Title: Antigens

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 requests that potential performers provide the following information regarding their qualifications:

a) Capability to produce, manufacture or provide inactive viral and bacterial antigens (see the catalog at: http://www.jpeocbd.osd.mil/packs/Default.aspx?pg=1220) of interest to DBPAO under QA/QC certified QMS using validated protocols and procedures any/all of the fourteen (14) Antigens and specificity panel of twenty eight (28) relevant environmental and biological entities included in the catalog.

b) If produced/manufactured, provide information on Biosafety Level capability to

include inactive viral and bacterial antigens produced/manufactured within containment levels as follows:

i. Biosafety Level 1&2 containment (bacteria/virus),
ii. Biosafety Level 3 containment (bacteria/virus),
iii. Biosafety Level 4 containment (virus)

c) Capability to conduct stability testing that captures reagent shelf life.

d) Quality assurances/controls (QA/QC) programs in place that meet the accreditation to the most appropriate international standards through an internationally recognized accreditation body of those reagents

e) QA/QC procedures in place that ensure critical reagents are shipped of verified quality, concentration and activity

f) Standardized receipt, cataloging, maintenance, and shipping procedures in place

g) Characterization procedures for viral and bacterial antigenic material in place

h) Subject Matter Expert (SME) 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)

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

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

In addition, respondents should indicate their willingness/capability to participate in a pilot inactivation (confirmation thereof) study.

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.