

Title: Third Party Conformance Testing

Description:

Objective: This is a Request for Information (RFI) for planning purposes only. It is not to be construed as a commitment by the Government nor will the Government pay for the information solicited. No solicitation document exists or is guaranteed to be issued as a result of this RFI. The Defense Biological Product Assurance Office (previously known as the Critical Reagents Program) is seeking information on the capabilities and willingness of commercial entities in the areas listed below.

Background: The Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD) develops medical and physical countermeasures to protect the warfighter from chemicals and biological threats under the DoD Chemical and Biological Defense Program. In executing this mission, JPEO-CBD is responsible for developing and evaluating detection and diagnostic capability solutions, developing and evaluating the effectiveness of medical and physical protection capability solutions, developing and evaluating medical treatment capabilities, and verifying the accuracy of test and evaluation equipment. Access to valid test materials, including potentially harmful biological materials known as BSAT (Biological Select Agents and Toxins) is required to perform these activities. JPEO-CBD established the CRP now DBPAO in Fiscal Year 1997 to ensure the standardization, quality, and availability of reagents that are crucial to the successful development, test and operation of DoD biological defense strategies. The DBPAO's mission is to employ best practices in providing the Department of Defense and its partners with a comprehensive collection of biological products that are thoroughly characterized, of the highest quality, adaptable, and traceable from source to application.

Requirement: The Government is interested in the following information from qualified performers:

Information on Third-Party Conformance Testing to include:

- a) Capability to work in Biosafety Level 1&2 containment (bacteria/virus)
- b) Capability to work in Biosafety Level 3 containment (bacteria/virus)
- c) Capability to work in Biosafety Level 4 containment (virus)

- d) Capability and willingness to perform third party verification of sterility testing on inactivated antigen (bacteria/virus) (see the product list at: <http://www.jpeocbd.osd.mil/packs/Default.aspx?pg=1220>). If yes, to what extent? For example would you be willing to work with bacteria including spores (i.e., Bacillus anthracis) and viruses?

- e) Understanding of Army Directive 2016-024 (DoD Biological Select Agent and Toxins Biosafety Program) (see AD 2016-024 at <http://www.apd.army.mil/Search/ePubsSearch/ePubsSearchForm.aspx?x=ARMY+DIR>)

- f) Knowledge of Army Biological Personnel Reliability Program (see AR50-1 at <http://www.apd.army.mil/Search/ePubsSearch/ePubsSearchForm.aspx?x=AR>)

- g) Experience with and/or possession of safer alternatives to substitute BSAT, BSAT Derivatives, and BSAT exempt materials

Respondents are invited to provide additional reading materials related to handling/testing of BSAT, commercial best practices, quality system, cost drivers in testing; quality controls and statistical process controls; and customer service capability.

Administration: The Government will retain comments and information received in response to this RFI. Proprietary information should be identified as Company Proprietary. Do not use Government security classification markings.

All written responses must be received by 12:00 PM Eastern Time, February 3, 2017. Responses should be sent by e-mail to: contracts.mcdc@ati.org, with Subject Line of Responding Organization and RFI Title. Material that is advertisement only in nature is not desired