

U.S. ARMY RESEARCH OFFICE

BROAD AGENCY ANNOUNCEMENT

W911NF-05-R-0003



Solutions for Physical Science and Technology
Chemical and Biological Defense Program

DECEMBER 2004

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SOLUTIONS FOR PHYSICAL SCIENCE & TECHNOLOGY
CHEMICAL AND BIOLOGICAL DEFENSE PROGRAM

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I. INTRODUCTION

The purpose of this Broad Agency Announcement (BAA) is to solicit proposals for the Department of Defense (DoD) Fiscal Year 2006 Physical Science and Technology (S&T) Chemical and Biological Defense Program (CBDP). The goal is to explore new and innovative ideas to fill identified technology gaps.

On 22 April 2003, the Undersecretary of Defense, Acquisition, Technology and Logistics (USD(AT&L)) approved the "Implementation Plan for the Management of the Department of Defense Chemical and Biological Defense Program." The plan defines the roles and responsibilities and provides the implementation procedures for CBDP management. The CBDP provides for planning, programming, budgeting and execution of the Chemical/Biological/Radiological/Nuclear (CBRN) defense research, development and acquisition; programming and budgeting for CBD equipment, sustainment, and training; establishing military requirements for CBRN defense; and test and evaluation of CBRN defense programs. This BAA is focused on S&T needs for chemical and biological defense.

II. FUNDING OPPORTUNITY DESCRIPTIONS

A. Overview

Proposals are being sought to identify viable solutions to technology gaps in the following CBD S&T areas: Detection; Modeling & Simulation/Battlespace (MSB); Protection; and Decontamination. General goals are listed here; specific technology issues to be addressed in each of these areas can be found in Section II.B. of this BAA.

Detection. The goal of the CBD detection program is to provide real-time capability to detect, identify, characterize, locate, and warn against all known or validated Chemical and Biological (CB) warfare agent threats. The CBDP seeks to:

- Optimize sensor technologies;
- Focus on improving tactical detection and identification capabilities for both chemical and biological warfare agents; and
- Focus efforts on multi-agent sensors for CB agent detection and remote/early warning CB detection.

Modeling and Simulation/Battlespace. The goals of the MSB Capability Area are as follows:

- Provide information superiority with respect to the CBRN environment;
- Integration with Command, Control, Communications, Computers, Intelligence, Surveillance, and Reconnaissance (C4ISR) networks;

- Accurate representation on the Common Operational Picture (COP);
- Rapid assessment of CBRN on operations;
- Automated decision support for the warfighter;
- DoD level theater / warfare simulation efforts for planning & training; and
- Provide decision support tools for resource allocation and program investment analyses.

Protection. Goals of the CBD Protection efforts are divided into two subareas:

- The goal of the individual CBD Protection effort is to reduce the physiological burden associated with wearing protective equipment while maintaining, and potentially improving, the already high level of protection against CB warfare agents and radiological particles.
- The goals of the collective CBD Protection area are to (1) reduce the weight, size, and power requirements of Collective Protection (CP) systems; (2) reduce the logistical burdens associated with the maintenance of CP filters; (3) improve protection capabilities against current and emerging threat agents, including Toxic Industrial Chemicals (TICs); and (4) improve the deployability of transportable shelter systems.

Decontamination. The decontamination capability area's objectives for FY 2006 include meeting the following:

- Sensitive Equipment and Interior Decontamination – Developing solutions and materials to decontaminate sensitive equipment inside platforms such as aircraft and tanks (interior decontamination);
- Solution Decontamination – Developing a single solution that is oxidative, non-corrosive, and environmentally benign; an effective broad-spectrum chemical and biological decontaminant; and suitable for use on a multitude of surfaces;
- Reactive Sorbent Decontamination – Developing reactive sorbent solid phase materials that are effective against chemical and biological agents;
- Reduced Decontamination Logistical Burden – Developing a formulation of decontaminants that reduce the currently disproportionate logistical burdens (volume, shelf-life, and/or special handling requirements) and excessive manpower requirements; and
- Self-Decontamination – Determining the feasibility and suitability of active and passive surface coatings that self-decontaminate.

B. Topic Areas.

Each submission must identify the specific topic area and issue addressed. Electronic submissions must be made following the instructions provided in Section IV of this BAA.

1. Detection

The detection capability area requests applied research proposals encompassing a wide range of technologies that are comparable to laboratory, high resolution test methodologies but are suitable for fieldable systems for fixed sites as well as mobile platform applications, to include the warfighter. Additionally, a limited number of basic research proposals that apply to the topics below will be considered. In all applications, the priority is given to minimizing the number of false alarms followed by the overall lifecycle cost, which is heavily dependent on the resources needed to maintain and use the system and includes the following specific detection topics:

- a) New signatures and/or software algorithms for standoff detection technologies will be examined to distinguish Chemical and Biological (CB) agents from background. Must demonstrate feasibility in post processing using current desktop PC, Intel P4 level as the baseline for computational power requirements.
- b) New excitation sources for standoff detection with increased detection range and/or discrimination for CB will be examined with a focus on “non traditional” regions of the Electromagnetic (EM) spectrum, such as the far infrared and millimeter wave regions. Must demonstrate reproducibly of excitation wavelengths with the appropriate performance parameters to support a detection system.
- c) New technologies that integrate detection and identification of CB contamination in water (source and treated) are being sought. Must demonstrate detection at Objective levels established in U.S. Tri-Service Water Quality Standards. See chart below.

U.S TRI-SERVICE WATER QUALITY STANDARDS

EXPOSURE PERIOD	<7 days		<1 year	
CONSUMPTION RATE	5 L/day	15 L/day	5 L/day	15 L/day
Physical Properties				
Color (color unit)	50	50	15	15
Odor (TON)	3	3	3	3
pH	5-9	5-9	5-9	5-9
Temperature (degrees C)	4-35	4-35	15-22	15-22
TDS (mg/L)	1000	1000	1000	1000
Turbidity (NTU)	1	1	1	1
Chemical Properties				
Arsenic (mg/L)	0.3	0.1	0.06	0.02
Cyanide (mg/L)	6	2	6	2
Chloride (mg/L)	600	600	600	600
Lindane (mg/L)	0.6	0.2	0.6	0.2
Magnesium (mg/L)	100	30	100	30
Sulfate (mg/L)	300	100	300	100
Microbiological				
Coliform (cfu/100 mL)	1	1	1	1
Radiological				
Gross α/β , $\mu\text{Ci/L}$	8	3	0.1	0.05
Chemical Agents				
Hydrogen cyanide (mg/L)	6	2		
BZ (incapacitants) ($\mu\text{g/L}$)	7	2.3		
Lewisite ($\mu\text{g/L}$ as arsenic)	80	27		
Sulfur mustard ($\mu\text{g/L}$)	140	47		
Nerve agents ($\mu\text{g/L}$)	12	4		
T-2 toxins ($\mu\text{g/L}$)	26	8.7		

- d) New concepts for the broad-spectrum point detection and identification of the next generation of bio agents. The technology will be equivalent to current nucleic acid based technologies (e.g., Polymerase Chain Reaction – PCR) performance in sensitivity and selectivity without the need for sample preparation and achieving a response time of less than 15 minutes. Standard laboratory based use of antibodies, nucleic acid, peptides, aptmers or other typical molecular recognition moieties converted into a micro-array format will not be considered.
- e) New technologies are being sought for the detection of low volatility materials in vapor, aerosol, liquid, and solid states.
- f) New or improved technology for the point detection of chemical and biological agents with faster response times (seconds), larger numbers of detectable targets (includes toxic industrial materials), reduced false alarms (at least 3 orders of magnitude), and minimal logistic burden (little or no

consumables) is being sought. For biological detection, disposable tickets/components/etc will not be considered. However, concepts for supported antibodies or other molecular recognition moieties that can be reused more than 100 times, if surfaces can be regenerated without the need for other consumables (except power) will be considered.

- g) New technologies are being sought to reduce power consumption and footprint size/weight as well as to increase collection efficiency for particles in the respirable range, i.e., 1-10 μ m. Technological applications under consideration include novel concepts and systems to improved collection and separation of biological and chemical aerosols while reducing energy, power, and size profile. Of primary interest are methods to improve collection efficiency for sub-micrometer particles and liquid (chemical) aerosols.

2. Modeling and Simulation/Battlespace

The modeling and simulation capability area requests applied research proposals, pertaining to chemical and biological defense for MSB and battle management capabilities that are technologically revolutionary, that are collaborative or complimentary, and leverage other efforts. Additionally, a limited number of basic research proposals that apply to the topics below will be considered.

- a) Battle Management. Develop a capability to utilize CB sensor data throughout the battlespace and integrate with other relevant battlespace information and C4ISR systems to display and disseminate operationally meaningful information to support decision-making. Within the Battle Management technology area, solutions are sought that are of a revolutionary nature (high risk/high pay-off) and to guide the system user or suggest a course of action through an automated set of steps or procedures to respond to a CB event or incident management. Specific areas of interest include:
 - Develop the concept of information fusion. Information fusion includes CBRN detectors, hazard prediction and incident management. Information fusion should feed decision support applications that are premised on active guidance. The goal of the active guidance based capability would be to develop a tool that identifies patterns, trends and relationships that assist the warfare commander in development of a course of action in response to an impending threat.
 - The Joint Warning And Reporting Network (JWARN) program is building the JWARN Component Interface Device (JCID). With the JCID, the number of detectors that are capable of being networked will rise significantly in the coming years. Detectors will continue to be unit assets. The operational reality is that detectors will join and then leave networks as units move through areas. Develop a program to determine the impact to contamination avoidance, hazard prediction, local situational

awareness and local CB coverage. Ensure that it can function in an operational environment.

- The CBRN data model is an evolving standard being produced by the Joint Program Executive Office – Chemical/Biological Defense (JPEO-CBD). Propose exploitation efforts of the CBRN data model for the purposes of verification and validation of the schema against emerging CB programs.
 - Multiple runs of a hazard prediction model typically accomplish the current process of locating detectors on the battlefield. This process works fine in an analytical environment but is not operationally suited for field use. Propose a sensor placement model not predicated on artificial intelligence techniques nor repetitive model runs.
 - Detector data is tactically reported over networks using commercial wireless technology or tactical radios. The ability to move that data from the single channel domain in which it was transmitted to classified networks has not been seriously addressed. Propose an affordable method for moving sensor data to a classified network that can be certified in an operational environment.
 - Detector locations in fixed sites typically employ a node concept. A node is an integration point where multiple detectors can be plugged in for the purposes of economizing on force protection and power. Employing multiple detectors at a node means that the limited assets are pooled and thus leaves other areas uncovered or exposed. Propose a concept for deploying detectors that avoids the node concept, addresses force protection concerns, and extends the coverage of the fixed site.
 - JWARN Component Interface Device (JCID)-on-a-chip. Field Programmable Gate-Array that has most of the features/functionality of JCID software embedded into it and has an area that allows message sets (personalities/protocols) to be dynamically programmed/loaded. These could ultimately end up in Automated Chemical Agent Detector Alarms (ACADAs), etc. so that the sensors ultimately come off the shelf net ready and speaking the right data protocol/language.
 - Global medical early warning capability.
- b) Chemical/Biological Weapon Environment Prediction. Develop capabilities to model and simulate threats from CB Warfare agents released in the environment, across a range of scales from individual to theater, to provide realistic treatment of agent dissemination, downwind dispersion and deposition, and agent fate; combine data from various CB sensors, and combine data from sensors with dispersion models, to provide comprehensive analyses of the threat environment; and improve accuracy and speed of

dispersion models in all domains. These capabilities will be employed in the joint programs Joint Effects Model (JEM) and JWARN. Within the Environment technology area solutions are sought that are of a revolutionary nature (high risk/high pay-off) and not evolutionary in nature. Areas of potential interest include:

- Background data on fusion algorithms; develop good environmental background models that are realistically spatially and temporarily correlated (in order to test fusion algorithms). These models should differentiate between particle sizes, biological content, etc.
 - Develop methodologies by which CB sensor data can be fused with existing dispersion models, by which the validity of the sensor data can be assessed, and by which more accurate subsequent dispersion model calculations can be made.
 - Develop the capability to estimate the location, size, and time of chemical and biological agent releases in a variety of natural and man-made environments.
 - Develop improved dispersion model performance (accuracy and speed) in all atmospheric domains to include open terrain, forested areas, mountainous terrain, urban areas, building interiors, open ocean, coastal areas, and high levels (stratosphere and above).
 - Develop improved ability to incorporate environmental data (e.g., land cover data) and data from meteorological models (e.g., model-generated parameters, ensemble statistics, etc.) in dispersion models.
 - Develop improved capabilities to estimate the source characteristics of CB agents released from intercepted missiles.
 - Develop improved waterborne transport models.
- c) Chemical/Biological Effects on Operations.
- Develop ability to model CBRN effects on mobile forces.
 - Develop capability to integrate of CBRN effects into theatre/campaign models such as the Joint Integrated Campaign Model (JICM).
 - Investigate and develop MSB operational capabilities to enable warfighters to operate in new threat and operational environments.
 - Assess CB Defense within context of Network-Centric Force.

- Investigate and demonstrate applicability of innovative computer programming/software techniques to MSB applications. Techniques might include genetic algorithms, neural networks, intelligent agents, fuzzy logic, search bots and spiders, etc. (Techniques from other disciplines are also acceptable.)
- Demonstrate ways to exploit recent IT hardware innovations such as Personal Digital Assistants (PDAs) and wireless communication to address MSB requirements.
- Expand CB operational effects tools to integrate with MSB capabilities currently under development such as urban contamination, littoral hazard prediction, high-resolution concentration fluctuations, automated warning and reporting, etc.

In evaluating operational effects upon facilities, current capabilities consider people and processes external to buildings during a CB incident. Internal building flow models are in development to evaluate an internal chemical or biological agents release. Additionally, there is work in progress to model the infiltration from an external release into a building. While JEM has a requirement to model building releases, there is a need to streamline/facilitate the interfaces between JEM and Joint Operational Effects Federation (JOEF). The need exists to evaluate processes that are performed inside facilities and the effects of a CB incident upon those processes to the overall operational effectiveness of the site. Additionally, there exists the need to evaluate agent release from a contaminated building and its effects on surrounding operations.

d) Other Topics.

- Develop a CBRN interoperability assessment engine that would provide a mechanism to codify existing/evolving Data/CBRN interfaces of systems. Evaluate those against a given set of Common Operating Interfaces (COIs) to perform an assessment of interoperability at the software/data level. Use dynamic discovery to identify, categorize the interfaces/types against the model/schema, and then produce an analysis.
- Common CBRN Software Services - Develop a common framework of standard systems and application services that ultimately abstract out the evolving Net-Centric Enterprise Services (NCES) Application Program Interfaces (APIs) and provide a common toolkit that becomes required for CBRN data/software systems.
- Develop a correlation of Concepts of Operations (CONOPS) to different alarm states from the CB sensor network. Review comparable capabilities and how to either interface or work integrated efforts.

- Models to support medical-related efforts to include: Epidemiological model of Biological Warfare agents to extend JEM, and Bio-sensor/medical surveillance node placement tool.

3. Protection

The protection capability area requests applied research proposals for protective clothing, protective masks, air purification systems and shelter materials/systems that are technologically revolutionary, that are collaborative or complimentary, and leverage other efforts. Additionally, a limited number of basic research proposals that apply to the topics below will be considered.

- a) Clothing. The clothing thrust area seeks to provide percutaneous protection technology that will focus on the development of lightweight materials capable of providing enhanced protection against classic Chemical Warfare Agent (CWA), aerosol, and Toxic Industrial Chemicals/Materials (TIC/TIM) while reducing physiological (primarily thermal) stress. Technological applications under consideration include:
 - Technologies to reduce aerosol penetration of garments (e.g. nanofiber mats, high moisture vapor transport membranes, novel closures, etc.).
 - Intelligent materials (textiles, membranes, etc.) suitable for advanced, lightweight CB garments (e.g. membranes that open and close their pores in response to external stimuli).
 - Technologies that can sense and indicate the remaining service life of garments (uncontaminated by CB).
 - Materials for glove applications that enhance tactility, durability, and protection.

- b) Masks. The masks thrust area seeks to provide respiratory/ocular protection technology that will focus on air purification technologies, materials technologies capable of providing enhanced protection against classic Chemical Warfare Agents (CWA), low volatility agents, solid aerosols, and TIC/TIM while reducing respiratory burden of the protective mask in a logistically supportable manner. Technological applications under consideration include:
 - Technologies that reduce the breathing resistance and improve the protection of masks to include advanced adsorbents, novel sorbent structures, advanced particulate removal media, etc.
 - Concepts and technologies that reduce leakage into masks possibly in the form of novel seals or sealing systems, etc., and technologies for indicating mask leakage.

- Non-sorbent based technologies for removing chemical agent vapor and/or biological and chemical agent aerosols from air.
 - Sorbents for addressing a broader spectrum of CWAs, TICs, low volatility agents, and solid aerosols.
- c) Air Purification. The air purification thrust area seeks to provide collective protection technologies that will provide enhanced protection against classic CWA, low volatility agents, solid aerosols, and TIC/TIM while reducing the size, weight, and power requirements of the component or system. Technological approaches will include advanced vapor removal/destruction technologies, and advanced aerosol/particulate removal/destruction technologies. Technological applications under consideration include:
- Revolutionary design concepts and technologies for removal/destruction of CBRN, low volatility agents, solid aerosols, and TIC gases/vapors and aerosols/particulates from air to be supplied to toxic free areas under positive pressure. An important consideration for technology is that it is easily transported (small footprint, cube, weight) and operated (power and personnel).
 - Broad spectrum sorbents.
 - Technologies for CO, SO_x, and NO_x removal and integration within existing filters or as independent unit process with air purification system.
- d) Shelters. The shelters thrust area seeks to provide collective protection in the form of protective shelters or shelter systems that can provide and maintain a toxic free area. Thrust will focus on the development of materials such as; engineered permeable materials, impermeable materials, and material treatments capable of providing enhanced protection against classic CWA, low volatility agents, solid aerosols, and TIC/TIM. Supporting technologies will be investigated to advance structural components, and test methodology.
- Advanced textiles, seaming technology and materials used for protective enclosures to improve the protection provided as well as the manufacturability, durability, and weight of shelters.
 - Broad-spectrum, fast-acting, self-decontaminating surfaces, coatings and fabrics.
 - Novel closures technologies for enclosures on mobile, transportable and fixed site shelter platforms, and protective clothing—may include seaming, zippers, etc.
 - Revolutionary shelter design concepts and technologies for fast and simple conversion of existing structures to provide toxic free areas.

- Shelter concepts using easily transported and erected “molds” and widely available indigenous materials.
- Non-toxic strippable or permanent coatings for on-demand application to structures for sealing a room, building, or vehicle to provide positive pressurization and prevent the penetration of contaminants.
- Technologies for rapidly (within seconds) processing personnel from decontamination station into the toxic free area. These technologies will replace or modify existing airlock schemes in tent systems, shipboard CPS, and fixed site applications and significantly reduce the wait time in between stages. The use of these technologies will not replace or significantly modify decontamination processes.

4. Decontamination

The decontamination capability area is seeking innovative and alternative technology applied research. Additionally, a limited number of basic research proposals that apply to the topics below will be considered. Proposals are needed in the areas of:

- Liquid phase (solution) decontamination for sensitive equipment and vehicle interiors.
- Solid phase reactive materials for use as sorbent beds to clean up mixed aqueous/organic solvent.

Materials and technologies that will not create a significant health hazard or environmental hazard are greatly preferred. Systems or formulations should meet, approach, or have as a goal the ability to remove or neutralize greater than (>) 99.9% of toxic material and/or sieve or remove 0.1 to 10 micrometer particles for infective agents and other biological agents or materials and ensure rapid, effective force reconstitution. Specific threshold and objective standards for decontamination are in the following table. Decontamination systems or formulations should be operationally effective through the temperature range of -32°C to +49°C and stable in storage from -46°C to +71°C (with at least 120-day stability under storage and warehousing temperatures).

Decontamination Standards	
Thresholds	Objectives
<p>1. Equipment Decontamination Efficacy</p> <p>Vapor Levels (mg/m³) from a Starting Liquid Challenge of 1g/m² for interior surfaces and 10g/m² for exterior surfaces.</p> <ul style="list-style-type: none"> - Nerve-G <0.00087 - Nerve-V <0.000036 - Blister-H <0.0058 <p>Contact Exposure Levels, mg/m² from a Starting Liquid Challenge of 1g/m²</p> <ul style="list-style-type: none"> - Nerve-G <1.7 - Nerve-V <0.04 - Blister-H <3.0 <p>Residual Levels of Representative Biological Agents from Starting Challenges of Greater Than 1.0x10⁸ Colony Forming Units (CFU)/Plaque Forming Units (PFU)/m²</p> <ul style="list-style-type: none"> - Bacterial endospores <100 CFU/m² - Vegetative bacteria <10 CFU/m² -Viruses <10 PFU/m² [T-I] 	<p>Vapor Levels (mg/m³) from a Starting Liquid Challenge of 1g/m²</p> <ul style="list-style-type: none"> - Nerve-G <0.0002 - Nerve-V <0.000024 - Blister-H <0.003 <p>Contact Exposure Levels, mg/m² from a Starting Liquid Challenge of 1g/m²</p> <ul style="list-style-type: none"> - Nerve-G 0.0 - Nerve-V 0.00 - Blister-H 0.0 <p>Residual Levels of Representative Biological Agents from Starting Challenges of Greater Than 1.0x10⁸ CFU/PFU/m²</p> <ul style="list-style-type: none"> - Bacterial endospores - 0 CFU/m² - Vegetative bacteria - 0 CFU/m² - Viruses - 0 PFU/m² [O-I] [T-II]
<p>2. Personnel Decontamination Efficacy</p>	<ul style="list-style-type: none"> - Decontaminate warfare agents HD, Soman (GD), VX and T-2 mycotoxins on skin to a level that eliminates toxic effects better than the M291 SDK [T-I]. - Decontaminate warfare agents; all other V, G, and H-series, L, Dusty H, Dusty Nerve, low volatility agents, selected TICs, anthrax spores and other biological warfare agents of operational concern on skin to a level that eliminates toxic effects better than the M291 SDK [O-I] [T-II].

Specific focus areas for the decontamination area are:

- a) Liquid phase decontaminants for sensitive equipment, interiors of vehicles, and exteriors of aircraft – The decontaminants for this focal area should be effective against the chemical and biological warfare agents, but also be compatible with sensitive surfaces including electronics. Aqueous-based solutions for the exteriors of aircraft are acceptable for consideration but are not acceptable for interiors and electronic equipment.
- b) Solid phase sorbents have traditionally had problems because of their associated environmental restoration need after use. For interiors, the need to remove the used particulate has been an issue. This BAA is looking for sorbent concepts that can be either readily removed after use or do not present a dirty particulate problem.

III. INFORMATION FOR OFFERORS

The solicitation is specifically for experimental and theoretical development of technologies for chemical and biological defense as described in Section II.B. Potential offerors are advised to read this announcement carefully. It explains the agencies' research needs upon which the topic is based and the terms and conditions of the solicitation.

A. Award Information

Through this solicitation the DoD CDBP and the Army Research Office (ARO) expect to make several awards for one- to four-year performance periods, subject to the availability of appropriations. Awards may be made as contracts or grants. Single-year, stand-alone proposals are encouraged; multi-year proposals will be considered, but funding will not be guaranteed for subsequent years. Therefore, multi-year proposals must have clear goals and milestones for each year.

Up to \$15 million per year is anticipated to be available under this solicitation. It is anticipated that funding for each award will be between \$100K and \$2M.

B. Eligibility

Proposals may be submitted by degree-granting universities, nonprofit organizations, or industrial concerns. Proposals are encouraged from Historically Black Colleges and Universities (as determined by the Secretary of Education to meet requirements of Title III of the Higher Education Act of 1965, as amended (20 U.S.C. § 1061)) and from Minority Institutions defined as institutions “whose enrollment of a single minority or a combination of minorities...exceeds 50 percent of the total enrollment.” [20 U.S.C. § 1067k(3) and 10 U.S.C. § 2323(a)(1)(C)]. The U.S. Department of Education list of Accredited Postsecondary Minority Institutions is available at <http://www.ed.gov/about/offices/list/ocr/edlite-minorityinst-as-vi.html>.

Federal laboratories, Federally Funded Research and Development Centers, and academic institutions that are federal government organizations (e.g., Naval Postgraduate School) may participate, but they cannot receive funds awarded through this solicitation. Instead, they are encouraged to contact the technical point of contact listed in Section III.D.

C. Military Recruiting

This is to notify potential offerors that each grant awarded under this announcement to an institution of higher education shall include the following term and condition:

“As a condition for receipt of funds available to the Department of Defense, DoD, under this award, the recipient agrees that it is not an institution of higher education (as defined in 32 Code of Federal Regulations (CFR) Part 216) that has a policy of denying, and that it is not an institution of higher education that effectively prevents, the Secretary of Defense from obtaining for military recruiting purposes: (A) entry to campuses or access to students on campuses; or (B) access to directory information pertaining to students. If the recipient is determined, using procedures in 32 CFR Part 216 to be such an institution of higher education during the period of performance of this agreement, and therefore to be in breach of this clause, the Government will cease all payments of DoD funds under this agreement and all other DoD grants and cooperative agreements, and it may suspend or terminate such grants and agreements unilaterally for material failure to comply with

the terms and conditions of award.” (32 CFR Part 216 may be accessed electronically at <http://www.gpoaccess.gov/cfr/index.html>.)

If your institution has been identified under the procedures established by the Secretary of Defense to implement Section 558 of Public Law 103-337, then: (1) no funds available to DoD may be provided to your institution through any grant, including any existing grant; (2) as a matter of policy, this restriction also applies to any cooperative agreement; and (3) your institution is not eligible to receive a grant or cooperative agreement in response to this solicitation.

This is to notify potential offerors that each contract awarded under this announcement to an institution of higher education shall include the clause: Defense Federal Acquisition Regulation Supplement (DFARS) 252.209-7005, Reserve Officer Training Corps and Military Recruiting on Campus.

D. Points of Contact

Technical point of contact for this BAA is Dr. Stephen J. Lee, Chemical Sciences Division, (919) 549-4365, email: stephen.lee2@us.army.mil. Questions regarding the administrative content of this BAA may be addressed to ARO at (919) 549-4375.

E. Department of Defense (DoD) Central Contractor Registration (CCR)

Prospective contractors/grantees must be registered in the DoD CCR database prior to award of an agreement. By submission of an offer resulting from this BAA, the offeror acknowledges the requirement that a prospective contractor/grantee must be registered in the CCR database prior to award, during performance, and through final payment of any agreement resulting from this BAA. The CCR may be accessed at <http://www.ccr.gov/>. Assistance with registration is available by phone at 1-888-227-2423.

F. Reporting Requirements

Reporting requirements for contracts and grants awarded under this BAA will be as described in ARO Form 18 located at <http://www.aro.army.mil/forms/forms2.htm>. Additional reports will be specified in the award document.

IV. APPLICATION AND SUBMISSION INFORMATION

A. Application and Submission Process

This solicitation will be conducted in two stages as follows:

Stage I – Interested offerors are required to submit white papers in accordance with instructions provided in Section IV.B. of this BAA. White papers will be evaluated against criteria in Section V.A. of this BAA. Based on this evaluation, selected offerors will be invited to submit full proposals for evaluation under Stage II.

Stage II – Selected offerors invited to submit full proposals under Stage I will submit proposals in accordance with the instructions provided in Section IV.C. of this BAA. Full proposals will be evaluated against criteria in Section V.B. of this BAA.

B. Stage I - White Paper Submission and Content

Interested offerors are required to submit a white paper consisting of a quad chart and a 2-page narrative to expand on the quad chart.

The white paper must be received by 4:00 PM Eastern Standard Time, January 31, 2005. The white paper must be transmitted electronically to the following address: whitepapers@arl.army.mil. The e-mail subject line should contain the following: W911NF-05-R-0003 White Paper.

Each submission (quad chart and narrative) must specify a single topic area and issues for consideration by identifying at the end of the project title the specific paragraph referenced in Section II.B. of this BAA (for example, II.B.1.c). See quad chart format and narrative guidelines below.

Quad Chart Format:

	<p>Title of Project, Submitting Principal Investigator, Organization</p>
<p>Objective: Clear, concise (1-2 sentence) description of the goal of the effort (Arial 12 point)</p> <p>Description of Effort: Brief description of the technology proposed for investigation and methodologies to be used during the course of investigation (Arial 12 pt)</p>	<p>Picture or graphic that illustrates the technology or concept</p>
<p>Benefit to warfighter: Brief statement of capability enhancement resulting from successful completion with respect to the Physical S&T Goals (Arial 12 pt)</p> <p>Challenges: A bullet list of the technical or scientific challenges being addressed (Arial 12 pt)</p> <p>Maturity of Technology: Describe the maturity of the proposed technology with respect to the Technical Readiness Level (TRL) *(Arial 12 pt)</p> <p>Capability Area: Detection, Modeling&Simulation/ Battlespace, Protection, or Decontamination</p>	<p>Major goals/milestones by fiscal year: •Bullet list (Arial 12 pt)</p> <p>Proposed Funding (\$K):</p> <p style="text-align: center;"><u>FY06</u> <u>FY07</u> <u>FY08</u> <u>FY09</u></p> <p>PI contact info: Dr. Marge N. Overra, (123) 123-1234, Marge.N.Overra@innovationsrus.com</p>

*See Attachment 1 to this BAA for Technology Readiness Levels (TRLs) for Chemical Biological Defense Programs.

The narrative expanding on the quad chart shall not exceed two pages, 8.5 x 11 inches, single-spaced, with one-inch margins in type not smaller than 12 points. The project title with topic paragraph referenced in Section II.B. must be included at the top of the page. The content of the narrative must be limited only to further explanation, as deemed necessary by the offeror, of the information being conveyed as requested in the quad chart. Do NOT include corporate or personnel qualifications, past experience, or any supplemental information not requested in the Quad Chart.

Feedback on the white papers and invitations to submit full proposals for selected white papers will be e-mailed directly to the proposed Principal Investigators not later than 4 March 2005.

C. Stage II - Full Proposal Submission and Content

1. Proposal Submission

Proposals will be accepted only from invited offerors. Proposals must be submitted electronically and must contain all information specified in Proposal Content below. The electronic proposal must be received at the Army Research Office by 4:00 PM Eastern Daylight Saving Time on April 18, 2005.

Proposals must be submitted in a single PDF formatted file and transmitted to the following address: baa@aro.arl.army.mil. The e-mail subject line should contain the following: W911NF-05-R-0003 (Principal Investigator's Last Name).

The proposal must contain three electronic forms: (1) ARO Form 51 (Proposal Cover Page); (2) ARO Form 99 (Summary Proposal Budget); and (3) ARO Current and Pending Support (unnumbered form). See Proposal Content below. These forms may be accessed electronically at <http://www.aro.army.mil/forms/forms2.htm>. The fillable PDF forms may be saved to a working directory on your computer and opened and filled in using the Adobe Acrobat software application. **The fillable Proposal Cover Page (ARO Form 51) should be printed, signed, and scanned into a PDF file with the proposal.**

If you have questions concerning electronic proposal submission, please contact the Army Research Office at (919) 549-4219. Proposals submitted by mail, facsimile, or hand-delivered will not be accepted.

Proposals received after the deadline will be handled in accordance with the provisions detailed in Section IV.E. of this BAA.

Acknowledgment of receipt of a proposal under this solicitation will be accomplished via e-mail to the addressee submitting the proposal.

2. Proposal Content

The full proposal should be broken down into two volumes, Volume I – Technical Proposal and Volume 2 – Cost Proposal.

Volume I - Technical Proposal. The technical proposal shall not exceed 25 pages. A page is defined as 8 ½ x 11 inches, single-spaced, with one-inch margins, and type not smaller than 12 points. The technical proposal must include the following components:

- a) Cover page. To be eligible for review, proposals must have a completed and signed ARO Form 51 as a cover page (See Section IV.C.1. of this BAA). The project title (Block 20) must be the same title used in the white paper submission and must reference the technical area being addressed in the effort by identifying the specific paragraph from Section II.B. (For example, II.B.1.c). In Block 2 on the Proposal Cover Page, check “Chemistry. In Block 19 on the Proposal Cover Page, check “Other” and specify “CBDP.”
- b) Summary page with the proposal title, the principal investigator(s), institution affiliation and a brief summary/abstract of the proposal (1 page).
- c) Objective, background and significance. A description of the objective, significance and applicability of the proposed research, appropriate scientific background, and a concise description of the advantages gained from the proposed technology (not to exceed 6 pages).
- d) Work to be performed. A detailed list that describes major tasks and supporting subtasks, expected results of each major task, and how the task will be accomplished (not to exceed 8 pages).
- e) Proposed schedule, milestones, and deliverables – technical and financial reports, data, hardware, software and documentation, as applicable (not to exceed 2 pages).
- f) Summary of qualifications of key personnel (not to exceed 1 page per person).
- g) Describe the facilities available for accomplishment of research objective. Describe the equipment planned for acquisition under this program and its application to the objective. When possible, equipment should be purchased very early in the research award period.
- h) Statement of Current and Pending Support. A statement of current and pending support must be included for each investigator listed in the proposal. Use the ARO Current and Pending Support form to submit this information (See Section IV.C.1. of this BAA). This statement requires that each

investigator specify all grants and contracts through which he or she is currently receiving or may potentially receive financial support.

NOTE: Failure to provide the requested information or exceed page limits may render the proposal non-responsive, and the proposal may not be evaluated.

Volume II – Cost Proposal.

The financial portion of the proposal should contain cost estimates sufficiently detailed for meaningful evaluation. Use ARO Form 99, Summary Proposal Budget, to submit budget data (See Section IV.C.1. of this BAA.). For budget purposes, use an award start date of November 1, 2005. The budget must include the total cost of the project, as well as a breakdown of the amount(s) by source(s) of funding (e.g., funds requested under this BAA, non-federal funds to be provided as cost sharing). The cost proposal is not considered part of the page count; there is no page limit for the cost proposal.

Budgeted cost elements should reflect the following:

- a) Time being charged to the project, for whom (principal investigator, graduate students, etc.), and the commensurate salaries and benefits. Allowable charges for graduate students include salary, appropriate research costs, and tuition. Allowable charges for undergraduate students include salary and research training costs, but not tuition.
- b) Cost of equipment, based on most recent quotations and broken down in sufficient detail for evaluation.
- c) Travel costs and time, and the relevance to stated objectives.
- d) Estimate of material and operating costs.
- e) Publication and report costs.
- f) Consultant fees (indicating daily or hourly rate) and travel expenses and the nature and relevance of such costs.
- g) Computer services.
- h) Sub-award costs and type (the portion of work to be sub-awarded and rationale). Include detailed cost summary.
- i) Communications costs not included in overhead.
- j) Other direct costs.

- k) Indirect costs.
- l) Fee, if any, which an industrial/commercial organization proposes.
- m) Facilities Capital Cost of Money: When an offeror elects to claim facilities capital cost of money as an allowable cost, the offeror should submit Form CASB-CMF and show the calculation of the proposed amount. (See FAR 31.205-10.)

NOTE: Failure to provide the requested information may render the proposal non-responsive, and the proposal may not be evaluated.

D. Marking of White Paper and Proposal and Disclosure of Proprietary Information outside the Government

1. The white paper/proposal submitted in response to this solicitation may contain technical and other data that the offeror does not want disclosed to the public or used by the Government for any purpose other than proposal evaluation. Public release of information in any white paper/proposal submitted will be subject to existing statutory and regulatory requirements. If proprietary information which constitutes a trade secret, proprietary commercial or financial information, confidential personal information, or data affecting the national security, is provided by an offeror in a white paper/proposal, it will be treated in confidence, to the extent permitted by law, provided that the following legend appears and is completed on the front of the white paper/proposal: “For any purpose other than to evaluate the white paper/proposal, this data shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed in whole or in part, provided that if an award is made to the offeror as a result of or in connection with the submission of this data, the Government shall have the right to duplicate, use or disclose the data to the extent provided in the agreement. This restriction does not limit the right of the Government to use information contained in the data if it is obtained from another source without restriction. The data subject to this restriction is contained in page(s) _____ of this white paper/proposal.” Any other legend may be unacceptable to the Government and may constitute grounds for removing the proposal from further consideration without assuming any liability for inadvertent disclosure. The Government will limit dissemination of properly marked information to within official channels. In addition, the pages indicated as restricted must be marked with the following legend: “Use or disclosure of the white paper/proposal data on lines specifically identified by asterisk (*) are subject to the restriction on the front page of this white paper/proposal.” The Government assumes no liability for disclosure or use of unmarked data and may use or disclose such data for any purpose.
2. In the event that properly marked data contained in a white paper/proposal submitted in response to this BAA is requested pursuant to the Freedom of Information Act, 5 USC 552, the offeror will be advised of such request and, prior to such release of information, will be requested to expeditiously submit to ARO a detailed listing of all

information in the white paper/proposal which the offeror believes to be exempt from disclosure under the Act. Such action and cooperation on the part of the offeror will ensure that any information released by ARO pursuant to the Act is properly determined.

3. By submission of a white paper/proposal, the offeror understands that proprietary information may be disclosed outside the Government for the sole purpose of technical evaluation. The ARO/RDECOM Acquisition Center will obtain a written agreement from the evaluator that proprietary information in the white paper/proposal will only be used for evaluation purposes and will not be further disclosed or utilized.

E. Late Submissions and Withdrawal of Proposals

1. Offerors are responsible for submitting electronic proposals so as to reach the Government office designated in this BAA by the time specified in this BAA.
2. If the electronic proposal is received at the Government office designated in this BAA after the exact time and date specified for receipt of offers, it is "late" and will not be considered.
3. Acceptable evidence to establish the time of receipt at the Government office includes documentary evidence of receipt maintained by the installation.
4. If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation closing date, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.
5. Proposals may be withdrawn by written notice received at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

V. EVALUATION CRITERIA AND SELECTION PROCESS

The white paper and proposal selection process will be conducted based upon a technical peer review as described in Federal Acquisition Regulation Subparts 6.102(d)(2) and 35.016 and DOD Grant and Agreement Regulations (DOD 3210.6-R (DODGARS), Section 22.315. All information necessary for the review and evaluation of the white paper and proposal must be contained in the White Paper and Full Proposal submissions as described in Sections IV.B. and IV.C. of this BAA. The evaluation criteria to be used to evaluate and select white papers and proposals are listed below:

A. White Paper (Stage I). The evaluation will be based on the following criteria, all of equal weight.

- a) Overall scientific and technical merits of the proposed research.
- b) Benefit over current technology
- c) Affordability
- d) Schedule realism

B. Full Proposal (Stage II). The evaluation will be based primarily on the following criteria, both of equal weight:

- a) Overall scientific and technical merits of the proposed research.
- b) Potential contributions of the research to the chemical and biological defense mission.

Other evaluation criteria, of lesser importance, but weighted equal to each other are:

- c) Offeror's capabilities, related experience, facilities, techniques, or unique combinations of these factors that support achieving the proposed objectives.
- d) Qualifications, capabilities, and experience of the proposed principal investigator, team leader or other key personnel who are critical in achieving proposed objectives.
- e) Offeror's record of past projects to include assessment of duplication with already completed or ongoing work.
- f) Realism and reasonableness of the proposed cost.

VI. NOTIFICATION TO OFFERORS

Notification of acceptance of full proposals will be mailed or e-mailed by ARO on or about October 3, 2005. Unsuccessful offerors will be notified shortly thereafter.

VII. INFORMATION TO BE REQUESTED FROM SUCCESSFUL OFFERORS

Offerors whose proposals are accepted for funding will be contacted before award to provide additional information required for award. This may include representations and certifications, revised budgets or budget explanations, certificate of current cost or pricing data, subcontracting plan for small businesses, and other information as applicable to the proposed award.

VIII. CERTIFICATIONS REQUIRED FOR GRANT AWARDS

A. Certification at Appendix A to 32 CFR Part 28 Regarding Lobbying

By signing and submitting a proposal that may result in the award of a grant exceeding \$100,000, the prospective awardee is certifying, to the best of his or her knowledge and belief, that:

(a) No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

(b) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit Standard Form-LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions.

(c) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.

B. Certification at Appendix A to 32 CFR Part 25 Regarding Debarment, Suspension, and Other Responsibility Matters --Primary Covered Transactions

(1) By signing and submitting this proposal, the prospective primary participant is providing the certification set out below.

(2) The inability of a person to provide the certification required below will not necessarily result in denial of participation in this covered transaction. The prospective participant shall submit an explanation of why it cannot provide the certification set out below. The certification or explanation will be considered in connection with the department or agency's determination whether to enter into this transaction. However,

failure of the prospective primary participant to furnish a certification or an explanation shall disqualify such person from participation in this transaction.

(3) The certification in this clause is a material representation of fact upon which reliance was placed when the department or agency determined to enter into this transaction. If it is later determined that the prospective primary participant knowingly rendered an erroneous certification, in addition to other remedies available to the Federal Government, the department or agency may terminate this transaction for cause or default.

(4) The prospective primary participant shall provide immediate written notice to the department or agency to which this proposal is submitted if at any time the prospective primary participant learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.

(5) The terms "covered transaction," "debarred," "suspended," "ineligible," "lower tier covered transaction," "participant," "person," "primary covered transaction," "principal," "proposal," and "voluntarily excluded," as used in this clause, have the meanings set out in the Definitions and Coverage sections of the rules implementing Executive order 12549. You may contact the department or agency to which this proposal is being submitted for assistance in obtaining a copy of those regulations.

(6) The prospective primary participant agrees by submitting this proposal that, should the proposed covered transaction be entered into, it shall not knowingly enter into any lower tier covered transaction with a person who is proposed for debarment under 48 CFR part 9, subpart 9.4, debarred, suspended, declared ineligible, or voluntarily excluded from participation in this covered transaction, unless authorized by the department or agency entering into this transaction.

(7) The prospective primary participant further agrees by submitting this proposal that it will include the clause titled "Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion--Lower Tier Covered Transaction," provided by the department or agency entering into this covered transaction, without modification, in all lower tier covered transactions and in all solicitations for lower tier covered transactions.

(8) A participant in a covered transaction may rely upon a certification of a prospective participant in a lower tier covered transaction that it is not proposed for debarment under 48 CFR part 9, subpart 9.4, debarred, suspended, ineligible, or voluntarily excluded from the covered transaction, unless it knows that the certification is erroneous. A participant may decide the method and frequency by which it determines the eligibility of its principals. Each participant may, but is not required to, check the List of Parties excluded from Federal Procurement and Nonprocurement Programs.

(9) Nothing contained in the foregoing shall be construed to require establishment of a system or records in order to render in good faith the certification required by this clause.

The knowledge and information of a participant is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

(10) Except for transactions authorized under paragraph 6 of these instructions, if a participant in a covered transaction knowingly enters into a lower tier covered transaction with a person who is proposed for debarment under 48 CFR part 9, subpart 9.4, suspended, debarred, ineligible, or voluntarily excluded from participation in this transaction, in addition to other remedies available to the Federal Government, the department or agency may terminate this transaction for cause or default.

Certification Regarding Debarment, Suspension, and Other Responsibility Matters--Primary Covered Transactions

The prospective primary participant certifies to the best of its knowledge and belief, that it and its principals:

(a) Are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded by any Federal department or agency;

(b) Have not within a three-year period preceding this proposal 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) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;

(c) Are not presently indicted for or otherwise criminally or civilly charged by a government entity (Federal, State or local) with commission of any of the offenses enumerated in paragraph (1)(b) of this certification; and

(d) Have not within a three-year period preceding this application/proposal had one or more public transactions (Federal, State or local) terminated for cause or default.

Where the prospective primary participant is unable to certify to any of the statements in this certification such prospective participant shall attach an explanation to this proposal.

C. Certification at Appendix C to 32 CFR Part 25 Regarding Drug-Free Workplace Requirements

(1) By signing and/or submitting this application or grant agreement, the grantee is providing the certification set out below.

(2) The certification set out below is a material representation of fact upon which reliance is placed when the agency awards the grant. If it is later determined that the grantee knowingly rendered a false certification, or otherwise violates the requirements of the Drug-Free Workplace Act, the agency, in addition to any other remedies available to

the Federal Government, may take action authorized under the Drug-Free Workplace Act.

(3) For grantees other than individuals, Alternate I applies.

(4) For grantees who are individuals, Alternate II applies.

(5) Workplaces under grants, for grantees other than individuals, need not be identified on the certification. If known, they may be identified in the grant application. If the grantee does not identify the workplaces at the time of application, or upon award, if there is no application, the grantee must keep the identity of the workplace(s) on file in its office and make the information available for Federal inspection. Failure to identify all known workplaces constitutes a violation of the grantee's drug-free workplace requirements.

(6) Workplace identifications must include the actual address of buildings (or parts of buildings) or other sites where work under the grant takes place. Categorical descriptions may be used (e.g., all vehicles of a mass transit authority or State highway department while in operation, State employees in each local unemployment office, performers in concert halls or radio studios).

(7) If the workplace identified to the agency changes during the performance of the grant, the grantee shall inform the agency of the change(s), if it previously identified the workplaces in question (see paragraph five).

(8) Definitions of terms in the Nonprocurement Suspension and Debarment common rule and Drug-Free Workplace common rule apply to this certification. Grantees' attention is called, in particular, to the following definitions from these rules;

Controlled substance means a controlled substance in schedules I through V of the Controlled Substances Act (21 U.S.C. 812), and as further defined by regulation (21 CFR 1308.11 through 1308.15);

Conviction means a finding of guilt (including a plea of nolo contendere) or imposition of sentence, or both, by any judicial body charged with the responsibility to determine violations of the Federal or State criminal drug statutes;

Criminal drug statute means a Federal or non-Federal criminal statute involving the manufacture, distribution, dispensing, use, or possession of any controlled substance;

Employee means the employee of a grantee directly engaged in the performance of work under a grant, including: (i) All "direct charge" employees; (ii) all "indirect charge" employees unless their impact or involvement is insignificant to the performance of the grant; and, (iii) temporary personnel and consultants who are directly engaged in the performance of work under the grant and who are on the grantee's payroll. This definition does not include workers not on the payroll of the grantee (e.g., volunteers,

even if used to meet a matching requirement; consultants or independent contractors not on the grantee's payroll; or employees of subrecipients or subcontractors in covered workplaces).

Certification Regarding Drug-Free Workplace Requirements
(Alternate I - Grantees Other Than Individuals)

The grantee certifies that it will or will continue to provide a drug-free workplace by:

(a) Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance is prohibited in the grantee's workplace and specifying the actions that will be taken against employees for violation of such prohibition;

(b) Establishing an ongoing drug-free awareness program to inform employees about--

(1) The dangers of drug abuse in the workplace;

(2) The grantee's policy of maintaining a drug-free workplace;

(3) Any available drug counseling, rehabilitation, and employee assistance programs; and

(4) The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace.

(c) Making it a requirement that each employee to be engaged in the performance of the grant be given a copy of the statement required by paragraph (a);

(d) Notifying the employee in the statement required by paragraph (a) that, as a condition of employment under the grant, the employee will--

(1) Abide by the terms of the statement; and

(2) Notify the employer in writing of his or her conviction for a violation of a criminal drug statute occurring in the workplace no later than five calendar days after such conviction;

(e) Notifying the agency in writing, within ten calendar days after receiving notice under paragraph (d)(2) from an employee or otherwise receiving actual notice of such conviction. Employers of convicted employees must provide notice, including position title, to every grants officer or other designee on whose grant activity the convicted employee was working, unless the Federal agency has designated a central point for the receipt of such notices. Notice shall include the identification number(s) of each affected grant;

(f) Taking one of the following actions, within 30 calendar days of receiving notice under paragraph (d)(2), with respect to any employee who is so convicted--

(1) Taking appropriate personnel action against such employee, up to and including termination, consistent with the requirements of the Rehabilitation Act of 1973, as amended; or

(2) Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;

(g) Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (a), (b), (c), (d), (e) and (f).

The grantee may insert in the space provided below the site(s) for the performance of work done in connection with the specific grant:

Place of Performance (Street address, city, county, state, zip code)

Check if there are workplaces on file that are not identified here.

(Alternate II - Grantees Who Are Individuals)

(a) The grantee certifies that, as a condition of the grant, he or she will not engage in the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance in conducting any activity with the grant;

(b) If convicted of a criminal drug offense resulting from a violation occurring during the conduct of any grant activity, he or she will report the conviction, in writing within 10 calendar days of the conviction, to every grants officer or other designee, unless the Federal agency designates a central point for the receipt of such notices. When notice is made to such a central point, it shall include the identification number(s) of each affected grant.

ATTACHMENT 1

Technology Readiness Levels (TRLs) for Chemical Biological Defense Programs

Introduction

Technology Readiness Levels (TRLs) are a systematic metric/measurement system that supports assessments of the maturity of a particular technology and the consistent comparison of maturity between different types of technology. TRLs were originally developed and used by the National Aeronautics and Space Administration for technology planning. The use of TRLs has been widely adopted in government and industry. The Department of Defense (DoD) has adopted the use of TRLs, as documented in the current DoD-5000 series publications. Table 1 provides a description of TRLs for hardware (HW) and software (SW) and notional TRL definitions for medical systems.

TRL level	Description
TRL 1	<p>Basic principles observed and reported.</p> <p>HW: Lowest level of technology readiness. Scientific research begins. Examples might include paper studies of a technology's basic properties.</p> <p>SW: Lowest level of software readiness. Basic research begins to be translated into applied research and development. Examples might include a concept that can be implemented in software or analytic studies of an algorithm's basic properties.</p> <p>Medical: Scientific Literature reviewed. Initial Markey Surveys initiated and assessed. Potential scientific application defined.</p>
TRL 2	<p>Technology concept and/or application formulated.</p> <p>HW/SW: Once basic principles are observed, practical applications can be invented. Applications are speculative and there is no proof or detailed analysis to support the assumptions. Examples are limited.</p> <p>Medical: Hypothesis generated. Research plans and protocols developed, peer reviewed, and approved.</p>
TRL 3	<p>Analytical and experimental critical function and/or characteristic proof-of-concept.</p> <p>HW: This includes analytical studies and laboratory studies to physically validate analytical predictions of separate elements of the technology. Examples include components that are not yet integrated into a system.</p> <p>SW: Active research and development is initiated. This includes analytical studies to produce code that validate analytical predictions of</p>

separate software elements. Examples include software components that are not yet integrated or representative but satisfy an operational need. Algorithms run on a surrogate processor in a laboratory.

Medical: Initial proof of concept is demonstrated in a limited number of in vitro and in vivo research models or other lab models. Conduct preliminary characterization of protective antigens. Develop model vaccines. Small scale safety and efficacy trials in small animal model.

EXIT – Initial proof of concept demonstrated in limited research models.

TRL 4

Component and/or breadboard validation in laboratory environment.

HW: Basic technological components are integrated to establish that they will work together. This is relatively “low fidelity” compared to the eventual system. Examples include integration of “ad hoc” hardware in the laboratory.

SW: Basic software components are integrated to establish that they will work together. They are relatively primitive with regard to efficiency and reliability compared to the eventual system. System software architecture development initiated to include interoperability, reliability, maintainability, extensibility, scalability, and security issues. Software integrated with simulated current/legacy elements as appropriate.

Medical: Proof of concept demonstrated for constructs or devices and animal models defined. Initial device master record completed. Complete laboratory research to refine hypothesis and identify data. Develop process for manufacture bench scale quantities. Formulate model vaccines to generic requirements. Develop assays for potency and identity. Conduct small animal safety, immunogenicity and efficacy studies to support down-select.

EXIT – Proof of concept demonstrated for candidate vaccine/animal model(s)/devices.

TRL 5

Component and/or bread board validation in relevant environment.

HW: Fidelity of breadboard technology increases significantly. The basic technological components are integrated with reasonably realistic supporting elements so that they can be tested in a simulated environment. Examples include “high fidelity” laboratory integration of components.

SW: Reliability of software ensemble increases significantly. The basic software components are integrated with reasonably realistic supporting elements so that they can be tested in a simulated environment. Examples include “high fidelity” laboratory integration of software components. System software architecture established. Algorithms run on a processor(s) with characteristics expected in the operational environment.

Software releases are ‘Alpha’ versions and configuration control initiated. Verification, Validation, and Accreditation (VV&A) initiated.

Medical: Sufficient data exists to justify preparation of Technical Data Package and development of Investigational New Drug (IND) application. Conduct “Good Laboratory Practice” (GLP) safety and toxicity studies in animal model systems. Produce non-GMP Pilot lots. Demonstrate surrogate marker of efficacy in appropriate animal model. Conduct expanded animal safety, immunogenicity, and efficacy studies in non-human primates. Investigations Device Exemptions submitted to, and review by, Center for Devices and Radiological Health, Food, and Drug Administration (FDA) to determine if clinical trials may proceed.

EXIT – IND submitted to and reviewed by FDA.

TRL 6

System/subsystem model or prototype demonstration in a relevant environment.

HW: Representative model or prototype system, which is well beyond that of TRL 5, is tested in a relevant environment. Represents a major step up in technology’s demonstrated readiness. Examples include testing a prototype in a high fidelity laboratory environment or in a simulated operational environment.

SW: Representative model or prototype system, which is well beyond that of TRL 5, is tested in a relevant environment. Represents a major step up in software demonstrated readiness. Examples include testing a prototype in a live/virtual experiment or in a simulated operation environment. Algorithm run on processor or operational environment integrated with actual external entities. Software releases are ‘Beta’ versions and configuration controlled. Software support structure in development. Verification, Validation, and Accreditation in process.

Medical: Conduct phase 1 clinical trials to demonstrate safety and immunogenicity. Phase 1 clinical trials meet clinical safety requirements and support proceeding to Phase 2 clinical studies. Manufacture cGMP Pilot Lots. Validate assays for potency and identity.

EXIT – Phase 1 trial complete. Supplement to IND for Phase 2 trial.

TRL 7

Systems prototype demonstration in an operational environment.

HW: Prototype near, or at, planned operation system. Represents a major step up from TRL 6, requiring demonstration of an actual system prototype in an operational environment. Examples include testing the prototype in a test bed.

SW: Represents a major step up from TRL 6, requiring the demonstration of an actual system prototype in an operational environment. Algorithms run on processor of the operational environment integrated with actual external entities. Software support structure in place. Software releases

are in distinct versions. Frequency and severity of software deficiency reports do not significantly degrade functionality or performance. VV&A completed.

Medical: Product immunogenicity and biological activity determined. Conduct Phase 2a clinical trials for dosing and scheduling. Validate efficacy through surrogate models. Conduct production readiness review.

EXIT – Phase 2 trials complete. Supplement to IND for Phase 3.

TRL 8

Actual system completed and “qualified” through test and demonstration.

HW: Technology has been proven to work in its final form and under expected conditions. In most all cases, TRL represents the end of true system development. Examples include developmental test and evaluation of the system in its intended system to determine if it meets design specifications.

SW: Software has been demonstrated to work in its final form and under expected conditions. In most cases, this TRL represents the end of system development. Examples include test and evaluation of the software in its intended system to determine if it meets design specifications. Software releases are production versions and configuration controlled, in a secure environment. Software deficiencies are rapidly resolved through support structure.

Medical: Phase 3 clinical trials or surrogate tests. Manufacture consistency lots. Perform lot release testing. Conduct large scale safety trials.

EXIT – Complete BLA submission for licensure.

TRL 9

Actual system proven through successful mission operations.

HW: Actual application of the technology in its final form and under mission conditions, such as those encountered in operational test and evaluation. In almost all cases, this is the end of the last “bug fixing” aspects of system development. Examples include using the system under operational mission conditions.

SW: Actual application of the software in its final form and under mission conditions, such as those encountered in operational test and evaluation. In almost all cases, this is the end of the last “bug fixing” aspects of system development. Examples include using the system under operational mission conditions. Software releases are production versions and configuration controlled. Frequency and severity of software deficiencies are at a minimum.

Medical: FDA licensure. Full rate production.

