EXECUTIVE SUMMARY

AR 15-6 INVESTIGATION REPORT – INDIVIDUAL AND INSTITUTIONAL ACCOUNTABILITY FOR THE SHIPMENT OF VIABLE *BACILLUS ANTHRACIS* FROM DUGWAY PROVING GROUND

December 17, 2015

Background: On 22 May 2015, a private company notified the Centers for Disease Control and Prevention (CDC) that it found a low concentration of viable (live) *Bacillus anthracis* spores in a shipment from the U.S. Army that should have only contained non-viable (dead) spores. The CDC notified the Department of Defense (DoD) of this unauthorized shipment of viable *Bacillus anthracis* and determined that the material originated at Dugway Proving Ground (DPG), Utah. As a result, the CDC and the DoD investigated DPG's history of *Bacillus anthracis* inactivation and determined that between 2004 and 2015, the Life Sciences Division at DPG (DPG-LSD) prepared a total of 86 lots of inactivated *Bacillus anthracis*, in support of the Critical Reagents Program (CRP) at Fort Detrick, Maryland. The CRP serves as a source for biological materials (such as inactivated *Bacillus anthracis*) used to develop countermeasures required to protect U.S. military forces from biological threats. The CRP maintains its Antigen Repository at DPG-LSD. The CRP routinely directs the shipment of biological materials produced at the Antigen Repository at DPG-LSD to external government and commercial laboratories involved in countermeasure development. The CRP Antigen Repository is the only DoD laboratory engaged in large-scale production and shipping of select agents to external entities.

At the time of production, DPG-LSD conducted viability testing that demonstrated that no live *Bacillus anthracis* remained, so a death certificate was issued for each of these 86 lots. Following the 22 May 2015 discovery by the private company, DPG-LSD used a newly developed CDC protocol to re-test the viability of the lots of inactivated *Bacillus anthracis* remaining in its inventory (33 of the original 86). Results showed that 17 of the 33 lots contained low concentrations of viable spores. It is still unclear whether or not this newly developed testing protocol would have identified the live *Bacillus anthracis* had DPG-LSD utilized it when originally conducting the viability test, or if some unknown scientific phenomenon allowed the spores to "heal" in the intervening time period. Ultimately, CDC, with support from DoD, determined that over a 12-year period samples from these 17 lots had been sent to 194 laboratories in all 50 states, the District of Columbia, three territories and nine foreign countries.

In response, DoD instituted a variety of measures to safeguard public health, including directing a 30-day review of the DoD's safety practices for generating and handling inactivated *Bacillus anthracis*. The findings of this 30-day review were documented in a report on 13 July 2015 (*Review Committee Report: Inadvertent shipment of live Bacillus anthracis spores by DoD*). On 23 July 2015, DoD issued a moratorium on the shipment of inactivated *Bacillus anthracis*. The Secretary of the Army, in an abundance of caution, subsequently directed safety reviews at all Army laboratories working with *Bacillus anthracis* and other deadly pathogens. He expanded the DoD moratorium to include all biological select agents and toxins (not just

Bacillus anthracis). He also directed the formation of two teams to address this situation. One team, led by LTG Thomas Spoehr, was tasked to prepare a comprehensive implementation plan to address the findings and recommendations of the 13 July 2015 DoD report. The second team, led by MG Paul Ostrowski, was tasked with conducting an investigation, under Army Regulation 15-6, into the facts and circumstances that contributed to the unintended and unacknowledged shipment of viable *Bacillus anthracis* spores from DPG-LSD.

The 15-6 investigation team reviewed the reports prepared by the CDC and DoD. The team developed an investigative plan and visited laboratories at the Edgewood Chemical and Biological Center (ECBC) and the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) to obtain a basic understanding of the science, organizational structure, and functions at two of the primary facilities working with *Bacillus anthracis*. From 17-21 August 2015 the team traveled to DPG-LSD to gather evidence. During the evidence gathering process, the 15-6 investigation team conducted environmental sampling and found contamination outside of primary containment in one of the laboratories at DPG-LSD. The CDC was notified, and in response conducted a re-inspection of DPG-LSD on 27-28 August 2015. On 28 August 2015, CDC suspended the certificate of registration for DPG-LSD to possess, use, and transfer *Bacillus anthracis* and directed that all *Bacillus anthracis* in DPG-LSD's possession be securely stored to prevent theft, loss, or release. On 31 August 2015, CDC suspended DPG-LSD's certificate of registration for all select agents. The remainder of this Executive Summary focuses on the findings and recommendations of the 15-6 investigation. All references to DPG and DPG-LSD leadership and management address only the specific individuals identified in the findings and recommendations of the 15-6 report of investigation.

<u>Findings</u>: The inadvertent shipment of viable *Bacillus anthracis* is a serious breach of regulations, but did not pose a risk to public health. Over the years, significant safeguards effectively ensured that the inadvertent shipments were not a threat. The preponderance of the evidence supports a finding that no individual or institution was directly responsible for the unauthorized shipment of low concentrations of viable *Bacillus anthracis*. However, several findings related to scientific, institutional, and individual failures may have been contributing factors.

Scientific: The 15-6 investigation team identified a number of scientific issues related to the production, inactivation and post-inactivation viability testing of *Bacillus anthracis*:

(1) There is a fundamental disconnect between science and regulatory policy. Current regulations require laboratories possessing even one viable *Bacillus anthracis* spore to register with the CDC. Laboratories possessing "non-viable" (i.e., 100% inactivated) *Bacillus anthracis* are exempt from this requirement, allowing a greater number of laboratories to work with *Bacillus anthracis*. Statistically, the only way to guarantee a sample is non-viable (i.e., contains zero viable spores) would be to test and consume 100% of the batch or sample. This is not practical as no material would remain available for use after viability testing. Therefore, the current regulatory policy doesn't account for the uncertainty associated with the inactivation process and impedes research capabilities by imposing an overly stringent, statistically unattainable requirement.

(2) There is a lack of scientific research regarding the gamma irradiation inactivation methods developed for *Bacillus anthracis*. Data regarding resistance properties of different strains of *Bacillus anthracis* to radiation is limited. Furthermore, the irradiation protocols currently in use were developed using limited datasets for other variables relevant to the irradiation process, including sample purity/concentration. These gaps in science must be closed to ensure that irradiation protocols are effective.

(3) There is a lack of scientific research regarding the ability of *Bacillus anthracis* spores to repair/heal following irradiation. Previous research supports the theory that *Bacillus anthracis* spores may undergo DNA repair following insult (i.e., damage due to gamma irradiation), but the extent of these repair processes has not been investigated. The 22 May 2015 discovery of a low concentration of viable spores, and subsequent positive re-test results of lots that had been irradiated as much as ten years earlier, highlights the potential importance of this gap in scientific understanding.

(4) There is a lack of scientifically validated and standardized protocols for both the irradiation of *Bacillus anthracis* and post-irradiation viability testing. The protocols for irradiation and viability testing used by each DoD laboratory are different and likely vary in effectiveness. The CDC viability testing protocol which identified viable spores in 17 of the 33 remaining lots was developed after the 22 May 2015 discovery and is evidence that a standardized, scientifically validated protocol is necessary.

Institutional: The 15-6 investigation team identified several institutional factors that may have contributed to the inadvertent shipment of viable *Bacillus anthracis*:

(1) Funding restraints, competing mission requirements and priorities, and finite resources present challenges to program and installation managers. Reductions in staff at DPG-LSD resulted in tasking personnel with additional duties and led to ineffective execution of critical processes. Management failed to allocate sufficient resources to crucial areas such as quality assurance/quality control. Additionally, one witness at DPG-LSD voiced a concern that competition for funding between different organizations/laboratories led to an unwillingness to collaborate and share information. The preponderance of the evidence does not support this claim. Although Army laboratories working with select agents receive most of their funding from the same sources, the work conducted is mostly complementary, not competitive. DPG-LSD, for example, is the only laboratory engaged in large scale production for external entities.

(2) The Army and Navy laboratories working with biological select agents and toxins report to four separate chains of command resulting in inefficient data flow. The lack of unity of command also resulted in each organization using different procedures and protocols. The current structural alignment lacks an overall executive agent to provide oversight and to manage and allocate resources for the DoD biological laboratory enterprise.

(3) Inspections failed to assess critical issues relating to inactivation and viability testing of *Bacillus anthracis*, and the frequency and scope of these inspections are insufficient. Laboratories extensively prepare and tend to curtail select agent operations for announced inspections. Inspectors examine written procedures and observe laboratory structural/cleanliness to determine compliance to regulatory policies and procedures. They do not inspect or review

production protocols. Inspections occur only every two to three years, which may not be frequent enough to ensure that biological laboratories are operating safely and efficiently. As a result, the various issues described in the 15-6 investigation report were not uncovered by previous inspections.

Individual: The 15-6 investigation team found that a preponderance of evidence does not exist to definitively attribute culpability for the inadvertent shipment of viable *Bacillus anthracis* to an individual or group of individuals at DPG. However, the DPG-LSD leaders identified in the 15-6 investigation report created conditions allowing a culture of complacency to flourish. As a result, laboratory personnel did not always follow rules, regulations, and procedures. Certain leadership and oversight staff failed to take appropriate action, and several laboratory technicians employed questionable laboratory practices. These oversight and laboratory deficiencies may have been contributing factors, but there is insufficient evidence to establish any single failure as the proximate cause for the inadvertent shipment.

Despite multiple safety-related incidents and mishaps in the laboratories and involving shipments to external customers, DPG leadership and DPG-LSD management repeatedly failed to take action by not conducting internal investigations or determining whether disciplinary action or re-training was warranted. Instead, DPG leadership and DPG-LSD management blamed external entities or downplayed the seriousness of the incidents in reports to higher headquarters.

Personnel at DPG identified in the 15-6 investigation report routinely failed to take appropriate steps or actions that could have limited the inadvertent shipment of viable *Bacillus anthracis*. Examples of these failures include the following: i) failure to investigate and hold personnel accountable for biological mishaps, ii) failure to hold personnel accountable for poor laboratory practices, iii) failure to reasonably identify and correct long-standing deficiencies, iv) failure to adhere to production-based practices, v) failure to account for contamination that could have introduced viable *Bacillus anthracis* spores into irradiated samples, vi) failure to execute an environmental sampling program, vii) failure to maintain a viable video surveillance program, viii) failure to properly review and approve Critical Reagents Program internal policies and procedures, ix) failure to integrate the Critical Reagents Program into the DPG-LSD team, x) failure to ensure biosafety officer qualification, xi) failure to notify the chain of command of biological mishaps, and xii) failure to safeguard classified information and ensure that personnel are trained on classification guidance. Additionally, the 15-6 investigation team found evidence that certain DPG-LSD personnel manipulated and carelessly generated critical documents used to capture process data and certify the inactivation of *Bacillus anthracis* (death certificates). Evidence showed that the culture of complacency existed at DPG-LSD since at least 2008. The 15-6 investigation team cannot definitively state that the inadvertent shipments of viable *Bacillus anthracis* could have been prevented if these failures had not occurred due to the scientific gaps and other institutional issues discussed above.

<u>Recommendations</u>: The 15-6 investigation team identified specific actions the Secretary of the Army should consider related to the scope of this investigation. These actions include: directing additional research to address existing gaps in scientific knowledge, making institutional changes aimed at reducing the overall risk associated with working with biological materials, and holding certain personnel at DPG, including the leadership, accountable for their failures to eliminate the culture of complacency and ultimately prevent additional mishaps from occurring in the future.

Scientific: The investigation team recommends that the Army:

(1) Collaborate with the DoD and the CDC to revise current policy and regulations, including 42 Code of Federal Regulation part 73, to define "Non-Viable Select Agents" and to determine how to demonstrate non-viability of a select agent. Furthermore, the DoD and CDC should consider allowing exempted amounts (below an infectious dose) of material to be treated as non-select agent and consider eliminating or re-categorizing inactivated biological select agents and toxins to account for the fact that it is not possible to verify that material has been inactivated with 100% certainty.

(2) Evaluate factors that could affect *Bacillus anthracis* spore resistance to gamma irradiation, to include the strain of *Bacillus anthracis*, the concentration of spores in the solution being irradiated, the total number of spores being irradiated, and the purity of the spore solution being irradiated. Conduct carefully controlled studies using varying doses of gamma irradiation in order to evaluate each of these factors as well as the potential confounding effects of multiple factors.

(3) Evaluate the potential for gamma irradiated spores to heal. In order for growth to be detected during viability testing, dormant spores (not killed during irradiation) must germinate to begin growing. Evidence suggests that time, variance in temperature, salt content, air pressure and the presence of nutrients may affect germination and healing rates of spores. Studies are needed to better understand this putative healing phenomenon.

(4) Research viability testing of irradiated *Bacillus anthracis* spores. An effective *Bacillus anthracis* irradiation program requires the establishment of a validated means to assess the viability of the irradiated spores. In order to ensure that irradiated spores are dead, conditions should be provided to optimize the opportunity for growth. Factors to evaluate under viability testing include: length of time spores are incubated in broth and on plates, types of growth media used for incubation in broth and on plates (tryptic soy agar, brain heart infusion agar, nutrient broth, etc.), temperature(s) for incubation in broth and on plates, and the portion of the irradiated sample that should be used for viability testing.

Institutional: The Army should consider taking specific steps in each of the following areas: uniting command and consolidating facilities dealing with biological select agents; appointing an executive agent with oversight over DPG-LSD, ECBC and USAMRIID to ensure effective resource allocation and information sharing amongst the laboratories; directing a mobile training team to travel to DPG-LSD to improve laboratory processes and procedures by sharing commonly accepted practices for production facilities; establishing developmental assignments where all Army laboratories exchange personnel to facilitate collaboration and development of best practices; ensuring that biological research personnel have appropriate opportunities for professional development; implementing a formal mentorship program and providing opportunities to routinely attend conferences to promote professional education and collaboration; leveraging existing incentive programs to attract and retain highly qualified scientists to DPG; and working with the CDC to enhance the effectiveness of joint inspections.

The U.S. Army Test and Evaluation Command should verify that all personnel assigned to biosafety, biosurety, and scientific positions are qualified and that all mishaps are thoroughly investigated. The leadership at DPG and DPG-LSD should establish and maintain a quality control and quality assurance program to monitor and assess all work with biological select agents and toxins in general and *Bacillus anthracis* specifically. The DPG and DPG-LSD leadership should ensure that all standard operating procedures and work instructions governing operations at DPG-LSD are subjected to a uniform review and approval process.

Individual: The 15-6 report of investigation identifies five leaders (including two former DPG Commanders) who failed to take appropriate action in response to past mishaps and allowed a culture of complacency to exist at DPG-LSD. It identifies four personnel who failed to adequately execute oversight responsibilities and to ensure compliance with DPG protocols and Army regulations. Finally, it identifies three laboratory technicians who failed to exercise due care in the performance of their duties. The Army should consider holding these twelve individuals accountable for their failures.

<u>Summary</u>: The preponderance of the evidence does not support a finding that any individual or institutional failure was directly responsible for the unauthorized shipment of low concentrations of viable *Bacillus anthracis*. However, several scientific knowledge gaps, institutional concerns, and individual failures may have been contributing factors. Details are provided in the full report.

AR 15-6 INVESTIGATION REPORT

INDIVIDUAL AND INSTITUTIONAL ACCOUNTABILITY FOR THE SHIPMENT OF VIABLE *BACILLUS ANTHRACIS* FROM DUGWAY PROVING GROUND

24 JULY 2015 – 15 DECEMBER 2015

INVESTIGATING OFFICER
MAJOR GENERAL PAUL A. OSTROWSKI

TABLE OF CONTENTS

I. Background

On 22 May 2015, a private company notified the Centers for Disease Control and Prevention (CDC) that it received a specimen of *Bacillus anthracis*[1] spores from the U.S. Army that was assumed to be inactivated. After testing the specimen of *Bacillus anthracis,* the private company verified that the specimen contained a low concentration of live spores.[2] The inadvertent transfer of live *Bacillus anthracis* failed to follow appropriate regulatory procedures. Upon receipt of this information, the CDC began an investigation and determined that the *Bacillus anthracis* sample, which originated at Dugway Proving Ground Life Sciences Division (DPG-LSD) in Utah on 20 April 2015 and was routed through the Edgewood Chemical Biological Center (ECBC) in Maryland, was not fully inactivated and contained a low concentration of viable *Bacillus anthracis* spores.[3]

The specimen of inactivated *Bacillus anthracis* (lot AGD0001667)[4] that was found to contain viable agent on 22 May 2015 was actually prepared and inactivated via gamma irradiation by DPG-LSD in December of 2013.[5] Immediately following irradiation, viability testing was conducted and the results indicated that the sample had been properly treated and was safe to ship, so DPG-LSD prepared a death certificate for this lot of inactivated *Bacillus anthracis*.[6] The death certificate[7] certifies inactivation/non-viability which in turn exempts the *Bacillus anthracis* from the federal regulations that govern work with biological select agents and toxins.[8] At this point the sample was moved from the biosafety level-3[9] laboratory where it had been grown to a biosafety level-2 laboratory where it could be handled and stored under less restrictive conditions.[10] A total of 300 1-mL vials of lot AGD0001667 were prepared[11] and a portion of the vials were subsequently shipped to 21 different laboratories, to include both commercial and U.S. government facilities.[12]

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[1] *See* Appendix E, *Glossary*.
[2] The number of live/viable spores in the sample was low enough to not pose a threat to public health.
[3] *See* Tab D-1.a, Memorandum from the Department of Health and Human Services, Centers for Disease and Control Prevention, to (b) (6) [redacted] RE: Entity Inspection Report: Life Science Test Facility (LSTF) (5 June 2015); and Tab D-1.b, Memorandum from the Department of Health and Human Services, Centers for Disease and Control Prevention, to (b) (6) [redacted] Department of Health and Human Services OIG, subject: Life Science Test Facility (Registration #C20121022-1418) (24 July 2015).
[4] Lot AGD0001667 was known as Ames Lot 008 internal to DPG-LSD prior to shipment.
[5] *See* Tab B-5.1.d, Enclosure 3, (b) (6) [redacted], DA Form 2823, Sworn Statement (20 Aug. 2015).
[6] *See* Tab C-19, Death Certificate for Lot AGD0001667 (18 Mar. 2014).
[7] The term "death certificate" is used internally at DPG-LSD for the document utilized to indicate and record that a biological sample has been inactivated. Death certificates are not regulatory documents.
[8] 42 C.F.R. pt. 73.16.
[9] *Figure 1*, described below, provides detailed information about biosafety levels.
[10] *See* Tab B-5.1.g, Enclosure 6, page 2, (b) (6) [redacted], Sworn Statement (20 Aug. 2015). Notes taken by (b) (6) (b) (6) [redacted] on 2 Jan. 2014 discuss the 300 dead vials and their movement from Room 506 (biosafety level-3) to the CRP freezers (biosafety level-2).
[11] *Id.*
[12] *See* Tab C-27, Daily Report #34, Task Force Anthrax, Joint Program Executive Office for Chemical and Biological Defense (7 Aug. 2015). Per the standard operating procedure that was in place at the time, viability testing was not repeated prior to shipping materials after having been in storage.

On 20 April 2015, DPG-LSD shipped samples from lot AGD0001667 (along with other inactivated pathogens and test materials) to the ECBC.[13] These samples were intended to be used in a competitive evaluation of diagnostics for the detection of biological threat agents being developed by six commercial companies. The ECBC provided logistical support to this competition on behalf of the Critical Reagents Program (CRP) Management Office at Fort Detrick, Maryland. Since the competitive evaluation was "blinded" (i.e., none of the competing companies were to know what organism was contained in any of the vials that they received), all identifying markings were removed from each sample and the samples were shipped to the six companies participating in the competition.[14] After receiving the shipment, one of the six private companies involved in the competition checked the viability of the materials they received.[15] This testing revealed a low concentration of live *Bacillus anthracis* spores so the CDC was notified.[16]

As a result of this finding, in late May of 2015 the CDC notified the Department of Defense (DoD) of this unauthorized shipment.[17] The CDC and the DoD subsequently investigated DPG-LSD's past history of *Bacillus anthracis* inactivation. These investigations determined that between 2004 and 2015, DPG-LSD prepared a total of 86 lots of inactivated *Bacillus anthracis* for the CRP.[18] As of May 2015, 33 of these lots remained in inventory at DPG-LSD. Using a protocol newly developed by the CDC,[19] DPG-LSD tested the viability of the 33 remaining lots of *Bacillus anthracis* and found that 17 of the lots contained low concentrations of viable spores.[20] The CDC, with support from the DoD determined that over a 12 year period, samples from these 17 lots that contained viable *Bacillus anthracis* had been sent to 88 primary labs who then shared it with 106 secondary labs for a total of 194 labs.[21] As a result of the CDC's findings and in an abundance of caution, the DoD has taken a number of steps to further safeguard the public, review internal procedures, and determine accountability.[22] This

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[13] *See* Tab C-26, FedEx Order 11211 (8 Apr. 2015).

[14] *See* Tab C-47, Email from (b) (6) [redacted] to (b) (6) [redacted] Subject: RE: W911QY15R0018 (2 Oct. 2015).

[15] *See* Tab C-32, Solicitation No. W911QY15R0018 (16 Apr. 2015). *See also*, Tab B-44.1.a, page 6, (b) (6) [redacted] DA Form 2823, Sworn Statement (19 Aug. 2015) where she stated "antigen was being sent as a "blind" or coded sample, reading only as "ANG 1" to labs who were competing for government contracts. Coded samples have to remove any identifying characteristics that would ID them as a certain organism. Lot numbers, batch record numbers, inactivation procedure and dosages would need to be removed since scientists working with the materials could infer the strain based on their own training and experience."

[16] *See* Tab D-1b, Memorandum from the Department of Health and Human Services, Centers for Disease and Control Prevention, to (b) (6) [redacted] Department of Health and Human Services OIG, subject: Life Science Test Facility (Registration #C20121022-1418) (24 July 2015).

[17] *See* Tab 27.1.a, page 4, (b) (6) [redacted], DA Form 2823, Sworn Statement (19 Aug. 2015); Tab 11.2.a., page 8-9, Ronald Fizer, DA Form 2823, Sworn Statement (10 Sept. 2015).

[18] *See* Tab C-27, Daily Report #34, Task Force Anthrax, Joint Program Executive Office for Chemical and Biological Defense (7 Aug. 2015).

[19] *See* Tab E-7, Centers for Disease and Control Prevention, Revised Viability Testing Protocol for Samples of Inactivated *Bacillus anthracis* (2015).

[20] *See* Tab C-27, Daily Report #34, Task Force Anthrax, Joint Program Executive Office for Chemical and Biological Defense (7 Aug. 2015).

[21] Department of Defense Laboratory Review, http://www.defense.gov/News/Special-Reports/DoD-Laboratory-Review (last visited Sept. 3, 2015).

[22] *Id.*

investigation was ordered to determine whether any individuals and/or institutions are accountable for the inadvertent shipment of viable *Bacillus anthracis*.[23]

This Report of Investigation is the product of the investigation team tasked to conduct a formal investigation using informal procedures under Army Regulation 15-6, Procedures for Investigating Officers and Boards of Officers.

Section I of this report provides a broad background discussion necessary to understand the findings and recommendations. The background section includes a discussion of the history of this investigation and related investigations/reviews; the facts and circumstances surrounding the discovery of *Bacillus anthracis* spores in May 2015; an overview of relevant command structures; an overview of past biological mishaps[24] at DPG-LSD; a discussion of the observed trends at DPG-LSD; and a discussion of the scientific procedures used to irradiate and test the viability of *Bacillus anthracis* spores.

Section II discusses the findings of the investigation and documents the facts and circumstances that may have contributed to the inadvertent shipment of viable *Bacillus anthracis* spores. The findings in Section II are broken down into three general areas: Scientific, Institutional, and Individual Accountability. The Scientific findings address the knowledge gaps in science that may have contributed to the inadvertent shipment of viable *Bacillus anthracis* including: a fundamental disconnect between science and regulatory policy regarding 100% inactivation of *Bacillus anthracis*; the lack of research into gamma radiation resistance properties of *Bacillus anthracis*; the lack of research regarding post-irradiation spore recovery theory; and the lack of scientifically validated and standardized protocols for post-irradiation viability testing. The Institutional portion addresses a number of internal concerns in the Army including a perceived issue with funding and competition amongst biological research organizations, a lack of unity of command, and the efficacy of inspections. The Individual Accountability portion addresses failures and deficiencies by leadership, oversight personnel, and laboratory technicians at DPG-LSD. All findings are based on a preponderance of the evidence, research, consultation with experts, and the collective working knowledge and experience of the 15-6 investigation team.

Section III is an outline of actions the DoD and the Army should consider related to the scope of this investigation. The suggested actions are broken down in three general areas: Scientific, Institutional, and Individual Accountability.

A. 15-6 Administrative Information

On 30 July 2015, the Secretary of the Army directed the Director of the Army Staff to conduct a full accountability assessment of the responsible institutions and individuals at DPG, including the chain of command. The Secretary directed the investigating officer to conduct an

[23] *See* Tab A-1, Memorandum from the Secretary of the Army, to Director of the Army Staff, subject: Appointment of Army Regulation 15-6 Investigating Officer (30 July 2015).

[24] For the purposes of this investigation a mishap is defined as a mistake and is not synonymous with a mishap as defined in U.S. DEP'T OF ARMY, REG. 385-10, ARMY SAFETY PROGRAM, glossary (27 Nov. 2013) [hereinafter AR 385-10]. *See* Appendix E, *Glossary*.

investigation of the specific actions at DPG that may have contributed to the unintended and unacknowledged shipment of viable *Bacillus anthracis* spores.[25] On 30 July 2015, the Director of the Army Staff appointed Major General Paul A. Ostrowski as the investigating officer.[26] The investigating officer assembled an investigatory team,[27] requested and received an extension of time,[28] and conducted the investigation from 30 July 2015 to 15 December 2015.[29]

In accordance with the Army Regulation 15-6 Appointment Memorandum dated 30 July 2015, the Director of the Army Staff defined the scope of the investigation as follows:

> *a. You are directed to investigate and document the facts and circumstances that contributed to the unintended and unacknowledged shipment of viable Bacillus anthracis (anthrax) spores from DPG to a large number of recipients. You will investigate the actions of all institutions and individuals at DPG, including the chain of command, which contributed to the inadvertent widespread shipments of viable anthrax spores.*
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> *b. Among other things, investigate the actions taken by individuals who are responsible for the safe processing and shipping of inactivated anthrax spores. Determine whether those personnel were aware of the statistical nature of both anthrax spore inactivation by irradiation and post-inactivation viability testing, as well as the degree to which DPG was operating outside the parameters of the available scientific data on anthrax inactivation. Assess the reasonableness of the actions and control measures taken by those personnel with the authority to prevent unsafe practices and procedures.*
>
> *c. Additionally, investigate whether DPG kept adequate records, ensured current procedures were documented correctly, and followed laboratory best practices. Document in your investigation report any failures in these areas and assess whether any individuals at DPG reasonably could have prevented the inadvertent and unacknowledged shipment of viable anthrax spores.*
>
> *d. Before you begin your investigation, you will review a copy of the investigation conducted by the Centers for Disease Control and Prevention, as well as Office of the Secretary of Defense's (OSD) Comprehensive Review Report.*
>
> *e. Your report of investigation should specifically assess whether any institutions and individuals at DPG should be held accountable for any failures or*

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[25] *See* Tab A-1, Memorandum from the Secretary of the Army, to Director of the Army Staff, subject: Appointment of Army Regulation 15-6 Investigating Officer (30 July 2015).
[26] *See* Tab A-2, Memorandum from the Director of the Army Staff, to Major General Paul A. Ostrowski, subject: Appointment as Investigating Officer (30 July 2015).
[27] *See* Tab A-3, Memorandum for Record, subject: Special Investigative Team (Aug. 2015).
[28] *See* Tab A-4, Memorandum from Major General Paul A. Ostrowski, to the Director of the Army Staff, subject: Extension (Aug. 2015); Tab A-5, Memorandum from the Director of the Army Staff, to Major General Paul A. Ostrowski subject: Extension (Aug. 2015).
[29] *See* Appendix F, *Timeline*.

deficiencies that may have contributed to unintended and unacknowledged shipments of viable anthrax spores, and make specific recommendations for appropriate action.[30]

The 15-6 investigation team began by reviewing the investigation conducted by the CDC[31] and the 13 July 2015 *DoD Review Committee Report, Inadvertent Shipment of Live Bacillus anthracis Spores* conducted by Dr. Vahid Majidi and his team.[32] After reviewing these reports, the investigation team developed the investigation methodology and visited ECBC, the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), and the Joint Program Executive Office for Chemical and Biological Defense to obtain a basic understanding of the science, organizational structure, and functions of U.S. Army biological research commands.[33] Interviews and general discussion at ECBC, USAMRIID, and the Joint Program Executive Office for Chemical and Biological Defense highlighted a number of concerns related to gaps in science, a lack of communication and cooperation by DPG-LSD personnel, and discrepancies in documenting the irradiation procedures that in turn assisted in framing the investigation team's approach.[34] The investigation team proceeded to DPG-LSD where they spent a week interviewing witnesses, reviewing laboratory documentation and evidence, and ordering an environmental sampling of the laboratory due to contamination concerns raised during the investigation. After returning from DPG-LSD, the investigation team continued to review and gather evidence, address deficiencies in the information obtained, drafted a preliminary Report of Investigation, referred a matter to the Department of the Army Inspector General for further investigation under the provisions of AR 20-1, and submitted the report for legal review on 9 October 2015.

On 22 October 2015, The Office of the Judge Advocate General advised the investigation team to address specific comments and questions requiring additional investigation. On 23 October 2015, pursuant to AR 20-1, The Inspector General authorized the investigating officer to investigate senior army officials "to determine if their failures to take appropriate action or provide appropriate oversight contributed to the unintended and unacknowledged shipment of viable *Bacillus anthracis*...."[35] On 27 October 2015, the investigating officer requested[36] and the

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[30] Tab A-2, page 2, Memorandum from the Director of the Army Staff, to Major General Paul A. Ostrowski, subject: Appointment as Investigating Officer (30 July 2015).
[31] *See* Tab D-1b, Memorandum from the Department of Health and Human Services, Centers for Disease and Control Prevention, to [redacted] Department of Health and Human Services OIG, subject: Life Science Test Facility (Registration #C20121022-1418) (24 July 2015).
[32] *See* Tab D-2, Review Committee Report: Inadvertent Shipment of Live *Bacillus anthracis* spores by DoD (July 13, 2015).
[33] These organizations were chosen because they also perform work with *Bacillus anthracis*.
[34] *See* Tab B-1.1, [redacted], DA Form 2823, Sworn Statement (11 Aug 2015); Tab B-8.1, [redacted] DA Form 2823, Sworn Statement (12 Aug. 2015); Tab B-13.1, [redacted], DA Form 2823, Sworn Statement (11 Aug. 2015); Tab B-38.1 [redacted] DA Form 2823, Sworn Statement (2 Sept. 2015); Tab B-43.1, [redacted] DA Form 2823, Sworn Statement (17 Sept. 2015).
[35] *See* Tab A-6, Memorandum from the Inspector General, to Major General Paul A. Ostrowski, subject: Authorization to Investigate Senior Officials (23 Oct. 2015).
[36] *See* Tab A-7, Memorandum from Major General Paul A. Ostrowski, to the Director of the Army Staff, subject: Extension (27 Oct. 2015).

Director of the Army Staff approved a second 60 day extension.[37] Additionally, the Director of the Army Staff approved the investigating officer's request for an investigator from Department of the Army Inspector General's Office to assist with the investigation of senior army officials.[38] The investigating officer examined the involvement of senior army officials at the Army Test and Evaluation Command, the Developmental Test Command, and DPG who served in leadership roles in these organizations from 2004-2015. After completing 30 additional interviews and gathering additional evidence, the investigating officer finalized this Report of Investigation.

B. General Background Information on *Bacillus anthracis*

To comprehend the scope and magnitude of this investigation, it is essential to understand the definition of and potential risks associated with *Bacillus anthracis*. *Bacillus anthracis* is a large, aerobic,[39] rod-shaped gram positive[40] bacterium that is the causative agent of anthrax, a serious infectious disease that afflicts both human beings and animals. *Bacillus anthracis* microbes are non-motile, can form environmentally resistant spores, and are found naturally in soil throughout the United States and elsewhere in the world. The spores can be spread by skin contact with infected animal tissue, bites from insects that have been feeding on infected animals, inhalation, and ingestion of contaminated undercooked meat. Inhalation is the most lethal form of transmission, with a lethal dose in the range of 8,000 – 50,000 organisms.[41] Due to the health risks associated with exposure to *Bacillus anthracis*, the organism is on the Biological Select Agents and Toxins list.[42] While *Bacillus anthracis* is designated as a Risk Group 2 organism (moderate individual risk, low community risk) by CDC and National Institutes of Health Guidelines, biosafety level-3 practices and facilities are recommended for work with *Bacillus anthracis* when dealing with production level (large) quantities or when utilizing aerosol generating procedures. Figure 1, extracted from the CDC's *Biosafety in Microbiological and Biomedical Laboratories* 5th Edition Manual, summarizes the various aspects of biosafety levels.[43]

[37] *See* Tab A-8, Memorandum from the Director of the Army Staff, to Major General Paul A. Ostrowski, subject: Request for Second Extension and DAIG Support (27 Oct. 2015).
[38] *Id.*
[39] *See* Appendix E, *Glossary*.
[40] *See* Appendix E, *Glossary*. Gram positive strains of bacteria stain purple with crystal violet dye.
[41] *See* Tab E-4, *Bacillus anthracis* - Material Safety Data Sheet (MSDS), http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/msds12e-eng.php (last visited 9 Sept. 2015); Friedlander AM, Current Clinical Topics in Infectious Diseases, Anthrax: clinical features, pathogenesis, and potential biological warfare threat, at vol. 20, pages 335-49 (2000). Samples that are the subject of this investigation were in liquid form (i.e., not inhalable) and contained spore counts lower than the lethal dose range.
[42] Select Agents and Toxins List, http://www.selectagents.gov/SelectAgentsandToxinsList.html (last visited 22 Sept. 2015).
[43] *See* Tab E-5, U.S. Dept. of Health and Human Services, HHS Pub. No. (CDC) 21-1112, Biosafety in Microbiological and Biomedical Laboratories, section IV (Dec. 2009) [hereinafter BMBL]; AR 385-10 requires the mandatory implementation of U.S. DEP'T OF ARMY, PAM 385-69, SAFETY STANDARDS FOR MICROBIOLOGICAL AND BIOMEDICAL LABORATORIES ch. 1-1 (6 May 2009), (RAR 8 Feb. 2013) [hereinafter DA PAM 385-69] requiring the Army to follow all national consensus standards including the BMBL.

BSL	Agents	Practices	Primary Barriers and Safety Equipment	Facilities (Secondary Barriers)
1	Not known to consistently cause diseases in healthy adults	Standard microbiological practices	■ No primary barriers required. ■ PPE: laboratory coats and gloves; eye, face protection, as needed	Laboratory bench and sink required
2	■ Agents associated with human disease ■ Routes of transmission include percutaneous injury, ingestion, mucous membrane exposure	BSL-1 practice plus: ■ Limited access ■ Biohazard warning signs ■ "Sharps" precautions ■ Biosafety manual defining any needed waste decontamination or medical surveillance policies	Primary barriers: ■ BSCs or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials ■ PPE: Laboratory coats, gloves, face and eye protection, as needed	BSL-1 plus: ■ Autoclave available
3	Indigenous or exotic agents that may cause serious or potentially lethal disease through the inhalation route of exposure	BSL-2 practice plus: ■ Controlled access ■ Decontamination of all waste ■ Decontamination of laboratory clothing before laundering	Primary barriers: ■ BSCs or other physical containment devices used for all open manipulations of agents ■ PPE: Protective laboratory clothing, gloves, face, eye and respiratory protection, as needed	BSL-2 plus: ■ Physical separation from access corridors ■ Self-closing, double-door access ■ Exhausted air not recirculated ■ Negative airflow into laboratory ■ Entry through airlock or anteroom ■ Hand washing sink near laboratory exit
4	■ Dangerous/exotic agents which post high individual risk of aerosol-transmitted laboratory infections that are frequently fatal, for which there are no vaccines or treatments ■ Agents with a close or identical antigenic relationship to an agent requiring BSL-4 until data are available to redesignate the level ■ Related agents with unknown risk of transmission	BSL-3 practices plus: ■ Clothing change before entering ■ Shower on exit ■ All material decontaminated on exit from facility	Primary barriers: ■ All procedures conducted in Class III BSCs or Class I or II BSCs in combination with full-body, air-supplied, positive pressure suit	BSL-3 plus: ■ Separate building or isolated zone ■ Dedicated supply and exhaust, vacuum, and decontamination systems ■ Other requirements outlined in the text

Figure 1: Summary of Recommended Biosafety Levels for Infectious Agents

There are 89 known strains of *Bacillus anthracis*, all of which exhibit different levels of pathogenicity (or the ability to cause disease).[44] This investigation is focused on the inadvertent shipment of the Ames strain, a particularly virulent (extremely harmful) strain that is well known for its use in the 2001 attacks (Amerithrax) in which letters containing *Bacillus anthracis* Ames spores were mailed to several media outlets and two U.S. Senators. The pathogenicity of each strain is related to the presence or absence of two plasmids,[45] known as pXO1 and pXO2. The pXO1 plasmid encodes for the anthrax toxin components and the pXO2 plasmid encodes for a capsule that allows the organism to shield itself and evade its host's immune system. In order for inactivated spores to be the most representative of virulent *Bacillus anthracis,* a strain containing both plasmids (e.g., *Bacillus anthracis* Ames strain) is used.[46] This is why DPG-LSD and the DoD Chemical and Biological Defense Program often use the Ames strain when developing technologies used to combat *Bacillus anthracis* threats.

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[44] Derzelle S, Thierry S., *Genetic diversity of Bacillus anthracis in Europe: genotyping methods in forensic and epidemiologic investigations.* BIOSECURITY AND BIOTERRORISM: BIODEFENSE STRATEGY, PRACTICE AND SCIENCE, pages S166-76 (2013).

[45] *See* Appendix E, *Glossary*. A plasmid is a small, circular, double-stranded DNA molecule that is distinct from the cell's chromosomal DNA. Plasmids carry genes that can provide bacteria with genetic advantages (for example, antibiotic resistance) that can render them more harmful or more difficult to treat.

[46] Pile JC, Malone JD, Eitzen EM, Friedlander AM., *Anthrax as a potential biological warfare agent*, ARCHIVES OF INTERNAL MEDICINE, pages 429-34 (1998).

C. Factual Background Pertaining to the 22 May 2015 Discovery of Viable *Bacillus anthracis*

The DoD maintains a Chemical and Biological Defense Program with the mission to enable the Warfighter to deter, prevent, protect, mitigate, respond, and recover from chemical, biological, radiological and nuclear threats and effects as part of a layered, integrated defense.[47] The biological portion of this mission addresses both the internal (medical) and external (non-medical systems) needs of the Warfighter.[48] Figure 2 depicts the DoD approach to biological defense.

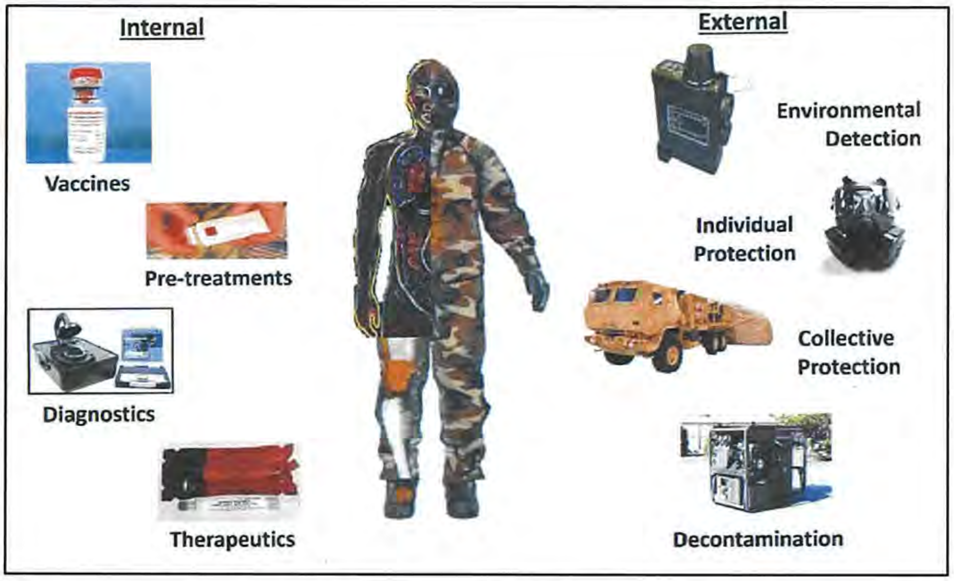

Figure 2: DoD Approach to Biological Defense

Internal biological defense technologies include:

- vaccines and pre-treatments designed to prevent the contraction and/or development of diseases
- diagnostic tools designed to identify pathogens and diseases
- therapeutics that cure and or minimize the impact of diseases after contraction

External biodefense systems include:

- devices capable of detecting and identifying biological warfare agents in the environment
- individual equipment such as masks and protective clothing
- collective protective equipment that creates safe, protected shelters and vehicle environments without the need for individual equipment
- decontamination systems designed to return personnel and equipment to service after exposure to biological agents and contaminants

[47] Chemical and Biological Defense, http://www.acq.osd.mil/cp/index.htm (last visited 29 Sept. 2015).
[48] *See* Tab E-36, DoD Briefing - Shipment of Inactivated Bacillus anthracis (10 June 2015).

In support of the overarching biological defense mission, the DoD operates four primary facilities (3 Army, 1 Navy) that conduct *Bacillus anthracis* research, development, production, and testing of medical countermeasures and biological defense systems. These facilities are as follows:

Facility Name	Acronym	Location
1. U.S. Army Medical Research Institute of Infectious Diseases	USAMRIID	Fort Detrick, Maryland
2. Edgewood Chemical and Biological Center	ECBC	Aberdeen, Maryland
3. Dugway Proving Ground - Life Sciences Division	DPG-LSD	Dugway Proving Ground, Utah
4. Naval Medical Research Center	NMRC	Silver Spring, Maryland

The USAMRIID, a subordinate of the U.S. Army Medical Command, is the DoD's lead laboratory for medical/internal biological defense research. The USAMRIID develops medical countermeasures such as therapeutics, vaccines, and diagnostics for the benefit of both military personnel and the civilian population.[49] The ECBC, a subordinate of the U.S. Army Materiel Command, is the DoD's principal resource for research and development of non-medical/external biological detection, protection, and decontamination systems.[50] The DPG-LSD, a subordinate of the Army Test and Evaluation Command (ATEC), conducts developmental and operational testing of both medical and non-medical technologies.[51] The Naval Medical Research Center (NMRC), a subordinate of the Navy Bureau of Medicine & Surgery, provides health and medical research solutions for the U.S. Navy.[52] The chains of command for these four facilities can be seen in Figure 3.

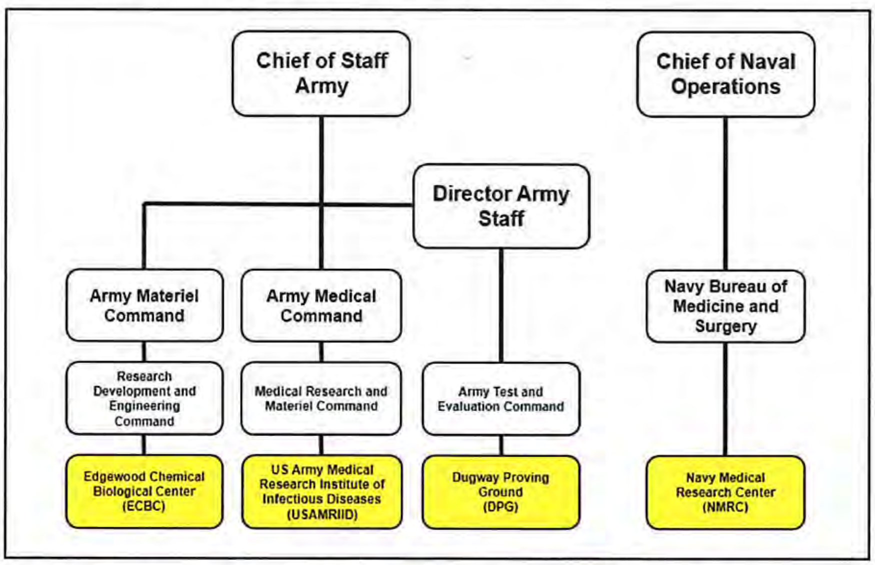

Figure 3: Chains of Command for DoD Biological Labs as of August 2015

[49] United States Army Medical Research Institute of Infectious Diseases, http://www.usamriid.army.mil/aboutpage.htm (last visited 29 Sept. 2015).
[50] Edgewood Chemical Biological Center, http://www.ecbc.army.mil/about/index.html (last visited 29 Sept. 2015).
[51] Life Sciences Division, http://www.dugway.army.mil/LifeSciences.aspx (last visited 29 Sept. 2015).
[52] About NMRC, http://www.med.navy.mil/sites/nmrc/Pages/about.htm

In order to support the testing, development, and sustainment of medical and non-medical biodefense technologies, the DoD must produce biological reference materials to test its myriad of biodefense systems. The Critical Reagents Program (CRP), a subordinate of the Joint Program Executive Office for Chemical and Biological Defense, is the principal resource for these materials. The CRP, which is managed by a team located at Fort Detrick, Maryland, acts as a broker for biological materials and measurement/assessment assays produced by the DoD labs and industry partners. Figure 4 is a breakdown of the CRP product portfolio (lab sources in parentheses), which is available through its online ordering system known as the Ordering System for CRP Assays and Reagents.[53] As seen in Figure 4, the CRP utilizes DPG-LSD to produce inactivated antigens,[54] USAMRIID for unified culture collection (strains), ECBC for genomic material, and NMRC for antibodies.[55] The focus of this investigation centers on DPG-LSD and the production of inactivated antigens, specifically *Bacillus anthracis*.

Figure 4: Critical Reagents Program Product Portfolio and Sources

The use, handling, and transport of biological materials considered to have potential bioterrorism applications are regulated under the Federal Select Agent Program. The Federal Select Agent Program implements the requirements imposed by 42 Code of Federal Regulations (CFR) Part 73, Select Agents and Toxins; 9 CFR Part 121, Possession, Use, and Transfer of Select Agents and Toxins; and 7 CFR Part 331, Possession, Use, and Transfer of Select Agents and Toxins. Stringent infrastructure, packaging, transport, and tracking requirements are imposed on both the sending and receiving entities when a select agent is shipped. As an

[53] Critical Reagents Program, http://www.jpeocbd.osd.mil/packs/Default.aspx?pg=1220 (last visited 29 Sept. 2015).
[54] *See* Appendix E, *Glossary*. An assay is a laboratory procedure used to qualitatively assess or quantitatively measure the presence or amount of something – in this case, a biological material or organism. A reagent is a substance or mixture for use in chemical analysis or other reactions. An antigen is any substance that can provoke the immune system to create antibodies to work against it.
[55] *See* Tab E-35, CRP Overview Brief, pg. 1 (1 Sept. 2015).

alternative, certain select agents, including *Bacillus anthracis*, may first be attenuated (decreasing their virulence, or ability to cause disease) or inactivated through a variety of means. Attenuated and inactivated select agents may then be excluded from the select agent regulations, rendering use, handling and transport of the material a far less complex and costly endeavor.

On 22 May 2015, a private company notified the CDC that it had received viable (live) *Bacillus anthracis* spores in a shipment from ECBC.[56] This company was participating in a technical competency assessment for Lateral Flow Immunoassays,[57] a CRP managed product whose contract with BBI Detection (see Figure 4) was expiring. The ECBC, which manages the research and development of Lateral Flow Immunoassays for the CRP, ordered inactivated *Bacillus anthracis* spores along with other inactivated antigens to be used in the assessment from DPG-LSD through the CRP catalog.[58] The DPG-LSD shipped the material, which included *Bacillus anthracis* from Lot AGD0001667, to ECBC on 20 April 2015.[59] This shipment was excluded from Federal Select Agent Program requirements due to the fact that the material, including the *Bacillus anthracis*, was believed to have been inactivated by DPG. Upon receipt, ECBC repackaged the material in accordance with the requirements of the competency assessment (which was a blind test, so all identifying markings were removed), and shipped it to each competitor.[60] After receiving the antigens, one private company involved in the competition chose to do a viability test on the materials it had received and discovered that the *Bacillus anthracis* sample contained a low concentration of viable spores.[61] Figure 5 depicts the material and information flow related to the unintended shipment of viable *Bacillus anthracis* spores.

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[56] *See* Tab D-1a, Memorandum from the Department of Health and Human Services, Centers for Disease and Control Prevention, to [redacted] RE: Entity Inspection Report: Life Science Test Facility (LSTF) (5 June 2015); and Tab D-1b, Memorandum from the Department of Health and Human Services, Centers for Disease and Control Prevention, to [redacted] Department of Health and Human Services OIG, subject: Life Science Test Facility (Registration #C20121022-1418) (24 July 2015).

[57] Appendix E, *Glossary*.

[58] *See* Tab C-32, Solicitation No. W911QY15R0018 (16 Apr. 2015).

[59] *See* Tab C-26, FedEx Order 11211 (8 Apr. 2015).

[60] *See note* 58. *See also*, Tab B-44.1.a, page 6, [redacted] DA Form 2823, Sworn Statement (19 Aug. 2015). [redacted] stated that the "antigen was being sent as a "blind" or coded sample, reading only as "ANG 1" to labs who were competing for government contracts. Coded samples have to remove any identifying characteristics that would ID them as a certain organism. Lot numbers, batch record numbers, inactivation procedure and dosages would need to be removed since scientists working with the materials could infer the strain based on their own training and experience."

[61] This viability test was not required by regulation. The company chose to conduct the viability test on its own because it was unsure about the nature of the materials it had received since the samples had been blinded.

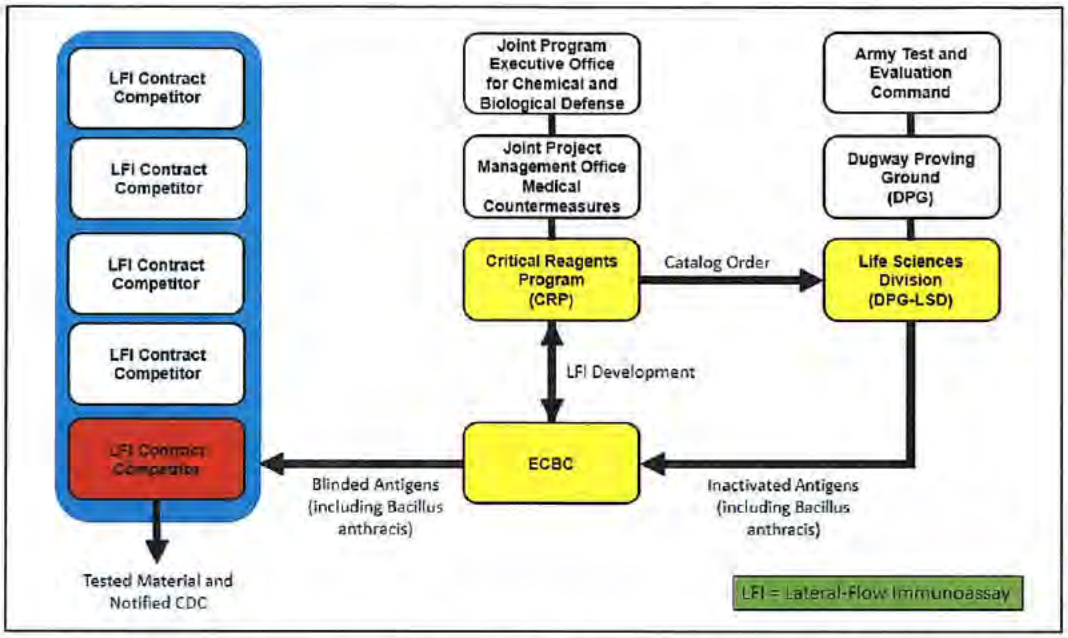

Figure 5: Biological Material and Information Flow Related to the 22 May 2015 Discovery

D. Reviews and Investigations into the 22 May 2015 Discovery of Viable *Bacillus anthracis*

The discovery of viable *Bacillus anthracis* spores on 22 May 2015 prompted multiple investigations and reviews:

On 26-28 May 2015, after being notified of the receipt of viable *Bacillus anthracis* by the private company, the CDC Division of Select Agents and Toxins conducted a site visit at the DPG-LSD. This team's findings and recommendations were published in an Entity Inspection Report on 05 June 2015, and DPG-LSD was ordered to suspend all shipments of *Bacillus anthracis* except those supporting the on-going investigation.[62] The Division of Select Agents and Toxins subsequently determined that DPG-LSD was negligent and on 24 July 2015 made a recommendation to the Department of Health and Human Services, Office of Inspector General (DHHS-OIG) that a civil penalty be levied.[63] A special agent from the Federal Bureau of Investigation was also part of this team, but no criminal actions were identified.[64]

On 29 May 2015, the Deputy Secretary of Defense directed the Under Secretary of Defense for Acquisition, Technology & Logistics to conduct a 30-day review of the DoD's safety

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[62] *See* Tab D-1a, Memorandum from the Department of Health and Human Services, Centers for Disease and Control Prevention, to (b) (6) [redacted] RE: Entity Inspection Report: Life Science Test Facility (LSTF) (5 June 2015).

[63] *See* Tab D-1b, Memorandum from the Department of Health and Human Services, Centers for Disease and Control Prevention, to (b) (6) [redacted] Department of Health and Human Services OIG, subject: Life Science Test Facility (Registration #C20121022-1418) (24 July 2015).

[64] *See note* 62.

practices for generating and handling *Bacillus anthracis*. The review committee published a report with its findings on 13 July 2015.[65]

On 30 July 2015, the Secretary of the Army directed the Assistant Secretary of the Army (Acquisition, Logistics and Technology) to lead a working group, in coordination with the Department of the Navy, to assess the findings of the DoD report.[66] The Director, Office of Business Transformation, Headquarters U.S. Army Staff, has tasking authority for this assessment.[67] Results are pending.

On 30 July 2015, the Secretary of the Army directed the Director of the Army Staff to appoint an Investigating Officer pursuant to Army Regulation 15-6, to conduct a full accountability assessment of the responsible institutions and individuals at DPG, including the chain of command.[68] This report documents the findings of the 15-6 investigation team.

On 19 August 2015, during a site visit to the DPG-LSD, a member of the 15-6 investigation team conducted environmental sampling in two laboratories. Evidence of contamination was found during the environmental sampling.[69] The CDC was immediately notified of the contamination as required by regulation (42 C.F.R. pt. 73.17, Records) and conducted a site visit and inspection, in coordination with the Department of the Army Inspector General, at DPG-LSD on 27-28 August 2015.[70] On 28 August 2015, the CDC notified DPG-LSD that their certificate of registration to possess, use, and transfer select agents and toxins was suspended for work with *Bacillus anthracis*.[71] Subsequently, on 31 August 2015, the CDC notified DPG-LSD that the suspension of registration had been extended to include work with all select agents and toxins, not solely *Bacillus anthracis*.[72] On 20 October 2015, the CDC notified DPG-LSD of several additional findings resulting from the 27-28 August 2015 inspection.[73]

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[65] *See* Tab D-2, Review Committee Report: Inadvertent Shipment of Live *Bacillus anthracis* spores by DoD (July 13, 2015).

[66] *See* Tab D-3a, Memorandum from the Secretary of the Army, to Assistant Secretary of the Army (Acquisition, Logistics and Technology), subject: Office of the Secretary of Defense Review Committee Report: Inadvertent Shipment of Live *Bacillus anthracis* Spores by Department of Defense (30 July 2015).

[67] *See* Tab D-3b, Action Memorandum from the Secretary of the Army for the Deputy Secretary of Defense, subject: Implementation Plan to Address OSD Review Committee Report: Inadvertent Shipment of Live Bacillus Anthracis Spores by DoD; Findings and Recommendations; Associated Deputy Secretary of Defense Directives; and Related Executive Agent Responsibilities (13 Aug. 2015).

[68] *See* Tab A-1, Memorandum from the Secretary of the Army, to Director of the Army Staff, subject: Appointment of Army Regulation 15-6 Investigating Officer (30 July 2015).

[69] *See* Tab B-16.1, [redacted] DA Form 2823, Sworn Statement (24 Aug. 2015); and Tab B-40, [redacted] DA Form 2823, Sworn Statement (27 Aug. 2015).

[70] *See* Tab D-4.a., Memorandum from the Department of Health and Human Services, Centers for Disease Control and Prevention, to [redacted] Life Science Test Facility, subject: Re-inspection of Life Science Test Facility (26 Aug. 2015).

[71] *See* Tab D-4.b., Memorandum from the Department of Health and Human Services, Centers for Disease Control and Prevention, to [redacted] Life Science Test Facility, subject: Suspension of Registration: Life Science Test Facility (28 Aug. 2015).

[72] *See* Tab D-4.c., Memorandum from the Department of Health and Human Services, Centers for Disease Control and Prevention, to [redacted] Life Science Test Facility, subject: Suspension of Registration: Life Science Test Facility (31 Aug. 2015).

[73] *See* Tab D-4.d., Memorandum from the Department of Health and Human Services, Centers for Disease Control and Prevention, to [redacted] Life Science Test Facility, subject: Entity Inspection Report - Life Science Test Facility (20 Oct. 2015).

E. Command Structure and Funding of U.S. Army Biological Research Organizations

In order to understand the scope and complexity of the issues that contributed to the inadvertent shipment of viable *Bacillus anthracis*, it is helpful to understand the pertinent command structure for the organizations. The Army's three primary organizations working with biological select agents and toxins are: DPG-LSD in Utah; the Biosciences Division of the ECBC at Aberdeen Proving Ground, Maryland; and the Science Directorate of the USAMRIID at Fort Detrick, Maryland.

Although these organizations work with select agents and toxins to accomplish their missions, and are subject to the same select agent requirements, the organizations are in separate chains of command due to their specific missions. The chains of command are shown in Figure 6 and described below.

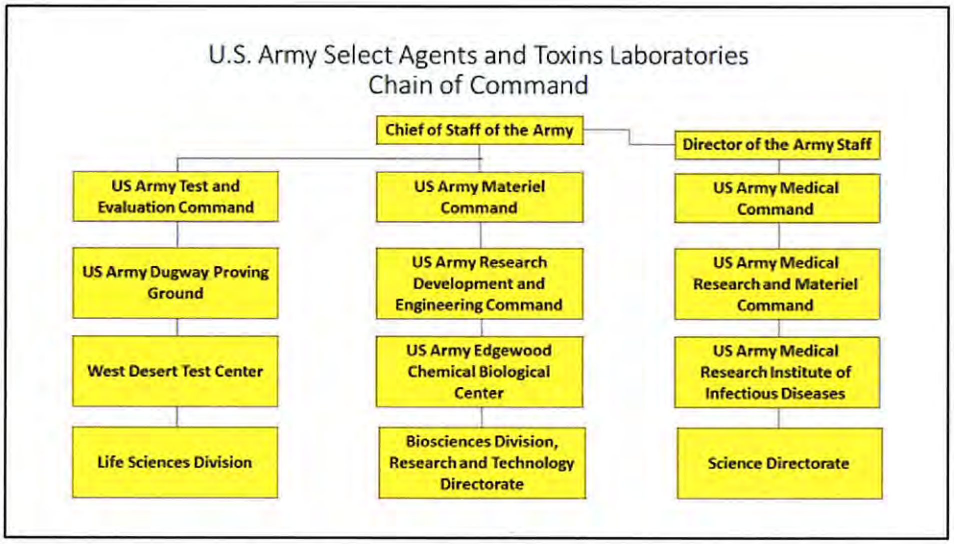


Figure 6: U.S. Army Select Agents and Toxins Laboratories Chain of Command

1. Chain of Command

a. Life Sciences Division – Dugway Proving Ground (DPG-LSD)

The ATEC is the Army's independent operational test activity and the independent evaluator for most Army systems.[74] ATEC is a Direct Reporting Unit of the United States Army. Its Commanding General is supervised by the Chief of Staff of the Army; the Director of the Army Staff assists the Chief in supervising ATEC.

[74] U.S. DEP'T OF ARMY, REG. 10-87, ARMY COMMANDS, ARMY SERVICE COMPONENT COMMANDS, AND DIRECT REPORTING UNITS, chapter 20 (4 Sept. 2007) [hereinafter AR 10-87].

The ATEC operates through subordinate commands and test centers, including the West Desert Test Center at U.S. Army Dugway Proving Ground, Utah. The West Desert Test Center is the Army's Major Range and Test Facility Base for chemical and biological defense testing.[75]

The West Desert Test Center at DPG has five divisions, one of which is the Life Sciences Division. The DPG-LSD tests biological defense systems, biosurveillance and medical countermeasures, and produces biological testing materials. The DPG-LSD also conducts work in support of the Critical Reagents Program.[76] The DPG-LSD contains the CRP Antigen Repository which is staffed by several DPG-LSD Microbiology Branch personnel.[77] Figure 7 depicts the organization of DPG, including the Life Sciences Division and its branches.[78]

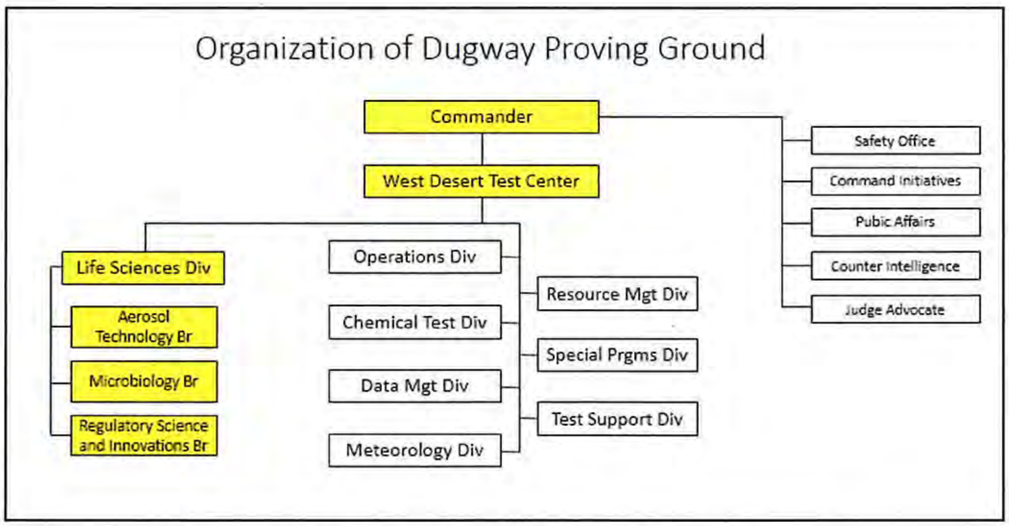


Figure 7: Organization of Dugway Proving Ground

b. Biosciences Division, ECBC

The U.S. Army Materiel Command is an Army Command (an organization with an Army-wide role and multidiscipline functions). Its Commanding General reports to the Chief of Staff of the Army. The Army Materiel Command is responsible for all aspects of the Army's materiel readiness.[79] One of its subordinate commands is the U.S. Army Research Development and Engineering Command, which operates through several laboratories and centers, including the

[75] West Desert Test Center, http://www.dugway.army.mil/WDTC.aspx. (last visited 29 Sept. 2015).
[76] The Critical Reagents Program, which is part of the Joint Program Executive Office for Chemical and Biological Defense portfolio, is managed by a team at Ft. Detrick, Maryland. The CRP utilizes lab space and dedicated personnel at DPG-LSD to manage its Antigen Repository. The personnel working in the Antigen Repository are managed/rated by DPG-LSD management, but work only on CRP related projects and often correspond directly with the management team at Ft. Detrick on CRP related issues.
[77] Life Sciences Division, http://www.dugway.army.mil/LifeSciences.aspx. (last visited 29 Sept. 2015).
[78] *See* Appendix B, Dugway Proving Ground Organization Charts.
[79] AR 10-87, chapter 4.

ECBC. The ECBC, located at Aberdeen Proving Ground, Maryland, is responsible for the acquisition lifecycle for non-medical chemical-biological defense materiel.[80]

Within ECBC, the Biosciences Division of the Research and Technology Directorate conducts research and development of sensor hardware, biological warfare field detection assays, bioremediation, microbiological testing, and bio-forensic analysis.[81]

c. Science Directorate, USAMRIID

The U.S. Army Medical Command is a Direct Reporting Unit of the United States Army. The Surgeon General is dual-hatted as the Commanding General of the U.S. Army Medical Command and is supervised by the Chief of Staff of the Army. The U.S. Army Medical Command is responsible for all aspects of medical support to the Army, including biomedical research and technology.[82]

The U.S. Army Medical Research and Materiel Command is a major subordinate command to the U.S. Army Medical Command. It is the Army's medical materiel developer, with responsibility for medical research, development, acquisition and medical logistics management. One of its subordinate commands, the USAMRIID, is the lead medical research laboratory for the U.S. Biological Defense Research Program.[83] Within the USAMRIID, the Directorate of Science conducts much of the medical biological defense research for the U.S. Army, addressing warfighter protection, disease outbreaks and threats to public health through therapeutics, vaccines, diagnostics, and information.[84]

2. Laboratory Funding

The three Army laboratories that produce, handle, test and distribute select agents (Figure 6) receive resources known as non-reimbursable and reimbursable funds. Non-reimbursable funds, provided by DoD centralized sources, cover the majority of the overhead and sustainment costs of DPG and USAMRIID but only a fraction of the costs at ECBC. The DoD centralized funding, known as defense-wide funds, provide budget stability for critical test facilities and laboratories. Reimbursable funds are provided by customers for specific projects and vary annually, depending on customer requirements.[85] The customer base for the facilities includes, but is not limited to, various entities in academia and industry, the Defense Threat Reduction Agency, and the Joint Program Executive Office for Chemical and Biological Defense. While the customer base that supports the three Army laboratories is rather small, and there is overlap in that some large programs (including the CRP) provide funding to all three laboratories, each laboratory supports different parts or phases of the programs so there is no direct competition for

[80] Edgewood Chemical Biological Center, http://www.ecbc.army.mil/about/index.html (last visited 29 Sept. 2015).
[81] Biosciences Division, http://www.ecbc.army.mil/research/biosciences/ (last visited 29 Sept. 2015).
[82] AR 10-87, chapter 15.
[83] United States Army Medical Research Institute of Infectious Diseases, http://www.usamriid.army.mil/aboutpage.htm (last visited 29 Sept. 2015).
[84] *See* Tab E-20, USAMRIID Organization and Funding Profile
[85] Appendix C contains graphs depicting the FY14 customer base/funding for each of the three labs

reimbursable funding. A detailed breakdown of the USAMRIID, ECBC, and DPG-LSD funding profiles, both reimbursable and non-reimbursable, can be found in Appendix C.

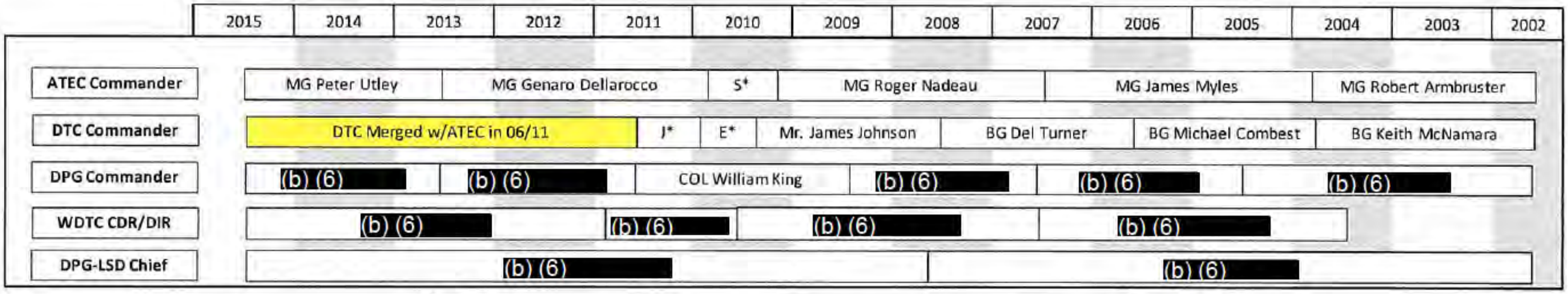
F. Historical Mishaps at Dugway Proving Ground Life Sciences Division

In accordance with the Public Health Security and Bioterrorism Preparedness and Response Act of 2002,[86] the CDC published a list of biological agents and toxins that have the potential to pose a severe threat to public health and safety. It is Army policy that operations involving these biological select agents and toxins in the possession or custody of the Army shall be conducted in a safe and reliable manner.[87] To enhance public confidence in the Army's handling of biological select agents and toxins, it is essential these operations are meticulously planned and executed. Integral to the safe and reliable custody of biological select agents and toxins materials, 42 Code of Federal Regulations part 73, Select Agents and Toxins, stipulates that select agents and toxins are to be transferred from one entity to another only upon authorization of the CDC.

As part of this investigation, the Investigating Officer directed a review of past mishaps at DPG-LSD to provide a background on how DPG-LSD management responded to these issues and if they implemented lessons learned, enhanced oversight, reporting protocols, re-training and disciplinary actions. The mishaps considered by the 15-6 investigation team include a series of eight shipping errors, four of which were reportable to the CDC due to their severity. Three additional shipping mishaps were not reportable to the CDC, and the remaining shipping error is still pending CDC reporting determination. The 15-6 investigation team also reviewed an additional mishap involving inactivation of *Bacillus anthracis* using an experimental chemical process and subsequent shipment to Lawrence Livermore National Laboratories (LLNL) in 2007.[88]

Figure 8 provides a summary of mishaps involving biological select agents and toxins occurring at or involving material originating from DPG-LSD since 2003. In addition to details about each event, Figure 8 also outlines the personnel occupying key leadership positions during each event. The intent of the figure is to establish which key leaders were in place during each event and to highlight personnel continuity at DPG-LSD.

[86] *See* 42 U.S.C. §§ 201, et. seq, 116 STAT. 594, P.L. 107-188.
[87] See Tab E-1, U.S. DEP'T OF ARMY, REG. 50-1, BIOLOGICAL SURETY para. 1-1a (28 July 2008) [hereinafter AR 50-1].
[88] Although the root cause of this incident is a matter of debate, it involves potential insufficient inactivation



S* = Dr. James Streilein J* = Mr. David Jimenez E* = Mr. Michael Etzinger

Events	June 2013 - June 2015	June 2011 - June 2013	June 2009 - June 2011	June 2007 - June 2009	June 2005 -June 2007	June 2003 -June 2005
Bacillus anthracis (*B. anthracis*) inactivation with subsequent growth (all lot numbers begin with AGD000) **CDC reportable; fines pending**	**03/14** Lot 1667 **09/14** Lot 1631 Date unknown Lot 1727			**10/07** Lot 0999 **08/08** Lot 1039 **05/09** Lot 1151	**04/06** Lots 0794, 0798, 0806, 0810 **06/06** Lot 0822 **08/06** Lot 0862 **10/06** Lot 0910	**01/04** Lots 0069, 0070 **08/04** Lots 0511, 0516
Possible shipment of viable Venezuelan Equine Encephalitis virus (VEE) as attenuated virus **CDC reportability not yet determined**	**08/15** CDC investigation of ECBC and USAMRIID includes VEE status as select agent	**05/12** DPG-LSD ships VEE to one private company **02/13** DPG-LSD asks USAMRIID about VEE inactivation	**9/10** DPG-LSD asks CDC about VEE inactivation		**08/06** DPG-LSD ships VEE to ECBC and two private companies **02/07** DPG-LSD ships VEE to Armed Forces Institute of Pathology and private company	**2003-2004** (date unknown) DPG-LSD receives VEE from USAMRIID; DPG-LSD believes it is inactivated **03/05** CDC adds VEE to select agent list
Non-exempt Botulinum toxin shipped to ECBC and NMRC as exempt from CDC Select Agent requirements **CDC reportable; fines assessed**		**11/11** DHHS declines to impose monetary penalty on DPG-LSD	**10/10** and **11/10** DPG-LSD ships incorrect quantity of Botulinum toxin to ECBC, NMRC **04/11** NMRC discovers and reports error **05/11** DAIG inspection fails DPG-LSD for shipping errors **06/11** CDC sends investigation report to DPG-LSD	**02/08** DPG-LSD ships incorrect quantity of Botulinum toxin to ECBC		
Incompletely inactivated *B. anthracis* shipped to LLNL following chlorine dioxide (ClO2) inactivation **CDC reportable; fines assessed**			**06/09** CDC sends investigation report to DPG-LSD **12/09** DHHS declines to impose monetary penalty on DPG-LSD		**04/07** DPG-LSD ships ClO2-inactivated *B. anthracis* to LLNL **05/07** LLNL finds growth, reports to CDC	
Shipping errors **Non-CDC reportable**	**04/14** DPG-LSD sends mislabeled inactivated *B. anthracis and Yersinia pestis* to Republic of Korea **09/14** DPG-LSD sends mislabeled Vaccinia to NSWC		**07/10** DPG-LSD switches shipments of inactivated agents between NSWC and a private company **12/10** DPG-LSD sends NSWC mislabelled *Bulkholderia mallei*			

Figure 8: Summary of Historical Mishaps and Key Personnel

1. Lawrence Livermore National Laboratories (2007-2010)

In April 2007, DPG-LSD shipped select agent *Bacillus anthracis* that it had attempted to chemically inactivate with chlorine dioxide to Lawrence Livermore National Laboratories (LLNL) in Livermore, California. The LLNL performed viability testing on the agent after receipt and identified a single viable *Bacillus anthracis* spore, implying that DPG-LSD had made an unauthorized shipment of select agent. The LLNL notified the CDC of the presence of the single viable spore on 26 April 2007, and the CDC subsequently notified DPG-LSD of the unauthorized shipment on 2 May 2007.[89] The DPG-LSD subsequently submitted three responses to the CDC in May of 2007 providing details on the inactivation and viability testing processes that were utilized, including relevant laboratory notebooks and Standard Operating Procedures. In November of 2007, the CDC provided recommendations to DPG-LSD to improve their processes moving forward and referred their investigation to the DHHS-OIG.[90] On 31 March 2008, the DHHS-OIG notified the [redacted] [redacted][91] that it had preliminarily determined that DPG-LSD violated federal regulations by shipping viable *Bacillus anthracis*,[92] and requested a response from DPG-LSD by 1 May 2008.[93]

The DHHS-OIG, in consultation with the CDC's Division of Select Agents and Toxins, determined that although the method of inactivation (vaporous chlorine dioxide) was scientifically acceptable,[94] DPG-LSD did not follow its own standard operating procedures to inactivate and test the viability of *Bacillus anthracis*. The CDC investigation included a comprehensive review of DPG-LSD's documentation concerning the inactivation procedure, including a copy of the relevant standard operating procedure (WDL-BIO-147), the principal investigator's clinical notebook, the inactivation certificate for the sample, and the viability test record. It was found that during the time in question, WDL-BIO-147 covered three acceptable methods for inactivating bacteria: heat, formalin (37% formaldehyde in liquid solution form), and gamma irradiation. It did not cover the use of chlorine dioxide.[95] The investigation also

[89] [redacted] Testimony from these leaders indicates that they were aware of the LLNL incident at the time and were supporting DPG-LSD personnel in providing evidence to the CDC in response to their inquiries. Although there is no evidence that either of them initiated a commander's inquiry or 15-6 Investigation, this is reasonable based on the fact that the CDC was still gathering facts and no formal findings had yet been submitted. *See* Tab B-46.1, [redacted] Memorandum for Record, subject: Summarized Testimony of [redacted] [redacted] (26 Oct. 2015); Tab B-51.1, [redacted] Memorandum for Record, subject: Summarized Testimony of [redacted] (retired) [redacted] (28 Oct. 2015).

[90] The 15-6 investigation team found no evidence indicating that DPG-LSD was notified that the CDC investigation had been referred to the Department of Health and Human Services, Office of Inspector General. DPG-LSD assumed that the matter was closed as of 16 November 2007.

[91] This notification was mistakenly addressed to [redacted] [redacted]

[92] *See* 42 U.S.C. §§ 73.

[93] *See* Tab C-41, pg. 59, LLNL Correspondence and Evidence.

[94] *See* Tab C-41, pg. 57, LLNL Correspondence and Evidence.

[95] WDL-BIO-147 covers both inactivation and viability/sterility testing. While WDL-BIO-147 does not contain procedures for using chlorine dioxide, the viability testing procedures it contains were still considered valid because they are organism specific and not dependent on inactivation method. This standard operating procedure was violated when the decision was made to destroy only the single vial that was "cloudy with contamination" and to ship the other vials, even though all of the material came from the same treated batch.

found that DPG-LSD did not test the chlorine dioxide inactivation method for efficacy prior to implementation.[96]

According to the CDC, the principal investigator's clinical notebook demonstrated that during viability testing, one of the five tubes that was to be shipped to Lawrence Livermore National Laboratories tested positive for viable *Bacillus anthracis* (all five tubes were originally tested), when a small portion was cultured in a brain-heart infusion broth. The CDC determined that this was evidence that the inactivation procedure was ineffective. The CDC found that the principal investigator's notes did not explain why the viable colony grew, whether the inactivation procedure was performed properly, or why the four remaining tubes were not retested for viability after a single tube failed the original viability testing.[97] Upon completion of the viability check, DPG-LSD destroyed the tube with excessive growth via autoclave, issued death certificates for the four remaining tubes and shipped them to LLNL. The *Bacillus anthracis* samples provided by DPG-LSD to LLNL were of the MLVA-15 Ames strain genotype, which was the same as the viable *Bacillus anthracis* identified at LLNL.[98]

After receiving notification from DHHS-OIG on 31 March 2008 of the preliminary finding that DPG-LSD was the source of contamination, (b) (6) [redacted] submitted two responses to the DHHS-OIG dated 28 April 2008 and 1 May 2008 respectively containing information compiled by the DPG-LSD staff.[99] The responses refuted the CDC finding that DPG-LSD was the source of contamination and stated that the single viable spore likely originated in the laboratory at LLNL. The responses from (b) (6) [redacted] did not consider or address the tube that failed during the original viability test. There was no evidence that (b) (6) [redacted] directed a commander's inquiry or 15-6 Investigation to resolve the inconsistencies/disagreement between the findings of the CDC/DHHS-OIG and those of the DPG-LSD staff. He relied on the staff at DPG-LSD to review themselves.[100]

There was no additional correspondence on the matter until 2 December 2009 when the DHHS-OIG concluded its investigation and notified the DPG Commander (at this time Colonel William King) that it had violated 42 Code of Federal Regulations Part 73.16 by making an unauthorized shipment of the biological select agent *Bacillus anthracis* to LLNL without obtaining pretransfer authorization from the CDC.[101] This notification from the DHHS-OIG was

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[96] *See generally* Tab C-41, LLNL Correspondence and Evidence.

[97] It was also found that during processing of this batch, two vials of material were broken while in a centrifuge. The batch was originally spread throughout 60 vials after being treated with the chlorine dioxide. These 60 vials were combined into 12 vials prior to being centrifuged. Two of these 12 vials were broken in the centrifuge, leaving ten vials remaining. These ten vials were then combined into the final five vials that were tested for viability. There was no concern that the broken vials represented a release of agent because the material had already been inactivated, but they are another potential source for contamination at DPG-LSD.

[98] *Id.*

[99] The response was coordinated by the DPG-LSD (b) (6) [redacted]

[100] *Id. See also* Tab B-49.1, (b) (6) [redacted] Memorandum for Record, subject: Summarized Testimony of (b) (6) (b) (6) [redacted]

[101] *See* Tab C-41, pgs. 70-72, LLNL Correspondence and Evidence. Note: the CDC conducts investigations on behalf of the Department of Health and Human Services and the Office of Inspector General reviews findings and adjudicates corrective action, which may include monetary penalties.

consistent with the preliminary findings and considered final with no expected formal response from DPG-LSD.

In addition to finding DPG-LSD responsible for the incident, the DHHS-OIG also determined that, under the Public Health Security and Bioterrorism Preparedness and Response Act,[102] a civil monetary penalty of up to $250,000 against an individual and up to $500,000 against any other person, including any entity that was in violation of any of the requirements found in the select agent regulations was authorized.[103] Based on all of the circumstances, including DPG-LSD's status as a Federal agency, the DHHS-OIG declined to enforce a civil monetary penalty. However, the DHHS-OIG stated that DPG-LSD should examine its current practices and policies, implement effective corrective actions and safeguards to ensure that future violations did not occur, and monitor such actions and safeguards on an on-going basis.[104]

In response to the 2 December 2009 notification, Colonel King directed [redacted][105] to "prepare a response and discussion" summarizing the LLNL incident.[106] [redacted] provided Colonel King with an email detailing the historical facts associated with the incident (which at this point had been on-going for more than two years) and a PowerPoint presentation that reinforced the idea that the contamination must have originated at LLNL.[107] Similar to the responses sent by DPG-LSD to the CDC in 2008, the responses from [redacted] failed to address the single tube that failed the original viability test. Colonel King testified that he directed a commander's inquiry into the LLNL incident to be led by the DPG Safety Office.[108] However, review of correspondence from that timeframe and interviews with witnesses at DPG indicate that the "response and discussion" provided by [redacted] was all that he requested.[109] [redacted] also drafted a written response to the DHHS-OIG dated 21 January 2010 which reiterated the DPG-LSD stance that the contamination originated at LLNL.[110] Colonel King testified that he reviewed this response and sent it to the DHHS-OIG with a signed cover letter.[111] There is no evidence of this signed cover letter and the DHHS-OIG has no record

[102] *See* 42 U.S.C. §§ 201, et. seq, 116 STAT. 594, P.L. 107-188.
[103] Enhanced Control of Dangerous Biological Agents and Toxins, 42 U.S.C. Part 262a(1) and Civil Money Penalties, 42 C.F.R. pt. 73.21.
[104] *See* Tab C-41, pg. 71, LLNL Correspondence and Evidence.
[105] [redacted]
[106] *See* Tab C-41, pg. 81, LLNL Correspondence and Evidence.
[107] *See* Tab C-41, pgs. 73-80, LLNL Correspondence and Evidence. [redacted] did not provide Colonel King with historical correspondence regarding the matter.
[108] *See* Tab B-23.2, [redacted] Memorandum for Record, subject: Transcribed Testimony of Brigadier General William King (Former Commander of Dugway Proving Ground from July 2009 to July 2011) (10 Nov. 2015).
[109] *See* Tab B-2.2, [redacted], Memorandum for Record, subject: Transcribed Testimony of [redacted] (12 Nov. 2015); Tab B-66.1, [redacted] Memorandum for Record, subject: Summarized Testimony of [redacted] (12 Nov. 2015); Tab B-68.1, [redacted] Memorandum for Record, subject: Summarized Testimony of [redacted]
[110] *See* Tab C-41, pg. 82, LLNL Correspondence and Evidence.
[111] *See* Tab B-23.2, [redacted] Memorandum for Record, subject: Transcribed Testimony of Brigadier General William King (Former Commander of Dugway Proving Ground from July 2009 to July 2011) (10 Nov. 2015).

of receiving the response.[112] Review of email correspondence from this timeframe indicates that the response memorandum was in the review process until at least April 2010. There is no evidence that it was ever signed and transmitted.[113]

Other than his testimony, there is no evidence that Colonel King directed a commander's inquiry or 15-6 Investigation to resolve the inconsistencies/disagreement between the findings of the CDC/DHHS-OIG and those of the DPG-LSD staff.[114] Review of the evidence indicates that [redacted] simply repackaged the information gathered for [redacted] in 2008. In spite of the fact that the CDC and DHHS-OIG findings were now considered final[115] and that a civil monetary penalty was authorized, no individual at DPG-LSD was formally disciplined in response to this mishap.

2. Naval Surface Warfare Center (2010)

In July 2010, the Naval Surface Warfare Center (NSWC) in Dahlgren, Virginia received a shipment from DPG-LSD containing Venezuelan Equine Encephalitis TC83 in lieu of *Bacillus anthracis* (Sterne strain) it had ordered from the CRP. The *Bacillus anthracis* Sterne had inadvertently been sent to ICX Biosystems, a private laboratory at La Jolla, California. ICX Biosystems had been expecting the Venezuelan Equine Encephalitis TC83 shipment. Neither the Venezuelan Equine Encephalitis TC83 strain nor the *Bacillus anthracis* (Sterne strain) are select agents, so this mishap was not reportable to the CDC. Both shipments had been packaged at the same time and had been shipped to the wrong customers. The NSWC contacted the CRP [redacted] The NSWC destroyed the vial of Venezuelan Equine Encephalitis TC83 and DPG-LSD sent the *Bacillus anthracis* Sterne that was original ordered.[116] [redacted] and [redacted], reported this mishap to their supervisor [redacted], but reporting stopped at [redacted] level.[117] Due to the initial and continued failure to report this event the chain of command was unable to investigate this mishap or take disciplinary actions. The DPG-LSD leadership is

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[112] *See* Tab B-69.1, [redacted] Memorandum for Record, subject: Summarized Testimony of [redacted] (12 Nov. 2015).

[113] *See* Tab C-41, pg. 97, LLNL Correspondence and Evidence.

[114] Note: the [redacted] The evidence indicates that [redacted] was engaged in the response to the LLNL incident in a support role, but since the Commander of DPG (Colonel King) was engaged directly, [redacted] was not responsible for the response.

[115] *See* Tab B-2.2, pg. 10, [redacted] Memorandum for Record, subject: Transcribed Testimony of [redacted] (12 Nov. 2015). DPG-LSD understood that this determination was final. The January 2010 response was drafted in an effort to formally document their continued disagreement with the CDC/DHHS-OIG finding.

[116] *See* Tab B-44.2.d, Enclosure 3, page 2 to [redacted] DA Form 2823, Sworn Statement (20 Aug. 2015); Tab B-44.2a, page 8, [redacted] Addendum to DA Form 2823, Sworn Statement (20 Aug. 2015). The *Bacillus anthracis* Sterne received by [redacted] was also destroyed.

[117] *See* Tab B-2.1.a, page 4, [redacted], DA Form 2823, Sworn Statement (21 Aug. 2015) [redacted] does not mention this mishap when summarizing past incidents in his statement, indicating he was unaware; Tab B-27.2a, page 7, [redacted], DA Form 2823, Sworn Statement (20 Aug 2015) states "[redacted] did keep me updated on her progress as she worked to resolve each incident which she did."

shown in Figure 8 above, and in Appendix A, *Enterprise View of Mishaps and Personnel (2003 – present)*.[118]

3. Three Erroneous Shipments of Botulinum neurotoxin A

On three separate occasions (27 February 2008, 20 October 2010, and 17 November 2010), [redacted][119] inadvertently shipped regulated quantities of Botulinum neurotoxin A to two separate entities. Quantities of Botulinum neurotoxin less than 0.5 mg total mass are exempt from the federal select agents and toxins list.[120] [redacted] believed the shipments contained 0.1 mg vials of Botulinum neurotoxin A, but the shipments contained 1.0 mg vials (a non-exempt quantity which requires handling as a select agent/toxin) due to errors made retrieving the vials from storage.[121]

Two of the erroneous shipments of Botulinum neurotoxin A were sent by DPG-LSD to ECBC located at Aberdeen Proving Ground, Maryland. One was sent on 27 February 2008 and the other was sent on 20 October 2010. Both of these shipments contained 1 mg/ml of Botulinum neurotoxin A (a regulated concentration), but the shipping documentation for each shipment indicated that the concentration was 0.1 mg/ml (an exempt concentration). The ECBC did not notice these discrepancies upon receipt.[122]

A third erroneous shipment of Botulinum neurotoxin A was sent from DPG-LSD to NMRC located in Forest Glen, Maryland on 17 November 2010. Similar to the shipments to ECBC, this shipment contained 1 mg/ml of Botulinum neurotoxin A (a regulated concentration) but the transfer documentation reflected 0.1 mg/ml (an exempt concentration). As with the 2008 and 2010 ECBC transfers, NMRC did not immediately notice that the vial received did not match the transfer documentation. The NMRC noticed the shipping error on 28 April 2011 and notified DPG-LSD, five months after the shipment was received. The DPG-LSD then immediately notified the CDC of the shipping error in a memorandum which also outlined corrective actions implemented to prevent similar shipping errors in the future.[123]

The DPG-LSD then conducted a search of their historical shipping database and discovered the earlier shipments to ECBC. The DPG-LSD notified the CDC of these two additional erroneous shipments in a memorandum dated 2 May 2011. The CDC responded to DPG-LSD and requested additional information about their inventory and database processes on 31 May 2011. The DPG-LSD provided the requested additional information on 8 June 2011. The CDC acknowledged receipt of this additional information in a memorandum dated 16 June 2011 and referred the matter to the DHHS-OIG.[124]

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[118] Figure 8 and Appendix A were used as tools to determine who knew, or should have known, about the various mishaps and track the actions that were taken in response.
[119] [redacted] has had numerous titles relating to storage and shipping during her tenure at DPG-LSD.
[120] *See* HHS Select Agents and Toxins, 42 C.F.R. pt. 73.3
[121] *See* Tab C-42, pg. 4, Bot A Correspondence and Evidence.
[122] *Id.*
[123] *See* Tab C-42, pg. 1, Bot A Correspondence and Evidence. The evidence indicates that [redacted] and Colonel King were all aware of this incident shortly after the initial notification was received.
[124] *See* Tab C-42, pgs. 3-16, Bot A Correspondence and Evidence.

On 3 November 2011, the DHHS-OIG issued its finding against DPG-LSD stating that the transfers of Botulinum neurotoxin A were unauthorized because DPG-LSD did not meet exemption requirements and did not obtain CDC authorization prior to transfer in accordance with 42 CFR Part 73.3 (HHS Select Agents and Toxins) and Part 73.16 (Transfers). Due to the severity of these shipping discrepancies, the DHHS-OIG was authorized to impose a civil monetary penalty of up to $250,000 against an individual and up to $500,000 against any other person/entity. However, since DPG-LSD is a government entity DHHS-OIG chose not to enforce the penalty. A penalty could have been levied separately for each of the three individual Botulinum neurotoxin A shipments.[125]

The DHHS-OIG recommended DPG-LSD examine its policies and procedures and implement corrective actions to prevent future improper shipments.[126] The causes of the three Botulinum neurotoxin A shipping mishaps were: (1) storing 1 ml vials having 1 mg/ml and 0.1 mg/ml concentrations together on the same shelf; (2) allowing these vials to have the same lot number and tracking number; (3) improper verification that the concentration requested (0.1 mg/ml) matched the concentration of the label on the vial pulled from storage (1 mg/ml); and (4) no established system of oversight to prevent human error.[127] As corrective actions, DPG-LSD physically separated vials containing various concentrations of Botulinum neurotoxin A, relabeled all vials with distinct lot/tracking numbers (by concentration), and instituted a two-person verification process prior to shipment.[128]

The Department of Army Inspector General (DAIG) and CDC were scheduled to conduct a joint Biological Surety/Select Agents Inspection of DPG-LSD from 9-13 May 2011. Coincidentally, this joint inspection was conducted concurrent to the initial notification and correspondence regarding the erroneous Botulinum neurotoxin A shipments. Because the erroneous shipments represented a violation of Army biological surety regulations, a failing deficiency was assigned against DPG-LSD by the DAIG. During the inspection out-brief, Colonel William King non-concurred with the failing deficiency based on an incorrect interpretation of DoD and Department of Transportation regulations.[129] The DAIG did not accept Colonel King's non-concurrence, and formalized the failing deficiency in their report on 29 June 2011.[130]

The DPG Commander, Colonel William King, ensured that DPG-LSD implemented remedial measures to prevent future shipping errors similar to the Botulinum neurotoxin A errors. However, Colonel King did not initiate either a commander's inquiry or a 15-6 investigation based on either the 13 May 2011 de-brief or the 29 June 2011 DAIG signed memorandum.[131]

[125] *See* Tab C-42, pg. 22, Bot A Correspondence and Evidence.
[126] *Id.*
[127] *See* Tab C-36, DAIG BSI 2011, para. 2-1.
[128] *See* Tab C-42, pg. 1, Bot A Correspondence and Evidence.
[129] *See* Tab C-36, DAIG BSI 2011, para. 2-1.
[130] *Id.* The BSI report executive summary states that the observations and deficiencies were also briefed to ATEC leadership.
[131] *See* Tab B-23.1.a, page 6, BG William King, Addendum to DA Form 2823, Sworn Statement (25 Sept. 2015); Tab C-31, page 2, Email from (b) (6) [redacted] to (b) (6) [redacted] Subject: 15-6 (30 Sept. 2015). Note: BG King claimed that he initiated an inquiry in his sworn statement, but no documentary evidence could be found to support this claim.

There is no evidence that any individual at DPG-LSD was formally disciplined in response to the shipping errors despite the fact that the errors resulted in a failed DAIG inspection and heavy civil penalties could have been imposed by the DHHS-OIG.

On 13 June 2011, Colonel King sent an email to leaders at ATEC and the Developmental Test Command (DTC) downplaying the seriousness of the shipping errors to his commanders:

> *It appears as reported earlier that CDC does not see the incident as serious as HQDA IG does and as previously reported is very comfortable with our reporting and immediate actions taken to address the circumstances to ensure it does not happen again.*[132]

This quote is in reference to the 31 May 2011 memorandum from the CDC.[133] The 15-6 investigation team reviewed this memorandum and interviewed associated personnel from the CDC and concluded that the evidence shows that the CDC considered this to be a serious incident, whereas Colonel King clearly did not. This is further supported by the CDC's decision to refer the matter to the DHHS-OIG.

4. Naval Surface Warfare Center Shipment of *Burkholderia mallei* (2010)

In December 2010, the Naval Surface Warfare Center (NSWC), received a shipment from DPG-LSD of inactivated *Burkholderia mallei* that had an incorrect lot number on the vials (extra digit was inserted), thereby not matching the enclosed death certificate, the accompanying certificate of analysis, or the shipping documentation. The NSWC contacted the [redacted] at DPG-LSD who told them to simply change the label. The NSWC declined to do that, so DPG-LSD sent a new death certificate, a new Certificate of Analysis, and new vial labels. However, DPG-LSD committed two additional errors in the course of this second shipment. First, the new Certificate of Analysis did not have correct concentration and genomic equivalent values. Second, the corrected labels had a different aliquot number. When NSWC questioned DPG-LSD about the different aliquot number on the new labels, DPG-LSD told them since all vials were from the same batch lot, the aliquot number was irrelevant.[134] The NSWC accepted this explanation and used the material as planned.

[redacted] notified the Joint Program Executive Office for Chemical and Biological Defense, CRP management office of actions she took, but she did not report the incident to the DPG-LSD chain of command.[135] [redacted], the DPG-LSD [redacted] also did not report this incident to the DPG-LSD chain of command. There was no formal reporting of this event, therefore the chain of command was unable to investigate this mishap or take disciplinary actions. The DPG-LSD leadership is shown in Figure 8 above, and in Appendix A, *Enterprise View of Mishaps and Personnel (2003 – present).*

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[132] *See* Tab C-42, pg. 12, Bot A Correspondence and Evidence.
[133] *See* Tab C-42, pg. 6, Bot A Correspondence and Evidence.
[134] *See* Tab B-44.2.d, Enclosure 3, page 2 to [redacted] DA Form 2823, Sworn Statement (20 Aug. 2015). This incident was not CDC reportable due to its administrative nature.
[135] *See* Tab B-44.2a, page 8, [redacted] Addendum to DA Form 2823, Sworn Statement (20 Aug. 2015).

5. Naval Surface Warfare Center Shipment of *Vaccinia* (2014)

In September 2014, a shipment of inactivated *Vaccinia* from DPG-LSD to Naval Surface Warfare Center (NSWC) was mislabeled with an incorrect lot number and "Live" *Vaccinia* nomenclature.[136] Viable *Vaccinia* virus is a research tool used in a variety of biomedical applications but it can be a human pathogen, making the live strain a Risk Group 2 organism.[137] The inactivated *Vaccinia* had been procured from a commercial vendor. [redacted] removed the commercial vendor labels from 17 vials and replaced them with DPG-LSD CRP labels that indicated viable *Vaccinia*, lot number AGD0000182. The correct label should have been inactivated *Vaccinia*, lot number AGD0000219. Two different DPG-LSD personnel failed to detect that the incorrect lot number was being shipped,[138] despite earlier findings and re-training implemented by the DPG-LSD leadership to ensure these types of mishaps did not continue to occur.[139]

Two of the seventeen vials were sent by the NSWC to the Midwest Research Institute in January 2015 where the labeling mistake was discovered. The NSWC notified one of the Joint Program Executive Office-Chemical Biological Defense, [redacted] and DPG-LSD ([redacted]). Upon notification, the DPG-LSD recalled the vials remaining in inventory at NSWC, re-labeled them to reflect the correct information, and returned them to the NSWC in January 2015.[140] Neither [redacted] nor [redacted] reported this mishap through the DPG-LSD chain of command.[141] DPG-LSD did not initiate an internal investigation or take any formal disciplinary actions related to this mishap. The leadership at the time of this incident is shown in Figure 8 above, and in Appendix A, *Enterprise View of Mishaps and Personnel (2003 – present).*

6. ECBC and USAMRIID Shipment of Venezuelan Equine Encephalitis (2003-2004)

On 25 August 2015, as part of an ongoing CDC investigation at ECBC and USAMRIID,[142] a potential incident was identified in which DPG-LSD may have improperly shipped Venezuelan Equine Encephalitis virus as a non-select agent (e.g., not a biological select agent and toxin).[143] Sometime during 2003-2004, USAMRIID shipped Venezuelan Equine Encephalitis virus to DPG-LSD. At the time of this shipment Venezuelan Equine Encephalitis virus was not

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[136] *See* Tab B-44.2a, page 8, [redacted] Addendum to DA Form 2823, Sworn Statement (20 Aug. 2015).
[137] *See* Tab E-5, BMBL, section II, Table 1, Classification of Infectious Microorganisms by Risk Group.
[138] See Tab E-10, Critical Reagents Program, Corrective Action Report (CAR) Form (13 Jan. 2015).
[139] *See* Tab C-42, pg. 1, Bot A Correspondence and Evidence.
[140] *See* Tab B-44.2.d, Enclosure 3, pages 3-8 to [redacted] DA Form 2823, Sworn Statement (20 Aug. 2015).
[141] *See* Tab B-44.2a, page 8, [redacted] Addendum to DA Form 2823, Sworn Statement (20 Aug. 2015).
[142] *See* Tab E-32, Memorandum from the Department of Health and Human Services, Centers for Disease Control and Prevention, to [redacted] U.S. Army Medical Research Institute of Infection Diseases, RE: Re-Inspection of U.S. Army Medical Research Institute of Infection Diseases (21 Aug. 2015).
[143] *See* Tab C-48, Email from MG Daniel L. Karbler, to LTG Gary H. Cheek Subject: Fw: Regulatory violations likely (15 Sept. 2015). *See also* Tab C-49 Spreadsheet with VEE Details (15 Sept. 2015).

considered a Biological Select Agent and Toxin.[144] However, on 18 March 2005, the CDC added Venezuelan Equine Encephalitis virus to the list of biological select agents and toxins.[145]

Between 2006 and 2012 DPG-LSD shipped what they believed were inactivated (i.e., killed) samples of this Venezuelan Equine Encephalitis virus to two U.S. Government laboratories (ECBC and the Armed Forces Institute of Pathology) and four commercial laboratories.[146] In 2010, DPG-LSD questioned whether this inactivated Venezuelan Equine Encephalitis virus should be considered a biological select agent and reached out to the CDC for an answer. The DPG-LSD wanted to know whether it could ship inactivated Venezuelan Equine Encephalitis without the Form 2, Request to Transfer Select Agents and Toxins, required for Biological Select Agents and Toxins and whether it could be shipped to a non-registered facility. The CDC indicated that if the Venezuelan Equine Encephalitis was not viable it would not fall under the Federal Select Agent Program, but also stated that it was up to DPG-LSD to determine whether it was viable or not.[147]

In February 2013, DPG-LSD reached out to USAMRIID to ask whether the inactivated Venezuelan Equine Encephalitis that USAMRIID sent in 2003-2004 had been tested for viability. (b) (6) [redacted] at USAMRIID responded that "work was done to give us evidence that the viruses were indeed killed by Trizol LS."[148] The CDC continues its investigation to determine if the shipments of Venezuelan Equine Encephalitis virus violated the requirements of the Federal Select Agent Program.[149]

7. Republic of Korea Shipment of *Bacillus anthracis* and *Yersinia pestis* (2014)

In March 2014, DPG-LSD shipped a mislabeled package to Republic of Korea containing inactivated *Bacillus anthracis* (now known to be viable) from lot AGD0001667 along with attenuated *Yersinia pestis*.[150] The error on the shipping label described the contents as "4 mL KILLER ORGANISM ON DRY ICE, UN1845."[151] DPG-LSD sent detailed information to the DPG Transportation Office, with the nomenclature "4 mL KILLED ORGANISM ON DRY ICE". The DPG Transportation Office made the typographical error on the shipping documentation (Transportation Control Number W67HY840850020XXX and Commercial

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[144] *Id.*
[145] Select Agents and Toxins, 42 C.F.R. pt. 73 (18 Mar. 2005).
[146] *See* Tab C-45, Email from (b) (6) [redacted], to Carmen Spencer, Douglas Bryce, and (b) (6) [redacted] Subject: RE: CDC Issues (15 Sept. 2015).
[147] *See* Tab C-44, Email from (b) (6) [redacted], to (b) (6) [redacted], Subject: Inactivated VEE Question (13 Sept. 2010).
[148] Tab C-43, Email from (b) (6) [redacted] to (b) (6) [redacted] Subject: Re: Need help finding an inactivation Confirmation for VEE Trinidad Trizol (1 Mar. 2013).
[149] *See* Tab C-48, Email from MG Daniel L. Karbler, to LTG Gary H. Cheek Subject: Fw: Regulatory violations likely (15 Sept. 2015). *See also* Tab C-49 Spreadsheet with VEE Details (15 Sept. 2015).
[150] *See* Appendix E, *Glossary*. A gram-negative bacteria that is the causative agent of plague.
[151] Although this shipment contained material from lot AGD0001667, this shipment was separate and distinct from the shipment to Korea that was found after the May 2015 discovery of viable *Bacillus anthracis*. There has been widespread public outcry and protests by Korean citizens in the aftermath of the May 2015 discovery, so the shipment of biological materials from the United States remains a sensitive issue for the Korean government: http://www.theguardian.com/world/2015/may/29/pentagon-anthrax-australia-2008.

Invoice) changing "KILLED" to "KILLER".[152] [redacted] did not catch the typographical error on the shipping documentation when she labelled the package for shipment.[153]

8. Summary

DPG leadership and DPG-LSD management were aware of four of the nine (eight shipping and one faulty inactivation) mishaps listed above and did not formally investigate or impose disciplinary actions on responsible individuals.[154] The DPG-LSD claims corrective actions were taken in each case,[155] but due to a lack of attention to detail, mishaps continued to occur. As seen in Figure 9, mishaps that required CDC notification were handled appropriately (Events 1, 3 and 6), but the chain of command was not made aware of the non-CDC reportable shipping errors.[156] Four of these events were serious enough that the DHHS-OIG had the option to enforce up to $2,000,000 in fines against DPG-LSD, but declined to do so since DPG-LSD is a Government entity. This does not include a potential $500,000 fine for the shipments related to the 22 May 2015 discovery of viable *Bacillus anthracis* at the center of this investigation.

Summary of DPG-LSD Historical Mishaps							
		Reported to or Has Knowledge of:					
	Event:	CDC	DPG CDR	LSD Director	[redacted]		
1	Lawrence Livermore National Laboratories - *Bacillus anthracis* (2007-2010)	Yes	This event was reported to the CDC and the Chain of Command was fully informed.				
2	Naval Surface Warfare Center - Venezuelan Equine Encephalitis (2010)	No	No	No	Yes	Yes	Yes
3	Three Erroneous Shipments of Botulinum neurotoxin A (2008-2010)	Yes	This event was reported to the CDC and the Chain of Command was fully informed.				
4	Naval Surface Warfare Center – *Burkholderia mallei* (2010)	No	No	No	No	Yes	Yes
5	Naval Surface Warfare Center – *Vaccinia* (2014)	No	No	No	No	Yes	Yes
6	ECBC and USAMRIID - Venezuelan Equine Encephalitis (2003-2004)	Yes	This event is currently under investigation by the CDC.				
7	Republic of Korea - *Bacillus anthracis* and *Yersinia pestis* (2014)	No	No	No	No	No	Yes

Figure 9: Summary of DPG-LSD Historical Mishaps

[152] *See* Tab C-21, Shipping Documents for Korea Incident (2014).
[153] *See* Tab C-28, Memorandum for Record, subject: Teleconference with Dugway Proving Ground Life Sciences Division (15 Sept. 2015).
[154] DPG Leadership was aware of at least four of the nine mishaps at the time of their occurrence. Also note that Event 3 in Figure 9 includes three separate shipments, bringing the total number of events considered to nine.
[155] *See* Tab B-2.1.a, page 4, [redacted] Addendum to DA Form 2823, Sworn Statement (21 Aug. 2015).
[156] Reporting for Event 2 ended at the [redacted] level, and reporting for Events 4, 5, and 7 never made it past the technicians that were involved.

Finally, the three additional non-select agent mishaps, which occurred under the DPG-LSD CRP team consisting of [redacted] were never reported to the DPG-LSD chain of command. One non-select agent shipping discrepancy is still under investigation by the CDC.[157] No internal investigations were conducted and no disciplinary action was taken against any DPG-LSD personnel for any of the shipping or faulty inactivation mishaps.[158]

G. Post 22 May 2015 Events at DPG-LSD

In response to the 22 May 2015 notification that the private company had received viable *Bacillus anthracis*, DPG-LSD began a comprehensive review of the CRP Antigen Repository shipping records and re-testing of inactivated *Bacillus anthracis* lots still in inventory to determine the extent of the inadvertent shipments.[159] On 23 May 2015 (Saturday), [redacted] notified [redacted] that the private company was able to grow Bacillus anthracis Ames from lot AGD0001667 (the lot at the center of this investigation) and directed her to report to work the following day to begin investigating the issue. On 24 May 2015 (Sunday), [redacted] pulled 15 random tubes from lot AGD0001667 and plated them onto tryptic soy agar plates, in triplicate, to see if she could repeat the observation found at the private laboratory. On 25 May 2015, (Monday, Memorial Day), [redacted] and [redacted] returned to the laboratory to read the plates and confirmed that all 15 aliquots were showing growth/a low concentration of vegetative bacillus colonies.[160]

On 26 May 2015 (Tuesday, first work day after Memorial Day), [redacted] directed that every lot of inactivated *Bacillus anthracis* currently still in storage at DPG-LSD undergo viability testing. When growth consistent with or characteristic to *Bacillus anthracis* was observed, the technicians were instructed to coordinate with the Polymerase Chain Reaction laboratory to confirm the *Bacillus anthracis* growth.[161] The staff at DPG-LSD were able to pull and test *Bacillus anthracis* from 33 lots produced between 2004 and 2015. Seventeen of the 33 lots tested positive for *Bacillus anthracis* growth. Personnel from the Joint Program Executive Office CRP management office compiled the chart in Figure 10 below which summarizes the test results for of the 33 lots of *Bacillus anthracis* that remained in the government's possession.

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[157] *See* Tab C-48, Email from MG Daniel L. Karbler, to LTG Gary H. Cheek Subject: Fw: Regulatory violations likely (15 Sept. 2015). *See also* Tab C-49 Spreadsheet with VEE Details (15 Sept. 2015).
[158] *See* Tab B-2.1.a, page 4, [redacted] Addendum to DA Form 2823, Sworn Statement (21 Aug. 2015).
[159] *See* Tab B-27.2a, page 6, [redacted] Addendum to DA Form 2823, Sworn Statement (20 Aug. 2015).
[160] *See* Tab B-44.2.a, page 4, [redacted] Addendum to DA Form 2823, Sworn Statement (20 Aug. 2015).
[161] *Id.*

Death Certificate	Date	Lot #	Hot?	Project Officer	Safety Officer	Responsible Official	SOP on DTC	kGy
DTC0105	1/22/04	AGD0000069	Yes	(b)(6) [redacted]	(b)(6) [redacted]	[redacted]	147 Ver 0	41
DTC0105	1/22/04	AGD0000070	Yes	[redacted]	[redacted]	[redacted]	147 Ver 0	41
DTC0121	8/8/04	AGD0000515	No	[redacted]	[redacted]	[redacted]	147 Ver 0	41
DTC0121	8/8/04	AGD0000511	Yes	[redacted]	[redacted]	[redacted]	147 Ver 0	41
DTC0121	8/8/04	AGD0000516	Yes	[redacted]	[redacted]	[redacted]	147 Ver 0	41
DTC0194	7/28/05	AGD0000644	No	[redacted]	[redacted]	[redacted]	147 Ver 0	33.67
DTC0195	7/28/05	AGD0000648	No	[redacted]	[redacted]	[redacted]	147 Ver 0	33.67
DTC0241	4/17/06	AGD0000774	No	[redacted]	[redacted]	[redacted]	147 Ver 0	39.01
DTC0242	4/17/06	AGD0000778	No	[redacted]	[redacted]	[redacted]	147 Ver 0	38.66
DTC0251	4/17/06	AGD0000790	No	[redacted]	[redacted]	[redacted]	147 Ver 0	48.78
DTC0252	4/17/06	AGD0000794	Yes	[redacted]	[redacted]	[redacted]	147 Ver 0	45.48
DTC0253	4/17/06	AGD0000798	Yes	[redacted]	[redacted]	[redacted]	147 Ver 0	45.48
DTC0257	4/17/06	AGD0000806	Yes	[redacted]	[redacted]	[redacted]	147 Ver 0	45.41
DTC0258	4/18/06	AGD0000810	Yes	[redacted]	[redacted]	[redacted]	147 Ver 0	52.93
DTC0268	6/1/06	AGD0000830	No	[redacted]	[redacted]	[redacted]	147 Ver 0	43.32
DTC0264	6/1/06	AGD0000822	Yes	[redacted]	[redacted]	[redacted]	147 Ver 0	45.74
DTC0278	8/23/06	AGD0000858	No	[redacted]	[redacted]	[redacted]	147 Ver 0	46.7
DTC0286	8/23/06	AGD0000862	Yes	[redacted]	[redacted]	[redacted]	147 Ver 0	36.5
DTC0310	10/25/06	AGD0000910	Yes	[redacted]	[redacted]	[redacted]	147 Ver 0	41.14
DTC0382	10/2/07	AGD0000950	No	[redacted]	[redacted]	[redacted]	147 Ver 0	49.59
DTC0383	10/2/07	AGD0000954	No	[redacted]	[redacted]	[redacted]	147 Ver 0	49.59
DTC0430	10/18/07	AGD0000999	Yes	[redacted]	[redacted]	[redacted]	147 Ver 0	40.75
DTC0498	8/4/08	AGD0001039	Yes	[redacted]	[redacted]	[redacted]	147 Ver 1	40.98
DTC0497	8/5/08	AGD0001035	No	[redacted]	[redacted]	[redacted]	147 Ver 1	43.29
DTC0572	5/18/09	AGD0001151	Yes	[redacted]	[redacted]	[redacted]	147 Ver 1	40.96
DTC0670	11/4/10	AGD0001331	No	[redacted]	[redacted]	[redacted]	147	57.58
DTC0723	10/29/12	AGD0001435	No	[redacted]	[redacted]	[redacted]	147	43.08
DTC0727	10/29/12	AGD0001451	No	[redacted]	[redacted]	[redacted]	147	40.16
DTC0803	3/18/14	AGD0001667	Yes	[redacted]	[redacted]	[redacted]	147 Ver 1	119.6
Not Available		AGD0001575	No	[redacted]	[redacted]	[redacted]		
DTC0791	9/9/14	AGD0001631	Yes	[redacted]	[redacted]	[redacted]	147	44.61
Not Available		AGD0001727	Yes	[redacted]	[redacted]	[redacted]		
DTC0825	1/8/15	AGD0001675	No	[redacted]	[redacted]	[redacted]	147	50.96
Colum D (Hot?): Yes=These lots tested positive in 2015, No=These lots tested negative in 2015								
Column H (SOP on Death Certificate): Red=Version of WDL-BIO-147 on the Death Certificate does not match the version in effect at the time								
Colum I (kGy): Green=Dose was within 40±2 kGy target dose, Red: Dose was lower than 40±2 kGy target dose; Yellow: Dose was higher than 40±2 kGy target								

Figure 10: DPG-LSD Test Results

From 26-28 May 2015, CDC personnel were present at DPG-LSD to conduct their own investigation and to determine if live *Bacillus anthracis* had been shipped to any other sites. The CDC determined that the cause of the inadvertent shipment of viable *Bacillus anthracis* spores from lot AGD0001667 was a failure of DPG-LSD to achieve 100% inactivation of the spores through treatment with gamma radiation. Their review of the inactivation and safety testing protocol indicated that DPG-LSD was using spore concentrations near the safety limits of the established dose, and that their safety/viability tests were not sufficient to detect spores which were not inactivated by the gamma radiation. The CDC inspectors observed that the DPG-LSD standard operating procedure for the irradiation of *Bacillus anthracis* spore suspensions did not account for the variable amounts of spores treated in the gamma cell irradiator.[162]

On 24 July 2015, the CDC sent a letter to the DHHS-OIG recommending that it assess DPG-LSD with a civil penalty in accordance with the provisions of section 262a(i) of Title 42 of the United States Code for violations of the select agent and toxin regulations, specifically sections 73.12 (Biosafety) and 73.16 (Transfers) of Title 42 of the Code of Federal Regulations. The CDC ruled that high concentrations of spore counts resulted in inactivation failures which in turn led to the transfer of viable *Bacillus anthracis* to at least 194 domestic registered and non-registered entities via 575 shipments (as of 2 October 2015). The CDC inspectors observed that the method used for the inactivation of *Bacillus anthracis* spore suspensions, Cobalt 60 gamma irradiation, was not validated using standardized control spore samples at varying concentrations, volumes, and levels of irradiation. As a result, viable *Bacillus anthracis* spore suspensions (spores floating freely in high purity lab water) were shipped from DPG-LSD as inactivated samples.[163]

The 15-6 investigation team visited DPG-LSD from 17-20 August 2015. On 19 August 2015, video footage of the previous 90 days (9 June 2015 –18 August 2015) of work performed in the DPG-LSD CRP laboratory suite was reviewed by one of the 15-6 investigation team members. Three incidents were observed. On 27 May 2015, a technician [redacted] dropped a rack of sample plates in the CRP Suite. Since the plates were removed from the incubator inside the biosafety level-3 suite, it is likely that live biological agent was present on the plates. On 14 June 2015, a technician [redacted] failed to wear a powered air purifying respirator while operating and opening a shaker/incubator in the CRP Suite. The DPG-LSD standard operating procedure requires a powered air purifying respirator to be worn whenever an operation might generate *Bacillus anthracis* aerosol (e.g. opening shaker). Finally, on 8 July 2015, [redacted] placed laboratory supplies on the front grille of the biosafety cabinet, impeding airflow both internally and externally to the primary containment barrier – an event that can cause a potential release of biological agent(s) outside the primary containment barrier.[164]

On 19 August 2015, in response to actions observed on the video footage and concerns raised during interviews with DPG-LSD personnel, the 15-6 Investigating Officer directed [redacted] (a member of the 15-6 investigation team) to conduct environmental sampling in the CRP laboratories with assistance from the DPG-LSD [redacted]. As a result of that sampling, on 20 August 2015, live *Bacillus anthracis* Ames was confirmed outside of primary containment in Room 506, a biosafety level-3 laboratory.[165]

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[162] *See* Tab D-1.a, Memorandum from the Department of Health and Human Services, Centers for Disease and Control Prevention, to [redacted], RE: Entity Inspection Report: Life Science Test Facility (LSTF) (05 June 2015).

[163] *See* Tab D-1.b, Memorandum from the Department of Health and Human Services, Centers for Disease and Control Prevention, to [redacted] Department of Health and Human Services OIG, subject: Life Science Test Facility (Registration #C20121022-1418) (24 July 2015).

[164] *See* Tab B-16.1, [redacted], DA Form 2823, Sworn Statement, (24 Aug. 2015). *See also* Tab B-35.2, [redacted] DA Form 2823, Sworn Statement (20 Aug. 2015). [redacted] observed [redacted] work in the hood as being "crowded" multiple times in the past.

[165] *See* Tab B-16.1, [redacted], DA Form 2823, Sworn Statement, (24 Aug. 2015).

On 20 August 2015, the CDC was notified that live *Bacillus anthracis* (Ames Strain) was found outside primary containment, as this is a CDC reportable event.[166]

On 27-28 August 2015, in response to the results of the environmental sampling performed by the 15-6 investigation team on 19-20 August 2015, the CDC sent a team to re-inspect DPG-LSD focusing on three issues: (1) identification of the source of the contamination outside of primary containment; (2) identification of any environmental contamination outside of biosafety level-3 suites; and (3) a determination if personnel who had potentially been exposed had an opportunity to be seen by occupational medical staff.[167] Based upon the results of this inspection, the CDC suspended DPG-LSD's Federal certificate of registration to possess, use, and transfer *Bacillus anthracis* on 28 August 2015. The suspension was based on DPG-LSD's continued failure to ensure that biosafety and containment procedures were sufficient to properly contain *Bacillus anthracis.*[168]

After further review, on 31 August 2015, the CDC formally suspended DPG-LSD's certificate of registration to possess, use, and transfer all select agents and toxins. Accordingly, DPG-LSD was directed to cease all select agent activities and securely store all select agents to prevent theft, loss, or release of those select agents and toxins. The CDC stated that the suspension of registration was based upon DPG-LSD's continued failure to ensure that biosafety and containment procedures were sufficient to properly contain *Bacillus anthracis*. The CDC also identified biosafety lapses that are associated with procedures (such as centrifugation) common to the manipulation of other select agents, so it decided to expand the suspension of *Bacillus anthracis* activities to include all select agents and toxins.[169] On 20 October 2015, the CDC provided DPG-LSD with an inspection report detailing the various findings of the 27-28 August 2015 inspection.[170]

On 15 September 2015, DPG-LSD had its High-Efficiency Particulate Arrestance (HEPA) filter system tested in accordance with annual testing and certification requirements. The HEPA filter system is designed to be a redundant safeguard to prevent release of biological agents present in the facility's air handling system. DPG-LSD contracted with Winergy Services to perform the test. Winergy published the test results in a written report dated 30 September 2015 which DPG-LSD received on 13 October 2015. The HEPA filter report indicated that HEPA Bank Filter C (lower right, lower left and upper right) and the lower HEPA Bank A (lower right)

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[166] *Id.*

[167] *See* Tab D-4.a., Memorandum from the Department of Health and Human Services, Centers for Disease Control and Prevention, to [redacted] Life Science Test Facility, subject: Re-inspection of Life Science Test Facility (26 Aug. 2015).

[168] *See* Tab D-4.b., Memorandum from the Department of Health and Human Services, Centers for Disease Control and Prevention, to [redacted] Life Science Test Facility, subject: Suspension of Registration: Life Science Test Facility (28 Aug. 2015).

[169] *See* Tab D-4.c., Memorandum from the Department of Health and Human Services, Centers for Disease Control and Prevention, to [redacted] Life Science Test Facility, subject: Suspension of Registration: Life Science Test Facility (31 Aug. 2015).

[170] *See* Tab D-4.d., Memorandum from the Department of Health and Human Services, Centers for Disease Control and Prevention, to [redacted] Life Science Test Facility, subject: Entity Inspection Report - Life Science Test Facility (20 Oct. 2015).

failed to pass the annual HEPA certification.[171] [redacted] stated that the failure may have originated in the structure of the HEPA filter unit, which allowed for leakage around the edges of the filters, not the filters themselves.[172] Previous HEPA filter certifications performed by ENV Services passed all regulatory requirements.[173] DPG-LSD contacted ENV Services and requested that they re-test the HEPA filters to verify the results obtained by Winergy. ENV Services test results matched those of Winergy Services.[174]

On 13 October 2015, DPG-LSD received the results of the report and notified the CDC of the filter failure.[175] On 19 October 2015, the CDC requested additional information about the filter failure. On 20 October 2015, DPG-LSD provided the CDC with the requested information. DPG-LSD immediately directed their maintenance personnel to isolate the failed HEPA C bank and to switch over to the HEPA Banks that passed the certification tests. DPG-LSD tagged the failed HEPA banks and starting coordination to decontaminate the failed banks. DPG-LSD developed a risk mitigation and environmental sampling plan and notified the CDC on 27 October 2015. At the direction of the CDC, DPG-LSD collected environmental samples from the post filter downstream exhaust tube, plated the collected material, and initiated decontamination procedures. On 2 November 2015, DPG-LSD submitted a request to the Executive Agent to have the DoD moratorium and stand-down directive placed on LSD temporarily suspended so that it could test the environmental samples that were collected.[176] The request was denied, so the samples were subsequently destroyed in the autoclave. Prior to destruction a visual inspection of the plates showed no growth for any bacteria. As of 17 November 2015, there is no evidence to indicate that DPG-LSD leadership has attempted to identify the root cause of the HEPA filter failure or investigate the issue beyond what was requested by the CDC.[177]

The investigation team learned about the HEPA filter failure during an interview with [redacted][178] He stated that the DPG-LSD response to the HEPA filter failure was troubling. The personnel at DPG-LSD were not proactive in their response to the failure and it was only after the CDC requested specific information from DPG-LSD that the CDC saw any evidence of risk assessment and or real action in response to the failure. [redacted] stated that he is frustrated with DPG-LSD, and that this frustration is due to his impression that "there does not seem to be anyone at DPG-LSD that is really thinking about biosafety, how they investigate incidents, what they should be doing to

[171] *See* Tab C-50, HEPA Filter Correspondence and Evidence.
[172] *See* Tab B-2.2, pg. 22, [redacted] Memorandum for Record, subject: Transcribed Testimony of [redacted] (12 Nov. 2015). [redacted] states that there was a very small leak around the side of the filter.
[173] *See* Tab C-50, HEPA Filter Correspondence and Evidence. The HEPA filters are inspected/tested annually. ENV Services conducted the annual inspections prior to 2015.
[174] *See* Tab B-2.2, [redacted] Memorandum for Record, subject: Transcribed Testimony of [redacted] (12 Nov. 2015).
[175] *See* Tab C-50, HEPA Filter Correspondence and Evidence.
[176] *Id.* DPG-LSD would not be allowed to test the downstream samples under the terms of the BSAT moratorium.
[177] *See* Tab B-2.2, [redacted] Memorandum for Record, subject: Transcribed Testimony of [redacted] (12 Nov. 2015).
[178] [redacted]

prevent future incidents, and how they assess the consequences for various incidents."[179] He reiterated that his larger concern is not with a potential escape, for which there was a low risk, but rather with the DPG-LSD response, which was insufficient until staff at DSAT started prodding DPG-LSD for information and action.[180] Also of note, [redacted] indicated that in light of historical issues with incidents not being reported up the chain of command in large complex organizations like the DoD, the CDC is changing its notification policy to require parallel notification to senior officials in the chain of command (they currently correspond only with the responsible officials at each lab).[181]

H. Institutional Trends at Life Sciences Division

The DPG-LSD, like other government institutions, has experienced personnel and budgetary changes over time that affected the organization. The changes over the past 20 years resulted in a reduction in personnel, a decrease in the level of education and experience of its personnel, and leadership changes in critical positions. However, since 2007 the leadership at the branch and division level has remained fairly stable.

1. Personnel Reductions

The Department of the Army has been affected by a reduced budget in recent years.[182] Proportionally, DPG and the DPG-LSD likewise experienced budget reductions. As a result, the civilian work force at DPG-LSD was forced to eliminate positions.[183]

In April 2014, DPG-LSD executed a reorganization aimed at mitigating these impacts within the constraints of authorizations from ATEC.[184] The end result was a 26% reduction in the division workforce.[185] In spite of these reductions, DPG-LSD continued to meet the mission requirements by tasking its personnel to take on additional duties.[186]

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[179] *See* Tab B-67.1, [redacted] Memorandum for Record, subject: Summarized Testimony of [redacted] (12 Nov. 2015).
[180] *Id.*
[181] *Id.*
[182] *See generally* Michelle Tan, Army lays out plan to cut 40,000 Soldiers, ARMY TIMES, Jul 10, 2015 http://www.armytimes.com/story/military/pentagon/2015/07/09/army-outlines-40000-cuts/29923339; and Brad Plumer, America's Staggering Defense Budget, In Charts, WASHINGTON POST, Jan. 7, 2013, http://www.washingtonpost.com/news/wonkblog/wp/2013/01/07/everything-chuck-hagel-needs-to-know-about-the-defense-budget-in-charts.
[183] *See* Tab B-2.1, page 1-2, [redacted] DA Form 2823, Sworn Statement (21 Aug. 2015). The most relevant reduction/reorganization has occurred in the quality assurance/quality control workforce. DPG-LSD lost its dedicated QA/QC person in the 2011 timeframe and responsibility for the overall QA/QC function has been moved from the division level to the test center level, reducing its bandwidth and overall effectiveness.
[184] *See* Tab B-11.2.a, page 6, [redacted] Addendum to DA Form 2823, Sworn Statement (10 Sept. 2015).
[185] *Id.*
[186] *See* Tab B-11.2, page 2, [redacted] DA Form 2823, Sworn Statement (10 Sept. 2015).

2. Level of Education and Experience

Compounding the impact of the budget and personnel reductions during this period, DPG-LSD experienced natural attrition of highly educated and experienced personnel due to retirement and other personal reasons. Furthermore, DPG-LSD often had a difficult time drawing in new highly educated and experienced scientists because of its remote location. This may have contributed to the erosion of many core capabilities.[187]

One of the major hindrances to hiring Ph.D. educated scientists at DPG is the fact that it is a remote installation. The east gate is approximately one hour (45 miles) from Tooele, Utah and approximately one and a half hours (90 Miles) west of Salt Lake City. The DPG-LSD Life Science Test Facility is another half-hour (17 miles) from the east gate. Most of the DPG-LSD personnel at the Life Science Test Facility live in Tooele. "As work expands, DPG is able to hire scientists with degrees from further away. As the work wanes, the degreed scientists leave because they are employable elsewhere."[188] These departures, coupled with budget cuts and the remote geographical location of DPG-LSD, make maintaining a roster of qualified, Ph.D. educated scientists a challenge.

This natural ebb and flow of Ph.D. educated scientists creates vacancies because the Army has difficulty hiring new Ph.D. accredited scientists to fill positions in an expeditious manner. As such, DPG-LSD has downgraded personnel duty descriptions to hire from within the local community. This practice allows the stable, local workforce the opportunity to advance and move into these newly available positions. The Army is also able to continue to meet its mission requirements, albeit with a less qualified workforce. However, the downside of this condition is that many of the employees in DPG-LSD, occupying positions once held by true Ph.D. Level microbiologists, do not have graduate level degrees. This practice frustrates the limited number of highly educated personnel that remain at DPG-LSD.[189] Additionally, this trend creates the impression that the hiring practices are governed by an inner circle prone to favoritism.[190]

To add more credence to this appearance, historically, civilian employees at DPG were not hired using hiring panels. Many of the current employees still point to old hiring actions as evidence that an inner circle exists. Hiring panels are now used to decrease the perception of favoritism and also to reassure the workforce that the hiring process was not biased.[191] However, due to the isolated nature of the installation, there are 3rd and 4th generation families that live near and work at DPG.[192] The remaining Ph.D. educated scientists have noted that, even with the new hiring panels, the limited number of highly educated personnel continues to perpetuate a less inquisitive workforce more inclined to merely meet mission requirements. [redacted] elaborated on the impact of not having senior scientists with Ph.D. level educations conducting or supervising operations within the DPG-LSD:

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[187] *Id.*
[188] *See* Tab B-30.1.a, page 5, [redacted] Addendum to DA Form 2823, Sworn Statement (20 Aug. 2015).
[189] *Id.*
[190] *Id.*
[191] *See* Tab B-11.2, page 2, [redacted], DA Form 2823, Sworn Statement (10 Sept. 2015).
[192] *See* Tab B-30.1.a, page 5[redacted] Addendum to DA Form 2823, Sworn Statement (20 Aug. 2015).

Further, the microbiology branch [LSD] has staffed their senior scientist positions (for instance the senior virologist... only has a high school degree) with people who do not have the expertise to ask the questions that due diligence would have required. This situation where nobody was looking for the right questions, and the information was hidden from anyone who might ask the right questions, was done purposefully to avoid interference with the need to accomplish intermediate mission goals.[193]

While this viewpoint cannot be discounted, DPG-LSD contains a core of senior personnel in supervisory positions that are Ph.D. educated scientists with 20 years of experience in the field who could provide the leadership and guidance these newer, less educated and experienced employees need.

3. DPG-LSD Leadership Changes

DPG-LSD has only had two Directors over the past 17 years. These two were [redacted] – each having very different leadership styles. [redacted] is a Ph.D. educated scientist who began his career at DPG on 24 March 1980 working on applied microbiology in the DPG-LSD's aerosol branch. [redacted] became the DPG-LSD Director in 1998. As the Director, [redacted] had a hands-on leadership style. He was involved with the staff in their day-to-day activities in the lab[194] and regularly held morale building events.[195] [redacted] left civilian service in January 2008. After [redacted] retired, [redacted] took the DPG-LSD Director position.

[redacted] is a Ph.D. educated scientist. [redacted] started working as a microbiologist in the in the microbiology branch at DPG-LSD in 1991. [redacted] transferred from the microbiology branch to the aerosol branch where he became the section chief in 2000 and ultimately he became the Director of the DPG-LSD in September 2008.[196] [redacted] is a highly accomplished and respected scientist. However, his leadership style is more hands off than his predecessor and this has resulted in isolation from the workforce and a lack of situational awareness.[197] [redacted] freely admits that he has less interaction with his personnel in the labs than he would like because of the administrative demands placed on him.[198]

Section II of the findings will show that the change in leaders and leadership styles, coupled with the reduction in personnel, and level of education and experience of its personnel had a negative impact on DPG-LSD.

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[193] *See* Tab B-33.1, page 2, [redacted], DA Form 2823, Sworn Statement (20 Aug. 2015).
[194] *See* Tab B-30.1, page 2, [redacted] DA Form 2823, Sworn Statement (20 Aug. 2015).
[195] *See* Tab B-33.1.a, page 11-12, [redacted], Addendum to DA Form 2823, Sworn Statement (20 Aug. 2015).
[196] *See* Tab B-2.1, page 1-2, [redacted] DA Form 2823, Sworn Statement (21 Aug. 2015).
[197] *See* Tab B-30.1, page 2, [redacted] DA Form 2823, Sworn Statement (20 Aug. 2015). *See also* Tab B-11.2, page 3-4, [redacted] DA Form 2823, Sworn Statement (10 Sept. 2015).
[198] *See note* 196.

I. Background on the Inactivation Process of *Bacillus anthracis*

Bacillus anthracis is a gram positive,[199] non-motile,[200] non-hemolytic,[201] spore forming[202] bacterium that is the causative agent[203] of anthrax in humans and animals. *Bacillus anthracis* is extensively distributed in the soil throughout the world (i.e. the United States, Canada, Europe, and the Middle East).[204] Outbreaks of *Bacillus anthracis* affected both humans and animals regularly prior to the development of a vaccine in the late 19th Century.[205] Periodic outbreaks of *Bacillus anthracis* affecting livestock and wildlife are still seen in parts of the United States, Canada, Europe and Africa.[206] While *Bacillus anthracis* has the capability to cause serious disease in humans, the disease is non-communicable[207] and is treatable either through vaccination or early administration of antibiotics.[208] Since *Bacillus anthracis* infections are non-communicable and are often treatable, the organism is classified as a Risk Group 2 organism (moderate individual risk, low community risk) by both the CDC and National Institutes of Health.[209]

An understanding of the rationale and procedures used to inactivate *Bacillus anthracis* is necessary in order to comprehend the potential scientific explanations for the inadvertent and viable shipment of *Bacillus anthracis* that occurred on 20 April 2015 and was reported on 22 May 2015. The biological industry routinely inactivates biological select agents and toxins to provide unregistered facilities easy access for the testing and development of vaccines and equipment used to detect various biological select agents and toxins. Figure 11 provides a simplified look at the life cycle of *Bacillus anthracis* and Figure 12 depicts the inactivation process and healing hypothesis for *Bacillus anthracis*, both of which are described in detail in the following paragraphs.

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199 *See* Appendix E, *Glossary*. Gram positive strains of bacteria stain purple with crystal violet dye.
200 *See* Appendix E, *Glossary*. Unable to move.
201 *See* Appendix E, *Glossary*. Will not break down red blood cells. Bacterial hemolysis can be identified following incubation on sheep blood agar. Hemolytic bacteria will have a ring of damaged red blood cells around the colony forming units.
202 *See* Appendix E, *Glossary*. Organisms that have the ability to form spores that facilitate survival in harsh environmental conditions.
203 *See* Appendix E, *Glossary*. An organism that results in disease.
204 Mullins JC, Garofolo G, Van Ert M, Fasanella A, Lukhnova L, Hugh-Jones ME, Blackburn JK., *Ecological niche modeling of Bacillus anthracis on three continents: evidence for genetic-ecological divergence?*, PLOS ONE, 2013, Volume 8, Epub. *See also* Smith KL, DeVos V, Bryden H, Price LB, Hugh-Jones ME, Keim P., *Bacillus anthracis diversity in Kruger National Park*, JOURNAL OF CLINICAL MICROBIOLOGY, 2000 at pages 3780-4.
205 Pile JC, Malone JD, Eitzen EM, Friedlander AM, *Anthrax as a potential biological warfare agent*, ARCHIVES OF INTERNAL MEDICINE, 1998 at pages 429-34.
206 *Bacillus anthracis*, http://www.healthmap.org/promed/?p=8982. (last visited 23 Sept. 2015).
207 *See* Appendix E, *Glossary*. Not transmissible from person to person.
208 *See* Pile JC, Malone JD, Eitzen EM, Friedlander AM, *Anthrax as a potential biological warfare agent*, ARCHIVES OF INTERNAL MEDICINE, 1998 at pages 429-34.
209 *See* Tab E-5, BMBL, section VIII, Bacterial Agents; U.S. Dept. of Health and Human Services, National Institutes of Health Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, Appendix B-II-A, (6 Nov. 2013) [hereinafter NIH Guidelines].

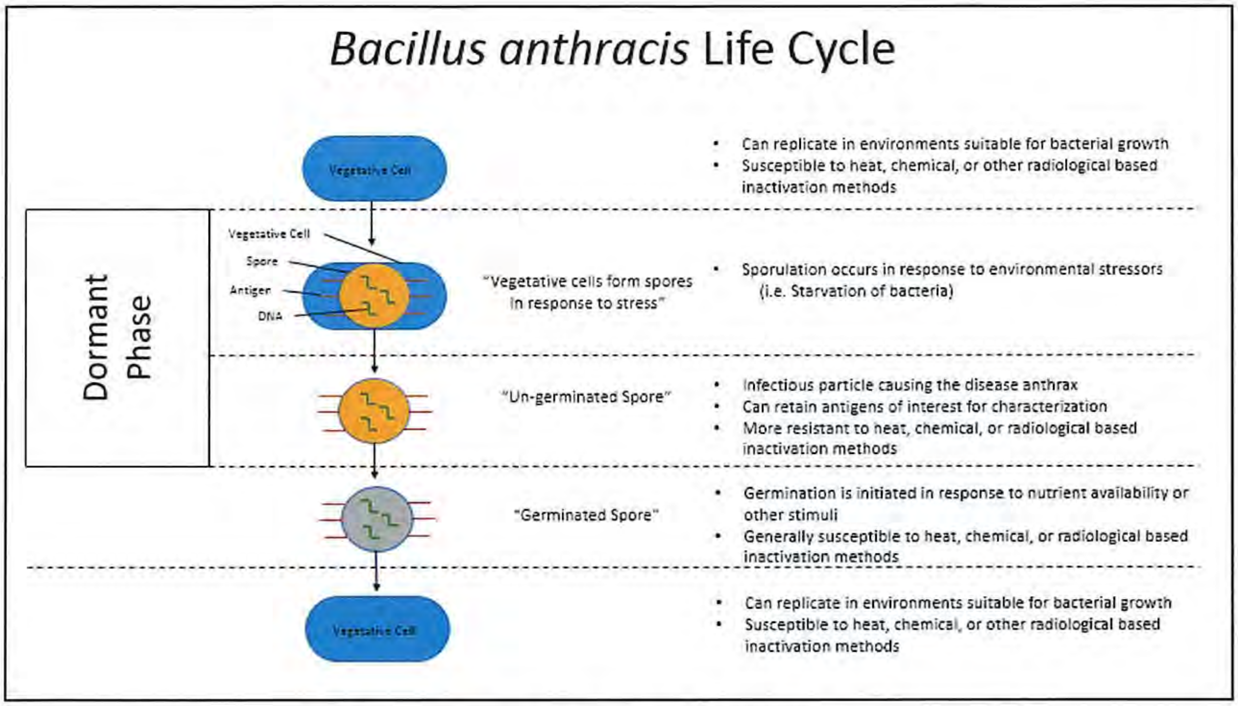

Figure 11: Bacillus anthracis Life Cycle

As seen in Figure 11, *Bacillus anthracis* can exist either as a vegetative cell[210] under normal environmental conditions or in a dormant spore form[211] through either natural or laboratory induced stressors. The vegetative cell produces a spore containing deoxyribonucleic acids (DNA) and enzymes used for growth and replication.[212] Antigens or surface proteins are present on both the spore form and the vegetative cell form and represent critical targets for researchers attempting to develop diagnostic assays for detection systems.[213] Because assay development primarily occurs outside of laboratories registered with the CDC Division of Select Agents and Toxins, it is important for researchers to be able to develop a method that both successfully inactivates the spores while preserving the critical antigens used for assay development.[214] The

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[210] *See* Appendix E, *Glossary*. A vegetative cell is a bacterial cell capable of replication and enzymatic activity. *See* Edwards KA, Clancy HA, Baeumner AJ, *Bacillus anthracis*: *toxicology, epidemiology and current rapid-detection methods*, ANALYTICAL BIOANALYTICAL CHEMISTRY, Jan. 2006, at pages 73-84.

[211] *See* Appendix E, *Glossary*. Dormant spore form is a state of existence where the cell is incapable of replication or enzymatic activity but is significantly more resistant to harsh environmental conditions. *See* Friedlander AM, *Anthrax: clinical features, pathogenesis, and potential biological warfare threat,* CURRENT CLINICAL TOPICS IN INFECTIOUS DISEASE, 2000, at pages 335-49; Liu J, Xu J, Chen W, *Present status and prospects for the detection of Bacillus anthracis--a review*, WEI SHENG WU XUE BAO, July 2012, at pages 809-15.

[212] *See* Setlow P., *Germination of Spores of Bacillus Species: What We Know and Do Not Know,* JOURNAL OF BACTERIOLOGY, Apr. 2014, at pages 1297-1305. [hereinafter Setlow P., *What We Know*].

[213] *See* Edwards KA, Clancy HA, Baeumner AJ, *Bacillus anthracis: toxicology, epidemiology and current rapid-detection methods*, ANALYTICAL BIOANALYTICAL CHEMISTRY, Jan. 2006, at pages 73-84; Liu J, Xu J, Chen W, *Present status and prospects for the detection of Bacillus anthracis--a review*, WEI SHENG WU XUE BAO, July 2012, at pages 809-15.

[214] *See* Edwards KA, Clancy HA, Baeumner AJ, *Bacillus anthracis: toxicology, epidemiology and current rapid-detection methods*, ANALYTICAL BIOANALYTICAL CHEMISTRY, Jan. 2006, at pages 73-84; Liu J, Xu J, Chen W,

dormant spore form of *Bacillus anthracis* is designed to protect it from a variety of environmental factors including excessive heat or dry conditions and it allows *Bacillus anthracis* to exist in this state for years in the absence of germination stimuli.[215]

Also seen in Figure 11, once *Bacillus anthracis* transitions from the vegetative cell form to the dormant spore form, a number of physiological changes occur in the organism. Two of the primary changes are the loss of water weight and enzymatic activity seen in a replicating vegetative cell. When *Bacillus anthracis* exists in the spore form, it is comprised of several layers including an exosporium, an outer spore coat, an outer membrane, a cortex, an inner membrane, and the spore core.[216] Both the outer and inner membrane help minimize transit of molecules from the spore coat to the spore core.[217] The spore core is comprised primarily of dipicolinic acid which binds to most of the remaining water within the organism during its dormant state.[218] All of these layers function to protect the spore core from the harsh environmental conditions that lead to the spore formation.

The spore core contains all of the elements required for growth and replication including DNA, transfer ribonucleic acids (RNA)[219] and enzymes that facilitate the transcription and translation of DNA to protein. While these elements are shared between the spore form and the vegetative cell form of *Bacillus anthracis*, the spore core also contains small acid soluble proteins and a dramatically decreased level of water which may function in gamma radiation resistance.[220] While in the spore form, *Bacillus anthracis* exhibits up to a seventy five-fold greater resistance to gamma radiation compared to the vegetative cell form.[221] The small acid soluble molecules have been shown to aid in resistance to chemicals and wet heat inactivation by forming a protective envelope around the DNA but this function has not been shown to effect gamma radiation resistance of *Bacillus anthracis*.[222] However, the decreased amount of water present in the spore core may have an effect on gamma radiation resistance of *Bacillus anthracis* since it may minimize both the transit of damaged molecules within the spore core and decrease

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Present status and prospects for the detection of Bacillus anthracis--a review, WEI SHENG WU XUE BAO, July 2012, at pages 809-15.

[215] *See* Setlow P., *Spore Resistance Properties*, MICROBIOLOGY SPECTRUM, Oct. 2014; Setlow P., *What We Know*.

[216] *See* Setlow P., *Spore Resistance Properties*, MICROBIOLOGY SPECTRUM, Oct. 2014; Setlow P., *What We Know*.

[217] *See* Setlow P., *What We Know*; Slieman TA and Nicholson WL, *Artificial and Solar UV Radiation Induces Strand Breaks and Cyclobutane Pyrimidine Dimers in Bacillus Subtilis Spore DNA*, APPLIED ENVIRONMENTAL MICROBIOLOGY, Jan. 2000, at pages 199-205.

[218] *See* Setlow P., *What We Know*.

[219] *See* Setlow P., *What We Know*.

[220] *See* Setlow P., *What We Know*.

[221] *See* Blatchley III ER, Meeusen A, Aronson AI, and Brewster L., *Inactivation of Bacillus Spores by Ultraviolet or Gamma Radiation*, JOURNAL OF ENVIRONMENTAL ENGINEERING, 2005, at pages 1245-1252; Bowen JE, Manchee RJ, Watson S, and Turnball PCB, *Inactivation of Bacillus anthracis Vegetative Cells and Spores by Gamma Irradiation*, SALISBURY MEDICAL BULLETIN Special Supplement 87, at pages 71-73; Slieman TA and Nicholson WL, *Artificial and Solar UV Radiation Induces Strand Breaks and Cyclobutane Pyrimidine Dimers in Bacillus Subtilis Spore DNA*, Applied Environmental Microbiology, January 2000, pages 199-205.

[222] *See* Tab E-33, Memorandum from [redacted] to [redacted], subject: *Bacillus anthracis* Questionnaire (28 Aug. 2015); Setlow P., *What We Know*.

the potential formation of hydroxyl radicals.[223] Additional reasons for resistance to gamma radiation remain unclear, but it is likely that some of the properties contributing to ultraviolet radiation resistance (i.e., DNA photochemistry, the spore coat, low water content and DNA repair) affect gamma radiation resistance as well.[224]

Figure 12 depicts the effects that irradiation has on a *Bacillus anthracis* spore and the proposed theory that the spore could undergo a healing phase and revert to a vegetative cell.

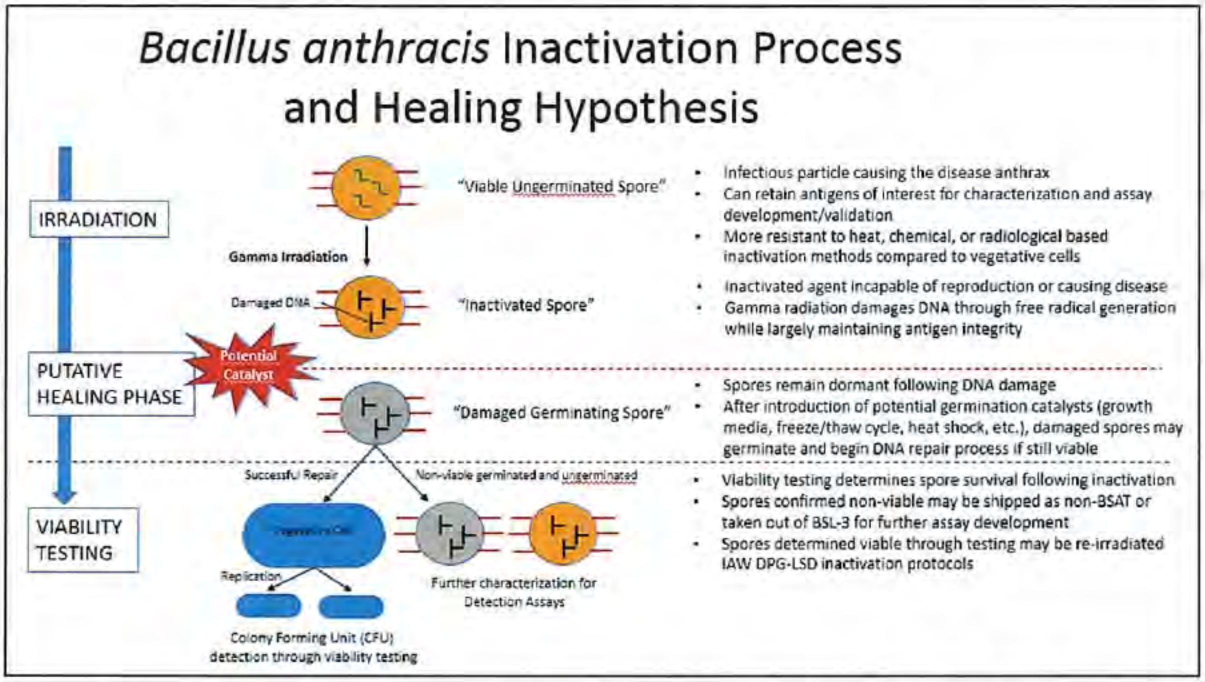

Figure 12: The Bacillus anthracis Inactivation Process and Healing Hypothesis

This putative healing phase is important because if the hypothesis is correct, it provides a potential explanation for why the initial viability test for *Bacillus anthracis* lot AGD0001667 (and the other lots addressed in Figure 10) showed no growth but subsequently did show growth when tested by the private entity. The putative healing phase has not been thoroughly researched by the scientific community. Potential research gaps associated with the putative healing phase that can be studied to optimize viability testing protocols include: (1) germination initiation parameters; (2) germinant receptor function post gamma irradiation; and (3) incubation

[223] *See* Appendix E, *Glossary*. A hydroxyl radical is an unstable form of the hydroxide molecule that can damage DNA. *See* Tab E-33, Memorandum from [redacted] to [redacted] subject: *Bacillus anthracis* Questionnaire (28 Aug. 2015)

[224] *See* Blatchley III ER, Meeusen A, Aronson AI, and Brewster L., *Inactivation of Bacillus Spores by Ultraviolet or Gamma Radiation*, JOURNAL OF ENVIRONMENTAL ENGINEERING, 2005, at pages 1245-1252; Tab E-34, Memorandum from [redacted] to [redacted], subject: *Bacillus anthracis* Questionnaire (31 Aug. 2015); Mizak L, Mierzejewski J., *Gamma Radiation Resistance of Bacillus anthracis Spores*, MEDYCYNA DOSWIADCZALNA I MIKROBIOLOGIA (WARSZAWA), 2003, at pages 315-23; Nicholson WL, Schuerger AC, Setlow P., *The solar UV environment and bacterial spore UV resistance: considerations for Earth-to-Mars transport by natural processes and human spaceflight*. MUTATION RESEARCH, Apr. 2005, at pages 249-64.

conditions (i.e. temperature, time and growth media).[225] Without addressing these gaps, researchers will continue to have difficulty balancing the need for definitive testing to validate the absence of viable agent with the need to deliver the best possible products to their customers.

As seen in Figure 12, at the onset of the Putative Healing Phase following exposure to gamma radiation, spores can continue to remain within the dormant state and likely do not initiate DNA repair processes until germination begins. While there is evidence of continued DNA to RNA transcription and RNA to protein translation processes in the early stages of spore formation, the absence of energy and nutrients curtails these processes in the dormant spore state.[226] Evidence suggests variance in temperature, time, salt content, air pressure and nutrients dramatically affect germination and growth rates of spores.[227] The introduction of a potential catalyst could serve to spur the onset of germination within the Damaged Germinating Spore. The potential catalyst could be any number of potential factors including but not limited to time, room temperature incubation, 37⁰C incubation, a freeze thaw cycle, or the introduction of growth media all of which require further study. Current protocols at DPG-LSD call for the initiation of viability testing within thirty minutes of *Bacillus anthracis* exposure to gamma irradiation.[228] In this instance, this rush to viability testing may not be ideal to allow the potential healing (and subsequent growth) of damaged *Bacillus anthracis* spores.[229]

Following the initiation of germination or the transition from the dormant spore form to the vegetative cell form, viability testing determines whether gamma radiation of *Bacillus anthracis* has achieved the desired outcome of an inactive, non-replicating spore (Figure 12). If gamma radiation has been successful, the sample is able to be removed from the laboratory for detection assay or countermeasure development. If however, the sample is determined to still be viable, replicating *Bacillus anthracis* is still present and gamma radiation has failed. The method that is used to determine whether gamma irradiated *Bacillus anthracis* is still viable is through the introduction of the sample to growth media. Growth media used to determine the viability of *Bacillus anthracis* can be either liquid nutrient broth or solid agar. After being introduced to growth media, the cell will initiate replication by making an identical copy of the DNA and any essential cellular materials (i.e. enzymes, molecules, and cell wall). Once the DNA and essential cellular materials are copied, the cell begins to divide and separate into two identical cells. The identical cells then resume the replication process to continue growth. After several cycles of replication, a colony forming unit becomes visible on the growth medium if *Bacillus anthracis* is still viable. On the other hand, and as shown in Figure 12, if the spore DNA and cellular components are damaged beyond repair capacity, the cell wall will either rupture upon

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[225] *See* Setlow P., *What We Know*.
[226] *See* Tab E-33, Memorandum from [redacted] to [redacted] subject: *Bacillus anthracis* Questionnaire (28 Aug. 2015); Segev E, Smith Y, Ben-Yehuda S., *RNA Dynamics in Aging Bacterial Spores*, CELL, Jan. 2012, at pages 139-49.
[227] *See* Chowdhury MS, Rowley DB, Anellis A, Levinson HS, *Influence Of Postirradiation Incubation Temperature On Recovery Of Radiation-Injured Clostridium Botulinum 62A Spores*, APPLIED ENVIRONMENTAL MICROBOLOGY, July 1976, at pages172-8; Moeller R, Raguse M, Reitz G, Okayasu R, Li Z, Klein S, Setlow P, Nicholson WL. *Resistance of Bacillus Subtilis Spore DNA to Lethal Ionizing Radiation Damage Relies Primarily on Spore Core Components and DNA Repair, With Minor Effects of Oxygen Radical Detoxification*, APPLIED ENVIRONMENTAL MICROBIOLOGY, Jan. 2014, at pages 104-9; Setlow P., *What We Know*.
[228] *See* Tab C-1, WDL-BIO-147.
[229] The revised CDC protocols for viability testing (see Tab E-7) attempt to standardize viability testing timeframes to address potential issues of this nature.

germination or the spore will not complete the transfer back to a vegetative cell and remain inactivated. This inactivated spore is the desired outcome of the gamma irradiation inactivation process since this yields a product that is useful for detection assay development that may be safely manipulated outside designated laboratories.

J. Rationale and Procedures for Inactivation of *Bacillus anthracis*

Biological laboratories must be able to inactivate *Bacillus anthracis* for a variety of reasons, but the key reason relevant to this investigation is that not all facilities have the biosafety infrastructure required to work with live *Bacillus anthracis*. Inactivation allows for *Bacillus anthracis* to be worked with at a lower biosafety level, thus increasing the number of facilities that can work with the organism and enhancing the industry's capability to develop countermeasures and detection systems. Manipulation of inactivated *Bacillus anthracis* does not require registration with the CDC Division of Select Agents and Toxins and inactivated, non-viable samples of *Bacillus anthracis* do not need to be shipped as a biological select agents,[230] thus reducing shipping timelines and costs. Furthermore, fewer precautionary measures are required (i.e., less personal protective equipment) to manipulate inactivated material in a laboratory because inactivated samples significantly reduce the potential for laboratory acquired infection.

Infectious samples of *Bacillus anthracis* are inactivated by Tier 1 entities (i.e., a facility allowed to work with activated Tier 1 biological select agents and toxins-such as DPG-LSD), to facilitate transfer and manipulation of *Bacillus anthracis* outside of registered laboratories with virtually no risk to personnel or the public.[231] *Bacillus anthracis* is considered a Tier 1 biological select agent and toxin because it can cause serious or potentially lethal disease through inhalation, ingestion, or contact with the skin.[232] *Bacillus anthracis* is classified as a Risk Group 2 (a low risk agent associated with human disease that is rarely serious and for which preventive and therapeutic interventions are often available) organism by the CDC and National Institutes of Health Guidelines.[233] The CDC recommends,[234] and the Army requires,[235] biosafety level-3 practices and containment for manipulation of production quantities or high concentrations of cultures of *Bacillus anthracis.*[236] This significantly restricts the number of laboratories that may manipulate *Bacillus anthracis* while also making it more expensive to train personnel, ship material and build facilities capable of containing live *Bacillus anthracis.* In order to maximize the number of laboratories that may conduct research involving *Bacillus anthracis*, it is important that *Bacillus anthracis* can be inactivated using a process that does not destroy the potentially valuable components such as antigens or surface proteins useful for diagnostic assays (i.e. tests).

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[230] *See* Overlap Select Agents and Toxins, 42 C.F.R. pt. 73.4 (12 May 2014)
[231] *See* 42 C.F.R. pt. 73.4 and 73.11.
[232] *Id.*
[233] *See* Tab E-5, BMBL, section VIII, Bacterial Agents.
[234] *Id.*
[235] *See* DA PAM 385-69, ch. 1-1.
[236] *See* Tab E-5, BMBL, section VIII, Bacterial Agents.

Researchers have many methods available for inactivation of *Bacillus anthracis* including chemical, heat/steam and gamma irradiation. Chemical inactivation of *Bacillus anthracis* can be accomplished primarily through halogen releasing agents such as a bleach solution or aldehyde based agents such as formaldehyde.[237] A problem with the use of halogen releasing agents is their potential to interact with and disrupt proteins resulting in an inactivated agent that is not useful for development of diagnostic tests.[238] Heat or steam inactivation methods can successfully inactivate *Bacillus anthracis,* but similar to chemical inactivation, the end product will not produce a useful inactivated agent for diagnostic test development since many proteins are not stable at high temperatures.[239] Gamma irradiation, on the other hand, maintains the efficacy of chemical and heat/steam methods while also preserving the integrity of the cellular components required to allow *Bacillus anthracis* samples to be useful for research and development.[240]

Gamma irradiation is a well-documented method for the inactivation of biological agents in general and *Bacillus anthracis* specifically.[241] Gamma irradiation of *Bacillus anthracis* provides the ability for researchers to test and develop diagnostic assays against antigens of interest with almost no risk to personnel after successful inactivation.[242] The 13 July 2015 DoD Review Committee Report documented the different *Bacillus anthracis* gamma irradiation procedures employed by DoD laboratories.[243] Since there was no standard process mandated by the CDC, DoD, or the Army, each laboratory used different procedures when performing irradiation. These procedures are summarized in Figure 13. It can be seen that there are several variables to consider when irradiating *Bacillus anthracis*, including but not limited to radiation dose, starting titer (initial concentration), starting volume, and sample temperature.

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[237] McDonnell G, Russell AD., *Antiseptics and disinfectants: activity, action, and resistance,* CLINICAL MICROBIOLOGICAL REVIEWS, Jan. 1999, at pages 147-79.
[238] *Id.*
[239] *See* Britt KA, Galvin J, Gammell P, Nti-Gyabaah J, Boras G, Kolwyck D, Ramirez JG, Presente E, Naugle G, *Endotoxin inactivation via steam-heat treatment in dilute simethicone emulsions used in biopharmaceutical processes,* BIOTECHNOLOGY PROGRESS, Sept-Oct. 2014, at pages 1145-60; McDonnell G, Russell AD., *Antiseptics and disinfectants: activity, action, and resistance,* CLINICAL MICROBIOLOGICAL REVIEWS, Jan. 1999, at pages 147-79.
[240] *See* Dauphin LA, Newton BR, Rasmussen MV, Meyer RF, Bowen MD, *Gamma irradiation can be used to inactivate Bacillus anthracis spores without compromising the sensitivity of diagnostic assays,* APPLIED ENVIRONMENTAL MICROBIOLOGY, at pages 4427-4433.
[241] *See* Horne, Turner and Willis, Inactivation of *Bacillus anthracis by G-radiation*, NATURE, 1959, at pages 475-476.
[242] *See* Dauphin LA, Newton BR, Rasmussen MV, Meyer RF, Bowen MD, *Gamma irradiation can be used to inactivate Bacillus anthracis spores without compromising the sensitivity of diagnostic assays,* APPLIED ENVIRONMENTAL MICROBIOLOGY, at pages 4427-4433.
[243] *See* Tab D-2, page 35, Review Committee Report: Inadvertent Shipment of Live *Bacillus anthracis* spores by DoD (July 13, 2015).

Laboratory	Irradiation						
	Dose (kGy)	Dose Determination	Starting Titer (cfu/ml)	Expected log Kill	Irradiator	Starting Volume (ml)	Temp Control
ECBC	54[a]	Calculated using time/decay rate of isotope and calibration data from instrument install	Max: 10^8 cfu/ml	>8	JL Shepard and Assoc. 484R-2 (Turntable)	Not defined	Controlled by irradiator
USAMRIID	40[b]	Not performed[b]	$10^5 - 10^{10}$ [b]	$10^{(d)}$	JL Shepard and Assoc. 484R (Turntable) Gammacell 220 (Surround)	8-15	Cold[d] or frozen prior to irradiation[b]
NMRC	Min: 32.5 Typical: 40 -50[b]	Not stated in protocol	$5.9x10^7$ - $6.9x10^9$ with majority $5x10^8$-$5x10^9$ [b]	6-8	JL Shepard &Assoc. Model 109 (Surround)[b]	<= 400[b]	Frozen prior to irradiation
Dugway	38-42	Alanine dosimeter test strips	$10^8 - 10^{11}$	10	JL Shepard and Assoc. 484R-2[c] (Turntable)	20-30[c]	Not stated in protocol

(a) Specified in 6/8/15 meeting at ECBC
(b) Specified in 6/9/15 meeting at USAMRIID
(c) Specified in 6/17/15 meeting at DPG
(d) Information provided after site visit

Figure 13: Gamma Irradiation Doses for Inactivation of Bacillus anthracis by DoD Laboratories

One of the missions of the Critical Reagents Program Antigen Repository at DPG-LSD was to provide inactivated *Bacillus anthracis* that could still be used in the development of diagnostic tests required by the DoD Chemical and Biological Defense Program (see Section I.C.). It was imperative that the program identify an irradiation dose high enough that it would effectively kill all *Bacillus anthracis* spores in a sample while not destroying the potentially valuable components such as antigens or surface proteins useful for diagnostic assays (i.e. tests).[244]

In order to standardize and control the process for inactivation of *Bacillus anthracis*, it is important to develop standard operating procedures and protocols that ensure repeatability independent of the personnel who are performing the procedure. Standard operating procedures require initial development by trained personnel coupled with an extensive review by subject matter experts to ensure that the procedure is suitable for the task to be performed.[245] Following the development and review process, the standard operating procedure can then be implemented once designated personnel are trained on the task outlined in the standard operating procedure.[246] This ensures that all personnel performing the selected task have the ability to perform the task in a fashion that is repeatable across the facility with minimal variation.

Prior to 22 May 2015, DPG-LSD had one properly vetted standard operating procedure[247] (WDL-BIO-147) to address the inactivation of *Bacillus anthracis*. All standard operating

[244] *See* Tab B-44.1, page 2, (b) (6) DA Form 2823, Sworn Statement (18 Aug. 2015).
[245] *See* AR 385-10, ch. 9-1; DA PAM 385-69, ch 3-5.
[246] *Id.*
[247] *See* The DPG-LSD CRP team was also using a work instruction to inactivate CRP materials, the complete vetting of which is questionable.

procedures performed by DPG-LSD are labeled according to their function. WDL references the West Desert Laboratory while any standard operating procedure featuring a BIO heading references biological agents. Since 2001, the inactivation standard operating procedure, WDL-BIO-147 changed eight times. From December 2001 thru March 2011, Versions 0-3 of Standard Operating Procedure WDL-BIO-147 did not specify a radiation dose required to inactivate any biological agents in general and *Bacillus anthracis* specifically. From March 2011 thru the present Versions 4 to 8 of this standard operating procedure specified a target dose of 40 ± 2 kilo Gray (kGy)[248] for *Bacillus* species; however, Standard Operating Procedure WDL-BIO-147 also stated that failure to demonstrate sterility/kill during viability testing should be followed by additional round(s) of irradiation with no specification on the upper acceptable limit (e.g., the upper limit would likely exceed the target dose of 40 ± 2 kGy).[249]

K. Procedures for Viability Testing of *Bacillus anthracis*

Post-irradiation viability testing is necessary to ensure that the inactivation procedure killed all *Bacillus anthracis* present in the sample.[250] Prior to the discovery of viable *Bacillus anthracis* on 22 May 2015, there was no consensus viability testing standard mandated by the CDC. When conducting viability testing, every opportunity should be provided for the inactivated specimen to grow. Because of the range of types of samples that require inactivation, there is extensive variability amongst entities both within and outside the government on what constitutes appropriate viability testing procedures.[251] There is extensive variability among facilities with respect to time lag between inactivation and the initiation of viability testing, incubation periods, types of growth media, and the amount of the sample to be used for viability testing. Incubation periods may range from as little as 48 hours to three weeks. Growth media may be comprised of either solid agar[252] or liquid broth in varying amounts and types. Viability testing sample sizes vary from as little as 5% to as much as 50% of the irradiated material. Figure 14 summarizes the different protocols for viability testing of inactivated *Bacillus anthracis* samples across the four primary DoD laboratories.[253]

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[248] *See* Appendix E, *Glossary*. Gray refers to absorbed dose of radiation in units of Joules per kilogram.
[249] *See generally* Tab C-1, WDL-BIO-147.
[250] Sample refers to an agent that is inactivated. The agent may be present as spores floating in liquid or other specimen (i.e. tissues, plasma, blood).
[251] *See* Tab D-2, page 36, Review Committee Report: Inadvertent Shipment of Live *Bacillus anthracis* spores by DoD (July 13, 2015).
[252] *See* Appendix E, *Glossary*. Type of media present in petri dishes used for growing biological agents.
[253] *See* Tab D-2, page 36, Review Committee Report: Inadvertent Shipment of Live *Bacillus anthracis* spores by DoD (July 13, 2015). For example, current DPG-LSD protocol calls for a 5% sample of the irradiated material to be inoculated into 2X nutrient broth (the concentration of nutrients are twice as high compared to standard growth media) and incubated at 34°C for 48 hours. Two hundred microliters of inoculated broth is then plated across 10 Tryptic Soy Agar plates and the plates are incubated for a minimum of 48 hours and in some cases as long as two weeks to determine growth.

Laboratory	Sterility Testing								
	Sampling	Culture Media		Incubation					
	Sterility Sampling %	Broth	Solid Media	Broth to Plate?	Direct Plating	Incubation Temp (°C)	Incubation Time (hrs)	Positive control?	Negative control?
ECBC	10%	None [(a)]	Tryptic Soy Agar [(a)]	No	100 ul/plate	25-37 "appropriate growth temp"	72 [(a)]	No	No
USAMRIID	10-50% [(b)]	None identified	Blood Agar [(b)]	None identified	None identified	37	48	No	Yes [(b)]
NMRC	Small vol: 1-10 µL Large vol: 1-5%	Brain Heart Infusion Broth +10% serum	Blood Agar, Brain Heart Infusion Agar, Nutrient Agar, Mueller-Hinton agar	1 µl and 200µl are plated	Broth: >=72 Plates: 72	35-37	72	Yes	Yes
Dugway	5%	25 ml 2X nutrient broth	Tryptic Soy Agar	200 µl/10 plates	No	34	96 – 336 [(c)]	Yes	Yes

(a) Specified in 6/8/15 meeting at ECBC
(b) Specified in 6/9/15 meeting at USAMRIID
(c) Specified in 6/17/15 meeting at DPG

Figure 14: Variability in Viability Testing Protocols across DoD Laboratories

The events surrounding the inadvertent shipment of live *Bacillus anthracis* discovered on 22 May 2015 resulted in a change in policy from the CDC. Due to the fact that numerous separate entities within and outside the U.S. Army inactivate *Bacillus anthracis* utilizing a variety of methods and conduct viability testing with extensive variation in growth media and incubation temperatures often without consultation outside of their own laboratories,[254] the CDC published revised, interim viability testing protocols for inactivated *Bacillus anthracis.* The revised CDC procedure requires the use of both solid and liquid growth media and a 14 day incubation period at both room temperature and 37°C.[255]

In summary, there have been years of research spent on the inactivation of *Bacillus anthracis*. The methods used to inactivate and test viability have morphed over time but scientists still lack a total understanding of how spore concentrations, strain differences in gamma radiation resistance, different gamma irradiation dosages, possible post gamma radiation healing of irradiated *Bacillus anthracis* spores (i.e. incubation time and potential catalysts), and growth processes affect overall viability. However, the benefits and rationale for inactivation are clear: (1) ease of use and transportation, (2) safety of researchers and the public, and (3) the fact that inactivated spores offer every bit as good of a mission product as viable *Bacillus anthracis.*

[254] *See* Tab D-2, pages 11-12, 14 and 16, Review Committee Report: Inadvertent Shipment of Live *Bacillus anthracis* spores by DoD (July 13, 2015).
[255] *See* Tab E-7, Centers for Disease and Control Prevention, Revised Viability Testing Protocol for Samples of Inactivated *Bacillus anthracis* (2015).

L. Background Discussion on Death Certificates

The U.S. Department of Health and Human Services and the U.S. Department of Agriculture have established regulatory requirements for the possession, use, and transfer of biological agents and toxins that have the potential to pose a severe threat to public health and safety, animal and plant health, and animal and plant products. The requirements related to public health and safety can be found at 42 Code of Federal Regulation Part 73 and are referred to as the select agent regulations. The select agent regulations state that non-viable select agents are to be excluded from these regulations. For the purpose of the regulations, "non-viable" and "non-functional" are similar terms that may be defined as the loss of biological activity. For a select agent, the term "non-viable" means that a select agent is no longer capable of growing, replicating, infecting, or causing disease.[256] As discussed in the paragraphs above, there are a variety of inactivation methods available to render a select agent non-viable, and viability testing is conducted to confirm that the inactivation process was successful. Subsequently, it is prudent to document the "death" of an organism that has gone through an inactivation process and confirmatory viability testing.

The DPG-LSD initially elected to use the Certificate of Inactivation, which was subsequently renamed the death certificate, as its means of demonstrating that a select agent has been rendered non-viable. The death certificate documents the following data: name of organism; place and date of sterilization; procedure used for sterilization; total dosage of irradiation applied; a brief description of the procedure used; reference (e.g., article, standard operating procedure, etc.); notebook page and location of results; and place of confirmation. The death certificate is signed by three individuals: (1) Project Manager or Principle Investigator; (2) Biological Safety Officer; and (3) Responsible Official (all of whom certify the accuracy of the data and that the organism was inactivated). A death certificate is sent with each sample of *Bacillus anthracis* that is shipped to another organization.[257]

II. Findings

The inadvertent shipment of viable *Bacillus anthracis* is a serious breach of regulations, but it did not pose a risk to public health. Over the years, checks and balances and significant safeguards were in place and effectively ensured the various mishaps described above were not a threat. Below is a discussion of findings the 15-6 investigation team made during the course of the investigation.

The 15-6 investigation team conducted extensive interviews and research to identify a specific cause or group of causes and to eliminate potential contributing factors. Insufficient evidence was found to link the incident reported on 22 May 2015 directly to one of these potential causes. The evidence did not allow for the elimination of any potential contributing factors, and in fact uncovered additional failures. Although the facts do not support a specific finding of what specifically caused the viable shipment, a number of scientific, institutional, and individual conditions/actions exist that contributed to an environment that permitted the shipment of *Bacillus anthracis* lot AGD0001667 and the sixteen additional lots that have since

[256] *See* Exemptions for HHS Select Agents and Toxins, 42 C.F.R. pt. 73.6.
[257] *See* Tab B-44.1.a, pages 5-6 [redacted] Addendum to DA Form 2823, Sworn Statement (18 Aug. 2015).

been identified as viable from 2004-2015. A preponderance of the evidence does not exist to support a finding that a group of individuals or institutions, or a specific individual or institution was the proximate cause for the unacknowledged and unintended shipment of viable *Bacillus anthracis*. The investigation process led to the conclusion that no one condition or action is the sole cause; rather, it is a combination of all conditions and actions that may have contributed to the viable shipment.

A. Scientific

Over the course of the investigation, a number of scientific and technical issues related to the production, inactivation and post-inactivation viability testing of *Bacillus anthracis* were identified. A knowledge gap exists in the state of the scientific research informing the current irradiation and viability testing protocols. This knowledge gap makes attributing accountability for shipment of viable *Bacillus anthracis* impossible since personnel have in most cases been adhering to established and accepted protocols now known to be inadequate. The following paragraphs provide detail on: (1) the fundamental disconnect between science and regulatory policy regarding 100% inactivation (i.e., killing) of *Bacillus anthracis* before shipping to various laboratories; (2) lack of research into gamma radiation resistance properties and inactivation methods of *Bacillus anthracis* (strains, spore counts, kill curves); (3) lack of research regarding post-irradiation spore recovery theory; and (4) lack of scientifically validated and standardized protocols for post-irradiation viability testing (incubation time, type of growth media).

1. A Fundamental Disconnect between Science and Regulatory Policy Regarding Non-viability (i.e., 100% Inactivation) of *Bacillus anthracis* Before Shipping to Various Laboratories

Current standards require that any entity possessing biological select agent and toxin strains of *Bacillus anthracis* must register with the CDC Division of Select Agents and Toxins based on the fact that it is considered an overlap select agent.[258] "Non-viable overlap select agents or nonfunctional overlap toxins" are excluded from being regulated.[259] The requirement for registration is independent of the amount of viable *Bacillus anthracis* even if the amount is as low as one colony forming unit. Therefore, the only way to guarantee a sample is non-viable or nonfunctional (i.e., 100% inactivation) would be to test and consume 100% of the batch or sample. This is obviously not feasible as there would be no usable product remaining. Current viability testing procedures for the primary DoD laboratories dealing with *Bacillus anthracis* generally utilize a 5-10% representative sample from the inactivated lot of *Bacillus anthracis.*[260] This means that 90-95% of the lot remains for end use after testing, but also implies that there will always remain a possibility that the portion of the lot that was not tested may not have been

[258] *See* Registration and Related Security Assessments, 42 C.F.R. pt. 73.7; and Overlap Select Agents and Toxins, 42 C.F.R. pt. 73.4.

[259] 42 C.F.R. pt. 73.4 defines overlap agents as having the potential to pose a severe threat to public health and safety, to animal health, or to animal products. Additionally, 42 C.F.R. pt. 73.4 does not define "non-viable viable overlap select agents or nonfunctional overlap toxins." Neither the CDC nor the U.S. Army has issued any guidance in the form of regulation, policy, guideline, or standard operating procedures.

[260] *See* Tab D-2, page 36, Review Committee Report: Inadvertent Shipment of Live *Bacillus anthracis* spores by DoD (July 13, 2015).

completely inactivated. It is important that regulators and entities registered to work with biological select agents and toxins come to an understanding to resolve the separate messages concerning viability testing.

It is clear that when conducting viability testing it is important to sample a large enough volume to maximize the likelihood of detecting any viable *Bacillus anthracis* spores while at the same time leaving enough sample to be used for other purposes. The ECBC, USAMRIID and NMRC all used different sample sizes when conducting viability testing.[261] Based on these differences, the CDC released interim guidance that requires that 10% of the sample be used for viability testing.[262] No registered entity working with *Bacillus anthracis* will be able to guarantee 100% inactivation unless all of the sample is consumed by viability testing. There will always be a measure of uncertainty involved with inactivation of biological select agents and toxins.

2. Lack of Research into Gamma Radiation Resistance Properties and Inactivation Methods of *Bacillus anthracis* (strains, spore counts, kill curves)

There is a lack of scientific research regarding the inactivation methods developed for *Bacillus anthracis*. While there are a number of Army laboratories that inactivate *Bacillus anthracis* through gamma irradiation, they rely on limited datasets derived from a small number of facilities.[263] Army facilities generating kill curves against *Bacillus anthracis* did not take into account different matrices such as whole blood, tissue specimens or standard buffer. Kill curves generated against *Bacillus anthracis* also do not take into account variations in stock purity or stock concentrations which can be as high as 10^{11} spores/ml.[264] In some cases, the expected efficacy of the gamma irradiation dose against *Bacillus anthracis* is extrapolated in the absence of data from tests using varying concentrations of *Bacillus anthracis* spores.[265]

There is also evidence that there is variability in gamma radiation resistance properties among the multiple strains of *Bacillus anthracis* that exist, but limited data on these strain specific resistance properties has been collected.[266] While significant variation is seen between vegetative cells and spores related to gamma irradiation resistance, one experiment demonstrated only slight differences are seen between *Bacillus anthracis* Ames and Sterne strains.[267] In one experiment, 41.5 kGy was sufficient to inactivate almost all lots of *Bacillus anthracis* spores, but

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[261] *Id.*

[262] *See* Tab E-7, Centers for Disease and Control Prevention, Revised Viability Testing Protocol for Samples of Inactivated *Bacillus anthracis* (2015).

[263] *See* Tab D-2, pages 11-12, 14 and 16, Review Committee Report: Inadvertent Shipment of Live *Bacillus anthracis* spores by DoD (July 13, 2015).

[264] *Id.* at page 35.

[265] *See* Tab B-33.1, pages 6-7, [redacted], DA Form 2823, Sworn Statement (20 Aug. 2015); Tab D-2, page 20, Review Committee Report: Inadvertent Shipment of Live *Bacillus anthracis* spores by DoD (July 13, 2015).

[266] *See* Bowen JE, Manchee RJ, Watson S, and Turnball PCB, *Inactivation of Bacillus anthracis Vegetative Cells and Spores by Gamma Irradiation*, SALISBURY MEDICAL BULLETIN, Special Supplement 87.

[267] *See* Bowen JE, Manchee RJ, Watson S, and Turnball PCB, *Inactivation of Bacillus anthracis Vegetative Cells and Spores by Gamma Irradiation*, SALISBURY MEDICAL BULLETIN, Special Supplement 87; Spotts Whitney EA., Beatty ME., Taylor TH. Jr., Weyant R., Sobel J., Arduino MJ., Ashford DA., *Inactivation of Bacillus anthracis Spores*, EMERGING INFECTIOUS DISEASES, June 2003, at pages 623-7.

failures following viability testing were seen in a small number of lots receiving doses up to 44 kGy.[268] It is important to determine if strain variance of gamma irradiation resistance is a significant variable with *Bacillus anthracis* spores. Evidence in the research literature is inconsistent and demonstrates both the need for further study and the need to avoid reliance on kill curves from a single irradiator on one strain of *Bacillus anthracis* spores to serve as the basis for all irradiator dosage determinations for all *Bacillus anthracis* strains. By simply relying on one target dose of gamma irradiation for inactivation of *Bacillus anthracis* spores, researchers open themselves up to potential inactivation failures due to strain variation in the absence of further methodology development prior to inactivation. Additional study is needed to close these gaps in validated studies related to gamma irradiation inactivation of *Bacillus anthracis*.

3. Lack of Research Regarding Post-Irradiation Spore Recovery Theory

Prior to the reported discovery of viable *Bacillus anthracis* of 22 May 2015, minimal research had been conducted into the theory of spore recovery following exposure to gamma irradiation. The 22 May 2015 discovery highlighted the gap in scientific understanding, and resurrected the need to better understand the theory of spore recovery. Previous research conducted supports the theory that *Bacillus anthracis* spores may have the ability to undergo DNA repair following insult (i.e., damage due to gamma irradiation), but the extent of these repair processes have not been determined.[269] In addition to the unknowns about the extent of DNA repair, the timeline for initiation of DNA repair processes is also not well understood with respect to spore germination timeframes.[270] Spores may survive gamma irradiation exposure through the germination process to revert back to a vegetative cell state and resume replication. However, it is unknown how much DNA damage can be sustained by *Bacillus anthracis* spores before they are unable to germinate and revert back to the vegetative cell state. Researchers have repeatedly demonstrated that *Bacillus anthracis* spores are significantly more resistant to gamma irradiation than vegetative cells but the reasons for this increased resistance remain unclear.[271] While DNA repair processes in *Bacillus anthracis* have been demonstrated following sublethal exposures to gamma irradiation, *Bacillus anthracis* spore recovery has not been shown following large scale damage from a lethal dose of gamma irradiation.[272] Prior to the discovery on 22 May 2015,

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[268] *See* Bowen JE, Manchee RJ, Watson S, and Turnball PCB, *Inactivation of Bacillus anthracis Vegetative Cells and Spores by Gamma Irradiation*, SALISBURY MEDICAL BULLETIN, Special Supplement 87.

[269] *See* Tab E-33, Memorandum from (b) (6) [redacted] to (b) (6) [redacted], subject: *Bacillus anthracis* Questionnaire (28 Aug. 2015); Yang H, Yung M, Li L, Hoch JA, Ryan CM, Kar UK, Souda P, Whitelegge JP, Miller JH, *Evidence that YycJ is a Novel 5'-3' Double-stranded DNA Exonuclease Acting in Bacillus anthracis Mismatch Repair*, DNA REPAIR (AMST); 1 May 2013, at pages 334-46; Yang H., Yung M., Sikavi C., Miller JH., *The Role of Bacillus anthracis RecD2 Helicase in DNA Mismatch Repair*, DNA REPAIR (AMST), Nov. 2011, at pages 1121-30; Setlow P., *What We Know*.

[270] *See* Setlow P., *What We Know*.

[271] *See* Mizak L, Mierzejewski J. *Gamma Radiation Resistance of Bacillus anthracis Spores*, Medycyna Doswiadczalna I Mikrobiologia (Warszawa), 2003, pages 315-23; Setlow P., *What We Know*; Slieman TA, Nicholson WL., *Artificial and solar UV radiation induces strand breaks and cyclobutane pyrimidine dimers in Bacillus subtilis spore DNA*, APPLIED ENVIRONMENTAL MICROBIOLOGY. Jan. 2000, at pages 199-205.

[272] *See* Memorandum from (b) (6) [redacted] to (b) (6) [redacted] subject: *Bacillus anthracis* Questionnaire (28 Aug. 2015); Memorandum from (b) (6) [redacted] to (b) (6) [redacted] subject: *Bacillus anthracis* Questionnaire (8 Sept. 2015); Yang H., Yung M., Li L., Hoch JA., Ryan CM., Kar UK., Souda P., Whitelegge JP., Miller JH., *Evidence that YycJ is a Novel 5'-3' Double-stranded DNA Exonuclease Acting in Bacillus anthracis Mismatch Repair*, DNA

Bacillus anthracis spore recovery was shown to be possible after exposure to sub-lethal levels of gamma irradiation but survival following exposure to lethal levels of gamma irradiation were thought to be dependent on innate resistance properties of *Bacillus anthracis* spores that are not well understood.[273] It is clear that there are unresolved questions related to *Bacillus anthracis* DNA repair following gamma irradiation, the extent of the *Bacillus anthracis* DNA repair process, the timeframe of the DNA repair process in relation to spore germination, and how much DNA damage can be sustained by *Bacillus anthracis* spores before they are unable to revert back to the vegetative cell state. It is also clear that there is a lack of data pertaining to optimal germination conditions for *Bacillus anthracis* spores and any intermediate processes (i.e. freeze/thaw, heating, and elevated pressure) that may be required prior to incubation on growth media. If these conditions are able to be determined and validated, researchers will be able to have increased confidence in viability testing if no growth is discovered on irradiated samples following ideal germination conditions.

4. Lack of Scientifically Validated and Standardized Protocols for post-Irradiation Viability Testing (Incubation Time and Type of Growth Media)

There is a lack of knowledge regarding optimal growth and germination conditions following gamma irradiation of *Bacillus anthracis* that may affect the putative spore recovery process. Standard conditions for growth of *Bacillus anthracis* may rely on removal of a representative sample (5-10%) and incubation on growth media[274] for a minimum of 48 hours. However, given the demonstrated wide range of both germination and growth rates of spore forming bacteria and the varying temperatures and growth conditions, further study of optimal growth conditions for *Bacillus anthracis* is necessary.[275]

B. Institutional

A number of institutional factors may have contributed to the inadvertent shipment of viable *Bacillus anthracis*. The investigation identified the following institutional concerns that spanned DPG-LSD's chain of command: (1) perception of competition for funding between biological research commands; (2) lack of unity of command; and (3) inadequate inspections.

1. Perception of Competition for Funding Between U.S. Army Biological Research Organizations

In the Background Section I.E.2. of this report, laboratory funding sources were discussed as being a mix of reimbursable (customer funded) and non-reimbursable (Army centrally funded).

REPAIR (AMST), May 2013, at pages 334-46; Yang H., Yung M., Sikavi C., Miller JH., *The Role of Bacillus anthracis RecD2 Helicase in DNA Mismatch Repair*, DNA REPAIR (AMST), Nov. 2011, at pages 1121-30.

[273] *See* Memorandum from [redacted] to [redacted], subject: *Bacillus anthracis* Questionnaire (28 Aug. 2015); Memorandum from [redacted] to [redacted], subject: *Bacillus anthracis* Questionnaire (8 Sept. 2015); Memorandum from [redacted] to [redacted], subject: *Bacillus anthracis* Questionnaire (28 Aug. 2015).

[274] *See* Tab D-2, page 36, Review Committee Report, Inadvertent Shipment of Live *Bacillus anthracis* spores by DoD (July 13, 2015).

[275] *See* Cook AM, Roberts TA, Widdowson JP., *Gamma Irradiation of Bacillus Subtilis Spore In the Presence of Sugars*, JOURNAL OF GENERAL MICROBIOLOGY, Feb. 1964, at pages 185-193.

Some within the U.S. Army Biological Research Organizations maintain a perception that this funding scheme leads to counterproductive competition between the laboratories. According to [redacted]:

> *As an Enterprise, the Chemical and Biological Defense Program organizations are very competitive. Although we have relatively defined lanes, we are all competing for the same funding. As a result, communication and collaboration between organizations like WDTC, USAMRIID, and ECBC is minimal. We do not share best practices and conduct peer reviews unless we are directed to do so. The prevailing mindset is that we don't want to give up business to each other, and anything that appears to "give away the store" to a competitor is avoided.*[276]

Evidence compiled by the 15-6 investigation team does not support [redacted] claim of actual competition. This evidence includes a direct comparison between the laboratories and the reimbursable funding each receives. While the laboratories share customers, their work is mostly complementary in that they support the customers in different ways and in different phases of their projects. Appendix C provides a detailed breakdown of the USAMRIID, ECBC, and DPG-LSD funding profiles (reimbursable and non-reimbursable).

While the perception of competition was unfounded, DPG and DPG-LSD experienced budget reductions over the last several years. In response to the budget reductions, DPG-LSD eliminated several positions and attempted to continue to meet mission requirements by tasking personnel to take on additional duties. At least one of the eliminated positions was critical to the effectiveness of the production mission of the CRP Antigen Repository.[277] An executive agent and overall unity of command directing the allocation of resources may have mitigated the impact of funding cuts and allowed DPG-LSD to retain personnel in critical positions.

2. Unity of Command

After a review of the number of commands and reporting channels within the DoD biological laboratory enterprise, the 15-6 investigation team has determined the U.S. Army command structure alignment lacks an overall Executive Agent to provide oversight for the separate reporting commands. An Executive Agent empowered to oversee the laboratory enterprise and address standardization of rules, practices, and procedures could potentially overcome this misalignment.

Figure 15 depicts the various chains of command for each of the DoD laboratories and shows that command and control of the biological laboratories is dispersed. Each laboratory has a different mission and first-line command. ECBC reports to the Research Development and Engineering Command, USAMRIID reports to the U.S. Army Medical Research and Materiel Command, and Dugway Proving Ground reports to ATEC. There is no convergence at a higher

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[276] Tab B-2.1, page 2, [redacted] DA Form 2823, Sworn Statement (21 Aug. 2015).

[277] See Section II.C.1.b.iv. One of these positions was for a dedicated quality assurance/quality control manager – a critical position providing oversight for production within the laboratories.

level of command.[278] Figure 16 depicts placement of the laboratories in the overall Army Command structure. The higher level commands for USAMRIID and DPG are the Army Medical Command and ATEC respectively. Figure 16 shows that ATEC and Army Medical Command are Direct Reporting Units to Headquarters Department of the Army. The ECBC ultimately reports to the Army Materiel Command, a distinct Army Command. While these commands may have some commonality at the working level, their over-arching missions are separate and distinct.

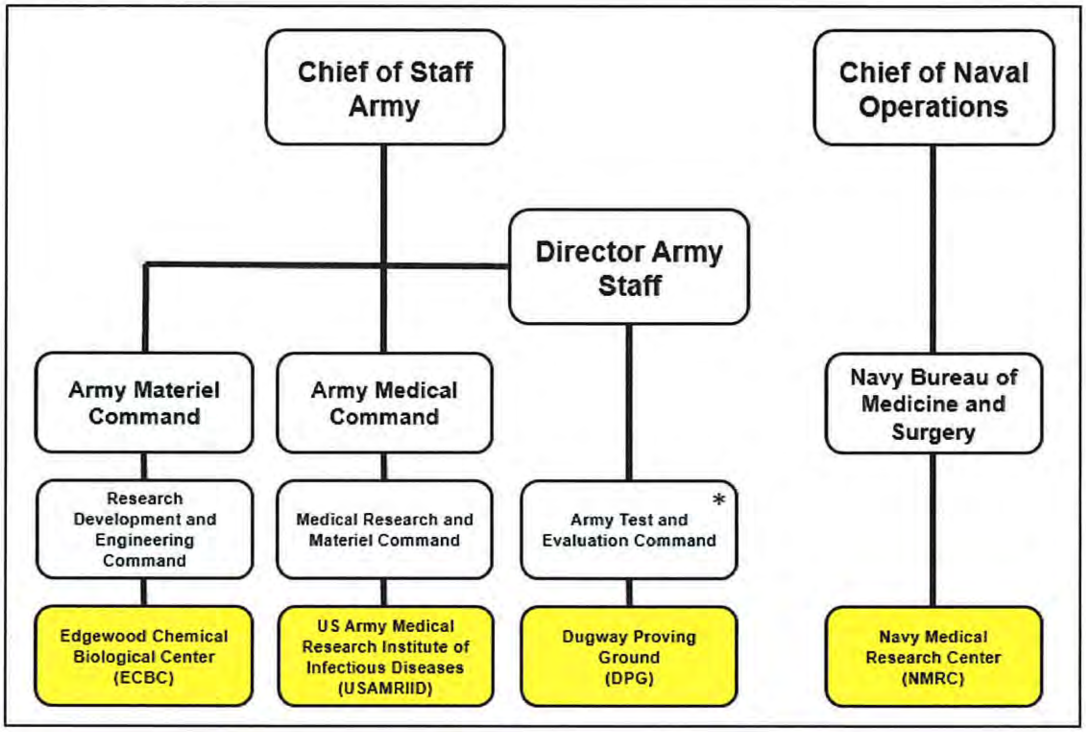

Figure 15: Chains of Command for DoD Biological Labs

[278] * Figure 15 represents the current command structure. Until 2011 there was an additional one star command between DPG and ATEC known as the Developmental Test Command (DTC). This command was absorbed into ATEC headquarters as part of base realignment and closure in 2011. Additional discussion regarding this realignment and its impact on operations at DPG is provided in Section II.C.2.

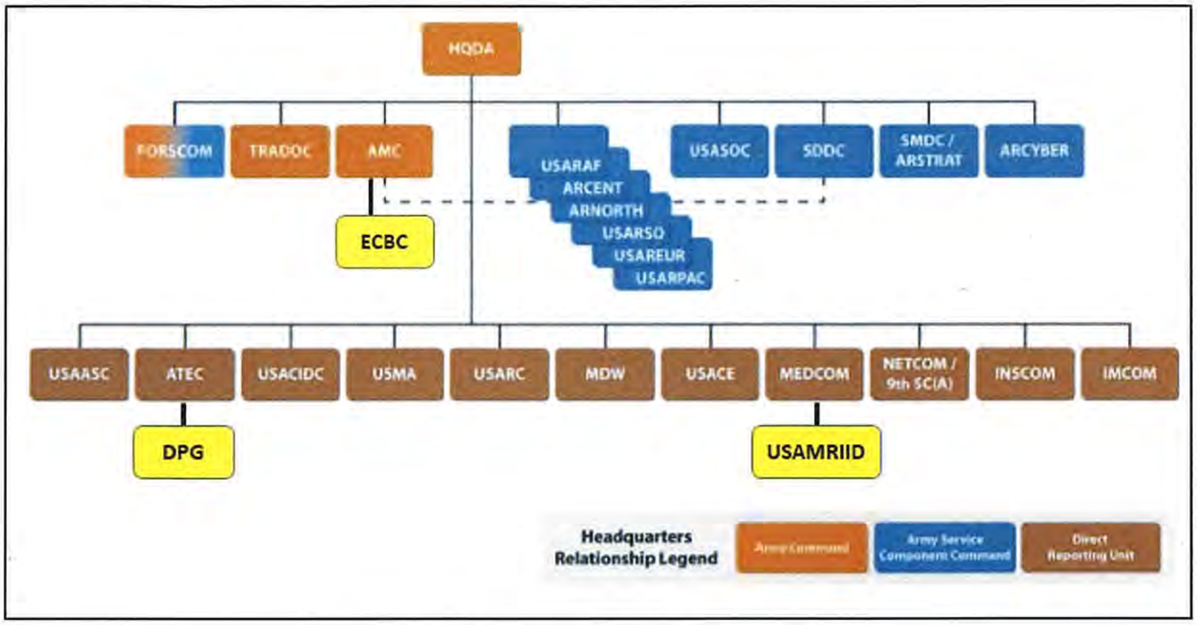

Figure 16: Army Command Structure

3. Failure to Inspect the Technical Aspect of *Bacillus anthracis* Inactivation

The final institutional area concerns the frequency and completeness of inspections. This includes the scope, frequency, and method of accomplishment (announced versus unannounced). Historically, major inspections have been announced, allowing the laboratories to extensively prepare. During inspection timeframes, laboratories typically do not perform select agent operations, so only written procedures and laboratory structural and cleanliness issues are normally observed. The inspections focus on policies and procedures as opposed to production protocols. In addition, conducting inspections every two or three years may not be frequent enough to ensure biological laboratories operate safely and efficiently.

Army laboratories are subjected to three main categories of external inspections; a) Federal Inspections, b) Army Biosurety Inspections, and c) Army Safety Inspections. Additionally, the 15-6 investigation team reviewed the findings of a technical audit performed by a commercial company at DPG-LSD in 2004 (paragraph d). Background information regarding the scope and purpose of the inspections as well as a summary of the findings of the 2004 audit is provided in the following paragraphs.

a. Federal Inspections

Federal inspections are conducted by the CDC and the Animal and Plant Health Inspection Service, Department of Agriculture, at Army laboratories that possess and use select agents. These two agencies are authorized in the Code of Federal Regulations to administer the Federal Select Agent Program. Organizations that possess or use select agents are required by law to register with the Federal Select Agent Program. Registrations must be renewed every three years. Before the renewal, the CDC and the Animal and Plant Health Inspection Service perform a joint inspection to ensure all the requirements in the various regulations are being followed.

These inspections are announced allowing the organizations to prepare for them. The CDC and the Animal and Plant Health Inspection Service may perform additional inspections on an as-needed basis (e.g., to register a new room for select agent work, to look at past problem areas, or to investigate a potential violation of the Federal Select Agent Program). These inspections may or may not be announced.[279]

b. Army Biosurety Inspections

Biosurety inspections are conducted by the Department of the Army Inspector General (DAIG) as mandated by Army Regulation 50-1, Biological Surety. Inspections normally occur every 24 months and are compliance-based vice science-based. These inspections ensure adherence to the technical, health, safety, accountability, security, and reliability standards detailed in appropriate regulations.[280] Since 2005, DPG-LSD has passed all of the DAIG inspections except for the 2011 inspection (failed due to the three erroneous Botulinum neurotoxin A shipments discussed in Section 1.F.3 above). Minor deficiencies were noted during each inspection, but only the 2011 inspection identified a failing deficiency. In advance of each biosurety inspection,[281] ATEC, with support from DTC, conducted Special Team Reviews and Staff Assistance Visits at DPG-LSD to ensure that all minor deficiencies from the previous inspection had been remediated. Details of each inspection are provided in the paragraphs below.

The initial DAIG inspection in 2005 was an unrated review meant to facilitate the establishment of a proper surety program.[282] In 2007, the first formal DAIG Biological Surety Inspection was conducted. Highlighted in that inspection was a tendency for DPG-LSD to simply react to a specific finding, not necessarily look for the root causes of the problem, but overall DPG was assessed as accomplishing its surety missions in a safe and secure manner.[283] The 2009 Biosurety Inspection specifically noted inattention to detail as an issue, but the report reached the same "safe and secure" conclusion as in 2007.[284] In 2011, DPG-LSD failed the DAIG inspection due to the erroneous shipment of Botulinum neurotoxin A discussed earlier in this report (see Section 1.F.3). This was the first biosurety inspection conducted in conjunction with the CDC Federal Select Agent Program as part of a federal effort to reduce the inspection workload on laboratories.[285] In 2013, the DAIG found DPG to be "proficient in all functional areas" but had 13 observations that needed to be addressed including a lack of focus on the calibration of test, measurement, diagnostics, and evaluation equipment.[286] In 2015, the DAIG and CDC conducted a third joint inspection of DPG-LSD. The team found five minor

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[279] *See* Select Agents and Toxins, 42 C.F.R. pt. 73; Possession, Use, and Transfer of Select Agents and Toxins, 9 C.F.R. pt. 121; and Possession, Use, and Transfer of Select Agents and Toxins, 7 C.F.R. pt. 331.
[280] *See* Tab E-1, AR 50-1, para. 2-1; Tab E-2, U.S. DEP'T OF ARMY, REG. 190-17, BIOLOGICAL SELECT AGENTS AND TOXINS SECURITY PROGRAM, para. 1-1 (3 Sept. 2009) [hereinafter AR 190-17]; DA PAM 385-69, para. 1-1.
[281] At a minimum. The 15-6 investigation team did not collect documentation on every ATEC Staff Assistance Visit to DPG-LSD, so there may have been more visits conducted for other reasons.
[282] *See* Tab C-33, DAIG BSI, 2005.
[283] *See* Tab C-34, DAIG BSI, 2007.
[284] *See* Tab C-35, DAIG BSI, 2009.
[285] *See* Tab C-36, DAIG BSI, 2011.
[286] *See* Tab C-37, DAIG BSI, 2013.

deficiencies in the areas of safety, three in security, and two in emergency response, but overall assessed that DPG was accomplishing its mission "to standard".[287]

The findings and overall message conveyed by each individual report was that DPG-LSD was accomplishing its mission in a safe and secure manner. It is reasonable that DPG, DTC, and ATEC leadership did not initiate any formal investigations into the minor deficiencies at the time of each inspection. However, a holistic review of the DAIG reports from 2005-2015 shows that inattention to detail (i.e., complacency) has been a common problem at DPG-LSD since at least 2007.

c. Army Safety Inspections

Army safety inspections are compliance or program based. There are three primary safety inspections that apply to Army facilities and organizations that utilize microorganisms:

1. Organizational Inspections
2. Standard Army Safety and Occupational Health Inspections
3. Laboratory Compliance Inspections

The first type of safety inspections are organizational inspections that evaluate the integration of the Army Safety Program into the organization's mission. Organizational inspections measure the overall effectiveness Army Safety Programs into an organization's business processes and mission execution. This is a formal inspection conducted by the parent command every 36 months at the minimum. These evaluations are programmatic assessments, and are planned and announced as part of the parent commands organizational inspection program. In addition, these inspections focus on Army safety program elements and do not include scientific reviews of protocols or procedures.[288]

The second type of inspection, the Standard Army Safety and Occupational Health Inspection, is a workplace inspection. The primary focus of this inspection is to evaluate implementation and maintenance of safety and health standards. The inspection is conducted annually by qualified safety and occupational health professionals or specially trained personnel competent to conduct the inspection. The Standard Army Safety and Occupational Health Inspection can be either announced or unannounced and it does not address scientific details, process reviews, technical procedures, or protocol reviews.[289]

The third type of safety inspection applies to laboratories that utilize infectious agents and toxins. Given the sensitivity of the materials handled within these labs and the fact that the materials are regulated, the laboratories must undergo inspections evaluating compliance with general safety practices as well as requirements applicable to the laboratory's biological safety level. These inspections are conducted by the safety officer, biosafety officer, or qualified safety and occupational health personnel designated by the Commander/Director and can be announced

[287] *See* Tab C-38, DAIG BSI, 2015.
[288] *See* AR 385-10, para. 2-10.
[289] *See* AR 385-10, para. 17-6.

or unannounced. Biosafety level-2 and toxin laboratories must be inspected at least semi-annually. Biosafety level-3 laboratories, and those in which dry forms of toxins are handled, are inspected at least quarterly.[290] These laboratory inspections utilize a checklist and do not go into scientific details or protocol reviews. Inspectors conducting these inspections may or may not have academic backgrounds in science or possess operational laboratory experience.

d. Technical Quality Audits

In addition to the inspections described above, the 15-6 investigation team was made aware of a two-week technical quality audit conducted by a single auditor from the Camber Corporation at DPG-LSD in 2004. The audit, sponsored by the CRP Management Office at Fort Detrick, focused on quality management of CRP processes and addressed antigen variability and product safety.[291] The audit resulted in several recommendations that facilitated improvement of the antigen production and irradiation processes through studies executed by the science and technology community.[292]

e. Summary

There are two common themes among the inspections that are conducted on a regular basis. First, the majority of inspections are announced which allows laboratories to exhaustively prepare for the inspection and curtail work during the inspection to reduce the risk of a negative finding. Second, federal, biosurety and safety inspections do not review the scientific details of agent inactivation and the viability testing protocols since they are focused solely on compliance.[293] However, the results of the 2004 technical audit conducted by the CRP management office show that it is possible to conduct inspections/audits addressing targeted scientific details over a similar timeframe as the existing inspections. These technical reviews are value-added and have the potential to minimize the likelihood of future mistakes.

C. Individual Accountability

Failures by leadership, oversight staff, and laboratory technicians were identified across the DPG-LSD enterprise. These failures may have contributed to the inadvertent shipment of viable *Bacillus anthracis*. There is not a direct causal link between any of the failures identified and the inadvertent shipment of viable *Bacillus anthracis*, however, the failures represent a complacent environment which may have allowed for the inadvertent shipment to occur. Section 1 below identifies the failures by leadership, oversight staff and laboratory technicians. Section 2 identifies responsible parties and summarizes individual culpability for failures and deficiencies

[290] *See* DA PAM 385-69, para. 3-10.
[291] *See* Tab C-24, Critical Reagents Program, CBMS-MITS Quality Site Audit, U.S. Army Dugway Proving Ground, Antigen Repository (27 Jan. 2004).
[292] *See* Tab B-10.2, [redacted], DA Form 2823, Sworn Statement (30 Sept. 2015).
[293] *See* Alison Young, Top U.S. lab regulator replaced in wake of incidents with bioterror pathogens, USA TODAY, Dec 08, 2015. Dr. Robbin Weyant was replaced as the Director of the CDC Division of Select Agents and Toxins, partially due to the fact that an internal CDC review found that the federal inspections were ineffective, and "focused too much on paperwork and bureaucratic minutiae, rather than meaningful measures of safety and security."

that caused a complacent environment. Organizational charts for DPG and DPG-LSD are provided for reference in Appendix B of this report.

1. Leadership, Oversight Personnel, and Laboratory Technicians Failures and Deficiencies

A preponderance of evidence does not exist to definitively attribute culpability for the inadvertent shipment of viable *Bacillus anthracis* to an individual or group of individuals. However, observations make clear that a lack of strong leadership at DPG-LSD has fostered an environment of complacency, and that DPG-LSD personnel have been selective in following rules, regulations, and procedures. These failures were exhibited across the spectrum of personnel at DPG-LSD including leadership, oversight staff, and laboratory technicians and some of the failures may have warranted disqualification from the biological personnel reliability program under the provisions of Army Regulation 50-1, Biological Surety, chapter 2.[294] These failures and deficiencies are discussed in detail below.

a. Manipulation and Carelessness in Generating *Bacillus anthracis* Death Certificates

The 15-6 investigation team found evidence that [redacted] altered death certificates after they had been signed and approved by the Principle Investigator, the Biological Safety Officer, and the Responsible Official in DPG's Test Mission Support System (a SharePoint tool used to automate and control the death certificate staffing process). [redacted] made these changes without notifying these individuals.[295] For example, the death certificate for lot AGD0001667 was signed by [redacted] on 18 March 2014. Normally, there is only one death certificate for each lot. However, there were three versions of the death certificate for lot AGD0001667. Each version has a different date of sterilization and radiation dose (124.02 kGy on 12 December 2013, 107.99 kGy on 16 December 2013, and 119.6 kGy on 16 December 2013).[296] The investigation found that all three of the radiation doses were incorrectly calculated. If calculated correctly in accordance with WDL-BIO-147, the total dose should have been 115.96 kGy.

While these could have been administrative changes made to correct inaccurate information, such changes should have been made prior to the finalization of the death certificates.[297] The

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[294] Certification in the biological personnel reliability program is required for an individual to have access to biological select agents and toxins. Negligence or delinquency in the performance of duty are potential grounds for disqualification, based on the certifying official's informed judgement. *See* Tab B-2.1, [redacted] DA Form 2823, Sworn Statement (21 Aug. 2015) where [redacted] states that he is the certifying official for the DPG biological personnel reliability program and has disqualified three individuals for conduct not related to these incidents, but has not disqualified individuals involved in the growth, irradiation, viability testing, or shipping of biological material. *See also* Tab B-27.2, page 3, [redacted], DA Form 2823, Sworn Statement (20 Aug. 2015) where [redacted] acknowledges that individuals performing unsafe or questionable laboratory practices should be considered for removal from the biological personnel reliability program, but did not believe any of his personnel fit that profile.

[295] *See* Tab B-44.1.a, page 5, [redacted] Addendum to DA Form 2823, Sworn Statement (19 Aug. 2015).

[296] *See* Tab C-20, Discrepant Death Certificates (Lot AGD0001667).

[297] *See* Tab B-26.1.a, page 4, [redacted] Addendum to DA Form 2823, Sworn Statement (19 Aug. 2015).

fact that the date/time stamp for each of the three signatures is the same on all three versions of the death certificate shows that these changes occurred after the original document was signed by all parties. [redacted] indicated that the content of the death certificate form cannot be modified after the Responsible Official signs it unless the signatures are removed. Once the signatures are removed and any modifications are made the form must go back through the review process and be re-signed (thereby creating a new date/time stamp).[298]

The 15-6 investigation team questioned [redacted] about these multiple death certificates. To the team's surprise, [redacted] stated that as the Principle Investigator she had permission to edit the death certificate after the document was signed by all of the parties.[299] Additionally, she indicated that an initial death certificate is produced in order to move a lot, for example AGD0001667, out of biosafety level-3 in order to prepare the sample for shipping to a customer.[300] Prior to shipping, [redacted] stated that she prepares a final death certificate by taking the existing certificate off of the database, saving it to her desktop as an editable Adobe PDF file, and adds clarity by including the finalized data the form needs (average irradiation amount and time of exposure). [redacted] circumvented the system by preserving the original valid signatures that the approving officials placed on the initial death certificate. As the Principle Investigator she believed that she did not need to get the document resigned to make these administrative changes.[301]

Additionally, when questioned about her justification as it pertained specifically to lot AGD0001667, [redacted] rationale fell apart. She stated that an initial death certificate was created to move a sample from biosafety level-3 to the biosafety level-2 laboratory.[302] However, [redacted] stated that lot AGD0001667 was moved out of biosafety level-3 in January after completing viability testing. At this time, [redacted] had all of her laboratory notes and data related to inactivation and viability testing documented in her laboratory notebook.[303] However, [redacted] did not create the death certificate for this lot until March.[304] [redacted] tried to explain this discrepancy by stating that she often prepared death certificates in batches, which directly conflicts with her statement that an initial death certificate was created to move a sample out of biosafety level-3.[305] Moreover, it was unnecessary to prepare an initial and final version of the death certificate for lot AGD0001667 because all of the necessary data needed to complete the certificate existed in January.

The preponderance of the evidence indicates: (1) [redacted] was trying to provide an excuse to cover her inattention to detail and resulting administrative errors on the death certificates; (2) [redacted] subverted the intent of the Test Mission Support System by downloading death certificates in Adobe format and manually modifying them with the original signatures and date/time stamps still intact; and (3) DPG-LSD had significant failures in properly preparing, managing and approving death certificates.

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[298] *See* Tab B-37.2, [redacted], DA Form 2823, Sworn Statement (19 Aug. 2015).
[299] *See* Tab B-44.2.a, page 6, [redacted] Addendum to DA Form 2823, Sworn Statement (19 Aug. 2015).
[300] *See* Tab B-44.1.a, page 5, [redacted], Addendum to DA Form 2823, Sworn Statement (19 Aug. 2015).
[301] *Id.*
[302] *Id.*
[303] *See* Tab B-5.1.a, page 5, [redacted], Addendum to DA Form 2823, Sworn Statement (20 Aug. 2015).
[304] *See* Tab C-20, Discrepant Death Certificates (Lot AGD0001667).
[305] *See* Tab B-44.2.a, page 6, [redacted] Addendum to DA Form 2823, Sworn Statement (19 Aug. 2015).

b. Failure to Take Action

Despite multiple shipping errors and incidents/mishaps within their labs, DPG leadership and DPG-LSD management repeatedly failed to conduct proactive internal investigations, take disciplinary action, or institute re-training when warranted. Instead, the observed response of DPG leadership and DPG-LSD management was to blame external entities or to downplay the seriousness of the associated actions and accusations. They only instituted reactive corrective actions to the immediate incident and did not consider potential indicators and deficiencies in related processes across the organization. These failures to act fostered a sense of complacency[306] which may have indirectly contributed to the inadvertent shipment of viable *Bacillus anthracis*. The following paragraphs discuss the various failures to take action in detail.

i. Failure to Investigate and Hold Personnel Accountable for Biological Mishaps

A key example of failure to investigate and hold personnel accountable is the DPG-LSD response to the 2007 shipment of viable *Bacillus anthracis* to the Lawrence Livermore National Laboratory, described in detail in Section I.F.1. In response to a question about what disciplinary action was taken in light of the fines levied on DPG-LSD by the CDC, [redacted] stated that no disciplinary actions were executed.[307] The DPG-LSD maintained throughout that the most likely cause of this incident was contamination in the receiving lab at LLNL despite the CDC finding that DPG-LSD failed to properly inactivate the spores and/or prevent contamination at its facility.[308] While it is possible that contamination at LLNL was the root cause, it is clear that DPG-LSD did not conduct an exhaustive self-examination of their personnel and procedures to arrive at this conclusion, particularly in light of the fact that one of the five sample tubes contained viable spores and was discarded via autoclave prior to shipping the other four tubes.

On 28 April 2008 [redacted] sent a memorandum to [redacted] (the investigating attorney at the DHHS-OIG for the LLNL incident) indicating that he had direct knowledge that the fifth tube was "cloudy with contamination" during viability testing.[309] The 15-6 team, CDC, and DHHS-OIG consider this fifth tube to be a critical piece of evidence. If the fifth tube was contaminated, it is not possible to determine with 100% certainty that the viable spore eventually found at LLNL did not also come from DPG-LSD. This fact was dismissed by [redacted] and resulted in acceptance of the advice of the DPG-LSD staff at face value without further investigation into the potential root cause of the incident.

Subsequently when DHHS-OIG rendered the final judgment on the LLNL incident on 2 December 2009, Colonel William King also relied upon the DPG-LSD staff for information and failed to investigate the issue. As described in Section I.F.1, Colonel King directed [redacted]

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[306] *See* Tab B-2.1.a, page 18, [redacted], Addendum to DA Form 2823, Sworn Statement (21 Aug. 2015).
[307] *Id.* at 4.
[308] *See* Tab B-2.1.c, [redacted], Enclosure 2 to DA Form 2823, Sworn Statement (21 Aug. 2015).
[309] *See* Tab C-41, pgs. 61-64, LLNL Correspondence and Evidence

[redacted][310] to "prepare a response and discussion" summarizing the LLNL incident. There is evidence that [redacted] failed to communicate the presence of contamination in the fifth tube to Colonel King in this response. However, Colonel King also indicated in recorded testimony that he did not review all of the historical correspondence associated with the incident compiled during 2007-2008 prior to his taking command at DPG.[311] A thorough review of the historical documentation should have been the first step in a formal inquiry, and would have provided him with knowledge of the contamination. It is a reasonable expectation for a commander to investigate the potential root cause of the incident, especially in light of the fact that the DHHS-OIG was authorized to impose a civil monetary penalty against DPG-LSD of up to $500,000.

In addition to the LLNL incident, Section I.F and Figure 9 detail eight additional incidents involving the inadvertent, incorrect, or improperly documented shipment of various biological materials from DPG-LSD in the time period between 2007-present. Although DPG-LSD implemented corrective actions to their processes (with questionable success) in response to each of these mishaps, they neglected to initiate formal inquiries, investigations, or disciplinary action on any of the personnel associated with the incidents. This is in spite of the fact that heavy civil penalties were recommended by the DHHS-OIG in the case of the Botulinum neurotoxin A shipments. The process improvements implemented in response to each incident were not sufficient to prevent recurrence of similar incidents in the future and formal disciplinary action in the form of re-training or counseling may have been more effective. DPG-LSD's repeated failure to hold personnel accountable is an indication that leadership may not fully understand the criticality of the operations they conduct and contributed to each subsequent mishap, including the current shipment of viable *Bacillus anthracis*.

ii. Failure to Hold Personnel Accountable for Poor Laboratory Practices

[redacted] failed to take appropriate action in response to multiple accusations of unsafe laboratory practices involving its personnel.[312] In response to a question about whether or not anyone on his team had ever complained about unsafe laboratory practices involving his personnel, [redacted] admits that he did in fact receive such a complaint from [redacted] in relation to [redacted] aseptic procedures.[313] Instead of dealing with the complaint directly, [redacted] contextualized it by referencing on-going animosity between [redacted] and [redacted] as a potential explanation. He also referenced what he believes to be an innate tendency of scientists to constantly question the skills of their colleagues as a reason why the accusation did not need to be taken seriously.[314] [redacted] decision to not take action against [redacted] in response to a single complaint is reasonable considering that he believed the complaint may have been unfounded. However,

[310] Colonel King took command at DPG in July 2009 after [redacted] relinquished command, and [redacted] became the Director of DPG-LSD in 2008 after [redacted] retired.

[311] *See* Tab B-23.2, pg. 17, Memorandum for Record, subject: Transcribed Testimony of BG William E. King, IV (10 Nov. 2015).

[312] [redacted] provided evidence that he has formally disciplined two DPG-LSD employees for poor laboratory practices not related to this investigation, but there was no evidence that he ever disciplined [redacted]

[313] *See* Tab B-27.2., page 1, [redacted], DA Form 2823, Sworn Statement (20 Aug. 2015).

[314] *Id.*

subsequent to this, and also documented in his statement, [redacted] admits that two other "prominent" biosafety level-3 lab workers expressed concerns about [redacted] lab practices.[315] These additional complaints did not prompt any formal corrective action against [redacted], nor did they prompt [redacted] to consider using the resources available to him (such as surveillance video recordings of activity in the biosafety-3 laboratories) to verify the legitimacy of the complaints. Given that [redacted] eventually played a role in the inadvertent shipment of viable *Bacillus anthracis*, the failure of [redacted] to take action in response to the numerous complaints received about her poor lab practices represents a key missed opportunity.

iii. Failure to Reasonably Identify and Correct Long-Standing Deficiencies

It is now known that the unintended shipment of samples with low concentrations of viable *Bacillus anthracis* spores was a long-standing problem dating back to 2004. It is critical to follow validated processes, procedures and protocols when operating in a highly-regulated, zero-defect environment required to work with biological select agents and toxins such as *Bacillus anthracis*. It is also necessary and reasonable to assess past inactivation results through a thorough review of prior inactivation events in order to understand whether established protocols and procedures are effective. Figure 17 presents a comparison of data contained in the death certificates for the 33 lots of *Bacillus anthracis* originally irradiated between 2004 and 2015 which remained in the DPG-LSD inventory in May 2015. These lots we re-checked for viability on 26 May 2015 following the incident reported on 22 May 2015 (note that death certificates were not available for two of the 33 lots). Figure 17 shows that of the 33 lots of irradiated *Bacillus anthracis* retested for viability, over 50% (17 of 33) showed viability when using the revised protocol provided by the CDC.[316] This data demonstrates that DPG-LSD had a long-standing, widespread problem that they failed to reasonably recognize or correct.

[315] *See* Tab B-27.2., page 1, [redacted], DA Form 2823, Sworn Statement (20 Aug. 2015).
[316] *See* Tab E-7, Centers for Disease and Control Prevention, Revised Viability Testing Protocol for Samples of Inactivated *Bacillus anthracis* (2015).

Death Certificate	Date	Lot#	Hot?	Project Officer	Safety Officer	Responsible Official	SOP on DTC	kGy
DTC0105	1/22/04	AGD0000069	Yes	(b)(6) [redacted]			147 Ver 0	41
DTC0105	1/22/04	AGD0000070	Yes	[redacted]			147 Ver 0	41
DTC0121	8/8/04	AGD0000515	No	[redacted]			147 Ver 0	41
DTC0121	8/8/04	AGD0000511	Yes	[redacted]			147 Ver 0	41
DTC0121	8/8/04	AGD0000516	Yes	[redacted]			147 Ver 0	41
DTC0194	7/28/05	AGD0000644	No	[redacted]			147 Ver 0	35.67
DTC0195	7/28/05	AGD0000648	No	[redacted]			147 Ver 0	35.67
DTC0241	4/17/06	AGD0000774	No	[redacted]			147 Ver 0	39.01
DTC0242	4/17/06	AGD0000778	No	[redacted]			147 Ver 0	38.66
DTC0251	4/17/06	AGD0000790	No	[redacted]			147 Ver 0	48.78
DTC0252	4/17/06	AGD0000794	Yes	[redacted]			147 Ver 0	45.48
DTC0253	4/17/06	AGD0000798	Yes	[redacted]			147 Ver 0	45.48
DTC0257	4/17/06	AGD0000806	Yes	[redacted]			147 Ver 0	45.41
DTC0258	4/18/06	AGD0000810	Yes	[redacted]			147 Ver 0	52.93
DTC0268	6/1/06	AGD0000830	No	[redacted]			147 Ver 0	43.32
DTC0264	6/1/06	AGD0000822	Yes	[redacted]			147 Ver 0	45.74
DTC0278	8/23/06	AGD0000858	No	[redacted]			147 Ver 0	46.7
DTC0286	8/23/06	AGD0000862	Yes	[redacted]			147 Ver 0	36.5
DTC0310	10/25/06	AGD0000910	Yes	[redacted]			147 Ver 0	41.14
DTC0382	10/2/07	AGD0000950	No	[redacted]			147 Ver 0	49.59
DTC0383	10/2/07	AGD0000954	No	[redacted]			147 Ver 0	49.59
DTC0430	10/18/07	AGD0000999	Yes	[redacted]			147 Ver 0	40.75
DTC0498	8/4/08	AGD0001039	Yes	[redacted]			147 Ver 1	40.98
DTC0497	8/5/08	AGD0001035	No	[redacted]			147 Ver 1	43.29
DTC0572	5/18/09	AGD0001151	Yes	[redacted]			147 Ver 1	40.96
DTC0670	11/4/10	AGD0001331	No	[redacted]			147	57.58
DTC0723	10/29/12	AGD0001435	No	[redacted]			147	43.08
DTC0727	10/29/12	AGD0001451	No	[redacted]			147	40.16
DTC0803	3/18/14	AGD0001667	Yes	[redacted]			147 Ver [illegible]	119.6
Not Available		AGD0001575	No	[redacted]				
DTC0791	9/9/14	AGD0001631	Yes	[redacted]			147	44.61
Not Available		AGD0001727	Yes	[redacted]				
DTC0825	1/8/15	AGD0001675	No	[redacted]			147	50.96

Colum D (Hot?): Yes=These lots tested positive in 2015, No=These lots tested negative in 2015

Column H (SOP on Death Certificate): Red=Version of WDL-BIO-147 on the Death Certificate does not match the version in effect at the time

Colum I (kGy): Green=Dose was within 40±2 kGy target dose, Red: Dose was lower than 40±2 kGy target dose; Yellow: Dose was higher than 40±2 kGy target

Figure 17: Analysis of Data Contained in 31 Death Certificates

Based on the data in Figure 17, there is no correlation between the viability test failure rate and the protocol or radiation dose. First, the viability testing failure rate for both the DPG-LSD standard protocol (WDL-BIO-147) or work instruction (CRPAR-WI-007) varied from 56-42% respectively. Both failure rates using either protocol are unacceptable and statistically significant. Second, eight of the 17 samples that eventually tested positive for viable spores were treated with a radiation dose above the target dose of 40±2 kGy while one "hot" sample received a low dose (36.5 kGy). More specifically, lot AGD0001667 reportedly received 119.9 kGy and was ultimately still viable when re-tested in 2015 whereas lot AGD0000778 received 38.66 kGy and proved to be inactivated upon re-testing. Clearly, the data available from DPG-LSD does not correlate to a root cause of the unintended shipment of viable *Bacillus anthracis* spores.

The evidence presented in Figure 17 suggests: (1) gaps in science exist as there does not seem to be any correlation between historic radiation doses (above or below the target dose of 40±2 kGy) and overall inactivation success; (2) DPG-LSD protocols were completely inadequate; (3) there was a widespread contamination issue present at DPG-LSD which affected various lots over time; or (4) the information is erroneous. Regardless, DPG-LSD personnel could have tabulated the data in Figure 17 and acted upon it if critical process reviews were being conducted. This demonstrates of DPG-LSD's failure to identify and correct long-standing deficiencies in their processes. In addition to the personnel whose names appear in Figure 17, particularly the Responsible Officials, the technical leadership ([redacted]. [redacted]) within DPG-LSD missed an opportunity to review the data, recognize trends, and potentially recognize problems with the inactivation and viability testing processes before a mishap occurred.

iv. Failure to Adhere to Production-Based Practices

The mission of the CRP team at DPG-LSD is to produce and distribute inactivated antigens for the CRP catalog in support of the CRP's role in serving as a broker for government, industry, and academia customers.[317] This mission is unique within DPG-LSD and in the ATEC community as a whole in that the CRP team produces material on a relatively large scale basis and ships it to external customers (as opposed to small production runs of biological material used to support specific, customer funded research in other DoD labs). The DPG-LSD failed to institute the rigor and control mechanisms required to create a repeatable production-based environment.[318]

Since the discovery of viable *Bacillus anthracis* on 22 May 2015, production as a core competency is being questioned at the highest levels of leadership within the ATEC. In a memorandum dated 20 July 2015, the ATEC Commander, Major General Daniel Karbler, requested that the Vice Chief of Staff of the Army transfer the mission for the production and shipment of antigen material from DPG-LSD to an alternate centralized provider.[319] When questioned about the motive for this request, Major General Karbler indicated that he does "not believe that production and shipment of antigen material is a core competency of ATEC."[320] The current Deputy to the Commander and Technical Director of ATEC, Mr. David Jimenez, echoed this sentiment.[321] The evidence suggests that CRP personnel at DPG-LSD operated with a research, test, and development mindset as opposed to a production mindset for the duration of the CRP's existence. The personnel at DPG are primarily trained and experienced in scientific research, development, and testing which is in-line with the overall ATEC mission. However, since CRP personnel are involved in production processes that create biological products for external end-users, their concentration should have been on the conduct of rigorous methodologies and requirements associated with controllable and repeatable production.

The CRP Antigen Repository at DPG-LSD (not DPG-LSD as a whole) is certified to International Standards Organization Guides 34[322] and 17025.[323] Guide 34 documents the

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[317] *See Figure* 4.
[318] *See* Tab E-3, U.S. DEP'T OF ARMY, REG. 702-11, ARMY QUALITY PROGRAM (25 Feb. 2014).
[319] *See* Tab C-29, Memorandum Thru Lieutenant General Gary H. Cheek, Director of the Army Staff; for General Daniel B. Allyn, Vice Chief of Staff of the Army, subject: Specific Recommendations for OSD Comprehensive Review: Production and Shipment of all Antigens from U.S. Dugway Proving Ground (20 July 2015).
[320] Tab B-22.1, page 2, Daniel Karbler, DA Form 2823, Sworn Statement (25 Aug. 2015).
[321] *See* Tab B-20.1, David Jimenez, DA Form 2823, Sworn Statement (10 Sept. 2015).
[322] *See* Tab C-39, General Requirements: Accreditation of ISO Guide 34 Reference Material Producers (June 2010).
[323] *See* Tab C-40, General Requirements: Accreditation of ISO / IEC 17025 Laboratories (Feb. 2015).

general requirements for accreditation of Reference Material Producers. A reference material is any material that is used as a "control" in a test or measurement process. Certification of reference materials (assurance that a reference material is of a known composition) is of critical importance to chemical and biological testing as most analytical instruments and assays are comparative in nature, so they require "accurate" reference materials to be effective. Guide 17025 accredits test and calibration procedures, and is essentially the standard by which the technical competence of the laboratory is assessed.

Certification to Guides 34 and 17025 represents a significant accomplishment for the CRP at DPG-LSD, but these certifications do not cover the entirety of the production process employed by the CRP for *Bacillus anthracis*, specifically the irradiation process.[324] Furthermore, these International Standards Organization standards do not define requirements and best practices for industrial production operations for external customers. As a result, the CRP production activity operated under the assumption that it was in compliance with acceptable standards for production, when in reality several gaps existed. Prominent among these gaps are: 1) No defined process change/configuration control plan; 2) No scheduled critical reviews of process data and metrics; and 3) No dedicated Quality Manager.

1) No Defined Process Change/Configuration Control Plan

All of the gaps identified above may have played a role in the failure to inactivate CRP lot ADG0001667 which triggered this investigation. During witness interviews and inspection of laboratory notebooks, the investigation team discovered that (b) (6) [redacted] executed an unauthorized deviation from the accepted irradiation process while irradiating lot ADG0001667.[325] The irradiator in service at DPG-LSD is a J&L Shepherd model 484-R2 Gamma Irradiator. This model employs three fixed Cobalt 60 radiation sources located at the rear of the main irradiation cavity (encapsulated in stainless steel tubes) that can be individually selected/deselected (turned on/off) to control the radiation dose. Samples are placed on a turntable inside the cavity that rotates at a constant speed to ensure that each sample is uniformly exposed to the radiation. Figure 18 depicts the irradiator in use at DPG-LSD.

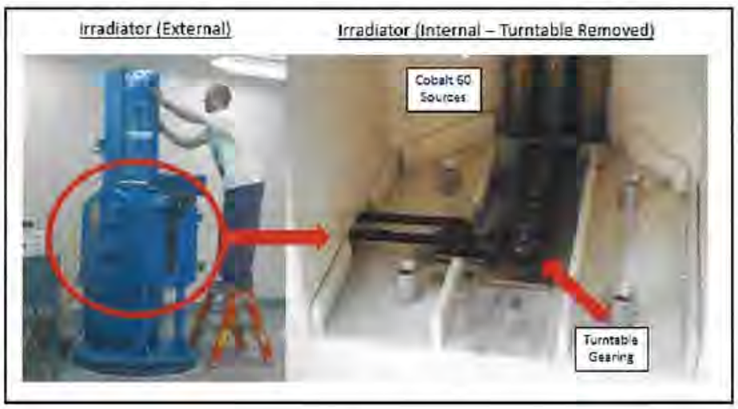

Figure 18: J&L Shepherd 484-R2 Gamma Irradiator at DPG-LSD

[324] *See* Tab B-44.1.c, (b) (6) [redacted] Enclosure 2 to DA Form 2823, Sworn Statement (18 Aug. 2015).
[325] *See* Tab B-4.1.a., page 5, (b) (6) [redacted] Addendum to DA Form 2823, Sworn Statement (18 Aug. 2015).

Since 2012 the irradiator experienced several malfunctions,[326] and since there was no maintenance/calibration contract in place, [redacted] performed repairs himself and modified the irradiation process to keep the production line moving. During irradiation of lot ADG0001667, the turntable was inoperative, so [redacted] decided to manually rotate samples 180 degrees halfway through irradiation to compensate. In his 20 August 2015 sworn statement [redacted] stated:

> *Here at DPG we do a lot of testing that falls outside the norm. We are sometimes required to design test apparatus that meets the customer needs. Troubleshooting and validating is often required. At times we are faced with the necessity of finding fixes or workarounds that enable the continuation of the test without compromising safety or the integrity of the data.*[327]

These actions are a testament to [redacted] ingenuity and dedication to timely mission completion, and are reasonable from the perspective of a tester. However, these actions are not in-line with controlled production environments, where changes to the baseline processes must be vetted to ensure repeatable results.

[redacted] stated that he consulted with other DPG-LSD personnel who also operate the irradiator [redacted]) for his proposed workaround, but there was no formal process required to vet and approve this course of action.[328] [redacted] manager, [redacted], was not immediately made aware of the issue.[329] This process deviation demonstrates how the CRP Antigen Repository was executing more as a research and development activity as opposed to a production facility mandated to maintain a controllable, repeatable process.

2) No Scheduled Critical Reviews of Process Data and Metrics:

One of the most critical activities required to maintain a defect-free, controlled, and repeatable production process is the collection and periodic review of critical process data and metrics. Production data and metrics can be used to proactively monitor the status of a production process, identify deficiencies in the process, and correct them before end products are affected. The CRP team at DPG-LSD does not conduct these formal, recurring data reviews, and missed opportunities to proactively identify inadequacies in the inactivation process that could have contributed to the inadvertent shipment of viable *Bacillus anthracis* spores.

The following example considers data collected, but not formally and critically reviewed by the CRP team, on radiation doses for various lots of CRP material since 2003. Figure 19 is a plot of Radiation Dosage vs. Lot Date for lots of *Bacillus anthracis* created by the 15-6 investigation team with data provided by the CRP.

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[326] *Id.*
[327] *See* Tab B-4.2., [redacted], DA Form 2823, Sworn Statement (20 Aug. 2015).
[328] *Id. See also* Tab B-35.2, [redacted], DA Form 2823, Sworn Statement (20 Aug. 2015).
[329] *See* Tab B-27.2.a., page 4, [redacted], Addendum to DA Form 2823, Sworn Statement (20 Aug. 2015). When made aware of the issue, [redacted] stated that it would "be corrected before any more materials were irradiated", indicating that he disagreed with [redacted] decision to rotate the samples without consulting his superiors.

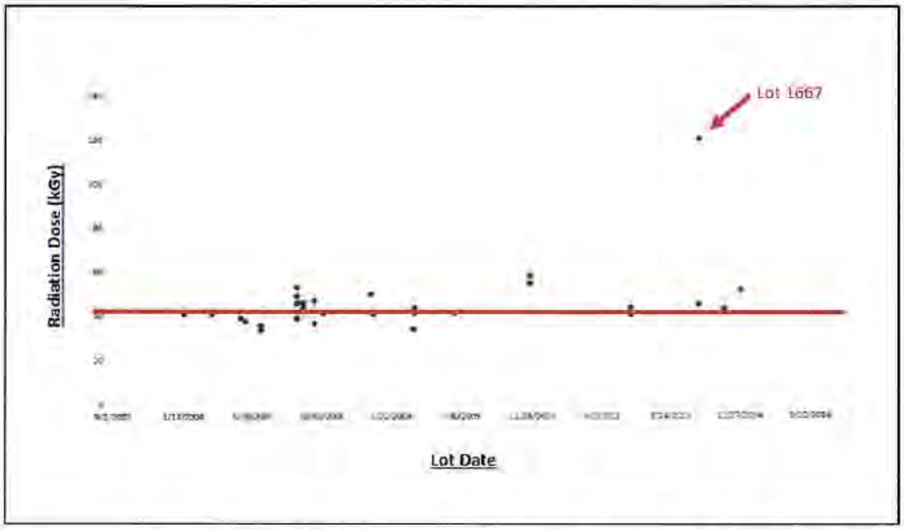

Figure 19: Critical Reagents Program Lots – Radiation vs. Lot Date

A review of this plot shows a process that is inadequate and not in control. According to DPG-LSD standard operating procedure WDL-BIO-147 (rev 8), the radiation dose required to inactivate gram positive bacteria such as *Bacillus anthracis* is 40±2 kGy.[330] Several lots of material received doses both above and below the standard dose required to achieve inactivation. In cases where lots of material required far in excess of the standard dose, including lot AGD0001667, which received nearly three times the documented required dose,[331] the samples were exposed to additional radiation after displaying growth after initial irradiation.

In the course of the investigation the 15-6 investigation team discovered that the "failure rate" for the irradiation process, that is, the rate at which samples need to be re-irradiated because growth is observed during viability testing after initial radiation, is in the range of 6-20%.[332]

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[330] *See* Tab C-1, WDL-BIO-147

[331] [redacted] did not implement a standardized scientific methodology or protocol when irradiating lot AGD0001667. Since the turntable was broken at the time of the initial irradiation, he developed remedial measures to irradiate this sample. The evidence collected does not indicate that he had a scientific basis for how much radiation to expose this lot to. For the first exposure, he estimated the exposure time for a half dose, stopped the irradiator, manually turned the sample, and continued irradiating it for the remaining time. *See* Tab B-4.1.a., [redacted] Addendum to DA Form 2823, Sworn Statement (18 Aug. 2015). The normal dose, as noted above, should be 40±2 kGy. However, it received an average dose of 59.8 kGy during the first exposure. [redacted] fixed the turntable after irradiating this lot while [redacted] conducted viability testing. During viability testing lot AGD0001667 showed growth for viable spores and had to be irradiated a second time. Any lot which requires a second dose of irradiation for inactivation should receive a maximum total average exposure of 80±4 kGy (40 kGy for each of two irradiation runs). However, this lot received an average dose of 56.16 kGy for the second exposure and a total average exposure of 115.96 kGy from both exposures (this number does not match the data annotated on the four death certificates for this lot, because [redacted] incorrectly annotated the exposure). This amount is nearly three times the normal dose of gamma radiation from only two exposures. *See* Tab B-44.1.i, [redacted] Addendum to DA Form 2823, Sworn Statement (18 Aug. 2015).

[332] *See* Tab B-2.1.a, page 8, [redacted] Addendum to DA Form 2823, Sworn Statement (21 Aug. 2015); Tab B-27.1.a., page 5, [redacted] Addendum to DA Form 2823, Sworn Statement (18 Aug. 2015); Tab B-35.2, [redacted], DA Form 2823, Sworn Statement (20 Aug. 2015).

Since 2003, a total of 483 vials of *Bacillus anthracis* have been irradiated by DPG-LSD. Twenty-nine vials have exhibited growth post irradiation – a 6% (29/483) failure rate.[333] The 483 vials were distributed across 156 lots. Twenty-two lots contained vials that exhibited growth post irradiation - a 14% (22/156) failure rate.[334] Additionally, [redacted] a non-CRP DPG-LSD employee who was utilizing the same inactivation standard operating procedure as the CRP does (WDL-BIO-147) for his work, states that approximately 20% of the irradiation runs he conducted on *Bacillus anthracis* strains required re-irradiation.[335] Combined, these percentages provide an estimated failure rate in the range of 6-20%.

A failure rate anywhere in this range is considered unacceptably high for a controlled, repeatable production process, and clearly indicates that the baseline process is inadequate. The DPG-LSD staff feels as though this failure rate is acceptable due to the balance required when trying not to over-irradiate *Bacillus anthracis* samples,[336] but it is not clear that they critically considered the data until after the current investigations began. Furthermore, the presence of both "passed" and "failed" vials within a single irradiation lot clearly indicates that the inactivation process is not repeatable due to inherent, uncharacterized variability. If formal, recurring process data and metrics reviews had been instituted by the CRP team, it is likely that they would have realized that the inactivation process was not adequate and that shipment of viable material was possible.

3) No Dedicated Quality Assurance/Quality Control Manager

Finally, DPG-LSD lacked a dedicated Quality Assurance/Quality Control manager. At DPG-LSD, Quality Assurance/Quality Control was considered an overhead function not billable to customers. As a result of funding cuts, DPG-LSD terminated a contractor position for dedicated Quality Assurance/Quality Control in 2011 because they could not defend the necessity of the billet.[337] The DPG-LSD management [redacted] were aware of the problems associated with losing this dedicated Quality Assurance/Quality Control position.[338] Subsequently, to compensate for the lack of a full-time Quality Assurance/Quality Control person, DPG-LSD leadership assigned the roles and responsibilities for CRP Quality Assurance/Quality Control to [redacted] as an additional duty.[339] This created a conflict of interest due to the fact that [redacted] is also the production technician for the CRP. In essence, leadership placed her in a position where she was responsible for both oversight and execution of the CRP inactivated antigen production processes. This was a questionable decision by

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[333] *See* Tab B-2.1.e, [redacted] Enclosure 4 to DA Form 2823, Sworn Statement (21 Aug. 2015).
[334] *Id.*
[335] *See* Tab B-35.2, [redacted], DA Form 2823, Sworn Statement (20 Aug. 2015).
[336] *See* Tab B-2.1.a, page 8, [redacted] Addendum to DA Form 2823, Sworn Statement (21 Aug. 2015).
[337] *See* Tab B-2.1, page 2, [redacted], DA Form 2823, Sworn Statement (21 Aug. 2015). [redacted] states that he tried to justify the position as "inherently government" when the contractor was lost, but was unsuccessful in having the position added to his TDA. The extent of justification he provided is not clear.
[338] *Id. See also* Tab B-27.2, page 2, [redacted], Addendum to DA Form 2823, Sworn Statement (20 Aug. 2015). These problems include lack of unbiased, external review of DPG-LSD procedures. [redacted] indicates that he believes the issues involving death certificate accuracy may have been caught by a dedicated quality person.
[339] *See* Tab B-7.2, [redacted] DA Form 2823, Sworn Statement (02 Sept. 2015); Tab B-44.2, [redacted] DA Form 2823, Sworn Statement (20 Aug. 2015).

leadership given the fact that [redacted] duties occur in a production environment where independent Quality Assurance/Quality Control is critical.

In summary, the CRP team is unique amongst the DPG-LSD and overall ATEC community in that it is engaged in the production of biological material for external customers. As a production team, it must ensure that its processes are not only safe, but also controllable and repeatable. Achieving this balance requires a level of rigor beyond that which is employed by laboratories engaged in in-house production and testing only, particularly as it relates to process change control and data collection and review. While production may not be a core competency of ATEC, if the CRP production mission is to remain at DPG-LSD it must be treated as such and resourced appropriately so that the proper level of rigor may be applied to ensure that the process remains safe, controllable, and repeatable. The evidence collected suggests that DPG-LSD was not aware of and did not implement the Army Quality Program.[340]

v. Failure to Account for Contamination

The preponderance of the evidence cannot rule out contamination as a potential root cause for the shipment of *Bacillus anthracis* that was discovered on 22 May 2015. Several individuals [redacted] questioned the laboratory practices of [redacted], who has been working inside the biosafety level-3 suites in support of the CRP Antigen Repository since 2005.[341] These individuals consistently mentioned that [redacted] would work with multiple strains of biological agents within the same biosafety cabinet at the same time.[342] This practice can lead to cross contamination. These statements were corroborated when the 15-6 investigation team conducted video surveillance on 19 August 2015. The surveillance video showed [redacted] moving a large amount of plates containing biological agents and dropping one of the plates on the floor outside the biosafety cabinet (See Figure 22). It also showed [redacted] placing laboratory consumables on the front grille of the biosafety cabinet which can affect the airflow of the cabinet and lead to cross contamination (See Figure 24). Finally, the discovery of *Bacillus anthracis* outside of primary containment during environmental sampling that was conducted by the 15-6 investigation team on 19-20 August 2015 (See Section I.G) raises additional questions about the role that contamination may have played in the inadvertent shipment at the center of this investigation as well as the other "hot lots" that have since been identified.[343]

To summarize, the discovery of *Bacillus anthracis* outside of primary containment, coupled with statements and video footage of [redacted] questionable lab practices prohibit elimination

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[340] *See* Tab E-3, U.S. DEP'T OF ARMY, REG. 702-11, ARMY QUALITY PROGRAM (25 Feb. 2014).
[341] *See* Tab B-4.1., [redacted], DA Form 2823, Sworn Statement (20 Aug. 2015); Tab B-5.2., [redacted] – Resume; Tab B-27.1, page 1, [redacted], DA Form 2823, Sworn Statement (20 Aug. 2015); Tab B-34.1, page 1, [redacted], DA Form 2823, Sworn Statement, (27 Aug. 2015); Tab B-40.1, page 1, [redacted] DA Form 2823, Sworn Statement, (27 Aug. 2015).
[342] *See* Tab B-4.1, [redacted], DA Form 2823, Sworn Statement, (20 Aug. 2015); Tab B-27.1, [redacted] DA Form 2823, Sworn Statement (20 Aug. 2015); Tab B-34.1 [redacted], DA Form 2823, Sworn Statement, (27 Aug. 2015); Tab B-40.1, [redacted] DA Form 2823, Sworn Statement, (27 Aug. 2015).
[343] *See* Tab B-16.1, [redacted] DA Form 2823, Sworn Statement, (24 Aug. 2015).

of contamination as a potential root cause of the shipment of viable *Bacillus anthracis* spores.[344] This also provides evidence that contamination should not have been dismissed by [redacted] Andersen as a potential root cause of the 2007 shipment of viable *Bacillus anthracis* to Lawrence Livermore National Laboratories. DPG-LSD [redacted]) and the [redacted] missed multiple opportunities to recognize that contamination could be an issue in their laboratories and failed to institute appropriate corrective actions.

vi. Failure to Execute an Environmental Sampling Program

Environmental sampling is a useful tool for management to establish whether personnel working within laboratories are utilizing best practices. Environmental sampling can also help determine if employees are provided a clean and safe laboratory to carry out their assigned duties. The goal of an environmental sampling program is to establish a periodic time frame to determine if any potential contamination of the laboratory environment occurred due to a spill or release of a persistent agent (i.e. *Bacillus anthracis)* outside of primary containment such as a biosafety cabinet. If sampling is conducted and only normal environmental bacteria is detected, it is likely that the laboratory is utilizing best practices.

In order to assess the DPG-LSD environmental sampling program, the 15-6 investigation team looked at practices implemented at other Army laboratories working with *Bacillus anthracis*. The U.S. Army Medical Research and Materiel Command Safety Program directs all of its laboratories that conduct research on "agents with environmental persistence" (i.e., *Bacillus anthracis*) to implement an environmental sampling program.[345] The USAMRIID has developed a written program in which they conduct a monthly random sampling of laboratories working with persistent biological agents, with monthly reports provided through their safety office to the USAMRMC safety office. In contrast, ECBC does not conduct environmental sampling in any of their laboratories since they rarely work with persistent biological agents, and when they do they thoroughly decontaminate the entire work area. Additionally, ECBC conducts an area decontamination twice a year.[346]

The DPG-LSD has a policy in place for implementation of an environmental sampling program that they failed to execute.[347] There is evidence that environmental sampling was conducted by DPG-LSD in the biosafety level-2 spaces from 2004-2008. Environmental sampling was conducted by DPG-LSD personnel once in the biosafety level-3 suites in 2004 in

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[344] *See* Tab B-4.1, [redacted] DA Form 2823, Sworn Statement, (20 Aug. 2015); Tab B-27.1, [redacted] DA Form 2823, Sworn Statement (20 Aug. 2015); Tab B-34.1, [redacted], DA Form 2823, Sworn Statement, (27 Aug. 2015); Tab B-40.1, [redacted] DA Form 2823, Sworn Statement, (27 Aug. 2015).

[345] *See* U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND, REG. 385-1, Safety Program, Ch. 8-P (13 May 2009).

[346] *See* Tab C-30, Email [redacted] to [redacted], subject: RFI BSL-3 lab monitoring (29 Sept. 2015).

[347] *See* Tab B-7.2, page 2, [redacted] DA Form 2823, Sworn Statement, (2 Sept 2015); Tab C-3, WDL-GEN-045, revision 3, (13 Nov. 2014). WDL-GEN-045 was originally implemented in February 2012, but [redacted] states that the latest revision (Rev. 3) was signed in November of 2014 with the goal of implementing an environmental sampling program. DPG-LSD blames a lack of resources/personnel for not implementing the program.

response to a construction issue. However, there is no evidence of any routine environmental sampling being conducted in the biosafety level-3 suites since 2004. The DPG-LSD [redacted] did conduct a one-time limited environmental sampling within room 506 (biosafety level-3 laboratory) in July 2015. During this limited sampling, [redacted] conducted both surface sampling inside the biosafety cabinets and air sampling of the room, but [redacted] did not sample common high-use surfaces such as the floor, countertops, door handles and chairs. Due to the limited nature of the environmental sampling in July 2015, [redacted] found no traces of viable *Bacillus anthracis* and therefore no reports were submitted to the chain of command.[348] The lack of routine environmental sampling was also a finding by the DoD Review Committee examining procedures for inactivation of *Bacillus anthracis* during their site visit to the DPG-LSD.[349]

The DPG-LSD did approve a policy for an environmental sampling program in February 2012 that was revised again in November 2014 but never implemented.[350] During the interview process, a number of DPG-LSD personnel expressed concerns about potential laboratory contamination to the 15-6 investigation team.[351] Out of concern for personnel safety and to help the 15-6 investigation team rule out contamination as a root cause of the events reported on 22 May 2015, the 15-6 Investigating Officer ordered that environmental sampling for *Bacillus anthracis* be conducted in rooms 203 and 506.[352]

Based on the Investigating Officer's order, a member of the 15-6 investigation team was tasked to conduct environmental sampling. He was provided appropriate clearances, briefed on procedures, and trained in accordance with DPG-LSD standard operating procedures inside biosafety level-3 laboratories prior to conducting the sampling. He utilized sterile swabs and water for sample collections. All samples were streaked on tryptic soy agar plates prior to incubation. Results were determined through culture morphology and confirmed through polymerase chain reaction assay. Twenty-nine samples were collected in room 203 and twenty-five samples were collected in room 506 (see Figure 20 and Figure 21). Following polymerase chain reaction analysis, five samples tested positive for *Bacillus anthracis* Ames strain in room 506 (Figure 21). Additional samples tested positive for a non-select agent strain of *Bacillus anthracis* in room 203. The discovery of contamination on the floors and surfaces within room 506 is indicative of poor laboratory practices that likely resulted from a spill. The likely spill could have been tracked across different areas within the laboratory and possibly across the suite.[353] According to Department of the Army Pamphlet 385-69 and 42 Code of Federal Regulations 73, any biological mishap involving biological select agents and toxins that occurs outside of primary containment (i.e. a biosafety cabinet) in a biosafety level-3 laboratory must be

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[348] *See* Tab 7.2.e, Enclosure 5 to [redacted] DA Form 2823, Sworn Statement, (2 Sept 2015)
[349] *See* Tab D-2, page 6, Review Committee Report, Inadvertent Shipment of Live *Bacillus anthracis* Spores by DoD (July 13, 2015).
[350] *See* Tab B-7.2, page 2, [redacted] DA Form 2823, Sworn Statement, (2 Sept 2015); Tab C-3, WDL-GEN-045, revision 3, (13 Nov. 2014).
[351] *See* Tab B-4.1, [redacted], DA Form 2823, Sworn Statement, (18 Aug. 2015); Tab B-16.1, [redacted] DA Form 2823, Sworn Statement, (24 Aug. 2015); Tab B-27.1, page 1, [redacted] DA Form 2823, Sworn Statement (20 Aug. 2015); Tab B-33.1.a, page 9, [redacted], DA Form 2823, Sworn Statement, (18 Aug. 2015).
[352] *See* Tab B-16.1, [redacted], DA Form 2823, Sworn Statement (24 Aug. 2015).
[353] *See* Tab B-16.1, [redacted], DA Form 2823, Sworn Statement (24 Aug. 2015).

immediately reported to the first general officer in the chain of command and the CDC Division of Select Agents and Toxins.[354] The 15-6 team found no evidence that the spills that caused the contamination found during the sampling it conducted were reported or documented.

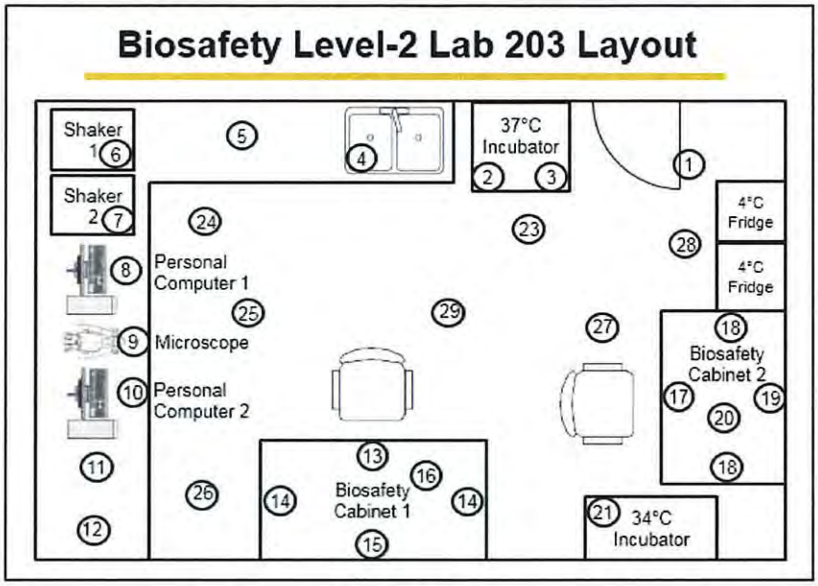

Figure 20: Layout of Lab 203 with Sample Locations

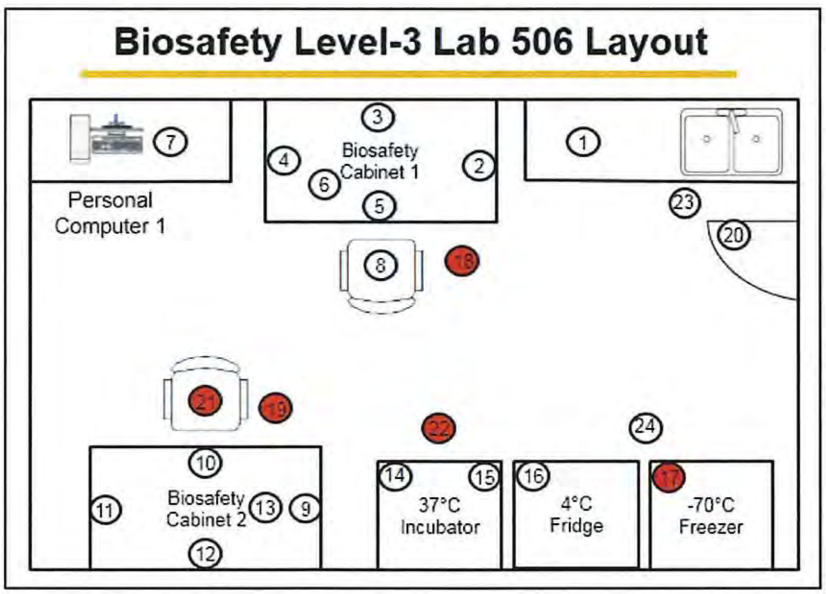

Figure 21: Layout of Lab 506 with Sample Locations. Circles Marked in RED Tested Positive for Bacillus anthracis Ames strain

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[354] *See* Notification of Theft, Loss, or Release, 42 C.F.R. pt. 73.19; DA Pam 385-69, para. 3-11.

The discovery of *Bacillus anthracis* outside of primary containment within room 506 represents a failure of the DPG-LSD technical and oversight management [redacted][355] to both enforce their environmental sampling policy[356] and ensure that their personnel were appropriately trained and following best practices. It is the responsibility of leadership to provide a clean and safe laboratory environment for all personnel assigned to work in the designated laboratories. This finding is the result of poor laboratory practices of personnel working within room 506. This creates additional hazards for personnel in room 506 but also has the potential to be transferred to other laboratories within the biosafety level-3 suite through foot traffic. The failure to routinely execute an environmental sampling program is perhaps the most questionable decision made by DPG-LSD leadership.

vii. Failure to Maintain a Viable Video Surveillance Program

Army laboratories registered to work with biological select agents and toxins are required by regulation to use Closed Circuit Television cameras for surveillance and to identify potential safety or security issues.[357] These cameras allow management to observe personnel within their working environment to determine if they are using safe laboratory practices. Prior to 22 May 2015, DPG-LSD had a program in place whereby [redacted] and [redacted] were supposed to view the closed circuit camera footage once a week for at least 15 minutes.[358] [redacted] indicated that he complied with this duty as defined, but [redacted] indicated that he rarely had time to break away from his other duties to do so. Regardless, the 15-6 investigation team found no evidence that any DPG-LSD personnel received counseling, training, or disciplinary action as a result of closed circuit television camera viewings.[359]

Surveillance footage of work performed in the biosafety level-3 suites between 9 June 2015 – 18 August 2015 was reviewed by the 15-6 investigation team on 19 August 2015. Three separate deviations from safe laboratory procedures by two individuals [redacted] were noted during this review.

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[355] See Tab C-3, WDL-GEN-045, Revision 3, *In-House Environmental Monitoring and Sampling Procedure for Bacillus anthracis*, paragraphs 1.5.a, 1.5.b and 1.5.h.
[356] *See* Tab B-2.1, pages 15-16, [redacted] DA Form 2823, Sworn Statement, (21 Aug. 2015); Tab B-7.2, page 1, [redacted] DA Form 2823, Sworn Statement, (2 Sept. 2015); Tab C-3, WDL-GEN-045, revision 3, (13 Nov. 2014).
[357] *See* Tab E-2, AR 190-17, para. 5-18.
[358] *See* Tab B-27.2.f, Enclosure 5, Appointment Letter Roving Observation
[359] *See* Tab B-2.1.a, page 18, [redacted] DA Form 2823, Sworn Statement, (21 Aug. 2015); Tab B-27.2.a, pages 5-6, [redacted], DA Form 2823, Sworn Statement, (20 Aug. 2015).

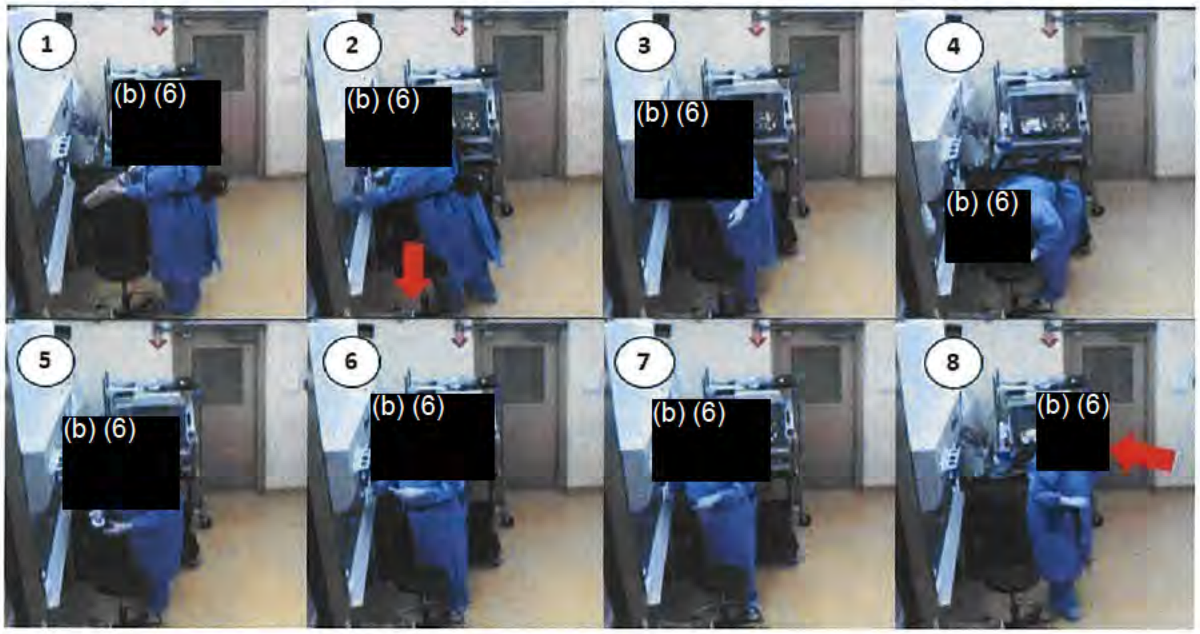

Figure 22:* [redacted] *Observations – 27 May 2015

Figure 22 is a series of frames from surveillance video recorded on 27 May 2015 showing [redacted] working in a biosafety level-3 laboratory at DPG-LSD. In frame #1 [redacted] attempts to place a tray of spread plates (petri dishes) into the biosafety cabinet from a 37°C incubator. One of the plates slips out of the tray and onto the floor (frame #2). [redacted] picks the plate off the floor, inspects it briefly, and places it in the biosafety cabinet so that she can continue working with it (frames #3-7). A few seconds later, [redacted] touches her face under her powered air purifying respirator mask (frame #8).[360] After dropping the plate, [redacted] should have immediately reported the spill to the DPG-LSD safety office. Further reporting to the CDC Division of Select Agents and Toxins and the Office of the Director of Army Safety would depend on the extent of the spill and the biological agent contained within the plate.

Figure 23 shows [redacted] working in a biosafety level-3 laboratory at DPG-LSD on 14 June 2015. [redacted] is inspecting samples that are being processed in a shaker-incubator machine without wearing the personal protective equipment (a powered air purifying respirator) required when working with liquid cultures.[361]

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[360] [redacted] bypassing her protective equipment by touching her face is an indication that she is not concerned about safety and the critical nature of the work she is doing. This is further evidence of her poor laboratory practices.

[361] *See* Tab C-7, Safety Guide for Working in High-Containment BSL-3, WDL-SAF-330, rev. 10 (28 Oct. 2014) [hereafter WDL-SAF-330].

Figure 23:* (b) (6) [redacted] *Observations – 14 June 2015

Figure 24 shows (b) (6) [redacted] working in a biosafety level-3 laboratory on 8 July 2015. It can be seen that there is a piece of laboratory equipment inside the biosafety cabinet she is working in. This would normally not be of concern, but the piece of equipment is hanging over the edge of the biosafety cabinet grille, potentially obstructing the airflow in the cabinet. Clear, unobstructed airflow is critical to the proper operation of the biosafety cabinet, in order to ensure optimal personnel safety and product protection.

Figure 24:* (b) (6) [redacted] *Observation – 8 July 2015

The 15-6 investigation team also observed that the camera angles available for room 506 provided sufficient wide-angle coverage of the room overall, but did not allow for viewing of all operational work within the laboratory, including inside the biosafety cabinets, as required by AR 190-17, paragraph 5-18.a.[362] Management must be able to review activities and procedures occurring inside the biosafety cabinets themselves because this is where the detailed work is being performed and where sample contamination is most likely to occur. Due to the insufficient camera angles in use in room 506, the 15-6 investigation team was unable to verify statements made by members of the DPG-LSD staff that [redacted] employed poor lab practices inside the biosafety cabinets.[363]

In summary, during video surveillance review on 19 August 2015 of the previous 90 days of work in the biosafety level-3 suites, the 15-6 investigation team discovered multiple deviations from laboratory procedures and that the camera angles currently employed do not provide complete coverage. DPG-LSD leadership [redacted] and the DPG-LSD [redacted] should have discovered the same things with diligent execution and maintenance of the video surveillance program.

viii. Failure to Properly Review and Approve Critical Reagents Program Internal Policies and Procedures

The use of validated, standardized protocols is key to working with biological select agents and toxins, particularly in a production environment that requires repeatable, tightly controlled processes. Established protocols protect the health and safety of individuals working with biological select agents and toxins and ensure that the materials produced meet customer needs. In order to ensure that protocols meet these requirements, it is critical that key staff including biosafety, biosurety, occupational health and quality assurance review and approve the processes contained in the protocols. The following key personnel either did not know of the existence of internal CRP Antigen Repository policies and procedures or were made aware of them after the 22 May 2015 discovery: [redacted] at DPG-LSD.[364] The fact that these individuals were unaware of CRP Antigen Repository policies and procedures does not appear to be their fault, but rather results from the [redacted] failure to appropriately share its policies and procedures.

Additionally, the review process for approving internal CRP Antigen Repository policies and procedures was less stringent than the review process for DPG-LSD's other inactivation policies and procedures. For example, the DPG-LSD protocol for the inactivation of biological agents, WDL-BIO-147,[365] underwent eight revisions since it was originally approved in 2001. The

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[362] *See* Tab E-2.

[363] *See* Tab B-4.1, page 1, [redacted] DA Form 2823, Sworn Statement, (20 Aug. 2015); Tab B-27.1, [redacted] DA Form 2823, Sworn Statement (20 Aug. 2015); Tab B-34.1, [redacted] DA Form 2823, Sworn Statement, (27 Aug. 2015); Tab B-40.1 [redacted], DA Form 2823, Sworn Statement, (27 Aug. 2015).

[364] *See* Tab B-6.1.a, page 4, [redacted] DA Form 2823, Sworn Statement, (19 Aug. 2015); Tab B-7.1.a., page 5, [redacted], DA Form 2823, Sworn Statement, (20 Aug. 2015); Tab B-15.1, page 2, [redacted] DA Form 2823, Sworn Statement, (18 Aug. 2015).

[365] *See* Tab C-1, WDL-BIO-147.

various versions were each reviewed by 12-18 individuals, to include the (b) (6) [redacted] various Branch and Division Chiefs, and the (b) (6) [redacted], and was approved by the Dugway Proving (b) (6) [redacted] In contrast, the CRP Antigen Repository Work Instruction 007 (CRPAR-WI-007[366]) for the production, inactivation and viability testing of Bacillus anthracis underwent five revisions since 2008. The current version of CRPAR-WI-007, approved in December 2014, was only reviewed by three individuals. A comparison of the reviewing officials for the most recent versions of WDL-BIO-147 and CRPAR-WI-007 Version 2.0 is provided in Figure 25. WDL-BIO-147 received a much more comprehensive review.

	Comparison of the Reviewing Officials for WDL-BIO-147 and CRPAR-WI-007		
	WDL-BIO-147 Version 8 Reviewers		**CRPAR-WI-007 Version 2.0 Reviewers**
1	(b) (6) [redacted]		(b) (6) [redacted]
2	[redacted]		[redacted]
3	[redacted]		[redacted]
4	[redacted]		
5	[redacted]		
6	[redacted]		
7	[redacted]		
8	[redacted]		
9	[redacted]		
10	[redacted]		
11	[redacted]		
12	[redacted]		
13	[redacted]		
14	[redacted]		
15	[redacted]		
16	[redacted]		
17	[redacted]		
18	[redacted]		
19	[redacted]		

Figure 25: Comparison of the Reviewing Officials of WDL-BIO-147 and CRPAR-WI-007 (Inactivation Protocols)

Moreover, it is critical to ensure that no confusion exists with regards to understanding the protocols used for specific work efforts. Several leaders at DPG and DPG-LSD (b) (6) [redacted] knew two inactivation protocols existed, but did not take appropriate steps to review and resolve issues that arose because the two protocols governed the same processes and procedures. A comparison of the different versions of WDL-BIO-147 with the corresponding version of CRPAR-WI-007 clearly shows that operating conditions found in the CRP Antigen Repository were fundamentally different from those within the rest of DPG-LSD (See Figure 26). These differences further highlight the leadership's failure to review and resolve conflicts and confusion among internal policies and procedures within DPG-LSD.

[366] *See* Tab C-9, CRPAR Work Instructions.

Year	Paramater	WDL-BIO-147	CRPAR-WI-007
2001	Version	0	Not in Effect
	kGy	Not stated	---
	Broth	5%	---
	Broth Time	48 hrs	---
	Broth Temp	35-37°C	---
	Plate Time	≥24 hrs	---
	Plate Temp	35-37°C	---
2006	Version	1	Not in Effect
	kGy	Not stated	---
	Broth %	5%	---
	Broth Time	48 hrs	---
	Broth Temp	35-37°C	---
	Plate Time	≥24 hrs	---
	Plate Temp	35-37°C	---
2008	Version	2	1
	kGy	Not stated	Not stated
	Broth %	5%	5%
	Broth Time	48 hrs	>48 hrs
	Broth Temp	35-37°C	34°C
	Plate Time	≥24 hrs	>48 hrs
	Plate Temp	35-37°C	34°C
2010	Version	3	1.1
	kGy	Not stated	Not stated
	Broth %	5%	5%
	Broth Time	48 hrs	≥48 hrs
	Broth Temp	35-37°C	34°C
	Plate Time	≥24 hrs	>48 hrs
	Plate Temp	35-37°C	34°C
2011	Version	4	1.2
	kGy	40±2 kGy	Not stated
	Broth %	5%	5%
	Broth Time	24±4 hrs	≥48 hrs
	Broth Temp	30°C	34°C
	Plate Time	48±8 hrs	≥48 hrs
	Plate Temp	30°C	34°C
2012	Version	5	2
	kGy	40±2 kGy	Not stated
	Broth %	5%	5%
	Broth Time	24±4 hrs	≥48 hrs
	Broth Temp	30°C	34°C
	Plate Time	48±8 hrs	≥48 hrs
	Plate Temp	30°C	34°C
2013	Version	6	2.1
	kGy	40±2 kGy	Not stated
	Broth %	5%	5%
	Broth Time	24±4 hrs	≥48 hrs
	Broth Temp	30°C	34°C
	Plate Time	48±8 hrs	≥48 hrs
	Plate Temp	30°C	34°C
2014	Version	7	5
	kGy	40±2 kGy	Not stated
	Broth %	5%	5%
	Broth Time	24±4 hrs	≥48 hrs
	Broth Temp	30°C	34+3°C
	Plate Time	48±8 hrs	≥48 hrs
	Plate Temp	30°C	34+3°C
2015	Version	8	No update
	kGy	40±2 kGy	Not stated
	Broth %	5%	5%
	Broth Time	24±4 hrs	≥48 hrs
	Broth Temp	30°C	34+3°C
	Plate Time	48±8 hrs	≥48 hrs
	Plate Temp	30°C	34+3°C

Figure 26: Comparison of Key Differences among Different Versions of WDL-BIO-147 and CRPAR-WI-007 (areas in which the two protocols were the same or different are highlighted in green and yellow, respectively)

ix. Failure to Integrate the Critical Reagents Program into the DPG-LSD Team

Evidence indicates that CRP Antigen Repository personnel perpetuated a perception that their activities were proprietary in nature and this resulted in the Antigen Repository being perceived and treated as a distinct and separate entity within the DPG-LSD which caused: (1) failure to thoroughly review and approve protocols that the CRP Antigen Repository used when inactivating *Bacillus anthracis* and conducting viability testing; (2) failure to conduct quality control/quality assurance reviews to ensure that the CRP Antigen Repository was following their own procedures; and (3) failure to ensure that appropriate laboratory practices were followed. The "proprietary" nature of the CRP Antigen Repository may have contributed to the inadvertent shipment of *Bacillus anthracis*.

The overarching belief throughout Dugway Proving Ground is that the CRP Antigen Repository is proprietary in nature, and does not have to fully cooperate and provide information to DPG-LSD and DPG leadership. (b) (6) [redacted] of the West Desert Test Center, is responsible for reviewing protocols and standard operating procedures for all quality-related efforts and International Standards Organization 17025 accreditation efforts across Dugway Proving Ground West Desert Test Center. [redacted] indicated in her sworn statement that the proprietary nature of the CRP Antigen Repository resulted in significantly less oversight than received by other programs/efforts within DPG-LSD.[367] Specifically, [redacted] denied two individuals who worked for [redacted] access to the results of an audit and other CRP Antigen Repository documents. [redacted] also stated that [redacted] told her that all she was allowed to provide to [redacted] was the scope of work and the International Standards Organization certificates and specifically stated that she could not provide [redacted] with anything related to production (e.g., standard operating procedures, protocols or work instructions).[368]

[redacted] stated that the CRP management office at Fort Detrick directed her to not share protocols and procedures due to their confidential nature;[369] however, this was taken completely out of context as explained in the sworn statements from [redacted] as well as [redacted] who indicated that they did not direct that CRP Antigen Repository protocols, standard operating procedures, or work instructions could not be shared with or reviewed by appropriate personnel at DPG-LSD.[370] The confusion seems to have stemmed from a misinterpretation of the CRP Security Classification Guide, and a requirement to protect sensitive spore production protocols and other intellectual property from being disseminated to external entities.[371]

Leadership at DPG and DPG-LSD knew that the CRP Antigen Repository considered certain aspects of its operation proprietary and did not take action to remedy the issue or verify that proper oversight was being provided. [redacted] requested and was denied access to the CRP Antigen Repository International Standards Organization 17025 accreditation records.[372] After being denied, he failed to press harder for access or to consider the broad technical implications associated with compartmentalization. Additionally, [redacted] with direct management responsibility for CRP Antigen Repository personnel, acknowledged the pseudo-compartmentalized nature of CRP operations but failed to recognize or act on the issues it caused within the facility.[373] [redacted] and also a key reviewing official of both CRP and non-CRP work instructions at DPG-LSD, failed to ensure that the CRP work instructions received the same level of review as other DPG-LSD work

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367 *See* Tab B-6.1, Page 2, [redacted] DA Form 2823, Sworn Statement (19 Aug. 2015).
368 *See Id.* at 2-3.
369 *See* Tab B-44.1.a, Page 4, [redacted] Addendum to DA Form 2823, Sworn Statement (19 Aug. 2015).
370 *See* Tab B-10.1, [redacted] DA Form 2823, Sworn Statement (1 Sept. 2015); Tab B-36.1, [redacted], DA Form 2823, Sworn Statement (14 Sept. 2015); Tab B-13.2, [redacted], DA Form 2823, Sworn Statement (11 Sept. 2015).
371 *See* Tab B-36.1, [redacted] DA Form 2823, Sworn Statement (14 Sept. 2015)
372 *See generally* Tab B-6.1, [redacted] DA Form 2823, Sworn Statement (19 Aug. 2015) and Tab B-14.1, [redacted], DA Form 2823, Sworn Statement (17 Aug. 2015). [redacted] indicated during his interview that he had requested the records and was denied. It took two years for the information to finally be shared.
373 *See generally* Tab B-2.1.a, [redacted] DA Form 2823, Sworn Statement (21 Aug. 2015) and Tab B-27.1, [redacted] DA Form 2823, Sworn Statement (19 Aug. 2015).

instructions, and failed to emphasize the importance of integrating the CRP Antigen Repository processes and procedures with the rest of the division.

The cause of the "proprietary" perception of the CRP Antigen Repository appears to have been [redacted]' misunderstanding of directives from the CRP team at Ft. Detrick and a lack of communication between the DPG-LSD leadership and the CRP Antigen Repository team. The CRP Antigen Repository operated in a pseudo-compartmentalized manner within DPG-LSD and as a result did not receive the scrutiny and review required for a group producing Biological Select Agents and Toxins intended for worldwide shipment. Although [redacted] bears partial responsibility for this failure, [redacted] and [redacted] should have questioned the proprietary nature of the CRP Antigen Repository, not accepted "proprietary" as an excuse when being denied access to certain aspects of the operation, and acted to more tightly integrate the CRP Antigen Repository personnel into DPG-LSD.

x. Failure to Ensure Biosafety Officer Qualification

Army safety regulations require that facilities conducting infectious agent and toxin research and all facilities that store select agents and toxins designate an individual as the biosafety officer.[374] Biosafety officers will be trained and qualified and meet the following qualifications:

1) Bachelor's degree with background in science
2) One year of laboratory experience at equivalent biological safety level
3) A 3, 4, or 5 day Department of the Army approved biosafety course
4) DoD biosafety course
5) Army on-line training in safety policy and standards and risk management[375]

Biosafety officers serve as a facility/activity's biological safety subject matter expert. They support the risk management process by conducting risk assessments, defining biological safety controls, managing the biological safety program, and assisting in development of standard operating procedures. They also provide and/or support biological safety training, inspections, emergency planning and response, and mishap notification/investigation/reporting.[376] Biological safety officers should be formally trained and understand the microbiology necessary to isolate, manipulate, and propagate pathogenic microorganisms. The biological safety officer must be able to apply practices and procedures to prevent occupational infections in the workplace or release of the organisms to the environment or public.[377] The Department of the Army Biological Safety and Health Council determined that the biological safety officer position is critical to biological operations. The biological safety officer position was made mandatory and promulgated into Army regulations in May of 2009.[378]

[374] *See* DA PAM 385-69, para. 3-3. *See also* Part 331, Title 7, Code of Federal Regulations, 9 Code of Federal Regulations Part 121, and 42 Code of Federal Regulations Part 73.
[375] DA PAM 385-69, para. 3-8.
[376] *See* DA PAM 385-69, para. 3-3.
[377] *See* American Biological Safety Association, https://www.absa.org/ (last visited Sept. 16, 2015).
[378] *See* DA PAM 385-69, para. 3-3; AR 385-10, ch. 20 requires mandatory implementation of DA PAM 385-69.

The DPG-LSD leadership had the responsibility to designate a qualified biological safety officer and failed to do so. [redacted] designated [redacted] because he did not meet the minimum requirements to be a biosafety officer.[379] The [redacted] position is unique to DPG-LSD and deviates from the biological safety officer requirement mandated by Army regulations. [redacted] assumed the responsibilities as an [redacted] in 2012,[380] and in this capacity signed standard operating procedures and death certificates, duties above and beyond those of an [redacted][381] [redacted] was not fully qualified because he did not meet the education requirements for a biosafety officer. [redacted] and ultimately the [redacted] should have appointed a person that met Department of the Army qualifications or formally asked for a waiver or exception to the policy.

xi. Failure to Notify the Chain of Command of Biological Mishaps

Biological mishap reporting is a key component of the Army safety program for the purpose of accident prevention and protecting human resources and the environment. The Army requires all biological mishaps[382] reported to the CDC or Animal and Plant Health Inspection Service be concurrently reported to the first General Officer in the chain of command.[383] Additionally, it is incumbent upon laboratory staff to report mishaps and errors to their supervisors to ensure that corrective action is taken. As discussed in Section I.F (Historical Mishaps at Life Sciences Division Dugway Proving Ground), notification through the chain of command for mishaps reportable to the CDC was handled appropriately. But, for the various shipping errors that were not reportable to the CDC, appropriate notification to the chain of command did not occur.

As shown in Figure 9, [redacted] was aware of the 2010 Venezuelan Equine Encephalitis shipping error but failed to notify [redacted] Both [redacted] and [redacted] were aware of the 2010 *Burkholderia mallei* and the 2014 *Vaccinia* shipping errors but failed to notify [redacted] [redacted] was aware of the 2014 *Yersinia pestis* shipping error but failed to notify anyone in her supervisory chain.

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379 [redacted] as one of her duties in her sworn statement (Tab B-7.1), but the [redacted] signature on several documents critical to this investigation (WDL-BIO-147 revs. 5-8 and several death certificates, including the one for Lot AGD0001667) were signed by [redacted]

380 *See* Tab B-14.1.b., [redacted] Enclosure to DA Form 2823, Sworn Statement (2 Sept. 2015).

381 *See* Tab C-19, Death Certificate for Lot AGD0001667 (18 Mar. 2014).

382 DA PAM 385-69, para. 3-11, defines a biological mishap as "an event in which the failure of laboratory facilities, equipment, or procedures appropriate to the level of potential pathogenicity or toxicity of a given etiologic agent may allow the unintentional, potential exposure of humans or the laboratory environment to that agent."

383 DA PAM 385-69, para. 3-11, requires the completed Form 3 be submitted to the CDC or Animal and Plant Health Inspection Service within seven calendar days, with a copy forwarded to the first general officer in the chain of command.

xii. Failure to Safeguard Classified Information and Ensure Personnel are Trained on Classification Guidance

In June 2015, DPG-LSD sent all *Bacillus anthracis* shipping records to the CRP office at Fort Detrick, Maryland for review by a task force that the Joint Program Executive Office for Chemical and Biological Defense established - Task Force Anthrax.[384] Task Force Anthrax was directed to determine which laboratories received inactivated *Bacillus anthracis* based on the 22 May 2015 discovery. During the review Task Force Anthrax discovered that DPG-LSD provided records containing classified information. DPG-LSD sent their records through unclassified means. The improper transfer of classified material is a violation of Army Regulation 380-5, Department of the Army Information Security Program.[385]

After the classified information was discovered, the Joint Program Office for Chemical and Biological Defense conducted an assessment and found a number of shipping records that contained classified information.[386] The assessment found no compromise to classified information, no damage to national security, and that the transfer was unknowing, but in violation of the CRP Security Classification Guide.[387]

Subsequent to the assessment, the Counterintelligence Office at DPG investigated this incident and found that CRP personnel at DPG were unaware of classified shipping records, and CRP personnel (excluding [redacted]) were unaware of the CRP Security Classification Guide.[388] Additionally, the investigation found [redacted] provided no security classification training to personnel who were involved with the CRP.[389] The investigation further found [redacted] and [redacted], were "not aware of the CRP Security Classification Guide, even though, in [redacted] case, she had been working at the CRP Antigen Repository for approximately 10 years."[390] As with the Joint Program Executive Office for Chemical and Biological Defense assessment, the DPG investigation found no compromise to classified information, and that this incident was not deliberate.[391] The investigation recommended [redacted] "provide training to all Life Sciences Test Facility personnel concerning the classification issues related to the

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[384] *See note* 12.

[385] U.S. DEP'T OF ARMY, REG. 380-5, DEPARTMENT OF THE ARMY INFORMATION SECURITY PROGRAM (29 Sept. 2000). This regulation establishes the policy for classification, transportation, and safe-guarding of information requiring protection in the interests of national security.

[386] *See* Tab C-16, Memorandum for Record, subject: Incident Report – Possible compromise of Classified Information (16 Jun 2015).

[387] *See* Tab C-16, Memorandum for Record, subject: Incident Report – Possible compromise of Classified Information (16 Jun 2015); Tab C-18, JOINT PROGRAM EXECUTIVE OFFICE FOR CHEMICAL AND BIOLOGICAL DEFENSE, CRITICAL REAGENTS PROGRAM (CRP) SECURITY CLASSIFICATION GUIDE (Nov. 2005).

[388] *See* Tab C-17, Memorandum for Record, subject: Inquiry of Violations of the Critical Reagent Program (CRP) Security Classification Guide (SCG) (18 June 2015).

[389] *Id.*

[390] Tab C-17, Memorandum for Record, subject: Inquiry of Violations of the Critical Reagent Program (CRP) Security Classification Guide (SCG), para. 4 (18 June 2015).

[391] *See* Tab C-17, Memorandum for Record, subject: Inquiry of Violations of the Critical Reagent Program (CRP) Security Classification Guide (SCG) (18 June 2015).

CRP"[392] and that "all new personnel assigned should receive the training within 30 days of assignment at the Life Sciences Test Facility."[393]

[redacted] failed to properly train DPG-LSD personnel on the requirements of the Critical Reagents Program Security Classification Guide. No disciplinary actions were taken against [redacted] or other DPG-LSD personnel as a result of the investigation conducted by DPG.

xiii. Summary of Failures to Take Action

Since 2007, DPG leadership and DPG-LSD management repeatedly displayed a tendency to question the validity of substantiated claims against DPG-LSD and downplayed the seriousness of incidents and mishaps occurring within the Life Sciences Test Facility. The leadership at DPG did not comprehensively investigate these mishaps, address incidents as training/educational opportunities, or take disciplinary action against personnel. The DPG-LSD failed to adhere to production based practices, failed to maintain and execute environmental sampling and video surveillance programs, and in general, failed to enact proactive management policies designed to continuously improve processes and prevent future mishaps.

When viewed holistically, these failures to act indicate complacency within the organization and personnel not committed to continuous process improvement and employee development. This complacent environment developed even after the DHHS-OIG repeatedly levied heavy civil penalties against DPG, but later declined to enforce them based on DPG's status as a government entity. Despite numerous findings, DPG leadership and DPG-LSD management failed to hold personnel accountable for their mistakes. This level of complacency and failure to act cannot be tolerated in a zero-defect environment where the health and safety of employees and the public are involved. The failure to look internally at each incident or mishap, and make every effort to improve the organization directly contributed to the current environment of complacency, and may have indirectly contributed to repeated biological mishaps, including the mishap that is the focus of this investigation.

c. Complacency

The culture of complacency at DPG-LSD has existed since at least 2008.[394] This culture is documented in various reports. For example, Brigadier General Les Smith conducted a 15-6 Investigation in 2011 and found a relaxed attitude toward accountability and security as a contributing factor to the temporary loss of a vial of chemical agent regulated by the Army

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[392] Tab C-17, Memorandum for Record, subject: Inquiry of Violations of the Critical Reagent Program (CRP) Security Classification Guide (SCG) para. 7 (18 June 2015).
[393] Tab C-17, Memorandum for Record, subject: Inquiry of Violations of the Critical Reagent Program (CRP) Security Classification Guide (SCG) para. 8 (18 June 2015).
[394] The 15-6 investigation team has identified the LLNL incident as the first indication that complacency may have been an issue at DPG-LSD. The notifications from the CDC in 2008 represent the first missed opportunity to scrutinize processes and procedures and in turn to potentially discover that complacency was a problem.

Surety Program resulting in a post shutdown.[395] Also, as discussed in Section II.B.3.b, a holistic review of the Department of the Army Inspector General Biosurety Inspection Reports show a trend of minor deficiencies attributed to inattention to detail and complacency.

The culture of complacency was also noted in the statements and testimony of various individuals who led or worked with DPG-LSD over the years. Below are multiple examples where complacency was noted as an issue by individuals.

The current ATEC Commander Major General Daniel Karbler stated:

> *I believe that over-confidence in abilities (as the Life Science subject matter experts are a very select group) led to complacent practices. I likened it to the failure of the Air Force's nuclear force who allowed the nuclear cruise missiles to be loaded and flown. Such a small, select group can become overconfident in their expertise, which could lead to complacent behavior.*[396]

[redacted] reported that a number of leaders at the West Desert Test Center were having struggles that created "notable performance issues."[397] [redacted] also noted that his assessment after his first 90 days in command was that "the personnel at DPG were very aware of their strengths but there was no appetite to openly identify weaknesses and therefore there was little being done to address those weaknesses."[398]

[redacted] expressed frustration that DPG-LSD is reactive vice proactive, lacks depth of thought in how it investigates and responds to mishaps, and in general does not have any personnel thinking critically about biosafety. In addition, he shared an example of a communication with DPG-LSD in which an employee stated "we have always done it this way" in response to a question about one of their procedures.[399]

[redacted] made multiple comments which suggested a complacent environment at DPG-LSD. [redacted] stated that "two generations of DPG scientists and technicians had grown to trust our sterility testing SOP and fostered a false belief that it was foolproof."[400] Additionally, [redacted] stated:

> *...management (specifically [redacted] is responsible for overall oversight of the Division's inactivation procedures and capabilities and it*

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[395] *See* Tab C-46, pages 36-7, 42, Findings and Recommendations, 15-6 Report – Chemical Accountability at DPG (4-28 Feb. 2011). This investigation was conducted while Colonel William King was in command at DPG. While this investigation focused on the Chemical Test Division, it is evidence that complacency was an issue at DPG.
[396] Tab B-22.1, Daniel Karbler, Daniel, DA Form 2823, Sworn Statement (25 Aug. 2015).
[397] Tab B-11.2.a., Page 1, [redacted], Addendum to DA Form 2823, Sworn Statement (10 Sept. 2015).
[398] Tab B-11.2.a., page 5, [redacted], Addendum to DA Form 2823, Sworn Statement (10 Sept. 2015).
[399] *See* Tab B-67.1, [redacted] Memorandum for Record, subject: Summarized Testimony of [redacted] (12 Nov. 2015).
[400] Tab B-27.1.a, Page 5, [redacted], Addendum to DA Form 2823, Sworn Statement (19 Aug. 2015).

> *is management that bares [sic] the responsibility for assuring that all personnel are adequately trained and proficient in conducting the processes delineated in WDL-BIO-157, WDL-GEN-036, and other associated safety SOPs.*[401]

Furthermore, [redacted] stated that:

> *Following the incident and the resulting internal reviews, it became obvious to me that we had developed a false sense of security in our sterility testing procedure and as this procedure was passed between generations of employees that we never stopped to conduct a critical review or perform any type of failsafe experimentation.*[402]

These statements on the part of [redacted] clearly indicate that complacency has been an issue, and that although he recognizes this now, he missed key opportunities to identify the problems prior to the inadvertent shipment of viable *Bacillus anthracis*.

[redacted] admitted to complacency in his own action. In his sworn statement, [redacted] admits that "he should consider being a bit more proactive in compliance and in addressing mistakes and violations."[403] He also states that he needs to "do a better job of integrating the efforts of the Microbiology Branch personnel with the RSI (Compliance) Branch personnel."[404]

In summary, working with biological select agents and toxins is critical work that requires great attention to detail and has little margin for error. This field is highly regulated with emphasis placed on ensuring that operations are conducted in a safe, secure, and reliable manner.[405] Throughout the 15-6 investigation it became abundantly clear that the overall environment within DPG-LSD was one of complacency. This impression was corroborated by personnel who have worked with DPG-LSD over the years. The various failures to act discussed in Section II.C.1.b result from the complacent atmosphere at DPG-LSD. This complacent atmosphere resulted in an organization plagued by mistakes and unable to identify systemic issues in the high-risk, zero-defects world of biological select agents and toxins.

2. Responsible Party Accountability Findings

A preponderance of evidence does not exist to definitively attribute culpability for the inadvertent shipment of viable *Bacillus anthracis* to an individual or group of individuals. However, evidence exists to support findings that leaders, oversight personnel, and lab technicians failed to exercise due care in the performance of their respective duties. Below is a discussion of the findings related to the leaders, oversight personnel, and the lab technicians who should or should not be held accountable.

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[401] Tab B-27.1.a, Page 3, [redacted], DA Form 2823, Sworn Statement (19 Aug. 2015).
[402] Tab B-27.1.a, Page 1, [redacted], Addendum to DA Form 2823, Sworn Statement (19 Aug. 2015).
[403] Tab B.2.1.a, Page 18, [redacted], Addendum to DA Form 2823, Sworn Statement (21 Aug. 2015).
[404] Tab B.2.1.a, Page 18, [redacted], Addendum to DA Form 2823, Sworn Statement (21 Aug. 2015).
[405] *See* Tab E-1, AR 50-1, para. 1-1.

a. Senior Leaders at the Army Test and Evaluation Command Headquarters, the Developmental Test Center, and Dugway Proving Ground

The 15-6 investigation team considered the level of management or command at which accountability for the various mishaps, failures, and overall complacency at DPG should ultimately rest. Figure 27 shows a pictorial view of senior leaders at West Desert Test Center, DPG, the Developmental Test Center,[406] and ATEC headquarters overlaid with key historical events at DPG. The intent of the figure is to assist in determining which senior leaders were in command and whether or not they knew about and acted reasonably in response to each incident. This figure does not include data for the "hot lots" shown in Figure 17. However, the seven events addressed in Figure 27 were missed opportunities where key leaders at DPG could have identified the scientific and complacency problems present at DPG-LSD.

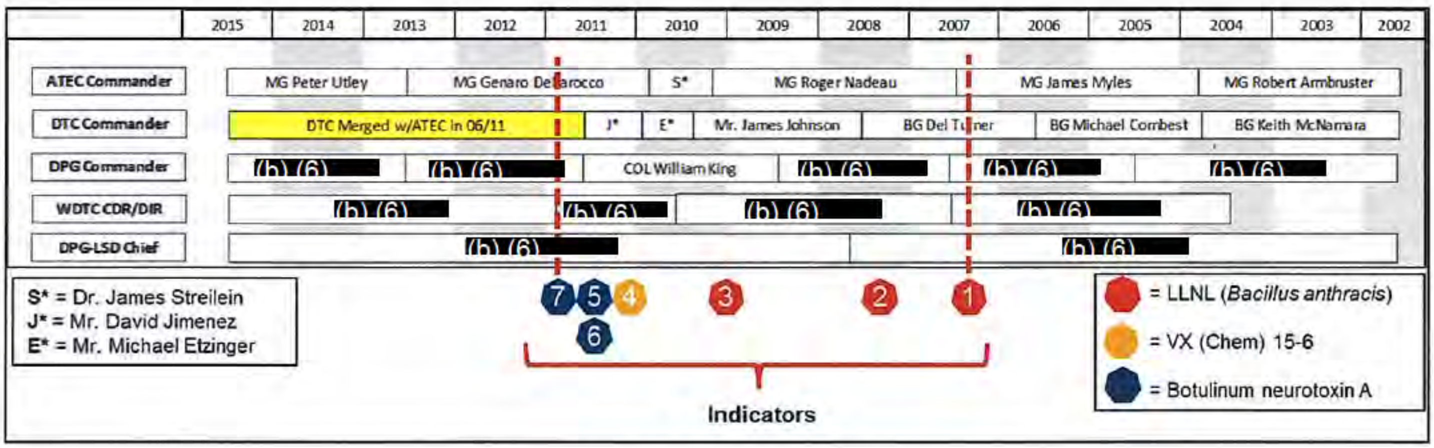

Figure 27: Analysis of Senior Leaders

The seven events addressed in Figure 27 were critical indicators and should have prompted senior leaders to take action. Events 1-3 in red are associated with the inadvertent shipment of viable *Bacillus anthracis* to Lawrence Livermore National Laboratories in 2007. Event 1 is the notification from Lawrence Livermore National Laboratories that it had found a viable spore in April 2007; event 2 is the initial notification to DPG-LSD that the DHHS-OIG may consider the shipment to be an unauthorized transfer of select agent in March 2008, and event 3 is the final notification to the DPG commander finding DPG-LSD to be at fault and authorizing civil monetary penalties to be imposed in December 2009.[407] Event 4 in amber encompasses the investigation and deliverables associated with BG Leslie Smith's 15-6 report on Chemical Accountability at DPG in early 2011.[408] Events 5-7 in blue are associated with the erroneous shipments of Botulinum neurotoxin A. Event 5 is the original notification from NMRC in April 2011; event 6 is DPG's failed Department of the Army Inspector General Biosurety Inspection in

[406] An intermediate one-star command that was merged with ATEC in 2011.

[407] *See* Section I.F.1; *See also* Tab C-41, LLNL Correspondence and Evidence.

[408] *See* Tab C-46, 15-6 Report, Chemical Accountability at DPG (4-28 Feb. 2011). This investigation and report was not focused on DPG-LSD. Given the severity of the incident and the findings about complacency, the 15-6 investigation team believes it should have prompted DPG leadership to investigate other labs as well.

May 2011; event 7 is the final notification to ATEC headquarters finding DPG-LSD to be at fault and authorizing civil monetary penalties to be imposed in November 2011.[409]

These historical events clearly correlate to the findings of the 15-6 team during the current investigation. Events 1-3 (LLNL) included failures in inactivation, viability testing, potential contamination, and a failure to investigate and hold personnel accountable at DPG-LSD. The 15-6 investigation tied to event 4 found that a "relaxed attitude" (i.e., complacency) was an issue in a laboratory conducting critical operations at DPG. Events 5-7 (Botulinum neurotoxin A) included inadvertent shipments, document errors, and again failures to investigate and hold personnel accountable for their actions. All of these failures had common attributes and were similar in nature to the inadvertent shipments of viable *Bacillus anthracis* prompting this investigation.

1. 2008-2011

As bracketed in red in Figure 27, the critical historical indicators which should have triggered command action occurred between 2008 and 2011.[410] The evidence collected shows that the indicators were readily apparent to the installation commanders at DPG. [redacted] and Colonel William King were the Commanders at DPG during this timeframe.

[redacted]

[redacted], [redacted] received the 31 March 2008 memorandum (Event 2) from the DHHS-OIG indicating that DPG-LSD violated select agent regulations in association with the LLNL event. The evidence gathered by his staff and contained in his response on 28 April 2008 included information about the questionable viability test results, specifically that the fifth vial that was "cloudy with contamination."[411] Given that [redacted] knew about this contamination, he had a duty to direct a comprehensive investigation to resolve the inconsistent findings between the DHHS-OIG and the DPG-LSD staff. He also had a duty to determine why the fifth vial was contaminated, and why the entire batch was not destroyed as per viability testing standard operating procedures.[412] He failed in these duties.[413] [redacted] failed to hold anyone accountable for the mishap, and missed an opportunity to critically review the inactivation and

[409] *See* Section I.F.3; *See also* Tab C-42, Bot A Correspondence and Evidence.
[410] The shipment to LLNL occurred in 2007, but the scope and severity of the issue was not understood until 2008 when the CDC first indicated that DPG-LSD may be found liable for having violated surety regulations.
[411] *See generally* Tab C-41, LLNL Correspondence and Evidence.
[412] *See* note 95.
[413] The investigative team identified an additional duty – to report this event to his higher headquarters. The evidence is inconclusive as to whether or not [redacted] reported this event to his commanders at DTC or ATEC. [redacted] indicated that he reported it to BG (now MG retired) Turner; however BG (now MG retired) Turner had no recollection of this event. BG (now MG retired) Turner agreed that this event should have been reported; however through a passage of time evidence and memories have been lost. *See* Tab B-58.1, [redacted], Memorandum for Record, subject: Summarized Testimony of MG (R) Del Turner (4 Nov. 2015); *See* Tab B-49.1, [redacted], Memorandum for Record, subject: Summarized Testimony of [redacted] (30 Oct. 2015).

viability testing processes utilized by DPG-LSD. Moreover, this is indicative that [redacted] did not appreciate the scope and severity of the LLNL incident.[414]

[redacted]	
Positions Held: [redacted] Position Description)	
Duties:	**Findings/Failures:**
* Serve as the [redacted] * Responsible for a wide variety of laboratory, chamber, and field testing of chemical/biological (CB) defense systems, obscurants and illuminants, and environmental characterization and remediation technologies * Executes the OSD-directed CB Joint Test Program * Responsible for the discipline, morale, health, and welfare for approximately 2500 military, civilians, contractors, and their families * Responsible for the security/FP, information assurance, environment, safety, and community activities as the Senior Commander	* Failed to conduct an internal investigation to resolve the discrepant findings of the CDC/DHHS-OIG and the DPG-LSD staff with respect to the LLNL incident * Failed to determine why the entire batch of *Bacillus anthracis* was not destroyed when one of five vials was found to be contaminated * Failed to determine the root cause of the contaminated fifth vial or to consider the role it played in the shipment * Failed to hold personnel accountable for the LLNL incident

Figure 28: [redacted]

Colonel William King

Colonel William King commanded DPG from July 2009 to July 2011. He spent the first few months of his command away from DPG attending a pre-command course. He was present to receive the 2 December 2009 memorandum (Event 3) from the DHHS-OIG finalizing the finding that DPG-LSD violated select agent regulations and authorizing a civil monetary penalty. Colonel King insisted in sworn testimony that he directed a commander's inquiry, to be led by [redacted] in response to this notification, but the evidence indicates that he only requested a "response and discussion" from [redacted][415]

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[414] The staff at DPG assumed that the LLNL event response was completed after the memorandum they provided to the DHHS-OIG on 1 May 2008. As a result, [redacted] did not specifically address this incident with Colonel King during their battle handover. The 2 December 2009 memorandum to Colonel King was a surprise to DPG leadership who assumed the case was closed.

[415] *See* Tab C-41, pg. 81, LLNL Correspondence and Evidence; *See also* Tab B-2.2, Memorandum for Record, subject: Transcribed Testimony of [redacted] (12 Nov. 2015); *See* Tab B-66.1, [redacted] Memorandum for Record, subject: Summarized Testimony of [redacted] (12 Nov. 2015). The testimonies of [redacted] and [redacted] are consistent and refute BG King's testimony about the "commander's inquiry". [redacted] recalled that [redacted] led the response and discussion and that he had little direct input.

[redacted] "response and discussion" reiterated the DPG-LSD conclusion from 2008 that LLNL was the source of contamination, but omitted information about the questionable viability test results (i.e., the contaminated fifth tube). This omission is important, but information about the contaminated fifth tube was available to Colonel King had he reviewed the past correspondence and documentation associated with the incident.[416] Colonel King had a duty to direct a comprehensive investigation to resolve the inconsistent findings between the DHHS-OIG report and the DPG-LSD staff explanation, particularly because as of December 2009, the findings against DPG-LSD were finalized and a civil monetary penalty was authorized, clearly establishing the scope and severity of the LLNL incident. Colonel King's testimony that he conducted a commander's inquiry is uncorroborated by the evidence which shows that it was merely a request for information from a single individual.

Colonel King received BG Smith's 15-6 investigation (event 4) warning of a "relaxed attitude" in a critical chemical laboratory at DPG. Colonel King, in conjunction with Major General Dellarocco, took appropriate action after receiving the results of the 15-6 investigation. He issued reprimands and removed personnel within the chemical test facility.[417] However, Colonel King did not assess the management personnel at DPG or consider that the negligence described in the 2011 15-6 report of investigation could extend to other facilities on DPG. This is in spite of the fact that he testified that he was aware that there was a problem with self-policing across all of DPG, to include the Life Sciences Division.[418] Colonel King missed an opportunity to assess the effectiveness of personnel and procedures at DPG as a whole.

Finally, Colonel King knew about the erroneous shipments of Botulinum neurotoxin A, and that these shipments caused DPG-LSD to fail the 2011 DAIG Biosurety Inspection (event 5 and 6). Instead of considering all of these events as indicators of potential deep-rooted and widespread problems at DPG, he attempted to minimize the impact of the events. Colonel King sent an email to leaders at ATEC and DTC downplaying the seriousness of the shipping errors (see Section II.F.3). This interpretation was refuted by CDC and DHHS-OIG personnel who have maintained their stance that this issue was always considered serious.[419] Colonel King also non-concurred with the failing deficiency in the 2011 DAIG Biosurety Inspection report, incorrectly citing DoD and DoT regulations.[420] These responses, when considered holistically, show that Colonel King was unwilling to take a deeper look at the operations he commanded, and ultimately perpetuated a complacent atmosphere.

Colonel King had personal knowledge of the all indicators described above. As a Commander he had a duty to think strategically about how these indicators are related, to notice that they had widespread implications across DPG, and to investigate and remedy problems

[416] Brigadier General King testified that he did not review past correspondence and documentation.
[417] *See* Tab B-23.2, Memorandum for Record, subject: Transcribed Testimony of BG William E. King, IV (10 Nov. 2015).
[418] *See* Tab B-23.1, pg. 3, William King, DA Form 2823, Sworn Statement (25 Sep. 2015).
[419] *See* Tab B-67.1 Memorandum for Record, subject: Summarized Testimony of [redacted] (12 Nov. 2015); *See* Tab B-69.1, [redacted] Memorandum for Record, subject: Summarized Testimony of [redacted] (12 Nov. 2015).
[420] *See* Tab C-36, DAIG BSI 2011, para. 2-1.

accordingly. Colonel King failed in these duties. Colonel King responded to each incident by correcting deficiencies identified by outside organizations, but he failed to conduct internal reviews to improve the operations of DPG and prevent future incidents. This indicates a lack of introspection and leadership expected from senior personnel. It should also be noted that during his command, Colonel King repeatedly deflected blame and minimized the severity of incidents. His tendency to deflect and minimize was reflected in his email correspondence[421] and also in his interactions with the 15-6 investigating officer.[422] During the course of the investigation it was apparent that even now, Brigadier General King lacks introspection and fails to recognize the scope and severity of the incidents that occurred during his command at DPG.

<table>
<tr><th colspan="2">COL (now BG) William E. King, IV</th></tr>
<tr><td colspan="2">Positions Held: DPG Commander (July 2009 to July 2011 - See Tab B-23.3, DPG Commander Position Description)</td></tr>
<tr><td><u>Duties:</u></td><td><u>Findings/Failures:</u></td></tr>
<tr><td>* Serve as the Installation Commander at Dugway Proving Ground
* Responsible for a wide variety of laboratory, chamber, and field testing of chemical/biological (CB) defense systems, obscurants and illuminants, and environmental characterization and remediation technologies
* Executes the OSD-directed CB Joint Test Program
* Responsible for the discipline, morale, health, and welfare for approximately 2500 military, civilians, contractors, and their families
* Responsible for the security/FP, information assurance, environment, safety, and community activities as the Senior Commander</td><td>* Failed to take reasonable command action and review historical documents and correspondence related to the LLNL incident
* Failed to conduct an internal investigation to resolve the discrepant findings of the CDC/DHHS-OIG and the DPG-LSD staff with respect to the LLNL incident
* Failed to make a holistic assessment of the management personnel at DPG or to consider that the negligence described in the 2011 15-6 report could extend to other facilities on DPG
* Minimized the CDC/DHHS-OIG findings regarding the erroneous Botulinum neurotoxin A shipments
* Failed to think strategically about how the indicators that occurred during his command are related, to notice that they had widespread implications across DPG, and to investigate and remedy them accordingly
* Failed to hold personnel accountable for mishaps</td></tr>
</table>

Figure 29: COL (now BG) William E. King, IV Summary

[421] *See* Tab C-42, pg. 12, Bot A Correspondence and Evidence
[422] *See* Tab B-23.2, Memorandum for Record, subject: Transcribed Testimony of BG William E. King, IV (10 Nov. 2015); Tab B-23.1, pg. 3, William King, Daniel, DA Form 2823, Sworn Statement (25 Sep. 2015).

Major General (R) Genaro Dellaracco

Major General (R) Genaro Dellarocco commanded ATEC from October 2010 to July 2013. He received the results of Brigadier General Smith's 15-6 investigation (event 4) and was in command during the entirety of the correspondence and response to the erroneous shipments of Botulinum neurotoxin A (events 5-7). Major General Dellarocco worked with Colonel King to take appropriate action in response to Brigadier General Smith's 15-6 investigation by issuing reprimands and removing personnel within the chemical test facility.[423] After receiving the final notification from the DHHS-OIG that DPG-LSD violated select agent regulations with the erroneous Botulinum neurotoxin A shipments, Major General Dellarocco implemented a Commander's Critical Information Report and personally tracked the next three shipments of select agent from DPG-LSD to ensure the effectiveness of the corrective actions and to emphasize that this was a command priority.[424] Major General Dellarocco candidly stated that in hindsight, with all of the facts he knows today, he should have picked up on the complacency issues at DPG.[425] Thus, he demonstrated the introspection expected of an effective leader by critically assessing his leadership of ATEC in light of new information presented to him during the investigation. The evidence indicates that Major General (R) Dellarocco acted reasonably in response to the indicators available to him at the time.

[redacted]

[redacted] The Lawrence Livermore National Laboratories events 2 and 3 occurred during his command, but as the [redacted] he did not have responsibility for responding to the event. [redacted][426] corresponded directly with the CDC, and the [redacted] [redacted] and Colonel King) had ultimate responsibility for taking action in response to the incident. In his testimony, [redacted] recalls being aware of the LLNL incident, and being indirectly involved in a support role, but evidence does not exist to allow the 15-6 investigation team to assess the reasonableness of [redacted] actions given his role at DPG at the time.

Other Senior Leaders at ATEC, DTC, and DPG

During the 2008-2011 timeframe, there was significant turnover and realignment of senior leadership positions at ATEC, DTC, and DPG. The O-5 West Desert Test Center command billet was eliminated in July 2010. Base Realignment and Closure resulted in the merging of DTC[427] with ATEC in June 2011. The command position was transitioned from military to

[423] *Id.*

[424] *See* Tab C-42, pg. 19, Bot A Correspondence and Evidence. MG Dellarocco required that he was personally notified, via CCIR, of the next three shipments of biological material from DPG-LSD and also that the material was verified upon receipt.

[425] *See* Tab B-50.1, Memorandum for Record, subject: Transcribed Testimony of MG Genaro Dellarocco (27 Oct. 2015)

[426] *See* Tab C-41, pg. 7, LLNL Correspondence and Evidence. [redacted] received the 2 May 2007 memorandum from the CDC.

[427] The merger also resulted in the elimination of the O-7 DTC command billet.

civilian in preparation for this three years earlier when Mr. James Johnson took command from Brigadier General Frank Del Turner. Mr. Johnson served nearly a full-term as Executive Director of DTC from July 2008 to May 2010, but was followed by two temporarily assigned Executive Directors in Mr. Mike Etzinger and Mr. David Jimenez prior to execution of the merger in 2011. Furthermore, the O-8 ATEC command billet, occupied by Major General Roger Nadeau from June 2007 to March 2010, was temporarily filled by a civilian Executive Director, Dr. James Streilein, between March and October 2010.

There is no evidence indicating that these personnel acted unreasonably or unprofessionally while in command. The evidence indicates that from the ATEC and DTC perspective, the incidents described above were being adequately addressed at the DPG command level. Generally, the leaders at the ATEC and DTC command level did not possess any information that would cause them to question the actions of the DPG Commanders. Furthermore, the evidence shows that the significant turnover and realignment within the ATEC and DTC organizations during this time period made communications through the chain of command difficult. As a result, it is reasonable that ATEC and DTC leadership would not have been able to assess the indicators of complacency as effectively as the commanders at the DPG level during this time frame.[428]

2. 2007 and Prior

It can be seen in Figure 27 that Major General (retired) Robert Armbruster, Brigadier General (retired) Marvin Keith McNamara, Brigadier General (retired) Michael Combest and [redacted] relinquished command well before the first event occurred. There is no evidence indicating that these personnel acted unreasonably or unprofessionally while in command. The shipment of viable *Bacillus anthracis* to Lawrence Livermore National Laboratories in April 2007 (event 1) occurred very near the end of the commands of Major General (retired) James Myles, [redacted] and at this point in time there were no conclusive findings to indicate a significant problem at DPG-LSD. There is no evidence indicating that these personnel acted unreasonably or unprofessionally while in command.

3. 2011 to May 2015

<u>Major General Peter Utley</u>

Major General Peter Utley commanded ATEC from July 2013 to June 2015. None of the incidents or indicators discussed above occurred during his command, nor was he briefed on them during his battle handover from Major General Dellarocco. Although Major General

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[428] *See* Tab B-47.1, [redacted] Memorandum for Record, subject: Summarized Testimony of MG(R) James Nadeau (26 Oct. 2015); Tab B-52.1, [redacted] Memorandum for Record, subject: Summarized Testimony of James Streilein (28 Oct. 2015)Tab B-56.1, [redacted] Memorandum for Record, subject: Summarized Testimony of Mike Etzinger (4 Nov. 2015)Tab B-57.1, [redacted] Memorandum for Record, subject: Summarized Testimony of James Johnson (4 Nov. 2015); Tab B-58.1, [redacted] Memorandum for Record, subject: Summarized Testimony of MG(R) Del Turner (4 Nov. 2015)

Utley's commanded ATEC at the time of the discovery of the inadvertent shipments of viable *Bacillus anthracis*, there were no indicators that he knew or should have known of this issue prior to its discovery in May 2015. Additionally, he was prepared to investigate the inadvertent shipments of viable *Bacillus anthracis*; however, the Director of the Army Staff decided that an investigator from outside ATEC was appropriate.[429] Based upon the facts discovered during this investigation, it appears Major General Utley complied with his duties and responsibilities.

[redacted]

[redacted]. [redacted] received the notification from the DHHS-OIG determining that DPG-LSD violated select agent regulations with the erroneous shipments of Botulinum neurotoxin A (event 7). [redacted] worked with Major General Dellarocco to execute the Commander's Critical Information Report which tracked the next three shipments of select agent from DPG-LSD to ensure that the corrective actions were effective and to emphasize that this was a command priority. The evidence indicates that there were no further indicators that should have triggered [redacted] to take action, and it appears that he complied with his duties and responsibilities.[430]

[redacted]

[redacted]. Although he was in command of DPG at the time of the discovery of the inadvertent shipments of viable *Bacillus anthracis*, he was not present for any of the indicators described above. [redacted] identified issues with complacency and leadership at DPG during his first 90 days in command after conducting a thorough review of command climate surveys, 15-6 investigations, commander's inquiries, and external inspections. In reference to the findings of the various issues he reviewed, [redacted] stated that "many of the findings indicated that those events [various prior mishaps] could have been prevented or the impact reduced if the Division and Branch Chiefs had exercised better leadership and supervision."[431] Based on this discovery, [redacted] placed an emphasis on leader development in order to develop effective supervisors. He further assessed that DPG "seemed to struggle to meet required timelines during the first year of my command."[432]

In addition, [redacted] had evidence that [redacted] was hindering efforts to develop the Division Chiefs. [redacted] stated that [redacted] would not support performance evaluations below a "top block"[433] even for those leaders whose performance did not justify this rating. This indicates that [redacted], who was serving in a critical technical management role at DPG, perpetuated the culture of complacency at DPG. Based on these observations, among others, [redacted] removed [redacted] from the rating chain and replaced him with [redacted]

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[429] *See* Tab B-41.1, Peter Utley, DA Form 2823, Sworn Statement (01 Sept. 2015).
[430] *See* Tab B-45.1, [redacted] Memorandum for Record, subject: Summarized Testimony of [redacted] 26 Oct. 2015)
[431] Tab B-11.2.a, Page 8, [redacted], Addendum to DA Form 2823, Sworn Statement (10 Sept. 2015).
[432] *Id.*
[433] Tab B-11.2., [redacted], DA Form 2823, Sworn Statement (10 Sept. 2015).

[redacted][434] After the change, [redacted] noted that [redacted] held the Division Chiefs more accountable. Additionally, [redacted] "received more direct feedback about those areas where individuals were not performing well."[435] DPG-LSD's ability to meet mission requirements appeared to improve during [redacted] second year in command. He attributed this improvement to removing [redacted] from the rating chain and replacing him with [redacted][436] Based upon the facts discovered during this investigation, it appears [redacted] identified complacency as an issue at DPG, took action to remedy it, and otherwise complied with his duties and responsibilities.

4. May 2015 to Present

Major General Daniel Karbler is the current ATEC Commander. [redacted] the curren[redacted]. Since assuming command, these personnel facilitated a litany of inspections and investigations at DPG-LSD. They effectively assisted the inspectors and investigators in gathering evidence and ensured that personnel at DPG receive the necessary resources and counseling needed to help them cope with the stress of these investigations.[437] The evidence indicates that Major General Karbler and [redacted] are effectively executing their duties and responsibilities.

b. West Desert Test Center Civilian Leadership

[redacted]

[redacted], had a duty to provide oversight to DPG-LSD. [redacted] is responsible for the management and operation of the West Desert Test Center which includes eight divisions; one of which is the Life Sciences Division. A thorough review of the evidence shows [redacted] recognized issues with the command climate, complacency, and a lack of personal accountability and attempted to address these problems through a variety of strategic initiatives.[438] The evidence shows that [redacted] has displayed leadership skills and has made significant efforts to address and improve the work environment at DPG.[439] Additionally, after being appointed to his current position, [redacted] has been observed to hold the various DPG Division Chiefs more accountable for their actions than did his predecessor, and was directly credited with assisting in improving operations at DPG-LSD by [redacted][440] There is no evidence that he failed in any of his leadership or oversight duties from November 2012 to present and/or contributed to the complacent environment at DPG-LSD.

[434] *See Id.* at 3.
[435] Tab B-11.2., page 3, [redacted], DA Form 2823, Sworn Statement (10 Sept. 2015).
[436] *Id.* [redacted] attributed part of the performance improvement to the "hard work by the employees to meet customer test requirements and also prepare for and successfully complete the numerous inspections."
[437] *See generally,* Tab B-24.1, [redacted] DA Form 2823, Sworn Statement (17 Aug. 2015).
[438] *See* Tab B-18.2, [redacted], DA Form 2823, Sworn Statement (20 Aug. 2015).
[439] *Id.*
[440] Tab B-11.2., page 3, [redacted], DA Form 2823, Sworn Statement (10 Sept. 2015).

[redacted]

[redacted] had the following duties but failed to execute them:

a. [redacted][441] failed to recognize and take action to address complacency at DPG-LSD. [redacted], having remained in key leadership positions at DPG as the military leadership rotated in and out, had perspective based on continuity that other senior leaders could not have had. He knew or should have known that DPG-LSD had a number of mishaps that were not addressed internally. [redacted] should have taken affirmative steps to educate, train, and look into each mishap (or advise the DPG commander to do so) to determine if internal policies and procedures should change. The evidence does not show that [redacted] was proactive in addressing these failures and as such he facilitated the complacent environment at DPG-LSD.

b. [redacted], had a duty to hold individuals and Division Chiefs responsible for their actions. [redacted] recognized [redacted] failure in leadership and failure to hold employees accountable for mistakes.[442] [redacted] observed that [redacted] did not support ratings below a top block for those that did not perform, and that his counseling and performance evaluations hindered efforts to develop Division Chiefs.[443] In addition, [redacted] failed to initiate or advise the command to initiate a commander's inquiry or a 15-6 investigation in response to the Botulinum neurotoxin A shipping errors despite the CDC's rendering of $1,500,000 worth of fines.[444] As a result of [redacted] failed leadership, in 2012, Colonel Fizer removed Dr. Gritton from the rating chain of Division Chiefs, and assigned the responsibility to [redacted].[445]

c. [redacted] from 2011 to the [redacted] had a duty to question the "proprietary" and isolated nature of the CRP, which resulted in pseudo-compartmentalized[446] operations at DPG-LSD. [redacted] had a duty to ensure that all standard operating procedures and work instructions received approval in compliance with standard DPG-LSD staffing procedures and other regulatory requirements. As the [redacted] sat in an oversight role that required him to be part of the review and approval process for all of the standard operating procedures used at DPG-LSD. [redacted] was

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441 *See* Appendix A. [redacted]

442 *See* Tab B-11.1, page 2, [redacted], DA Form 2823, Sworn Statement (13 Aug. 2015); Tab B-11.2, page 3, [redacted], DA Form 2823, Sworn Statement (10 Sept. 2015).

443 *See* Tab B-11.2, page 3, [redacted], DA Form 2823, Sworn Statement (10 Sept. 2015).

444 *See* Tab B-14.2, [redacted], Memorandum for Record, subject: Summarized Testimony of [redacted] (15 Dec. 2015). Note that the maximum civil monetary penalty authorized for this violation is $500,000, but since there were three separate shipments/violations $1,500,000 in penalties could have been levied.

445 *Id.* [redacted] was not formally demoted nor did he receive disciplinary action, only the rating chain was modified.

446 This term is used by the 15-6 investigation team to characterize the relatively isolated nature of the CRP Antigen Repository within DPG-LSD. The CRP team at DPG-LSD in many ways acted as if they were an entirely separate entity from the rest of DPG-LSD when in fact the compartmentalization was derived from the misinterpretation of guidance they received about intellectual property and security classification.

aware of the alleged "proprietary" nature of the CRP work instructions and International Standards Organization certification documentation for years and even requested copies. However, after being denied access to the documents, he did not further question (b) (6) [redacted] or the CRP leadership at Fort Detrick about the nature of this alleged limitation.[447] Because (b) (6) [redacted] failed to take any action beyond requesting these documents, there was no oversight or proper approval of documents governing CRP operations at DPG-LSD. (b) (6) [redacted] knew or should have known of these duties, but failed to execute them.

(b) (6) [redacted]	
Positions Held: (b) (6) [redacted]	
<u>Duties:</u>	**<u>Findings/Failures:</u>**
* Serve as the (b) (6) [redacted] * Support in management of 2200 personnel and 120 active test programs * Responsible for technical control, coordination, and management of DPG's test programs	* Failed to conduct internal investigations at DPG-LSD * Failed to take appropriate disciplinary action in response to mishaps * Failed to hold personnel accountable for lack of performance * Failed to recognize and remediate complacency at DPG-LSD * Failed to question the proprietary nature of the CRP * Failed to maintain technical control/oversight over the CRP Antigen Repository * Failed to review CRP SOPs in accordance with process used for other DPG SOPs

Figure 30:* (b) (6) [redacted] *Summary

c. DPG-LSD Leadership

(b) (6) [redacted]

(b) (6) [redacted], as the (b) (6) [redacted] had the following duties but failed to execute them:

a. (b) (6) [redacted] had a duty to hold personnel accountable for mistakes and deficiencies. (b) (6) [redacted] knew or should have known that he had this duty and negligently failed to execute it. On two occasions (2009-2010 LLNL incident response and the 2011 Botulinum neurotoxin A response), (b) (6) [redacted] failed to take any corrective action against employees despite the seriousness of the associated incidents. These incidents could have resulted in over $2,000,000 of CDC fines. (b) (6) [redacted] placed blame for the incidents on external organizations rather than conducting internal inquiries or advising the command to conduct 15-6 investigations to address deficiencies and improve the performance of DPG-LSD.[448]

[447] *See* Tab B-14.1, (b) (6) [redacted], DA Form 2823, Sworn Statement (17 Aug. 2015); Tab B-14.3, (b) (6) [redacted] Biography.

[448] *See* Section II.C.1.b., Failure to Take Action, where it describes leadership's repeated failure to investigate mishaps and take appropriate disciplinary action.

b. [redacted] had a duty to manage, supervise, and lead personnel and to prevent complacency at DPG-LSD. He knew or should have known that he had these duties, but negligently failed to execute them. His leadership created and fostered a culture of limited supervision, a lack of oversight, and widespread complacency. For example:

i. Witnesses describe [redacted] as being passive, isolated, in his office, not a people person, and not proactive.[449]

ii. Witnesses stated the transition of leadership from [redacted] to [redacted] resulted in a decrease in workplace morale.[450]

iii. [redacted] freely admits that "I need to spend more time getting around the Division and stepping into the weeds with Division personnel. My concern is that I am not familiar enough about the details of what is going on in the lab. This is not due to lack of interest, but is simply a reflection of lack of time, and perhaps needing to be more organized."[451]

iv. [redacted] described the command climate at DPG-LSD as "generally average to frustrated and somewhat depressed... many personnel attributed that to the fact that they did not feel that [redacted] cared or was engaged."[452] These leadership deficiencies prompted [redacted] to increase the emphasis on leadership skills as part of the performance objectives for all of the Division Chiefs at DPG.[453]

c. [redacted] knew or should have known that he had a duty to provide Colonel King with all relevant facts concerning the Lawrence Livermore National Laboratories incident. [redacted] negligently failed to perform this duty. [redacted] testified that he did not include any information in his briefing materials for Colonel King or the draft response to the DHHS-OIG about variations from the accepted viability testing procedures, particularly the destruction of the fifth vial containing viable *Bacillus anthracis*.[454] His negligent failure to provide Colonel

[449] *See* Tab B-30.1, page 2, [redacted] DA Form 2823, Sworn Statement (20 Aug. 2015); Tab B-11.2, pages 3-4, [redacted], Addendum to DA Form 2823, Sworn Statement (10 Sept. 2015) stated "He is very passive and introverted; generally not the first one to provide feedback. When he did demonstrate a willingness to provide feedback it was often after being asked. He generally defers to senior leadership positions, many times without offering any recommendations or analysis of potential impacts."; Tab B-35.1.a, page 4, [redacted] Addendum to DA Form 2823, Sworn Statement (18 Aug. 2015) stated [redacted] "really isolates himself in his office and only seems to care about what is going on before any inspection or VIP arrives."

[450] *See* Tab B-30.1, page 2, [redacted] DA Form 2823, Sworn Statement (20 Aug. 2015) stated "It was extremely hard for life sciences personnel to transition from extroverted people person [redacted] to quiet introverted [redacted] It resulted in a morale deficit for years."; Tab 34.1.a, [redacted], Addendum to DA Form 2823, Sworn Statement (10 Sept. 2015) stated "I believe a lot of it is because of the loss of strong leadership; [redacted] really did all he could to keep us all together. But he retired, and current management does not take as large a role in fostering strong morale among the workers in the office."

[451] Tab B-2.1.a., page 14, [redacted], Addendum to DA Form 2823, Sworn Statement (21 Aug. 2015).

[452] Tab B-11.2, pages 2, [redacted], Addendum to DA Form 2823, Sworn Statement (10 Sept. 2015).

[453] *See* Tab B-11.2, pages 8, [redacted], Addendum to DA Form 2823, Sworn Statement (10 Sept. 2015).

[454] *See* Tab B-2.2, [redacted] Memorandum for Record, subject: Transcribed Testimony of [redacted] (12 Nov. 2015). As discussed in Section II.C.1.b.i, the contamination that caused the fifth tube to fail was introduced in the lab at DPG-LSD. This tube was destroyed as a result, but the other four tubes were shipped to LLNL without being retested.

King this information adversely affected Colonel King's ability to make an informed decision regarding the incident. The failure to provide this information did not alleviate Colonel King's duty to take reasonable command action and review historical documents and correspondence related to the LLNL incident in which information about the destruction of the fifth vial is readily available.

d. [redacted] knew or should have known that he had a duty to maintain an environmental sampling program (a laboratory best practice) in the biosafety level-3 suites at DPG-LSD but failed to do so. Environmental sampling is a critical tool in ensuring biosafety and effective laboratory work practices. The 15-6 investigation discovered live *Bacillus anthracis* Ames spores outside of primary containment when conducting environmental sampling of DPG-LSD Room 506. This could have been prevented, and the risk for contamination within the laboratories at DPG-LSD could have been minimized, had DPG-LSD effectively executed a routine environmental sampling program.[455]

e. [redacted] knew or should have known that he had a duty to maintain a dedicated quality assurance/quality control manager at both DPG-LSD and the CRP, but he failed to do so. He placed personnel in positions where they were responsible for performing oversight of their own operations. [redacted] states "The Quality function within the life sciences division is currently assigned to our Biosurety Officer which makes him dual-hatted. He does not have the bandwidth to adequately address quality assurance for all processes across our division."[456] Furthermore, the quality function within the CRP is assigned to [redacted] making her dual-hatted as well. Since 2011, no one acted in a dedicated oversight capacity at DPG-LSD, including the CRP.

f. [redacted] had a duty to enforce the closed circuit television video surveillance program required by Army regulations within the biosafety level-3 laboratory suites.[457] [redacted] admits that he failed to adequately participate in this program and observe the activities of subordinate employees.[458] Active participation in this program could have uncovered poor lab practices and led to preventative measures, remedial training, or environmental sampling being conducted within the DPG-LSD, which would have advanced the safety and professionalism of his organization and prevented mishaps.

g. [redacted] had a duty to ensure classified information was not transferred through unclassified means and personnel were properly trained on security classification guidelines. His failure to ensure proper training of personnel led to a violation of the CRP security classification

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[455] *See* Section II.C.1.b.vi, Failure to Execute an Environmental Sampling Program.

[456] *See* Tab B-2.1, page 2, [redacted], DA Form 2823, Sworn Statement (21 Aug. 2015). [redacted] is clearly aware that quality assurance is not being adequately addressed at DPG-LSD.

[457] *See* Tab E-2, AR 190-17, para. 5-18. The evidence indicates that [redacted] delegated the day-to-day responsibility for this duty to [redacted] but [redacted] says in his sworn statement that he sometimes finds it difficult to break away from his other duties when it is his turn to view the video, indicating that he still maintains this duty to some degree.

[458] *See* Tab B-2.1.a., page 18, [redacted] Addendum to DA Form 2823, Sworn Statement (21 Aug. 2015).

guide.[459] Subsequent to this security violation, [redacted] also had a responsibility to act, but he failed to take disciplinary action against the personnel involved.[460]

h. [redacted] knew or should have known that he had a duty to oversee all activities that took place within the DPG-LSD, and is ultimately responsible for the actions and failures of all DPG-LSD personnel. [redacted] failed in this duty by not taking appropriate action at his level of supervisory authority. This inaction created a culture that inhibited oversight, introspection, and professional development of DPG-LSD personnel. For example:

(1) [redacted] should have questioned the alleged "proprietary" nature of the CRP work instructions and pseudo-compartmentalized operations of the personnel working on products for this program. [redacted] was aware of the alleged "proprietary" nature of the CRP work instructions and operations for years; however, he failed to question DPG-LSD personnel working on this program or the CRP leadership at Fort Detrick about the nature of this alleged limitation.[461] Additionally, he had a duty to inform the chain of command, regulatory oversight personnel, and other staff members that the personnel working on CRP projects used an additional work instruction that was not part of the DPG-LSD approved standard operating procedures. Moreover, there was no effort to ensure this work instruction was approved, in compliance, or consistent with DPG-LSD standard operating procedures and other regulatory requirements.[462]

(2) [redacted] had a duty to ensure that DPG-LSD personnel were aware of and complied with reporting requirements for all incidents, including shipping errors.[463] He knew or should have known he had this duty, but failed to execute it. This failure facilitated an environment in which transparency and swift reporting of mishaps to the chain of command and regulatory agencies did not exist.[464]

i. [redacted] was very cooperative and forthright with information during the investigation.

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[459] *See* Section II.C.b.xii, Failure to Safeguard Classified Information and Ensure Personnel are Trained on Classification Guidance.
[460] As of 2 October 2015, the investigation team has not discovered any evidence to suggest that [redacted] has disciplined any personnel for these failures.
[461] *Id.*
[462] *See* Tab B-2.1.a., page 18, [redacted] Addendum to DA Form 2823, Sworn Statement (21 Aug. 2015) states "My impression is that they [CRP] are accountable for the same practices / methods / protocols as the rest of life sciences division." This statement shows [redacted] did not have knowledge or oversight of CRP internal policy review and approval process. For the supporting facts and circumstances, see Section II.C.1.b.viii, Failure to Properly Review and Approve Critical Reagents Program Internal Policies and Procedures.
[463] *See* Sections II.C.1.b and II.C.2 for specific instances of improper mishap reporting.
[464] Mishaps require reporting through the chain of command to ensure compliance with Department of the Army Pamphlet 385-69, chapter 3-11 and Commander's Critical Information Requirements. DPG-LSD personnel should also be aware of CDC reporting requirements which are independent of these chain of command reporting requirements.

<table>
<tr><td colspan="2" align="center">(b) (6) [redacted]</td></tr>
<tr><td colspan="2">Positions Held: (b) (6) [redacted] (see Tab B-2.4 - (b) (6) [redacted] - Position Description)</td></tr>
<tr><td align="center"><u>Duties:</u></td><td align="center"><u>Findings/Failures:</u></td></tr>
<tr><td>* Planning, coordinating, and supervising the Life Sciences Division programs
* Directs operation of Life Sciences Division laboratories for the production, storage, quality control and filling of biological materials, simulants, and tracers
* Reviews, analyzes, and evaluates reports generated within the division for overall technical validity and adequacy. Reviews test plans for adequacy and feasibility taking into consideration the resources and capability of the organization to accomplish the stated requirements and recommends changes in data requirements or outlines necessary recourses required to accomplish the test plan.</td><td>* Failed to fully investigate biological mishaps
* Failed to maintain an environmental sampling program
* Failed to maintain a dedicated Quality Assurance/Quality Control manager
* Failed to maintain and utilize the video surveillance program
* Failed to question the proprietary nature of the CRP Antigen Repository
* Failed to maintain technical control/oversight over the CRP team at DPG-LSD
* Failed to review CRP SOPs in accordance with process used for other DPG SOPs
* Negligently failed to provide Colonel King with all relevant information associated with the LLNL mishap</td></tr>
<tr><td>* Performs personnel management's responsibilities for subordinates. Provides administrative and technical supervision, establishes priorities, assigns duties, initiates personnel actions, e.g., recommends promotions, selects new employees for vacancies, makes reassignments, handles minor disciplinary problems, establishes performance</td><td>* Negligently failed to take appropriate disciplinary action in response to mishaps
* Negligently failed to supervise and lead personnel
* Negligently failed to hold personnel accountable for lack of performance
* Negligently failed to assess biosurety qualifications for DPG-LSD personnel
* Failed to prevent and correct instances of transfer of classified information through unclassified means
* Failed to recognize and remediate complacency at DPG-LSD, and potentially contributed to it with his leadership style</td></tr>
<tr><td colspan="2">Positive Findings: (b) (6) [redacted] was very cooperative and forthright with information when asked to provide it by the 15-6 investigation team</td></tr>
</table>

Figure 31:* (b) (6) [redacted] *Summary

[redacted]

[redacted] had the following duties but failed to execute them:

a. [redacted] had a duty to mentor, educate, train, and hold personnel accountable for known deficiencies. He also had a duty to prevent complacency within his Branch. He knew or should have known that he had these duties, but negligently failed to execute them. Additionally, [redacted] had knowledge of [redacted] poor laboratory practices and took no action to correct them.[465] He allowed [redacted], who had repeatedly demonstrated poor lab practices (as reported by several of her peers) to continue working on critical projects without any professional development or corrective action.

b. [redacted] had a duty to question the "proprietary" and isolated nature of the CRP resulting in compartmentalization of operations conducted in his Branch. He had a duty to inform the chain of command, regulatory oversight personnel, and other staff members that the personnel working on CRP projects were operating outside approved standard operating procedures. He had a duty to ensure that all standard operating procedures and work instructions were properly reviewed and approved. [redacted] knew or should have known that he had these duties, but negligently failed to execute them.[466] The personnel working in his Branch, specifically [redacted] and [redacted], operated without proper oversight and this may have contributed to the unintended shipment of viable *Bacillus anthracis*.

c. [redacted] knew or should have known that he had a duty to maintain an environmental sampling program (a laboratory best practice) in the biosafety level-3 suites at DPG-LSD but failed to do so. Environmental sampling is a critical tool in ensuring biosafety and effective laboratory work practices. The 15-6 investigation discovered live *Bacillus anthracis* Ames spores outside of primary containment when conducting environmental sampling of DPG-LSD Room 506. This could have been prevented, and the risk for contamination within the laboratories at DPG-LSD could have been minimized, had DPG-LSD effectively executed a routine environmental sampling program.[467]

d. [redacted] knew or should have known that he had a duty to maintain a dedicated quality assurance/quality control manager at the CRP Antigen Repository, but he failed to do so by assigning [redacted] to serve as the quality assurance/quality control reviewer of her own work.[468]

e. [redacted] had a duty to ensure that the death certificates were properly completed with accurate information by his subordinate [redacted] [redacted] knew or should have known

[465] *See* Section II.C.1.a., Failure to Take Action, describing leadership's repeated failure to investigate mishaps and take appropriate disciplinary action.
[466] *See* Section II.C.1.b.viii, Failure to Properly Review and Approve Critical Reagents Program Internal Policies and Procedures.
[467] *See* Section II.C.1.b.vi, Failure to Execute and Environmental Sampling Program.
[468] *See* Section II.C.1.b.iv, Failure to Adhere to Production Based Practices.

that he had this duty. He failed to ensure that she had accurate data in the form before sending it to the biosafety officer and responsible official for signature and certification. He failed to supervise (b) (6) [redacted] and allowed her to manipulate the data in the death certificates at any time, unrestricted, and unbeknownst to the biosafety officer and responsible official, both of whom had duties to certify the accuracy of the data in this form.[469]

f. (b) (6) [redacted] had a duty to report biological mishaps to the Chief, DPG-LSD. He knew or should have known that he had this duty. (b) (6) [redacted] knew of and failed to report the Venezuelan Equine Encephalitis event that occurred in 2010.[470] Due to his failure to report this event, DPG-LSD had no oversight or ability to assist in correcting the failings associated with this event.

g. (b) (6) [redacted] had a duty to ensure classified information was not transferred through unclassified means and personnel were properly trained on security classification guidelines. His failure to ensure proper training of personnel led to a violation of the CRP security classification guide.[471] Subsequent to this security violation, (b) (6) [redacted] also had a responsibility to act, but he failed to take disciplinary action against the personnel involved.[472]

h. (b) (6) [redacted] was not only forthright with information, but also accepted responsibility for several of the failures that occurred within his Branch. (b) (6) [redacted] displayed an understanding of the deficiencies within the organization and expressed a desire to improve the operations of the DPG-LSD.

(b) (6) [redacted]	
Positions Held: (b) (6) [redacted] [redacted] [redacted] (See Tab B-27.3, (b) (6) [redacted] - Position Description)	
Duties:	**Findings/Failures:**
* Functions as the (b)(6) [redacted] (b)(6) [redacted] of the Life Sciences Division.	* Failed to fully investigate and report biological mishaps
* Manages a variety of complex technical and administrative activities involving the integration of GS-9-12 level work and the overall coordination of program and business development activities within the commodities of the Bio Technology Branch.	* Failed to maintain and utilize the video surveillance program

[469] *See* Section II.C.1.a., Manipulation and Carelessness in Generating *Bacillus anthracis* Death Certificates.
[470] *See Section II.C.1.b., Failure to Report and Investigate Biological Mishaps* for facts and circumstances surrounding the failure to report and investigate biological mishaps. See *Section I.F., Historical Mishaps at Dugway Proving Ground Life Sciences Division* for facts and circumstances surrounding historical mishaps.
[471] *See* Section II.C.1.b.xii, Failure to Safeguard Classified Information and Ensure Personnel are Trained on Classification Guidance.
[472] As of 2 October 2015, the investigation team has not discovered any evidence to suggest that (b) (6) [redacted] has disciplined any personnel for these failures.

* Supervises development of applied test methodology for new agents in the field of biology such as bacteria, viruses, toxins, biologically active compounds, smokes and obscurants. Devises assay procedures that are simple to perform and provide data with statistically high reproducibility. Devises methods for decontaminating or inactivating those substances required as challenge test materials.	* Failed to maintain an environmental sampling program * Failed to maintain a dedicated Quality Assurance/Quality Control manager * Failed to ensure accuracy of death certificates * Failed to question the proprietary nature of the CRP Antigen Repository * Failed to maintain technical control/oversight over the CRP team at DPG-LSD * Failed to review CRP SOPs in accordance with process used for other DPG SOPs
* Performs personnel management responsibilities including scheduling and assigning work to subordinates, evaluating employee performance, giving advice and counsel to employees, recommending promotions, selections, reassignments, etc., resolving employee complaints, effecting minor disciplinary measures, identifying training needs and recommending training and promoting programs such as EEO, upward mobility, etc.	* Negligently failed to take appropriate disciplinary action in response to mishaps * Negligently failed to supervise and lead personnel * Negligently failed to mentor, train, and hold personnel accountable for lack of performance * Failed to prevent and correct instances of transfer of classified information through unclassified means * Failed to recognize and remediate complacency at DPG-LSD, and potentially contributed to it with his leadership style
Positive Findings: [redacted] was not only forthright with information, but also accepted responsibility for several of the failures that occurred within his Branch. [redacted] displayed an understanding of the deficiencies within the organization and expressed a desire to improve the operations of the DPG-LSD.	

Figure 32:* [redacted] *Summary

d. DPG-LSD Oversight Staff

[redacted]

[redacted] had the following duties but failed to execute them:

a. [redacted] had a duty to administer the DoD biological safety/surety program at DPG-LSD. [redacted] knew or should have known that she had this duty, but failed to perform it by not appointing a qualified individual to serve as the Biological Safety Officer. [redacted] improperly delegated the responsibilities of the Biosafety Officer to an [redacted] in contravention of Army regulation. Due to the highly sensitive nature of the work done at DPG-LSD and the regulatory requirement, [redacted] should have ensured the appointment of a Biosafety Officer with proper experience, training, and qualifications.[474] Furthermore, [redacted] failed to ensure that the DPG-LSD

[473] [redacted]

[474] *See* Section II.C.1.b.x, Failure to Ensure Biosafety Officer Qualification.

environmental sampling and video surveillance plans were effectively executed. This failure limited DPG-LSD's ability to ensure the safety of the personnel working in its laboratories as well as the safety of the public.

[redacted][475] had a duty to ensure that the death certificates were properly completed and contained accurate information.[476] Although [redacted] had the duty to certify that lots of *Bacillus anthracis* were inactivated prior to shipping, the scientific gaps relieve her from being held accountable for the inadvertent shipments of viable *Bacillus anthracis*. Nevertheless, she should remain accountable for failing to confirm the accuracy of the data in the death certificates prior to signing and certifying them.

[redacted]	
Positions Held: [redacted] - Bio and Position Description and Figure 17)	
Duties:	**Findings/Failures:**
[redacted] and is responsible for a variety of technical and administrative tasks. * Administers the Department of Army (DoD) Biological safety/surety program to support the Division Chief (Certifying Official) in the areas of safety information, inspections, health hazard and risk mitigation education, facility safety controls, engineering controls, biosafety practices, decontamination, and lab emergency response. * Plans and assigns work, sets priorities, advises employees on program management and division goals and objectives and makes decisions on work problems presented by subordinate employees. Responsible for maintaining safe operating conditions in the biosafety level 3 laboratories at Life Sciences Division.	* Failed to effectively administer the biological safety/surety program by failing to appoint a qualified biosafety officer * Failed to ensure that the DPG-LSD environmental sampling and video surveillance plans were effectively executed * Failed to ensure accuracy of death certificates

Figure 33: [redacted] ***ummary***

[redacted]

[redacted] had a duty to ensure that the death certificates were properly completed and contained accurate information. [redacted] also had the duty to ensure that proper oversight of the death certificate approval process was in place. [redacted] routinely exercised this duty when he signed and certified that lots of *Bacillus anthracis* were

[475] *See* Figure 17 and Note 379. [redacted] was the [redacted] for 10 lots and the [redacted] for 4 lots that were determined to be viable after initial inactivation.

[476] *See* Section II.C.1.a., Manipulation and Carelessness in Generating *Bacillus anthracis* Death Certificates.

inactivated and thus should no longer be considered biological select agents and toxins.[477] [redacted] was unaware, but should have known, that [redacted] regularly manipulated data in death certificates after all parties had signed and should have noticed that death certificates routinely referenced improper standard operating procedures or work instructions.[478] Although [redacted] had the duty to certify that a lot of *Bacillus anthracis* was inactivated prior to shipping, the scientific gaps relieve him from being held accountable for the inadvertent shipments of viable *Bacillus anthracis*. Nevertheless, he should remain accountable for failing to have a proper certificate approval process in place to confirm the accuracy of the data on the death certificates.

[redacted]	
Positions Held: [redacted] and [redacted] (See Tab B-26.3, [redacted] - Bio and Resume and Tab E-39 CDC Responsible Official Guidance Document)	
Duties:	**Findings/Failures:**
* [redacted] with line management responsibilities across the spectrum of the Division's mission and functions. * The RO is the individual designated by the registered entity with the authority and responsibility to act on behalf of the entity to ensure compliance with the select agent regulations.	* Failed to ensure accuracy of death certificates

Figure 34:* [redacted] *Summary

[redacted]

[redacted] had a duty to ensure that the death certificates were properly completed and contained accurate information. [redacted] knew or should have known that he had this duty, but he failed to execute it when he signed the death certificate for lot AGD0001667.[479] The Biological Safety Officer is the first line of oversight in the death certificate process, and is tasked with reviewing the form after it has been completed by the Principle Investigator and prior to sending it to the Responsible Official for final signature.[480] While it has been established in this report that [redacted] was not qualified for and inappropriately delegated the responsibilities of the Biological Safety Officer position at DPG-LSD, it is not beyond the scope of his education and experience to at least review documents that he signs for accuracy and completeness. While [redacted] cannot be held responsible for not effectively administering the DoD biological safety/surety program at DPG-LSD due to his lack of appropriate qualifications,[481] he should not be relieved of accountability for administrative tasks such as death certificate data review. Although [redacted] had the duty to validate the data on the death certificates and ensure that the correct inactivation standard operating procedures were followed, the scientific gaps relieve him from being held accountable for the inadvertent shipments of viable *Bacillus anthracis*.

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[477] *See Figure* 17. [redacted] was the [redacted] for 4 lots of Bacillus anthracis that were determined to be viable after initial inactivation, to include two lots signed for by [redacted] at [redacted] direction.
[478] See Section II.C.1.a., Manipulation and Carelessness in Generating *Bacillus anthracis* Death Certificates.
[479] *See Figure* 17 and Tab C-19, Death Certificate for Lot AGD0001667 (18 Mar. 2014).
[480] *See* Section I.L, Background Discussion on Death Certificates.
[481] It is recommended that [redacted] be held accountable for this failure.

[redacted]	
Positions Held: [redacted] - Position Description)	
Duties:	**Findings/Failures:**
* Serves as the [redacted] responsible for leading team members in the development, coordination, implementation, and evaluation of inspections as directed by higher command relating to Biological Safety, Surety, and biological security at Life Sciences and other sites on Dugway. * Takes the leadership role in overseeing and carrying out inspections that supports and conducts comprehensive evaluations of biological safety program, biological surety, and biological security program for compliance with regulatory requirements. * Enforces regulations and takes a pro-active approach based on education, outreach, and training.	* Failed to ensure accuracy of death certificates

Figure 35:* [redacted] *Summary

[redacted]

[redacted][482] had a duty to ensure that the death certificates were properly completed and contained accurate information when he reviewed them in lieu of the Responsible Official. [redacted] knew or should have known that he had this duty, but he failed to execute it when he signed the death certificate for lot AGD0001667.[483] Although, [redacted] had the duty to validate the data on the death certificates and ensure that the correct inactivation standard operating procedures were followed, the scientific gaps relieve him from being held accountable for the inadvertent shipments of viable *Bacillus anthracis*. Nevertheless, he should be held accountable for failing to validate the data in the death certificates prior to signing and certifying them.

[redacted]	
Positions Held: [redacted] - Position Description and Tab E-39 CDC Responsible Official Guidance Document)	
Duties:	**Findings/Failures:**
* Performs the duties of the [redacted] defined as the individual designated by the registered entity with the authority and responsibility to act on behalf of the entity to ensure compliance with the select agent regulations, in the absence of [redacted]	* Failed to ensure accuracy of death certificates

Figure 36: Mr. Donald Simmons Summary

482 The Responsible Official is required to review and sign the death certificate as per DPG-LSD policy (not a CDC requirement). The Alternate Responsible Official is empowered to conduct the review when the Responsible Official is unable to do so. [redacted] was approved as an [redacted] by the CDC in 2010 (Tab C-51, DPG-LSD CDC Registration and [redacted] Designation - 22Oct12 to 22Oct15).

483 *See Figure* 17; Tab C-19, Death Certificate for Lot AGD0001667 (18 Mar. 2014); and Tab B-26.1.a, page 4, [redacted] Addendum to DA Form 2823, Sworn Statement (19 Aug. 2015). [redacted] signed as the [redacted] on behalf of [redacted] who was on annual leave from 17-18 March 2014.

e. DPG-LSD Laboratory Technicians

[redacted]

[redacted] for CRP projects/shipments, had the following duties but failed to execute them:

a. [redacted] had a duty to practice safe laboratory procedures. [redacted] knew or should have known that she had this duty, but failed to perform it. During a review of laboratory practices through closed circuit television camera recordings at the DPG-LSD, the 15-6 investigation team observed [redacted] opening a shaker incubator containing biological agents in liquid culture without wearing a powered air purifying respirator. At approximately 0808 hours on June 14, 2015, [redacted] entered room 506 in the DPG-LSD without wearing a powered air purifying respirator. [redacted] then opened the shaker incubator which contained a series of Erlenmeyer flasks with liquid cultures of biological agents. According to the standard operating procedures contained in WDL-SAF-330, Safety Guide for Working in High-Containment BSL-3, all employees must wear a powered air purifying respirator during aerosol generating procedures.[484] The movement of the shaker incubator combined with the liquid culture meets the definition of an aerosol generating procedure, therefore [redacted] was required to wear a powered air purifying respirator during these activities.[485] By not wearing a powered air purifying respirator during these activities [redacted] risked exposing herself to biological select agent and toxins.

b. [redacted] had a duty to properly calculate and document the data contained in the death certificates that she prepared. [redacted] knew or should have known that she had this duty but failed to perform it. On more than one occasion she documented the incorrect dosage that a lot was exposed to during irradiation. This incorrect information was ultimately sent to the biosafety officer and responsible official to certify that a lot of *Bacillus anthracis* was properly inactivated. Furthermore, [redacted] admitted to manipulating the data on the death certificate for lot AGD0001667 after the Biosafety Officer and Responsible Official had signed the form.[486] She then did not notify those previous signatories that she was making these substantive edits to the form after it was certified.[487] [redacted] was willfully negligent. She intentionally modified the death certificates after they had already been signed by her superiors, destroying the credibility of the death certificate validation process. While the improper documentation and subsequent modification of the data on the death certificates was not a direct cause of the

[484] All employees performing work in BSL-3 laboratories at DPG-LSD are aware of and trained to this standard operating procedure.

[485] Powered air purifying respirators protect laboratory staff during manipulations of potentially infectious aerosols in two different ways. First is through the use of the High Efficiency Particulate Air Filters on the powered air purifying respirator which filters at least 99.97% of all air particulates when used appropriately. Second is through mucous membrane protection since the powered air purifying respirator face shield covers the eyes, nose and mouth during operations. This can prevent any potential transfer of infectious agents from gloved hands to the mucous membranes if personnel touch their face during laboratory procedures.

[486] *See* Tab B-44.2.a, page 8, [redacted] Addendum to DA Form 2823, Sworn Statement (Aug. 2015).

[487] *See* Section II.C.1.a, Manipulation and Carelessness in Generating *Bacillus anthracis* Death Certificates.

shipment of viable *Bacillus anthracis*, they indicate poor laboratory data accounting and an inadequate overall quality control process.

c. [redacted] had a duty to oversee the work of [redacted]. [redacted] knew or should have known that [redacted] was executing poor lab practices and should have taken corrective action to eliminate these practices. The 15-6 investigation team reviewed video surveillance footage and noted several instances wherein [redacted] exercised poor laboratory practices.[488] These direct observations were corroborated by the testimonies of several DPG-LSD personnel. [redacted] failed to review video (or directly observe) and address [redacted] poor laboratory practices.

d. [redacted] had a duty to report numerous shipping incidents to the DPG-LSD chain of command. The incidents include the December 2010 *Burkholderia mallei* shipment and the September 2014 Vaccinia shipment. [redacted] knew or should have known that she had this duty, but she failed to execute it.[489] Since [redacted] failed to report these incidents to the DPG-LSD[490] chain of command, it was not possible for leadership to comply with regulatory reporting requirements and/or take corrective or disciplinary action.

e. [redacted] had a duty to ensure classified information was not transferred through unclassified means and to ensure personnel were properly trained on security classification guidelines, but failed to execute it during the CRP data review conducted in June 2015.[491]

[redacted]	
Positions Held: [redacted] (See Tab B-44.3, [redacted] - Bio and Resume)	
<u>Duties:</u>	**<u>Findings/Failures:</u>**
* Test officer managing the day-to-day operations of the Critical Reagents Program (CRP) Antigen Repository. * Plans, schedules, and monitors all bacterial antigen production phases within the CRP Antigen Repository. * Monitors and approves all batch records and technical data for bacterial antigen production prior to shipping these antigens to customers. * Develops and reviews SOPs and internal operating procedures for microbiological and analytical assays.	* Failed to practice safe laboratory procedures * Failed to properly calculate and document the data in the death certificates and negligently manipulated signed death certificates * Failed to properly oversee the work of subordinate employees, particularly Ms. Marlene Bragg * Failed to report numerous shipping incidents through the DPG-LSD chain of command * Failed to prevent and correct instances of transfer of classified information through unclassified means

Figure 37:* [redacted] *Summary

[488] *See* Section II.C.1.b.vii, Failure to Maintain a Viable Video Surveillance Program.
[489] *See* Section I.F., Historical Mishaps at Dugway Proving Ground Life Sciences Division.
[490] [redacted] did not report these events to the DPG-LSD chain of command; however, she reported them to the leadership at the Critical Reagents Program at Fort Detrick, MD. *See* Tab B-44.2.a, page 8, [redacted] Addendum to DA Form 2823, Sworn Statement (Aug. 2015).
[491] *See* Section II.C.1.b.xii, Failure to Safeguard Classified Information and Ensure Personnel are Trained on Classification Guidance.

[redacted]

a. [redacted] knew or should have known that she had a duty to follow safe laboratory procedures. She negligently failed in this duty multiple times as observed by the 15-6 investigation team during review of surveillance video.[492] Other personnel at DPG-LSD have observed [redacted] working with more than one organism, working with multiple strains, and working with both live and inactivated materials under a biosafety level-3 cabinet, which increased the risk of cross contamination.[493] In 2007, [redacted] was allegedly observed taking an irradiated organism out of a biosafety level-3 laboratory the day the organism was irradiated without performing viability testing.[494] In 2013, [redacted] was observed taking an irradiated organism out of a biosafety level-2 laboratory the day the organism was irradiated without completing viability testing.[495] More than one laboratory technician has indicated that they do not want to work in the laboratory with [redacted] due to her poor lab practices.[496] These poor laboratory practices could have exposed employees working in biosafety level-3 to biological select agents and toxins on more than one occasion.

b. [redacted] knew or should have known she had the duty to report a spill of biological select agent and toxin outside primary containment. [redacted] negligently failed in this duty when she did not report that she dropped a sample plate outside of primary containment and also failed to subsequently decontaminate the laboratory.[497] Army Pamphlet 385-69, Safety Standards in Microbiological and Biomedical Laboratories requires that an incident of this nature is reported immediately after it occurs.[498] There was no documentation of this mishap being reported to either the DPG-LSD, the West Desert Test Center Safety Office, or the CDC. Therefore, no corrective actions could be made by leadership.

c. [redacted] was assigned the duties of the [redacted] for the CRP Antigen Repository. There is insufficient evidence to support a conclusion that she failed in these duties, however, as stated in the findings against [redacted], these duties should have been assigned to a dedicated [redacted]

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492 See Section II.C.1.b.vii, Failure to Maintain a Video Surveillance Program.

493 *See* Tab B-34.1, [redacted] DA Form 2823, Sworn Statement (10 Sept. 2015); Tab 40.1, [redacted] DA Form 2823, Sworn Statement (27 Aug. 2015); Tab B-12.1, [redacted] DA Form 2823, Sworn Statement (26 Aug. 2015); Tab 35.2, [redacted], DA Form 2823, Sworn Statement (20 Aug. 2015).

494 *See* Tab B-34.1, [redacted] DA Form 2823, Sworn Statement (10 Sept. 2015). There is no further corroborating evidence besides this statement, and [redacted] denies having done so.

495 *Id.* Biosafety level-2 organisms, while not as dangerous as biosafety level-3 organisms, can still cause illness in humans and are sometimes inactivated and tested for sterility similar to biosafety level-3 organisms.

496 *See* Tab B-34.1, [redacted] DA Form 2823, Sworn Statement (10 Sept. 2015); Tab 40.1, [redacted] DA Form 2823, Sworn Statement (27 Aug. 2015); Tab B-12.1, [redacted] DA Form 2823, Sworn Statement (26 Aug. 2015); Tab 35.2, [redacted], DA Form 2823, Sworn Statement (20 Aug. 2015).

497 *See* Section II.C.1.b.vii, Failure to Maintain a Viable Video Surveillance Program.

498 *See* DA PAM 385-69, Chapter 3-11.

[redacted]	
Positions Held: [redacted] (See Tab B-5.2, [redacted] - Resume)	
Duties:	**Findings/Failures:**
* Planning and executing the cultivation, harvest and down-stream processing of bacteria, viruses, and toxins/toxoids. * Maintain an antigen repository of primary/secondary stocks of viruses, toxins and bacteria. * Maintain accountability for compliance, sustainment, and monitoring. * Develop and evaluate resources and activities to maintain an effective quality assessment (QA) plan, carry out internal audits, and facilitate external audits.	* Failed to practice safe laboratory procedures * Failed to report a spill of biological select agent outside of primary containment

Figure 38:* [redacted] *Summary

[redacted]

[redacted] had a duty to ensure that all agents were prepared, packaged, and shipped in accordance with Federal, state and local regulations.[499] Furthermore, she had a duty to report all shipping errors to her supervisors, [redacted][500] [redacted] is negligent in that she failed in these duties when she made the following erroneous shipments:

a. In July 2010, the Naval Surface Warfare Center in Dahlgren, Virginia received a shipment from DPG-LSD containing Venezuelan Equine Encephalitis TC83 in lieu of the *Bacillus anthracis* (Sterne strain) they had ordered. The intended vial of *Bacillus anthracis* Sterne ordered from the CRP that was supposed to be shipped to the Naval Surface Warfare Center had inadvertently been sent to [redacted] a private laboratory at La Jolla, California. [redacted] failed to ensure the shipments went to the appropriate customers. [redacted] was the technician responsible for these erroneous shipments.[501]

b. On three separate occasions (27 February 2008, 20 October 2010, and 17 November 2010), [redacted] shipped regulated quantities of Botulinum neurotoxin A, a regulated select toxin, to two separate entities (shipping BSAT material without all of the safety procedures in accordance with 42 CFR part 73). In all three cases, [redacted] violated DPG-LSD standard operating procedure (WDL-BIO-120) by not determining the proper classification of the biological material prior to shipment. [redacted] was the technician responsible for these erroneous shipments.[502]

c. In December 2010, the Naval Surface Warfare Center, received a shipment from DPG-LSD of inactivated *Burkholderia mallei* that had an incorrect lot number on the vials, thereby not matching the enclosed death certificate, or the accompanying certificate of analysis, or the

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[499] *See* Tab B-17.3, [redacted] Performance Evaluations, DA Form 7222 (2011-2014).
[500] *Id.*
[501] See Section I.F., Historical Mishaps at Dugway Proving Ground Life Sciences Division.
[502] *Id.*

shipping documentation. [redacted] failed to ensure the shipment contained accurate shipping documents to match the items shipped. [redacted] was the technician responsible for this erroneous shipment. Additionally, she failed to report this mishap to the DPG-LSD chain of command.[503]

d. In September 2014, a shipment of “inactivated” *Vaccinia* from DPG-LSD to Naval Surface Warfare Center, was mislabeled with an incorrect lot number and “Live” *Vaccinia* nomenclature. Viable *Vaccinia* virus can be a human pathogen, making the live strain a Risk Group 2 organism. Instead of the correct label with inactivated *Vaccinia*, lot number AGD0000219, incorrect labels stating viable *Vaccinia*, lot number AGD0000182 were applied to the labels. [redacted] failed to detect that the incorrect lot number was being shipped. She failed to report this mishap to the DPG-LSD chain of command.[504]

e. In March 2014, [redacted] shipped a mislabeled package to the Republic of Korea containing inactivated *Bacillus anthracis* from lot AGD0001667 and attenuated *Yersinia pestis*. The shipping label described the contents as “4 mL KILLER ORGANISM ON DRY ICE, UN1845.” [redacted] did not catch the typographical error on the shipping documentation when she labeled and shipped the package. She failed to report this mishap to the DPG-LSD chain of command.[505]

[redacted]	
Positions Held: [redacted] (See Tab B-17.2, [redacted] - Position Description)	
Duties:	**Findings/Failures:**
* Manage the biological agent repository and will develop a system to ensure that reference (stock) materials meet quality, surety and security requirements. * Obtain and maintain certification for Transport of Biomedical Materials Division 6.1 and 6.2 materials and oversee the coordination of shipments and transfers of all life science organisms. * Works in BSL-2 and BSL-3 laboratories and ensures that agents are prepared, packaged and shipped IAW applicable Federal, Army, State, and local regulations.	* Negligently failed to ensure that all agents were prepared, packaged, and shipped in accordance with Federal, state and local regulations. * Negligently failed to report all shipping errors to her supervisors.

Figure 39:* [redacted] *Summary

[503] *Id*.
[504] *Id*.
[505] *Id*. Note that the material sent to the Republic of Korea was from the same lot (AGD0001667) as the one at the center of this investigation. This lot was believed to have been inactivated at the time of shipment, so this really was simply a typographical error even though subsequent viability re-testing has shown that this lot was not completely inactivated.

III. Recommendations

A. Scientific

The 15-6 investigation team concluded that a preponderance of evidence does not support a finding that a group of individuals or institutions were directly responsible for the inadvertent shipment of viable *Bacillus anthracis*. However, a potential contributing factor is a gap in scientific understanding of the irradiation and viability testing processes. The U.S. Army should consider the following:

1. Collaborate with the DoD and the CDC to revise current policy and regulations, including 42 Code of Federal Regulation part 73, to define "Non-Viable Select Agents" and to determine how to demonstrate non-viability of a select agent. Furthermore, the DoD and CDC should consider allowing exempted amounts (below an infectious dose) of material to be treated as non-select agent and consider eliminating or re-categorizing inactivated biological select agents and toxins to account for the fact that it is not possible to verify that material has been inactivated with 100% certainty.

2. Conduct studies to evaluate factors that could affect *Bacillus anthracis* spore resistance to gamma irradiation. A variety of factors can affect resistance to gamma irradiation to include: (i) the strain of *Bacillus anthracis*, (ii) the concentration of spores in the solution being irradiated, (iii) the total number of spores being irradiated, and (iv) the purity of the spore solution being irradiated. Carefully controlled studies using varying doses of gamma irradiation should be conducted to evaluate each of these factors as well as the potential confounding effects of multiple factors. The desired outcome would be the development of kill curves for selected strains and spore concentrations of *Bacillus anthracis* under controlled conditions that could be replicated by production facilities.

3. Conduct studies to evaluate the potential for gamma irradiated spores to heal. For growth to be detected during viability testing, dormant spores (that were not actually killed during irradiation) must germinate first in order to begin growing. The triggers that allow for this transition are not clearly understood; however, there is evidence that suggests that time, variance in temperature, salt content, air pressure and nutrients dramatically affect germination and growth rates of spores. There is also evidence that the introduction of a catalyst could spur the onset of germination within a damaged germinating spore. The catalyst could be any number of potential factors including, but not limited to the following: time, incubation temperature, a freeze thaw cycle, or the introduction of growth media.

4. Conduct studies to evaluate factors that could affect viability testing of irradiated *Bacillus anthracis* spores: Key to the establishment of an effective *Bacillus anthracis* irradiation program is the establishment of a validated means of assessing the viability of the irradiated spores. In order to ensure that irradiated spores have truly been killed, conditions should be provided that optimize the opportunity for growth. Factors to evaluate under viability testing include: length of time spores are incubated in broth and on plates, types of growth media used for incubation in broth and on plates (tryptic soy agar, brain heart infusion agar, nutrient broth,

etc.), temperature(s) for incubation in broth and on plates, and the portion of the irradiated sample that should be used for viability testing.

B. Institutional

1. U.S. Army

To reduce the risk of future mishaps involving biological material, the U.S. Army should consider the following:

a. Unity of Command/Consolidation of Facilities

i. Appointing an Executive Agent with oversight over the laboratories at DPG-LSD, ECBC and USAMRIID as well as any other entity working with biological select agents and toxins administered by the Department of the Army.[506]

ii. The Executive Agent should study consolidation of the laboratories involved in working with biological select agents and toxins in order to leverage unity of command and minimize risk.

iii. The Executive Agent could assist in the development of common policies related to laboratory practices, cross fertilization of lessons learned/best practices, increased communication between colleagues and provide incentive to cross-talk between organizations.

iv. The Army should consider working with the CDC to create policy that addresses how correspondence between the CDC and Army biological laboratories is delivered to the chain of command. Currently communications occur between CDC representatives and the Responsible Officials at each individual laboratory, so reporting of significant events that may require action by senior leaders is not required or guaranteed by existing policy.

v. The Army should study whether opportunities exist to reduce risk by partnering with industry for the production and services of biological select agents and toxins in lieu of maintaining this capability internal to the Army.

vi. The Army should consider removing the CRP operations from DPG-LSD and re-align it under another laboratory (whether government or commercial) that may be better suited to execute production for external customers.

b. Mobile Training Team

Executing a mobile training team, comprised of Ph.D. level microbiologists from ECBC, USAMRIID, NMRC, and CDC, to travel to DPG-LSD to initiate a complete review of laboratory practices and procedures at DPG-LSD. The main goal of the mobile training team should be to improve laboratory processes and procedures by sharing commonly accepted practices as they apply to production facilities.

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[506] The 15-6 investigation team understands that this recommendation has already been executed.

c. Developmental Assignments

Establish programs wherein all Army laboratories exchange personnel to facilitate collaboration and development of best practices. The expectation is that cross-pollination of knowledge, experience, and best practices will occur, allowing for the intellectual development of associated personnel, as well as the advancement of science. Furthermore, it will create a culture among the labs that will allow for better communication and collaboration.

d. Professional Development of Biological Research Personnel

i. Review conference and symposium attendance policy for biological research personnel. Conferences and symposia are critical information exchange venues for this community, and are key opportunities to promote professional education and collaboration with commercial industry.

ii. Implement a formal mentorship program to ensure that personnel engaged in work with all aspects of biological select agents and toxins, to include laboratory technicians, safety personnel, regulatory oversight personnel, and inspectors, are adequately trained. The mentorship process should include an annual side-by-side, in-person peer review.

e. Hiring Incentives. Leverage existing incentive programs to attract and retain highly qualified scientists to DPG.

f. Inspections. Work with the CDC to enhance the effectiveness of joint inspections. The following five critical areas should be considered:

i. Frequency of Inspections. Synchronize the various inspections (Federal Agencies, Army, and Command) to ensure adequate overall inspection frequency.

ii. Notification of Inspections. Implement unannounced inspections.

iii. Scope of Inspections. Review the scope of inspections to include production standards and protocol process reviews. Appoint a scientific protocol review audit team to review the validity of inactivation and viability testing protocols. Current inspections primarily focus on compliance and conformance related matters – not technical matters. This recommendation is aligned with the recommendations of the DoD Review Committee Report.

iv. Composition of Inspection Teams. Ensure inspection teams are comprised of subject matter experts with operational experience and familiar with the current scientific data and standards in the areas to be inspected. Each team should include microbiologists and credentialed biosafety professionals with experience in working with biological select agents and toxins. Command representatives should review inspection reports for Army wide implications. These issues should be submitted to the Office of the Director of Army Safety to be presented to the Department of the Army Biological Safety and Health Council in order to update Army policy. The council serves as the peer review forum for discussion of lessons learned and recommendations for policy development.[507]

v. Department of the Army Inspector General Reviews. Convert the Army Biological Surety Inspections, which are required by AR 50-1, to be a mix of non-rated and rated[508] reviews that focus on systemic, non-scientific issues such as security, accountability, personnel reliability, equipment maintenance, emergency response, medical services, and external support issues. Rated reviews hinder open dialog, honesty about deficiencies, and the overall effectiveness of the reviews. Furthermore, it creates the perception that the inspected organization is trying to avoid "failing" at all costs.

2. U.S. Army Test and Evaluation Command

The Army Test and Evaluation Command should consider the following:

a. Complacency. Investigate whether complacency is widespread throughout DPG.

b. Personnel Qualification. Assess and ensure that all personnel assigned to biosafety, biosurety, and scientific positions are qualified.

c. Mishap Investigation and Reporting. Ensure all mishaps are internally investigated and that responsible parties are held accountable if appropriate.

d. Review Army Regulation 702-11, Army Quality Program, and determine whether ATEC, DPG, and DPG-LSD are in compliance with this regulation as it relates to the production of *Bacillus anthracis* and other biological materials.

3. Dugway Proving Ground – Life Sciences Division (DPG-LSD)

The leadership at Dugway Proving Ground and the Life Sciences Division should consider the following:

a. Quality Assurance/Quality Control Program

i. Resource and ensure external oversight of a full-time Quality Assurance/Quality Control Manager position.

ii. Execute and enforce the existing environmental sampling/inspection program.

iii. Develop and enforce production procedures that prohibit operations where live select agents are used in the same laboratory where viability testing is conducted.

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[507] *See* AR 385-10, para. 2-18 (27 Nov. 2013).

[508] The current reviews are rated, meaning they can result in failing deficiencies and negative action against the inspected entities. Non-rated inspections have the potential to be more effective in that they remove the incentive for an entity to hide deficiencies and instead focus on process improvement rather than simply "passing" the inspection.

iv. Prohibit production work on multiple organisms or multiple strains of one organism within the same biosafety cabinet.

v. Develop the existing video surveillance program and utilize the video as a tool to improve laboratory practices in accordance with regulatory requirements. Ensure that closed circuit television cameras are placed in locations that are conducive to the proper monitoring of safety, security, and general laboratory practices within the laboratories, including inside the biosafety cabinets.

vi. Implement formal, recurring data reviews of CRP processes in an effort to identify trends and issues before they affect end products.

vii. Established validated protocols for CRP production processes to ensure that process deviations are adequately vetted prior to implementation.

viii. Enforce maintenance and calibration procedures and schedules for all CRP tools and equipment. When necessary, contract with vendors to ensure that repairs are adequate and thorough.

ix. Develop and enforce maintenance procedures and schedules for irradiators.

b. Internal Policies and Procedures

i. Ensure that all standard operating procedures and work instructions governing operations at DPG-LSD are nested as appropriate and subjected to a uniform review and approval process. Notify the chain of command and request approval from the Director of DPG-LSD prior to implementing any deviations from standard operating procedures.

ii. Ensure that the irradiator source decay curves are consulted, in conjunction with the readings from the dosimeters, when calculating required time for irradiating a sample. Any issues with the irradiator should immediately be brought to the attention of the Radiation Safety Officer, the Radiation Safety Committee and the DPG-LSD Director. All individuals operating irradiation equipment should receive documented comprehensive training on the equipment.

iii. Revise the death certificate process to restrict the modification of certificates after all reviewers have signed the document. Train the signatories on their respective responsibilities to establish a better understanding of their responsibilities and the importance of a critical review of the certificate. Amend the certificate to accurately reflect the protocol and work instructions that are being followed. Also consider reverting to the "inactivation certificate" title.

c. Personnel Qualification. Assess and ensure that all personnel assigned to biosafety, biosurety, and scientific positions are qualified and fully vetted by the Biological Personnel Reliability Program, as appropriate.

d. Mishap Investigation and Reporting. Ensure all mishaps are investigated and appropriately reported and that responsible parties are held accountable, as appropriate.

e. Hiring Incentives. Leverage existing Army incentive programs to attract and retain highly qualified scientists.

C. Individual Accountability

A preponderance of the evidence does not exist to support a finding that a group of individuals or institutions, or a specific individual or institution was the proximate cause for the unacknowledged and unintended shipment of viable *Bacillus anthracis*. Nevertheless, failures by leadership, oversight staff, and laboratory technicians were identified across the DPG-LSD enterprise. These failures may have contributed to the inadvertent shipment of viable *Bacillus anthracis*. The following individuals should be held accountable for their respective failures as addressed in Section II.C above.

1. The following leaders should be held accountable for their failure to take action:

   a. Brigadier General William E. King, IV (See Figure 29 for Summary of Findings)

   (b) (6) [redacted]

   (b) (6) [redacted]

   (b) (6) [redacted]

   (b) (6) [redacted]

2. The following personnel with oversight responsibilities should be held accountable for their failure to take action:

   (b) (6) [redacted]

   (b) (6) [redacted]

   (b) (6) [redacted]

   (b) (6) [redacted]

3. The following individuals should be held accountable for failing to exercise due care in the performance of their duties:

   (b) (6) [redacted]

(b) (6) [redacted]

   (b) (6) [redacted]

The following individuals should **NOT** be held accountable – no failures have been identified:

a. Major General Daniel Karbler

b. Major General(R) Peter Utley

c. Major General(R) Genaro Dellarocco

d. Dr. James Streilein (SES Retired)

e. Major General(R) Roger Nadeau

f. Major General(R) James Myles

g. Major General(R) Robert Armbruster

h. Major General(R) Del Turner

i. Mr. David Jimenez (SES)

j. Mr. Michael Etzinger (SES)

k. Mr. James Johnson (SES)

l. Brigadier General(R) Michael Combest

m. Brigadier General(R) Marvin Keith McNamara

(b) (6) [redacted]

(b) (6) [redacted]

(b) (6) [redacted]

(b) (6) [redacted]

(b) (6) [redacted]

(b) (6) [redacted]

(b) (6) [redacted]

(b) (6) [redacted]

(b) (6) [redacted]

IV. Conclusion

No single event, discrepancy, individual or institution caused the inadvertent shipments of low concentrations of viable *Bacillus anthracis* samples from DPG-LSD. The evidence collected is insufficient to attribute any action or inaction by any institution and/or individual as the likely cause.

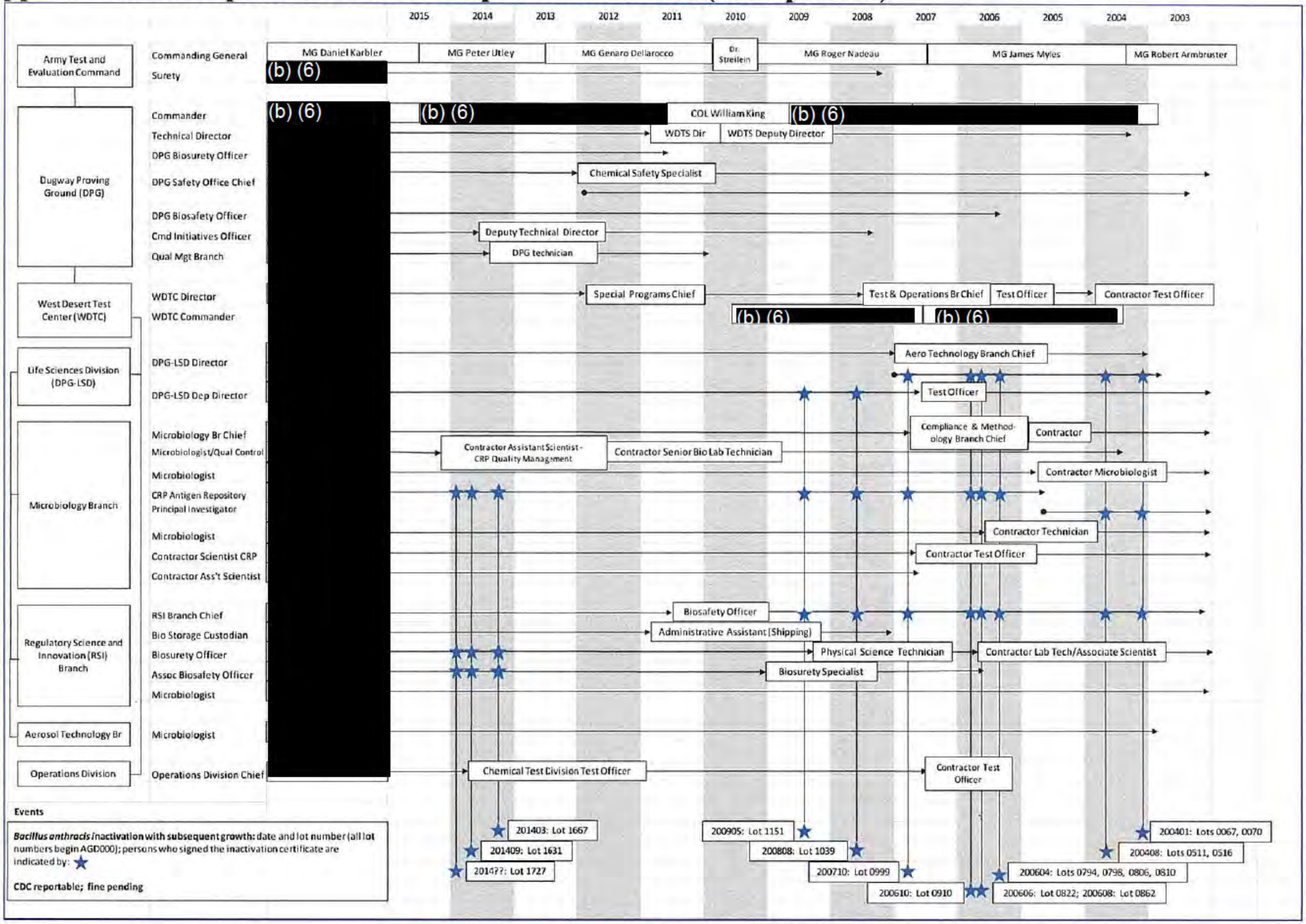
Although the facts do not support a specific finding of what likely caused the viable shipments, a number of scientific, institutional, and individual conditions/actions existed that may have contributed to the unintended shipments of low concentrations of viable *Bacillus anthracis* between 2004-2015.

To effectively remedy the issues identified in this report, the Army should consider implementing the aforementioned recommendations as a holistic approach to resolving the numerous scientific, institutional, and individual deficiencies associated with the inactivation of *Bacillus anthracis*.

OSTROWSKI.PAUL.ADAM.1115533769 Digitally signed by OSTROWSKI.PAUL.ADAM.1115533769 DN: c=US, o=U.S. Government, ou=DoD, ou=PKI, ou=USA, cn=OSTROWSKI.PAUL.ADAM.1115533769 Date: 2015.12.21 12:22:21 -05'00'

PAUL A. OSTROWSKI
MG, USA
Investigating Officer

Appendix A: Enterprise View of Mishaps and Personnel (2003-present)



Critical Reagent Program (CRP) laboratory contamination: The AR 15-6 investigation team conducted environmental sampling of the BSL-2 and BSL-3 labs used by the CRP
- Five samples positive for *Bacillus anthracis* (*B. anthracis*) Ames strain in the BSL-3 lab
- DPG-LSD notified CDC per Select Agent regulations; CDC sent an investigation team to DPG, finds *B. anthracis* Sterne strain (non-BSAT) contamination in another lab

CDC fine pending

Timeline:
- 201508 CDC sends investigation team to DPG-LSD
- 201508 DPG-LSD notifies CDC of the contamination
- 201508 DPG-LSD notified of CRP lab environmental sampling: positive for *B. anthracis* contamination

Vaccinia Virus Elstree (Lister) shipment, Naval Surface Warfare Center (NSWC):
- NSWC requested specific lots of inactivated Vaccinia from DPG; DPG sends vials that are mislabeled as live; NSWC did not note label discrepancies
- NSWC sent 2 vials to Midwest Research Institute (MRI); MRI noted that label lot number did not match certificate lot number
- NSWC noted that labels are for live Vaccinia (per lot number and "LIVE" on label)
- DPG-LSD notified NSWC that the requested inactivated lot was sent with the wrong label. **Not reportable to the CDC**

Timeline:
- 201501 NSWC notes that labels indicate "LIVE"; DPG-LSD states that labels are wrong and agent is dead
- 201501 NSWC ships 2 vials to MRI; MRI identifies incorrect lot numbers
- 201409 DPG-LSD sends mislabeled Vaccinia vials to NSWC

***B. anthracis* and *Yersinia pestis* (*Y. Pestis*) shipment, Republic of Korea:**
- DPG-LSD sent sample of inactivated agents to *B. anthracis* and *Y. pestis* to Korea; typo on shipping label read "KILLER" instead of "KILLED." **Not reportable to the CDC**

Timeline:
- 201404 DPG-LSD sends mislabeled inactivated *B. anthracis* and *Y. pestis* vials to Republic of Korea

***Burkholderia mallei* (*B. mallei*) shipment to NSWC:**
- DPG-LSD sent sample of inactivated *B. mallei* to NSWC; vial label did not match certificate (missing digit on lot number; concentration not listed the same)
- NSWC notified DPG [redacted] of label and certificate errors; DPG told NSWC to correct lot number; NSWC declined; DPG sent new labels and certificate
- New label had different aliquot number than original; new certificate reversed concentration and genomic equivalent value. **Not reportable to the CDC**

Timeline:
- 201103 NSWC receives new label and certificate from DPG-LSD
- 201101 NSWC discovers and reports the mismatched labels and certificate
- 201012 DPG-LSD sends *B. mallei* shipment to NSWC with mismatched label vs certificate

Venezuelan Equine Encephalitis Virus (VEE) shipment, NSWC:
- DPG-LSD shipped inactivated VEE to NSWC instead of requested inactivated *B. anthracis* Sterne
- NSWC notified DPG-LSD [redacted]; DPG-LSD [redacted] provided the death certificate and tech data for the VEE. DPG-LSD [redacted] confirmed that the wrong vial had been shipped (a switch with a shipment intended for a private company)
- **Not reportable to the CDC**

Timeline:
- 201007 NSWC autoclaves the VEE
- 201007 NSCW requests and DPG-LSD provides VEE death certificate and tech data
- 201007 DPG-LSD ships inactivated VEE to NSWC instead of requested inactivated *B. anthracis* (DPG switched shipments with another company)

Botulinum toxin shipment to ECBC and Naval Medical Research Center (NMRC):
- DPG-LSD shipped Botulinum toxin to ECBC (twice) and NMRC; 0.1 mg was requested and shippping documents indicated that 0.1 mg was sent (an amount exempt from select toxin requirements)
- 1.0 mg actually sent (as noted on label); should have been shipped as a select toxin with CDC approval
- CDC investigation identified DPG-LSD violations; **CDC fine assessed**; DHHS OIG declined to impose penalty (individual up to $250K, entity up to $500K)

Timeline:
- 201111 DHHS OIG elects not to impose civil monetary penalty
- 201106 CDC investigation report on shipment errors
- 201105 DAIG inspection fails DPG for shipment errors
- 201104 NMRC notes shipment discrepancy, reports to DPG-LSD and CDC
- 201011 DPG-LSD ships Botulinum toxin to NMRC
- 201010 DPG-LSD ships Botulinum toxin to ECBC
- 200802 DPG-LSD ships Botulinum toxin to ECBC

***B. anthracis* shipment to Lawrence Livermore National Laboratory (LLNL):**
- DPG-LSD inactivated *B. anthracis* with Clorine dioxide (ClO_2); during viability testing, one of five vials tested positive for *B. anthracis* and was destroyed; remainng four vials issued death certificates with no additional testing
- DPG-LSD shipped *B. anthracis* to LLNL; LLNL test of sample found growth (one spore)
- CDC investigation identified DPG-LSD as source of the spore; **CDC fine assessed**; DHHS OIG declined to impose penalty (individual up to $250K, entity up to $500K)

Timeline:
- 200912 DHHS OIG elects not to impose civil monetary penalty
- 200906 CDC investigation report on LLNL shipment
- 200704-05 LLNL tests spores, finds growth, reports to CDC
- 200704 DPG-LSD ships 4 vials ClO_2-inactivated *B. anthracis* to LLNL
- 200703 DPG inactivates spores with ClO_2; 4 of 5 vials (no growth) issued death certificates

Venezuelan Equine Encephalitis Virus (VEE) shipments:
- USAMRIID sends DPG-LSD what DPG believes is inactivated VEE; CDC subsequently adds VEE to select agent list
- DPG-LSD shipped VEE as inactivated to ECBC, Armed Forces Institute of Pathology (AFIP), and four private companies
- DPG-LSD asks CDC about VEE status; CDC response is that it is up to DPG-LSD to ensure the VEE is completely inactivated
- DPG-LSD asks USAMRIID about the inactivation with inconclusive results.
- CDC investigation of ECBC and USAMRIID includes whether VEE was improperly shipped by DPG-LSD; **CDC investigation results pending**

Timeline:
- 201508 CDC investigation of ECBC, USAMRIID including VEE status as select agent
- 201302 DPG-LSD asks USAMRIID about VEE inactivation status
- 201205 DPG-LSD ships VEE to one private company
- 201009 DPG-LSD asks CDC about VEE inactivation status
- 200702 DPG-LSD ships VEE to AFIP and one private company
- 200608 DPG-LSD ships VEE to ECBC and two private companies
- 200503 CDC includes VEE on select agent list
- 2003-04 USAMRIID ships VEE to DPG-LSD; DPG-LSD believes it to be inactivated

(Timeline axis: 2015, 2014, 2013, 2012, 2011, 2010, 2009, 2008, 2007, 2006, 2005, 2004, 2003)

Appendix B: Dugway Proving Ground Organizational Charts

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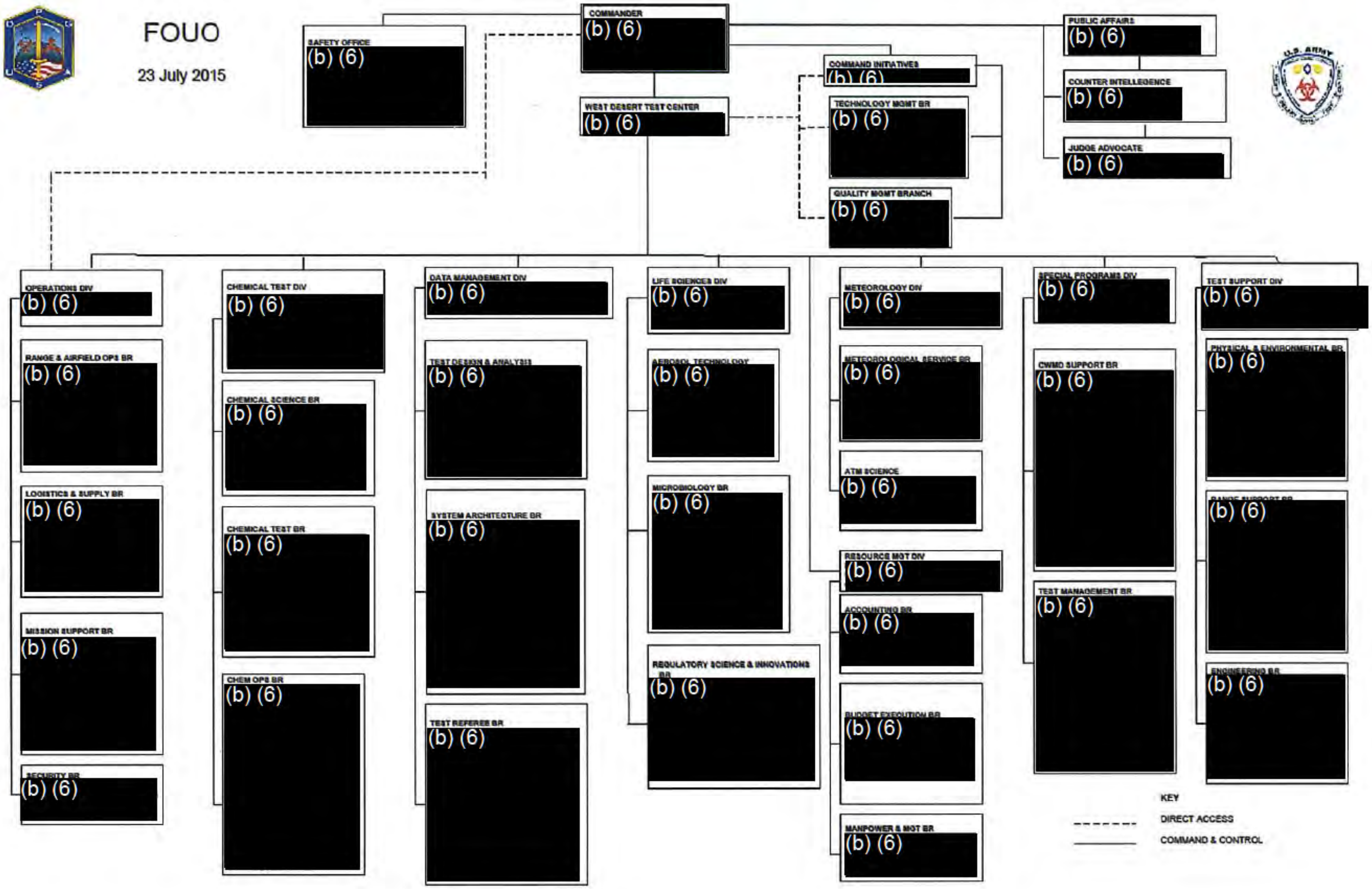
23 July 2015



Life Sciences Division

Division Chief
(b) (6) [redacted]

Division Deputy
(b) (6) [redacted]

Government
(b) (6) [redacted]

Other Government
(b) (6) [redacted]

Aerosol Technology
(b) (6) [redacted]

Government
(b) (6) [redacted]

Jacobs Support
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DDST Support
(b) (6) [redacted]

Regulatory Science & Innovations
(b) (6) [redacted]

Government
(b) (6) [redacted]

Jacobs Support
(b) (6) [redacted]

Acting Jacobs Management
(b) (6) [redacted]

Microbiology
(b) (6) [redacted]

Government
(b) (6) [redacted]

Jacobs Support
(b) (6) [redacted]

Appendix C: Army Biological Laboratory Funding Profiles

This section provides a detailed breakdown of the funding profiles for the three U.S. Army laboratories involved in work with biological select agents and toxins. These details were investigated in order to assess the validity of claims that the laboratories are in direct competition for funding and to determine how the competition, or lack thereof, affects operations and working environments at the laboratories. The 15-6 investigation team ultimately concluded that the claims made by (b) (6) [redacted] that competition for funding was adversely affecting operations at DPG-LSD were unfounded.

Life Sciences Division, West Desert Test Center, Dugway Proving Ground

The DPG-LSD total FY14 budget was about $5,714,000 balanced between centrally provided non-reimbursable funds and reimbursable customer funds. Figure 40 shows that about half the FY14 RDTE funds were non-reimbursable dollars from the Major Range and Test Facility Base (MRTFB), defense-wide funding line. These dollars provided operating funds to DPG-LSD to ensure that DoD test customers were only charged the direct costs of testing, and that the overhead costs were centrally funded.[509]

Reimbursable funding to DPG-LSD from customers covered the remaining half of the annual costs (Figure 40). A majority of the reimbursable funding for DPG-LSD came from the Joint Program Executive Office for Chemical and Biological Defense for projects including (1) the production of reagents for the CRP, and (2) test and evaluation for the Joint USFK (United States Forces Korea) Portal and Integrated Threat Recognition (JUPITR), the Joint Biological Tactical Detection System (JBTDS), and the Next Generation Diagnostic System (NGDS) programs. The remaining reimbursable funds covered the certification cost of the new Dugway Whole System Live Agent Testing (WSLAT) chamber and support to academia, industry, other services and foreign customers for testing and evaluation.[510]

[509] *See* Tab E-18, DPG-LSD Funding Profile.
[510] *Id.*

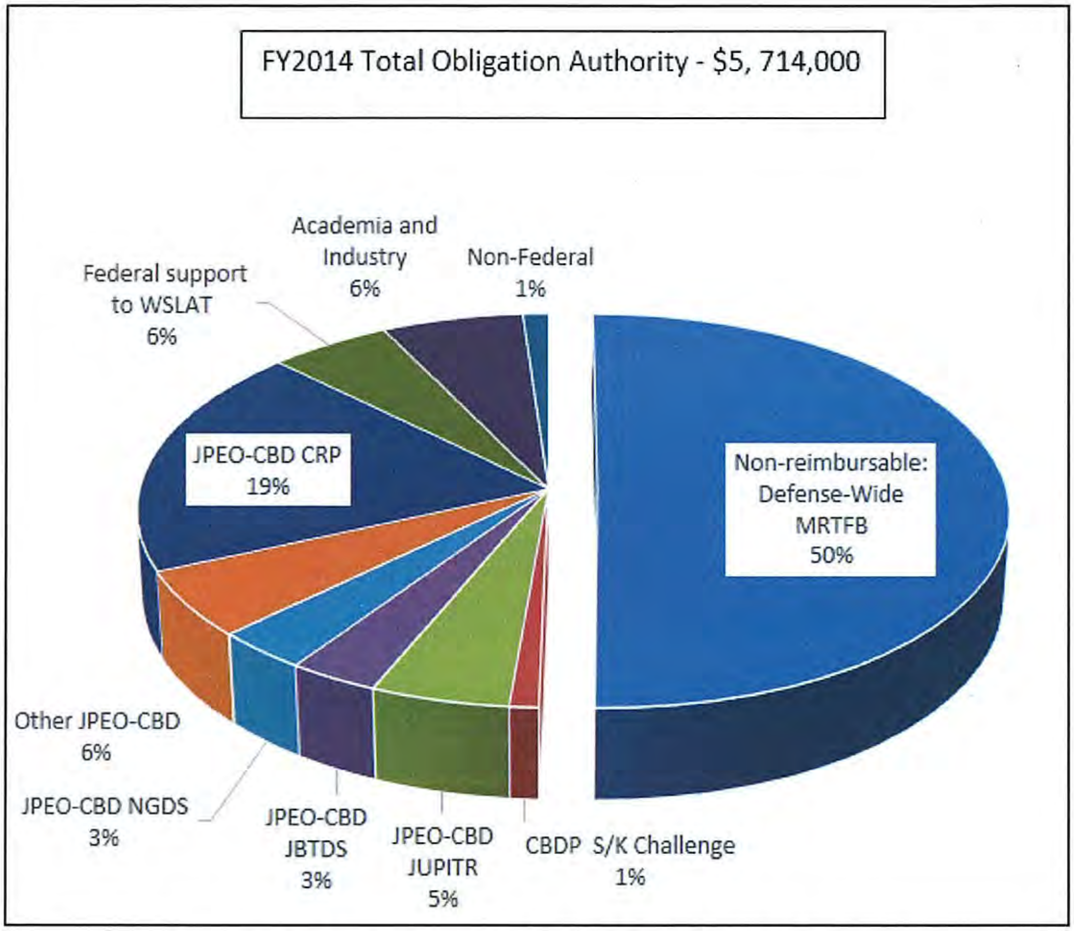

Figure 40: Funding Profile for the Life Sciences Division

Biosciences Division, Edgewood Chemical Biological Center

In Fiscal Year 2014, the Biosciences Division at ECBC received about $25,103,000 for biological defense support (Figure 41). Nearly all of the FY14 funds were reimbursable dollars split between the Defense Threat Reduction Agency and Joint Program Executive Office for Chemical and Biological Defense. The Joint Science and Technology Office at Defense Threat Reduction Agency (DTRA JSTO) provided funding for various research projects, including Biological Intelligence, Reconnaissance, and Surveillance (Bio-ISR). The Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD) provided funding for the CRP, focused on limited production of genomic materials. The Joint Program Executive Office for Chemical and Biological Defense also funded research, development and prototyping of programs including the Joint USFK (United States Forces Korea) Portal and Integrated Threat Recognition (JUPITR), the Next Generation Diagnostic System (NGDS), Biological Interoperability Capability Sets (BICS) and a sensing system known as Luminex Mag. A small amount of funding came from academia and industry.[511]

[511] *See* Tab E-19, ECBC Funding Profile.

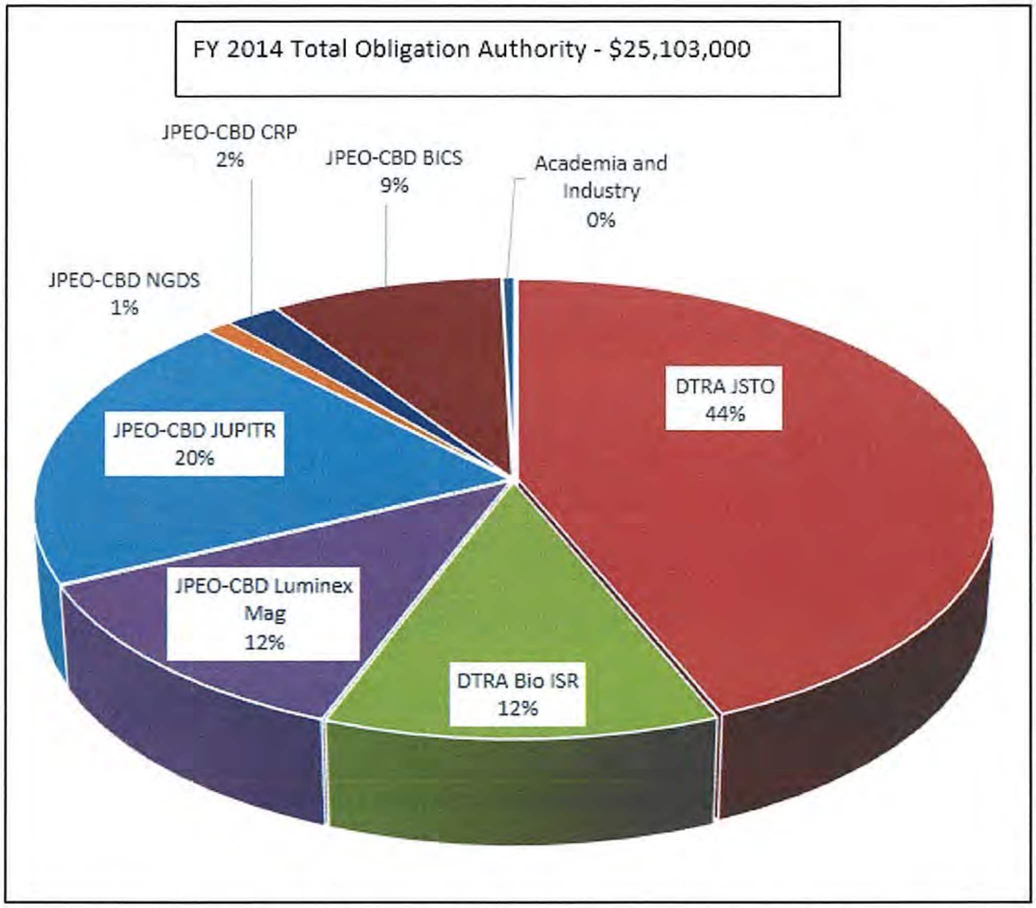

Figure 41: Funding Profile for the Biosciences Division at ECBC

Science Directorate, U.S. Army Medical Research Institute of Infectious Diseases

In Fiscal Year 2014, the Science Directorate, USAMRIID received $102,500,000, split about evenly between non-reimbursable and reimbursable funds (Figure 42). Approximately 56 percent of the total funding was non-reimbursable from the Defense Health Program and the Department of the Army and was used for basic research and capability upgrades.[512]

The remaining 44 percent of the funding was reimbursable for medical and clinical direct program costs. The Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD) provided funding for the CRP Unified Culture Collection and for Medical Countermeasure Systems (JPEO-CBD MCS). In addition, the Defense Threat Reduction Agency Cooperative Biological Engagement Program (DRTA CBEP) and the Military Vaccine Agency (MILVAX) each provided funding that helped make up the 44 percent of total reimbursable funding. The remaining reimbursable funding supported other federal agencies such as the Department of Health and Human Services, academia and industry.[513]

[512] *See* Tab E-20, USAMRIID Funding Profile.
[513] *Id.*

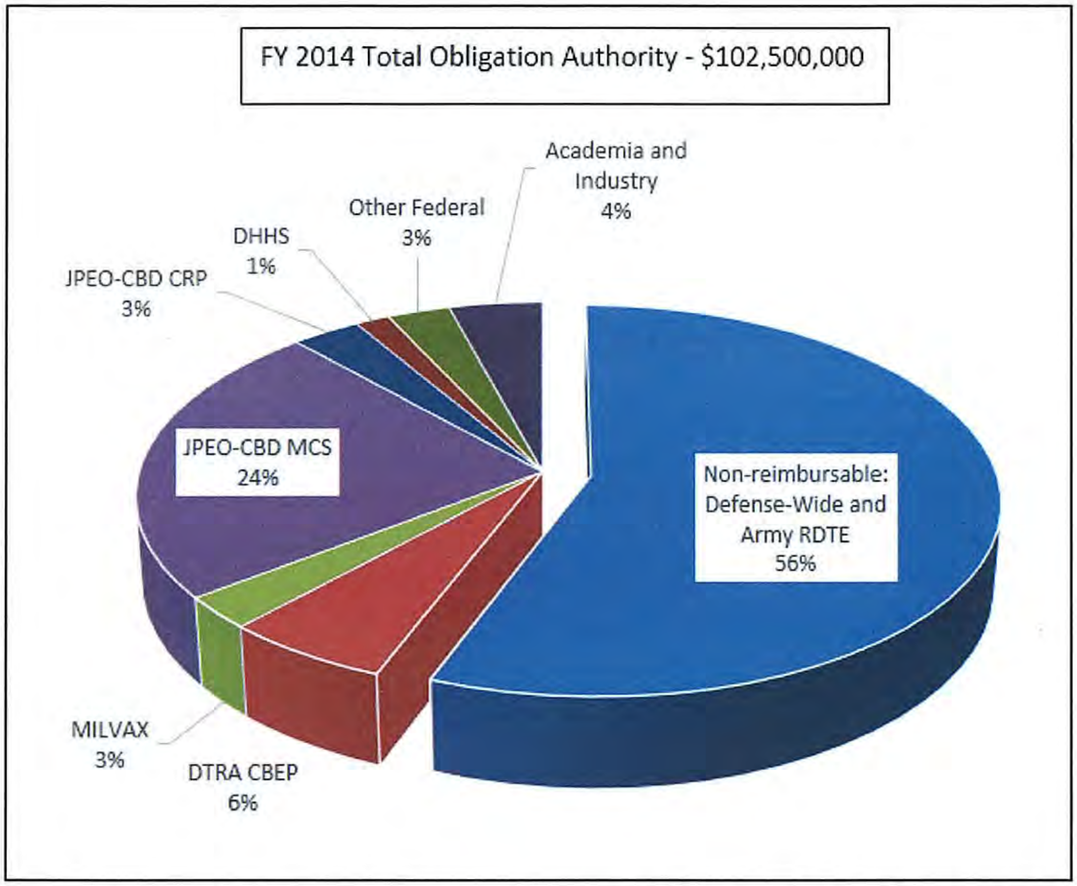

Figure 42: Funding Profile for the Science Directorate, U.S. Army Medical Research Institute of Infectious Diseases

Extent of competition:

While there may be a perception of competition with other Army laboratories among some members of the DPG-LSD workforce, the 15-6 investigation team's research into the funding for all three laboratories yielded no data to support the conclusion that there is true competition. In 2014, programs from the Joint Program Executive Office for Chemical Biological Defense funded all three of the Army labs, but their work was mostly complementary and not in direct competition (Figure 423). Most of the customer overlap occurred between DPG-LSD and Biosciences Division at ECBC, but the two labs supported different phases of larger program efforts. For example, the Biosciences Division conducted research and developed prototypes for the Joint USFK (United States Forces Korea) Portal and Integrated Threat Recognition (JUPITR) program while DPG-LSD tested the capabilities of the new systems. Traditionally, the DoD biological defense community provides reimbursable funding to the DPG-LSD for testing and evaluation, while steering science and technology efforts to the Biosciences Division at ECBC. The Science Directorate at USAMRIID has been the DoD medical and clinical focal point. The 15-6 investigation team determined that the CRP divided their $3.5M of FY14 program funding between the three Army labs based on their historical competencies and expertise.

Customer	Life Sciences Division, Dugway Proving Ground	Biosciences Division, Edgewood Chemical Biological Center	Science Directorate, US Army Medical Research Institute of Infectious Diseases
Defense Threat Reduction Agency		Yes	Yes
Joint Program Executive Office for Chemical and Biological Defense	Yes	Yes	Yes
- JPEO-CBD Medical Countermeasure Systems			Yes
- JPEO-CBD JUPITR	Yes	Yes	
- JPEO-CBD Next Generation Diagnostic System	Yes	Yes	
- JPEO-CBD Joint Biological Tactical Detection System	Yes	Yes	
- JPEO-CBD Critical Reagent Program	Yes	Yes	Yes
- JPEO-CBD Luminex Mag		Yes	
- JPEO-CBD Biological Interoperability Capability Sets		Yes	
Military Vaccine Agency			Yes
Department of Health and Human Services		Yes	Yes
Department of Homeland Security		Yes	
Department of Energy		Yes	
Other Federal Agencies		Yes	
Academia and Industry	Yes		Yes

Figure 43: Comparison of Customers

Appendix D: Acronyms

Acronym	Definition
ATEC	U.S. Army Test and Evaluation Command
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CRP	Critical Reagents Program
CRPAR	Critical Reagents Program Antigen Repository
DAIG	Department of the Army Inspector General
DHHS	Department of Health and Human Services
DHHS-OIG	Department of Health and Human Services, Office of Inspector General
DoD	Department of Defense
DNA	Deoxyribonucleic Acid
DPG	Dugway Proving Ground
DPG-LSD	Dugway Proving Ground – Life Sciences Division
ECBC	Edgewood Chemical and Biological Center
LLNL	Lawrence Livermore National Laboratory
NMRC	Naval Medical Research Center
NSWC	Naval Surface Warfare Center
OSD	Office of the Secretary of Defense
RNA	Ribonucleic Acid (tRNA = Transfer RNA)
RSI	Regulatory Science and Innovation Branch (at DPG-LSD)
USAMRIID	U.S. Army Medical Research Institute of Infectious Diseases

Appendix E: Glossary

Term	Definition
Aerobic	An aerobic organism can survive and grow in an oxygenated environment.
Agar	A culture medium having an agar (gelatin-like) base. This report references Trypticase soy agar, which is a general purpose media that provides enough nutrients for microorganisms to grow.
Amerithrax	The FBI case name for the 2001 anthrax mail attacks.
Analyte	A substance of interest in an analytical procedure (such as an assay)
Antigen	A substance that causes an immune system to produce antibodies against it.
Assay	An investigative procedure for qualitatively assessing or quantitatively measuring the presence or amount of an entity (analyte).
Attenuate	To reduce the virulence of a pathogen but still keep it viable (live).
Bacillus anthracis	A bacterium that is the causative agent of the disease anthrax.
Biological Select Agent	The U.S. government's term for viruses, bacteria and toxins with the potential to be used as bioweapons or posing significant risk to agriculture or public health.
Botulinum Neurotoxin A	A bacterium that is the causative agent of the disease botulism.
Burkholderia mallei	A bacterium that is the causative agent of the disease Glanders.
Causative Agent	A biological pathogen, such as a bacterium, virus, parasite or fungus, that causes a disease.
Death Certificate	A document used at DPG-LSD to certify and track the death/inactivation of biological materials.
Dormant Spore Form	A state of existence where a cell is incapable of replication or enzymatic activity but is significantly more resistant to harsh environmental conditions.
Gram Stain	A method of differentiating between bacterial species into two large groups (gram-negative and gram-positive).
Gray	A unit of measure of radiation equal to the absorption of one joule of energy per one kilogram of matter.
Hydroxyl Radical	The neutral form of the hydroxide ion.
Lateral Flow Immunoassay	A simple device used to detect the presence of an analyte. The home pregnancy test is a common example.
Mishap	For purposes of this report, a mishap is a mistake and is not synonymous with the formal definition provided in Army safety regulations.
Non-Communicable	A condition or disease that is not infectious or not transmissible.
Non-Hemolytic	A substance that does not cause hemolysis (the breaking down of red blood cells).
Non-Motile	A spore or other microorganism that is not capable of movement.
Overlap Select Agent	A select agent that affects both humans and agriculture.
Pathogenicity	The potential of certain microorganisms to cause disease.
Plasmid	A small, circular, double-stranded DNA molecule that is distinct from the cell's chromosomal DNA. Plasmids carry genes that can provide bacteria with genetic advantages (for example, antibiotic resistance) that can render them more harmful or more difficult to treat.
Polymerase Chain Reaction	A technology used in molecular biology to amplify DNA copies across several orders of magnitude.
Reagent	A substance that is added to a system to cause a chemical reaction or to see if a chemical reaction occurs.

Strain	A genetic variant or sub-type of a microorganism.
Vaccinia	A large, complex virus belonging to the poxvirus family. The active constituent of the vaccine that eradicated smallpox.
Vegetative Cells	Any of the cells in a plant or animal that are not reproductive cells.
Venezuelan Equine Encephalitis	A mosquito borne viral pathogen that can infect all equine species and humans. (VEE)
Viable	The ability of a living thing to maintain itself. For the purposes of this report, viable is synonymous with "live".
Virulence	The degree of pathogenicity of a microorganism.
Yersinia pestis	A bacterium that is the causative agent of the disease plague.

Appendix F: Timeline

29 JUL 2015:

- Appointment orders signed by the Director of the Army Staff and sent to Major General Ostrowski and The Office of The Judge Advocate General.

30 JUL 2015:

- Legal advisor met with Major General Ostrowski and provided him with an initial brief on the investigation.
- The legal advisor sent Major General Ostrowski and Assistant Investigator [redacted] all of the information he collected on the case via 6 email messages.

31 JUL 2015:

- Major General Ostrowski held a teleconference with his assistant investigators [redacted] legal advisor, and Mr. Carmen Spencer. The group was briefed by Mr. Spencer (Program Executive Officer for the Joint Program Executive Office for Chemical and Biological Defense) on the historical facts of the case.
- Major General Ostrowski held a face to face meeting with Mr. Spencer. Also in attendance were [redacted], and legal advisor. On the conference call was [redacted]. The investigative team received a detailed brief from Mr. Spencer.
- 1600 phone call with MEDCOM Commander.

3 AUG 2015: (the investigator was TDY 3-7 AUG 2015)

- 0800 Partial investigative team met to discuss the theory of the case and investigative plan. [redacted], [redacted] (JPEO-CBD), and [redacted], legal advisor, [redacted] (NRMC BIO Safety), [redacted] (G-3/5/7 BIO Surety))
- 0930 phone call with investigator – discussed the investigation and information gathering.
- 1300 phone call with investigator – discussed the investigation and information gathering.
- 1600 phone call with investigator – discussed the investigation and information gathering.

4 AUG 2015:

- 0800 Partial investigative met and was assigned specific tasks based on their area of expertise.
- Phone call with investigator – discussed the investigation, information gathering, and received further focus areas for analysis.
- [redacted] (USAMRIID Microbiologist) joined the investigative team.
- 1300 [redacted], [redacted] and [redacted] meet with Dr. Vahid Majidi (DASD-NM).
- 1600 Partial investigative team met for the day's update meeting.
- [redacted] met with Dr. Chris Hassel (DASD-CBD) and [redacted].

5 AUG 2015:

- 0800 Partial investigative team met [redacted] was on the phone).
- The team broke to work on their respective focus areas.
- 1030 Investigative team met to discuss how the research progressing, what RFIs to DPG were needed, and to introduce [redacted] to the team.

- Worked on the document control plan, automation, and the taking of sworn statements. Request paralegal support.
- Looking into requesting email messages
- updated the witness list.

6 AUG 2015:

- 0800 Partial investigative team met and discussed the investigative plan and the need for an extension,
- Additional legal advisor was assigned, [redacted]
- 0930 phone call with investigator. The investigative team provided him with an update brief.

[redacted] joined the team to be the administrative support officer.

- Deadline extension request and investigative team memorandum for record drafted.
- 1600 closeout meeting

7 AUG 2015:

- 0800 Morning Huddle
- 0930 phone call with investigator. The investigative team provided him with an update brief.
- Team broke out to research, revise methodology and problem statement. Prepared briefing documents for Director of the Army Staff update on Monday, 10 AUG 2015.
- Assistant IOs prepared for and conducted an interview with [redacted]

10 AUG 2015:

- 0830 Morning Huddle.
  Scrubbed Director of the Army Staff update brief.
  Discussed the extension memo request.
  Discussed development of an Interview plan and the RFIs that need to be sent to DPG.
- 1430 interview with Dr. Majidi.
- 1645 Director of the Army Staff update.

11 AUG 2015:

- Investigative team traveled to USAMRIID for a tour of the facility and discussions with key personnel at the facility.
- Interviewed approximately six people.

12 AUG 2015:

- Investigative team traveled to ECBC for a tour of the facility and discussions with key personnel at the facility.
- Interviewed approximately three people.

13 AUG 2015:

- Team prepared to interview approximately 22 personnel at DPG.
- Developed standardized and specific questions for relevant DPG personnel.

14 AUG 2015:

- Team prepared to interview approximately 22 personnel at DPG.
- Developed standardized and specific questions for relevant DPG personnel.
- Phone interview with [redacted]

16 AUG 2015:

- Investigative team traveled to DPG and continued preparation for interviews.

17 – 21 AUG 2015: DPG Site Visit.

- Investigative team received an in-brief and tour of DPG-LSD.
- Investigative team conducted interviews with 28 personnel from DPG.
- Investigative team gathered documentary evidence.
- Investigative team assisted DPG in conducting environmental sampling of Biosafety Level-2 and 3 labs.

24 AUG 2015:

- Morning huddle – reviewed IOs notes on the draft report.
- Finalized slides for the Director of the Army Staff update on 25 AUG.
- Developed list of additional personnel to be interviewed. Prepared a list of relevant questions for each.
- Team continued reviewing the documentary evidence collected at DPG.

25 AUG 2015:

- 0800 Director of the Army Staff update.
- 0840 Morning huddle – reviewed investigator's notes on the draft report.
- The team worked on organizing all documentary evidence.
- Personnel worked on drafting an outline of the relevant topics that must be included in the report of investigation (with sub headings).
- 1615 Interviewed MG Karbler, ATEC Commander (June 2015 to present).

26 AUG 2015:

- 0800 Morning huddle – discussed the draft outline for the report of investigation.
- Team continued organizing all documentary evidence.
- Personnel worked on finalizing the outline with sub headings and topics.
- Team began another review of the evidence collected.
- 1600 Evening huddle – reviewed investigator's notes on the draft report.

27 AUG 2015:

- 0700 Interview with MG Utley, former ATEC Commander (2013 – 2015).
- 0800 Morning huddle – reviewed investigator's notes on the draft report.
- 1330 Follow-up interview with [redacted] (2013-2015).
- Team continued organizing all documentary evidence.
- Personnel worked on drafting the report.
- Team began another review of the evidence collected.
- 1600 Evening huddle – reviewed investigator's notes on the draft report.
- Prepared a draft report for the investigator to read overnight.

28 AUG 2015:

- 0800 Morning huddle the investigative team discussed the draft report.
- Team continued organizing all documentary evidence.
- Personnel worked on drafting the report.
- Team began another review of the evidence collected.
- 1600 Evening huddle – reviewed investigator's notes on the draft report.
- Prepared a draft report for the investigator to read overnight.

31 AUG 2015:

- 0800 Morning huddle – reviewed investigator's notes on the draft report.
- 1130 Interview with Mr. Jimenez, Deputy to the Commanding General of ATEC (JAN 2015 to present).
- Interview with (b) (6) [redacted]
- 1500 Interview with BG King.
- 1600 Evening huddle – reviewed IOs notes on the draft report.
- Prepared a draft report for the investigator to read overnight.

1 SEP 2015:

- No Morning huddle.
- Team assisted in responding to congressional inquiry resulting from CDC subsequent Inspection at DPG.
- 0940 Phone call with (b) (6) [redacted]
- 1600 Evening huddle – reviewed IOs notes on the draft report.
- Prepared a draft report for the investigator to read overnight.

2 SEP 2015:

- 0800 Morning huddle.
- Continued support to congressional inquiry.
- 1600 Evening huddle – reviewed investigator's notes on the draft report.
- Prepared a draft report for the investigator to read overnight.

3 Sep 2015:

- 0800 Morning huddle.
- Continued support to congressional inquiry.
- 1600 Evening huddle – reviewed investigator's notes on the draft report.
- Prepared a draft report for the investigator to read overnight.

4 Sep 2015:

- 0800 Morning huddle.
- Continued support to congressional inquiry.
- 1600 Evening huddle – reviewed investigator's notes on the draft report.
- Prepared a draft report for the investigator to read overnight.

8 SEP 2015:

- 0800 Morning huddle – reviewed investigator's notes on the draft report.
- Conducted a follow-up interview and statement of [redacted]
- Finalized MG Utley's statement.
- Interviewed [redacted]
- 1600 Evening huddle – reviewed investigator's notes on the draft report.
- Prepared a draft report for the investigator to read overnight.

9 SEP 2015:

- 0800 Morning huddle – reviewed investigator's notes on the draft report.
- Finalized the following statements: [redacted]
- Worked on revising the report of investigation.
- Followed-up with DPG-LSD on CCTV videos.
- 1600 Evening huddle – reviewed investigator's notes on the draft report.
- Prepared a draft report for the investigator to read overnight.

10 SEP 2015:

- 0800 Morning huddle – reviewed investigator's notes on the draft report.
- Worked on revising the report of investigation.
- Coordinated Red Team Travel.
- Phone interview with [redacted]
- 1600 Evening huddle – reviewed investigator's notes on the draft report.
- Prepared a draft report for the investigator to read overnight.

11 SEP 2015:

- 0800 Morning huddle – reviewed investigator's notes on the draft report.
- Worked on revising the report of investigation.
- Finalized Red Team members.
- Director of the Army Staff status update on the progress of the investigation.
- 1600 Evening huddle – reviewed Investigator's notes on the draft report.
- Prepared a draft report for the investigator to read overnight.

14 SEP 2015:

- 0900 Attended Army huddle on safety review and moratorium.
- 1000 Morning huddle – reviewed investigator's notes on the draft report.
- Worked on revising the report of investigation. Revised section on Bio lab funding.
- Coordinated Red Team Travel.
- 1600 Evening huddle – reviewed investigator's notes on the draft report.
- Prepared a draft report for the investigator to read overnight.

15 SEP 2015:

- 0800 Morning huddle – reviewed investigator's notes on the draft report.
- Worked on revising the report of investigation.
- Coordinated Red Team Travel.
- 1600 Evening huddle – reviewed investigator's notes on the draft report.
- Prepared a draft report for the investigator to read overnight.

16 SEP 2015:

- 0800 Morning huddle – reviewed investigator's notes on the draft report.
- Worked on revising the report of investigation.
- 1600 Evening huddle – reviewed investigator's notes on the draft report.
- Prepared a draft report for the investigator to read overnight.

17 SEP 2015:

- 0800 Morning huddle – reviewed investigator's notes on the draft report.
- Worked on revising the report of investigation.
- Coordinated Red Team Travel.
- 1600 Evening huddle – reviewed investigator's notes on the draft report.
- Prepared a draft report for the investigator to read overnight.

18 SEP 2015:

- 0800 Morning huddle – reviewed investigator's notes on the draft report.
- Worked on revising the report of investigation.
- Finalized Red Team Travel.
- 1600 Evening huddle – reviewed investigator's notes on the draft report.
- Prepared a draft report for the investigator to read overnight.

21 SEP 2015:

- 0800 Morning huddle – reviewed investigator's notes on the draft report.
- Worked on revising the report of investigation.
- Received evidence of 2004 quality audit.
- 1200 Red Team began the review of the ROI.
- 1300 Update to the Director of the Army Staff.
- 1600 Evening huddle – reviewed investigator's notes on the draft report.
- Prepared a draft report for the investigator to read overnight.

22 SEP 2015:

- 0800 Morning huddle – reviewed investigator's notes on the draft report.
- Worked on revising the report of investigation.
- 1400 Received feedback from Red Team on the Background section.
  - Suggested implementing a process chart for Lot 1667.
  - Suggested creating a glossary/definitions section.
- 1600 Evening huddle – reviewed investigator's notes on the draft report.
- Prepared a draft report for the investigator to read overnight.

23 SEP 2015:

- 0800 Morning huddle – reviewed investigator's notes on the draft report.
- Worked on revising the report of investigation.
- Received feedback from Red Team on the Findings section.
- 1600 Evening huddle – reviewed investigator's notes on the draft report.
- Prepared a draft report for the investigator to read overnight.

24 SEP 2015:

- 0800 Morning huddle – reviewed investigator's notes on the draft report.
- Worked on revising the report of investigation.
- Interview with [redacted]
- Follow-up interview with BG King. Sent BG King additional questions.
- Received feedback from Red Team on the recommendations section and revisions that were implemented based on previous recommendations.
- 1600 Evening huddle – reviewed investigator's notes on the draft report.
- Prepared a draft report for the investigator to read overnight.

25 SEP 2015:

- 0800 Morning huddle – reviewed investigator's notes on the draft report.
- Worked on revising the report of investigation.
- 1600 Evening huddle – reviewed investigator's notes on the draft report.
- Prepared a draft report for the investigator to read overnight.

28 SEP – 2 OCT 2015:

- Investigative team reviewed the entire draft report for final edits.
- Investigative team reviewed the footnotes and fact checked the document.
- Prepared a draft report for the investigator to read overnight.

5 – 7 OCT 2015:

- Reviewed investigator's notes on the draft report.
- Investigative team reviewed the entire draft report for final edits.
- Investigative team reviewed the footnotes and fact checked the document.
- Prepared a draft report for the investigator to read overnight.

8 OCT 2015:

- Investigative team reviewed the entire draft report and made final edits.

9 OCT 2015:

- Turned in report and evidence to The Office of the Judge Advocate General for a legal review.

22 OCT 2015:

- The Office of the Judge Advocate General directed the investigation team address specific comments and questions requiring additional investigation and findings.

23 OCT 2015:

- 0800 Morning huddle – Investigative team worked on a way ahead, an additional witness list, and started contacting witnesses.
- Pursuant to AR 20-1, The Inspector General authorized the investigating officer to investigate senior army officials.

26 OCT 2015:

- 0800 Morning huddle – developed an interview plan and drafted an extension request.

- Interview with [redacted] JUN 2011 – JUN 2013).
- Interview with [redacted] JUN 2004 – JUN 2007).
- Interview with MG(R) Roger Nadeau (ATEC CDR JUN 2007 – MAR 2010).

27 OCT 2015:

- 0800 Morning huddle.
- The investigating officer requested and the Director of the Army Staff approved a second 60 day extension.
- Additionally, the Director of the Army Staff approved the investigating officer's request for an investigator from Department of the Army Inspector General's Office to assist the team.
- Interview with MG(R) Genaro Dellarocco (ATEC CDR OCT 2010 – JUL 2013).
- Interview with [redacted]
- Interview with [redacted]

28 OCT 2015:

- 0800 Morning huddle.
- Interview with [redacted] JUN 2005 – JUN 2007).
- Interview with Dr. Streilein (ATEC Executive Director MAR – OCT 2010).
- Interview with MG(R) James Myles (ATEC CDR MAY 2004 – JUN 2007).
- Interview with [redacted] JUN 2002 – JUL 2005).

29 OCT 2015:

- 0800 Morning huddle.
- Interview with MG(R) Robert E. Armbruster (ATEC CDR JUN 2002 – MAY 2004).
- Interview with [redacted] FEB 2008 - Present).

30 OCT 2015:

- 0800 Morning huddle.
- Interview with [redacted]
- Researched contact information for DTC personnel.

4 NOV 2015:

- Interview with Mr. Michael Etzinger (DTC Executive Director MAY – DEC 2010).
- Interview with Mr. James Johnson (DTC Executive Director JUL 2008 – MAY 2010).
- Interview with MG(R) Del Turner (DTC CDR AUG 2006 – OCT 2011).
- Interview with BG(R) Keith McNamara (DTC CDR NOV 2008 – MAY 2004).

5 NOV 2015:

- 0800 Morning huddle.
- Interview with [redacted] JAN 2011 – Present).
- Interview with BG(R) Michael Combest (DTC CDR OCT 2004 – AUG 2006).
- Interview with [redacted] JUN 2002 – MAY 2004).

6 NOV 2015:

- 0800 Morning huddle.
- Interview with [redacted] APR 2000 – JAN 2015).

9 NOV 2015:

- 0800 Morning huddle.
- Team worked on revising the report and transcribing statements.

10 NOV 2015:

- 0800 Morning huddle.
- Follow-up interview with [redacted]
- Follow-up interview with BG William King.

12 NOV 2015:

- 0800 Morning huddle.
- Follow-up with [redacted]
- Interview with [redacted] APR 2000 – JAN 2015).
- Interview with [redacted]
- Interview with [redacted]
- Follow-up Interview with [redacted]
- Interview with [redacted]

13 NOV 2015:

- 0800 Morning huddle.
- Examined Evidence.
- Interviewed [redacted]
- Draft final report of investigation.

16-20 NOV 2015:

- Examined Evidence.
- Draft final report of investigation.

23 NOV 2015:

- 0800 Morning huddle.
- Final review and report editing.
- Submitted report to OTJAG and OGC at 1700.

3-15 DEC 2015:

- Reviewed and incorporated OTJAG and OGC recommended changes.

Appendix G: Evidence

Evidence is provided digitally and in hard copy. The evidence is organized in 5 Tabs:

Tab A: Administrative Documents

#	Document	Notes
1	SECARMY Directive	30 July 2015 Memo from SECARMY to DAS appointing a 15-6 IO
2	15-6 Appointment Memo from DAS	Memo from DAS to MG Ostrowski appointing him as 15-6 IO
3	Investigation Team Assignment Memo	MFR formalizing the assignment of the 15-6 investigative team
4	60 Day Extension Request	First request for 60 day extension
5	60 Day Extension Approval	First approval of 60 day extension
6	Authorization to Inv. Senior Officials	23 October 2015 Memo from DAIG authorizing MG Ostrowski to investigate senior officials
7	2nd 60 Day Extension Request	Second request for 60 day extension
8	2nd 60 Day Extension Approval	Second approval of 60 day extension

Tab B: Sworn Statements

#	Witness	#	Witness
1	(b) (6) [redacted]	39	(b) (6) [redacted]
2		40	
3		41	Utley, Peter
4		42	(b) (6) [redacted]
5		43	
6		44	
7		45	Estes, Allen
8		46	Tamilio, Douglas
9		47	Nadeau, Roger
10		48	(b) (6) [redacted]
11		49	
12		50	Dellarocco, Genaro
13		51	(b) (6) [redacted]
14		52	Streilein, James
15		53	Myles, James
16		54	(b) (6) [redacted]
17		55	Armbruster, Robert
18		56	Etzinger, Michael
19		57	Johnson, James
20	Jimenez, David	58	Turner, Frank (Del)
21	(b) (6) [redacted]	59	McNamara, Keith
22	Karbler, Daniel	60	Combest, Michael
23	King, William	61	Wolf, Andrew
24	(b) (6) [redacted]	62	(b) (6) [redacted]
25		63	
26		64	
27		65	
28		66	
29		67	
30		68	
31		69	
32			
33			
34			
35			
36			
37			
38			

Tab C: Documentary Evidence

#	Document	Notes
1	WDL-BIO-147 (Revs 0-8)	DPG SOP for Inactivation and Sterility Testing of Biological Agents (Revs 0-8; 12/01 to present)
2	WDL-GEN-036 (Revs 0-7)	DPG SOP for Irradiator Operations (Revs 0-7; 2004-present)
3	WDL-GEN-045 (Rev 3)	DPG SOP for Environmental Sampling/Monitorinig (13 November 2014)
4	WDL-BIO-094 (Revs 0-5)	DPG SOP for PCR (Polymerase Chain Reaction) (Revs 0-7; 1/09 to present)
5	WDL-BIO-120 (Revs 0-12)	DPG SOP for Shipment of Biological Materials (Revs 0-12; 10/03 to present)
6	WDL-SAF-326	DPG Laboratory Safety Manual (Rev 9)
7	WDL-SAF-330	DPG BSL-3 Safety Guide (Rev 10; 9/14)
8	CRPAR Mgt. Proced. PD-001, 003 and 007	CRP Antigen Repository Procedures - Mgt. Review Procedures, Uncertainties, Environment Procedure
9	CPR Work Instructions (001…)	CRP Antigen Repository Work Instructions
10	2006 March - (b) [redacted] Lab Notebook	(b) (6) [redacted] notebook #0205 (March 2006)
11	2007 October - (b) [redacted] Lab Notebook	(b) (6) [redacted] notebook #0428 (October 2007)
12	2013 August - (b) [redacted] Lab Notebook	(b) (6) [redacted] notebook #0530 (August 2013)
13	2013 September - (b) [redacted] Lab Notebook	(b) (6) [redacted] notebook #0542 (September 2013) - includes Lot 1667 irradiation notes
14	Spore Concentration Table	Table of initial spore concentrations for various CRP lots of Ba
15	CRP Program - Info on Irradiated Lots	Radiation info (SOP, dose, etc.) for all CRP lots of Ba
16	Incident Report - Comp of Class Info	MFR - Incident Report - Possible Compromise of Classified Information (CRP; 16 June 2015)
17	Memo - CRP SCG Violations	Memo for DPG Commander - CRP Violations of Security Classification Guide (18 June 2015)
18	CRP Security Classification Guide	CRP Security Classification Guide (November 2005)
19	Lot 1667 Death Certificate	Lot 1667 Death Certificate
20	Lot 1667 - Discrepant Death Certs	Lot 1667 - three versions of Death Certificate

21	Shipping Documents Korea Incident (2014)	"Killer Organism" shipping documentation
22	(b) (6) Email 1 (ODASAF)	(b) (6) [redacted] email - ODASAF no record of historical DPG incidents (03 September 2015)
23	(b) (6) Email 2 (ODASAF)	[redacted] (b) (6) email - ODASAF no record of current DPG incident (14 September 2015)
24	2004 Camber Audit	2004 Technical Audit of CRPAntigen Repository by Camber Corporations
25	(b) (6) [redacted] Email (blind study details)	Email from (b) (6) [redacted] with details about blinded study that led to current discovery (31 August 2015)
26	FedEx Shipping Docs (8 Apr 2015)	Fedex shipping documentation for Lot 1667 to private entity in April 2015 (subject of investigation)
27	Task Force Anthrax - Daily Report #34	Task Force Anthrax daily report (01 October 2015)
28	20150915 Telecon with DPG Record	Memo to document telecon between 15-6 team and DPG personnel on 15 September 2015
29	20150720 - Karbler Memo (transfer CRP)	Memo from MG Karbler to the VCSA requesting transfer of CRP mission from DPG
30	(b) (6) Email - ECBC Env Mon. Notice	Email from (b) (6) [redacted] with information about ECBCs Environmental Sampling procedures
31	20150930 - Emails with DPG JAG	Emails from DPG JAG stating that there are no records for investigations into historical incidents
32	Solicitation No. W911QY-15-R-0018	Solicitation for the blinded study associated with the May 2015 discovery of viable Ba
33	DAIG BSI Report (2005)	DAIG Biosurety Inspection Report from 2005
34	DAIG BSI Reports (2007)	DAIG Biosurety Inspection Report from 2007
35	DAIG BSI Reports (2009)	DAIG Biosurety Inspection Report from 2009
36	DAIG BSI Reports (2011)	DAIG Biosurety Inspection Report from 2011
37	DAIG BSI Reports (2013)	DAIG Biosurety Inspection Report from 2013
38	DAIG BSI Reports (2015)	DAIG Biosurety Inspection Report from 2015
39	ISO Guide 34	ISO Guide for Accreditation of Biological Reference Material Producers

40	ISO Guide 17025	ISO Guide for General Accreditation of Biological Laboratories
41	LLNL Correspondence and Evidence	Compiled correspondence and evidence associated with the 2007-2010 LLNL Ba incident
42	Bot A Correspondence and Evidence	Compiled correspondence and evidence associated with the 2008-2010 Bot A shipments
43	[redacted] Emails - VEE (2013)	Emails between [redacted] (USAMRIID) and [redacted] regarding VEE inactivation (March 2013)
44	[redacted] Emails - VEE (2010)	Emails between [redacted] and [redacted] regarding VEE shipment (September 2010)
45	[redacted] Emails - VEE (2015)	Emails from [redacted] regarding VEE shipments/material disposition (September 2015)
46	2011 15-6 Investigation Report	BG Smith's 15-6 investigation report on Chemical Accountability at DPG (February 2011)
47	Email - [redacted] (2015 Blind study info)	Email from [redacted] (ACC) with details about the blinded stufy solicitation
48	Email - Daniel Karbler (VEE Shipments)	Email from MG Karbler to the DAS with information about VEE shipments
49	Spreadsheet with VEE Details	VEE tracking spreadsheet
50	HEPA Correspondence and Evidence	Compiled correspondence and evidence associated with the 2015 HEPA filter failure at DPG-LSD
51	DPG-LSD CDC Registration and RO-ARO Designation	Document identifying CDC Responsible Official and Assistant Responsible Officials at DPG-LSD

Tab D: Previous Investigations

#	Document	Notes
1a	20150605 CDC Entity Insp	Report on CDC inspection of DPG-LSD in June 2015 (after discovery of viable Ba)
1b	20150724 CDC Civil Penalty	Memo from CDC to DHHS OIG recommended a civil monetary penalty for current Ba issues
2	20150713 OSD Report	July 2015 "Majidi" report
3a	20150730 SECARMY - ASAALT Memo	Memo from SECARMY to ASA(ALT) directing a working group to assess the findings of the Majidi report
3b	20150730 SECARMY - DSD Memo	Memo from SECARMY to DEPSECDEF with implementation plan
4a	20150826 CDC Reinspection	Report on CDC re-inspection of DPG-LSD after 15-6 team found contamination during environmental sampling (26 August 2015)
4b	20150828 CDC Suspension (Ba)	CDC memo to DPG-LSD suspending DPG-LSD registration to work with Ba (28 August 2015)
4c	20150831 CDC Suspension (all)	CDC memo to DPG-LSD suspending DPG-LSD registration to work with all select agents (31 August 2015)
4d	20151020 CDC Entity Inspection Report	CDC memo to DPG-LSD containing the detailed findings of the 27-28 August 2015 re-inspection

Tab E: References

#	Document	Notes
1	AR 50-1 Biological Surety	
2	AR 190-17 BSAT Security	
3	AR 702-11 Army Quality Program	
4	Bacillus Anthracis MSDS	
5	BMBL	Biosafety in Microbiological and Biomedical Facilities
6	CDC - Biosafety Levels	Information on various BSL levels
7	CDC - Revised Viability Testing Protocol	Revised viability testing protocol from the CDC based on new (2015) findings
8	20140711 - CDC Report on Exposure to Anthrax	
9	20110119 - CRPAR Corrective Action Report	
10	20150113 - CRPAR Corrective Action Report	
11	DA PAM 385-69 Safety Standards for Bio Labs	
12	ECBC Safety Brief	
13	ECBC Safety Program Overview Brief	
14	ECBC SOP - RSB 143 - BSL-3 Lab Operations	
15	ECBC SOP - RSB 179 - Ba Decon SOP	
16	ECBC SOP - RSB 319- Production of Bacteria and Viruses	
17	FDA - Current Good Manufacturing Practice	
18	Funding Profile - DPG LSD	
19	Funding Profile - ECBC	
20	Funding Profile - USAMRIID	
21	20150724 - House Hearing on FSAP	24 July 2015 House Committee on Energy and Commerce Hearing on the Federal Select Agents Program
22	20150817 - BSAT Moratorium Clarification	
23	NMRC SOP - 1N50-05 - Autoclave Ops	
24	NMRC SOP - IN50-07 - Movement of Live Cultures	
25	NMRC SOP - 1N50-10 - Sterility Purity Testing	
26	NMRC SOP - Declaration of Sterility or Purity	
27	NMRC SOP - IRRAD 1.0 - Gamma Irradiation Inactivation of Ba	
28	ECBC Proposal to Research Ba Inactivation	Past proposal from ECBC to investigate and standardize Ba irradiation/inactivation variables
29	USAMRIID SOP - DS-94-09 Culture and ID of Ba	
30	USAMRIID SOP - DS-94-21 DuPont Qualicon	

31	USAMRIID SOP - SA-02-15 Inactivation of Viral Stocks	
32	20150821 - CDC Notice of Inspection USAMRIID	
33	Memo - (b) (6) [redacted] - BA Questionnaire	Information from SME about Ba inactivation and resistance properties
34	Memo - (b) (6) [redacted] - BA Questionnaire	Information from SME about Ba inactivation and resistance properties
35	CRP Overview Brief	
36	20150610 - DoD Briefing - Shipment of Inactivated Ba	
37	AR 20-1 (IG Activities and Procedures)	
38	Email - King to DTC/ATEC (FBI Volume Discrepancy Issue)	Email with information about the 2009 FBI BSAT volume discrepancy incident
39	CDC RO Guidance Document	Guidance document from CDC for responsible officials
40	20151026 Memo - Executive Agent Delegation	Memo from SECARMY to the Surgeon General delegating Executive Agent duties