the point of contact for this acquisition. Any questions or concerns regarding this acquisition shall be submitted electronically via e-mail to jennifer.jackson1@us.army.mil.

L.2. Proposal Submission

Offerors shall submit their proposal in accordance with the instructions outlined in Section L of the RFP. Failure to submit all documents concurrently and in accordance with the instructions outlined in Section L may render a proposal NON-RESPONSIVE.

Proposals shall be in 12-point Times New Roman font with margins no smaller than 1" on the top, bottom, and sides.

1. Submission of Questions: Offerors will be instructed to submit questions no later than Thursday 26 January 2012 at 3:00 PM Eastern Time to the Contract Specialist and Contracting Officer. Offerors shall **submit one set** of questions only; multiple emails will not be accepted. Questions not submitted electronically will not be answered. Answers to all relevant and appropriate questions will be issued via amendment to the solicitation.

2. Submission of Proposals: Each section shall be separate and complete, so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the others.

a. Electronic Format Submission

The Offeror shall provide:

Two (2) compact discs (CD's) containing its complete proposal, including all technical and cost data. The CDs shall be clearly labeled with: Offeror's name, solicitation number, and date.

Three (3) CD's containing only the Non-Price Proposal as stated for Volume III

Volume I and Volume III must be submitted in **BOTH** Microsoft Office format and Adobe Acrobat .pdf. Specifically, in the Price Volume (Volume II) the pricing and cost buildup sections must be submitted in **BOTH** Microsoft EXCEL and Adobe Acrobat .pdf formats.

Failure to provide copies of the proposal in the acceptable formats may render a proposal non-responsive.

b. Hardcopy Submission

The Offeror shall provide four (4) hardcopies of its complete proposal, including all technical and cost data submitted in the proposal. The volume of each proposal shall be contained in a separate three-ring binder with appropriate identification.

Proposals shall be submitted to the following address:

Director
US Army Medical Research Acquisition Activity
ATTN: MCMR-AAA-W (J. Jackson)
820 Chandler Street
Fort Detrick, MD 21702-5014

All packages must be clearly marked with the Solicitation Number. No proposal received by FAX or email will be accepted.

- c. Offerors are referred to FAR 52.215-1, Instructions to Offerors – Competitive Acquisition, for general instructions on: submission, modification, revision and withdrawal of proposals; late proposals and revisions; offer expiration date; restrictions on disclosure and use of data; and contract award.
- d. Evaluation of Proposals: The Government will evaluate proposals in accordance with the evaluation criteria set forth in RFP W81XWH-12-R-0001.
- e. An offeror's proposal must stipulate that it is predicated upon all the terms and conditions of this RFP.
- f. It is understood that the offeror's proposal will become part of the official contract file.

3. Proposal Contents: Proposals shall be clear, specific, complete, and concise, presenting complete effective methods and approaches for satisfying the RFP's requirements. Content shall be indexed (cross-indexed, as appropriate) and logically assembled. The Government will evaluate **only one** proposal from each prime Offeror.

Offerors shall submit proposals in three parts no later than Friday 24 February 2012 at 3: 00 PM Eastern Time.

Volume I – Cover Letter and Executed RFP Documents

In Volume I, the Offeror shall complete and include all certifications required by the solicitation. This volume shall include the following:

- a) Company cover letter
- b) Standard Form 33 – Solicitation, Offeror, and Award, with blocks 12 – 18 completed by the Offeror.

- c) Executed RFP documents (Section K Representations, Certifications and Other Statements of Offerors)

Volume II - Pricing Proposal

RFP Section B — Supplies or Services and Prices, offeror’s are instructed to complete these CLINS to include a total price for the service and other direct costs (Offeror’s are to use the Governments proposed estimates for Other Direct Costs and indirect costs factors that would be applied).

Price information shall be included in the Pricing Proposal Volume II **only** and shall not be discussed or exhibited in any other part of the Offeror’s proposal.

Offerors shall demonstrate they have the necessary financial capacity to perform this contract without assistance from any outside sources.

The Offeror shall propose a labor mix and level of effort to perform the required as outlined in the performance work statement. The Governments historical staffing is only for information purposes only. This information is not to be construed as either mandatory or necessarily the best technical approach. It is only in place as a reference to allow Offerors to better understand the general scope of this effort from the Government’s perspective. The Government is seeking the best level of effort and labor mix that the contractor has determined is right to accomplish the mission contained in the performance work statement. Offeror’s are not bound to propose these labor categories, rather they are expected to provide their best solution citing the labor mix and quantity required to accomplish the tasks.

The Offeror shall provide a statement of the methodology and assumptions utilized as the basis for pricing the service. The price must be sufficiently detailed to evaluate the reasonableness and realism for the proposed level of effort. Offerors shall address at a minimum all escalation factors applied, and calculations of all indirect cost factors to include historical and audited rates.

Volume III - Non-Price Proposal

This volume shall include five (5) sections, as follows:

<u>Sub-section</u>	<u>Page Limitation</u>
Tab a) Executive Summary/Abstract - - - - -	1 Page
Tab b) Technical Approach - - - - -	40 Pages
Tab c) Management and Staffing Approach - - - - -	50 Pages
Tab d) Past Performance - - - - -	No Limit (3-5 References)
Tab e) Subcontracting Plan (if applicable) - - - - -	No Limit

The Government will not consider pages submitted in excess of the stated page limitations. Tabs, table of content, resumes and letters of intent will not be counted against any page limits stated within the RFP.

Note: Quality Control Plan (QCP): Offerors shall provide their proposed QCP in the Technical Approach – the QCP is included in the Technical Approach 40 page limit.

L.3. Pre-Proposal Site Visit

A preproposal site visit is scheduled for **January 18, 2012** during 9:30 AM -12:30 PM EST, at the Walter Reed Army Institute of Research (WRAIR) Annex Forest Glen, Bldg. 501, Room 46, Silver Spring, MD. The site visit objective is to provide a tour of the PBF.

Interested parties shall email to Ms. Jennifer Jackson (jennifer.jackson1@us.army.mil) the names and contact information of individuals planning to attend the pre-proposal conference/site visit no later than **January 12, 2012, 1:00 P.M.** Foreign nationals are prohibited from attending the pre-proposal conference.

Contractor Attendees are advised that:

- Remarks and explanations at the conference shall not qualify the terms of the solicitations; and,
- Terms of the solicitation and specifications remain unchanged unless the solicitation is amended in writing.

CLAUSES INCORPORATED BY REFERENCE

52.204-6	Data Universal Numbering System (DUNS) Number	APR 2008
52.214-34	Submission Of Offers In The English Language	APR 1991
52.214-35	Submission Of Offers In U.S. Currency	APR 1991
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
52.222-24	Preaward On-Site Equal Opportunity Compliance Evaluation	FEB 1999
52.222-46	Evaluation Of Compensation For Professional Employees	FEB 1993
52.237-1	Site Visit	APR 1984

CLAUSES INCORPORATED BY FULL TEXT

52.215-1 INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION (JAN 2004)

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

“Discussions” are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

“In writing or written” means any worded or numbered expression which can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

“Proposal modification” is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

“Proposal revision” is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

“Time”, if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) Amendments to solicitations. If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) Submission, modification, revision, and withdrawal of proposals. (1) Unless other methods (e.g., electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show--

(i) The solicitation number;

(ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);

(iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;

(iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and

(v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) Submission, modification, or revision, of proposals.

(i) Offerors are responsible for submitting proposals, and any modifications, or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

(ii)(A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

(1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

(3) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be

deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.

(5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.

(6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(d) Offer expiration date. Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

(e) Restriction on disclosure and use of data. Offerors that include in their proposals data that they do not want disclosed to the public for any purpose, or used by the Government except for evaluation purposes, shall--

(1) Mark the title page with the following legend: This proposal includes data that shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed--in whole or in part--for any purpose other than to evaluate this proposal. If, however, a contract is awarded to this offeror as a result of--or in connection with-- the submission of this data, the Government shall have the right to duplicate, use, or disclose the data to the extent provided in the resulting contract. This restriction does not limit the Government's right to use information contained in this data if it is obtained from another source without restriction. The data subject to this restriction are contained in sheets [insert numbers or other identification of sheets]; and

(2) Mark each sheet of data it wishes to restrict with the following legend: Use or disclosure of data contained on this sheet is subject to the restriction on the title page of this proposal.

(f) Contract award. (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

(2) The Government may reject any or all proposals if such action is in the Government's interest.

(3) The Government may waive informalities and minor irregularities in proposals received.

(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number

of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

(5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

(6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.

(7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

(9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.

(10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(11) If a post-award debriefing is given to requesting offerors, the Government shall disclose the following information, if applicable:

(i) The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer.

(ii) The overall evaluated cost or price and technical rating of the successful and the debriefed offeror and past performance information on the debriefed offeror.

(iii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection.

(iv) A summary of the rationale for award.

(v) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

(vi) Reasonable responses to relevant questions posed by the debriefed offeror as to whether source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities were followed by the agency.

(End of provision)

52.216-1 TYPE OF CONTRACT (APR 1984)

The Government contemplates award of a firm-fixed price contract resulting from this solicitation.

(End of provision)

52.233-2 SERVICE OF PROTEST (SEP 2006)

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the Government Accountability Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from USAMRAA, ATTN: MCMR-AAA-W/W.Harper, 820 Chandler St. Fort Detrick, MD 21702-5014.

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of provision)

52.252-5 AUTHORIZED DEVIATIONS IN PROVISIONS (APR 1984)

(a) The use in this solicitation of any Federal Acquisition Regulation (48 CFR Chapter 1) provision with an authorized deviation is indicated by the addition of "(DEVIATION)" after the date of the provision.

a. The use in this solicitation of any Defense Federal Acquisition Regulation (48 CFR Chapter 2) provision with an authorized deviation is indicated by the addition of "(DEVIATION)" after the name of the regulation.

(End of provision)

Section M - Evaluation Factors for Award

EVALUATION FACTORS**M.1. Basis for Award**

This is a best value procurement. One award will be made based on the best overall value proposal that is determined to be the most beneficial to the Government. The Government may select to award to other than the lowest priced proposal, based on the evaluation of the non-priced factors and the best value to the Government. Proposals submitted in response to the RFP will be evaluated based on the following evaluation factors listed in descending order of importance: Factor 1 – Technical Approach, Factor 2 – Management and Staffing Approach, Factor 3. Past Performance and Factor 4 Price. The non-price factors combined are significantly more important than the price factor however, as the collective non-price factors begin to reach equivalency in the evaluation the price factor becomes more important in the trade-off analysis. If any of the non-price factors receives an individual rating of “unacceptable”, the offeror’s proposal will be deemed unacceptable. Only proposals receiving at least a rating of “acceptable” or higher will be considered for award. Proposals that are unrealistic in terms of non-price factors will be deemed reflective of an inherent lack of technical competence or indicative of the offeror’s failure to comprehend the complexity and risks of the contract requirements and may be grounds for rejection of the proposal. Offers are cautioned that the award may not necessarily be made to the lowest-price Offeror. The Government reserves the right to: reject any or all proposals, award no contract at all depending on the quality of the proposal(s) submitted, award to other than lowest-price offeror, waive informalities and minor irregularities in offers received and award a contract without discussions.

M.2. Technical Evaluation Factors.

1. Technical Approach. The Offeror shall present a technical approach that conveys its capabilities, technical expertise, tools, techniques, strategies, and methodologies to be applied to the task objectives as outlined in the performance work statement. The proposal must indicate a thorough understanding of the Performance Work Statement (PWS) and provide a comprehensive approach as to how the services will be accomplished. Contractor must demonstrate knowledge of the laws and regulations governing vaccine production, ie. FDA, CGMP manufacturing, etc. Finally offerors must include a Quality Control Plan (QCP) for the required services.

1.1 Combined Technical Risk Rating Scale

Rating	Description
Outstanding	Proposal meets requirements and indicates an exceptional approach and understanding of the requirements. Strengths far outweigh any weaknesses. Risk of unsuccessful performance is very low.
Good	Proposal meets requirements and indicates a thorough approach and understanding of the requirements. Proposal contains strengths which outweigh any weaknesses. Risk of unsuccessful performance is low.
Acceptable	Proposal meets requirements and indicates an adequate approach and understanding of the requirements. Strengths and weaknesses are offsetting or will have little or no impact on contract performance. Risk of unsuccessful performance is no worse than moderate.
Marginal	Proposal does not clearly meet requirements and has not demonstrated an adequate approach and understanding of the requirements. The proposal has one or more weaknesses which are not offset by strengths. Risk of unsuccessful performance is high.
Unacceptable	Proposal does not meet requirements and contains one or more deficiencies. Proposal is unawardable.

2. Management and Staffing Approach. This evaluation factor will assess the offeror's management and staffing approach to satisfy the required services. Offerors shall clearly delineate the line of authority associated with the proposed organization and its ability to plan, organize, and use resources in a coordinated and timely manner in order to achieve technical requirements and control prices. The contractor must demonstrate ability to provide qualified and experienced personnel to perform the PWS. The offeror shall provide documentation that the qualifications, education, training, knowledge and work experience of key personnel are commensurate with the scientific and/or managerial expertise required to perform the necessary tasks in the Performance Work Statement. Complete resumes and/or curriculum vitae (CVs) for all proposed key personnel shall accompany and be a part of the offer. Offeror shall provide letters of intent from key personnel. Contractor shall demonstrate their ability to recruit and maintain a stable workforce. Any (if applicable) teaming arrangement/subcontractor agreement(s) contemplated by the Offeror must be presented to the Government in detail in a teaming agreement/subcontracting plan. The teaming agreement/subcontracting plan(s) shall be included as a part of the Offeror's management approach. The agreement/plan(s) shall disclose the teaming firm's/subcontractor's tasks and be presented in enough detail to allow the Government to determine how much teaming/subcontracting the Offeror contemplates. All proposed subcontracting/teaming arrangements must also include signed agreement(s) between the parties..

2.1 Combined Technical Risk Rating Scale

Rating	Description
Outstanding	Proposal meets requirements and indicates an exceptional approach and understanding of the requirements. Strengths far outweigh any weaknesses. Risk of unsuccessful performance is very low.
Good	Proposal meets requirements and indicates a thorough approach and understanding of the requirements. Proposal contains strengths which outweigh any weaknesses. Risk of unsuccessful performance is low.
Acceptable	Proposal meets requirements and indicates an adequate approach and understanding of the requirements. Strengths and weaknesses are offsetting or will have little or no impact on contract performance. Risk of unsuccessful performance is no worse than moderate.
Marginal	Proposal does not clearly meet requirements and has not demonstrated an adequate approach and understanding of the requirements. The proposal has one or more weaknesses which are not offset by strengths. Risk of unsuccessful performance is high.
Unacceptable	Proposal does not meet requirements and contains one or more deficiencies. Proposal is unawardable.

3. Past Performance. Past performances consist of two aspects for evaluation, past performance relevancy and performance confidence. The first aspect is to evaluate the offeror's past performance to determine how relevant a recent effort accomplished by the offeror is to the effort to be acquired through the source selection. Common aspects of relevancy include similarity of service/support, complexity, dollar value, contract type, and degree of subcontract/teaming. The past performance evaluation results in an assessment of the offeror's probability of meeting the solicitation requirements. The past performance evaluation considers each offeror's demonstrated recent and relevant record of performance in providing services that meet the contract's requirements. One performance confidence assessment rating is assigned for each offeror after evaluating the offeror's recent past performance, focusing on performance that is relevant to the contract requirements. The second aspect of the past performance evaluation is to determine how well the contractor performed on the contracts.

3.1. The Offeror will be evaluated based on the narrative description and type of contract work performed similar in scope and complexity to the requirements of this solicitation. Offeror shall provide a brief description of contract

work and comparability to the proposed effort. Offerors are required to provide a reference point of contact, dollar value of contract and dates of contract performance. It is not sufficient to state that it is similar in magnitude and scope, a rationale must be provided to demonstrate that it is comparable. Projects completed or in progress described in the narrative will be evaluated for scope and degree of support to DOD, other federal agencies, or other comparable international organizations.

3.2. Offerors shall describe problems encountered in the performance of similar services and describe how the problems was/were resolved.

3.3. A minimum of three (3), not to exceed five (5) past performance questionnaires shall be provided.

3.4. Each Offeror will be required to forward a copy of the Past Performance Questionnaire to references in their narratives. The questionnaire shall then be returned directly to the Contract Specialist by the selected references prior to the closing date and time of the solicitation. This information will be used to assess the narrative past performance description for the relevancy and confidence assessment in accepting each offeror's proposal.

3.5. Past performance information may be obtained from any other sources available to the Government, to include, but not limited to, the Past Performance Information Retrieval System (PPIRS), Federal Awardee Performance and Integrity Information System (FAPIS), Electronic Subcontract Reporting System (eSRS), or other databases; interviews with Program Managers, Contracting Officers, and Fee Determining Officials; and the Defense Contract Management Agency.

3.6. In the case of an offeror without a record or no relevant past performance exists within the offeror's organization or for whom information on past performance is not available, the Offeror may not be evaluated favorably or unfavorably on past performance. The Offeror's lack of past performance will be evaluated as an unknown/neutral having no favorable or unfavorable impact on the evaluation.

3.7 Past Performance Relevancy Ratings.

Rating	Definition
Very Relevant	Present/past performance effort involved essentially the same scope and magnitude of effort and complexities this solicitation requires.
Relevant	Present/past performance effort involved similar scope and magnitude of effort and complexities this solicitation requires.
Somewhat Relevant	Present/past performance effort involved some of the scope and magnitude of effort and complexities this solicitation requires.
Not Relevant	Present/past performance effort involved little or none of the scope and magnitude of effort and complexities this solicitation requires.

3.8. Past Performance Confidence Assessments Ratings.

Rating	Description
Substantial Confidence	Based on the offeror's recent/relevant performance record, the Government has a high expectation that the offeror will successfully perform the required effort.
Satisfactory Confidence	Based on the offeror's recent/relevant performance record, the Government has a reasonable expectation that the offeror will successfully perform the required effort.

Limited Confidence	Based on the offeror's recent/relevant performance record, the Government has a low expectation that the offeror will successfully perform the required effort.
No Confidence	Based on the offeror's recent/relevant performance record, the Government has a low expectation that the offeror will 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.

4. Price Analysis. The objective of a price analysis is to ensure that the final agreed-to price is fair and reasonable and consistent with the effort proposed. The price analysis, will not only consider the total price, including options, but also the prices for the individual CLINS to ensure that they are not unbalanced. All offeror's separately priced line items will be analyzed to determine if the prices are unbalanced.

4.4.1 The offeror shall submit information other than price or pricing data so that the Government may perform a price analysis. Before making the award, the Contracting Officer must determine that the proposed price(s) is fair and reasonable.

4.4.2. Offerors will be placed on notice that any proposals that are unrealistic in terms of Non-Price factors commitment or unrealistically low in price(s) will be deemed reflective of an inherent lack of technical competence or indicative of failure to comprehend the complexity and risk of contract requirements, and may be grounds for rejection of the proposal.

4.4.3. Although price will not be a consideration for the SSEB to evaluate, the price of each proposal will be evaluated by the Contract Specialist and the Contracting Officer and evaluations will be shared with the SSEB after evaluations are completed.

4.4.4. Price will not receive an adjectival rating. However, if proposal evaluations result in findings that Offerors are essentially rated equally in non-price factors, price could become a determining factor based upon an assessment of price realism and fee/profit.

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52.217-5 EVALUATION OF OPTIONS (JUL 1990)

Except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests, the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement. Evaluation of options will not obligate the Government to exercise the option(s).

(End of provision)