Opening Statement

Dr. David C. Hassell, Deputy Assistant Secretary of Defense
for Chemical, and Biological Defense Programs

Hearing of the

House Energy and Commerce Oversight and Investigations Subcommittee

On

Shipment of Inactivated *Bacillus anthracis* (Anthrax)

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Not for Public Release until Approved by the

House Energy and Commerce Oversight and Investigations Subcommittee

Chairman Murphy, Ranking Member DeGette, Distinguished Members of the Subcommittee, thank you for this opportunity to brief you on the Department of Defense's inadvertent shipments of samples containing live *Bacillus anthracis* spores ("anthrax").

Use of inactivated anthrax remains an important element of longstanding Department of Defense (DoD) programs to develop ways to protect warfighters and the public from known biological threats. Inactivated (or dead) anthrax has been used to develop detection systems, protection equipment, diagnostics, and decontamination capabilities. It is also used for training, validation and testing of existing biodetection and diagnostic systems throughout the country. To ensure that the Department obtains the best technologies for national security, those development efforts, including research projects, involve partnerships with many other government organizations, industry, academic institutions and Allies.

We first learned of these incidents on May 22, 2015, when the Centers for Disease Control and Prevention (CDC) received a call from a private company regarding the growth of live anthrax in a sample that was inactivated by a laboratory at the Army's Dugway Proving Ground, Utah. The company was involved in a competitive procurement for new detection systems, and decided to test their sample before using it to ensure it had been inactivated. The CDC immediately

began an investigation, working with DoD laboratories, state officials, and the Federal Bureau of Investigation.

By May 25, 2015, all known laboratories that received inactivated anthrax samples from that same batch had been notified and instructed to stop working with the samples and to follow CDC instructions. Also on May 25, 2015, the four DoD laboratories that produce inactivated anthrax in support of defensive research and development (i.e., Dugway Proving Ground, U.S. Army Medical Research Institute of Infectious Diseases, Naval Medical Research Center and the Edgewood Chemical Biological Center) were directed to stop producing, shipping and working with any inactivated anthrax, other than for purposes related to this current matter.

Subsequent tests by Dugway of other batches of inactivated anthrax identified as containing live anthrax. Recipients of samples from those batches were notified and instructed to stop working with the samples and to follow CDC instructions. As a further precaution, beginning on June 2, 2015, the Department of Defense notified all known recipients of inactivated anthrax from Dugway to stop working with the material, whether it was confirmed to contain live anthrax or not.

There are no known or suspected cases of anthrax infection among workers at any of the laboratories that produced or received inactivated anthrax, and there is no

known risk to the general public and very little risk to laboratory workers. This is due to the low concentration of live anthrax in the samples, the samples were in liquid, and the sample vials were securely packed and transported in accordance with the Department of Transportation and International Air Transport Association requirements. As a precaution, 31 U.S. citizens (8 non-DoD and 23 DoD) were initially placed on post-exposure prophylaxis after an evaluation of their use of biosafety practices, which were appropriate for inactivated anthrax but not for live anthrax; 2 non-DoD citizens subsequently discontinued treatment. All personnel are expected to have completed post-exposure prophylaxis by July 31, 2015. Personnel from other countries did not require post-exposure prophylaxis.

Returning to the subject of the four DoD Laboratories that produce inactivated anthrax, on May 29, 2015, the Deputy Secretary directed that those four DoD laboratories test previously inactivated anthrax in inventory to identify the presence of live spores. Testing of the samples is now complete, and the results are as follows:

Since 2003, the four DoD laboratories irradiated a total of 149 batches of live anthrax spores and reported them as inactivated and safe for subsequent testing. Every one of those batches have been accounted for and either tested or destroyed.

Fifty three of the 149 batches are no longer in DoD inventory. Of the remaining 96 samples available to test, 17 of those 96 tested positive for the regrowth or presence of live anthrax, and every one originated from Dugway Proving Ground.

In other words, of the total batches in Dugway's inventory, 17 of 33 batches tested positive, which is over 50%.

We now know that over the last 12 years, 86 laboratories in 20 states, the District of Columbia, and seven foreign countries ultimately received inactivated spores that were live, all directly from Dugway. In addition, the CDC has informed us that an additional 106 labs received "secondary transfers" from some of the original 86 recipient labs. This brings the total to 192 labs in all 50 States, the District of Columbia, and 3 Territories (Guam, Puerto Rico, The U.S. Virgin Islands).

Also on May 29, Deputy Secretary of Defense Work directed the Under Secretary of Defense for Acquisition, Technology, and Logistics (USD(AT&L) to oversee a Comprehensive Review, focusing on:

- The root causes of the incomplete inactivation of anthrax;
- DoD laboratory biosafety procedures and protocols relating to the inactivation of anthrax;
- Laboratory adherence to established procedures and protocols; and

- Identification of systemic problems and the steps necessary to fix those problems.

The DoD Comprehensive Review was completed on June 30. The 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.
- 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).
- Inactivated anthrax originating from DPG are the only samples that have tested positive for live anthrax.
- 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.

- Laboratory biosafety protocols and procedures are not standardized amongst the DoD laboratories; this is potentially due to the fact that the laboratories are managed under multiple chains of command.

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.

In a memorandum dated 23 July, 2015, the Deputy Secretary of Defense directed the following:

- The Under Secretary of Defense for Acquisition, Technology and Logistics (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:

- The Secretary of the Army is designated as the DoD Executive Agent for the DoD Biological Select Agent and Toxin (BSAT) Biosafety Program.
- Continuation of 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, until all the recommendations in the Report are addressed.
- 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.

The Department is committed to putting in place the systems so that ensure that this does not occur again, and will implement the recommendations of the Report and the further directives outlined by Deputy Secretary Work on July 23. DoD and CDC continue to work closely to understand the issues relating to the inactivation of anthrax and necessary changes to the viability testing protocol in order to respond to the findings of the investigation and review. In the interim, the DoD

moratorium on producing, shipping and working with any inactivated anthrax, other than for purposes related to developing the science basis for irradiation and viability testing, will remain in effect.

Our top priority is the safety of all involved, and we remain fully committed to complete transparency of information. Thank you for the opportunity to testify today and I welcome your questions.