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ACQUISITION,
TECHNOLOGY,
AND LOGISTICS

ACTION MEMO

July 22, 2015

FOR: DEPUTY SECRETARY OF DEFENSE

FROM: Frank Kendall, USD(AT&L) 22 July 2015

SUBJECT: Report of the Comprehensive Review of Department of Defense Laboratory Procedures, Processes, and Protocols Associated with Inactivating *Bacillus anthracis* (Anthrax) Spores

- In response to your direction of May 29, 2015, following the discovery that viable anthrax spores, which were supposed to have been inactivated by irradiation, had been shipped to a commercial laboratory, I commissioned an independent, 30-day review of the Department of Defense's (DoD) procedures for inactivating and verifying inactivation of anthrax spores. Attached at Tab B is the final Report of the Comprehensive Review Committee of DoD laboratory procedures, processes, and protocols associated with inactivating anthrax spores. This Report is the consensus product of a team that included subject matter experts from the Departments of Agriculture, Defense, Energy, and Homeland Security, and the Federal Bureau of Investigation. A list of team members is in Appendix C of Tab B.

- The Comprehensive Review Committee's key findings are:

  - In certain cases, DoD procedures to irradiate and kill live anthrax spores, and to test the viability of irradiated (and presumed inactivated) samples, are ineffective.

  - The primary systemic issue responsible for failures in the preparation of inactivated anthrax spores is the lack of specific validated standards to guide the development of protocols, processes, and quality assurance measures (Page 16).

  - The development and implementation of ineffective irradiation and viability testing procedures took place over the last decade; this represents an institutional problem particularly at Dugway Proving Ground (DPG; Page 13).

  - Inactivated anthrax originating from DPG are the only samples that have tested positive for live anthrax (Page 12).

  - The confluence of large production quantities associated with DPG, low sampling volume of the inactivated material for viability testing, and a very short time period between the completed irradiation cycle and start of the viability testing may have exacerbated the likelihood of not properly identifying live anthrax spores in inactivated samples (Page 12).

- Laboratory biosafety protocols and procedures are not standardized amongst the DoD laboratories (Page 16); this is potentially due to the fact that the laboratories are managed under multiple chains of command (Page 18, TAB C).

- The Comprehensive Review Committee's recommendations are grouped into three broad areas. The Review Committee recommends DoD laboratories that work with hazardous select agents and other pathogens:

  - Enhance quality control programs, particularly regarding inactivation and viability testing protocols.

  - Establish anthrax spore inactivation and viability testing protocols that are based on relevant scientific data, standards, and studies conducted to fill knowledge gaps.

  - Improve program management to ensure adequate laboratory space, equipment, and time to conduct relevant research for select agents and other pathogens.

- After a careful reading of the Comprehensive Review Report and discussion with subject matter experts, my conclusion is that while this is an institutional failure that spanned more than a decade and involved multiple organizations and multiple leadership changes, there is nevertheless significant evidence from previous incidents that steps should have been taken to address the problems identified by the Review Committee, particularly at DPG. The Review Committee's findings and the viability testing conducted since the discovery that viable anthrax spores had mistakenly been shipped, confirms that the only institution known to have experienced a failure to inactivate and detect failed inactivation was the Army's DPG. I agree with the Review Committee that the combination of unique characteristics at DPG, to include high volume production, low sampling size, intentionally impure products, and more immediate post-inactivation viability testing are possible contributing factors. However, the Report also indicates that in recent years DPG has had a relatively high incidence (20%) of post-inactivation viability tests that showed unsuccessful inactivation, but failed to address all the root causes of this high incidence.

- In my opinion, the technical leadership at DPG, particularly the individuals who are responsible for the safe processing and shipping of inactivated anthrax spores, should have been well aware of the statistical natures of both anthrax spore inactivation by irradiation and post-inactivation viability testing, as well as of the degree to which DPG was operating outside the parameters of the available scientific data on anthrax inactivation, specifically with respect to spore concentration. In addition, there are indications in the Report that the Microbiology Office of the Life Sciences Division at DPG was not keeping adequate records, failing to ensure current procedures were documented correctly, or following laboratory best practices. Although the Review Committee found that the problems at DPG did "not necessarily reflect on any one individual," I believe that individual accountability should be investigated more completely. As a result, I recommend that in addition to implementation of the Review Committee recommendations, you direct the Army to conduct a thorough formal investigation of the institutions and individuals at DPG, including the chain of command, that are responsible for the widespread, unintended viable anthrax spore shipments.

- I agree with the Review Committee's conclusion that the science of anthrax inactivation is not adequately understood and that additional work is needed to establish effective standards and protocols for inactivation and viability testing; this is an institutional problem that involves organizations outside the Department. The problem has existed for ten years, and the Review Committee's observations and recommendations apply to all DoD labs that conduct inactivation of anthrax. It is clear that the situation must be corrected per the recommendations of the Review Committee, with particular focus on a re-evaluation of both the underlying science and the structure of the DoD biological laboratory system.

- To ensure that the recommendations of the Report are effectively implemented and that a similar incident does not occur in the future, I recommend you sign the Memorandum at TAB A that directs:

  - The Secretary of the Army, in coordination with the Secretary of the Navy, to 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 you for review in 30 days, with periodic updates on progress quarterly 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 in support of the Chemical and Biological Defense Program mission to develop countermeasures for the warfighter against chemical and biological threats.

  - The Secretary of the Army initiate 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.

  - Designation of 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.

  - My office to work with DoD stakeholders, the Centers for Disease Control and Prevention (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.

- Continuation of the moratorium on the production, work with, and shipment of inactivated anthrax until all recommendations are addressed, except as required for the development of standardized, peer-reviewed, and validated protocols for inactivation and viability testing.

COORDINATION: OGC

RECOMMENDATION: Sign memorandum at TAB A.

Attachments:
TAB A: DSD Implementation of the Recommendations in the Comprehensive Review Report: Inadvertent Shipment of Live *Bacillus anthracis* (Anthrax) Spores by Department of Defense
TAB B: Comprehensive Review Report
TAB C: DoD Laboratory Chains of Command