Request For Information (RFI): Physical and Biological Dosimetry Techniques and Devices Useful in Initial Triage After Radiologic and Nuclear Events

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*** BACKGROUND *** The Department of Health and Human Services (HHS) has the lead responsibility within the federal government to protect the health of the civilian population against chemical, biological, radiological, and nuclear (CBRN) threats by providing leadership in research, development, acquisition, and deployment of effective medical countermeasures. On July 21, 2004 President Bush signed into law the *Project BioShield Act of 2004* (P.L. 108-276) specifically mandating the development and accelerated acquisition of countermeasures to address chemical, biological, and radiological/nuclear (CBRN) threats. The Pandemic and All-Hazards Preparedness Act of 2006 (P.L. 109-417) codified HHS as the lead of Federal public health and medical response to public health emergencies and incidents covered by the National Response Plan (or any successor plan such as the current National Response Framework). The legislation also specified that one of the duties of the HHS Assistant Secretary for Preparedness and Response is to oversee advanced research, development, and procurement of qualified countermeasures and qualified pandemic or epidemic products. The Biomedical Advanced Research and Development Authority (BARDA) within ASPR is responsible for coordinating the advanced research, development, and

acquisition of medical countermeasures needed for the mitigation or treatment of radiation injuries. This is a Request for Information (RFI) on current and new technologies developed for measurement of individual radiation doses using biodosimetry tools (such as devices and bioassays) that might be employed in the management of a radiologic or nuclear event. It is not a request for proposals and does not commit the U.S. Government (USG) to issue a solicitation, make an award, or pay any costs associated with responding to this announcement. All submitted information should remain with the USG and will not be returned.

*** OBJECTIVES *** As stated in the Department of Health and Human Services (HHS) Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Implementation Plan for Chemical, Biological, Radiological and Nuclear Threats, HHS regards radiological and nuclear agents as a significant threat to national security. Biodosimetry capability will be essential for medical management of those acutely exposed to radiation and is integral to triage and management processes. Medical decision tools and processes that will be used for medical triage must allow for rapid, rational initiation of necessary medical intervention, including medical countermeasures, in the midst of a large-scale emergency.

The USG has estimated that over 1 million people may seek information on their personal risk (radiation exposure level), if an event (such as a 10 kiloton detonation of an improvised nuclear device) occurs in a large metropolitan area. There will be a need for immediate triage of these individuals within 48 hours of the event to determine a first-pass identification of subjects receiving greater than a 2 Gy exposure. Individuals exposed at levels exceeding 2 Gy will need immediate treatment and further evaluation with more sophisticated and precise methods to ascertain their absorbed dose. BARDA is seeking information on dosimetry systems or tools (such as devices, bioassays, biomarkers and tests) that can be used to quickly assess an individual's radiation dose after large radiological/nuclear events.

The USG is seeking information on products that can satisfy one or more of the following Objectives:

OBJECTIVE 1: Self-Assessment Dosimetry Tools: A personal self-assessment tool for immediate determination of exposure to ionizing radiation at doses >2Gy which is immediately interpretable by the handler using minimal handling. The USG prefers an interpretive mechanism that requires no processing. The tool must be accurate, rugged (i.e. works under possible adverse environmental conditions), maintains reliability over time even under adverse conditions, and, requires no sample preparation or handling. Ideally the tool should be portable and may be included in any contemporary personal domestic platform, hold the information for at least one week, and be capable of reporting exposures >2 Gy with a stated statistical certainty. If electronic, the device or tool should be able to continue to operate reliably and continuously following exposure to an electromagnetic pulse (EMP) of sufficient magnitude to disable standard personal electronic platform circuitry.

OBJECTIVE 2: Quick, Rapid, High Throughput (up to 1 million assays in 48 hours), Dosimetry Assays: In addition to the self-assessment tool in Objective 1, the USG seeks information on a high throughput tool capable of up to 1 million assays in 48 hours (multiple stations acceptable), that is of low cost, and simple to operate and interpret. The tool should be capable of measuring a subject's exposure to ionizing radiation when greater than 2Gy with accuracy and precision with a stated statistical certainty. The tool should also be rugged for in-field use under potentially adverse environmental conditions. The device should be portable and capable of operating from a self-contained power supply. The source of the assay's biomarker(s) should be preferably procured from subjects non-invasively (e.g., sputum, urine, fingernails).

OBJECTIVE 3: A Dose-Ranging (0.5 – 10 Gy) Assessment: USG seeks information on an analysis tool that can assess >200,000 assays over a one week period (multiple stations acceptable) and determine with a stated accuracy and precision an individual's radiation exposures over the range of 0.5 Gy to 10 Gy . The tool may be used up to several days after an event, may require field ruggedness, an internal power source, and minimal use of reagents for sample preparation and analysis.

OBJECTIVE 4: A "Gold Standard" Assay: The USG seeks information on a tool that can provide accurate and precise results with a stated statistical certainty over the range of 0.01 - 10 Gy. The tool may be a laboratory-based single or multiple assay system, sensitive and specific, and useful for accurate post-event follow-up of patients who have been stabilized and removed from a restrictive environment or original event environment. Methods requiring extensive sample preparation (i.e. hours) along with days to weeks for assay time, or use of exotic reagents, are not excluded from consideration, but cost of the test is a consideration.

Each of these needs has negotiable levels of accuracy. The techniques and biomarkers should be validated and confounding factors addressed. For each Objective, the tools should be able to determine a person's exposure to ionizing radiation and inform medical personnel attending the subject so that the patient is triaged appropriately (no treatment/treatment). Bioassay systems or methods employed in Objectives 1 and 2 requiring instrumentation should be robust in terms of control of signal drift, power stability, and operation in compromising environments (operable outside of standard room temperature, humidity, dust, and other controllable conditions). In Objectives 3 and 4 , the USG is seeking tools that are envisioned to be hospital-ready and operable under controlled standard laboratory conditions and that may require more time per assay and have improved sensitivity and specificity for assessing patients with lower exposures (0.01 Gy – 2 Gy) to allow for extended follow-up of medical therapeutic interventions.

We are currently accepting white papers, the guidelines for which are listed below. These white papers will be evaluated by BARDA program staff using the following factors to select organizations that will be invited to present their concepts in a meeting with BARDA.

- Level of maturity of the medical countermeasure development program
- Program balance among the four objectives

This is a new effort for BARDA and there are no incumbent contractors. Organizations that currently develop or manufacture devices and bioassay systems that can meet the Objectives in this RFI or that have technologies, devices, or manufacturing capabilities under development that are targeted to these Objectives are invited to submit statements of their product to BARDA in a White Paper format described below:

White Paper Format:
White Papers may include narrative, pictures, figures, tables, and charts in a legible size and must be accompanied by a one-page QUAD chart (printable as its own separate page; see example below).

Overall White Paper Format details are:
• Paper Size – 8.5-by-11-inch paper
• Margins – 1 inch
• Spacing – Single- or double-spaced
• Font – Times New Roman, no smaller than 12 point. Text embedded within graphics or tables in the body of the white paper or the quad chart may not be smaller than 10 point.

• Number of Pages – No more than 10 single-sided pages, plus a one-page QUAD Chart on a separate page. Therefore, the entire mandatory White Paper plus QUAD Chart submission will not exceed eleven (11) pages. Do not include a cover sheet (this is not the cover page discussed below), as one will be automatically generated for submitted white papers. If a cover sheet is submitted with the white paper, it will be counted toward the eleven-page white paper plus QUAD Chart limit. White papers exceeding the page limit will not be evaluated.

• PDF format - The White Paper should consist of an electronic file in portable document format (PDF), readable by IBM-compatible personal computers (PCs). The QUAD chart must be submitted in the same file as the White Paper and not be an imported image. The White Paper file size must be no more than 10 megabytes (MB). The White Paper should capture the essence of the technology and its utility per the USG Objectives 1 to 4.

White Papers should be succinct and should include, as a minimum, the following:

• Cover Page: The cover page (This is not the cover sheet previously discussed) should be labeled “White Paper”, and should include the FBO RFI number, proposed title, points of contact, with telephone numbers, facsimile numbers, and Internet addresses. An authorized Officer of the company or business entity will sign the cover page.

• Executive Summary and Utility to BARDA: This section will contain a concise description of the scientific, technical, engineering, and management approach of your product, a description of the various features of the proposed technology, and relevant details about how it will meet any or all of the stated Objectives 1 through 4. The White

Paper should describe the potential of the prototype for meeting the desired topic attributes and desired features as outlined in Objectives 1 to 4.

• Technical Approach: This section will contain a description of the basic scientific or technical concepts that comprise your product. Explain what is unique about your product, and what advantages it might afford compared to other approaches that have been taken in this area. Illustrate the particular scientific, technical, or engineering issues that need to be addressed and resolved to demonstrate feasibility.

For marketed products, list each facility (domestic or international) where the device is manufactured, include the name and address of the manufacturing facility, and include the FDA Device Establishment Registration Number (if it exists) (see: http://www.fda.gov/cdrh/).

For each manufacturing facility listed, describe the specific device or assay system that is manufactured. Include the proprietary name of the device; specific features of the device or assay including convenience or ease of use, durability or useful life, whether it is intended as a single-use or multi-use device or multiple assays. Also include whether the manufactured device, assay system, or product is labeled with a finite shelf-life. List specific factors that determine the product's labeled shelf-life and discuss the technical feasibility of extending the product's shelf-life.

Describe the existing inventory, production cycle time, baseline production rates and current surge capacity for the manufacture of the product and all required consumables (such as assay cartridges and required reagents). If the manufacturing facility is located in the U.S., describe specific dependencies on raw materials from non-domestic sources, and the feasibility of converting to domestic sources for these raw materials.

Describe the storage requirements for the product and any consumables including pallet size (footprint), number of units per pallet, and special environmental requirements (e.g., temperature, humidity, light-UV protection, etc.) and current storage capabilities (or feasibility of expanding such storage) for the product and any consumables at this manufacturing facility that might enable stockpiling of required consumables or spare parts under a vendor managed inventory; and the ability to track distribution of the product after it has left the manufacturing facility.

For new technologies, describe how it may potentially enhance existing device or assay performance or manufacturing capabilities. For devices or bioassays/biomarkers under development, describe anticipated comparability to currently-marketed devices or bioassays/biomarkers with respect to:

a) Functionality in adverse conditions of humidity, temperature, dust, and electronic drift or susceptibility to power fluctuations,

b) Convenience of use (required training and operator dependence) of the device or bioassay system,

c) Durability, anticipated useful life, potential for re-use, shelf-life (if applicable),

d) Production (manufacture) as well as bioassay/cycle times (and biomarker kinetics, if known), and,
e) Source materials and source material constraints on manufacture.

If applicable, describe the stage of integration into existing device designs (i.e. radiation detector in a standard civilian device or platform). If seeking agency or industrial standards certifications i.e. NIOSH, NIST, CIRMS, or IEEE (see: http://www.cirms.org/library/CIRMS%204th%20Report%20on%20Needs%20in%20Ionizing%20Radiation%20Measurements.pdf and http://standards.ieee.org/getN42/index.html), describe the current stage in the certification process and timeline to clearance. If seeking FDA device clearance (http://www.fda.gov/cdrh), describe the current stage in the regulatory process and anticipated timeline to certification.

• Operational Capability (includes key personnel - qualifications and experience): This section will briefly describe the Company's personnel, qualifications and experience in similar development efforts. The qualifications of the principal technical team leaders should be included in the White Paper and should describe the extent of your team's past experience in working with or developing technologies that comprise your solution.

• Cost of the Product and Contact Information: The White Paper should provide a brief summary of the cost of the product, volume discounts, cost of associated peripherals (i.e. required sample holders, assay cartridges, reagents, and other consumables) and cost of maintenance of the product, including replacement parts. Describe all required material, such as previously developed technology, test facilities, or other information that must be provided by the Government to support the proposed work. Include in Frame 4 of the QUAD chart the necessary contact information.

• QUAD Chart Format – QUAD charts will not use any font smaller than 12-point, except in graphics or tables, which may use 10-point fonts, and will be organized as follows (see template below):

QUAD Chart Template:

Executive Summary and Utility to BARDA: Provide a simple but sufficiently detailed graphic that will convey the main idea of the final capability and context for the concept and any prototype(s), and its technological methodology.	**Proposed Technical Approach:** 1. Explain how the technology or product would meet and/or exceed the requirement/goals detailed in any, or all four, of the RFI objectives. 2. Describe the technology or product, sample throughput capabilities, and manner of data presentation. 3. Describe current status of the proposed technology or product, and, 4. Describe any related ongoing efforts on technical improvements.
Operational Capability: 1. Performance targets 2. Quantify performance for key parameters 3. Key personnel, and, 4. Address how the proposed technology or product satisfies any or all of the four RFI objectives.	**Costs & Contact Info:** <u>Costs of the product</u>: Describe the total costs of the technology or product, economy of scale, and include all peripheral needs such as hardware, software, reagents and data presentation. <u>Corporate Information</u>: You must include: product name, company name, and POC (full name, address, phone numbers, and e-mail).

Data obtained from this RFI will be used by BARDA in making recommendations and decisions on the development of an appropriate advanced development and/or procurement strategy for meeting civilian dosimetry needs following a radiologic or nuclear event.

All information submitted to BARDA will be kept confidential as allowed by relevant Federal law.

Information must be submitted by 4:00 p.m. (DST) on **July 7, 2008.** Include the name, email address and telephone number of a primary contact point at your organization for this RFI in the event that BARDA has additional questions or requires clarification on the submitted information. Responses are limited to 10 pages plus the QUAD chart (QUAD chart cannot be an embedded image format).

Historically Black Colleges and Universities (HBCU), Minority Institutions (MI), Small Business concerns, Small Disadvantaged Business concerns, Women-Owned Small

Business concerns, Veteran-Owned Small Business concerns, Service-Disabled Veteran-Owned Small Business concerns, and Historically Underutilized Business Zone (HUBZone) small businesses concerns are encouraged to submit white papers. They are also encouraged to join others as team members in submitting white papers.

Please provide one (1) hard copy and one (1) CD to the primary point of contact whose address is noted below. In addition please e-mail one (1) electronic copy in PDF format to carl.newman@hhs.gov . No collect calls will be accepted. No facsimile transmissions will be accepted. In your submission, indicate if the product or item meets the Federal Acquisition Regulations (FAR) definition of "commercial item" as specified in FAR 2.101. The type of business submitting the response (i.e., small business, large business, hub-zone, small and disadvantaged business, etc.) must be identified in your response. Use "Not exceeding 500 employees" as the small business size standard for responses to this RFI. If the product can be acquired on a GSA schedule, VA schedule, or other Government-wide acquisition vehicle, please supply the contract title and number, contract point of contact information and the name of the awarding agency.

Contracting Office Address:
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