



DEPUTY SECRETARY OF DEFENSE
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JUL 23 2015

MEMORANDUM FOR SECRETARY OF THE ARMY
SECRETARY OF THE NAVY
SECRETARY OF THE AIR FORCE
UNDER SECRETARY OF DEFENSE FOR ACQUISITION,
TECHNOLOGY AND LOGISTICS

SUBJECT: Implementation of the Recommendations in the Comprehensive Review Report:
Inadvertent Shipment of Live *Bacillus anthracis* (Anthrax) Spores by Department of
Defense

On May 22, 2015, the Department of Defense (DoD) became aware that live anthrax spores, believed to have been inactivated, had been shipped to a commercial laboratory from the Army's Dugway Proving Ground (DPG). The Department took immediate action to ensure the safety of everyone involved and to understand the scope of the problem. The Centers for Disease Control and Prevention (CDC) immediately launched an investigation and reported their findings to DPG on June 5, 2015. On May 29, 2015, I tasked the Under Secretary of Defense for Acquisition, Technology and Logistics (USD(AT&L)) to lead a 30-day comprehensive review of DoD laboratory procedures, processes, and protocols associated with inactivating anthrax consisting of 1) root cause analysis for the incomplete inactivation of anthrax; 2) DoD laboratory biohazard safety procedures and protocols; 3) laboratory adherence to established procedures and protocols; and 4) identification of systemic problems and the steps necessary to fix those problems. This review was conducted by a team of technical experts. The Comprehensive Review Report of DoD laboratory procedures, processes, and protocols associated with inactivating *Bacillus anthracis* spores was finalized on July 13, 2015.

I have reviewed this Report as well as the CDC's report and the recommendations from the USD(AT&L). The report substantiates that DoD sent live anthrax to 86 labs in 20 states, the District of Columbia, and seven countries. I take no comfort in the fact that no one was infected, and that public safety risks were very low as a result of these shipments. This was an inexcusable institutional failure. The CDC found that DPG failed to adequately inactivate anthrax spores and failed to validate that the inactivation was successful before creating samples that would be released from the facility. The Review Committee's key finding is that there is a lack of specific validated standards to guide the development of protocols, processes, and quality assurance measures for the irradiation and viability testing of inactivated anthrax spores. Further, the Review Committee found that laboratory protocols and procedures are not standardized amongst the DoD laboratories and recommended that a standardization effort be pursued.

USD(AT&L) has endorsed the findings recommendations of the Review Committee. In addition, he recommended that the Army conduct a formal investigation of the institutions and

individuals at DPG, including the chain of command, as well as the actions of DPG that led to the inadvertent widespread shipments of viable anthrax spores.

To ensure that the recommendations of the Report are effectively implemented and that a similar incident does not occur in the future, I direct the following:

The USD(AT&L) will:

- Work with DoD stakeholders, the CDC, and other relevant departments and agencies to develop a plan for research related to the development of standardized irradiation and viability testing protocols;
- Establish standards, in coordination with DoD stakeholders, the CDC, and other relevant departments and agencies, for irradiation and viability testing using the results of research conducted;
- Ensure sufficient funding is available through the Chemical and Biological Defense Program for research related to the development of standardized irradiation and viability testing protocols;
- Review, and revise as necessary, DoD biosafety and biosecurity policy and ensure consistent application across DoD laboratories; and
- Oversee Military Department and Service implementation of the Review Committee's recommendations.

The Secretary of the Army will:

- Conduct a full accountability assessment of the responsible institutions and individuals at DPG, including the chain of command, to include initiating a formal investigation by an appropriate investigative organization, of the specific actions at DPG that contributed to the unintended and unacknowledged shipment of viable anthrax spores to a large number of recipients;
- In coordination with the Secretary of the Navy, develop an implementation plan for addressing the specific recommendations in the Report on quality assurance, peer review, and program management;
- Provide the implementation plan to me for review in 30 days, with quarterly updates on progress thereafter;
- Review laboratory missions and chains of command and provide policy and organizational recommendations to ensure consistent application of biosafety and biosecurity policies across the laboratories; and
- Assess the optimal distribution of research, development, and production activities at the laboratories that support the Chemical and Biological Defense Program mission to develop countermeasures for the warfighter against chemical and biological threats.

In addition, I am designating the Secretary of the Army as the DoD Executive Agent for the DoD Biological Select Agent and Toxin (BSAT) Biosafety Program. As the DoD Executive Agent for the DoD BSAT Biosafety Program, the Secretary of the Army shall be responsible for the technical review, inspection, and harmonization of biosafety protocols and procedures across DoD laboratories that handle BSAT and shall have tasking authority of all DoD components for

this purpose. The Army shall designate a certified biological safety officer to execute this responsibility.

Until all the recommendations in the Report are addressed, I direct the moratorium on the production, handling, testing, and shipment of inactivated anthrax, except as required for the development of standardized, peer-reviewed, validated protocols for inactivation and viability testing. USD(AT&L) will work with all DoD and interagency stakeholders to mitigate the impacts of the continuing moratorium on important research, development, and production activities related to the development of countermeasures to protect the warfighter and the Nation from biological threats.

A handwritten signature in black ink, appearing to read "Robert M. Gates". The signature is fluid and cursive, with a large initial "R" and "G".

cc:
Chairman of the Joint Chiefs of Staff
Under Secretary of Defense for Policy
Under Secretary of Defense for Personnel and Readiness