DRAFT STATEMENT OF WORK – dated 1 December 2008

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). The Medical Chemical Defense Research Program 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, 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 or non-DoD users of the facility. The awardee is responsible for ensuring that the overhead cost for the requested work from any outside agency is comparable to the costs incurred by the DoD for similar work. 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 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.

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 wil1 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 (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.

1. Personnel:

a. Must 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.

b. 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.

c. 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.

d. 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.

e. 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.

f. Biomedical engineering expertise is required to make needed design and system changes as rapidly as possible to meet changing requirements.

g. 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).

h. 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.

i. 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.

j. 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.

B. 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.

C. Facility: The contractor's facility must: (1) meet all safety and surety requirements for storage, handling, use, and disposal of CSM, RDT&E dilute solutions, and hazardous materials; (2) have the capability of conducting

research and testing to satisfy the requirements of Good Laboratory Practices (GLP) regulations and guidelines; and (3) allow DoD (DTRA, USAMRMC, CBMS), other U.S. Government and other USAMRMC contractor personnel to work within the facility on an as needed basis. Contractor shall have a management concept plan for facility operation to include capability to conduct RDT&E, the latter in accordance with Government-approved research protocols and/or standard test procedures. It is anticipated that the staff should consist of professional scientific personnel, technical support, and administrative support staff. The Management and Operational (M&O) 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.

1. Facility must be dedicated 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 (l) liter of neat agent or neat agent equivalent (aggregate total of all CSM) must be provided.

2. Facility must be accredited by the American Association for Accreditation of Laboratory Animal Care International (AAALAC) and registered with the U.S. Department of Agriculture. Facility shall consist of heated and/or air-conditioned space for laboratory research, animal holding, laboratory support, office/administrative space, and storage. 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:

a. CSM storage and dilution laboratory facilities
b. Animal inhalation dosing capability
c. Percutaneous dosing capability
d. in vitro testing capability
e. Analytical chemistry capability
f. Animal pathology support

3. The laboratory research area must 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.

4. Special consideration must be given to hood configuration for exposing and holding animals given percutaneous exposure with agent. Animal holding in hoods will be short-term (1 day - 2 weeks).

a. 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.

b. Must be readily adaptable to changing RDT&E requirements and priorities.

5. Waste Disposal:

a. 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.

b. Nonrecoverable, decontaminated solid waste from agent studies must be destroyed via pathological incinerator and/or other means consistent with applicable requirements.

c. 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.

D. Safety - The laboratory will 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.

E. Good Laboratory Practices (GLP) - The contractor shall have GLP capability and associated quality assurance (QA) programs. Up to 20 percent of the research, testing, and evaluation effort may require GLP compliance. Task orders will specify if GLP compliance is required.

F. 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.

IV. Research Capabilities:

A. 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.

B. 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.

C. Screen and evaluate candidate pretreatment and treatment compounds in mouse, guinea pig, swine, rabbit, rat, and non-human primate models.

D. Collect, organize, analyze, and report experimental data and ensure that experimental protocols are conducted in appropriate randomized fashion.

E. 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 cGLP 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.

F. Perform necropsy protocols supporting research, development, test, and evaluation work.

G. Develop and utilize tests for screening prophylaxis and therapeutic compounds for efficacy in specialized animal models exposed by the inhalation route.

H. Validate an in vivo and in vitro model developed in a USAMRMC laboratory or by a USAMRMC contractor, using one or more agents.

I. 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.

J. Design, develop, and/or implement analytical chemistry methodologies as needed to ensure quality assurance and quality control of research compounds.

K. Synthesize radiolabeled or unlabeled compounds as needed to support research operations.

L. Pivotal GLP Animal Efficacy Studies for Nerve Agent. 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.

M. 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.

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

V. 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.

(4) All dossiers for personnel being assigned to PRP positions will be made available for review. Certifying Officials may request a dossier for rereview purposes.

VI. PERSONNEL RELIABILITY PROGRAM 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 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 Battelle 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) The Security Manager for USAMRICD will notify Battelle's Contract Security Officer with clearance/investigation results for any Battelle 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 Battelle employee requires a more in-depth investigation, the Battelle Security Officer will submit the investigation request via e-QIP, indicating the USAMRICD UIC as the "Return Results To" recipient.

(2) 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.

(3) 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.

(4) 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 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. REPORTING REQUIREMENTS

A. The contractor shall submit the following technical reports:

(1) Contract Progress Reports (Quarterly, Annual, and Final Progress Reports). (see Section F/To be determined (TBD))

(2) Task Order Study Reports. (see Attachment 5/TBD).

(3) Copies of manuscripts submitted for publication (see Section F/TBD).

(4) Copies of abstracts for professional meetings (see Section F/TBD).

(5) Reprints of publications when available (see Section F/TBD).

(6) News releases related to this contract (see Section F/TBD).

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/TBD).