

**Department of Homeland Security (DHS) Science and Technology Directorate
(S&T) Chemical and Biological Defense Division (CBD) OBAA 14-003/Call 0015**

1. **Announcement Number:** Open Broad Agency Announcement Number (OBAA) 14-003/Call 0015
2. **FBO Solicitation Number:** HSHQDC-14-R-B0009
3. **Call 15 Event Dates/Time (Local Eastern Time):**
 - Notification to Submit Full Proposals–December 8, 2015
 - Full Proposal Due Date– January 19, 2016
 - Notification of Selection/Non Selection of Full Proposals– February 19, 2016

There will be no exceptions to the time and date on which responses are due, unless determined otherwise by the Government. Full Proposals received after the designated closing date/time will not be considered.

Note: This Call will be conducted in accordance with the Single-Phased Evaluation Process as described under Section 1.6 of the OBAA. The OBAA 14-003/Solicitation HSHQDC-14-R-B0009 was posted on Federal Business

Opportunities on June 16, 2014. See Link.

<https://www.fbo.gov/index?s=opportunity&mode=form&id=3935288433485a6ee877134ac7d2a8a9&tab=core>

This Call will consist of the consist of the solicitation, receipt, and evaluation of a Full Proposal, limited to 30 pages, excluding the Formal Transmittal Letter, Cover Page, Summary of Costs and Related Information, Table of Contents and resumes/biographical information for proposed performers. Once the Full Proposal review process has been completed, offerors will be notified via e-mail, or in writing, that its proposal has been selected, selected but not funded, or not selected for award.

4. OBAA Call Technical Topic Area (TTA) of Interest:

Chemical and Biological Research and Development CBD.01 – Diagnostics and Agent Characterization: Research to develop rapid, robust, and affordable diagnostic tools to support detection, response, recovery, and real-time bio-surveillance and situational awareness. CBD's interest in diagnostics includes efforts in the areas of biological assays, sample preparation, advanced diagnostics (e.g. multiplex, high throughput, low-cost, field-deployable, complex sample matrices (environmental, milk, blood, oral/nasal, sputum), multiple target types, pathogen agnostic diagnostics), and agent characterization of chemical or biological materials. CBD's interest includes new or improved rapid diagnostic tests that facilitate foreign animal disease (FAD) outbreak surveillance, response, and recovery in livestock.

4.1. Research Opportunity Description

4.1.1. DHS S&T: Creation and Validation of Saxitoxins Detection Assays.

Background

The U.S. Department of Homeland Security (DHS) is committed to using cutting-edge technologies and scientific talent in its quest to make America safer. The DHS Directorate of Science and Technology (S&T) is tasked with researching and organizing the scientific, engineering, and technological resources of the United States and leveraging these existing resources into technological tools to help protect the homeland. The Chemical and Biological Defense Division (CBD) of S&T supports this mission by identifying and developing technologies for the DHS operational components that are needed to reduce the probability and potential consequences of a biological pathogen or a chemical attack on the nation's civilian population, its infrastructure, or its agricultural system.

DHS's mission space includes preventing, detecting, responding to, and recovering from intentional or accidental introduction of biological and chemical agents which present a threat against the Nation's human population and critical infrastructure. To support this mission, DHS and its state and local partners have a need to quickly collect reliable information to enable a swift and confident response to a biological and chemical threat. CBD within DHS S&T is working toward developing and transitioning technologies that ***demonstrate significant improvements*** to current analytical approaches in sensing and identifying chemical or biological contaminants in all types of environmental samples (solid, vapor, liquid, serum, blood, growth media) with high confidence.

First responders and public health officials require validated detection assays to analyze suspected biothreat samples and enable them to take appropriate actions in the interest of public safety (e.g., evacuating a building) and public health (e.g., distributing antibiotics). The BioAssays Project enables capabilities to rapidly screen and detect high consequence biological pathogens and toxins that can have a significant Public Health impact. The project develops, tests, evaluates and validates nucleic acid detection assays (TaqMan PCR), antigen detection assays (immunoassays) and rapid antimicrobial susceptibility assays (based on microculture and PCR), using the Government Unique Standards for the Implementation of Public Health Actionable Assays (PHAA) for deployment and employment through the Centers for Disease Control and Prevention Laboratory Response Network and other federally-sponsored laboratory response networks. These assays are intended to be dual use assays that can be used for environmental sample analysis as well as clinical specimen analysis. This project encompasses developing bio-informatics resources, reference strain repository, antibody repository, and the appropriate standards. Finally, the PHAA and BioAssays Project will also evaluate novel approaches to recognize and identify emerging, advanced, and enhanced threat agents.

This project for the creation and validation of saxitoxins assays seeks to build on the legacy of successful DHS S&T Public Health Actionable Assay development projects. DHS S&T requires the creation and validation of saxitoxins detection assays. The laboratory based confirmatory detection assays and rapid point of care diagnostic tests for this select biological agents will be used in the clinical and public health laboratories as well as point of care settings. A thorough validation of these assays will be completed on the prototypes by the performer via the use of Government required panels of non-clinical environmental, pre-clinical and clinical samples. Most likely, spiking studies with target agents and near neighbors will be conducted for validation studies. Respondents should demonstrate skill, knowledge, experience, and commercialization successes in similar types of tasks, *i.e.*, in the creation of saxitoxins

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monoclonal antibodies capable of detecting complex organic molecules of similar characteristics as the actual target agents, and the successful transition of viable, and cost effective commercial assays. Full proposals shall be accepted, no white papers are necessary.

4.1.2. Description Technical Topic Areas

The performer will create, test, evaluate, and characterize *de novo* and novel monoclonal antibodies to produce prototype assays for further validation against the panel of Government determined inclusivity (toxins) and exclusivity materials and compounds. The performer will work with Government guidance to validate the final assays, and shall have the capability of commercially and rapidly producing them for sale to other designated end users. DHS may also conduct specialized and specific analysis, test, evaluation, and validation of assays to help characterize and deploy the assays for use by DHS customers with areas of responsibility for biological defense, detection, and surveillance.

The Government has established metrics for assessing the capabilities and qualifications of the offeror to successfully meet the requirements of the task. The criteria shown in the Evaluation Criteria section shown below will be given **equal** weight in determining the final decisions of the source selection committee. An offeror may submit a **full** proposal to this technical topic area. The proposal will be reviewed by a panel of Government subject matter experts for several criteria as described below in Evaluation Criteria section. Failure to address each criteria fully will result in rejection of the proposal as non-responsive.

Note also that the emphasis with respect to past performance for the topic area will be based on demonstrated and prior experience as judged by reviewers to yield the highest possible quality of performance to assist the DHS in its biological detection and surveillance portfolio. Offerors are encouraged to submit brief and concise plans to execute the tasks, and to include information that will allow the reviewers to judge against the criteria shown in the Evaluation Criteria section.

Specific elements of the task areas to be included in the full proposal shall be:

- 1) Creation of novel monoclonal antibodies specifically recognizing saxitoxins; the in-house capability of testing, evaluating, and validating assays for the specific targets of the antibodies.
- 2) Synthesizing partial saxitoxins analogues, and fragments of saxitoxins for use as immunogens.
- 3) Assembly of the respective monoclonal antibody reagents into lateral flow assays or suspension bead-based assay chemistries. Production of reagents and assembly of reagents for test kits to support test, evaluation, and validation studies.
- 4) Test functionality of each assay alone in Lateral Flow Assay (LFA) format, and potentially in a multiplex format, using sub-select agent amounts of each toxin.
- 5) Perform Quality Assurance / Quality Control (QA/QC) of reagents in kits prior to initiation of test and evaluation studies.

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- 6) Conduct appropriate studies to support reagent stability and test sample stability for test and evaluation studies.
 - 7) Development and writing of test plans for saxitoxins assays.
 - 8) Meeting performance metrics of 95% specificity; Limit of detection (LOD) of 100 ng or better for sensitivity.
5. **Number of Selections:** It is anticipated that multiple selections may be made depending on the quality of the Proposals and availability of funds.
6. **Anticipated Ceiling:** Although subject to official fiscal appropriation and availability, it is anticipated that approximately \$700,000 of Fiscal Year (FY) 2016 funds will be available for any resultant awards under this OBAA Call. **The Government will reserve the right to incrementally fund any resultant contracts awarded from this OBAA Call as provided by the FAR 52.232-22, "Limitation of Funds."** Contracts or other agreements that obligate funds will not have an initial period of performance that exceeds 18 months from the date of contract award. However, Offerors will be able to propose a base effort with additional option years.
7. **Anticipated Award Type:** Award type is anticipated to be in the form of Cost Reimbursement type contracts however the Government reserves the right to award firm-fixed price contracts, cooperative agreements, Other Transactions (OTs) (if authorized by law at time of award), or interagency agreements to appropriate parties should the situation warrant.
- In the event an offeror or subcontractor is a Federally Funded Research and Development Center (FFRDC), Department of Energy National Laboratory, or other Federally funded entity, DHS/S&T will work with the appropriate sponsoring agency to issue an interagency agreement pursuant to the Economy Act (31 U.S.C. 1535) or other appropriate authority.
8. **Anticipated Award Dates:** The 3rd Quarter of Fiscal Year 2016 is when the government anticipates making any resultant contract awards under this Call for those Proposals are selected. However, the award date for any resultant contract award may vary based on the quality of the proposals received and the availability of funds.
9. **White Paper Instructions:** NA – No white papers are being requested in response to this Call.
10. **Full Proposal Instructions:** Offerors shall submit their Full Proposals in accordance with OBAA 14-003, Section 5.4 - Format and Content of Full Proposals. See FBO link above for access to OBAA 14-003/Solicitation Number HSHQDC-14-R-B0009.
11. **Evaluation Criteria:** Full Proposals will be evaluated in accordance with the following evaluation criteria:

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Criterion I: Scientific Merit: The Offeror must demonstrate understanding of the critical technology and scientific challenges required to achieve the desired performance metrics and strategy as described in Section 4.1.2 of this announcement. The research approach should be scientifically sound, practical, and technically defensible. The technical approach is innovative and has advantages over other solutions, if successfully implemented. The research must contribute to scientific knowledge in the topic area and the research must enumerate potential benefits of the proposed research. The proposal shall demonstrate an awareness of the state-of-the-art. The proposal should be well-prepared with supportive information that is self-explanatory.

Criterion II: Sound Technical Approach: Of importance is how the proposed technology will meet or exceed the performance requirements for this program and be commercially applicable (how the proposed technology will be transitioned into a sustainable commercial market and what the intended use, or concept of operations, would be). All critical scientific and technical issues and risks are clearly identified, and the planned development approach and risk mitigation efforts are clearly defined and feasible. The merit of the technical approach over other competing approaches should be clearly delineated.

Criterion III: Sound Management Approach: Presentation of a sound managerial approach to the proposed work, including a demonstrated understanding of the issues and challenges associated with achieving the goals of the topic, and a strategy to address those issues and challenges. A successful team will possess multidisciplinary expertise to address the complexity of the effort.

Criterion IV: Capability to Perform and History of Performance: Demonstration of a capability to perform the proposed work, including history of previous performance in developing related solutions and technologies. Specific considerations will include:

- The Offeror must possess clear and convincing qualifications and must have a proven record of performance and experience, including successful production of similar types of assays and subsequent commercialization of the assays. Authorship on peer reviewed publications related to projects associated with the creation, and assessment of performance of detection assays for biothreat agents.
- The Principle Investigator must possess at a minimum, a doctoral level degree from an accredited university.
- The Offeror must have an expert understanding and knowledge of assay development and technical requirements associated with the specialized organic- synthetic chemistry involved in this effort.
- Offerors knowledge of chemical/biological detection systems
- Offerors team is sufficiently complete: key personnel are identified with the required range of competencies to execute this effort and the team includes appropriate experience

Criterion V: Cost Realism/Reasonableness: Presentation of accurate, well-founded and reasonable estimates of all costs related to performance of the proposed effort, including an appropriate allocation of labor resources. Members of the Government Review Panel will focus on overall *best* value to the Government.

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- 12. Foreign Concerns:** Foreign persons are advised that their participation may be subject to Export Control restrictions in accordance with OBAA 14-003 Section 8.3. Any such restrictions shall be reviewed on an individual award basis.
- 13. iDURC Requirements:** The performer and any proposed sub-performer(s) working under any award resulting from this BAA Call shall conduct all research involving agents and toxins identified in sections III.1 and 6.2.1 of the USG Policy for Oversight of Dual Use Research of Concern and USG Policy for the Institutional Oversight of Dual Use Research of Concern, respectively, in accordance with both policies referenced above and in accordance with any additional requirements set forth in related DHS policies and instructions. Each performer and any sub-performer(s) planning to perform research involving agents and toxins identified in sections III.1 and 6.2.1 of the USG DURC policies under this award must attest at the time of seeking funding that they are in compliance with all aspects of the Policies.
- 14. Questions:** Any questions concerning this call must be submitted via email to the Contracting Officer at Michael.Jones@hq.dhs.gov no later than **January 11, 2016 3:00 PM EST** in the following format:

Question #	Reference	Contractors' Question
1	General (if there is no specific document reference)	
2	(Example) OBAA 14-003, page 15, Section 5.2, first paragraph, second sentence	
3	(Example) OBAA 14-003/Call 0015, page 2, Section 9, first sentence	

Please include "Questions for OBAA 14-003/ Call 0015" in the subject line. All questions and responses will be posted on the Federal Business Opportunities website <http://www.fbo.gov> and <https://baa2.st.dhs.gov> . Questions will only be accepted or answered electronically.