1. The purpose of this amendment is to post the Questions and Answers received as of COB Friday, February 23, 2007.

Questions and Answers

GENERAL QUESTIONS

QUESTION 1:

The BAA shows Basic Research as a capability area (Section 2.2.1). Is there basic research topics listed in a separate capability area named 'Basic Research"?

ANSWER: No; in this BAA, topics soliciting basic research are included in the respective capability area associated with the research subject area. Topics that solicit basic research will state "This topic solicits basic research".

QUESTION 2:

What is the minimum and maximum duration of funding (years)?

ANSWER: Historically, individual awards have had a period of performance that typically ranges 12 - 24 months in duration.

QUESTION 3: Are there funding caps? If so, are there caps for each year and/or for the total budget?

ANSWER: There is no dollar limit per award; historically, individual awards for the types of research and development projects listed in prior BAA solicitations have ranged from approximately $250,000 and $2,500,000 depending on level of effort and period of performance.

QUESTION 4:

How many awards will be given for the above topics?

ANSWER: There is no specific number of awards designated for individual topics.

QUESTION 5:

Are there transitional or follow-on opportunities?

ANSWER: At the conclusion of the period of performance associated with the awards made in conjunction with this solicitation, there may be technology transition opportunities.

QUESTION 6:

Is it desired for proposers to collaborate with other awardees?

ANSWER: There is no requirement to collaborate with other awardees.

TOPIC SPECIFIC QUESTIONS

QUESTION 7:

Regarding Topic CBT-08-DEC-02 (Reactive/Self-Decontaminating Coating System): Is the surface contaminated before or after application of the coating? The text of the topic as shown in the BAA states that additives should be positioned at the air interface which implies the substrate is not contaminated. This makes it sound like a protective coating rather than decontaminating a contaminated substrate. Or does the topic desire protection as well as decontamination capabilities?

ANSWER: The offeror has the latitude to address the topic through a variety of innovative approaches. The coating could be on the surface prior to becoming contaminated; however, an alternative scenario may be acceptable if the coating could protect the surface and offer some level of decontamination that would occur at the contaminant-coating interface.

QUESTION 8:

Regarding Topic CBDIF-07-DET-02 (Standardized Library of Biological Signatures): Is this topic restricted to using GC-MS, or can signatures also be generated from LC-MS-MS? Are there a minimum number of cultures to be tested?

ANSWER: Topic CBDIF-07-DET-02 is limited to GC/MS. Alternative MS based techniques are not acceptable. Signatures must be developed for the seven Eubacteria species listed in the topic.

QUESTION 9

Regarding Topic CBDIF-07-DET-02 (Standardized Library of Biological Signatures): Does DTRA have a current virus pathogen priority list?

ANSWER: Viruses are specifically not included in the list of organisms to be studied. Submitted proposals must address developing signatures for the seven Eubacteria listed in the topic.

QUESTION 10:

Regarding Topic CBDIF-07-DIAG-02: Is there a general protocol for the discovery & validation of host response markers applicable to infection by toxin, virus, and bacteria or specific to a single select agent?

ANSWER: The offeror must propose an appropriate protocol. A single representative agent can be used as a model organism.

QUESTION 11:

Regarding Topic CBDIF-07-DIAG-02 (Discovery and Validation of Host Response Biomarkers). Would the Government provide access to samples or appropriate facilities to generate exposure samples as GFI or GFR?

ANSWER: A collaboration through a Government laboratory would be necessary to gain access to samples or appropriate facilities

QUESTION 12:

Regarding Topic CBDIF-07-DIAG-02 (Discovery and Validation of Host Response Biomarkers). Do the markers developed under this program have to be compatible with ECL, RT-PCR, and microarray, or ECL, RT-PCR or microarray?

ANSWER: It is highly desirable that the markers be adaptable to currently funded and future instrument platforms.

QUESTION 13:

Regarding Topic CBDIF-07-DIAG-02 (Discovery and Validation of Host Response Biomarkers). Does the requirement for microarray compatibility include both nucleic acid and protein arrays?

ANSWER: It is highly desirable that microarray compatibility include both nucleic acid and protein arrays – however, it is not a requirement.

QUESTION 14:

Regarding Topic CBDIF-07-DIAG-02 (Discovery and Validation of Host Response Biomarkers). Are metabolite-based markers of interest to this program?

ANSWER: Yes, metabolomics are of interest.

QUESTION 15:

Regarding Topic CBT-08-IST-01 (CBRN Data Backbone Data Model Expansion):

Is DTRA interested only in solutions that complement the current data model, or that can be integrated with the current model, or is this solicitation open to solutions that propose a new modeling approach that may require reworking the current model but will enable easier future expansion?

ANSWER: Solutions that leverage and complement the current data model developed by the Chemical and Biological Defense Joint Program Manager – Information Systems (JPM-IS) are requested. Such solutions may involve adaptation of the current model to facilitate future expansion.

QUESTION 16:

Regarding Topic CBT-08-IST-01 (CBRN Data Backbone Data Model Expansion): Is system integration an issue here, or is the challenge primarily in allowing users to extend the model using their own data types, schemas, etc.?

ANSWER: System integration is not the issue; rather, the challenge is to expand the data model and to make future expansion easier.

QUESTION 17:

Regarding Topic CBT-08-IST-01 (CBRN Data Backbone Data Model Expansion): The solicitation refers to a need for the CBRN data backbone model to be expanded for a wider user community. Can you give examples of who these users are? Can you give examples of how users use the CBRN data backbone? Would contacts be provided for a user study during this effort?

ANSWER: A user is anyone employed via a DoD funded contract who uses or has a need for structured CBRN data. The CBRN data backbone is a developing concept, and therefore there are no current CBRN data backbone users. Points of Contact will be provided after contract award in order to facilitate the proposed effort in developing a user study.

QUESTION 18:

Regarding Topic CBT-08-IST-01 (CBRN Data Backbone Data Model Expansion): Would it be feasible to narrow the scope and concentrate on experiences with users in this domain and especially those in the medical intelligence community?

ANSWER: A solution that considers a broader range of threat agents is sought through this topic.

QUESTION 19:

Regarding Topic CBDIF-07-PRET-01 (Immunomodulators as Adjuvant Additions to Enhance Vaccine Responses). Can DTRA assist in establishing a co-development relationship between private industry or academia and Government laboratories? If yes, when might it be appropriate to discuss possible co-development partners with DTRA?

ANSWER: DTRA may be able to discuss teaming arrangements between industry or academia and Government labs that are approved to conduct work associated with biological agents. The appropriate time to discuss these arrangements in any detail is after contract award. Prior to contract award (e.g., during proposal development), it is the responsibility of the prime contractor (e.g., industry, academia, etc) to establish the groundwork in forming a cooperative agreement with a potential candidate laboratory.

QUESTION 20:

Regarding Topic CBDIF-07-PRET-01 (Immunomodulators as Adjuvant Additions to Enhance Vaccine Responses): If proof-of-concept animal studies and Phase 1 studies have already been completed, is funding available for further clinical evaluation and development? Will funding be available to manufacture cGMP material for animal toxicology and clinical studies? Will funding be available to for delivery device development?

ANSWER: The types of studies proposed in the question represent maturity beyond a Phase 1 clinical trial and are therefore beyond the scope of the Chemical and Biological Defense Science and Technology Program and beyond the scope of this topic. The studies cited in the question are at the stage of 'Technology Demonstration' which is outside the scope of the Research and Development mission of the Joint Science and Technology Office for Chemical and Biological Defense.

QUESTION 21:

Regarding Topic CBDIF-07-PRET-01 (Immunomodulators as Adjuvant Additions to Enhance Vaccine Responses): Will funding be available for delivery device development?

ANSWER: Device development is outside of the scope of the Applied Research topic as described in the BAA.

QUESTION 22:

Regarding Topic CBT-08-PRO-02 (Integrated Reactive Fibers). Does this topic include very small sensors that could be sewn into fabrics and operate at very low power?

ANSWER: This topic is looking for controlled response technologies that can be incorporated directly into the fibers throughout uniform. The idea is to make the uniform

itself into a sensor grid vs. 'hanging more ornaments on the tree'; even if the sensors are sewn on. This topic seeks innovative technologies where the fibers become the sensors.

QUESTION 23:

Regarding Topic CBT-08-PRO-03 (Collective Protection System Alternatives). Define "pressure control" as referred to in the topic.

ANSWER: "Pressure control" refers to the ability to maintain & control overpressure and the pressure differential between the exterior, the airlock (contamination control area), and the interior (toxic free area) during routine operations (such as ingress/egress) in collective protection systems.

QUESTION 24:

Regarding Topic CBT-08-PRO-05 (Human Performance Studies): The topic appears to seek modeling and/or novel data collection processes. Would DTRA also consider novel predictive models based on physiology and empirical studies?

ANSWER: As described, the predictive model proposed does not correlate the physiological effects to cognitive performance, which is the primary goal of this topic area.

QUESTION 25:

Regarding Topic CBT-08-PRO-05 (Human Performance Studies): Would reliable methods for EEG collection during high activity be considered as a novel data collection process according to the topic request?

ANSWER: EEG collection could be considered an acceptable method as long as it is used to correlate cognitive performance with physiological performance.

QUESTION 26:

Regarding Topic CBT-08-PRO-07 (Protective Fabric System Model): Is it appropriate to include some laboratory tests of the computer model that to be developed in our labs? The project is listed as 'TRL5 expected by 4Q FY09'. According to the definition of TRL5, "Component and/or breadboard validation in relevant environment". Does this mean that we need to identify a partner at a DOD lab to perform testing of the model predictions before the end of 2009?

ANSWER: Relevant environment should compare model results to permeation performance of modeled materials. Permeation performance should be relative to standard test methods (currently AVLAG TOP 8-2-501). Validation can be based on the use of simulants, but should include some testing with live agents. Partnering with DoD lab or with a commercial surety facility with live agent test capability operating under a

bailment agreement from U.S. Army Edgewood Chemical and Biological Center (ECBC). Identifying the specific surety facility is not necessary for the white paper, but will become a consideration should a full proposal (Phase II) be requested.

QUESTION 27:

Regarding Topic CBT-08-PRO-09 (Novel Detoxifying/Anti-Microbial Reactive Additives). Are there any other details available at this time, besides the 1 microliter, 24 h parameters for performance demonstration of the catalytic systems?

ANSWER: It is important to note that the 1 ul drop challenge = a 1 ul neat liquid drop and that detoxification = rendering the 1 ul drop into benign byproducts with complete mass balance/accountability.

QUESTION 28:

Regarding Topic CBT-08-PRO-09 (Novel Detoxifying/Anti-Microbial Reactive Additives). The solicitation says that TRL 3 is expected by 4Q FY08. Does that mean that the project performance period is restricted to ~6month period assuming the award is made by Feb 1, 2008?

ANSWER: Assuming award by 1 Feb 2008, the goal is to reach TRL 3 by 4Q FY08. The performance period for the project will continue to strive to reach the designated goal until the funds are either exhausted or expire.

QUESTION 29:

Regarding Topic CBT-08-PRO-09 (Novel Detoxifying/Anti-Microbial Reactive Additives). Define the term "hygienically safe" as used in the topic.

ANSWER: In this context "hygienically safe" equates to the biocide being non-cytotoxic to eukaryotic cell lines and having no adverse effects when the biocide is in prolonged contact with human skin (standard methods available).

QUESTION 30:

Regarding Topic CBT-08-PRO-09 (Novel Detoxifying/Anti-Microbial Reactive Additives). The terminology "sufficiently long service life" is used in the topic. About how long is considered acceptable?

ANSWER: The threshold is 90 days; the goal is indefinite (equates to having a lifetime greater than the expected service lifetime of the material to which the catalyst has been added).

QUESTION 31:

Regarding Topic CBDIF-07-PRO-013 (Nanoscale Aerosol Science). The topic refers to aerosols with nm sized "particles." Do these include studies with solid particles or refer to essentially liquid droplets?

ANSWER: Studies should address both liquid droplets and solid particles. They are both of interest.

QUESTION 32:

Regarding Topic CBT-08-PRO-013 (Nanoscale Aerosol Science):
Does the phrase "investigate....the effect of electrostatic charge on submicron particles" refer to electrostatic charges on the walls of the monolith, or to electrostatic charges on the surface of the nanoparticles?

ANSWER: Effects of electrostatic interactions between the submicron particles and the monolith should be addressed. Both the charge on the monolith and the charge of the submicron particles should be considered.

QUESTION 33:

Regarding Topic CBT-08-PRO-013 (Nanoscale Aerosol Science): Do surface chemistry issues need to be addressed in the investigation pertaining to this topic? That is to say: do those walls contain functional groups that interact with the chemistry of the nanoparticles?

ANSWER: The effects (if any) of broad changes in surface energy of the monolith should be addressed. Local surface interactions with specific functional groups need not be addressed.

QUESTION 34:

Regarding Topic CBDIF-07-TAS-02 (Tissue Permeability of Traditional and Non-traditional Chemical Warfare Agents): Does DTRA have access to tissue permeability data that the awardee may acquire through a confidentiality agreement?

ANSWER: There is a limited amount of tissue permeability data; these data could potentially be made available to a successful offeror upon contract award. Note that this topic focuses on development of computational data.

This completes the Questions and Answers session for this BAA.