

SOLICITATION, OFFER AND AWARD			1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)		RATING	PAGE OF PAGES 1 93	
2. CONTRACT NO.		3. SOLICITATION NO. W81XWH-10-R-0001	4. TYPE OF SOLICITATION [] SEALED BID (IFB) [X] NEGOTIATED (RFP)	5. DATE ISSUED 30 Jun 2010	6. REQUISITION/PURCHASE NO.		
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		CODE	TEL: FAX:

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

SOLICITATION

9. Sealed offers in original and _____ copies for furnishing the supplies or services in the Schedule will be received at the place specified in Item 8, or if handcarried, in the depository located in _____ until 12:00 PM local time 06 Aug 2010
(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 LISA SAWYER	B. TELEPHONE (Include area code) (NO COLLECT CALLS) (301) 619-6661	C. E-MAIL ADDRESS lisa.sawyer@amedd.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

15A. NAME AND ADDRESS OF OFFEROR	CODE	FACILITY	16. NAME AND TITLE OF PERSON AUTHORIZED TO SIGN OFFER (Type or print)
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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
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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)	TEL:	27. UNITED STATES OF AMERICA	28. AWARD DATE
	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 A - Solicitation/Contract Form

AWARD INFORMATION

TITLE: Chemical Surety, Management Support, and Studies Supporting the Medical Chemical Defense Research Program

TERM OF CONTRACT: 2 November 2010 – 1 November 2013 (Research ends 1 May 2013)

PROGRAM MANAGER: TBD

PRINCIPAL INVESTIGATOR: TBD

TOTAL AMOUNT OF CONTRACT: TBD

FUNDS PROVIDED TO DATE: \$0 (Funding will be provided on individual task orders.)

CONTRACT TYPE: Cost-Plus-Fixed-Fee (Indefinite Delivery/Indefinite Quantity)

Note: TBD = to be determined

Section B - Supplies or Services and Prices

MINIMUM & MAXIMUM QUANTITIES

A minimum of 3 task orders will be issued during the 3-year base period. A maximum of 30 task orders is anticipated to be issued during the 3-year base period. A maximum of 45 task orders are anticipated, if each of the options years are exercised.

ITEM NO	SUPPLIES/SERVICES	MAX QUANTITY UNDEFINED	UNIT	UNIT PRICE	MAX AMOUNT
0001	CHEM SURETY & MGMT SPT (3 YEARS) CPFF Administrative Support, Proposal Preparation, and Scientific Interaction to Operate a Chemical Surety Program and Provide Management Support for the Medical Chemical Defense Research Program (3 years)				
	FOB: Destination				
				MAX COST	
				FIXED FEE	
				TOTAL MAX COST + FEE	

ITEM NO	SUPPLIES/SERVICES	MAX QUANTITY UNDEFINED	UNIT	UNIT PRICE	MAX AMOUNT
0002	STUDIES (3 YEARS) CPFF Studies Supporting the Medical Chemical Defense Research Program (3 years)				
	FOB: Destination				
				MAX COST	
				FIXED FEE	
				TOTAL MAX COST + FEE	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
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0003

OTHER DIRECT COSTS (ODCs)
COST

ODCs associated with travel and other miscellaneous costs. Required Travel shall be negotiated per individual task order, and may include attendance at training sessions or conferences associated with the required performance under each individual task order.

Travel requests shall be forwarded to the COR 90 - 120 days prior to travel. Travel costs will be reimbursed in accordance with the Joint Travel Regulations. Justification for travel costs in excess of the approved rates must be submitted and approved by the COR. Unplanned or emergency travel will be approved by the COR on a case-by-case basis. Reimbursement for travel initiated prior to proper approval may be denied.

The offeror shall not include a price for this CLIN. The Not To Exceed estimate of this CLIN is \$37,000 over three-year period.

FOB: Destination

ESTIMATED COST

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
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0004

**CONTRACTOR MANPOWER REPORTING (CMR)
FFP**

The Contractor shall provide the resources to fulfill the requirements of the Contractor Manpower Reporting requirements as set forth in Section C, Contract Manpower Reporting.

The Unite Identification Codes are as follows:

The organizational titles and Unit Identification Codes (UICs) for using activities are included below for Contractor Manpower Reporting (CMR) purposes:

U.S. Army Medical Research Institute of Chemical Defense (USAMRICD) UIC is W4D7AA

Chemical Biological Medical Systems Joint Project Management Office (CBMS) UIC is W6DZ01.

Defense Threat Reduction Agency (DTRA) - NOTE: DTRA is a DOD organization, therefore UIC is N/A.

FOB: Destination

NET AMT

ITEM NO	SUPPLIES/SERVICES	MAX QUANTITY	UNIT	UNIT PRICE	MAX AMOUNT
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1001
OPTION

**CHEM SURETY & MGMT SPT (OPTION YEAR 1)
CPFF**

Administrative Support, Proposal Preparation, and Scientific Interaction to Operate a Chemical Surety Program and Provide Management Support for the Medical Chemical Defense Research Program (1 Year)

FOB: Destination

MAX COST

FIXED FEE

TOTAL MAX COST + FEE

ITEM NO	SUPPLIES/SERVICES	MAX QUANTITY	UNIT	UNIT PRICE	MAX AMOUNT
1002 OPTION	STUDIES (OPTION YEAR 1) CPFF Studies Supporting the Medical Chemical Defense Researach Program (1 Year)	UNDEFINED			
	FOB: Destination				
				MAX COST	
				FIXED FEE	
				TOTAL MAX COST + FEE	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1003 OPTION	OTHER DIRECT COSTS (ODCs) COST ODCs associated with travel and other micellaneous costs. Required Travel shall be negotiated per individual task order, and mayay include attendance at training sessions or conferences associated with the required performance under each individual task order.				
	Travel requests shall be forwarded to the COR 90 - 120 days prior to travel. Travel costs will be reimbursed in accordance with the Joint Travel Regulations. Justification for travel costs in excess of the approved rates must be submitted and approved by the COR. Unplanned or emergency travel will be approved by the COR on a case-by-case basis. Reimbursement for travel initiated prior to proper approval may be denied.				
	The offeror shall not include a price for this CLIN. The Not To Exceed estimate of this CLIN is \$13,000.				
	FOB: Destination				
				ESTIMATED COST	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1004 OPTION	CONTRACTOR MANPOWER REPORTING (CMR) FFP				

The Contractor shall provide the resources to fulfill the requirements of the Contractor Manpower Reporting requirements as set forth in Section C, Contract Manpower Reporting.

The Unite Identification Codes are as follows:

The organizational titles and Unit Identification Codes (UICs) for using activities are included below for Contractor Manpower Reporting (CMR) purposes:

U.S. Army Medical Research Institute of Chemical Defense (USAMRICD) UIC is W4D7AA

Chemical Biological Medical Systems Joint Project Management Office (CBMS) UIC is W6DZ01.

Defense Threat Reduction Agency (DTRA) - NOTE: DTRA is a DOD organization, therefore UIC is N/A.

FOB: Destination

NET AMT

ITEM NO	SUPPLIES/SERVICES	MAX QUANTITY	UNIT	UNIT PRICE	MAX AMOUNT
2001 OPTION	CHEM SURETY & MGMT SPT (OPTION YEAR 2) CPFF Administrative Support, Proposal Preparation, and Scientific Interaction to Operate a Chemical Surety Program and Provide Management Support for the Medical Chemical Defense Research Program (1 Year)	UNDEFINED			
	FOB: Destination				
				MAX COST	
				FIXED FEE	
				TOTAL MAX COST + FEE	<hr/>

ITEM NO	SUPPLIES/SERVICES	MAX QUANTITY	UNIT	UNIT PRICE	MAX AMOUNT
2002 OPTION	STUDIES (OPTION YEAR 2) CPFF Studies Supporting the Medical Chemical Defense Researach Program (1 Year)	UNDEFINED			
	FOB: Destination				
				MAX COST	
				FIXED FEE	
				TOTAL MAX COST + FEE	<hr/>

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
2003 OPTION	OTHER DIRECT COSTS (ODCs) COST				

ODCs associated with travel and other miscellaneous costs. Required Travel shall be negotiated per individual task order, and may include attendance at training sessions or conferences associated with the required performance under each individual task order.

Travel requests shall be forwarded to the COR 90 - 120 days prior to travel. Travel costs will be reimbursed in accordance with the Joint Travel Regulations. Justification for travel costs in excess of the approved rates must be submitted and approved by the COR. Unplanned or emergency travel will be approved by the COR on a case-by-case basis. Reimbursement for travel initiated prior to proper approval may be denied.

The offeror shall not include a price for this CLIN. The Not To Exceed estimate of this CLIN is \$14,000.

FOB: Destination

ESTIMATED COST

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
2004 OPTION	CONTRACTOR MANPOWER REPORTING (CMR) FFP				

The Contractor shall provide the resources to fulfill the requirements of the Contractor Manpower Reporting requirements as set forth in Section C, Contract Manpower Reporting.

The Unite Identification Codes are as follows:

The organizational titles and Unit Identification Codes (UICs) for using activities are included below for Contractor Manpower Reporting (CMR) purposes:

U.S. Army Medical Research Institute of Chemical Defense (USAMRICD) UIC is W4D7AA

Chemical Biological Medical Systems Joint Project Management Office (CBMS) UIC is W6DZ01.

Defense Threat Reduction Agency (DTRA) - NOTE: DTRA is a DOD organization, therefore UIC is N/A.

FOB: Destination

NET AMT

Section C - Descriptions and Specifications

PERFORMANCE WORK STATEMENT

PERFORMANCE WORK STATEMENT

C.1 BACKGROUND

The Department of Defense's (DoD's) Medical Chemical Defense Science and Technology Research Program is strategically managed by the Defense Threat Reduction Agency and executed by the U.S. Army Medical Research and Materiel Command (USAMRMC) and the Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD). The Medical Chemical Defense Research Program (MCDRP) focuses on the prevention of, and the provision for, chemical warfare agent casualties. The Department of Defense's Advanced Developer of chemical medical countermeasures is the Chemical Biological Medical Systems Joint Project Management Office (CBMS). Their combined mission is to protect the soldier against any chemical threat requiring a medical response. These efforts contribute significantly to the readiness and sustainment of the DoD's warfighting capability. Success on the future battlefield will depend heavily on the presence of a superior medical technology base that can respond rapidly with required countermeasures to emerging health hazards. The combined efforts of these DoD assets provide the expertise to meet the challenges of the future battlefield. Advances in military medicine also lead to important breakthroughs in civilian medicine and public health.

C.2 SCOPE OF WORK

I. Task order contract: It is in the best interest of the Government to establish a contractual agreement with a chemical surety capable research facility on a task order basis. A task order contract is appropriate due to the unspecified number of research efforts for which the Government will need such a facility to augment DoD capability. The costs associated with the establishment/maintenance of a chemical surety facility, meeting the requirements specified below, will be shared by all the surety related tasks requested by DTRA/USAMRMC/CBMS/USAMRICD, other DoD tasks and approved non-DoD tasks. In the interest of program continuity, the Government reserves the right to independently fund these general overhead costs for chemical surety program maintenance as the initial task, and to require subsequent deduction of such initial costs from the cost of follow-on Government tasks. The contractor must identify costs associated with the operation and maintenance of a chemical surety program with an expectation of potential proration of those costs among all users of the facility. Any use of the chemical surety facility requested by outside agencies must first be requested by the contractor and approved by the Government in writing and must include a mechanism to account for the surety costs associated with the work which will reduce the estimated costs of maintaining the surety program to the Government.

II. The costs associated with operating a chemical surety facility, identified above, will be incurred by all DoD and non-DoD users of the facility. It is understood that unless otherwise negotiated through the Contacting Officer's Representative, the DoD work being conducted at the laboratory must have priority over surety tasks funded by non-DoD dollars. Use of Government Furnished Equipment for tasks for any organization outside of the DTRA/USAMRMC/CBMS umbrella, DOD or otherwise, requires prior written approval and submission of a statement describing the impact, if any, on DTRA/USAMRMC/CBMS/USAMRICD funded tasks ongoing at the facility. Use of surety material for non-DoD tasks requires prior approval by Headquarters, Department of the Army (HQDA) as identified under the Army Standard Surety Clauses for Use of Chemical Agents at Contractor-Owned/Contractor-Operated (COCO) Facilities as required by Army Regulation (AR) 50-6, Chemical Surety, which can be found at the following website http://www.army.mil/usapa/epubs/pdf/r50_6.pdf.

III. Minimum Requirements:

A. General - The contractor shall furnish the necessary personnel, facilities/equipment, and supplies to perform research, development, testing, and evaluation (RDT&E) to answer and validate basic, applied, and developmental biomedical questions critical to providing improved medical countermeasures against existing chemical warfare agents and emerging threats. The RDT&E effort will involve animal models, alternatives to

animal models, and comprehensive bench top procedures utilizing chemical surety materials (CSM), RDT&E dilute solutions of CSM and other hazardous chemicals. A minimal list of chemical surety materiel that the facility must be capable of handling is provided (see Section J, Attachment 1). The contractor's facility must provide adequate space for short-term studies in multiple animal species (see Section J, Attachment 2), in vitro models to include isolated organ systems and cell culture, and bench top analytical and medicinal chemistry procedures. The contractor shall comply with the Army Standard Surety Clauses for Use of Chemical Agents at Contractor-Owned/Contractor-Operated (COCO) Facilities as required by Army Regulation (AR) 50-6, Chemical Surety (see Section J Attachment 3), Guidelines for Managing an RDTE Dilute Solution Laboratory at the Medical Research and Evaluation Facility (MREF) (see Section J Attachment 4), and all other federal, state, and local regulatory requirements. The contractor shall conduct semi-annual reviews to provide scientific and business updates on the overall program and task order progress.

B. Technical Capabilities to include, but not limited to, the following:

1. Design, develop, and/or implement quantitative in vivo and in vitro models to assess dermal or systemic toxicity, penetration, inhalation, absorption, metabolism, and excretion of the full spectrum of chemical warfare agents and/or other hazardous materials.
2. Design, develop, and/or implement quantitative models for assessing the efficacy of pretreatment and therapeutic compounds and/or skin decontaminates against exposure to chemical agents.
3. Screen and evaluate candidate pretreatment and treatment compounds in mouse, guinea pig, swine, rabbit, rat, and non-human primate models.
4. Collect, organize, analyze, and report experimental data and ensure that experimental protocols are conducted in appropriate randomized fashion.
5. Design, develop, implement, and/or conduct pre-clinical and non-clinical (e.g., toxicology, pharmacokinetic, pharmacodynamic, and pivotal efficacy) studies using the appropriate animal species on an identified compound in compliance with Good Laboratory Practices (GLP) requirements and prepare data for inclusion in a filing with the Food and Drug Administration (FDA). Contractor must be prepared to defend those data to FDA personnel.
6. Perform necropsy protocols supporting research, development, test, and evaluation work.
7. Develop and utilize tests for screening prophylaxis and therapeutic compounds for efficacy in specialized animal models exposed by the inhalation route.
8. Validate an in vivo and in vitro model developed in a USAMRMC laboratory or by a USAMRMC contractor, using one or more agents.
9. Revalidate an experiment conducted in another laboratory using chemical warfare agents and other hazardous materiel. Many basic research and some applied research experiments may require that a principal investigator and technician from another laboratory (university or commercial) actually conduct the study because of its specialized technical nature and/or because experience with special equipment and/or procedures may be critical to the outcome.
10. Design, develop, and/or implement analytical chemistry methodologies as needed to ensure quality assurance and quality control of research compounds.
11. Synthesize radiolabeled or unlabeled compounds as needed to support research operations.
12. Pivotal GLP Animal Efficacy Studies with Chemical Agents. These pivotal studies would support NDA/BLA regulatory submissions to the FDA under provisions of the Animal Rule. Proof of concept and

Preclinical studies would support IND submissions to the FDA. FDA Centers involved would be CDER and CBER.

13. Provide capability for supporting development of drinking water toxicity sensor technology using toxic industrial chemicals. Comparison of existing sensor systems and identification of appropriate detection limits to allow for rank ordering of systems.

14. Provide capability for toxicology testing in small mammals, biomarker discovery, and genomics and proteomics analysis.

15. The Contractor shall ensure that the following capabilities and performance characteristics are met:

- The building(s), personnel, equipment, and supplies necessary to operate a RDT&E facility must be fully operational and capable of conducting and supporting studies using CSM, RDT&E dilute solutions, and hazardous materials no later than 2 November 2010.
- The facility must meet all safety and surety requirements for storage, handling, use, and disposal of CSM, RDT&E dilute solutions, and other hazardous materials.
- The contractor must be capable of conducting research and testing to satisfy the requirements of the FDA (e.g., GLP regulations).
- Provisions will be required for DoD (DTRA, CBMS, USAMRMC, and USAMRICD) and their associated contractor personnel to work within the facility on an as-needed basis.
- The contractor and the facility must be readily adaptable to changing RDT&E requirements and priorities (i.e. within 30 days).

16. Environmental & Energy Conservation: The Contractor shall prepare a plan for Chemical Surety Materiel (CSM) operations that addresses surety, safety, security, occupation health and environmental concerns enumerated in the solicitation and in accordance with Chapter 3, AR-50-6. The "Army Standard Surety Clauses for Use of Chemical Agents at COCO Facilities", which contains specific criteria that shall be met for these areas.

C. Facility Requirements:

1. The contractor's facility shall: (1) meet all safety and surety requirements for storage, handling, use, and disposal of CSM, RDT&E dilute solutions, and hazardous materials; and (2) have the capability of conducting research and testing to satisfy the requirements of Good Laboratory Practices (GLP) regulations and guidelines.

2. Facility shall be primarily for use in studies involving the full spectrum of chemical threats in accordance with procedures described in current DOD, Department of Army, and USAMRMC regulations. Neat agent (CSM) storage for up to one (1) liter of neat agent or neat agent equivalent (aggregate total of all CSM) shall be provided.

3. Facility shall be accredited by the American Association for Accreditation of Laboratory Animal Care International (AAALAC) and registered with the U.S. Department of Agriculture. Additional nearby animal holding space is required for quarantine, conditioning, and long-term animal holding in accordance with AAALAC standards. The physical laboratory research area shall, as a minimum include:

- CSM storage and dilution laboratory facilities
- Animal inhalation dosing capability
- Percutaneous dosing capability
- in vitro testing capability

- Analytical chemistry capability
- Animal pathology support

4. The laboratory research area shall be capable of supporting percutaneous studies with the full spectrum of chemical threat agents in multiple species of animals, analytical chemistry support for environmental and proof of decontamination monitoring, analytical methodology development, determination of candidate compound stability, performance of clinical chemistry tests, inhalation studies, and in vitro model development and screening.

5. Facility shall have hood configuration for exposing and holding animals given percutaneous exposure with agent. Animal holding in hoods shall be short-term (1 day - 2 weeks).

6. Short-term Animal Holding Area meeting AAALAC requirements. Facilities must be capable of housing multiple rodent and multiple non-rodent species listed in Section J at one time to include non-human primates.

7. Shall be readily adaptable to changing RDT&E requirements and priorities.

8. The contractor will support administrative space for a COR to visit on a regularly established schedule including a functional office, interfaced computer and phone commensurate with the duties of a senior researcher. The COR will have unfettered access to the facilities and files pertaining to the Government contract

9. Waste Disposal:

- The facility shall have specialized systems for solid waste handling and disposal that meet all applicable federal, state, and local requirements. All monitoring for agent contamination and disposal must be in accordance with current DOD, DA, and USAMRMC regulations;
- Nonrecoverable, decontaminated solid waste from agent studies must be destroyed via pathological incinerator and/or other means consistent with applicable requirements; and
- A liquid waste disposal system must enable monitoring to meet Environmental Protection Agency (EPA) point source discharge requirements and be treated in accordance with regulatory requirements prior to discharge into waste treatment systems.

10. The facility shall operate its safety, surety, and security programs in accordance with the Army Standard Clauses for the Use of Chemical Agents at Contractor-Owned/Contractor-Operated (COCO) Facilities as required by Army Regulation 50-6.

11. The facilities have GLP capability and associated quality assurance (QA) programs. Up to 20 percent of the research, testing, and evaluation effort on a task order basis may require GLP compliance. Task orders will specify if GLP compliance is required.

D. Personnel Qualifications:

1. Shall have experience working with CSM/RDT&E dilute solutions and other hazardous materials. All personnel working with or around CSM shall be required to be enrolled in the Personnel Reliability Program in accordance with the Army Standard Surety Clauses for Use of Chemical Agents at Contractor-Owned/Contractor-Operated (COCO) Facilities as required by Army Regulation (AR) 50-6, Chemical Surety at http://www.army.mil/usapa/epubs/pdf/r50_6.pdf.

2. All technical support staff working with research animals shall be American Association for Laboratory Animal Science (AALAS) certified as Laboratory Animal Technicians. All animal use protocols will be approved using a duly appointed Animal Use Committee and the USAMRMC Animal Care and Use Review Office (ACURO).

3. Personnel training programs are required in the use of the CSM, RDT&E dilute solutions, and hazardous materiel in conducting in vivo and in vitro RDT&E studies.
4. Scientific and technical staff shall be experienced in developing and/or validating quantitative in vivo and in vitro models for efficacy testing, safety, and/or toxicologic studies. Willingness and capability to conduct such research with chemical surety materiel is a requirement.
5. Scientific and technical staff experience is required in conducting percutaneous studies in animals; toxicological studies with special emphasis in dermatotoxicity and pulmonary toxicology; in vivo and in vitro modeling; analytical, physical, and clinical chemistry; pharmacology with emphasis on drug screening; pathophysiology; veterinary medicine; animal care, handling and maintenance; and related sciences.
6. Biomedical engineering expertise is required to make needed design and system changes as rapidly as possible to meet changing requirements.
7. Scientific, technical, and managerial capabilities are required to simultaneously conduct multiple studies involving multiple species of animals, some with large sample sizes. Consideration must be given to problems of containment of CSM in hoods and difficulties of animal experimentation therein (e.g., controlling percutaneous exposure variable within existing safety/surety regulations).
8. Capability and experience in biomedical scientific writing is required to include record of timeliness of submission of reports, i.e., task order study reports and quarterly, annual, and final reports.
9. Automated data processing (ADP) capabilities are required to support data processing, storage, retrieval, and reporting. ADP capabilities must be compatible with USAMRMC software, i.e., Windows NT and Microsoft Office.
10. Capability in biostatistics is required for experimental design and data analysis with consideration given to statistical analysis of data in developing quantitative standardized biomedical models for research, testing, and evaluation.

E. Management Plan:

1. The Management Plan shall allow for commitment of scientific and technical staff time for research and testing based on protocols and standard test procedures provided by the Government and commitment of staff time in direct support of research and testing conducted jointly with U.S. Government employees and/or other USAMRMC contract personnel.
2. Accessibility - The development of new tasks requires close consultation by Government representatives with the awarded laboratory. The staff of the awarded facility will be available to discuss, plan, and negotiate the development of new tasks to be performed at the facility within 48 hours of notification of a request for such information.
3. Procedures to periodically review the Contractor's in-house organizational functions, program reviews and controls, inspections, and subsequent coordination with the Government.

IV. Contracting Officer's Representative - The Contracting Officer's Representative (COR) will be the Government's representative in all dealings with the contracted facility. All negotiated tasks will be reviewed, edited and prioritized by the COR and he/she will have overall scientific oversight of all research projects being conducted at the facility. These responsibilities include, but are not limited to, regular monitoring of progress; consultation and liaison between the Government task representatives and the contracted laboratory, negotiation of task associated costs, and reimbursement for the outside use of the surety facility or any Government owned equipment. Adequate office space will be provided for a regularly visiting COR as well as visiting personnel using the facilities on a short-term basis. On-site Contractor support to a visiting COR includes a functional

office, interfaced computer and phone commensurate with the duties of a senior researcher. The COR will have unfettered access to the facilities and files pertaining to the Government contract.

V. PERSONNEL RELIABILITY PROGRAM (PRP) CERTIFYING OFFICIALS

a. Certifying Officials must be military or DOD civilian personnel. DOD contractor personnel are prohibited from acting as certifying officials.

b. No one will be assigned to a PRP position until the Certifying Official screens and certifies the individual as suitable for the PRP.

c. Certifying Officials will --

- (1) Determine PRP suitability and ensure that individuals are qualified, trained, and are proficient before being assigned to chemical duties;
- (2) Continuously evaluate personnel assigned to PRP positions;
- (3) Promptly remove, or in contracted operations, direct the contractor to remove from chemical duties, any individual whose reliability becomes suspect. In such cases, the Certifying Official will take prompt action to expeditiously resolve the issue and either reinstate or permanently disqualify the individual; and
- (4) All dossiers for personnel being assigned to PRP positions will be made available for review. Certifying Officials may request a dossier for review purposes.

VI. PERSONNEL RELIABILITY PROGRAM (PRP) FOR CONTRACTOR EMPLOYEES

a. Certifying Official. The Army COR designated by the Contracting Officer will be the Certifying Official for DOD contractor employees authorized to perform chemical duties. The Contracting Officer may authorize delegation of Certifying Official duties to subordinate military or Army civilian personnel. The Contracting Officer's delegation letter to the COR must stipulate such delegation. Certifying Officials will ensure that contracts require contractor employees performing PRP duties in positions subject to this regulation to meet the PRP reliability standards in accordance with AR 50-6 and in approved surety contract clauses. Specifically, the contractor will --

- (1) Inform managerial, supervisory, medical and other contractor personnel of the purposes, standards, procedures, and responsibilities required for implementing the PRP.
- (2) Inform and instruct each employee assigned chemical duties of the significance of assignment, importance of reliable performance, PRP standards, safety and security considerations, and continuing evaluation requirements for self-reporting and peer review of factors and situations that could affect job performance or reliability. The contractor will foster a positive attitude toward both the PRP and chemical duties among PRP employees and will ensure that each PRP employee understands that maintaining PRP standards is a condition of continued employment in the chemical agent facility.
- (3) Ensure that each employee to be assigned to a PRP position is subjected to a Personnel Security Investigation (PSI), medical record evaluation, substance abuse testing, personal interview, and continuing evaluation under the reliability standards of the PRP outlined in AR 50-6.
- (4) Ensure that each employee assigned to a PRP position has received the formal course of instruction and/or experience applicable to the chemical duties assigned and is proficient in those duties.
- (5) Provide the investigating organization the Unit Identification Code (UIC) for USAMRICD in the "Return Results To" space. USAMRICD will be the recipient of all investigative results for The Contractor's individuals assigned to USAMRICD efforts. The contractor will provide the Certifying Official with results of medical record evaluations, and substance abuse testing of any

contractor employee assigned, or proposed to be assigned to a PRP position. In addition, the contractor must report immediately any other information about an employee relevant to maintaining PRP reliability standards.

(6) Provide for the continuing evaluation of employees assigned to PRP positions by contractor supervisory personnel.

(7) Immediately remove an employee from a PRP position on notification by the Certifying Official that the employee has been disqualified and notify the Certifying Official in writing within 15 days of the removal action. Disqualification from the PRP requires that the following:

(a) The employee will be instructed to cease performance of chemical duties and will be restricted from working with chemical agent.

(b) The employee will be prevented from entering any USAMRICD sponsored chemical laboratory area and immediate laboratory supporting area that would allow the individual access to areas containing chemical agent and the employee's entry credential will be confiscated or removed from the entry control system to the USAMRICD sponsored chemical laboratory and immediate laboratory supporting area.

(c) The employee will be removed from a PRP position on determination by the Certifying Official that the employee no longer meets PRP reliability standards and has been permanently disqualified. This action will be made a matter of permanent record.

(8) Provide to the Defense Security Service (DSS), ATTN: 50831, 2780 Airport Drive, Suite 400, Columbus, OH 43219-2268, a list of all personnel in the PRP that have security clearances granted by DSS. Update lists as needed. Lists will include the full name and SSN of each employee; name and address of the employing contractor facility; and the title, address, and DSN telephone number of the Army Certifying Official for the contract.

b. PRP Administration Official

(1) At COCO facilities, the Certifying Official may designate one or more senior supervisory contractor employees to assist in administering day-to-day certifying official duties. This official will be nominated by the contractor and approved by the COR. This individual will be enrolled in the PRP.

(2) The PRP administration official may perform all duties normally associated with the certifying official except for the decision-making functions of determining PRP suitability and disqualifying personnel from the PRP. The contractor may, however, administratively remove employees from PRP duties as needed. The Certifying Official must complete DA Form 3180, parts V and IX. The PRP administration official may be delegated authority to sign part VI.

(3) The PRP administration official may be delegated the authority to medically restrict an individual from performing chemical duties. However, in cases where the individual does not wish medical authorities to forward such personal information to the PRP administration official, the Certifying Official must perform the medical restriction function.

(4) The PRP administration official may be authorized to authenticate the CDPR. (Also see paragraph 2-5c of AR 50-6).

C. Personnel Security Investigations (PSI) (exception to paragraph 2-33c of AR 50-6)

(1) Security: The Contractor shall have the ability to obtain a DOD site clearance for handling classified material. The Contractor shall be required to have appropriate storage area, such as a

safe or file cabinet with a combination lock, in which classified materials can be safely secured. The Contractor shall ensure that only minimum essential personnel know the combination to these secure areas and that combination to secure areas are changed periodically. Key management and operational personnel shall be required to have security clearances commensurate with the security level of information that they handle.

(2) The Security Manager for USAMRICD will notify The Contractor's Security Officer with clearance/investigation results for any Contractor employees submitted by the USAMRICD Security Manager. The Security Manager for USAMRICD will submit PSI requests in the case of NAC/ANACI/NACI for all contractor employees considered for assignment to PRP positions. If the Contractor's employee requires a more in depth investigation, the Contractor's Security Officer will submit the investigation request via e-QIP, indicating the USAMRICD UIC as the "Return Results To" recipient.

(3) The contractor is required to provide the USAMRICD Security Manager with any derogatory information that would be sent to DSS/OPM if the employee were cleared under the DOD Industrial Security Program. The contractor will send NAC requests through the USAMRICD Security Manager using SF 86 (Questionnaire for National Security Positions), and FBI Form 258 (Applicant Fingerprint Card). The correct form(s) must be completed as provided by e-QIP. The USAMRICD Security Manager will provide all information to the Certifying Official.

(4) For contractor employees not requiring a security clearance, the contractor will send NAC requests to the USAMRICD Security Manager using e-QIP, FBI Form 258 (Applicant Fingerprint Card), for submission to DSS/OPM. The correct form(s) must be completed as provided by e-QIP. The USAMRICD Security Manager will provide all information to the Certifying Official.

(5) The USAMRICD Security Manager will coordinate with the investigating organization to ensure that any reports of investigation are returned to USAMRICD. The USAMRICD Security Manager will in turn provide results to the Certifying Official. The Certifying Official will adjudicate the Personnel Security Investigation (PSI) results based upon PRP criteria. Under no circumstances will the USAMRAA contracting office, the USAMRICD Security Manager, or Certifying Official disclose to the contractor any information about a contractor employee developed in the course of official investigations. In the event the PSI is unfavorable for PRP purposes, the contractor will simply be told that the employee is unsuitable for the PRP. Permanent disqualification procedures will then be initiated.

VII. GOVERNMENT FURNISHED PROPERTY

All property furnished by the Government shall remain the property of the Government. Title to all property purchased by the Contractor, for the cost of which the Contractor is entitled to be reimbursed as a direct item of cost under this contract, and shall be passed to, and vested in the Government upon delivery of such property by the vendor. Title to other property, the cost of which is reimbursable to the Contractor under the contract, shall be passed to and vested in the Government upon (i) issuance for use of such property in the performance of this acquisition, or (ii) commencement of processing or use of such property in the performance of the contract, or (iii) reimbursement of the cost thereof by the Government in whole or in part, whichever first occurs. However, the Government intends to minimize all property to be furnished by or purchased on behalf of the Government.

VIII. REPORTING REQUIREMENTS

A. The contractor shall submit the following technical reports:

(1) Contract Progress Reports (Quarterly, Annual, and Final Progress Reports). (see Section F Reporting Requirements.)

- (2) Task Order Study Reports. (see Attachment 5).
- (3) Copies of manuscripts submitted for publication (see Section F of the solicitation).
- (4) Copies of abstracts for professional meetings (see Section F of the solicitation).
- (5) Reprints of publications when available (see Section F of the solicitation).
- (6) News releases related to this contract (see Section F of the solicitation).

B. Complete, accurate, and timely reports on the progress and/or findings of the research supported by this contract are required.

C. Contractor Manpower Reporting (see Section C of the solicitation).

IX. Quality Control: The Contractor shall develop and maintain an effective Quality Control Program (QCP) to ensure services are performed in accordance with this PWS. The Contractor shall develop and implement procedures to identify, prevent, and ensure non-recurrence of defective services. The Contractor's QCP is the means by which it assures that this work complies with the requirements of the contract. The QCP is to be submitted with the contractor's proposal.

X. Quality Assurance: The Government will evaluate the Contractor's performance under this contract in accordance with the Quality Assurance Surveillance Plan (See Attachment 8). This plan is primarily focused on what the Government must do to ensure that the Contractor has performed in accordance with the performance standards. It defines how the performance standards will be applied, the frequency of surveillance, and the minimum acceptable defect rate.

ACRONYMS:

AAALAC	American Association for Accreditation of Laboratory Animal Care International
AALAS	American Association for Laboratory Animal Science
ACURO	Animal Care and Use Review Office
ADP	Automated Data Processing
ANACI	Access National Agency Check with Inquiries
AQL	Acceptable Quality Level
AR	Army Regulation
BLA	Biologic License Application
CBMS	Chemical Biological Medical Systems
CBER	Center for Biologics Evaluation and Research
CDER	Center for Drug Evaluation and Research
CMR	Contractor Manpower Reporting
COCO	Contractor-Owned/Contractor-Operated
COR	Contracting Officer's Representative
CSM	Chemical Surety Material
DA	Department of Army
DCAA	Defense Contract Audit Agency
DOD	Department of Defense
DSN	Defense Security Number
DSS	Defense Security Service
DTO	Defense Technology Objective
DTRA	Defense Threat Reduction Agency
EA	Environmental Assessment
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
GLP	Good Laboratory Practices
HQDA	Headquarters, Department of the Army
IND	Investigational New Drug
JPEO-CBD	Joint Program Executive Officer for Chemical and Biological Defense
MCDRP	Medical Chemical Defense Research Program
M&O	Management and Operational
MREF	Medical Research Facility
NAC	National Agency Check
NACI	National Agency Check with Inquires
NDA	New Drug Application
PRP	Personnel Reliability Program
PRS	Performance Requirements Summary
PSI	Personnel Security Investigation
PWS	Performance Work Statement
QA	Quality Assurance
QAP	Quality Assurance Program
QASP	Quality Assurance Surveillance Plan
QCP	Quality Control Plan
RDT&E	Research, Development, Testing, and Evaluation
RFP	Request for Proposal
SSN	Social Security Number
UIC	Unit Identification Code
USAMRICD	U.S. Army Medical Research Institute of Chemical Defense
USAMRMC	U.S. Army Medical Research and Materiel Command

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CONTRACTOR MANPOWER REPORTING (CMR) - (ACCOUNTING FOR CONTRACT SERVICES) (OCT 2007) (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 number is 703-377-6199 for any technical questions. 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.

52.004-4002 Contractor Performance Assessment Reporting System (CPARS) (USAMRAA) (September 2009)

The Contractor Performance Assessment Reporting System (CPARS) has been adopted electronically to capture assessment data and manage the evaluation process. CPARS is used to assess a contractor's performance and provide a record, both positive and negative, on a given contract during a specific period of time. The CPARS Automated Information System (AIS) collection tool and other CPARS information can be accessed at <https://www.cpars.csd.disa.mil>. CPARS collects contractor performance information and passes it to the Federal Past Performance Information Retrieval System (PPIRS) where it can be retrieved by Federal Government Agencies including the DoD Services. The CPARS process is designed with a series of checks and balances to facilitate the objective and consistent evaluation of contractor performance. Both government and contractor program management perspectives are captured on the CPAR form and together make a complete CPAR. The Contractor shall assign and provide to the Contracting Officer's Representative (COR), within 10 calendar days after award, the name, title, email address and phone number of the designated Contractor Representative (CR) within their firm who will be responsible for CPAR information and reviewing the Government's proposed assessment for the period of performance. A User ID and Password for the CPARS will be provided to the designated CR for this purpose of accessing the CPARS. The CR has the authority to: Receive the Government evaluation; Review/comment/return the evaluation to the Government within 30 calendar days after the Government's evaluation is completed; Request a meeting to discuss the CPAR. This meeting must be requested, in writing, no later than seven calendar days from the receipt of the CPAR and must be held during the contractor's 30-day review period. The CR must either concur or nonconcur to each CPAR.

RDS (RDTE DILUTE SOLUTIONS)(DEC 2006)(USAMRAA)

(a) The Contractor shall operate in a safe environment, with properly safe equipment and procedures. This means that, at a minimum, the Contractor shall satisfy the RDS-RDTE Dilute Solutions Standard located at <http://www.usamraa.army.mil> (then click on "Assistance Agreements" then under "Documents" click on "RDS (RDTE Dilute Solutions) Standard (November 2000)."

(b) All RDS disposal shall be addressed prior to expiration of the contract.

(c) Requests for RDS shall be provided, in writing, to the Chief, Safety & Chemical Operations Officer at:

Commander
US Army Medical Research Institute of
Chemical Defense
3100 Ricketts Point Road
ATTN: MCMR-CDZ-S
Aberdeen Proving Ground, MD 21010-5400
(410) 436-4433 and fax: (410) 436-3004

with a copy furnished to the Contracting Officer at:

Director
US Army Medical Research Acquisition Activity
820 Chandler Street
ATTN: MCMR-AAA-B (Lisa Sawyer)
Fort Detrick, MD 21702-5014
(301) 619-6661

and the Contracting Officer's Representative (COR) at:

To Be Determined (TBD) upon award

and shall furnish the following information:

Name of the Principal Investigator:
Name(s) and phone number(s) of custodian(s):
Shipment Address:
Contract Number:
RDS, Concentration, Amount, Diluent (if applicable),
and Specific Activity (if applicable)

FACILITY SAFETY PLAN STATUS REPORT (DEC 2006) (USAMRAA)

1. A Facility Safety Plan Status Report must be submitted annually starting no later than 1 year after obtaining the initial approval of the institution's Facility Safety Plan. In the event that the Principal Investigator changes during the performance under this contract, the new Principal Investigator shall complete the "Newly Appointed Principal Investigator Assurance" form (see paragraph 3).

2. As a part of the annual Facility Safety Plan Status Report, the Facility Safety Director/Manager must provide the following: A brief description of any parts of the Facility Safety Plan that may have changed during the past 12 months. (Additional pages may be attached.)

During the past 12 months:

1. Have any change(s) in Research Operation Safety Procedure(s) been made?

Yes _____ No _____

If yes, briefly describe:

2. Have any modifications to the facility, equipment, and description (e.g., new equipment purchased, hood ventilation certification) been made?

Yes _____ No _____

If yes, briefly describe:

3. Hazard Analysis: Have any new hazards been identified for any of the awards supported by the USAMRMC?

Yes _____ No _____

If yes, provide a hazard analysis for each new hazard.

4. Radioactive Materials: Have any significant change(s) occurred in the use of the radioactive materials?

Yes _____ No _____

If yes, briefly describe:

a. Are there any additional radioactive materials in use?

Yes _____ No _____

If yes, list additional material(s).

b. Is the radioactive material licensure current?

Yes _____ No _____

If no, please explain.

I certify that all of the above elements are true and correct to the best of my knowledge, and I assure that this institution provides a safe environment for its employees working in research laboratories in accordance with Federal, State, and local government regulations. This safety office provides employee safety training and periodic laboratory inspections in an effort to minimize, eliminate, or control potential hazards to the employees and the public.

I understand that the Safety Office, USAMRMC, may conduct periodic site visits in order to ensure the indicated elements are in compliance with regulatory requirements.

Name of the Institution: _____

Name of Safety Director/Manager: _____

Signature: _____ Date: _____

Safety Director/Manager

E-mail Address: _____

Phone Number: _____

Fax Number: _____

Facility Safety Plan approved by USAMRMC Safety Office: _____ Date _____

3. Newly Appointed Principal Investigator Assurance

_____ I assure that I have coordinated with the Facility Safety Director/Manager in the research, and have discussed with him/her all aspects of the research-related specific safety issues, and will help him/her prepare the annual Facility Safety Plan Status Report.

_____ I assure that I will comply with my institution's safety program and its requirements.

_____ I understand that I am directly responsible for all aspects of safety and occupational health specific to my research protocol.

_____ I assure that I will report to the Facility Safety Director/Manager any changes in the safety or occupational health practices due to changes in my originally planned research.

_____ I assure that hazards associated with my research have been identified, eliminated and/or controlled.

_____ I assure that all safety requirements are in compliance with 32 CFR 626 and 627, "Biological Defense Safety Program and Biological Defense Safety Program, Technical Safety Requirements" (if applicable).

Name of Principal Investigator (print)

Signature

Date

Mailing Address: _____

Street

City

State

Zip Code

Phone Number: _____

Fax: _____

E-mail Address: _____

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.

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.

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.

52.035-4036 PROHIBITION OF USE OF HUMAN CADAVERS (JAN 2005) (USAMRAA)

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

Research under this award using human cadavers 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 cadavers 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 this approval will be provided to the US Army Medical Research Acquisition Activity for the official file. Non-compliance with any provision of this clause may result in withholding of funds and or the termination of the award.

KEY PERSONNEL (MAR 1999) (USAMRAA)

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

PROGRAM MANAGER: TBD

PRINCIPAL INVESTIGATOR: TBD

- 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.

Note: TBD = to be determined.

CHEMICAL, BIOLOGICAL, RADIOLOGICAL, NUCLEAR, AND EXPLOSIVES (CBRNE) TRAINING (DEC 2006) (USAMRAA)

Some or all contractor employees working under this contract are considered supplemental staffing personnel in that they supplement the efforts of U.S. Army Medical Research and Material Command military and civil service employees in their regular and continuing duties. All supplemental staffing employees shall complete an appropriate Army Medical Department CBRNE Training Course offered by the Army Training Support Center. Course access is achieved through enrollment in the Army Correspondence Course Program at <http://www.atsc.army.mil/accp/aipdnew.asp>. Upon course completion, the contractor shall provide a copy of each individual's training certificate to the Contracting Officer. The CBRNE course shall be completed within forty-five (45) calendar days of the individual's commencement of contract services.

The course(s) applicable for this award are annotated below:

CBRNE Basic - For personnel who would not be employed as responders during a CBRNE event.....such as contractor personnel working in administrative positions.

CBRNE Executive - For personnel in executive leadership positions.

CBRNE Clinician - For health care providers who would or may have clinical duties in response to a CBRNE event.

CBRNE Operator/Responder - For all personnel, other than health care providers, who would or could be involved in planning or responding to a CBRNE event.

Section D - Packaging and Marking

COMMERCIAL PACKING AND MARKING

- a. Packing shall be standard commercial to ensure acceptance by common carrier for safe delivery to destination unless otherwise specified in the specifications or descriptions of the item.
- b. All shipping or mailing containers shall be marked showing Contract Number and the destination address shown in Section F.

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	Destination	Government
0002	Destination	Government	Destination	Government
0003	Destination	Government	Destination	Government
0004	Destination	Government	Destination	Government
1001	Destination	Government	Destination	Government
1002	Destination	Government	Destination	Government
1003	Destination	Government	Destination	Government
1004	Destination	Government	Destination	Government
2001	Destination	Government	Destination	Government
2002	Destination	Government	Destination	Government
2003	Destination	Government	Destination	Government
2004	Destination	Government	Destination	Government

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52.246-8 INSPECTION OF RESEARCH AND DEVELOPMENT-- COST-REIMBURSEMENT (MAY 2001)

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

"Contractor's managerial personnel," means the Contractor's directors, officers, managers, superintendents, or equivalent representatives who have supervision or direction of--

- (1) All or substantially all of the Contractor's business;
- (2) All or substantially all of the Contractor's operation at any one plant or separate location where the contract is being performed; or
- (3) A separate and complete major industrial operation connected with performing this contract.

"Work," includes data when the contract does not include the Warranty of Data clause.

(b) The Contractor shall provide and maintain an inspection system acceptable to the Government covering the work 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 work called for by the contract, to the extent practicable at all places and times, including the period of performance, and in any event before acceptance. The Government may also inspect the plant or plants of the Contractor or its subcontractors engaged in the contract performance. The Government shall perform inspections and tests in a manner that will not unduly delay the work.

(d) If the Government performs any inspection or test on the premises of the Contractor or a subcontractor, the Contractor shall furnish and shall require subcontractors to furnish all reasonable facilities and assistance for the safe and convenient performance of these duties.

(e) Unless otherwise provided in the contract, the Government shall accept work as promptly as practicable after delivery, and work shall be deemed accepted 90 days after delivery, unless accepted earlier.

(f) At any time during contract performance, but no later than 6 months (or such other time as may be specified in the contract) after acceptance of all of the end items (other than designs, drawings, or reports) to be delivered under the contract, the Government may require the Contractor to replace or correct work not meeting contract requirements. Time devoted to the replacement or correction of such work shall not be included in the computation of the above time period. Except as otherwise provided in paragraph (h) below, the cost of replacement or correction shall be determined as specified in the Allowable Cost and Payment clause, but no additional fee shall be paid. The Contractor shall not tender for acceptance work required to be replaced or corrected without disclosing the former requirement for replacement or correction, and, when required, shall disclose the corrective action taken.

(g)(1) If the Contractor fails to proceed with reasonable promptness to perform required replacement or correction, the Government may--

(i) By contract or otherwise, perform the replacement or correction, charge to the Contractor any increased cost, or make an equitable reduction in any fixed fee paid or payable under the contract;

(ii) Require delivery of any undelivered articles and shall have the right to make an equitable reduction in any fixed fee paid or payable under the contract; or

(iii) Terminate the contract for default.

(2) Failure to agree on the amount of increased cost to be charged the Contractor or to the reduction in fixed fee shall be a dispute.

(h) Notwithstanding paragraphs (f) and (g) above, the Government may at any time require the Contractor to remedy by correction or replacement, without cost to the Government, any failure by the Contractor to comply with the requirements of this contract, if the failure is due to (1) fraud, lack of good faith, or willful misconduct on the part of the Contractor's managerial personnel or (2) the conduct of one or more of the Contractor's employees selected or retained by the Contractor after any of the Contractor's managerial personnel has reasonable grounds to believe that the employee is habitually careless or unqualified.

(i) This clause shall apply in the same manner to a corrected or replacement end item or components as to work originally delivered.

(j) The Contractor has no obligation or liability under the contract to correct or replace articles not meeting contract requirements at time of delivery, except as provided in this clause or as may otherwise be specified in the contract.

(k) Unless otherwise provided in the contract, the Contractor's obligations to correct or replace Government-furnished property shall be governed by the clause pertaining to Government property.

(End of clause)

(a) At the time of each delivery of supplies or services under this contract, the Contractor shall prepare and furnish to the Government a material inspection and receiving report in the manner and to the extent required by Appendix F, Material Inspection and Receiving Report, of the Defense FAR Supplement.

(b) Contractor submission of the material inspection and receiving information required by Appendix F of the Defense FAR Supplement by using the Wide Area WorkFlow (WAWF) electronic form (see paragraph (b) of the clause at 252.232-7003) fulfills the requirement for a material inspection and receiving report (DD Form 250). Two copies of the receiving report (paper copies of either the DD Form 250 or the WAWF report) shall be distributed with the shipment, in accordance with Appendix F, Part 4, F-401, Table 1, of the Defense FAR Supplement.

(End of clause)

Section F - Deliveries or Performance

CBRNE TRAINING CERTIFICATES

As stated in Section C, Chemical, Biological, Radiological, Nuclear, and Explosives (CBRNE) Training, upon course completion, the contractor shall provide a copy of each individual's training certificate to the Contracting Officer. The CBRNE course shall be completed within 45 calendar days of the individual's commencement of contract services. Copies of certificates may be submitted electronically as a .pdf via e-mail to the Contract Specialist to be named in block 6 of the Standard Form 26.

PERIOD OF PERFORMANCE

- a. The Government anticipates award of a base contract for three (3) years with a provision for two (2) one-year options.
- b. In the event the Government elects to exercise its option(s) pursuant to the terms of this contract, the period of performance and effective ordering period for each option shall be as set forth in the following provision "Option to Extend Services" of this contract. The Period of Performance inclusive of all options may not exceed 5 years.

DELIVERY INFORMATION

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	UIC
0001	POP 02-NOV-2010 TO 01-NOV-2013	N/A	USA MED RESEARCH MAT CMD JUANITA LIVINGSTON 504 SCOTT STREET FORT DETRICK MD 21702-5012 FOB: Destination	W23RYX
0002	POP 02-NOV-2010 TO 01-NOV-2013	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W23RYX
0003	POP 02-NOV-2010 TO 01-NOV-2013	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W23RYX
0004	POP 02-NOV-2010 TO 01-NOV-2013	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W23RYX
1001	POP 02-NOV-2013 TO 01-NOV-2014	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W23RYX
1002	POP 02-NOV-2013 TO 01-NOV-2014	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W23RYX

1003	POP 02-NOV-2013 TO 01-NOV-2014	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W23RYX
1004	POP 02-NOV-2010 TO 01-NOV-2013	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W23RYX
2001	POP 02-NOV-2014 TO 01-NOV-2015	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W23RYX
2002	POP 02-NOV-2014 TO 01-NOV-2015	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W23RYX
2003	POP 02-NOV-2014 TO 01-NOV-2015	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W23RYX
2004	POP 02-NOV-2010 TO 01-NOV-2013	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W23RYX

CLAUSES INCORPORATED BY REFERENCE

52.247-34	F.O.B. Destination	NOV 1991
52.247-55	F.O.B. Point For Delivery Of Government-Furnished Property	JUN 2003

CLAUSES INCORPORATED BY FULL TEXT

REPORTING REQUIREMENTS (OCT 2009) (USAMRAA)

Technical reporting requirements (Monthly, Quarterly, and/or Annual/Final Reports) applicable to this award are annotated below with an "X":

See Note **MONTHLY TECHNICAL PROGRESS REPORTS**

***** (NOTE: Will be designated in individual task orders if required.) *****

a. The contractor shall submit a Monthly Technical Progress Report covering work accomplished during each month of contract performance. It shall be brief, factual, and informal, and shall be prepared in accordance with the following:

- (l) Cover containing:
 - (a) Contract number and title
 - (b) Type of report, sequence number of report, and period of performance being reported
 - (c) Contractor's name, address, and telephone number

(d) Principal Investigator

(e) Date of publication

(f) Contracting Officer's Representative

(2) Section I - A brief introduction covering the purpose and scope of the research effort.

(3) Section II - A brief description of overall progress to date plus a separate description for each task or other logical segment of work on which effort was expended during the report period. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved.

(4) Section III - Problem Areas

(a) A description of current problems that may impede performance along with proposed corrective action.

(b) A description of anticipated problems that have a potential to impede progress and what corrective action is planned should the problem materialize.

(5) Section IV - A description of work to be performed during the next reporting period.

(6) Section V - Administrative Comments (Optional) - Description of proposed site visits and participation in technical meetings, journal manuscripts in preparation, coordination with other organizations conducting related work, etc.

(7) Section VI - A Gantt Chart showing actual progress versus scheduled progress.

b. Monthly Technical Progress Reports shall be prepared by the seventh day following the month being reported, and shall be received within 10 days of the report month. The Monthly Technical Progress Report shall be submitted to the following addresses (**electronic submission preferred**):

***** Applicable addresses will be specified on individual task orders as required. *****

QUARTERLY REPORTS

a. Quarterly reports are the most immediate and direct contact between the Principal Investigator (PI) and the Contracting Officer's Representative (COR). The reports provide the means for keeping this Command advised of developments and problems as the contract effort proceeds. The quarterly reports also provide a measure against which decisions on release of funding and on requests for supplements are made.

b. In accordance with Section C., a Quarterly Report shall be submitted for each three-month period beginning with the effective date of the contract. This requirement includes all three-month periods of the contract.

c. Copies of each report shall be submitted in the quantities indicated to the addresses shown below within fifteen (15) days after the end of each quarter. Internal Government distribution will be made by those offices (**electronic submission preferred**).

(1) One (1) copy of the report to:

Defense Threat Reduction Agency (DTRA)
ATTN: DTRA-CBM/ *****POC name to be inserted upon award*****
8725 John J. Kingman Road, Stop 6201

Fort Belvoir, VA 22060-6201
e-mail: *****to be inserted upon award*****

(2) One (1) copy of the report to:

Commander
U.S. Army Medical Research Institute of Chemical Defense
ATTN: MCMR-CDR-I/ *****POC name to be inserted upon award*****
3100 Ricketts Road
Aberdeen Proving Ground, MD 21010-5400
e-mail: *****to be inserted upon award*****

(3) One (1) copy of the report to:

Project Manager
Chemical Biological Medical Systems
ATTN: SFAE-CBD-CBMS/ *****POC name to be inserted upon award*****
64 Thomas Johnson Drive
Frederick, MD 21702
e-mail: *****to be inserted upon award*****

(4) One (1) copy of the report to:

Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-RTM/ *****POC name to be inserted upon award*****
504XX Scott Street
Fort Detrick, MD 21702-5012
e-mail: *****to be inserted upon award*****

(5) One (1) copy of the report to:

Director
U.S. Army Medical Research Acquisition Activity
ATTN: MCMR-AAA-B/ *****POC name to be inserted upon award*****
820 Chandler Street
Fort Detrick, MD 21702-5014

d. The Quarterly Report sample (See following Quarterly Report Format) shall serve as the format. Each item of the report format shall be completed.

QUARTERLY REPORT FORMAT

1. Contract No. _____ 2. Report Date _____
3. Reporting period from _____ to _____
4. PI _____ 5. Telephone No. _____

6. Institution _____

7. Project Title _____

8. Current staff, with percent effort of each on project.

_____ % _____ %

_____ % _____ %

9. Contract expenditures to date (as applicable):

This Qtr/Cumulative	This Qtr/Cumulative
Personnel _____ / _____	Travel _____ / _____
Fringe Benefits _____ / _____	Equipment _____ / _____
Supplies _____ / _____	Other _____ / _____

This Qtr/Cumulative
Subtotal _____ / _____
Indirect Costs _____ / _____
Fee _____ / _____
Total _____ / _____

10. Comments on administrative and logistical matters.

11. Use additional page(s), as necessary, to describe scientific progress for the quarter in terms of the tasks or objectives listed in the statement of work for this contract.

12. Use additional page(s) to present a brief statement of plans or milestones for the next quarter.

FORMAT REQUIREMENTS FOR ANNUAL/FINAL REPORTS

a. Annual reports must provide a complete summary of the research accomplishments to date with respect to the approved Statement of Work. Journal articles can be substituted for detailed descriptions of specific aspects of the research, but the original articles must be attached to the report as an appendix and appropriately referenced in the text. The importance of the report to decisions relating to continued support of the research cannot be over-emphasized. An annual report shall be submitted within 30 calendar days of the anniversary date of the award for the preceding 12-month period. If the award period of performance is extended by the Contracting Officer then an annual report must still be submitted within 30 calendar days of the anniversary date of the award. A final report will be due upon completion of the extended performance date that describes the entire research effort.

b. A final report summarizing the entire research effort, citing data in the annual reports and appended publications shall be submitted at the end of the award performance period. The final report will provide a complete reporting of the research findings. Journal publications can be substituted for detailed descriptions of specific aspects of the research, but an original copy of each publication must be attached as an appendix and appropriately referenced in the text. All final reports must include a bibliography of all publications and meeting abstracts and a list of personnel (not salaries) receiving pay from the research effort.

Although there is no page limitation for the reports, each report shall be of sufficient length to provide a thorough description of the accomplishments with respect to the approved Statement of Work. Submission of the report in electronic format (PDF or Word file only) shall be submitted to <https://ers.amedd.army.mil>.

All reports shall have the following elements, in this order:

FRONT COVER: A Sample front cover is provided at <https://mrmc.amedd.army.mil/rpindex.asp>. The Accession Document (AD) Number should remain blank.

STANDARD FORM 298: A Sample SF 298 is provided at <https://mrmc.amedd.army.mil/rpindex.asp>. The abstract in Block 13 must state the purpose, scope, major findings and be an up-to-date report of the progress in terms of results and significance. Subject terms are keywords that may have previously assigned to the proposal abstract or are keywords that may be significant to the research. The number of pages shall include all pages that have printed data (including the front cover, SF 298, table of contents, and all appendices). Please count pages carefully to ensure legibility and that there are no missing pages as this delays processing of reports. Page numbers should be typed: please do not hand number pages.

TABLE OF CONTENTS: Sample table of contents provided at <https://mrmc.amedd.army.mil/rpindex.asp>.

INTRODUCTION: Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

BODY: This section of the report shall describe the research accomplishments associated with each task outlined in the approved Statement of Work. Data presentation shall be comprehensive in providing a complete record of the research findings for the period of the report. Provide data explaining the relationship of the most recent findings with that of previously reported findings. Appended publications and/or presentations may be substituted for detailed descriptions of methodology but must be referenced in the body of the report. If applicable, for each task outlined in the Statement of Work, reference appended publications and/or presentations for details of result findings and tables and/or figures. The report shall include negative as well as positive findings. Include problems in accomplishing any of the tasks. Statistical tests of significance shall be applied to all data whenever possible. Figures and graphs referenced in the text may be embedded in the text or appended. Figures and graphs can also be referenced in the text and appended to a publication. Recommended changes or future work to better address the research topic may also be included, although changes to the original Statement of Work must be approved by the Army Contracting Officer's Representative. This approval must be obtained prior to initiating any change to the original Statement of Work.

KEY RESEARCH ACCOMPLISHMENTS: Bulleted list of key research accomplishments emanating from this research.

REPORTABLE OUTCOMES: Provide a list of reportable outcomes that have resulted from this research to include:

manuscripts, abstracts, presentations; patents and licenses applied for and/or issued; degrees obtained that are supported by this award; development of cell lines, tissue or serum repositories; infomatics such as databases and animal models, etc.; funding applied for based on work supported by this award; employment or research opportunities applied for and/or received based on experience/training supported by this award.

CONCLUSION: Summarize the results to include the importance and/or implications of the completed research and when necessary, recommend changes on future work to better address the problem. A "so what section" which evaluates the knowledge as a scientific or medical product shall also be included in the conclusion of the report.

REFERENCES: List all references pertinent to the report using a standard journal format (i.e. format used in Science, Military Medicine, etc.).

APPENDICES: Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

Pages shall be consecutively numbered throughout the report. **DO NOT RENUMBER PAGES IN THE APPENDICES.**

Mark all pages of the report which contain proprietary or unpublished data that should be protected by the U.S. Government. **REPORTS NOT PROPERLY MARKED FOR LIMITATION WILL BE DISTRIBUTED AS APPROVED FOR PUBLIC RELEASE.** It is the responsibility of the Principal Investigator to advise the U.S. Army Medical Research and Materiel Command when restricted limitation assigned to a document can be downgraded to Approved for Public Release. **DO NOT USE THE WORD "CONFIDENTIAL" WHEN MARKING DOCUMENTS.**

CLAUSES INCORPORATED BY FULL TEXT

52.242-15 STOP-WORK ORDER (AUG 1989) - ALTERNATE I (APR 1984)

(a) The Contracting Officer may, at any time, by written order to the Contractor, require the Contractor to stop all, or any part, of the work called for by this contract for a period of 90 days after the order is delivered to the Contractor, and for any further period to which the parties may agree. The order shall be specifically identified as a stop-work order issued under this clause. Upon receipt of the order, the Contractor shall immediately comply with its terms and take all reasonable steps to minimize the incurrence of costs allocable to the work covered by the order during the period of work stoppage. Within a period of 90 days after a stop-work is delivered to the Contractor, or within any extension of that period to which the parties shall have agreed, the Contracting Officer shall either--

(1) Cancel the stop-work order; or

(2) Terminate the work covered by the order as provided in the Termination clause of this contract.

(b) If a stop-work order issued under this clause is canceled or the period of the order or any extension thereof expires, the Contractor shall resume work. The Contracting Officer shall make an equitable adjustment in the delivery schedule, the estimated cost, the fee, or a combination thereof, and in any other terms of the contract that may be affected, and the contract shall be modified, in writing, accordingly, if--

(1) The stop-work order results in an increase in the time required for, or in the Contractor's cost properly allocable to, the performance of any part of this contract; and

(2) The Contractor asserts its right to the adjustment within 30 days after the end of the period of work stoppage; provided, that, if the Contracting Officer decides the facts justify the action, the Contracting Officer may receive and act upon the claim submitted at any time before final payment under this contract.

(c) If a stop-work order is not canceled and the work covered by the order is terminated for the convenience of the Government, the Contracting Officer shall allow reasonable costs resulting from the stop-work order in arriving at the termination settlement.

(d) If a stop-work order is not canceled and the work covered by the order is terminated for default, the Contracting Officer shall allow, by equitable adjustment or otherwise, reasonable costs resulting from the stop-work order.

(End of clause)

TASK/DELIVERY ORDERS - ALTERNATE III (DEC 2006) (USAMRAA)

a. The contractor shall perform in accordance with the contract schedule and as called for by orders issued in accordance with this clause.

b. The SF 1155 or 1449 will be used to issue task assignments and to signify Contracting Officer notification to commence work under the individual task orders. The contractor shall not proceed with the task until notification is received from the Contracting Officer.

c. The task/delivery orders, and modifications to task/delivery orders, will be numbered by the issuing office. Modifications to the task/delivery orders will be designated by the modification number and contain the original task order number.

d. The contractor shall identify all correspondence, reports, drawings, and other pertinent papers in connection with the contract by imprinting thereon the task/delivery order and the contract number, plus any other references furnished by the Contracting Officer.

e. The total of all completed and outstanding Task/Delivery Orders will at no time exceed the current amount obligated.

f. The Competition Advocate for the U.S. Army Medical Research Materiel Command, Fort Detrick, Maryland has been designated as the Ombudsman for this contract. (applicable to multiple award contracts only)

g. Procedures:

(1) Prior to issuance of a Task/Delivery Order and upon definition of the Government requirement, the Contracting Officer will, in writing, issue to the contractor a Task/Delivery Order Request for Proposal (RFP) which will designate a preferred Task/Delivery Order type.

(2) Where the level of effort identified by the Government is not sufficient to accomplish the task assigned or if the contractor determines that the task may expose the contractor to unacceptable hazards and/or risks, the contractor

shall promptly notify the Contracting Officer of the problems encountered. Notwithstanding any other provisions, the unacceptable portion of any task order shall be resolved to both the Government's and the contractor's mutual satisfaction prior to commencement of work in these areas.

(3) The contractor shall submit one electronic copy to the Contract Specialist by a date mutually agreed upon but no later than **10 working days** after receipt of the RFP:

a. Technical proposal (or Task Execution Plan (TEP)) which sets forth the contractor's understanding of the requirement, performance schedule, staffing plan, and level of effort required. The technical proposal/TEP should also address other documentation required by the Government to perform the task or any specific issues raised in the RFP.

b. Cost proposal which sets forth all costs associated with furnishing the required services, including cost or price data.

Note: If longer than **10 working days** will be required, the contractor shall provide justification to the Contracting Officer, in writing, as soon as possible after receipt of a task assignment.

The contractor's technical proposal/TEP shall be consistent with Section C and the technical and cost proposals incorporated into the contract. The contractor shall also identify any necessary differences between the technical proposal/TEP and the technical and business proposals incorporated into the contract.

(4) Upon receipt of the contractor's proposal, the Government will proceed to evaluate the same, subsequent to which negotiations will take place between the Contracting Officer and the contractor. The contractor is expressly forbidden from discussing with the Contracting Officer's Representative (COR), or any other Government technical personnel, any aspects of any pending Task/Delivery Orders absent expressed written permission from the Contracting Officer to that effect.

(5) Upon approval of the contractor's proposal, written authorization will be provided to initiate the study. Each separate study must have institution review approval. The contractor shall begin work on the approved task no later than 60 days following receipt of written authorization to initiate the study. The contractor agrees to initiate the study sooner than 60 days after receiving written authorization if effort of the required staff is available to devote to the task order. It is estimated that at least 60 days may be required to obtain both contractor's IRB approval and the Government's human use approval. Both parties agree to obtain approvals as expeditiously as possible after a requirement has been identified.

(6) Following the conclusion of negotiations, the Contracting Officer will issue a fully executed Task/Delivery Order, containing all agreed-to terms and conditions, specifying the task to be performed, technical contact for the particular study involved, special reporting requirements and total estimated cost and fixed fee. The contractor shall in no event exceed the total estimated cost of the Task/Delivery Order (see FAR 52.232-20 and 52.232-22)

Whenever it appears to the contractor that the actual cost to complete any task may exceed the estimated cost of such task, the contractor shall immediately, and in no event later than 14 calendar days prior to the time that the actual costs for which the contractor requires reimbursement will equal the estimated cost, notify the Contracting Officer in writing and furnish a revised estimate for the completion of the task. The contractor shall not incur costs to perform work under any specific task in excess of the cost estimate authorized for the task until the Contracting Officer notifies the contractor in writing that such amount has been increased. Issuance of a task order is not authorization for the contractor to incur costs in excess of the funds obligated to-date under the contract.

(7) In the event that the parties fail to agree on Task Order type, price, costs and/or fixed fee or profit for any Task Order hereunder, the Contracting Officer may render a unilateral written decision as to what type of Task Order and what level of price or costs and/or fee/profit is reasonable under the circumstances for the services required pursuant to the Task Order, and will subsequently unilaterally issue the Task Order in accordance with that decision. Said decision shall constitute a decision rendered concerning a question of fact within the meaning of and governed by the terms of FAR Clause 52.233-1 in Section I of this contract.

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. W81XWH-10-D- 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."

Note: TBD = to be determined

Section G - Contract Administration Data

CLAUSES INCORPORATED BY FULL TEXT

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 throughout the period of performance of this contract, extensions thereof, and any successor or follow-on contracts, and for one(1) additional year thereafter.

CLAUSES INCORPORATED BY FULL TEXT

REPRESENTATIONS AND CERTIFICATIONS (MAR 1999) (USAMRAA)

The representations, certifications, and other statements submitted by the contractor, dated TBD, are incorporated herein by reference.

Note: TBD = to be determined

CONTRACT CEILING (MAR 1999) (USAMRAA)

The ceiling price of this contract is \$51.2 Million. The contractor agrees that the work performed under this contract shall be accomplished within the specified ceiling price. Unless and until the Contracting Officer has notified the contractor in writing that the ceiling price has been increased and the amount of the increase, any costs incurred in excess of the ceiling price shall be borne by the contractor. The contractor's attention is directed to Section F of this contract, entitled "Task/Delivery Orders". Contractor entitlement to the monies specified as the contract ceiling is derived solely from the issuance and successful performance of task/ delivery orders against that ceiling amount.

VOUCHERS (DEC 2006) (USAMRAA)

- a. The Contractor shall submit an original and one copy of public vouchers (SF 1034), with supporting documentation, not less frequently than monthly to the cognizant Defense Contract Audit Agency (DCAA) for review and approval with a copy to the U.S. Army Medical Research Acquisition Activity, ATTN: MCMR-AAA-B/W81XWH-10-D-TBD-TBD, 820 Chandler Street, Fort Detrick, MD 21702-5014 for our records.
- b. All vouchers shall state the total amount claimed and the subtotals claimed, by category. The Government will make payments to the Contractor in amounts determined to be allowable by the Contracting Officer in accordance with the FAR clause at 52.216-7, Allowable Cost and Payment. For instance, travel costs shall include, as a minimum: date and place (city, town, or other similar designation) of the expenses; purpose of the trip; name of person and that person's title or relationship to the contractor, number of trips, public carrier rates, per diem costs, incidental costs, etc.
- c. Cumulative totals of expenditures in each category shall also be shown.
- d. Each voucher submitted must state the period of performance. Each voucher submitted must request payment for only those man-hours or cost expenditures incurred in that period.
- e. The Contracting Officer shall be notified immediately in the event a budget category is expected to deviate from the negotiated budget.
- f. The completion voucher shall be submitted by the Contractor to the Contract Specialist.

NOTE: TBD = to be determined

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 **120 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.

GOVERNMENT-FURNISHED PROPERTY/ MATERIEL – Alternate I (MAR 1999) (USAMRAA)

The dilute chemical surety materiel and Mark I kits required for the performance of this contract shall be provided by the U.S. Army on an as needed basis and shall be coordinated between the contractor and the Contracting Officer. No work shall be performed using dilute chemical surety materiel prior to Government written approval of the contractor's Facility Safety and Surety Plan.

a. Pursuant to the Government Property Clause set forth in the General Provisions of this contract, the Government shall furnish F.O.B. contractor's place of performance, the Government-owned property/materiel listed in paragraph "d" below for use in the performance of this contract.

b. The items shall be delivered in accordance with the schedule set forth in paragraph "d" below.

c. If the items are not received in accordance with the schedule set forth in "d" below, the contractor shall immediately notify the Contracting Officer in writing.

d. Government-furnished property/materiel delivery schedule:

Description	Estimated Quantity	Time of Delivery
To be Determined	To Be Determined	As Required

PROPERTY ADMINISTRATOR (MAR 1999) (USAMRAA)

The designated property administrator for Government property acquired for use under this contract is TBD.

Note: TBD = to be determined

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.

LIST OF GOV'T PROPERTY AVAIL

LIST OF GOVERNMENT PROPERTY AVAILABLE:

Pursuant to the Government Property Clause, FAR 52.245-5, a list of Government property available to offerors is contained in Section J, Attachment 6. This equipment will be available within 90 days following contract award. Government Furnished Equipment is provided "as is." The Government does not intend to replace/repair equipment.

FIXED FEE

The estimated fee stated in Section B of the contract schedule is an estimate only due to the nature of an indefinite deliver/indefinite quantity contract. An appropriate fixed fee will be negotiated for each task order prior to task order award. The fee will be commensurate with the level of difficulty of the task, contractor's risk, and other factors.

Fixed fee shall be billed in the ratio that costs incurred bear to the estimated cost of each negotiated task order. Payment of the full amount of the fixed fee shall be contingent upon completion and delivery of all items as stated in the contract.

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	JUL 1995
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	SEP 2007
52.204-2	Security Requirements	AUG 1996
52.204-4	Printed or Copied Double-Sided on Recycled Paper	AUG 2000
52.209-6	Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment	SEP 2006
52.215-2	Audit and Records--Negotiation	MAR 2009
52.215-2 Alt II	Audit and Records--Negotiation (Mar 2009) - Alternate II	APR 1998
52.215-8	Order of Precedence--Uniform Contract Format	OCT 1997
52.215-10	Price Reduction for Defective Cost or Pricing Data	OCT 1997
52.215-11	Price Reduction for Defective Cost or Pricing Data--Modifications	OCT 1997
52.215-12	Subcontractor Cost or Pricing Data	OCT 1997
52.215-13	Subcontractor Cost or Pricing Data--Modifications	OCT 1997
52.215-14	Integrity of Unit Prices	OCT 1997
52.215-15	Pension Adjustments and Asset Reversions	OCT 2004
52.215-17	Waiver of Facilities Capital Cost of Money	OCT 1997
52.215-18	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) Other than Pensions	JUL 2005
52.215-19	Notification of Ownership Changes	OCT 1997
52.215-21	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data--Modifications	OCT 1997
52.216-7	Allowable Cost And Payment	DEC 2002
52.216-8	Fixed Fee	MAR 1997
52.216-11	Cost Contract--No Fee	APR 1984
52.216-11 Alt I	Cost Contract--No Fee (Apr 1984) Alternate I	APR 1984
52.219-3	Notice of Total HUBZone Set-Aide	JAN 1999
52.219-8	Utilization of Small Business Concerns	MAY 2004
52.219-9	Small Business Subcontracting Plan	APR 2008
52.219-16	Liquidated Damages-Subcontracting Plan	JAN 1999
52.222-3	Convict Labor	JUN 2003
52.222-20	Walsh-Healey Public Contracts Act	DEC 1996
52.222-21	Prohibition Of Segregated Facilities	FEB 1999
52.222-26	Equal Opportunity	MAR 2007
52.222-35	Equal Opportunity For Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans	SEP 2006
52.222-36	Affirmative Action For Workers With Disabilities	JUN 1998
52.222-37	Employment Reports On Special Disabled Veterans, Veterans Of The Vietnam Era, and Other Eligible Veterans	SEP 2006
52.222-50	Combating Trafficking in Persons	FEB 2009
52.222-54	Employment Eligibility Verification	JAN 2009

52.223-3	Hazardous Material Identification And Material Safety Data	JAN 1997
52.223-6	Drug-Free Workplace	MAY 2001
52.223-14	Toxic Chemical Release Reporting	AUG 2003
52.225-14	Inconsistency Between English Version And Translation Of Contract	FEB 2000
52.226-1	Utilization Of Indian Organizations And Indian-Owned Economic Enterprises	JUN 2000
52.227-1	Authorization and Consent	DEC 2007
52.227-2	Notice And Assistance Regarding Patent And Copyright Infringement	DEC 2007
52.228-7	Insurance--Liability To Third Persons	MAR 1996
52.230-2	Cost Accounting Standards	OCT 2008
52.230-3	Disclosure And Consistency Of Cost Accounting Practices	OCT 2008
52.230-6	Administration of Cost Accounting Standards	MAR 2008
52.232-9	Limitation On Withholding Of Payments	APR 1984
52.232-17	Interest	OCT 2008
52.232-19	Availability Of Funds For The Next Fiscal Year	APR 1984
52.232-20	Limitation Of Cost	APR 1984
52.232-23	Assignment Of Claims	JAN 1986
52.232-25	Prompt Payment	OCT 2008
52.232-33	Payment by Electronic Funds Transfer--Central Contractor Registration	OCT 2003
52.233-1	Disputes	JUL 2002
52.233-3 Alt I	Protest After Award (Aug 1996) - Alternate I	JUN 1985
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
52.243-2 Alt V	Changes--Cost-Reimbursement (Aug 1987) - Alternate V	APR 1984
52.244-5	Competition In Subcontracting	DEC 1996
52.244-6	Subcontracts for Commercial Items	AUG 2009
52.245-1	Government Property	JUN 2007
52.245-1 Alt II	Government Property (Jun 2007) Alternate II	JUN 2007
52.245-9	Use And Charges	JUN 2007
52.247-63	Preference For U.S. Flag Air Carriers	JUN 2003
52.249-5	Termination For Convenience Of The Government (Educational And Other Nonprofit Institutions)	SEP 1996
52.249-6	Termination (Cost Reimbursement)	MAY 2004
52.249-14	Excusable Delays	APR 1984
52.251-1	Government Supply Sources	APR 1984
52.252-4	Alterations in Contract	APR 1984
52.253-1	Computer Generated Forms	JAN 1991
252.201-7000	Contracting Officer's Representative	DEC 1991
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 (52.204-7) Alternate A	SEP 2007
252.205-7000	Provision Of Information To Cooperative Agreement Holders	DEC 1991
252.209-7004	Subcontracting With Firms That Are Owned or Controlled By The Government of a Terrorist Country	DEC 2006
252.215-7000	Pricing Adjustments	DEC 1991
252.215-7002	Cost Estimating System Requirements	DEC 2006
252.219-7003	Small Business Subcontracting Plan (DOD Contracts)	APR 2007

252.223-7001	Hazard Warning Labels	DEC 1991
252.223-7004	Drug Free Work Force	SEP 1988
252.225-7001	Buy American Act And Balance Of Payments Program	JAN 2009
252.225-7002	Qualifying Country Sources As Subcontractors	APR 2003
252.225-7012	Preference For Certain Domestic Commodities	DEC 2008
252.227-7016	Rights in Bid or Proposal Information	JUN 1995
252.227-7017	Identification and Assertion of Use, Release, or Disclosure Restrictions	JUN 1995
252.227-7019	Validation of Asserted Restrictions--Computer Software	JUN 1995
252.227-7028	Technical Data or Computer Software Previously Delivered to the Government	JUN 1995
252.227-7030	Technical Data--Withholding Of Payment	MAR 2000
252.227-7037	Validation of Restrictive Markings on Technical Data	SEP 1999
252.231-7000	Supplemental Cost Principles	DEC 1991
252.232-7003	Electronic Submission of Payment Requests and Receiving Reports	MAR 2008
252.235-7002	Animal Welfare	DEC 1991
252.242-7004	Material Management And Accounting System	JUL 2009
252.243-7002	Requests for Equitable Adjustment	MAR 1998
252.247-7023	Transportation of Supplies by Sea	MAY 2002
252.247-7023 Alt III	Transportation of Supplies by Sea (May 2002) Alternate III	MAY 2002
252.247-7024	Notification Of Transportation Of Supplies By Sea	MAR 2000
252.251-7000	Ordering From Government Supply Sources	NOV 2004

CLAUSES INCORPORATED BY FULL TEXT

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.

52.209-8 UPDATES OF INFORMATION REGARDING RESPONSIBILITY MATTERS (APR 2010)

(a) The Contractor shall update the information in the Federal Awardee Performance and Integrity Information System (FAPIS) on a semi-annual basis, throughout the life of the contract, by entering the required information in the Central Contractor Registration database at <http://www.ccr.gov> (see 52.204-7).

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

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

(3) With the exception of the Contractor, only Government personnel and authorized users performing business on behalf of the Government will be able to view the Contractor's record in the system. Public requests for system information will be handled under Freedom of Information Act procedures, including, where appropriate, procedures promulgated under E.O. 12600.

(End of clause)

52.216-18 ORDERING. (OCT 1995)

(a) Any supplies and services to be furnished under this contract shall be ordered by issuance of delivery orders or task orders by the individuals or activities designated in the Schedule. Such orders may be issued from TBD through TBD [insert dates].

(b) All delivery orders or task orders are subject to the terms and conditions of this contract. In the event of conflict between a delivery order or task order and this contract, the contract shall control.

(c) If mailed, a delivery order or task order is considered "issued" when the Government deposits the order in the mail. Orders may be issued orally, by facsimile, or by electronic commerce methods only if authorized in the Schedule.

Note: TBD = to be determined.

(End of clause)

52.216-19 ORDER LIMITATIONS. (OCT 1995)

(a) Minimum order. When the Government requires supplies or services covered by this contract in an amount of less than \$10,000.00, the Government is not obligated to purchase, nor is the Contractor obligated to furnish, those supplies or services under the contract.

(b) Maximum order. The Contractor is not obligated to honor:

(1) Any order for a single item in excess of \$5,000,000.00 (insert dollar figure or quantity);

(2) Any order for a combination of items in excess of \$11,000,000.00 (insert dollar figure or quantity); or

(3) A series of orders from the same ordering office within 30 days that together call for quantities exceeding the limitation in subparagraph (1) or (2) above.

(c) If this is a requirements contract (i.e., includes the Requirements clause at subsection 52.216-21 of the Federal Acquisition Regulation (FAR)), the Government is not required to order a part of any one requirement from the Contractor if that requirement exceeds the maximum-order limitations in paragraph (b) above.

(d) Notwithstanding paragraphs (b) and (c) above, the Contractor shall honor any order exceeding the maximum order limitations in paragraph (b), unless that order (or orders) is returned to the ordering office within 10 days after issuance, with written notice stating the Contractor's intent not to ship the item (or items) called for and the reasons. Upon receiving this notice, the Government may acquire the supplies or services from another source.

(End of clause)

52.216-22 INDEFINITE QUANTITY. (OCT 1995)

(a) This is an indefinite-quantity contract for the supplies or services specified, and effective for the period stated, in the Schedule. The quantities of supplies and services specified in the Schedule are estimates only and are not purchased by this contract.

(b) Delivery or performance shall be made only as authorized by orders issued in accordance with the Ordering clause. The Contractor shall furnish to the Government, when and if ordered, the supplies or services specified in the Schedule up to and including the quantity designated in the Schedule as the "maximum". The Government shall order at least the quantity of supplies or services designated in the Schedule as the "minimum".

(c) Except for any limitations on quantities in the Order Limitations clause or in the Schedule, there is no limit on the number of orders that may be issued. The Government may issue orders requiring delivery to multiple destinations or performance at multiple locations.

(d) Any order issued during the effective period of this contract and not completed within that period shall be completed by the Contractor within the time specified in the order. The contract shall govern the Contractor's and Government's rights and obligations with respect to that order to the same extent as if the order were completed during the contract's effective period; provided, that the Contractor shall not be required to make any deliveries under this contract after **TBD** [insert date].

Note: TBD = to be determined

(End of clause)

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 of the end of the then current performance period.

(End of clause)

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 calendar days of the end of the then current performance period; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 60 calendar 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 and 6 months..

(End of clause)

52.222-2 PAYMENT FOR OVERTIME PREMIUMS (JUL 1990)

(a) The use of overtime is authorized under this contract if the overtime premium cost does not exceed \$3,000.00 or the overtime premium is paid for work --

- (1) Necessary to cope with emergencies such as those resulting from accidents, natural disasters, breakdowns of production equipment, or occasional production bottlenecks of a sporadic nature;
- (2) By indirect-labor employees such as those performing duties in connection with administration, protection, transportation, maintenance, standby plant protection, operation of utilities, or accounting;
- (3) To perform tests, industrial processes, laboratory procedures, loading or unloading of transportation conveyances, and operations in flight or afloat that are continuous in nature and cannot reasonably be interrupted or completed otherwise; or
- (4) That will result in lower overall costs to the Government.

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

- (1) Identify the work unit; e.g., department or section in which the requested overtime will be used, together with present workload, staffing, and other data of the affected unit sufficient to permit the Contracting Officer to evaluate the necessity for the overtime;
- (2) Demonstrate the effect that denial of the request will have on the contract delivery or performance schedule;
- (3) Identify the extent to which approval of overtime would affect the performance or payments in connection with other Government contracts, together with identification of each affected contract; and
- (4) Provide reasons why the required work cannot be performed by using multishift operations or by employing additional personnel.

(End of clause)

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

(a) As used in this clause--

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

Made means--

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

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

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

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

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

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

(2) License. (i) The Contractor shall retain a nonexclusive royalty-free license throughout the world in each subject invention to which the Government obtains title, unless the Contractor fails to disclose the invention within the times specified in paragraph (c) of this clause. The Contractor's license extends to any domestic subsidiaries and affiliates within the corporate structure of which the Contractor is a part, and includes the right to grant sublicenses to the extent the Contractor was legally obligated to do so at contract award. The license is transferable only with the written approval of the agency, except when transferred to the successor of that part of the Contractor's business to which the invention pertains.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(f) Reporting on utilization of subject inventions. The Contractor shall submit, on request, periodic reports no more frequently than annually on the utilization of a subject invention or on efforts at obtaining utilization of the subject invention that are being made by the Contractor or its licensees or assignees. The reports shall include information

regarding the status of development, date of first commercial sale or use, gross royalties received by the Contractor, and other data and information as the agency may reasonably specify. The Contractor also shall provide additional reports as may be requested by the agency in connection with any march-in proceeding undertaken by the agency in accordance with paragraph (h) of this clause. The Contractor also shall mark any utilization report as confidential/proprietary to help prevent inadvertent release outside the Government. As required by 35 U.S.C. 202(c)(5), the agency will not disclose that information to persons outside the Government without the Contractor's permission.

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

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

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

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

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

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

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

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

(j) Communications. There are no specific agency instructions.

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

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

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

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

(End of clause)

52.244-2 SUBCONTRACTS (JUN 2007)

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

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

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

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

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

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

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

(2) Is fixed-price and exceeds—

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

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

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

TBD

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

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

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

(iii) Identification of the proposed subcontractor.

(iv) The proposed subcontract price.

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

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

(vii) A negotiation memorandum reflecting—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

TBD

Note: TBD = to be determined

(End of clause)

52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

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

<http://www-usamraa.army.mil>

(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)

252.235-7010 Acknowledgment of Support and Disclaimer. (MAY 1995)

(a) The Contractor shall include an acknowledgment of the Government's support in the publication of any material based on or developed under this contract, stated in the following terms: This material is based upon work supported by the Defense Threat Reduction Agency, U.S. Army Medical Research and Materiel Command, and the Chemical Biological Medical Systems Joint Project Management Office under Contract No. W81XWH-10-D-TBD awarded

by the U.S. Army Medical Research Acquisition Activity.

(b) All material, except scientific articles or papers published in scientific journals, must, in addition to any notices or disclaimers by the Contractor, also contain the following disclaimer: Any opinions, findings and conclusions or recommendations expressed in this material are those of the author(s) and do not necessarily reflect the views of the U.S. Army Medical Research Acquisition Activity.

Note: TBD = to be determined

Section J - List of Documents, Exhibits and Other Attachments

EXHIBITS & ATTACHMENTS

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Attachment 1	Minimal List of Chemical Agents	1
Attachment 2	Minimal List of Laboratory Animals	1
Attachment 3	Guidelines for Managing an RDTE Dilute Solution Laboratory	23
Attachment 4	Task Order Report	3
Attachment 5	Available Property Listing	2
Attachment 6	Past Performance Questionnaire & Instructions	4
Attachment 7	DD Form 254 DOD Contract Security Classification Specification	2
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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
52.209-2	Prohibition on Contracting with Inverted Domestic Corporations--Representation	JUL 2009
52.215-6	Place of Performance	OCT 1997
52.222-38	Compliance With Veterans' Employment Reporting Requirements	DEC 2001
252.209-7001	Disclosure of Ownership or Control by the Government of a Terrorist Country	JAN 2009
252.225-7031	Secondary Arab Boycott Of Israel	JUN 2005
252.227-7028	Technical Data or Computer Software Previously Delivered to the Government	JUN 1995

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)

CLAUSES INCORPORATED BY FULL TEXT

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

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

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

(End of provision)

CLAUSES INCORPORATED BY FULL TEXT

52.204-8 ANNUAL REPRESENTATIONS AND CERTIFICATIONS (FEB 2009)

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

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

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

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

(2) If the clause at 52.204-7 is not included in this solicitation, and the offeror is currently registered in CCR, and has completed the ORCA electronically, the offeror may choose to use paragraph (d) of this provision instead of completing the corresponding individual representations and certifications in the solicitation. The offeror shall indicate which option applies by checking one of the following boxes:

Paragraph (d) applies.

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

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

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

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

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

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

(ii) 52.203-11, Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions. This provision applies to solicitations expected to exceed \$100,000.

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

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

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

(B) Exceed the simplified acquisition threshold; and

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

- (v) 52.209-5, Certification Regarding Responsibility Matters. This provision applies to solicitations where the contract value is expected to exceed the simplified acquisition threshold.
- (vi) 52.214-14, Place of Performance--Sealed Bidding. This provision applies to invitations for bids except those in which the place of performance is specified by the Government.
- (vii) 52.215-6, Place of Performance. This provision applies to solicitations unless the place of performance is specified by the Government.
- (viii) 52.219-1, Small Business Program Representations (Basic & Alternate I). This provision applies to solicitations when the contract will be performed in the United States or its outlying areas.
- (A) The basic provision applies when the solicitations are issued by other than DoD, NASA, and the Coast Guard.
- (B) The provision with its Alternate I applies to solicitations issued by DoD, NASA, or the Coast Guard.
- (ix) 52.219-2, Equal Low Bids. This provision applies to solicitations when contracting by sealed bidding and the contract will be performed in the United States or its outlying areas.
- (x) 52.222-22, Previous Contracts and Compliance Reports. This provision applies to solicitations that include the clause at 52.222-26, Equal Opportunity.
- (xi) 52.222-25, Affirmative Action Compliance. This provision applies to solicitations, other than those for construction, when the solicitation includes the clause at 52.222-26, Equal Opportunity.
- (xii) 52.222-38, Compliance with Veterans' Employment Reporting Requirements. This provision applies to solicitations when it is anticipated the contract award will exceed the simplified acquisition threshold and the contract is not for acquisition of commercial items.
- (xiii) 52.223-1, Biobased Product Certification. This provision applies to solicitations that require the delivery or specify the use of USDA-designated items; or include the clause at 52.223-2, Affirmative Procurement of Biobased Products Under Service and Construction Contracts.
- (xiv) 52.223-4, Recovered Material Certification. This provision applies to solicitations that are for, or specify the use of, EPA-designated items.
- (xv) 52.225-2, Buy American Act Certificate. This provision applies to solicitations containing the clause at 52.225-1.
- (xvi) 52.225-4, Buy American Act--Free Trade Agreements—Israeli Trade Act Certificate. (Basic, Alternate I, and Alternate II) This provision applies to solicitations containing the clause at 52.225-3.
- (A) If the acquisition value is less than \$25,000, the basic provision applies.
- (B) If the acquisition value is \$25,000 or more but is less than \$50,000, the provision with its Alternate I applies.
- (C) If the acquisition value is \$50,000 or more but is less than \$67,826, the provision with its Alternate II applies.
- (xvii) 52.225-6, Trade Agreements Certificate. This provision applies to solicitations containing the clause at 52.225-5.
- (xviii) 52.225-20, Prohibition on Conducting Restricted Business Operations in Sudan--Certification.
- (xix) 52.226-2, Historically Black College or University and Minority Institution Representation. This provision applies to--

(A) Solicitations for research, studies, supplies, or services of the type normally acquired from higher educational institutions; and

(B) For DoD, NASA, and Coast Guard acquisitions, solicitations that contain the clause at 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns.

(2) The following certifications are applicable as indicated by the Contracting Officer:

(Contracting Officer check as appropriate.)

----(i) 52.219-19, Small Business Concern Representation for the Small Business Competitiveness Demonstration Program.

----- (ii) 52.219-21, Small Business Size Representation for Targeted Industry Categories Under the Small Business Competitiveness Demonstration Program.

----- (iii) 52.219-22, Small Disadvantaged Business Status.

----- (A) Basic.

----- (B) Alternate I.

----- (iv) 52.222-18, Certification Regarding Knowledge of Child Labor for Listed End Products.

----- (v) 52.222-48, Exemption from Application of the Service Contract Act to Contracts for Maintenance, Calibration, or Repair of Certain Equipment Certification.

----- (vi) 52.222-52 Exemption from Application of the Service Contract Act to Contracts for Certain Services-- Certification.

----- (vii) 52.223-9, with its Alternate I, Estimate of Percentage of Recovered Material Content for EPA- Designated Products (Alternate I only).

----- (viii) 52.223-13, Certification of Toxic Chemical Release Reporting.

----- (ix) 52.227-6, Royalty Information.

----- (A) Basic.

----- (B) Alternate I.

----- (x) 52.227-15, Representation of Limited Rights Data and Restricted Computer Software.

(d) The offeror has completed the annual representations and certifications electronically via the Online Representations and Certifications Application (ORCA) website at <http://orca.bpn.gov>. After reviewing the ORCA database information, the offeror verifies by submission of the offer that the representations and certifications currently posted electronically that apply to this solicitation as indicated in paragraph (c) of this provision have been entered or updated within the last 12 months, are current, accurate, complete, and applicable to this solicitation (including the business size standard applicable to the NAICS code referenced for this solicitation), as of the date of this offer and are incorporated in this offer by reference (see FAR 4.1201); except for the changes identified below (offeror to insert changes, identifying change by clause number, title, date). These amended representation(s) and/or certification(s) are also incorporated in this offer and are current, accurate, and complete as of the date of this offer.

FAR Clause	Title	Date	Change
-----	-----	-----	-----
-----	-----	-----	-----

Any changes provided by the offeror are applicable to this solicitation only, and do not result in an update to the representations and certifications posted on ORCA.

(End of Provision)

CLAUSES INCORPORATED BY FULL TEXT

52.209-5 CERTIFICATION REGARDING RESPONSIBILITY MATTERS (APR 2010)

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

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

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

(B) Have () have not (), within a three-year period preceding this offer, been convicted of or had a civil judgment rendered against them for: commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) contract or subcontract; violation of Federal or State antitrust statutes relating to the submission of offers; or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, violating Federal criminal tax laws, or receiving stolen property (if offeror checks "have", the offeror shall also see 52.209-7, if included in this solicitation); and

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

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

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

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

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

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

(ii) The IRS has filed a notice of Federal tax lien with respect to an assessed tax liability, and the taxpayer has been issued a notice under I.R.C. Sec. 6320 entitling the taxpayer to request a hearing with the IRS Office of Appeals

contesting the lien filing, and to further appeal to the Tax Court if the IRS determines to sustain the lien filing. In the course of the hearing, the taxpayer is entitled to contest the underlying tax liability because the taxpayer has had no prior opportunity to contest the liability. This is not a delinquent tax because it is not a final tax liability. Should the taxpayer seek tax court review, this will not be a final tax liability until the taxpayer has exercised all judicial appeal rights.

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

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

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

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

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

(c) A certification that any of the items in paragraph (a) of this provision exists will not necessarily result in withholding of an award under this solicitation. However, the certification will be considered in connection with a determination of the Offeror's responsibility. Failure of the Offeror to furnish a certification or provide such additional information as requested by the Contracting Officer may render the Offeror nonresponsible.

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

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

(End of provision)

52.209-7 INFORMATION REGARDING RESPONSIBILITY MATTERS (APR 2010)

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

Administrative proceeding means a non-judicial process that is adjudicatory in nature in order to make a determination of fault or liability (e.g., Securities and Exchange Commission Administrative Proceedings, Civilian Board of Contract Appeals Proceedings, and Armed Services Board of Contract Appeals Proceedings). This includes administrative proceedings at the Federal and State level but only in connection with performance of a Federal contract or grant. It does not include agency actions such as contract audits, site visits, corrective plans, or inspection of deliverables.

Federal contracts and grants with total value greater than \$10,000,000 means--

- (1) The total value of all current, active contracts and grants, including all priced options; and
- (2) The total value of all current, active orders including all priced options under indefinite-delivery, indefinite-quantity, 8(a), or requirements contracts (including task and delivery and multiple-award Schedules).
- (b) The offeror () has () does not have current active Federal contracts and grants with total value greater than \$10,000,000.
- (c) If the offeror checked “has” in paragraph (b) of this provision, the offeror represents, by submission of this offer, that the information it has entered in the Federal Awardee Performance and Integrity Information System (FAPIS) is current, accurate, and complete as of the date of submission of this offer with regard to the following information:
- (1) Whether the offeror, and/or any of its principals, has or has not, within the last five years, in connection with the award to or performance by the offeror of a Federal contract or grant, been the subject of a proceeding, at the Federal or State level that resulted in any of the following dispositions:
- (i) In a criminal proceeding, a conviction.
- (ii) In a civil proceeding, a finding of fault and liability that results in the payment of a monetary fine, penalty, reimbursement, restitution, or damages of \$5,000 or more.
- (iii) In an administrative proceeding, a finding of fault and liability that results in--
- (A) The payment of a monetary fine or penalty of \$5,000 or more; or
- (B) The payment of a reimbursement, restitution, or damages in excess of \$100,000.
- (iv) In a criminal, civil, or administrative proceeding, a disposition of the matter by consent or compromise with an acknowledgment of fault by the Contractor if the proceeding could have led to any of the outcomes specified in paragraphs (c)(1)(i), (c)(1)(ii), or (c)(1)(iii) of this provision.
- (2) If the offeror has been involved in the last five years in any of the occurrences listed in (c)(1) of this provision, whether the offeror has provided the requested information with regard to each occurrence.
- (d) The offeror shall enter the information in paragraphs (c)(1)(i) through (c)(1)(iv) of this provision in FAPIS as required through maintaining an active registration in the Central Contractor Registration database at <http://www.ccr.gov> (see 52.204-7).

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

(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 (MAY 2004) - ALTERNATE I (APR 2002)

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

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

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

(b) 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) (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.

(5) (Complete only if the offeror represented itself as a veteran-owned small business concern in paragraph (b)(4) of this provision.) The offeror represents as part of its offer that it () is, () is not a service-disabled veteran-owned small business concern.

(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--

(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)(6)(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.

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

___ Black American.

___ Hispanic American.

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

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

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

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

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

Service-disabled veteran-owned small business concern--

(1) Means a small business concern--

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

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

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

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

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

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

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

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

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

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

(d) Notice.

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

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

(i) Be punished by imposition of fine, imprisonment, or both;

(ii) Be subject to administrative remedies, including suspension and debarment; and

(iii) Be ineligible for participation in programs conducted under the authority of the Act.

(End of provision)

52.219-22 SMALL DISADVANTAGED BUSINESS STATUS (OCT 1999)

(a) General. This provision is used to assess an offeror's small disadvantaged business status for the purpose of obtaining a benefit on this solicitation. Status as a small business and status as a small disadvantaged business for general statistical purposes is covered by the provision at FAR 52.219-1, Small Business Program Representation.

(b) Representations.

(1) General. The offeror represents, as part of its offer, that it is a small business under the size standard applicable to this acquisition; and either--

___ (i) It has received certification by the Small Business Administration as a small disadvantaged business concern consistent with 13 CFR 124, Subpart B; and

(A) No material change in disadvantaged ownership and control has occurred since its certification;

(B) Where the concern is owned by one or more disadvantaged individuals, the net worth of each individual upon whom the certification is based does not exceed \$750,000 after taking into account the applicable exclusions set forth at 13 CFR 124.104(c)(2); and

(C) It is identified, on the date of this representation, as a certified small disadvantaged business concern in the database maintained by the Small Business Administration(PRO0Net); or

___ (ii) It has submitted a completed application to the Small Business Administration or a Private Certifier to be certified as a small disadvantaged business concern in accordance with 13 CFR 124, Subpart B, and a decision on that application is pending, and that no material change in disadvantaged ownership and control has occurred since its application was submitted.

(2)___ For Joint Ventures. The offeror represents, as part of its offer, that it is a joint venture that complies with the requirements at 13 CFR 124.1002(f) and that the representation in paragraph (b)(1) of this provision is accurate for the small disadvantaged business concern that is participating in the joint venture. [The offeror shall enter the name of the small disadvantaged business concern that is participating in the joint venture: _____.]

(c) Penalties and Remedies. Anyone who misrepresents any aspects of the disadvantaged status of a concern for the purposes of securing a contract or subcontract shall:

- (1) Be punished by imposition of a fine, imprisonment, or both;
- (2) Be subject to administrative remedies, including suspension and debarment; and
- (3) Be ineligible for participation in programs conducted under the authority of the Small Business Act.

(End of provision)

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

The offeror represents that --

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

(End of provision)

52.222-25 AFFIRMATIVE ACTION COMPLIANCE (APR 1984)

The offeror represents that

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

(End of provision)

52.223-13 CERTIFICATION OF TOXIC CHEMICAL RELEASE REPORTING (AUG 2003)

- (a) Executive Order 13148, of April 21, 2000, Greening the Government through Leadership in Environmental Management, requires submission of this certification as a prerequisite for contract award.

(b) By signing this offer, the offeror certifies that--

- (1) As the owner or operator of facilities that will be used in the performance of this contract that are subject to the filing and reporting requirements described in section 313 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA) (42 U.S.C. 11023) and section 6607 of the Pollution Prevention Act of 1990 (PPA) (42 U.S.C. 13106), the offeror will file and continue to file for such facilities for the life of the contract the Toxic Chemical Release Inventory Form (Form R) as described in sections 313(a) and (g) of EPCRA and section 6607 of PPA; or

(2) None of its owned or operated facilities to be used in the performance of this contract is subject to the Form R filing and reporting requirements because each such facility is exempt for at least one of the following reasons: (Check each block that is applicable.)

(i) The facility does not manufacture, process, or otherwise use any toxic chemicals listed in 40 CFR 372.65;

(ii) The facility does not have 10 or more full-time employees as specified in section 313.(b)(1)(A) of EPCRA 42 U.S.C. 11023(b)(1)(A);

(iii) The facility does not meet the reporting thresholds of toxic chemicals established under section 313(f) of EPCRA, 42 U.S.C. 11023(f) (including the alternate thresholds at 40 CFR 372.27, provided an appropriate certification form has been filed with EPA);

(iv) The facility does not fall within the following Standard Industrial Classification (SIC) codes or their corresponding North American Industry Classification System sectors:

(A) Major group code 10 (except 1011, 1081, and 1094.

(B) Major group code 12 (except 1241).

(C) Major group codes 20 through 39.

(D) Industry code 4911, 4931, or 4939 (limited to facilities that combust coal and/or oil for the purpose of generating power for distribution in commerce).

(E) Industry code 4953 (limited to facilities regulated under the Resource Conservation and Recovery Act, Subtitle C (42 U.S.C. 6921, et seq.), 5169, 5171, or 7389 (limited to facilities primarily engaged in solvent recovery services on a contract or fee basis); or

(v) The facility is not located within the United States or its outlying areas.

(End of clause)

52.226-2 HISTORICALLY BLACK COLLEGE OR UNIVERSITY AND MINORITY INSTITUTION REPRESENTATION (OCT 2008)

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

Historically black college or university means an institution determined by the Secretary of Education to meet the requirements of 34 CFR 608.2. For the Department of Defense, the National Aeronautics and Space Administration, and the Coast Guard, the term also includes any nonprofit research institution that was an integral part of such a college or university before November 14, 1986.

Minority institution means an institution of higher education meeting the requirements of Section 365(3) of the Higher Education Act of 1965 (20 U.S.C. 1067k), including a Hispanic-serving institution of higher education, as defined in Section 502(a) of the Act (20 U.S.C. 1101a).

(b) Representation. The offeror represents that it--

is is not a historically black college or university;

is is not a minority institution.

(End of provision)

52.227-6 ROYALTY INFORMATION (APR 1984)

(a) Cost or charges for royalties. When the response to this solicitation contains costs or charges for royalties totaling more than \$250, the following information shall be included in the response relating to each separate item of royalty or license fee:

(1) Name and address of licensor.

(2) Date of license agreement.

(3) Patent numbers, patent application serial numbers, or other basis on which the royalty is payable.

(4) Brief description, including any part or model numbers of each contract item or component on which the royalty is payable.

(5) Percentage or dollar rate of royalty per unit.

(6) Unit price of contract item.

(7) Number of units.

(8) Total dollar amount of royalties.

(b) Copies of current licenses. In addition, if specifically requested by the Contracting Officer before execution of the contract, the offeror shall furnish a copy of the current license agreement and an identification of applicable claims of specific patents.

(End of provision)

52.230-1 COST ACCOUNTING STANDARDS NOTICES AND CERTIFICATION (OCT 2008)

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

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

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

I. DISCLOSURE STATEMENT--COST ACCOUNTING PRACTICES AND CERTIFICATION

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

(b) Any offeror submitting a proposal which, if accepted, will result in a contract subject to the requirements of 48 CFR Chapter 99 must, as a condition of contracting, submit a Disclosure Statement as required by 48 CFR 9903.202. When required, the Disclosure Statement must be submitted as a part of the offeror's proposal under this

solicitation unless the offeror has already submitted a Disclosure Statement disclosing the practices used in connection with the pricing of this proposal. If an applicable Disclosure Statement has already been submitted, the offeror may satisfy the requirement for submission by providing the information requested in paragraph (c) of Part I of this provision.

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

(c) Check the appropriate box below:

(1) Certificate of Concurrent Submission of Disclosure Statement.

The offeror hereby certifies that, as a part of the offer, copies of the Disclosure Statement have been submitted as follows: (i) original and one copy to the cognizant Administrative Contracting Officer (ACO) or cognizant Federal agency official authorized to act in that capacity (Federal official), as applicable, and (ii) one copy to the cognizant Federal auditor.

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

Date of Disclosure Statement: _____ Name and Address of Cognizant ACO or Federal Official Where Filed: _____

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

(2) Certificate of Previously Submitted Disclosure Statement.

The offeror hereby certifies that the required Disclosure Statement was filed as follows:

Date of Disclosure Statement: _____ Name and Address of Cognizant ACO or Federal Official Where Filed: _____

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

(3) Certificate of Monetary Exemption.

The offeror hereby certifies that the offeror, together with all divisions, subsidiaries, and affiliates under common control, did not receive net awards of negotiated prime contracts and subcontracts subject to CAS totaling more than \$50 million (of which at least one award exceeded \$1 million) in the cost accounting period immediately preceding the period in which this proposal was submitted. The offeror further certifies that if such status changes before an award resulting from this proposal, the offeror will advise the Contracting Officer immediately.

(4) Certificate of Interim Exemption.

The offeror hereby certifies that (i) the offeror first exceeded the monetary exemption for disclosure, as defined in (3) of this subsection, in the cost accounting period immediately preceding the period in which this offer was submitted and (ii) in accordance with 48 CFR 9903.202-1, the offeror is not yet required to submit a Disclosure Statement. The offeror further certifies that if an award resulting from this proposal has not been made within 90 days after the end of that period, the offeror will immediately submit a revised certificate to the Contracting Officer, in the form specified under subparagraph (c)(1) or (c)(2) of Part I of this provision, as appropriate, to verify submission of a completed Disclosure Statement.

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

II. COST ACCOUNTING STANDARDS--ELIGIBILITY FOR MODIFIED CONTRACT COVERAGE

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

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

CAUTION: An offeror may not claim the above eligibility for modified contract coverage if this proposal is expected to result in the award of a CAS-covered contract of \$50 million or more or if, during its current cost accounting period, the offeror has been awarded a single CAS-covered prime contract or subcontract of \$25 million or more.

III. ADDITIONAL COST ACCOUNTING STANDARDS APPLICABLE TO EXISTING CONTRACTS

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

YES NO

(End of clause)

252.204-7007 ANNUAL REPRESENTATIONS AND CERTIFICATIONS (52.204-8) ALTERNATE A

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

(2) If the clause at 52.204-7 is not included in this solicitation, and the offeror is currently registered in CCR, and has completed the ORCA electronically, the offeror may choose to use paragraph (b) of this provision instead of completing the corresponding individual representations and certifications in the solicitation. The offeror shall indicate which option applies by checking one of the following boxes:

Paragraph (c) applies.

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

(c) 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 have been entered or updated within the last 12 months, are current, accurate, complete, and applicable to this solicitation (including the business size standard applicable to the NAICS code referenced for this solicitation), as of the date of this offer, and are incorporated in this offer by reference (see FAR 4.1201); except for the changes identified below [offeror to insert changes, identifying change by clause number, title, date]. These amended representation(s) and/or certification(s) are also incorporated in this offer and are current, accurate, and complete as of the date of this offer.

FAR/DFARS clause No.	Title	Date	Change
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Any changes provided by the offeror are applicable to this solicitation only, and do not result in an update to the representations and certifications posted on ORCA.

(End of Provision)

252.227-7028 TECHNICAL DATA OR COMPUTER SOFTWARE PREVIOUSLY DELIVERED TO THE GOVERNMENT (JUN 1995)

The Offeror shall attach to its offer an identification of all documents or other media incorporating technical data or computer software it intends to deliver under this contract with other than unlimited rights that are identical or substantially similar to documents or other media that the Offeror has produced for, delivered to, or is obligated to deliver to the Government under any contract or subcontract. The attachment shall identify--

- (a) The contract number under which the data or software were produced;
- (b) The contract number under which, and the name and address of the organization to whom, the data or software were most recently delivered or will be delivered; and
- (c) Any limitations on the Government's rights to use or disclose the data or software, including, when applicable, identification of the earliest date the limitations expire.

(End of clause)

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

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

(b) Representation. The Offeror represents that it:

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

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

(c) Any contract resulting from this solicitation will include the Transportation of Supplies by Sea clause. If the Offeror represents that it will not use ocean transportation, the resulting contract will also include the Defense FAR Supplement clause at 252.247-7024, Notification of Transportation of Supplies by Sea.

(End of provision)

Section L - Instructions, Conditions and Notices to Bidders

INSTRUCTIONS TO OFFERORS

INSTRUCTIONS TO OFFERORS

L.A. PREPARATION OF PROPOSALS

L.A.1. Responses to this RFP shall be in four separate sections: (1) A technical proposal (limited to 100 pages excluding resumes (no page limit), Facility Safety Surety Plan (no page limit), (2) cost/business proposal (no page limit), (3) past performance information (no page limit), and (4) environmental information (no page limit), (5) cover pages and table of contents also have no page limit. Each of the parts shall be separate and complete, so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the others. Offerors shall submit proposals on four separate **Compact Discs (CDs)** in Word or .pdf format. Technical Exhibits included with the business proposal may be in Excel or .pdf format. An original set of four (4) CDs and six (6) copies of the set of four (4) CDs shall be provided. All documents submitted shall have a cover page with the identifying RFP title, the solicitation number, and name of the offeror. NOTE: If your records are currently under audit cognizance of a Government audit agency, the address and telephone number of that office should be furnished with your cost proposal. Proposals shall be submitted to the following address:

Director
U.S. Army Medical Research Acquisition Activity
ATTN: MCMR-AAA-B/RFP W81XWH-10-R-0001
820 Chandler Street
Fort Detrick, MD 21702-5014

Offerors are cautioned that proposals will be evaluated on proposal content; offerors must not assume that members of the evaluation panel are familiar with an offeror's experience and other qualifications. **All Questions on the solicitation must be submitted no later than Noon Eastern Standard Time on 12 July 2010. All Answers to questions will be posted via a solicitation amendment on about 23 July 2010. All proposals shall be submitted no later than Noon Eastern Standard Time on 6 August 2010.**

L.A.1.1. The offeror shall submit a proposal comprehensive enough to provide the basis for a sound evaluation by the Government. Information must be precise, factual, and complete. Legibility, clarity, completeness, and responsiveness are of the utmost importance. Proposals shall be sufficiently detailed to enable the Government to determine the acceptability of the proposal strictly from its contents. The Government will not assume or consider anything that is not specifically addressed in the proposal except for past performance. Data submitted previously or presumed to be known (e.g., previous projects performed for the Government) cannot be considered as part of the proposal unless physically incorporated therein. Therefore, it is incumbent upon the offeror to submit proposals initially which are responsive to the Government's requirements and which clearly present the offeror's capabilities and offer.

L.A.1.2. The general organization and minimum contents of proposals are stipulated here to identify certain technical, management, and cost areas where the offeror's approach must be stated specifically. The outline is not intended to rule out the submission of other data which the offeror feels is pertinent to this solicitation. The amount of detail to be presented in each section of the proposal is left to the offeror's discretion. The information must be presented in sufficient detail for the Government to make a comprehensive evaluation of the offeror's understanding of the RFP's requirements and performance capability to meet the requirements. The offeror's proposal package should demonstrate this understanding and capability in a concise and logical manner, and should not contain superfluous material that is not related directly to this RFP.

L.A.1.3. Sample Research Task Orders

The following sample task orders are representative of actual tasks to be issued under the contract. A Task Execution Plan (TEP) shall be prepared for each sample task and provided with the offeror's proposal for evaluation according to the evaluation factors set forth in Section M.

L.A.1.3.1. In Vitro Screens for Nerve Agents (**Sample Task 1**)

(1) Develop an in vitro assay to measure the effect of candidate pretreatment and treatment (P&T) compounds on acetylcholinesterase (AChE) inhibition and test up to 200 compounds during one year. The assay should allow for the determination of the bimolecular rate constant of binding and the extent of protection against nerve agents.

(2) Develop an in vitro assay to measure the rate and extent of recovery of AChE activity after exposure to nerve agents and test up to 200 P&T compounds in one year on their effect of AChE recovery.

L.A.1.3.2. In Vitro Screen for Vesicating Agents (**Sample Task 2**)

Develop an in vitro assay for indication of tissue injury induced by vesicating agents and test up to 200 P&T compounds in one year for efficacy in preventing and treating injury induced by vesicants.

L.A.1.3.3. In Vivo Screens (**Sample Task 3**)

Develop an in vivo assay method to measure the ability of compounds to catalyze the hydrolysis of nerve agents and screen up to 200 compounds per year. The method should be capable of providing a means of rank ordering test compounds both by rate of reaction and extent of association.

L.A.1.3.4. Effect of Pretreatment and Treatment Compounds on non-human primate task accomplishment (**Sample Task 4**)

(1) Carry out pharmacokinetic studies of P&T compounds to determine optimum testing schedules.

(2) Develop an in vivo test protocol to conduct GLP compliant efficacy testing of prophylactic and treatment compounds in Non-Human Primates. These studies may be the definitive studies required for FDA approval of these compounds. The test protocol must be designed so that the results can be included in final reports appropriate for inclusion in submissions to the FDA.

L.A.1.3.5. Genomics/Proteomics Data Mining Capability (**Sample Task 5**)

Maintain the capability to perform genomics/proteomics evaluations on cells/tissues harvested after exposure to chemical warfare agents. Maintain the expertise and equipment to mine the data generated by these research methods to assess the impact of the exposure at the DNA or protein level and to draw conclusions as to the biochemical mechanisms influenced and the resulting pathology of CWA exposure.

L.A.2. TECHNICAL PROPOSAL CONTENT

L.A.2.1. Task Orders will be placed on an as-needed basis. The quantity of research task orders beyond the base task is unknown; however, the technical proposal should be predicated on a reasonable expectation for the maximum number of studies for the five-year term is 45 (i.e., 9 per year) with a minimum anticipated of 1 per year (3 during the three year base period). **THE TECHNICAL PROPOSAL SHALL NOT CONTAIN REFERENCE TO COST.** However, labor hours and categories, consultants, subcontracts, travel, materials, equipment, and other information of interest to technical reviewers shall be contained in the technical proposal in sufficient detail so that the offeror's understanding of the scope of work may be adequately evaluated. Response to the Evaluation Factors for Award (Section M) shall be presented in the same order listed in the RFP.

I. COVER PAGE – Must contain RFP title, solicitation number, name and location of offeror, and name of principal investigator.

II. TABLE OF CONTENTS – The technical proposal shall be divided by subject into numbered sections, within which the page numbering shall be separate, e.g., I-1, I-2, etc.

III. INTRODUCTION – (including background)

IV. SCOPE OF WORK – As outlined in Section C.

V. TECHNICAL CAPABILITY

The Offeror shall submit a technical proposal, which effectively demonstrates the Offeror's understanding of the requirements, and ability to meet all of the functional requirements, terms and conditions contained herein. Additionally, it shall provide a successful technical solution for the prospective contract. The Offeror proposal shall include the technical approach, methodology, and flexibility that shall be utilized in accomplishing any resultant contract.

The Offeror shall describe its technical approach and overall ability to perform the requirements outlined in Section C.2 Performance Work Statement. Additionally, the Offeror shall address the specific criteria below:

1. Describe evidence of understanding the scope and type of work, and the nature of deliverables;
2. Describe capabilities to perform the Performance Work Statement based on the technical proposal and sample tasks orders identified in Section L of the solicitation;
3. Describe the ability to problem solve;
4. Describe ability to deal with chemical surety materials and running a chemical surety program; and
5. Describe ability to deal with the environmental & energy conservation plan for Chemical Surety Materiel (CSM) operations that addresses surety, safety, security, occupation health and environmental concerns enumerated in the solicitation and in accordance with Chapter 3, AR-50-6.
6. Environmental information must be addressed to demonstrate the contractor's awareness and expertise with regard to all local, state, and federal requirements, to include applicable Department of Defense and Army regulations that would affect facility location and operation. Discussion should address anticipated community response to having defensive medical research and development done using chemical warfare agents in their area.

a. Proposals will be individually evaluated for environmental considerations. Based on the specifics of each proposal, the Government will conduct an environmental analysis for those offerors determined to be in the competitive range and will determine what the appropriate level of environmental documentation is, i.e., categorical exclusion, environmental impact assessment, environmental impact statement. In any case, if an environmental assessment results in a decision that an environmental impact statement is needed, then that additional environmental work will be accomplished.

b. ENVIRONMENTAL CERTIFICATIONS - To assist the USAMRMC in ensuring that contracts are in compliance with all applicable federal, state, and local environmental laws and regulations, the contractor shall submit a Certification of Environmental Consideration (CEC). The CEC is located at <http://www-usamraa.army.mil/pages/index.cfm>, appendices. Prior to signing this certification, contractors must consider their current status of compliance/noncompliance as well as the impact of the proposed research including, but not limited to, handling and disposal of hazardous/toxic substances; handling, transportation, disposal of hazardous materials, and clean air and clean water concerns.

c. The Council of Environmental Quality (CEQ) regulations (40 CFR 1508) that implement the National Environmental Policy Act (NEPA) (PL 91-190 as amended) require all federal agencies to examine possible environmental consequences of their proposed and on-going actions. The type of projects, which must be evaluated for environmental impact, includes medical research and development activities conducted in the U.S. The proposal should address potential

environmental impacts of a project so that an environment analysis and proper documentation can be prepared in compliance with NEPA. The proposal should include:

- (1) Full description of laboratories, including a floor plan to scale, where research will be performed;
- (2) Description of hoods, containment facilities, filters, and other air pollution control, if applicable;
- (3) Complete listing of all hazardous or radioactive chemical and biological substances to be utilized during the research;
- (4) Description of the packaging and disposal of all solid/liquid wastes, radioactive substances, medical/infectious wastes, and toxic/hazardous substances utilized in the research effort;
- (5) Name, address, and telephone number of the offeror's environmental official; and
- (6) Is the proposed research covered under any existing environmental documents (e.g., environmental impact statement or environmental assessment)? If so, list the title and date of the document.

VI. FACILITIES:

1. Describe the facilities operations plan;
2. Provide evidence that the proposed facilities and equipment can accommodate RDT&E studies involving the full spectrum of chemical threats;
3. Provide evidence that the proposed facility meets regulatory requirements for conducting research involving CSM, RDT&E dilute solutions, and hazardous materiel, etc, in accordance with GLP, Army Regulation (AR) 50-6, and all applicable Government regulations;
4. Provide evidence that the proposed facilities are in accredited by the American Association for Accreditation of Laboratory Animal Care (AAALAC) animal facilities and registered with the U.S. Department of Agriculture;
5. Describe procedures for access to Contractor's facility by U.S. Government and Government Contractor personnel; and
6. FACILITY SAFETY SURETY PLAN (FSSP): Offerors are required to submit an approved FSSP. Preparation instructions for the FSSP are located at <https://mrmc.detrick.army.mil/index.asp?EntryURL=/crprcqsohd.asp>. The successful offer or is required to have a satisfactory FSSP in place on the effective date of the contract.

VII. PERSONNEL QUALIFICATIONS

1. Describe experience to conduct all aspects of Research Development Test & Evaluation (RDT&E) involving chemical surety material (CSM) and RDT&E dilute solutions, toxic compounds, and other highly hazardous materials by providing history of management accomplishments, including the project managers' accomplishments that relate to this project. Provide evidence of managerial authority and control of resources for the project. Provide evidence that the key personnel (Program Manager and Principal Investigator) have a comprehensive understanding of the requirements and regulations governing the running of a chemical surety material program and the capability to simultaneously conduct multiple studies involving multiple species of animals, some with large sample sizes. Additionally, address the following:
 - (a) Provide a curriculum vitae and bibliographic data on proposed key personnel. Evidence of academic, professional and technical background of proposed staff, recent experience using surety material, and specific scientific or technical accomplishments are required for the principal professional and technical personnel. Describe the contribution(s) that each of the proposed personnel is expected to make with emphasis on their experience to conduct tasks described in Section C.
 - (b) Describe manpower schedule to include the skills and man-hours committed to this project.

- (c) Describe the manpower availability for this project. Describe how professional and technical staff with unique capabilities will be made available for specific tasks.
2. Describe ability to simultaneously conduct multiple studies involving multiple species of animals, some with large sample sizes to include addressing the following:
- (a) Discuss the mix of managerial, professional, technical, and administrative personnel required to conduct the statement of work;
 - (b) Describe experience preparing protocols, developing, and/or validating quantitative in vivo and in vitro models for efficacy testing; conducting safety and/or toxicological studies in animals; conducting toxicological studies with special emphasis in dermal toxicity and pulmonary toxicology; in vivo and in vitro modeling; analytical, physical, and clinical chemistry; pharmacology with emphasis on drug screening; pathophysiology; veterinary medicine; animal care; handling and maintenance; and related sciences;
 - (c) Provide evidence of willingness and capability to conduct such research with chemical surety material (CSM).
 - (d) Provide evidence of Good Laboratory Practices (GLP) experience and capability and associated quality assurance (QA) programs. Scientific and technical depth in the organization is required to include backup (on call) personnel to accommodate scheduled and unscheduled absences as well as personnel turnover;
 - (e) Describe experience conducting percutaneous studies in animals, toxicological studies with special emphasis in dermatotoxicity and pulmonary toxicology, in vivo and in vitro modeling, analytical, physical, and clinical chemistry; pharmacology with emphasis on drug screening; pathophysiology; veterinary medicine; animal care, handling and maintenance; and related sciences;
 - (f) Provide evidence of support personnel with ability to provide data processing, storage, retrieval, and reporting;
 - (g) Provide evidence of biomedical engineering expertise to make needed design and system changes as rapidly as possible to meet changing requirements. Evidence of biomedical scientific writing experience is required to include record of timeliness of submission of deliverables/reports and expertise in biostatistics is required for experimental design and data analysis with consideration given to statistical analysis of data in developing quantitative standardized biomedical models for research, testing, and evaluation; and
3. Provide evidence of Good Laboratory Practices experience by providing professional and technical expertise of a Program Manager to conduct studies.

VIII. MANAGEMENT PLAN

1. Describe the management operations plan;
2. Describe management's commitment and ability to maintain stable manpower resources to achieve the objectives and complete each task order assignment;
3. Describe management's interface plan between the Offeror's key personnel and the USAMRMC Contracting Officer's Representative;
4. Describe procedures to periodically review the Offeror's in-house organizational functions, program reviews and controls, inspections, and subsequent coordination with the Government; and
5. Describe offeror's experience maintaining a personnel reliability program insuring all employees associated with the program have had adequate background checks and are qualified to hold security clearances commensurate with the duties they are called on to perform and consistent with Army regulations. Demonstrate offeror's knowledge of the process. Provide a listing of current work for other clients requiring clearances.

L.A.3. COST PROPOSAL INSTRUCTIONS

L.A.3.1. The cost/business proposal shall include, but is not limited to, the items which include the contract forms and representations, certifications and other statements of the offerors (Section K) which will be incorporated into the contract by reference.

L.A.3.1.1. Each sample task order should be priced separately. For consistency, the same five studies should be priced out for the Base Period, and two (2) Option Years. The offeror shall use the SF 1411, Contract Pricing Proposal Cover Sheet, and the format indicated in FAR 15.408, Table 15-2, in submitting the cost proposal.

L.A.3.1.2. Section K, Representations, Certifications and Other Statements of Offerors – The offeror shall complete, sign, date, and include an original in the cost proposal.

L.A.3.1.3. In addition, include information reasonably required to explain offeror's estimating process, including: (a) judgmental factors applied and mathematical or other methods used in the estimate, including those used in projecting from known data; and (b) the nature and amount of any contingencies included in the proposed price.

L.A.3.1.4 A statement of the methodology and assumptions utilized as the basis for estimating costs. As a minimum, the offeror must address escalation factors applied to base costs, the basis for estimating labor utilization, basis for estimating material costs, the source of travel cost estimates, and the current audit status of all indirect cost factors.

L.A.3.1.5 Information to support the offeror's cost proposal for the sample task orders shall be in accordance with the Federal Acquisition Regulation (FAR) Part 31.2, and must include, but is not limited to, the following:

Direct Labor: The basis for the estimated hours broken down by personnel classification and labor rates. The proposed rates are current, and should be accurate, and complete with escalation rates for the outyears. Indicate number of man-hours equal to a man-year for the employees.

Material: Detailed listing of materials including quantity, unit cost, basis and/or source of cost estimate, cost of packaging, and distribution of the materials.

Equipment: All equipment, instrumentation, and software to be obtained with Government funds under this contract shall be listed by manufacturer, model number, and estimated cost.

Subcontractor(s): If the offeror plans to subcontract any of the work to be performed, list proposed subcontractors by name. Provide a breakdown of specific work to be subcontracted and the appropriate cost involved. Include information concerning any organization or ownership relationship between the offeror and any proposed subcontractors in accordance with the Federal Acquisition Regulation (FAR) Part 2, Definitions of Words and Terms, and FAR 15.408, Table 15-2.

Consultant(s): List any proposed consultant(s) by name and expertise. Indicate the nature of the service, estimated number of hours, fee rate, and other allowable related costs which may be involved. Consultant fees may not be paid to employees of the contractor or employees of the U.S. Government in accordance with the FAR Part 2, Definitions of Words and Terms, and FAR 31.205-33.

Other Direct Costs: The breakdown of all travel by trips, including origin and destination, mode of travel, duration of travel, estimated transportation expenses, and per diem costs. The estimated cost for other direct costs is \$37,000 for the Base Period, \$13,000 for Option Year I, and \$14,000 for Option Year II.

Indirect Costs: Indicate current rates as well as the basis for the same. Include a historical trend for the last three-year period for use in evaluating the reasonableness of the proposed rates.

Facilities Capital Cost of Money: When the offeror elects to claim facilities capital cost of money as an allowable cost, the offeror must complete and submit Forms CASB-CMF and DD Form 1861-2 (see FAR 31.205-10).

Additional Facilities or Properties: In the event the Offeror contemplates acquiring additional facilities or property in performance of this work, such facilities or properties shall be separately identified.

Contractor Manpower Reporting (CMR): As outlined in Section C, provide pricing for the base period and option periods. Please identify if the CMR requirement is not separately priced.

L.A.4. PAST PERFORMANCE

Offerors shall submit the following information as part of their proposal (in a separate document) for both the offeror and proposed major subcontractors.

L.A.4.1. The offeror shall submit a description of its ongoing and previous contracts (all prime and major subcontracts) during the past three (3) years that are relevant to the effort required in this solicitation. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments, and commercial customers. Include the following information for each contract and subcontract:

- a. Name of contracting activity
- b. Contract number
- c. Contract type
- d. Total contract value
- e. Specific detail for each contract listed, why or how that effort is considered relevant or similar to the effort required in this RFP.
- f. Contracting officer and telephone and e-mail address
- g. Program manager and telephone and e-mail address
- h. Administrative contracting officer, if different from f, and telephone and e-mail address
- i. List of major subcontractors and details of subcontractor work
- j. Contract award date, total period of performance, end date at time of award, and any contract extensions or projected extensions.

L.A.4.2. Identify in specific detail, for each contract listed, why or how you consider that effort relevant or similar to the effort required in the solicitation. The offeror shall provide information on problems encountered on contracts and subcontracts identified above and corrective actions taken to resolve those problems. Offerors should not provide general information on their performance on the identified contracts. General performance information will be obtained from the references.

L.A.4.3. The offeror shall provide the above required information for all contracts that have been terminated, in whole or in part, for default during the past five years, to include those currently in the process of such termination as well as those which are not similar to the proposed effort. The offeror shall list each time the delivery schedule was revised and provide an explanation of why revisions were necessary.

L.A.4.4. The offeror may describe any quality awards or certifications that indicate the offeror possesses a high-quality process for developing and producing the product or service required. Identify what segment of the company (one division or the entire company) that received the award or certification. Describe when the award or certification was bestowed. If the award or certification is over three years old, present evidence that the qualifications still apply.

L.A.4.5. Performance Under Existing Contracts/Prior for Similar Products/Services

Each offeror will be evaluated on his/her performance under existing and prior contracts for similar products or services. Performance information will be used as an evaluation factor against which offerors' relative rankings will be compared to assure best value to the government. The government will focus on information that demonstrates quality of performance relative to the size and complexity of the procurement under consideration. The Past

Performance Questionnaire identified in Section J will be used to collect this information. Each offeror must request completion of past performance questionnaires (attachment 7) from those companies/customers, whose requirement is/was relevant to this work statement. The questionnaire should be forwarded to the Contract Specialist administering the award. Companies completing **the questionnaire must submit it directly to Ms. Lisa Sawyer no later than Noon Eastern Standard Time, 6 August 2010** using one of the following methods: fax completed questionnaires to the attention of Ms. Lisa Sawyer at 301-619-2254, e-mail completed questionnaires to lisa.sawyer@amedd.army.mil, or mail completed questionnaires to: U.S. Army Medical Research Acquisition Activity, ATTN: MCMR-AAA-B (Ms. Lisa Sawyer), 820 Chandler Street, Fort Detrick, MD 21702-5014. References other than those identified by the offeror may be contacted by the Government with the information received used in the evaluation of the offeror's past performance.

L.A.4.6. Information required in the above paragraphs shall be provided for each proposed subcontractor who will perform a significant portion of the effort. "Significant" is defined as more than 20 percent of the work to be performed. With regard to prime contract assignments that will be performed by you and not a proposed subcontractor, offerors shall indicate:

- a. What internal corporate bodies/divisions will accomplish which portions of the effort;
- b. Whether or not those divisions were responsible for performance under the previous contracts cited for the instant proposal; and,
- c. If those divisions have relocated since the accomplishment of previous cited contract efforts, a description of any changes arising from that relocation in terms of key personnel, facilities, and equipment.

L.A.4.7. The government will focus on information that demonstrates quality of performance relative to the size and complexity of the procurement under consideration. The Past Performance Questionnaire identified in Section J, will be used to collect this information. The Government may contact references other than those identified by the offeror. This information will be used to evaluate the offeror's past performance.

L.A.4.8. New Corporate Entities

New corporate entities may submit data on prior contracts involving its officers and employees. However, in addition to the other requirements in this section, the offeror shall discuss in detail the role performed by such persons in the prior contracts cited.

L.B. GOVERNMENT FURNISHED EQUIPMENT (GFE)

Upon the Government's request, the apparent successful offeror shall specifically identify equipment (from Attachment 6) desired in the performance of the Statement of Work.

CLAUSES INCORPORATED BY REFERENCE

52.215-1	Instructions to Offerors--Competitive Acquisition	JAN 2004
52.215-1 Alt I	Instructions to Offerors--Competitive Acquisition (Jan 2004) - Alternate I	OCT 1997
52.215-15	Pension Adjustments and Asset Reversions	OCT 2004
52.215-20	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data	OCT 1997
52.222-24	Preaward On-Site Equal Opportunity Compliance Evaluation	FEB 1999

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52.215-16 FACILITIES CAPITAL COST OF MONEY (JUN 2003)

(a) Facilities capital cost of money will be an allowable cost under the contemplated contract, if the criteria for allowability in FAR 31.205-10(b) are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(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 The U.S. Army Medical Research Acquisition Activity, 820 Chandler Street, ATTN: MCMR-AAA-B, 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.

252 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

BASIS FOR AWARD

M.1. The Government will award a contract to the responsible Offeror, whose proposal is determined to be the best value to the Government based on a trade-off analysis. Proposals that are unrealistic in terms of technical or schedule commitments or unrealistically high or low in cost may 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.

M.2. PROPOSAL EVALUATION

Each offeror's proposal will be evaluated in accordance with the factors that are deemed critical. The following evaluation factors are listed in descending order of importance: Technical Capability, Facilities, Personnel Qualifications, Management Plan, Past Performance and Cost.

If upon final evaluation, an offeror is deemed unacceptable for any individual factor, they will be considered unacceptable for award. In the event two or more proposals are deemed essentially equal in technical merit, cost may become more important in the consideration for award. Cost will be evaluated on reasonableness, allowability and allocability. Cost will be examined independently but is not rated.

The Government will review and evaluate the sample task order cost proposals, and evaluate the separate cost elements and profit/fee to determine how well the proposed costs represent what the cost of the sample task orders should be, assuming reasonable economy and efficiency.

M.3. EVALUATION FACTORS

M.3.a. TECHNICAL CAPABILITY

Government will assess the Offeror's:

1. Describe evidence of understanding the scope and type of work, and the nature of deliverables;
2. Describe capabilities to perform the Performance Work Statement based on the technical proposal and sample tasks orders identified in Section L of the solicitation;
3. Describe the ability to problem solve;
4. Describe ability to deal with chemical surety materials and running a chemical surety program;
5. Describe ability to deal with the environmental & energy conservation plan for Chemical Surety Materiel (CSM) operations that addresses surety, safety, security, occupation health and environmental concerns enumerated in the solicitation and in accordance with Chapter 3, AR-50-6; and
6. Environmental information must be addressed to demonstrate the contractor's awareness and expertise with regard to all local, state, and federal requirements, to include applicable Department of Defense and Army regulations that would affect facility location and operation. Discussion should address anticipated community response to having defensive medical research and development done using chemical warfare agents in their area.

a. Proposals will be individually evaluated for environmental considerations. Based on the specifics of each proposal, the Government will conduct an environmental analysis for those offerors determined to be in the competitive range and will determine what the appropriate level of environmental documentation is, i.e., categorical exclusion, environmental impact assessment, environmental impact statement. In any case, if an environmental assessment results in a decision that an environmental impact statement is needed, then that additional environmental work will be accomplished.

b. ENVIRONMENTAL CERTIFICATIONS - To assist the USAMRMC in ensuring that contracts are in compliance with all applicable federal, state, and local environmental laws and regulations, the contractor shall submit a Certification of Environmental Consideration (CEC). The CEC is located at <http://www-usamraa.army.mil/pages/index.cfm>, appendices. Prior to signing this certification, contractors must consider their current status of compliance/noncompliance as well as the impact of the proposed research including, but not limited to, handling and disposal of hazardous/toxic substances; handling, transportation, disposal of hazardous materials, and clean air and clean water concerns.

c. The Council of Environmental Quality (CEQ) regulations (40 CFR 1508) that implement the National Environmental Policy Act (NEPA) (PL 91-190 as amended) require all federal agencies to examine possible environmental consequences of their proposed and on-going actions. The type of projects, which must be evaluated for environmental impact, includes medical research and development activities conducted in the U.S. The proposal should address potential environmental impacts of a project so that an environment analysis and proper documentation can be prepared in compliance with NEPA. The proposal should include:

- (1) Full description of laboratories, including a floor plan to scale, where research will be performed.
- (2) Description of hoods, containment facilities, filters, and other air pollution control, if applicable.
- (3) Complete listing of all hazardous or radioactive chemical and biological substances to be utilized during the research.
- (4) Description of the packaging and disposal of all solid/liquid wastes, radioactive substances, medical/infectious wastes, and toxic/hazardous substances utilized in the research effort.
- (5) Name, address, and telephone number of the offeror's environmental official.
- (6) Is the proposed research covered under any existing environmental documents (e.g., environmental impact statement or environmental assessment)? If so, list the title and date of the document.

M.3.b. FACILITIES:

The Government will assess:

1. Describe facility operations plan;
2. Provide evidence that the proposed facilities and equipment can accommodate RDT&E studies involving the full spectrum of chemical threats;
3. Provide evidence that the proposed facility meets regulatory requirements for conducting research involving CSM, RDT&E dilute solutions, and hazardous materiel, etc, in accordance with GLP, Army Regulation (AR) 50-6, and all applicable Government regulations;
4. Provide evidence that the proposed facilities are in accredited by the American Association for Accreditation of Laboratory Animal Care (AAALAC) animal facilities and registered with the U.S. Department of Agriculture;
5. Describe procedures for access to Contractor's facility by U.S. Government and Government Contractor personnel; and
6. FACILITY SAFETY SURETY PLAN (FSSP): Offerors are required to submit an approved FSSP. Preparation instructions for the FSSP are located at <https://mrmc.detrack.army.mil/index.asp?EntryURL=/crprcqsohd.asp>. The successful offer or is required to have a satisfactory FSSP in place on the effective date of the contract.

M.3.c. PERSONNEL QUALIFICATIONS

The Government will assess:

1. Describe experience to conduct all aspects of Research Development Test & Evaluation (RDT&E) involving chemical surety material (CSM) and RDT&E dilute solutions, toxic compounds, and other highly hazardous materials by providing history of management accomplishments, including the project managers' accomplishments that relate to this project. Provide evidence of managerial authority and control of resources for the project. Provide evidence that the key personnel (Program Manager and Principal Investigator) have a comprehensive understanding of the requirements and regulations governing the running of a chemical surety material program and the capability to simultaneously conduct multiple studies involving multiple species of animals, some with large sample sizes. Additionally, address the following:

- (a) Describe manpower schedule to include the skills and man-hours committed to this project.
- (b) Describe the manpower availability for this project. Describe how professional and technical staff with unique capabilities will be made available for specific tasks.
- (c) Provide a curriculum vitae and bibliographic data on proposed key personnel. Evidence of academic, professional and technical background of proposed staff, recent experience using surety material, and specific scientific or technical accomplishments are required for the principal professional and technical personnel. Describe the contribution(s) that each of the proposed personnel is expected to make with emphasis on their experience to conduct tasks described in Section C.

2. Describe the Offeror's ability to simultaneously conduct multiple studies involving multiple species of animals, some with large sample sizes to include addressing the following:

- (a) Discuss the mix of managerial, professional, technical, and administrative personnel required to conduct the statement of work;
- (b) Describe experience preparing protocols, developing, and/or validating quantitative in vivo and in vitro models for efficacy testing; conducting safety and/or toxicological studies in animals; conducting toxicological studies with special emphasis in dermal toxicity and pulmonary toxicology; in vivo and in vitro modeling; analytical, physical, and clinical chemistry; pharmacology with emphasis on drug screening; pathophysiology; veterinary medicine; animal care; handling and maintenance; and related sciences;
- (c) Provide evidence of willingness and capability to conduct such research with chemical surety material (CSM).
- (d) Provide evidence of Good Laboratory Practices (GLP) experience and capability and associated quality assurance (QA) programs. Scientific and technical depth in the organization is required to include backup (on call) personnel to accommodate scheduled and unscheduled absences as well as personnel turnover;
- (e) Describe experience conducting percutaneous studies in animals, toxicological studies with special emphasis in dermatotoxicity and pulmonary toxicology, in vivo and in vitro modeling, analytical, physical, and clinical chemistry; pharmacology with emphasis on drug screening; pathophysiology; veterinary medicine; animal care, handling and maintenance; and related sciences;
- (f) Provide evidence of support personnel with ability to provide data processing, storage, retrieval, and reporting;
- (g) Provide evidence of biomedical engineering expertise to make needed design and system changes as rapidly as possible to meet changing requirements. Evidence of biomedical scientific writing experience is required to include record of timeliness of submission of deliverables/reports and expertise in biostatistics is required for

experimental design and data analysis with consideration given to statistical analysis of data in developing quantitative standardized biomedical models for research, testing, and evaluation; and

3. Provide evidence of Good Laboratory Practices experience by providing professional and technical expertise of a Program Manager to conduct studies.

M.3.d. MANAGEMENT PLAN

The Government will assess:

1. Describe management operation plan;
2. Describe management's commitment and ability to maintain stable manpower resources to achieve the objectives and complete each task order assignment;
3. Describe management's interface plan between the Offeror's key personnel and the USAMRMC Contracting Officer's Representative;
4. Describe procedures to periodically review the Offeror's in-house organizational functions, program reviews and controls, inspections, and subsequent coordination with the Government; and
5. Describe offeror's experience maintaining a personnel reliability program insuring all employees associated with the program have had adequate background checks and are qualified to hold security clearances commensurate with the duties they are called on to perform and consistent with Army regulations. Demonstrate offeror's knowledge of the process. Provide a listing of current work for other clients requiring clearances.

M.3.e

PAST PERFORMANCE

The Government will assess:

1. The past performance questionnaires received from offeror's references on existing and prior contracts for similar products or services, and information obtained from the Contractor Performance Assessment Reporting System (CPARS). Performance information will be used as an evaluation factor against which Offeror's relative ratings will be compared to assure best value to the Government. The Government will focus on information that demonstrates quality of performance relative to the size and complexity of the procurement under consideration. The Past Performance Questionnaire identified in Section J will be used to collect this information. On the occasion that no relevant past performance exists for an Offeror, or for whom information on past performance is unavailable, the Offeror will not be evaluated favorably or unfavorably on past performance, but will be treated as an unknown performance risk.
2. If the Offeror is truly a new entity, and none of the company principals have relevant work experience, the Offeror is considered to have no past performance. In the case of an Offeror without a record of relevant past performance or for whom information on past performance is not available, the Offeror's lack of past performance shall be evaluated as unknown risk, having no favorable or unfavorable impact on the evaluation.
3. The Contracting Office may contact the references provided by the Offeror to support past performance evaluation.

M.3.f.

COST/PRICE

1. Cost will be evaluated separately to determine whether the proposed cost for Completeness, accuracy, defensibility, and reasonableness of the proposal. The Government will review and evaluate the cost of the sample task orders, and evaluate the separate cost elements and profit/fee to determine how well the proposed cost represent what the cost of the sample task order should be, assuming reasonable economy and efficiency.
2. The Government will utilize the Defense Contract Audit Agency (DCAA) to assist in the acceptability evaluation of the proposed cost, the Offeror's accounting system, and financial capability. The Government will independently evaluate specific elements of the Offeror's cost estimate to determine whether the estimated cost elements are realistic for the work to be performed; reflect a clear understanding of the requirements, and are consistent with the unique methods of performance and materials described in the Offeror's technical approach. The Government will utilize weighted guidelines to analyze the Offeror's profit or fee to determine if it is reasonable in light of the associated risk.

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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)