



# Prophylactic Ionizing Radiation Protection Capability

*October 10, 2015*

Fiscal Year 2015 Report to Congress



Homeland  
Security

# Message from the Secretary

October 10, 2015

I am pleased to submit the following report, "Prophylactic Ionizing Radiation Protection Capability," which has been prepared by the Department of Homeland Security (DHS) Science and Technology Directorate.

This report was prepared pursuant to language in House Report 113-481 accompanying the *Fiscal Year 2015 DHS Appropriations Act* (P.L. 114-4).

Pursuant to congressional requirements, this report is being provided to the following Members of Congress:



The Honorable John R. Carter  
Chairman, House Appropriations Subcommittee on Homeland Security

The Honorable Lucille Roybal-Allard  
Ranking Member, House Appropriations Subcommittee on Homeland Security

The Honorable John Hoeven  
Chairman, Senate Appropriations Subcommittee on Homeland Security

The Honorable Jeanne Shaheen  
Ranking Member, Senate Appropriations Subcommittee on Homeland Security

Should you have any questions, please contact the Department's Deputy Under Secretary for Management and Chief Financial Officer, Chip Fulghum, at (202) 447-5751.

Sincerely,

A handwritten signature in black ink, appearing to read "Jeh Charles Johnson". The signature is stylized with large loops and a long horizontal stroke extending to the right.

Jeh Charles Johnson



# Prophylactic Ionizing Radiation Protection Capability

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# I. Legislative Language

This report was prepared pursuant to language in House Report 113-481 accompanying the *Fiscal Year 2015 Department of Homeland Security (DHS) Appropriations Act* (P.L. 114-4).

House Report 113-481 states:

## Prophylactic Radiation Protection Capability

The Committee directs the Secretary to report, not later than 120 days after the date of enactment of this Act, on cooperation between DoD's Chemical Biological Medical Systems Directorate and the Armed Forces Radiobiology Research Institute regarding a mature prophylactic radiation protection capability for America's military. The report should include an assessment of how that capability might be developed to include rapid distribution to the civilian population in the event of a nuclear or radiological incident.

## II. Introduction

The U.S. Department of Homeland Security (DHS) takes part in an intergovernmental relationship to develop threat assessments and facilitate distribution of countermeasures from the Department of Health and Human Services (HHS)-maintained Strategic National Stockpile. The Department of Defense (DOD) currently funds efforts to protect the warfighter from a radiological or nuclear event. To determine and review the composition of the Strategic National Stockpile Program assets, HHS Assistant Secretary for Preparedness and Response and the Centers for Disease Control and Prevention (CDC) consider many factors, such as current biological, radiological, nuclear, and/or chemical threats; the availability of medical and nonmedical countermeasures; and the ease of distribution, dispensation, and administration of therapeutics and supportive care.

One of the most significant factors in determining Strategic National Stockpile composition, however, is the vulnerability associated with the lack of sufficient quantity or access of medical countermeasures to protect the affected U.S. civilian population. The Strategic National Stockpile is designed for medical countermeasures to be delivered within 72 hours of exposure. Distribution of prophylactic agents (which are designed to be administered before exposure) from the Strategic National Stockpile will be most effective when distributed to populations that have not been exposed, including those sufficiently downwind from an incident or to responders deploying to an incident. These agents have limited effectiveness for already exposed populations. DOD currently has in place strategic partnerships with HHS to transition radiological or nuclear prophylactic and therapeutic (which are designed to be administered post-exposure) candidates to the Strategic National Stockpile when these candidates are mature enough for incorporation.

### III. Cooperation between the Department of Defense Chemical Biological Medical Systems Directorate and the Armed Forces Radiobiology Research Institute

Joint Project Manager - Medical Countermeasure Systems (previously the DOD Chemical Biological Medical Systems Directorate), as part of the Joint Program Executive Office for Chemical and Biological Defense, which is funded primarily by the DOD Chemical and Biological Defense Program, is the advanced developer for DOD of medical countermeasures to prevent, diagnose, and treat the effects of chemical, biological, radiological, and nuclear threats. As the advanced developer, Joint Project Manager - Medical Countermeasure Systems works closely with the U.S. Army Medical Research and Materiel Command and with civilian counterparts within the Biomedical Advanced Research and Development Authority at HHS to evaluate promising candidates identified through basic research by science and technology partners within academia, industry, and government.

A guiding principle for this partnership between the defense and civilian agencies is to leverage each other's efforts to meet both military and civilian requirements for the development of medical countermeasures against the radiological or nuclear threat. Within DOD, chemical, biological, radiological, and nuclear defense advanced development priorities are identified through the Joint Staff, and radiological or nuclear advanced development efforts proceed according to this prioritization and as funding permits. The Joint Staff is currently drafting requirements for prophylactic and therapeutic countermeasures for Acute Radiation Syndrome.

Currently, a portfolio of candidates from across the science and technology partner community is undergoing assessment by the Biomedical Advanced Research and Development Authority and DOD to determine suitability for meeting these requirements. One of the science and technology partners is the Armed Forces Radiobiology Research Institute. The Armed Forces Radiobiology Research Institute has a lead role for DOD in providing candidates for the radiological or nuclear pipeline and coordinates with Joint Project Manager - Medical Countermeasure Systems through an overarching Capability Technology Transition Agreement. The Capability Technology Transition Agreement defines the initial development of several candidate compounds/technologies to fill the existing technology gap in the area of radiation countermeasures. Product-specific technology transition agreements will be developed upon identification of more mature specific technologies. The Armed Forces Radiobiology Research Institute candidates for transition will have to compete with other

chemical, biological, radiological, and nuclear defense priorities for advanced development funding.

Candidate technologies that have demonstrated the ability to meet licensing criteria of the U.S. Food and Drug Administration (FDA), when identified and as funding permits, can transition into the advanced development pipeline for establishment of manufacturing and production processes that are compliant with the FDA.

Through this cooperative effort, a medical countermeasure that has matured sufficiently to transition to advanced development, and is able to support both DOD and civilian needs, can be jointly developed for both fielding to the military and availability for civilian use, including the Strategic National Stockpile.

## IV. Department of Homeland Security Role in Interacting with and Informing the Strategic National Stockpile

DHS has an intergovernmental relationship with the HHS Strategic National Stockpile.

The DHS Science and Technology Directorate develops Material Threat Assessments that support the Department with the issuance of Material Threat Determinations that assist the Biomedical Advanced Research and Development Authority in making decisions on the size and contents of the Strategic National Stockpile. The DHS Domestic Nuclear Detection Office produces the Radiological/ Nuclear Terrorism Risk Assessment. This assessment also informs the Biomedical Advanced Research and Development Authority on the radiological and nuclear threat to the United States and assists the Authority in making decisions on the size and contents of the medical countermeasures stockpile.

The DHS Office of Health Affairs manages the DHS Medical Countermeasures Program. The program is designed to provide emergency medical countermeasures to DHS employees, those in DHS care and custody, and mission-critical contractors and includes antivirals, antibiotics, and potassium iodide. The potassium iodide is intended for the DHS workforce assigned to an area where a radiological disaster has occurred.

The DHS Federal Emergency Management Agency provides logistical support for deploying medical elements in the event of a catastrophic event and coordinates the delivery of the needed medical countermeasures to the geographic region that has been affected by the event.

## V. Conclusion

DHS plays an integral role in developing Material Threat Assessments and issuing Material Threat Determinations that inform the Biomedical Advanced Research and Development Authority on the threat to the civilian population, and assists the Authority in making decisions on the size and contents of the medical countermeasures stockpile. HHS, in connection with state and local authorities, is responsible for the logistics of distributing materials from the Strategic National Stockpile to the affected civilian population.

DOD currently is investing in prophylactic ionizing radiation protection capabilities and leverages its relationships with HHS and other science and technology partners to integrate any transitioned candidates into the Strategic National Stockpile.