



## **United States of America**

Confidence Building Measure Return covering 2013

Convention on the Prohibition of the Development, Production and Stockpiling of  
Bacteriological (Biological) and Toxin Weapons and on their Destruction

Submitted to the United Nations on  
April 15, 2014

**Declaration form on Nothing to Declare or Nothing New to Declare for use in the information exchange**

<b>Measure</b>	<b>Nothing to declare</b>	<b>Nothing new to declare</b>	<b>Year of last declaration if nothing new to declare</b>
A, part 1			
A, part 2 (i)			
A, part 2 (ii)			
A, part 2 (iii)			
B			
C			
E			
F		√	1997
G			

Date: April 15, 2014

State Party to the Convention: United States of America

Date of ratification/accession to the Convention: March 26, 1975

National point of contact: Mr. Christopher Park, Department of State

Inquiries may be directed to BWC\_USCBM@state.gov.

## **Report of the United States of America to the United Nations Department for Disarmament Affairs**

Pursuant to the procedural modalities agreed upon in April 1987 at the "Ad Hoc Meeting of Scientific and Technical Experts for STATES Parties to the Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction," the United States of America submits the following information under Article V of the Convention:

### **Confidence Building Measure A, Part 1**

Exchange of data on research centres and laboratories page 4

### **Confidence Building Measure A, Part 2**

Exchanges of information on national biological defence research and development programmes

- (i) Declaration page 13
- (ii) Description page 15
- (iii) Facilities page 32

### **Confidence Building Measure B**

Exchange of information on outbreaks of infectious diseases and similar occurrences caused by toxins page 126

### **Confidence Building Measure C**

Encouragement of publication of results and promotion of use of knowledge page 142

### **Confidence Building Measure E**

Declaration of legislature, regulations, and other measures page 145

### **Confidence Building Measure F**

Declaration of past activities in offensive and/or defensive biological research and development programmes page 149

### **Confidence Building Measure G**

Declaration of vaccine production facilities page 151

### **Appendix A**

List of the Biological Select Agents and Toxins, and NIAID Category A, B and C Priority Pathogens page 156

### **Appendix B**

Compiled list of biological agents and toxins used for biodefense research page 160

**Form A, Part 1 (i)**

**BWC - Confidence Building Measure**

**Exchange of data on research centres and laboratories**

United States of America

April 15, 2014

**Exchange of data on research centres and laboratories<sup>1</sup>**

**1. Name(s) of facility<sup>2</sup>**

National Biodefense Analysis and Countermeasures Center (NBACC)

[Declared in accordance with Form A, Part 2 (iii)]

**2. Responsible public or private organization or company.**

U.S. Department of Homeland Security, Science & Technology Directorate  
operated by Battelle National Biodefense Institute LLC

**3. Location and postal address.**

8300 Research Plaza, Fort Detrick, Maryland 21702

**4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence.**

Department of Homeland Security (DHS)

Department of Defense (DOD) - partly

Department of Justice (DOJ)

**5. Number of maximum containment units<sup>3</sup> within the research centre and/or laboratory, with an indication of their respective size (m<sup>2</sup>).**

BSL-4 Laboratory = 980 m<sup>2</sup>

**6. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate.**

NBACC conducts studies to better understand current and future biological threats; to assess vulnerabilities; and to determine potential impacts to guide the development of biological countermeasures such as detectors, drugs, vaccines, and decontamination technologies. When needed, NBACC conducts experimental programs to better characterize the benefits and risks of changes in U.S. biodefense preparations. NBACC also develops bioforensic assays and provides operational bioforensic analysis to support the attribution of biocrime and bioterrorism.

The types of agents registered for use at NBACC are BSL-2 toxins, BSL-2 gram-positive and gram-negative bacterial agents, BSL-2 viral agents, BSL-3 gram-positive and gram-negative bacterial agents, BSL-3 viral agents, and BSL-4 viral agents.

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<sup>1</sup> The containment units which are fixed patient treatment modules, integrated with laboratories, should be identified separately.

<sup>2</sup> For facilities with maximum containment units participating in the national biological defence research and development programme, please fill in name of facility and mark "Declared in accordance with Form A, part 2 (iii)".

<sup>3</sup> In accordance with the latest edition of the WHO Laboratory Biosafety Manual, or equivalent.

**Exchange of data on research centres and laboratories**

**1. Name(s) of facility.**

U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)  
[Declared in accordance with Form A, Part 2 (iii)]

**2. Responsible public or private organization or company.**

U.S. Army Medical Research and Materiel Command

**3. Location and postal address.**

1425 Porter Street, Fort Detrick, Frederick, Maryland 21702

**4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence.**

U.S. Department of Defense (DOD) - wholly

**5. Number of maximum containment units<sup>3</sup> within the research centre and/or laboratory, with an indication of their respective size (m<sup>2</sup>).**

BSL-4 Laboratory = 1186 m<sup>2</sup>

**6. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate.**

USAMRIID conducts research to develop strategies, products, information, procedures and training programs for medical defense against biological warfare threats and infectious diseases. Medical products developed to protect military personnel against biological agents include vaccines, drugs, diagnostic capabilities and various medical management procedures.

Additional information can be found at: <http://www.usamriid.army.mil/>

**Exchange of data on research centres and laboratories<sup>1</sup>**

**1. Name(s) of facility<sup>2</sup>.**

CDC Office of Infectious Diseases (OID)

[Declared in accordance with Form A, Part 2 (iii)]

**2. Responsible public or private organization or company.**

Centers for Disease Control and Prevention, Department of Health and Human Services

**3. Location and postal address.**

1600 Clifton Road Northeast, Atlanta, Georgia 30333

**4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence.**

Department of Health and Human Services (HHS)

Department of Homeland Security (DHS)

Agency For International Development (USAID)

Department of State (DOS)

Department of Defense (DOD) – partly

**5. Number of maximum containment units<sup>3</sup> within the research centre and/or laboratory, with an indication of their respective size (m<sup>2</sup>).**

BSL-4 Laboratory = 136 m<sup>2</sup>

BSL-4 Laboratory = 271 m<sup>2</sup>

BSL-4 Laboratory = 136 m<sup>2</sup>

**6. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate.**

Activities include developing diagnostic assays for public health, conducting molecular and antigenic characterization of microorganisms, determining pathogenicity and virulence of infectious agents, determining natural history of infectious organisms, and conducting epidemiologic studies and surveillance for diseases. Biodefense activities include those with select agents

(<http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20List.html>).

**Exchange of data on research centres and laboratories<sup>1</sup>**

**1. Name(s) of facility<sup>2</sup>.**

Integrated Research Facility at Fort Detrick (IRF – Frederick)

[Declared in accordance with Form A, Part 2 (iii)]

**2. Responsible public or private organization or company.**

National Institutes of Health, Department of Health and Human Services

Operated by Battelle Memorial Institute

**3. Location and postal address.**

8200 Research Plaza, Frederick, Maryland 21702

**4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence.**

Department of Health and Human Services

**5. Number of maximum containment units<sup>3</sup> within the research centre and/or laboratory, with an indication of their respective size (m<sup>2</sup>).**

BSL-4 Laboratory = 1305 m<sup>2</sup>

**6. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate.**

The Integrated Research Facility at Fort Detrick in Frederick, Maryland (IRF-Frederick) is a component of the Division of Clinical Research of the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health (NIH). The mission of the IRF-Frederick is to manage, coordinate, and facilitate the conduct of emerging infectious disease and biodefense research to develop vaccines, countermeasures, and improved medical outcomes for patients. Research emphasis is placed on elucidating the nature of high consequence infections, including NIAID Category A priority pathogens and newly emerging infectious disease including Category A agents and newly emerging infectious disease microbes. Investigators began conducting Category A research in BSL-4 containment in 2013, although no research involving U.S. select agents commenced. Additional information can be found at: <http://www.niaid.nih.gov/about/organization/dcr/OCSIRF/Pages/OCSIFR.aspx>

**Exchange of data on research centres and laboratories<sup>1</sup>**

**1. Name(s) of facility<sup>2</sup>.**

Integrated Research Facility at Rocky Mountain Laboratories (IRF-RML)

[Declared in accordance with Form A, Part 2 (iii)]

**2. Responsible public or private organization or company.**

National Institutes of Health, Department of Health and Human Services

**3. Location and postal address.**

903 South 4th Street, Hamilton, Montana 59840

**4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence.**

Department of Health and Human Services

**5. Number of maximum containment units<sup>3</sup> within the research centre and/or laboratory, with an indication of their respective size (m<sup>2</sup>).**

BSL-4 Laboratory = 1145 m<sup>2</sup>

**6. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate.**

Rocky Mountain Laboratories is a component of the Division of Intramural Research of the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health (NIH). The RML mission is to play a leading role in the nation's efforts to develop diagnostics, vaccines, and therapeutics to combat emerging and re-emerging infectious diseases. Research at the Integrated Research Facility at Rocky Mountain Laboratories (IRF-RML) is dedicated to understanding the mechanisms of pathogenesis of microbial agents associated with or likely to cause serious or lethal human diseases using molecular methods and animal model systems. Additional information can be found at: <http://www.niaid.nih.gov/about/organization/dir/rml/Pages/integratedResearchFacility.aspx>

**Exchange of data on research centres and laboratories<sup>1</sup>**

**1. Name(s) of facility<sup>2</sup>.**

Galveston National Laboratory (GNL) Complex including Robert E. Shope Laboratory

**2. Responsible public or private organization or company.**

The University of Texas Medical Branch

**3. Location and postal address.**

301 University Boulevard, Galveston, Texas 77555

**4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence.**

Universities

U.S. Department of Agriculture (USDA)

Private Foundations

Pharmaceutical Industry

U.S. Department of Energy (DOE)

U.S. Department of Defense (DOD) - partly

U.S. Department of Homeland Security (DHS)

National Institutes of Health (NIH)

**5. Number of maximum containment units<sup>3</sup> within the research centre and/or laboratory, with an indication of their respective size (m<sup>2</sup>).**

BSL 4 Laboratory: 186 m<sup>2</sup> Shope Laboratory

BSL 4 Laboratory: 1022 m<sup>2</sup> GNL Laboratory

**6. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate.**

The mission of the Galveston National Laboratory is to assist the National Institute of Allergy and Infectious Diseases and the nation in the development of an improved means for the prevention, diagnosis and treatment of potentially life-threatening diseases caused by naturally emerging and purposefully disseminated infectious agents. To accomplish this goal GNL conducts multidisciplinary research into the causes, modes of transmission, and mechanisms of infectious diseases. Studies focus on a number of pathogens requiring BSL-4 containment, primarily those that cause viral hemorrhagic fevers, as well as some zoonotic viruses requiring enhanced BSL-3 containment. Products likely to emerge from research and investigations within the GNL include novel diagnostic assays, improved therapeutics and treatment models, and preventative measures such as vaccines.

Additional information can be found at: <http://www.utmb.edu/gnl/>

**Exchange of data on research centres and laboratories<sup>1</sup>**

**1. Name(s) of facility<sup>2</sup>.**

The Betty Slick and Lewis J. Moorman, Jr. Laboratory Complex, Department of Virology and Immunology

**2. Responsible public or private organization or company.**

Texas Biomedical Research Institute

**3. Location and postal address.**

P.O. Box 760549, San Antonio, Texas 78245-0549

**4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence.**

National Institutes of Health (NIH)

U.S. Department of Defense (DOD) - partly

U.S. Department of Homeland Security (DHS)

Private Sector Companies

Private Donors

**5. Number of maximum containment units<sup>3</sup> within the research centre and/or laboratory, with an indication of their respective size (m<sup>2</sup>).**

BSL 4 Laboratory: 114 m<sup>2</sup>

**6. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate.**

The mission of the Laboratory is to develop vaccines and therapeutics against viral pathogens, and to determine how viruses replicate and spread. Scientists are studying new and emerging disease threats, possible bioterrorism agents, and as-yet uncharacterized agents for biodefense. TXBiomed (formerly Southwest Foundation for Biomedical Research) has permits from the U.S. Department of Agriculture and the Centers for Disease Control to work on select agents. Additional information can be found at: <http://www.TXBiomed.org>.

**Exchange of data on research centres and laboratories<sup>1</sup>**

**1. Name(s) of facility<sup>2</sup>.**

Viral Immunology Center - National B Virus Resource Laboratory

**2. Responsible public or private organization or company.**

Georgia State University

**3. Location and postal address.**

P. O. Box 4118, Atlanta, Georgia 30302-4118

**4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence.**

National Institutes of Health (NIH)

Georgia Research Alliance

Immunology Core Support

Elizabeth R. Griffin Research Foundation

**5. Number of maximum containment units<sup>3</sup> within the research centre and/or laboratory, with an indication of their respective size (m<sup>2</sup>).**

BSL 4 Laboratory      60 m<sup>2</sup>

**6. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate.**

The Viral Immunology Center provides a global resource to assist in the identification of zoonotic disease transmissions and to develop enhanced strategies to detect viral infections in macaques. Current projects in the National B Virus Resource Laboratory are focused on the molecular biology of human and non-human primate alphaherpesviruses and the diseases they cause. Studies focus on the mechanisms by which virus kills the host and how that process can be circumvented with:

- **Early identification** - research focuses on the design and development of new approaches to more effectively identify these agents in both natural and foreign hosts;
- **Appropriate antiviral drugs** - researchers continually screen the efficacy of existing as well as novel antiviral agents to inhibit the growth of viruses that can potentially cross into the human population, either through occupational exposure or through more subtle contact; and
- **In the future, effective vaccines.**

Additional information can be found at <http://www2.gsu.edu/~wwwvir/Research/Index.html>

**Form A, Part 2 (i)**

**BWC - Confidence Building Measure**

**National biological defence research and development programmes - Declaration**

United States of America

April 15, 2014

**National biological defence research and development programme: Declaration**

**Are there any national programmes to conduct biological defence research and development within the territory of the State Party, under its jurisdiction or control anywhere? Activities of such programmes would include prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research.**

Yes      ☒ X

No        ☐

If the answer is Yes, complete Form A, part 2 (ii) which will provide a description of each programme.

**Form A, Part 2 (ii)**

**BWC - Confidence Building Measure**

**National biological defence research and development programmes - Description**

United States of America

April 15, 2014

**National biological defence research and development programmes**

The United States Government conducts a broad effort to reduce the risks presented by the deliberate or accidental release of biological agents and to defend against those threats in the event they occur. As called for by the *National Strategy for Countering Biological Threats*, this encompasses a range of initiatives, including improving global access to the life sciences to combat infectious disease regardless of its cause; establishing and reinforcing norms of safe and responsible conduct within the life sciences; improving capacity to detect and respond to outbreaks as they occur; and instituting a suite of coordinated activities that collectively help to influence, identify, inhibit, and/or interdict those who seek to misuse the life sciences.

One key element of this effort is the U.S. biodefense enterprise, which itself includes a variety of research and development programs aimed at protecting against the deliberate use of biological materials to cause harm. These programs focus on the identification of harmful pathogens and outbreaks of infectious diseases and their containment, treatment, and elimination from the environment. These programs are managed by several agencies with direct stakes in national security, environmental protection, and human and animal health and safety, including the Departments of Agriculture, Defense, Energy, Health and Human Services, Homeland Security, and the Environmental Protection Agency.

Historically, certain pathogens were selected for use as biological weapons because of their pathogenicity. Research on these pathogens, including study of molecular mechanisms and related diagnostic, vaccine and therapeutic development work, not only increases U.S. biodefense preparedness, but also offers inherent benefits for broader public health needs. Efforts to improve medical product stability, potency and ease-of-use that cut across disease targets could yield significant benefits for public health systems that cannot support existing treatments that require refrigeration, multiple doses or sophisticated diagnostic techniques. Similarly, biodefense initiatives to improve human and animal host defenses, to monitor emerging infectious diseases and drug-resistant microbes, and to clean up the site of a biological weapons attack have civilian applications that benefit public health services, such as epidemiological disease surveillance and environmental remediation.

To promote the benefits gained by these programs and to ensure that the research is available to the scientific community both domestically and internationally, the United States Government encourages the publication of research funded by its biodefense programs.

For more information on U.S. Government strategies related to biodefense, including biological threat preparedness and response, please consult:

- Management of Domestic Incidents (Homeland Security Presidential Directive 5 [HSPD-5]) and the related National Response Framework;
- Presidential Policy Directive 8: National Preparedness (PPD-8);
- National Strategy for Defense of United States Agriculture and Food (HSPD-9);
- National Biodefense Strategy (HSPD-10/National Security Presidential Directive-33 [NSPD-33]);
- Medical Countermeasures against Weapons of Mass Destruction (HSPD-18);
- Public Health and Medical Preparedness (HSPD-21);
- National Strategy to Combat Weapons of Mass Destruction (NSPD-17/HSPD-4);
- Executive Order 13527 (“Establishing Federal Capabilities for the Timely Provision of Medical Countermeasures following a Biological Attack”); and
- National Strategy for Countering Biological Threats.

**National biological defence research and development programmes: Description**

**1. State the objectives and funding of each programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research.**

The Department of Defense Biological Defense Program provides support and capabilities to protect the U.S. Armed Forces against biological warfare threats and emerging infectious diseases; improve biological defense preparedness; reduce risk to the nation; and field the appropriate mix of defensive capabilities for sustained military operations with minimum degradation of combat effectiveness attributed to current biological hazards and emerging infectious disease threats.

The Program works to counter biological threats by providing medical countermeasure capabilities to counter known and unknown threats, including novel and naturally-occurring emerging infectious diseases. Current research focuses on signaling mechanisms between host and bacterial cells; pre- and post-exposure therapeutics for bacterial select agents and novel threats; battlefield detection and identification methods, protective systems, and decontamination systems; the development of rapid and deployable detection assays for troop protection; and medical defenses against neurotoxins.

The Program also works on producing self-disinfecting and/or self-decontaminating materials as well as developing, producing, and fielding a system for sampling, detecting, and identifying biological agents.

Biological defense-related work conducted by the Department of Defense is carried out by the military services and biological defense program-focused agencies. These include funding agencies and service laboratories within the Departments of the Air Force, Army, and Navy; the Defense Threat Reduction Agency/Joint Science and Technology Office; the Joint Program Executive Office for Chemical and Biological Defense; and the Defense Advanced Research Projects Agency.

**2. State the total funding for each programme and its source.**

\$692,300,000 U.S. Department of Defense (DOD)

**3. Are aspects of these programmes conducted under contract with industry, academic institutions, or in other non-defence facilities?**

Yes

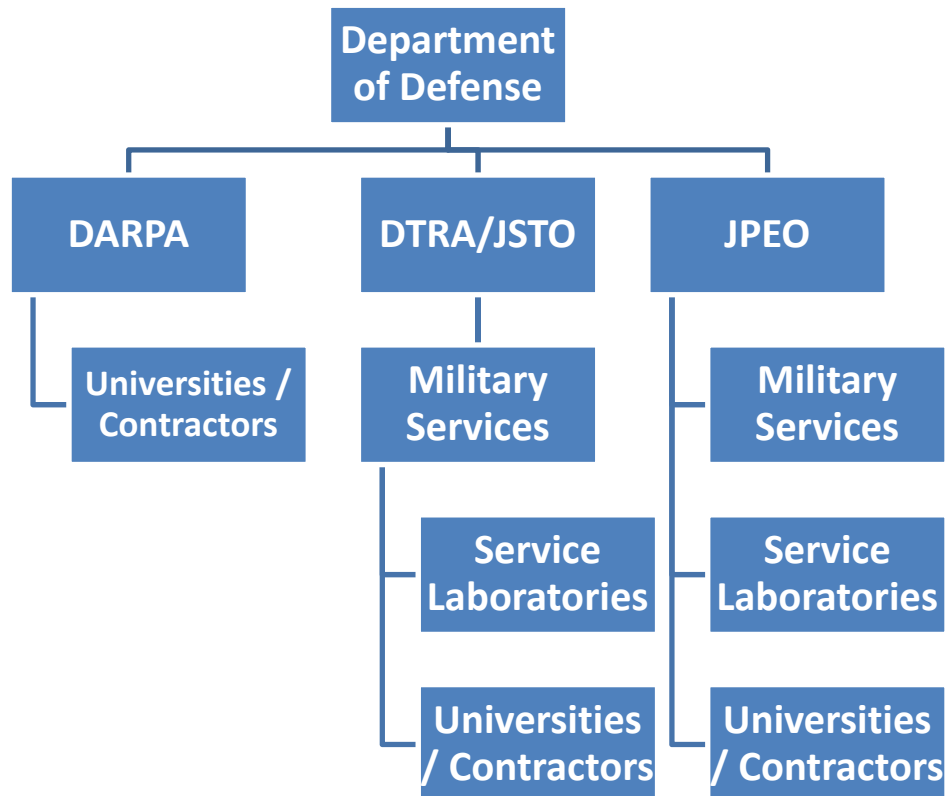
**4. If yes, what proportion of the total funds for each programme is expended in these contracted or other facilities?**

64 %

**5. Summarize the objectives and research areas of each programme performed by contractors and in other facilities with the funds identified under paragraph 4.**

- Provide support and world-class capabilities to protect the U.S. Armed Forces against biological warfare threats and emerging infectious diseases
- Development of medical countermeasure capabilities
- Development of vaccines and therapeutics
- Development of self-disinfecting and/or self-decontaminating materials
- Testing of detection and identification methods, protective equipment, and decontamination systems
- Development and testing of biological diagnostic detection systems

**6. Provide a diagram of the organizational structure of each programme and the reporting relationships (include individual facilities participating in the programme).**



**7. Provide a declaration in accordance with Form A, part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to each national biological defence research and development programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.**

- Air Force Research Laboratory (AFRL), Molecular Signatures (RHXBC)
- Lothar Salomon Test Facility (LSTF)
- Naval Medical Research Center (NMRC)
- Naval Research Laboratory (NRL)
- Naval Surface Warfare Center-Dahlgren Division Chemical, Biological, Radiological (CBR) Defense Laboratory
- U.S. Army Medical Research Institute of Chemical Defense (USAMRICD)
- U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)
- U.S. Army Edgewood Chemical and Biological Center

Note: In the 2013 U.S. CBM return, the Department of Defense reported three facilities that do not appear in the current return: Air Force Research Laboratory Materials and Manufacturing Directorate, Tyndall Air Force Base-1, and Tyndall Air Force Base-2. No biodefense research was conducted at Air Force Research Laboratory Materials and Manufacturing Directorate in 2013. Tyndall Air Force Base-1 was closed in 2013 and no biodefense research was conducted there in 2013. No biodefense research was conducted at Tyndall Air Force Base-2 in 2013.

**National biological defence research and development programmes: Description**

**1. State the objectives and funding of the programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.**

The Environmental Protection Agency (EPA)'s mission is to protect public health and the environment. The National Homeland Security Research Center (NHSRC), part of the EPA's Office of Research and Development, conducts and reports on research to improve capacity to respond to and recover from environmental contamination of water infrastructure, buildings and outdoor areas by chemical, biological, radiological and nuclear (CBRN) agents. The NHSRC biodefense program focuses on EPA's two biodefense responsibilities: 1) assistance in the protection of the American water supply, and 2) decontamination of indoor and outdoor areas should the U.S. suffer a contamination incident.

EPA is designated as the government's lead sector-specific agency for water, and is responsible for protecting water systems and detecting and recovering from terrorist attacks affecting them. EPA's homeland security research is responsible for developing products and providing expertise to protect, detect, respond to, and recover from terrorist attacks on the nation's water and wastewater infrastructure.

EPA is also the lead federal agency for the remediation of areas contaminated by terrorist events involving the release of biological organisms, biotoxins, chemical warfare agents, toxic industrial chemicals, toxic industrial materials, and radiological materials. Terrorist acts may involve biological, chemical, and radiological agents not previously encountered as environmental pollutants. EPA's homeland security research is responsible for providing procedures and methods that will assist EPA's responders in the detection and containment of contamination, and in the remediation of sites following terrorist attacks.

**2. State the total funding for the programme and its source.**

\$7,000,000      Environmental Protection Agency (EPA)

**3. Are aspects of the programme conducted under contract with industry, academic institutions, or in other non-defense facilities?**

Yes

**4. If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?**

31 %

**5. Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified in paragraph 4.**

NHSRC has research being conducted by contractors to assess risks of biological agents. Exposure studies are being conducted to estimate doses that result in adverse health effects from biological hazards. To address the need for remediating contaminated sites, NHSRC has been evaluating as well as developing analytical methods for biological agents.

**6. Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in this programme.)**



**7. Provide a declaration in accordance with Form A part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defense research programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.**

Not Applicable

**National biological defence research and development programmes: Description**

**1. State the objectives and funding of each programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research.**

Improving our nation's defenses against bioterrorism is a key part of the U.S. Government's homeland security effort. The Department of Health and Human Services (HHS) supports activities to improve local and state public health systems, to expand existing biosurveillance efforts, and to fund research on medical countermeasures against potential bioterror agents.

The National Institutes of Health (NIH) biodefense program is supported by funding from HHS. The NIH, and specifically the National Institute of Allergy and Infectious Diseases (NIAID), has the primary responsibility within the U.S. Government for civilian biodefense research. The intent of the program is to provide countermeasures to be used to protect the U.S. civilian population through the development of vaccines, therapeutic agents and rapid, agent-specific assays.

**2. State the total funding for each programme and its source.**

\$77,997,988     Department of Health and Human Services

**3. Are aspects of these programmes conducted under contract with industry, academic institutions, or in other non-defence facilities?**

Yes

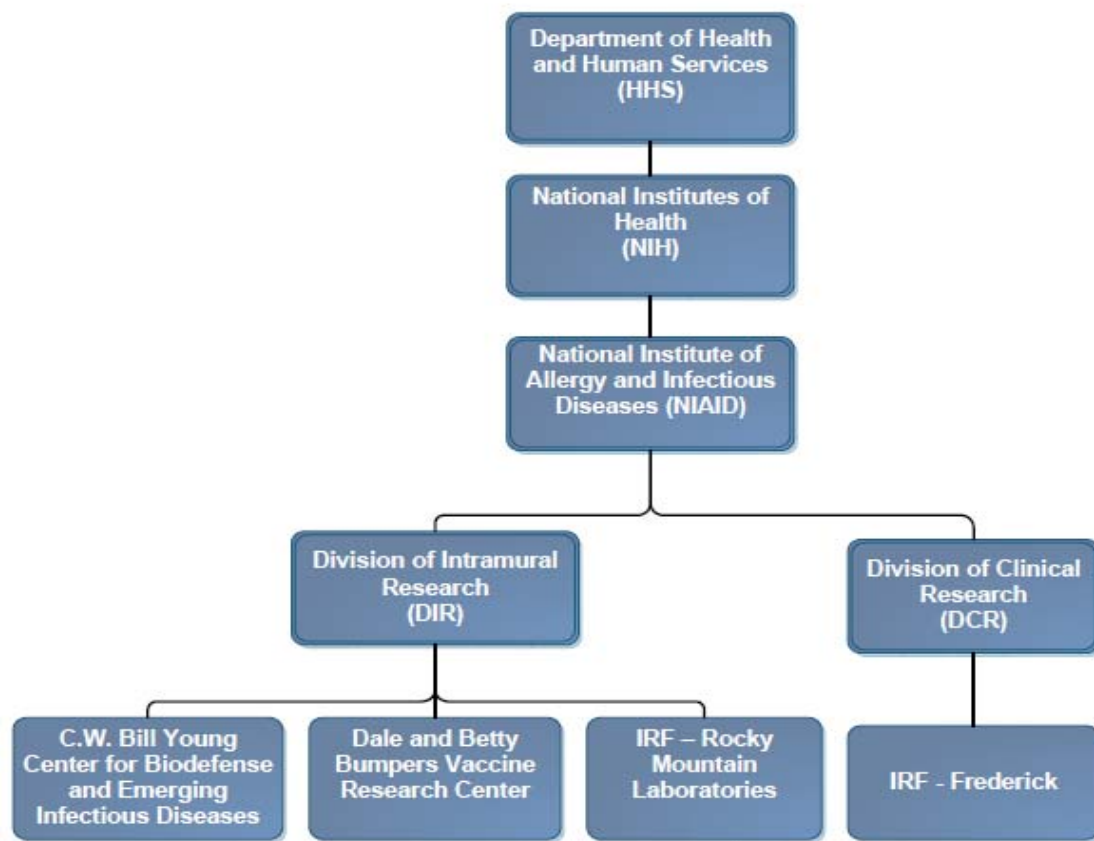
**4. If yes, what proportion of the total funds for each programme is expended in these contracted or other facilities?**

13%

**5. Summarize the objectives and research areas of each programme performed by contractors and in other facilities with the funds identified under paragraph 4.**

Battelle Memorial Institute facilitates scientific research at the IRF-Frederick, including refinement of animal models to facilitate countermeasure development, as directed by the IRF Scientific Steering Committee.

**6. Provide a diagram of the organizational structure of each programme and the reporting relationships (include individual facilities participating in the programme).**



**7. Provide a declaration in accordance with Form A, part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to each national biological defence research and development programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.**

- C.W. Bill Young Center for Biodefense and Emerging Infectious Diseases
- Dale and Betty Bumpers Vaccine Research Center
- Integrated Research Facility at Fort Detrick (IRF-Frederick)
- Integrated Research Facility at Rocky Mountain Laboratories (IRF-RML)

**National biological defence research and development programmes: Description**

**1. State the objectives and funding of each programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research.**

The objective of the Mass Spectrometry Toxin Laboratory and the Chemical Threats Method Development Laboratory within CDC's National Center for Environmental Health, Division of Laboratory Sciences is to develop toxin assays that are critical for better detection and diagnosis during a public health response to biological toxins.

**2. State the total funding for each programme and its source.**

\$2,310,316      Department of Health and Human Services

**3. Are aspects of these programmes conducted under contract with industry, academic institutions, or in other non-defence facilities?**

No

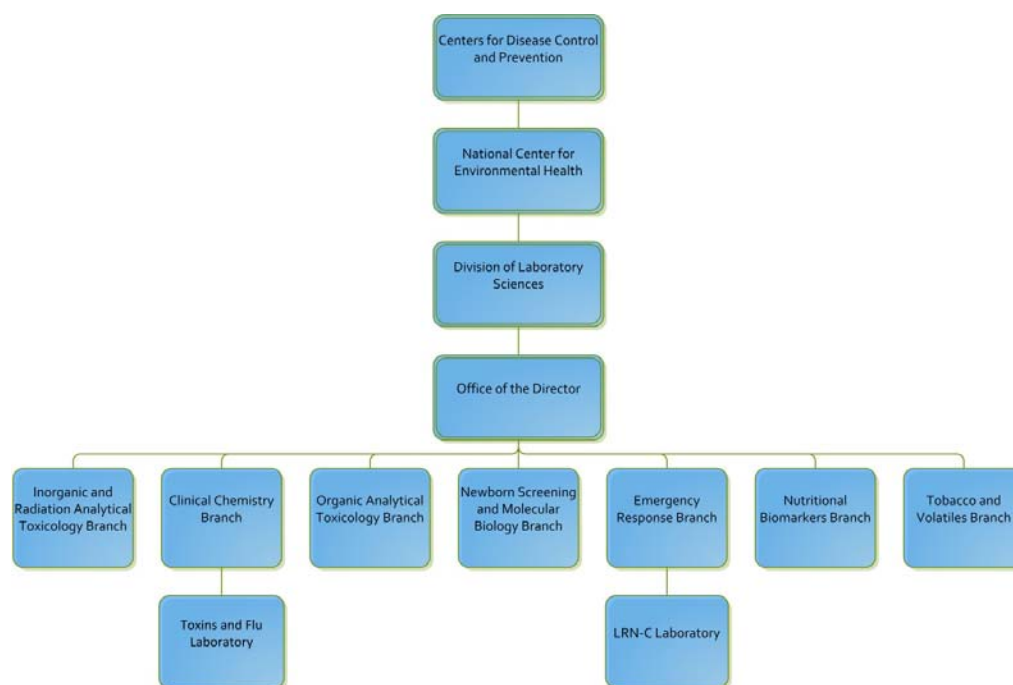
**4. If yes, what proportion of the total funds for each programme is expended in these contracted or other facilities?**

N/A

**5. Summarize the objectives and research areas of each programme performed by contractors and in other facilities with the funds identified under paragraph 4.**

N/A

**6. Provide a diagram of the organizational structure of each programme and the reporting relationships (include individual facilities participating in the programme).**



**7. Provide a declaration in accordance with Form A, part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to each national biological defence research and development programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.**

- CDC, National Center for Environmental Health (NCEH), Division of Laboratory Sciences (DLS)

**National biological defence research and development programmes: Description**

**1. State the objectives and funding of each programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research.**

The activities of the CDC Office of Infectious Disease (OID) include developing diagnostic assays for public health, conducting molecular and antigenic characterization of microorganisms, evaluating decontamination methods, determining pathogenicity and virulence of infectious agents, determining the natural history of infectious organisms, and conducting epidemiologic studies and surveillance for diseases. Biodefense activities include those with select agents

(<http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20List.html>). OID includes the National Center for Emerging Zoonotic Infectious Diseases (NCEZID) and the National Center for Immunization and Respiratory Diseases (NCIRD).

**2. State the total funding for each programme and its source.**

\$24,526,348     Department of Health and Human Services

**3. Are aspects of these programmes conducted under contract with industry, academic institutions, or in other non-defence facilities?**

Yes

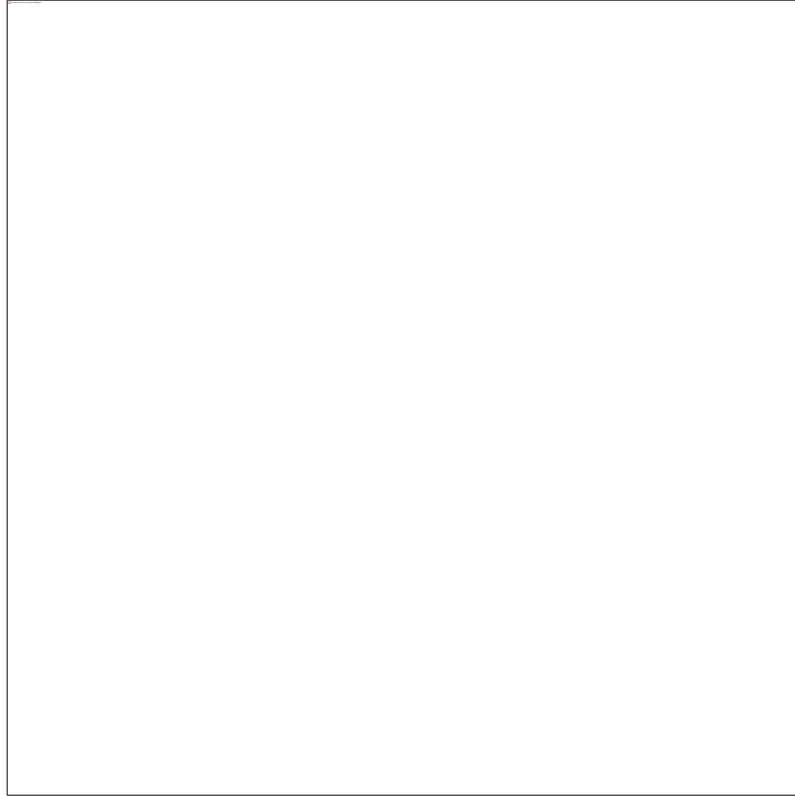
**4. If yes, what proportion of the total funds for each programme is expended in these contracted or other facilities?**

5 %

**5. Summarize the objectives and research areas of each programme performed by contractors and in other facilities with the funds identified under paragraph 4.**

Vaccine efficacy trials, reagent development, bioterrorism preparedness and response activities, avian influenza preparedness, and disease surveillance in CDC field locations.

**6. Provide a diagram of the organizational structure of each programme and the reporting relationships (include individual facilities participating in the programme).**



**7. Provide a declaration in accordance with Form A, part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to each national biological defence research and development programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.**

- CDC, OID, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Vector Borne Diseases (DVBD) - Ft. Collins
- CDC, Office of Infectious Diseases (OID)

**National biological defence research and development programmes: Description**

**1. State the objectives and funding of the programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.**

**Background**

Foreign animal diseases represent a major threat to U.S. agriculture. Introduction of these agents, either accidental or deliberate, has devastating social and economic effects not only in the country's agricultural systems but also in a wide range of economic activities. Diseases of concern include but are not limited to Foot-and-Mouth Disease, Avian Influenza, Rift Valley Fever, Classical Swine Fever, African Swine Fever, Exotic Newcastle disease, Vesicular stomatitis, and Exotic Bluetongue.

Animal health officials define an exotic or foreign animal disease (FAD) as an important transmissible livestock or poultry disease believed to be absent from the U.S. and its territories that has a potential significant health or economic impact. Foreign animal diseases are considered a threat to the U.S. when they significantly affect human health or animal production and when there is an appreciable cost associated with disease control and eradication efforts. To protect the long-term health and profitability of U.S. animal agriculture, incursions of a FAD must be rapidly controlled.

In the U.S., control usually means disease eradication. Disease eradication is currently accomplished by eliminating the animal, resulting in loss of protein, loss of income to the farm community, public opposition and environmental disruption. In addition to control costs, one of the most immediate and severe consequences of a FAD occurrence in the U.S. will be the loss of export markets. As we move into the 21st century, many new issues and factors are affecting FAD prevention, control, management, and recovery. These factors include free trade agreements, free trade blocks, regionalization, increased international passenger travel, intensification of animal production, the constant evolution of infectious agents, and the uncertain impact of biotechnology and bioterrorism.

Current methods for prevention and control of high consequence diseases, including prevention, detection, control and eradication, are not socially or economically acceptable. Rapid detection and characterization tools for prevention, control and eradication of foreign animal diseases are inadequate or not currently available. Our understanding of pathogenesis, transmission, and immune response is insufficient to rapidly control and eradicate foreign animal diseases. Effective measures to prevent, control and eradicate foreign animal diseases are lacking or inadequate.

**Strategic Objectives**

- Establish Agriculture Research Service (ARS) laboratories into a fluid, highly effective research network, to maximize use of core competencies and resources
- Access to specialized high containment facilities to study zoonotic and emerging diseases
- Develop an integrated animal and microbial genomics research program
- Establish centers of excellence in animal immunology
- Launch a biotherapeutic discovery research program providing alternative strategies to prevent and treat infectious diseases
- Build a technology-driven vaccine and diagnostic discovery research program
- Develop core competencies in field epidemiology and predictive biology
- Develop internationally recognized OIE expert collaborative research laboratories
- Establish best in class training center for our nation's veterinarians and scientists
- Develop a model technology transfer program to achieve the full impact of our research discoveries

**Research Needs**

In order to control foreign animal disease, a wide variety of agent detection platforms need to be developed and validated. Information for design of these platforms will come in part from further knowledge of pathogen genomics and proteomics and in part from understanding the evolution and genetic variability of disease agents. Although many of the foreign animal diseases have existed for many years in many countries there is still much more fundamental knowledge of these agents that is required.

There is still a lack of understanding of what drives host range specificity and tissue tropism, carrier state, duration and routes of shedding, transmission mechanisms, (e.g. vectors, fomites, aerosols), ecology and epidemiology (e.g., wildlife reservoirs). If these diseases should occur in the U.S. more effective prevention and control tools such as identifying suitable control strategies compatible with short time recovery from disease outbreaks need to be developed. There is a need for development of vaccines and biotherapeutics suitable for strategic stockpiles, integrated methods of disease control including vector control and animal management, which all lead to a better capability to regain country disease-free status and retain economic sustainability.

**Expected Outputs:**

- Better anticipation of introduction of foreign animal diseases
- Capability to advise regulatory officials on scientific procedures for the prevention of introduction of FADs
- Better capability to produce effective products to control and eliminate foreign animal diseases
- Real-time detection of agents in a wide range of farm matrices
- Searchable databases of genome and proteome information for major known FAD agents
- Improved ability to predict or anticipate emergence or introduction of FAD agents
- Discovery of effective candidate biotherapeutics
- Discovery of effective candidate vaccines that allow differentiation of infected animals from vaccinated animals (DIVA)
- Viable integrated vector control strategies that minimize losses

The USDA-ARS biodefense research program is intramural and implemented in ARS high containment facilities in the following locations: Ames, Iowa; Orient Point, New York; Athens, Georgia; Frederick, Maryland.

**2. State the total funding for the programme and its source.**

\$14,800,000 U.S. Department of Agriculture (USDA)

**3. Are aspects of the programme conducted under contract with industry, academic institutions, or in other non-defence facilities?**

No

**4. If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?**

Not Applicable

**5. Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified in paragraph 4.**

Not Applicable

**6. Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in this programme.)**



**7. Provide a declaration in accordance with Form A part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defence research programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.**

- Foreign Disease-Weed Science Research Unit
- Plum Island Animal Disease Center (PIADC)
- Southeast Poultry Research Laboratory
- National Animal Disease Center (NADC)

**National biological defence research and development programmes: Description**

**1. State the objectives and funding of the programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.**

The Biological Countermeasures Program in the Science and Technology (S&T) Directorate of the Department of Homeland Security (DHS) is broken into three research and development categories: Bioagent Detection, Bioagent Threat Assessment, and Bioagent Attack Resiliency. The goal of the program is to leverage emerging technologies to protect against biological attacks targeting the U.S. population, agriculture, or infrastructure. The program focuses on biological countermeasures research, development, testing, and evaluation (RDT&E) efforts, and on the transition of resultant technologies to operational use. The five main areas of study are: 1) systems studies and decision support tools, 2) threat awareness, 3) surveillance and detection research and development (R&D), 4) forensics, and 5) response and restoration. The program supports other U.S. Federal agencies in overall coordination of national biodefense efforts.

Efforts conducted during 2013 include comprehensive threat and risk assessments to guide prioritization of the Nation's biodefense investments, biodefense knowledge management, the development of next-generation detectors for biological threat agents for critical infrastructure and urban areas, decontamination of transit systems, and bioforensics research in support of criminal investigations and attribution. Efforts at the National Biodefense Analysis and Countermeasures Center (NBACC) included biological threat characterization, development of response plans and risk communication; and at the Plum Island Animal Disease Center, development of vaccines and diagnostics for foreign animal diseases.

The DHS Compliance Review Group, chaired by the DHS Deputy Secretary, reviews all DHS-funded biological defense projects for compliance with the provisions of the Biological Weapons Convention and associated U.S. domestic laws and policies.

**2. State the total funding for the programme and its source.**

\$108,000,000 U.S. Department of Homeland Security (DHS)

**3. Are aspects of the programme conducted under contract with industry, academic institutions, or in other non-defence facilities?**

Yes

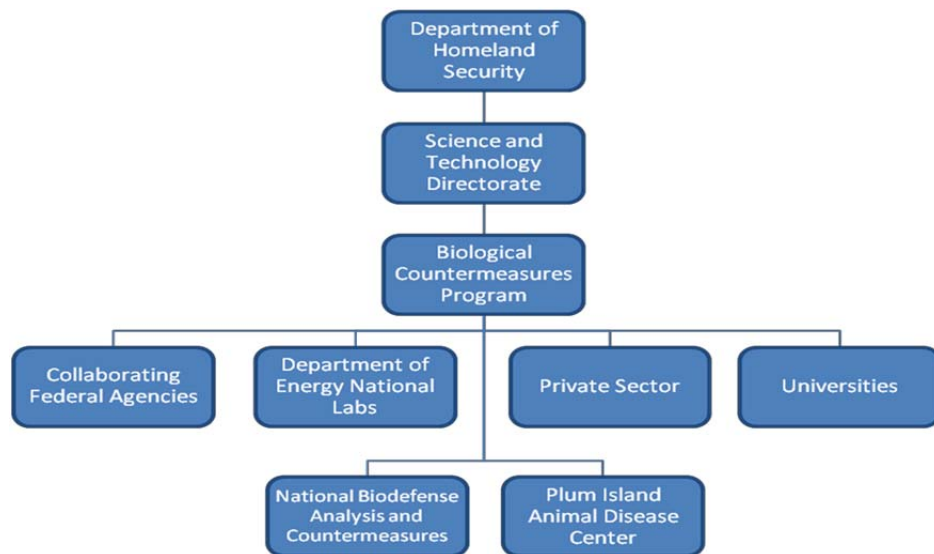
**4. If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?**

100 %

**5. Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified in paragraph 4.**

Same as response to Question 1 above

**6. Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in this programme).**



**7. Provide a declaration in accordance with Form A part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defence research programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.**

- National Biodefense Analysis and Countermeasures Center (NBACC)
- Plum Island Animal Disease Center (PIADC)

**Form A, Part 2 (iii)**

**BWC - Confidence Building Measure**

**National biological defence research and development programmes - Facilities**

United States of America

April 15, 2014

**National biological defence research and development programme**

The U.S. Government identified potential concerns associated with public release of information regarding highly pathogenic microorganisms and toxins at specific facilities. To balance these concerns with a desire to promote transparency, the U.S. public CBM return characterizes microorganisms and toxins studied at each facility on Form A, Part 2 (iii) as Select Agents and/or NIAID Category A pathogens. Furthermore, Appendix B lists the specific microorganisms and toxins studied for biodefense research and development at *all* facilities reported on Form A, part 2 (iii) below.

To maintain a high level of transparency to States Parties, the U.S. makes available, via the restricted-access portion of the ISU website, a Supplement containing information on microorganisms and toxins studied at each individual facility reported on Form A, part 2 (iii).

As stated in the U.S. working paper for the 2013 Meeting of Experts (BWC/MSP/2013/MX/WP.X), “the United States will report microorganisms and toxins that appear on either the Select Agent or the National Institute of Allergy and Infectious Diseases (NIAID) Category A pathogen lists, beginning in 2014.” These lists are reproduced in Appendix A for reference.

Biological Select Agents and Toxins (Select Agents) are biological agents or toxins that have the potential to pose a severe threat to public, animal or plant health, or to animal or plant products. Possession, use and transfer of Select Agents are regulated by the Select Agent Rules. Detailed information on Select Agents and their regulation can be found at: <http://www.selectagents.gov>.

The NIAID designated Category A pathogens as priorities for additional research efforts as part of the NIAID biodefense research agenda. Detailed information about NIAID Category A pathogens can be found at: <http://www.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/Pages/CatA.aspx>.

**National biological defence research and development programmes: Facilities**

**1. What is the name of the facility?**

National Biodefense Analysis and Countermeasures Center (NBACC)

**2. Where is it located (provide both address and geographical location)?**

8300 Research Plaza, Fort Detrick, Maryland 21702

**3. Floor area of laboratory areas by containment level:**

BSL-2: 1282 m<sup>2</sup>

BSL-3: 2564 m<sup>2</sup>

BSL-4: 980 m<sup>2</sup>

Total laboratory floor area: 4826 m<sup>2</sup>

**4. The organizational structure of each facility:**

**(i) Total number of personnel** 151

**(ii) Division of personnel:**

Military	0
Civilian	151

**(iii) Division of personnel by category:**

Scientists	30
Engineers	35
Technicians	49
Administrative and support staff	37

**(iv) List the scientific disciplines represented in the scientific/engineering staff:**

Aerobiology, Bacteriology, Biochemistry, Bioinformatics, Biological Science, Biomedical Science, Biophysics, Biotechnology, Cell Biology, Chemistry, Computer Science, Genetics, Immunology, Molecular Biology, Toxicology, Veterinary Medicine, Virology

**(v) Are contractor staff working in the facility? If so, provide an approximate number:**

Yes Number: 151

**(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Homeland Security (DHS)

U.S. Department of Justice (DOJ)

U.S. Department of Defense (DOD) - partly

**(vii) What are the funding levels for the following program areas:**

Research	\$3,615,074
Development	\$8,065,690
Test and evaluation	\$0
Total	\$11,680,764

**(viii) Briefly describe the publication policy of the facility:**

The NBACC publication policy is to present research results to the greater scientific community as widely as possible. As a Federally Funded Research and Development Center engaged in research with select agents/regulated pathogens, NBACC has established a formal, multi-tiered review system to ensure compliance and conformance with U.S. Government regulations including export control regulations under EAR/ITAR, the Biological Weapons Convention, and internal U.S. Department of Homeland Security (DHS) policies. Prior to submittal to journals or release, all publications are reviewed by NBACC and DHS for security, clarity, and accuracy with regard to the description of the work.

**(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)**

1. Bradnam KR, Fass JN, Alexandrov A, Baranay P, et al. Assemblathon 2: evaluating de novo methods of genome assembly in three vertebrate species. *Gigascience*. 2013 Jul 22; 2(1):10. <http://www.gigasciencejournal.com/content/2/1/10>
2. Colella J, Johnson B, Fitch JP, Weaver P. The endurance testing process: a methodology to verify the functionality of biocontainment, security, and life safety systems in BSL-3 and BSL-4 laboratories. *Appl Biosaf*. 2013 Mar 30; 18(1):18-23. <http://www.absa.org/pubabjindex.html>
3. Ghodsi M, Hill CM, Astrovskaya I, Lin H, Sommer DD, Koren S, Pop M. De novo likelihood-based measures for comparing genome assemblies. *BMC Res Notes*. 2013 Aug 22; 6:334. <http://www.biomedcentral.com/1756-0500/6/334>
4. Harhay GP, Koren S, Phillippy AM, McVey DS, Kuszak J, Clawson ML, Harhay DM, Heaton MP, Chitko-McKown CG, Smith TP. Complete closed genome sequence of *Mannheimia haemolytica* serotypes A1 and A6 isolated from cattle. *Genome Announc*. 2013 May 16; 1(3). pii: e00188-13. <http://genomea.asm.org/content/1/3/e00188-13.full>
5. Harrington R, Ondov BD, Radune D, Friss MB, Klubnik J, Diviak L, Hnath J, Cendrowski SR, Blank TE, Karaolis D, Friedlander AM, Burans JP, Rosovitz MJ, Treangen TJ, Phillippy AM, Bergman NH. Genome sequence of the attenuated carboxap vaccine strain of *Bacillus anthracis*. *Genome Announc*. 2013 Jan 15; 1(1). pii: e00067-12. doi: 10.1128/genomeA.00067-12. <http://genomea.asm.org/content/1/1/e00067-12.full?sid=abee6c29-b34d-4df5-af2b-6649f1e25138>
6. Higgins JJ, Weaver P, Fitch JP, Johnson B, Pearl RM. Implementation of a personnel reliability program as a facilitator of biosafety and biosecurity culture in BSL-3 and BSL-4 laboratories. *Biosecur Bioterror*. 2013 Jun 7; 11(2): 130-7. doi: 10.1089/bsp.2013.0024. <http://online.liebertpub.com/doi/abs/10.1089/bsp.2013.0024>
7. Koren S, Harhay GP, Smith TP, Bono JL, Harhay DM, Mcvey DS, Radune D, Bergman NH, Phillippy AM. Reducing assembly complexity of microbial genomes with single-molecule sequencing. *Genome Biol*. 2013 Sep 13; 14(9):R101. <http://genomebiology.com/2013/14/9/R101>
8. Motley ST, Redden CL, Sannes-Lowery KS, Eshoo MW, Hofstadler SA, Burans JP, Rosovitz MJ. Differentiating microbial forensic qPCR target and control products by electrospray ionization mass spectrometry. 2013 May 15; 11(2):107-17. doi: 10.1089/bsp.2012.0062. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3696942/>
9. Treangen TJ, Koren S, Sommer DD, Liu B, Astrovskaya I, Ondov B, Darling AE, Phillippy AM, Pop M. MetAMOS: a modular and open source metagenomic assembly and analysis pipeline. *Genome Biol*. 2013 Jan 15; 14(1):R2. <http://genomebiology.com/2013/14/1/R2>
10. \*\*Treangen TJ, Phillippy AM. Irreconcilable differences: divorcing geographic mutation and recombination rates within a global MRSA clone. *Genome Biol*. 2012 Dec 27; 13(12):181. <http://genomebiology.com/2012/13/12/181>

**5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms<sup>4</sup> and/or toxins studied, as well as outdoor studies of biological aerosols:**

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<sup>4</sup> Including viruses and prions.

**Objectives:** The NBACC mission is to provide the nation with the scientific basis for characterization of biological threats and bioforensic analysis to support attribution investigations. NBACC conducts studies to fill in information gaps to better understand current and future biological threats; to assess vulnerabilities; and to determine potential impacts to guide the development of biological countermeasures such as detectors, drugs, vaccines, and decontamination technologies. When needed, NBACC conducts experimental programs to better characterize the benefits and risks of changes in U.S. biodefense preparations. NBACC also develops bioforensic assays and provides operational bioforensic analysis to support the attribution of biocrime and bioterrorism.

**Microorganisms and/or toxins studied:** Select Agents, NIAID Category A pathogens, Simulants

**Outdoor Studies:** No outdoor studies performed

\*\* Note: This 2012 publication was inadvertently omitted from the 2013 U.S. CBM Return and is therefore included here for the sake of completeness.

**National biological defence research and development programmes: Facilities**

**1. What is the name of the facility?**

Plum Island Animal Disease Center (PIADC)

**2. Where is it located (provide both address and geographical location)?**

40550 Route 25, Orient Point, New York 11957

**3. Floor area of laboratory areas by containment level:**

BSL-2: 292 m<sup>2</sup>

BSL-3: 18,046 m<sup>2</sup>

Total laboratory floor area: 18,338 m<sup>2</sup>

**4. The organizational structure of each facility:**

**(i) Total number of personnel** 411

**(ii) Division of personnel:**

Military 0

Civilian 411

**(iii) Division of personnel by category:**

Scientists 102

Engineers 5

Technicians 26

Administrative and support staff 278

**(iv) List the scientific disciplines represented in the scientific/engineering staff:**

Biological science, Chemistry, Electrical Engineering, Facility Engineering, Microbiology, Molecular Biology, Computational Biology, Pathology, Veterinary Medicine

**(v) Are contractor staff working in the facility? If so, provide an approximate number:**

Yes Number: 268

**(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Agriculture (USDA)

U.S. Department of Homeland Security (DHS)

**(vii) What are the funding levels for the following program areas:**

Research \$8,000,000

Development \$10,500,000

Test and evaluation \$5,000,000

Total \$23,500,000

**(viii) Briefly describe the publication policy of the facility:**

Publications are peer reviewed and approved by USDA or DHS for security, clarity, and accuracy with regard to the description of work prior to submittal to journals or release. USDA Agricultural Research Service (ARS) has several publication policies: 1) Policy Number 150.1 "Dissemination of Public Information by ARS," <http://www.afm.ars.usda.gov/ppweb/PDF/150-01.pdf>; 2) Number 113.1 "Publishing (Print and Electronic)," [www.afm.ars.usda.gov/ppweb/2010/113-1-ARS.pdf](http://www.afm.ars.usda.gov/ppweb/2010/113-1-ARS.pdf); and 3) Number

152.1 "Procedures for Publishing Manuscripts and Abstracts with Non-USDA Publishers (Outside Publishing)," <http://www.afm.ars.usda.gov/ppweb/pdf/152-01.pdf>.

**(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)**

Animal and Plant Health Inspection Service (APHIS):

1. Bracht AJ, Armien AG, Carrillo C, O'Hearn ES, Fabian AW, Moran KE, Lu Z, Ariyakumer DS, Rasmussen JM, Metwally SA. Isolation and characterization of a Cervidpoxvirus from a goitered gazelle (*Gazella subgutturosa*) from a zoologic park in Minnesota. J Zoo Wildl Med. 2013 Sep; 44(3):589-95. <http://dx.doi.org/10.1638/2012-0090R2.1>
2. Ehizibolo DO, Perez AM, Carrillo C, Pauszek SJ, Alkhamis M, Ajogi I, Umoh JU, Kazeem HM, Ehizibolo PO, Fabian AW, Berninger M, Moran KE, Rodriguez LL, Metwally SA. Epidemiological Analysis, Serological Prevalence and Genotypic Analysis of Foot-and-Mouth Disease in Nigeria 2008-2009. Transbound Emerg Dis. 2013 Jan 24.[Epub ahead of print] doi: 10.1111/tbed.12054. <http://www.ncbi.nlm.nih.gov/pubmed/?term=Epidemiological+Analysis%2C+Serological+Prevalence+and+Genotypic+Analysis+of+Foot-and-Mouth+Disease+in+Nigeria+2008-2009>
3. Ventura A, Gonzalez W, Barrette RW, Swenson SL, Bracht AJ, Rowland J, Fabian AW, Moran KE, Mohamed F, O'Hearn ES, Jenkins-Moore M, Toms D, Shaw J, Morales P, Pyburn D, Carrillo C, Mayr GA, McIntosh MT, Deng MY. Virus and Antibody Diagnostics for Swine Samples of the Dominican Republic Collected in Regions Near the Border to Haiti. ISRN Virology. Volume 2013 (2013), Article ID 425831, 7 pages <http://dx.doi.org/10.5402/2013/425831>
4. Xu L, Hurtle W, Rowland JM, Casteran KA, Bucko SM, Grau FR, Valdazo-González B, Knowles NJ, King DP, Beckham TR, McIntosh MT. Development of a universal RT-PCR for amplifying and sequencing the leader and capsid-coding region of foot-and-mouth disease virus. J Virol Methods. 2013 Feb 1; 189(1):70-6. doi: 10.1016/j.jviromet.2013.01.009. <http://dx.doi.org/10.1016/j.jviromet.2013.01.009>

Agricultural Research Services (ARS):

5. Alejo DM, Moraes MP, Liao X, Dias CC, Tulman ER, Diaz-San Segundo F, Rood D, Grubman MJ, Silbart LK. An adenovirus vectored mucosal adjuvant augments protection of mice immunized intranasally with an adenovirus-vectored foot-and-mouth disease virus subunit vaccine. Vaccine. 2013 Mar 13; 31(18):2302-9. doi: 10.1016/j.vaccine.2013.02.060. <http://dx.doi.org/10.1016/j.vaccine.2013.02.060>
6. Di Giacomo S, Brito BP, Perez AM, Bucafusco D, Pega J, Rodriguez LL, Borca MV, Pérez-Filgueira M. Heterogeneity in the antibody response to foot-and-mouth disease primo-vaccinated calves. Transbound Emerg Dis. 2013 Jul 30. doi: 10.1111/tbed.12130. <http://onlinelibrary.wiley.com/doi/10.1111/tbed.12130/pdf>
7. Diaz-San Segundo F, Dias CC, Moraes MP, Weiss M, Perez-Martin E, Owens G, Custer M, Kamrud K, de los Santos T, Grubman MJ. Venezuelan equine encephalitis replicon particles can induce rapid protection against foot-and-mouth disease virus. J Virol. 2013 Mar 6; 87(10):5447-60. doi: 10.1128/JVI.03462-12. <http://jvi.asm.org/content/early/2013/02/28/JVI.03462-12.full.pdf+html>
8. Diaz-San Segundo F, Montiel N, de los Santos T, Grubman MJ. Understanding the mechanisms of interferon-induced protection against foot-and-mouth disease. Virology II – Advanced Issues. iConcept Press; 2013. <http://www.iconceptpress.com/download/paper/12053121304244.pdf>
9. Gladue DP, O'Donnell V, Baker-Branstetter R, Holinka LG, Pacheco JM, Fernández-Sainz I, Lu Z, Ambroggio X, Rodriguez LL, Borca MV. Foot-and-mouth disease virus modulates cellular vimentin for virus survival. J Virol. 2013 Apr 10; 87(12):6794-803. doi: 10.1128/JVI.00448-13. <http://jvi.asm.org/content/early/2013/04/04/JVI.00448-13.full.pdf>
10. Grubman MJ, de los Santos T. Foot-and-mouth disease virus L peptidase. In: Rawlings ND, Salvesen GS, editors. Handbook of Proteolytic Enzymes. 3rd ed. Oxford, UK: Academic Press; 2013. p. 2183-2186. <http://dx.doi.org/10.1016/B978-0-12-382219-2.00490-7>

11. Howey EB, O'Donnell V, de Carvalho Ferreira HC, Borca MV, Arzt J. Pathogenesis of highly virulent African swine fever virus in domestic pigs exposed via intraoropharyngeal, intranasopharyngeal, and intramuscular inoculation, and by direct contact with infected pigs. *Virus Res.* 2013 Sep 26; 178(2):328-39. doi: 10.1016/j.virusres.2013.09.024. <http://dx.doi.org/10.1016/j.virusres.2013.09.024>
12. LaRocco M, Krug PW, Kramer E, Ahmed Z, Pacheco JM, Duque H, Baxt B, Rodriguez LL. A continuous bovine kidney cell line constitutively expressing bovine alphaV-beta6 integrin has increased susceptibility to foot-and-mouth disease virus. *J Clin Microbiol.* 2013 Mar 20; 51(6):1714-20. doi: 10.1128/JCM.03370-12. <http://jcm.asm.org/content/51/6/1714.full.pdf+html>
13. Lawrence P, LaRocco M, Baxt B, Rieder E. Examination of soluble integrin resistant mutants of foot-and-mouth disease virus. *Virol J.* 2013 Jan 2; 10:2. doi: 10.1186/1743-422X-10-2. <http://www.virologyj.com/content/pdf/1743-422X-10-2.pdf>
14. Lawrence P, Pacheco JM, Uddowla S, Hollister J, Kotecha A, Fry E, Rieder E. Foot-and-mouth disease virus with a stable FLAG epitope in the VP1 G-H loop as a new tool for studying FMDV pathogenesis. *Virology.* 2013 Feb 5; 436(1):150-61. doi: 10.1016/j.virol.2012.11.001. <http://dx.doi.org/10.1016/j.virol.2012.11.001>
15. Loughran G, Libbey JE, Uddowla S, Scallan MF, Ryan MD, Fujinami RS, Rieder E, Atkins JF. Theiler's murine encephalomyelitis virus contrasts with encephalomyocarditis and foot-and-mouth disease viruses in its functional utilization of the StopGo non-standard translation mechanism. *J Gen Virol.* 2013 Feb; 94(Pt 2):348-53. doi: 10.1099/vir.0.047571-0. [http://vir.sgmjournals.org/content/94/Pt\\_2/348.full.pdf+html](http://vir.sgmjournals.org/content/94/Pt_2/348.full.pdf+html)
16. Ludi A, Rodriguez LL. Novel approaches to foot-and-mouth disease vaccine development. *Dev Biol (Basel).* 2013 May 14; 135:107-16. doi: 10.1159/000313913. <http://www.karger.com/Article/Pdf/313913>
17. Maree FF, Blignaut B, de Beer TA, Rieder E. Analysis of SAT type foot-and-mouth disease virus capsid proteins and the identification of putative amino acid residues affecting virus stability. *PLoS One.* 2013 May 22; 8(5):e61612. doi: 10.1371/journal.pone.0061612. <http://dx.plos.org/10.1371/journal.pone.0061612>
18. Montiel NA, Smoliga GR, Arzt J. Time-dependent biodistribution and transgene expression of a recombinant human adenovirus serotype 5-luciferase vector as a surrogate for rAd5-FMDV vaccines in cattle. *Vet Immunol Immunopathol.* 2013 Jan 15; 151(1-2):37-48. doi: 10.1016/j.vetimm.2012.10.003. <http://dx.doi.org/10.1016/j.vetimm.2012.10.003>
19. Pacheco JM, Gladue DP, Holinka LG, Arzt J, Bishop E, Smoliga GR, Pauszek SJ, Bracht AJ, O'Donnell V, Fernández-Sainz I, Fletcher P, Piccone ME, Rodriguez LL, Borca MV. A partial deletion in non-structural protein 3A can attenuate foot-and-mouth disease virus in cattle. *Virology.* 2013 Sep 6; 446(1-2):260-7. doi: 10.1016/j.virol.2013.08.003. <http://dx.doi.org/10.1016/j.virol.2013.08.003>
20. Patch JR, Kenney M, Pacheco JM, Grubman MJ, Golde WT. Characterization of cytotoxic T lymphocyte function after foot-and-mouth disease virus infection and vaccination. *Viral Immunol.* 2013 Jul 5; 26(4):239-49. doi: 10.1089/vim.2013.0011. <http://dx.doi.org/10.1089/vim.2013.0011>
21. Pedersen LE, Harndahl M, Nielsen M, Patch JR, Jungersen G, Buus S, Golde WT. Identification of peptides from foot-and-mouth disease virus structural proteins bound by class I swine leukocyte antigen (SLA) alleles, SLA-1\*0401 and SLA-2\*0401. *Anim Genet.* 2013 Jun; 44(3):251-8. doi: 10.1111/j.1365-2052.2012.02400.x. <http://www.ncbi.nlm.nih.gov/pubmed/22984928>
22. Pega J, Bucafusco D, Di Giacomo S, Schammas JM, Malacari D, Capozzo AV, Arzt J, Pérez-Beascochea C, Maradei E, Rodriguez LL, Borca MV, Pérez-Filgueira M. Early adaptive immune responses in the respiratory tract of foot-and-mouth disease virus-infected cattle. *J Virol.* 2013 Mar; 87(5):2489-95. doi: 10.1128/JVI.02879-12. <http://jvi.asm.org/content/87/5/2489.full.pdf+html>
23. Rai DK, Schafer EA, Singh K, McIntosh MA, Sarafianos SG, Rieder E. Repeated exposure to 5D9, an inhibitor of 3D polymerase, effectively limits the replication of foot-and-mouth disease virus in

host cells. *Antiviral Res.* 2013 Apr 8; 98(3):380-5. doi: 10.1016/j.antiviral.2013.03.022.  
<http://dx.doi.org/10.1016/j.antiviral.2013.03.022>

24. Toka FN, Golde WT. Cell mediated innate responses of cattle and swine are diverse during foot-and-mouth disease virus (FMDV) infection: a unique landscape of innate immunity. *Immunol Lett.* 2013 May 30; 152(2):135-43. doi: 10.1016/j.imlet.2013.05.007.  
<http://dx.doi.org/10.1016/j.imlet.2013.05.007>
25. Uddowla S, Pacheco JM, Larson C, Bishop E, Rodriguez LL, Rai DK, Arzt J, Rieder E. Characterization of a chimeric foot-and-mouth disease virus bearing a bovine rhinitis B virus leader proteinase. *Virology.* 2013 Oct 1; 447(1-2):172-80. doi: 10.1016/j.virol.2013.08.035.  
<http://dx.doi.org/10.1016/j.virol.2013.08.035>
26. Zhu JJ, Arzt J, Puckette MC, Smoliga GR, Pacheco JM, Rodriguez LL. Mechanisms of foot-and-mouth disease virus tropism inferred from differential tissue gene expression. *PLoS One.* 2013 May 28; 8(5):e64119. doi: 10.1371/journal.pone.0064119.  
<http://dx.plos.org/10.1371/journal.pone.0064119>

Department of Homeland Security (DHS):

27. Colby M, Coats M, Brake DA, Fine J. The role of the Department of Homeland Security, Science and Technology Directorate in the development of vaccines and diagnostics for Transboundary Animal Diseases. *Dev Biol (Basel).* 2013 May 14; 135:3-14. doi: 10.1159/000265588.  
<http://www.karger.com/Article/Pdf/265588>

**5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms<sup>4</sup> and/or toxins studied, as well as outdoor studies of biological aerosols.**

**Objectives:** PIADC provides the only research and development and confirmatory diagnostic capability for specific high-consequence, contagious, foreign animal diseases of livestock, including foot-and-mouth disease, in the U.S. Technologies researched and developed are vaccines, antivirals and diagnostic methods.

**Microorganisms and/or toxins studied:** Select Agents

**Outdoor Studies:** None

**National biological defence research and development programmes: Facilities**

**1. What is the name of the facility?**

Air Force Research Laboratory (AFRL), Molecular Signatures (RHXBC)

**2. Where is it located (provide both address and geographical location)?**

2510 Fifth Street, Building 840 W215.01, Wright-Patterson Air Force Base, Ohio 45433

Research conducted at leased facility: 231 Albert Sabin Way, Cincinnati, OH 45267

**3. Floor area of laboratory areas by containment level:**

BSL-2 120 m<sup>2</sup>

BSL-3 250 m<sup>2</sup>

BSL-4 0 m<sup>2</sup>

Total laboratory floor area 370 m<sup>2</sup>

**4. The organizational structure of each facility.**

**(i) Total number of personnel** 16

**(ii) Division of personnel:**

Military 0

Civilian 16

**(iii) Division of personnel by category:**

Scientists 13

Engineers 0

Technicians 1

Administrative and support staff 2

**(iv) List the scientific disciplines represented in the scientific/engineering staff.**

Molecular Biology, Microbiology, Cell Biology

**(v) Are contractor staff working in the facility? If so, provide an approximate number.**

Yes Number: 13

**(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Defense (DOD) - wholly

**(vii) What are the funding levels for the following program areas:**

Research \$3,500,000

Development \$0

Test and evaluation \$0

Total \$3,500,000

**(viii) Briefly describe the publication policy of the facility:**

Unlimited release, all publications submitted to Air Force Public Affairs and Science and Technology Information review, and peer reviewed.

**(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)**

1. Su S, Saldanha R, Pemberton A, Bangar H, Kawamoto SA, Arnow B, Hassett DJ, Lamkin TJ.  
Characterization of stable, constitutively expressed, chromosomal green and red fluorescent

transcriptional fusions in the select agent bacterium, *Francisella tularensis* Schu S4 and the surrogate type B live vaccine strain (LVS). Appl Microbiol Biotechnol. 2013 Oct;97(20):9029-41

<http://link.springer.com/article/10.1007/s00253-013-5081-9>

2. Saldanha RJ, Pemberton A, Shiflett P, Perutka J, Whitt JT, Ellington A, Lambowitz AM, Kramer R, Taylor D, Lamkin TJ. Rapid targeted gene disruption in *Bacillus anthracis*. BMC Biotechnol. 2013 Sep 18;13:72. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3848504/>

**5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms\* and/or toxins studied, as well as outdoor studies of biological aerosols.**

**Objectives:** Provide capabilities for the development of new prophylactics, pre- and post-exposure therapeutics for bacterial biological select agents and novel threats.

**Microorganisms and/or toxins studied:** Select Agents (HHS, Overlap), NIAID Category A pathogens

**Outdoor Studies:** None

## Lothar Salomon Test Facility (LSTF)

2029 Burns Road, TEDT-DPW-LS MS#6, Dugway, Utah 84022

Total laboratory floor area 1046 m<sup>2</sup>

Civilian	48
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## Administrative and support staff 8

Aerobiology, Bacteriology, Biochemistry, Engineering, Immunology, Microbiology, Molecular Biology, Toxicology, Virology

Yes Number: 11

U.S. Department of Justice (DOJ)

Total	\$4,103,500
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Professional scientists are encouraged to publish papers in peer-reviewed journals. All publications must obtain the necessary command permission before submission.

**(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)**

None

**5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms\* and/or toxins studied, as well as outdoor studies of biological aerosols.**

**Objectives:** To test battlefield detection and identification methods, protective equipment, and decontamination systems, to include interferent testing of biological detectors; and to develop/validate aerosol particle dispersion models to enhance countermeasure efficacy.

**Microorganisms and/or toxins studied:** Select Agents (HHS, Overlap) and Toxins, NIAID Category A pathogens, Simulants

**Outdoor Studies:** Yes - using simulants

Naval Medical Research Center (NMRC)

8400 Research Plaza, Fort Detrick, Maryland 21702

BSL-2: 2000 m<sup>2</sup>BSL-3: 0 m<sup>2</sup>BSL-4: 0 m<sup>2</sup>

Total laboratory floor area      2000 m<sup>2</sup>

(i) Total number of personnel	72
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## Military 13

Civilian	59
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## Scientists 20

Engineers	0
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Technicians	44
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Administrative and support staff	8
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Biochemistry, Computational Biology, Immunology, Microbiology, Molecular Biology

Yes Number: 54

U.S. Department of Defense (DOD) - wholly

Research	\$5,218,438
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Development	\$0
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Test and evaluation	\$0
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Total	\$5,218,438
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Professional scientists are encouraged to publish worthy papers in peer-reviewed journals. All publications must obtain the necessary command and public affairs permission before submission.

## Page 45 of 161

1. Schully KL, Sharma S, Peine KJ, Pesce J, Elberson MA, Fonseca ME, Prouty AM, Bell MG, Borteh H, Gallovic M, Bachelder EM, Keane-Myers AM, Ainslie KM. Rapid vaccination using an acetalated dextran microparticulate subunit vaccine confers protection against triplicate challenge by *Bacillus anthracis*. *Pharm Res*. 2013 May;30(5):1349-61. Epub 2013 Jan 25.  
<http://link.springer.com/article/10.1007%2Fs11095-013-0975-x>
2. Larson MA, Ding S-J, Slater SR, Hanway A, Bartling AM, Fey PD, Lockridge O, Francesconi SC, Hinrichs SH. Application of chromosomal DNA and protein targeting for the identification of *Yersinia pestis*. *Proteomics Clin Appl*. 2013 Jun;7(5-6):416-23. Epub 2013 May 10.  
<http://onlinelibrary.wiley.com/doi/10.1002/prca.201200092/abstract>
3. Fouts DE, Klumpp J, Bishop-Lilly KA, Rajavel M, Willner KM, Butani A, Henry M, Biswas B, Li M, Albert MJ, Loessner MJ, Calendar R, Sozhamman S. Whole genome sequencing and comparative genomic analyses of two *Vibrio cholerae* O139 Bengal-specific Podoviruses to other N4-like phages reveal extensive genetic diversity. *Virol J*. 2013 May 28; 10:165.  
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3670811/>
4. Peine KJ, Bachelder EM, Vangundy Z, Papenfuss T, Schully KL, Pesce J, Keane-Myers AM, Ainslie KM. Efficient delivery of the TLR-agonists Poly I:C and CpG to macrophages by acetalated dextran microparticles. *Mol Pharmaceutics*. 2013, 10(8):2849-2857. Epub ahead of print 2013 Jun 14.  
<http://pubs.acs.org/doi/abs/10.1021/mp300643d>
5. Bishop-Lilly KA, Ge H, Butani A, Osborne B, Verratti K, Mokashi V, Nagarajan M, Pop M, Read TD, Richards AL. Genome sequencing of four strains of *Rickettsia prowazekii*, the causative agent of epidemic Typhus, including one flying squirrel isolate. *Genome Announc*. 2013 May/June; 1(3) e00399-13. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3695431/>
6. Leski TA, Vora GJ, Barrows BR, Pimentel G, House BL, Nicklasson M, Wasfy M, Abdel-Maksoud M, Taitt CR. Molecular Characterization of Multidrug Resistant Hospital Isolates Using the Antimicrobial Resistance Determinant Microarray. *PLoS ONE*. 2013 Jul 25 8(7):e69507. doi:10.1371/journal.pone.0069507 <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3723915/>
7. Xu K, Bockx B, Xie Y, DeBuysscher BL, Fusco DL, Zhu Z, Chan Y-P, Luu T, Cer RZ, Feldmann H, Mokashi V, Dimitrov DS, Bishop-Lilly KA, Broder CC, Nikolov DB. Crystal structure of the Hendra virus attachment G glycoprotein bound to a potent cross-reactive neutralizing human monoclonal antibody. *PLoS Pathog*. 2013;9(10):e1003684. doi: 10.1371/journal.ppst. 1003684. Epub 2013Oct10.  
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3795035/>
8. Cosby MT, Pimentel G, Nevin RL, Ahmed SF, Klena JD, Amir E, Younan M, Browning R, Sebeny PJ. Outbreak of H3N2 influenza at a US military base in Djibouti during the H1N1 pandemic of 2009. *PLoS ONE* 8(12): e82089. doi: 10.1371/journal.pone.0082089. Epub 2013Dec5.  
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3855413/>
9. Herrera-Galeano JE, Hirschberg D, Mokashi V, Solka J. OGA: an ontological tool of human phenotypes with genetic associations. *BMC Research Notes* 2013 (5 Dec 2013), 6:511. doi:10.1186/1756-0500-6-511. <http://www.biomedcentral.com/1756-0500/6/511>
10. Plaut RD, Beaber JW, Zemansky J, Kaur AP, George M, Biswas B, Henry M, Bishop-Lilly KA, Mokashi V, Hannah RM, Pope RK, Read TD, Stibitz S, Calendar R, Sozhamannan S. Genetic evidence for the involvement of the s-layer protein gene, sap, and the sporulation genes spo0A, spo0B, and spo0F in phage AP50c infection of *Bacillus anthracis*. *J Bacteriol*. 2013Dec20 [Epub ahead of print]. <http://jb.asm.org/content/196/6/1143.long>

**5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms\* and/or toxins studied, as well as outdoor studies of biological aerosols.**

**Objectives:** The goal of the program is the development of rapid and deployable detection assays to protect deployed troops. In 2013, NMRC personnel started studying clinical cases of sepsis in austere environments in order to understand host-pathogen interactions and develop new diagnostic assays and better treatment strategies against relevant infectious diseases.

**Microorganisms and/or toxins studied:** Select Agents (HHS, Overlap) and Toxins, NIAID Category A pathogens

**Outdoor Studies:** None

**National biological defence research and development programmes: Facilities**

**1. What is the name of the facility?**

Naval Research Laboratory (NRL)

**2. Where is it located (provide both address and geographical location)?**

4555 Overlook Avenue Southwest, Washington, District of Columbia 20375

**3. Floor area of laboratory areas by containment level:**

BSL-2: 2816 m<sup>2</sup>

BSL-3: 0 m<sup>2</sup>

BSL-4: 0 m<sup>2</sup>

Total laboratory floor area: 2816 m<sup>2</sup>

**4. The organizational structure of each facility:**

**(i) Total number of personnel** 39

**(ii) Division of personnel:**

Military 1

Civilian 38

**(iii) Division of personnel by category:**

Scientists 29

Engineers 3

Technicians 7

Administrative and support staff 0

**(iv) List the scientific disciplines represented in the scientific/engineering staff:**

Biochemistry, Biology, Biophysics, Chemical Engineering, Chemistry, Electrical Engineering, Engineering, Immunology, Mechanical Engineering, Microbiology, Molecular Biology, Physics

**(v) Are contractor staff working in the facility? If so, provide an approximate number:**

Yes Number: 10

**(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Defense (DoD) - partly

National Institutes of Health (NIH)

**(vii) What are the funding levels for the following program areas:**

Research \$7,165,000

Development \$3,193,000

Test and evaluation \$0

Total \$10,358,000

**(viii) Briefly describe the publication policy of the facility:**

Employees are encouraged to publish. Employees must follow appropriate U.S. DoD guidelines for publishing information related to biological defense efforts and have all publications approved by the appropriate command authority. Public release of unclassified technical information is subject to sponsor approval.

**(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)**

1. Stine, R., Mulvaney, S.P., Robinson, J.T., Tamanaha, C.R., Sheehan, P.E., "Fabrication, Optimization, and Use of Graphene Field Effect Sensors," Anal. Chem., 2013, 85, 2, 509-521. <http://pubs.acs.org/doi/abs/10.1021/ac303190w>
2. Hu X, Compton JR, Abdulhameed MD, Marchand CL, Robertson KL, Leary DH, Jadhav A, Hershfield JR, Wallqvist A, Friedlander AM, Legler PM . 2013. 3-Substituted Indole Inhibitors Against Francisella tularensis FabI Identified by Structure-Based Virtual Screening. J Med Chem. 2013 Jul 1. [Epub ahead of print] <http://pubs.acs.org/doi/abs/10.1021/jm4001242>
3. Janosi L, Compton JR, Legler PM, Steele KE, Davis JM, Matyas GR, Millard CB. 2013. Disruption of the putative vascular leak peptide sequence in the stabilized ricin vaccine candidate RTA1-33/44-198. Toxins (Basel). 5(2):224-48 <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3640533/>
4. Zabetakis, D, Anderson, G.P., Bayya, N., Goldman, E.R. 2013 Contributions of the Complementarity Determining Regions to the Thermal Stability of a Single-Domain Antibody. PLOS ONE. 8(10) e77678. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3797041/>
5. Anderson, G.P., Glaven, R.H., Algar, W.R., Susumu, K., Stewart, M.H., Medintz, I.L., Goldman, E.R. 2013 Single Domain Antibody-Quantum Dot Conjugates for Ricin Detection by Both Fluoroimmunoassay and Surface Plasmon Resonance. Analytica Chimica Acta.786:132-138. <http://www.sciencedirect.com/science/article/pii/S0003267013006594>
6. Lui, J.L., Zabetakis, D., Lee, P.A.B., Goldman, E.R., Anderson, G.P. 2013 Single Domain antibody-Alkaline Phosphatase Fusion Proteins for Antigen Detection- Analysis of Affinity and Thermal Stability of Single Domain Antibody. Journal of Immunological Methods. 393:1-7. <http://www.sciencedirect.com/science/article/pii/S0022175913001026>
7. Walper, S.A., Lee, P.A.B , Anderson, G.P., Goldman, E.R. 2013 Selection and Characterization of Single Domain Antibodies Specific for *Bacillus anthracis* Spore Proteins. Antibodies 2:152-167. <http://www.mdpi.com/2073-4468/2/1/152>
8. Boeneman, K., Deschamps, J., Delehanty, J.B.; Susumu, K. Stewart, M.H., Glaven, R.H., Anderson, G.P., Goldman, E.R., Huston, A. Medintz, I.L. 2013 Optimizing Protein Coordination to Quantum Dots with Designer Peptidyl Linkers. Bioconjugate Chemistry 24:269-281. <http://pubs.acs.org/doi/abs/10.1021/bc300644p>
9. Legler, P.M., Zabetakis, D., Anderson, G.P., Lam, A., Hol, W.G.J., Goldman, E.R. 2013 Structure of a low melting temperature Anti-Cholera Toxin Llama VHH domain. Acta. Cryst. Sect. F. 69:90-93. <http://scripts.iucr.org/cgi-bin/paper?S1744309112050750>
10. Walper, S.A., Lee, P.A.B., Goldman, E.R., Anderson, G.P. 2013 Comparison of Single Domain Antibody Immobilization Strategies Evaluated by Surface Plasmon Resonance. Journal of Immunological Methods. 388:68-77 <http://www.sciencedirect.com/science/article/pii/S0022175912003493>
11. Liu, J.L., Zabetakis, D., Goldman, E.R., Anderson, G.P. 2013 Selection and evaluation of single domain antibodies towards MS2 phage and coat protein. Molecular Immunology. 53:118-125. <http://www.sciencedirect.com/science/article/pii/S0161589012003574>
12. Verbarg, J.; Plath, W.D.; Shriver-Lake, L.C Howell, Jr, P.B.; Erickson, J.S.; Golden, J.P.; Ligler, F.S "Catch and Release: Integrated system for multiplexed detection of bacteria" Analytical Chemistry, 85(10), 4944-4950. <http://pubs.acs.org/doi/abs/10.1021/ac303801v>
13. Shriver-Lake, L.C; Golden, J.P.; Bracaglia, L.; Ligler, F.S. (2013) "Simultaneous assay for ten bacteria and toxins in spiked clinical samples using a Microflow Cytometer" Analytical and Bioanalytical Chemistry, 405(16), 5611-5614. <http://link.springer.com/article/10.1007%2Fs00216-013-6980-4>

14. Shriver-Lake LC, North SH, Dean SN, Taitt CR. 2013. Antimicrobial peptides for detection and diagnostic assays. In *Designing Receptors for the Next Generation of Biosensors*. S Piletsky and M Whitcombe Eds. Springer. Pp. 85-104. <http://link.springer.com/book/10.1007%2F978-3-642-32329-4>
15. Staton SJ, Kim SY, Hart SJ, Collins GE, Terray A. Pico-force optical exchange (pico-FOX): utilizing optical forces applied to an orthogonal electroosmotic flow for particulate enrichment from mixed sample streams. *Anal Chem*. 2013 Sep 17;85(18):8647-53. <http://pubs.acs.org/doi/abs/10.1021/ac401369h>
16. Staton SJ, Terray A, Collins GE, Hart SJ. Orthogonal optical force separation simulation of particle and molecular species mixtures under direct current electroosmotic driven flow for applications in biological sample preparation. *Electrophoresis*. 2013 Apr;34(8):1175-81. <http://onlinelibrary.wiley.com/doi/10.1002/elps.201200553/abstract>
17. Kim S, Taylor JD, Ladouceur HD, Hart SJ, Terray A. Radiation Pressure Efficiency Measurements of Nanoparticle Coated Microspheres. *Applied Physics Letters*. 2013; 103(23):4101. <http://scitation.aip.org/content/aip/journal/apl/103/23/10.1063/1.4836516>
18. Sivaprakasam V, Huston AL, Schultz A, Eversole JD. A novel polarized elastic scatter detection method of aerosol particle velocimetry with reduced errors due to coincidence and phantom particles. *Aerosol Science and Technology*. 2013; 47(3): 249-257. <http://www.tandfonline.com/doi/abs/10.1080/02786826.2012.746777#.UwzZRm1cfXM>
19. Coneski PN, Weise NK, Fulmer PA, Wynne JH. Development and evaluation of self-polishing urethane coatings with tethered quaternary ammonium biocides. *Progress in Organic Coatings*, 2013 Oct;76(10):1376–1386. <http://www.sciencedirect.com/science/article/pii/S0300944013001136>

**5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms\* and/or toxins studied, as well as outdoor studies of biological aerosols.**

**Objectives:** The objective of research at NRL is to develop and test reliable systems for the detection of chemical and biological (CB) warfare agents in order to provide early warning and contamination avoidance information.

**Microorganisms and/or toxins studied:** HHS Select Toxins, Simulants

**Outdoor Studies:** None

**National biological defence research and development programmes: Facilities**

**1. What is the name of the facility?**

Naval Surface Warfare Center-Dahlgren Division, Chemical, Biological, Radiological (CBR) Defense Laboratory

**2. Where is it located (provide both address and geographical location)?**

6149 Welsh Road, Dahlgren, Virginia 22448

**3. Floor area of laboratory areas by containment level:**

BSL-2: 190 m<sup>2</sup>

BSL-3: 26 m<sup>2</sup>

BSL-4: 0 m<sup>2</sup>

Total laboratory floor area: 216 m<sup>2</sup>

**4. The organizational structure of each facility:**

**(i) Total number of personnel** 189

**(ii) Division of personnel:**

Military 0

Civilian 189

**(iii) Division of personnel by category:**

Scientists 72

Engineers 48

Technicians 14

Administrative and support staff 55

**(iv) List the scientific disciplines represented in the scientific/engineering staff:**

Aerospace Engineering, , Chemical Engineering, Chemistry, Computer Engineering, Computer Science, Electrical Engineering, Industrial Engineering, Mathematics, Mechanical Engineering, Microbiology, Molecular Biology, Operations Research Analysis, Physics, Toxicology

**(v) Are contractor staff working in the facility? If so, provide an approximate number.**

Yes Number: 32

**(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Defense (DOD) - partly

Private Sector Companies

Internal (Laboratory Directed Research and Development [LDRD])

Other Governmental Agencies

**(vii) What are the funding levels for the following program areas:**

Research \$980,000

Development \$7,860,000

Test and evaluation \$6,850,000

Total \$15,690,000

**(viii) Briefly describe the publication policy of the facility:**

Employees are encouraged to publish. Employees must follow appropriate U.S. DoD guidelines for publishing information related to biological defense efforts and have all publications approved. Public release of unclassified technical information is subject to sponsor approval.

**(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)**

1. Buhr TL, Wells CM, Young AA, Minter ZA, Johnson CA, Payne AN, McPherson DC. Decontamination of materials contaminated with *Bacillus anthracis* and *Bacillus thuringiensis* Al Hakam spores using PES-Solid, a solid source of peracetic acid. J Appl Microbiol. 2013 Aug; 115(2):398-408. <http://onlinelibrary.wiley.com/doi/10.1111/jam.12253/abstract>

**5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms\* and/or toxins studied, as well as outdoor studies of biological aerosols.**

**Objectives:** Efforts at this defense laboratory are focused on biological detection systems, collective and individual protection systems, hazard mitigation technologies, risk assessment tools and consequence management planning.

**Microorganisms and/or toxins studied:** Select Agents (Overlap), NIAID Category A pathogens, Simulants

**Outdoor Studies:** None

**National biological defence research and development programmes: Facilities**

**1. What is the name of the facility?**

U.S. Army Edgewood Chemical and Biological Center

**2. Where is it located (provide both address and geographical location)?**

5183 Blackhawk Road, Aberdeen Proving Ground, Maryland 21010

**3. Floor area of laboratory areas by containment level:**

BSL-2: 532 m<sup>2</sup>

BSL-3: 177 m<sup>2</sup>

BSL-4: 0 m<sup>2</sup>

Total laboratory floor area: 709 m<sup>2</sup>

**4. The organizational structure of each facility:**

**(i) Total number of personnel** 265

**(ii) Division of personnel:**

Military 0

Civilian 265

**(iii) Division of personnel by category:**

Scientists 184

Engineers 33

Technicians 20

Administrative and support staff 28

**(iv) List the scientific disciplines represented in the scientific/engineering staff:**

Aerobiology, Aerospace Engineering, Biochemistry, Biomedical Engineering, Biotechnology, Chemical Engineering, Chemistry, Computer Engineering, Electrical Engineering, , Immunology, Mathematics, Mechanical Engineering, Microbiology, Molecular Biology. Operations Research Analysis, Physics, Physiology, Toxicology, Toxinology, Virology

**(v) Are contractor staff working in the facility? If so, provide an approximate number.**

Yes Number: 121

**(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Defense (DoD) - wholly

**(vii) What are the funding levels for the following program areas:**

Research \$1,115,000

Development \$21,785,000

Test and evaluation \$0

Total \$22,900,000

**(viii) Briefly describe the publication policy of the facility:**

Publications are prepared in accordance with Army regulations. Scientists are encouraged to publish their results in peer-reviewed scientific literature and to present their work at national and international professional meetings.

**(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)**

1. Jabbour RE, Wright JD, Deshpande SV, Wade MM, McCubbin P, Bevilacqua VL. Metaproteomics analyses as diagnostic tool for differentiation of *Escherichia coli* strains in outbreaks. Proceedings Volume 8710: Chemical, Biological, Radiological, Nuclear, and Explosives (CBRNE) Sensing XIV June 2013. <http://proceedings.spiedigitallibrary.org/proceeding.aspx?articleid=1692720>
2. Andersen PS, Stegger M, Aziz M, Contente-Cuomo T, Gibbons HS, Keim, P, Sokurenko EV, Johnson JR, Price LB. Complete Genome Sequence of the Epidemic and Highly Virulent CTX-M-15-Producing H30-Rx Subclone of *Escherichia coli* ST131. Genome Announc. November/December 2013; <http://genomea.asm.org/content/1/6/e00988-13.abstract>
3. Sagripanti JL, Voss L, Marschall H, Lytle CD. Inactivation of vaccinia virus by natural sunlight and by artificial UVB radiation. Photochem Photobiol 2013; 89(1): 132-8. <http://onlinelibrary.wiley.com/doi/10.1111/j.1751-1097.2012.01207.x/abstract>
4. Sagripanti, J.L.; Niederwöhrmeier, B.; Grote, G.; Marschall, H. Inactivation of *Pseudomonas aeruginosa* by direct sunlight. Photochem Photobiol 2013; 89(4):1000-3. <http://onlinelibrary.wiley.com/doi/10.1111/php.12059/abstract>
5. Tran H, Killops KL, Campos LM. Advancements and challenges of patterning biomolecules with sub-50 nm features. Soft Matter, 2013, 9:6578-6586. <http://pubs.rsc.org/en/content/articlelanding/2013/sm/c3sm00149k#!divAbstract>

**5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms\* and/or toxins studied, as well as outdoor studies of biological aerosols.**

**Objectives:** Development of non-medical defensive material against biological agents to include: research, development, and engineering for methods of rapid detection, identification, decontamination, and physical protection from biological threat agents.

**Microorganisms and/or toxins studied:** Select Agents (HHS, Overlap) and Toxins, NIAID Category A pathogens, Simulants

**Outdoor Studies:** None

U.S. Army Medical Research Institute of Chemical Defense (USAMRICD)

3100 Ricketts Point Road, Aberdeen Proving Ground, Maryland 21010

BSL-2: 300 m<sup>2</sup>BSL-3: 0 m<sup>2</sup>BSL-4: 0 m<sup>2</sup>

Total laboratory floor area      300 m<sup>2</sup>

(i) Total number of personnel	8
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Military	0
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Civilian	8
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Scientists	3
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Engineers	0
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Technicians	5
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Administrative and support staff	0
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Biochemistry, Biology, Molecular Biology, Pharmacology, Physiology

Yes Number: 4

U.S. Department of Defense (DoD) - wholly

Research	\$583,000
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Development	\$0
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Test and evaluation	\$0
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Total	\$583,000
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Publications are prepared and published in accordance with Army regulations.

## Page 55 of 161

1. Andres D, Keyser BM, Petrali J, Benton B, Hubbard KS, McNutt PM, Ray R. Morphological and functional differentiation in BE(2)-M17 human neuroblastoma cells by treatment with Trans-retinoic acid. BMC Neurosci. 2013 Apr 18;14:49. <http://www.biomedcentral.com/1471-2202/14/49>
2. Gut IM, Beske PH, Hubbard KS, Lyman ME, Hamilton TA, McNutt PM. Novel application of stem cell-derived neurons to evaluate the time- and dose-dependent progression of excitotoxic injury. PLoS One. 2013 May 14;8(5):e64423. <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0064423>
3. Hubbard KS, Gut IM, Lyman ME, McNutt PM. Longitudinal RNA sequencing of the deep transcriptome during neurogenesis of cortical glutamatergic neurons from murine ESCs. F1000Res. 2013 Feb 7;2:35. <http://f1000research.com/articles/2-35/v1>

**5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms\* and/or toxins studied, as well as outdoor studies of biological aerosols.**

**Objectives:** The Institute's mission involves research on medical defenses against neurotoxins.

**Microorganisms and/or toxins studied:** HHS Select Toxins

**Outdoor Studies:** None

**National biological defence research and development programmes: Facilities**

**1. What is the name of the facility?**

U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)

**2. Where is it located (provide both address and geographical location)?**

1425 Porter Street, Fort Detrick, Frederick, Maryland 21702

**3. Floor area of laboratory areas by containment level:**

BSL-2: 26,026 m<sup>2</sup>

BSL-3: 3,139 m<sup>2</sup>

BSL-4: 1186 m<sup>2</sup>

Total laboratory floor area            30,351 m<sup>2</sup>

**4. The organizational structure of each facility:**

**(i) Total number of personnel**            827

**(ii) Division of personnel:**

Military    204

Civilian    623

**(iii) Division of personnel by category:**

Scientists    265

Engineers    5

Technicians    291

Administrative and support staff            266

**(iv) List the scientific disciplines represented in the scientific/engineering staff.**

Aerobiology, Biochemistry, Chemistry, Clinical Immunology Entomology, Genetics, Immunology, Microbiology, Molecular Biology, Toxicology, Veterinary Medicine, Virology

**(v) Are contractor staff working in the facility? If so, provide an approximate number.**

Yes    Number: 315

**(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Defense (DoD) - wholly

**(vii) What are the funding levels for the following program areas:**

Research    \$4,331,126

Development    \$50,078,031

Test and evaluation    \$4,888,000

Total    \$59,297,157

**(viii) Briefly describe the publication policy of the facility:**

Publications are prepared in accordance with Army regulations. Scientists are encouraged to publish their results in peer-reviewed scientific literature and to present their work at national and international professional meetings.

**(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)**

1. Ayithan N, Bradfute SB, Anthony SM, Stuthman KS, Dye JM, Bavari S, Bray M, Ozato K. Ebola virus-like particles stimulate type I interferons and proinflammatory cytokine expression through the toll-like receptor and interferon signaling pathways. *J Interferon Cytokine Res*. 2013 Oct 8; Epub ahead of print <http://online.liebertpub.com/doi/abs/10.1089/jir.2013.0035>
2. Benton CG, West MW, Hall SM, Marko ST, Johnson JC. Effect of short-term pair housing of juvenile rhesus macaques (*Macaca mulatta*) on immunologic parameters. *J Am Assoc Lab Anim Sci*. 2013 May; 52(3):240-6. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3690444/>
3. Brocato RL, Hammerbeck CD, Bell TM, Wells JB, Queen LA, Hooper JW. A lethal disease model for hantavirus pulmonary syndrome in immunosuppressed Syrian hamsters infected with Sin Nombre virus. *J Virol*. 2013 Nov 6. Epub ahead of print. <http://jvi.asm.org/content/early/2013/10/31/JVI.02906-13.long>
4. Bukreyev AA, Chandran K, Dolnik O, Dye JM, Ebihara H, Leroy EM, Mühlberger E, Netesov SV, Patterson JL, Paweska JT, Saphire EO, Smither SJ, Takada A, Towner JS, Volchkov VE, Warren TK, Kuhn JH. Discussions and decisions of the 2012–2014 International Committee on Taxonomy of Viruses (ICTV) Filoviridae Study Group, January 2012–June 2013. *Arch Virol*. 2013 Oct 13. <http://link.springer.com/article/10.1007%2Fs00705-013-1846-9>
5. Cai Y, Yú S, Mazur S, Dong L, Janosko K, Zhang T, Müller MA, Hensley LE, Bavari S, Jahrling PB, Radoshitzky SR, Kuhn JH. Nonhuman transferrin receptor 1 is an efficient cell entry receptor for ocozocoautla de espinosa virus. *J Virol*. 2013 Oct 9; 87(24):13930-935. <http://jvi.asm.org/content/87/24/13930.long>
6. Chang J, Warren TK, Zhao X, Gill T, Guo F, Wang L, Comunale MA, Du Y, Alonzi DS, Yu W, Ye H, Liu F, Guo JT, Mehta A, Cuconati A, Butters TD, Bavari S, Xu X, Block TM. Small molecule inhibitors of ER alpha-glucosidases are active against multiple hemorrhagic fever viruses. *Antiviral Res*. 2013 April 8; 98(3):432-40. <http://www.sciencedirect.com/science/article/pii/S0166354213000867>
7. Chaudhury S, Abdulhameed MD, Singh N, Tawa GJ, D'haeseleer PM, Zemla AT, Navid A, Zhou CE, Franklin MC, Cheung J, Rudolph MJ, Love J, Graf JF, Rozak DA, Dankmeyer JL, Amemiya K, Daefler S, Wallqvist A. Rapid countermeasure discovery against *Francisella tularensis* based on a metabolic network reconstruction. *PLoS One*. 2013 May 21; 8(5):0063369. <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0063369>
8. Copeland AM, Altamura LA, Van Deusen NM, Schmaljohn CS. Nuclear relocation of polyadenylate binding protein during rift valley fever virus infection involves expression of the NSs gene. *J Virol*. 2013 Aug 21; 87(21):11659-69. <http://jvi.asm.org/content/87/21/11659.abstract>
9. D'Souza AJ, Mar KD, Huang J, Majumdar S, Ford BM, Dyas B, Ulrich RG, Sullivan VJ. Rapid deamidation of recombinant protective antigen when adsorbed on aluminum hydroxide gel correlates with reduced potency of vaccine. *J Pharm Sci*. 2013 Feb; 102(2):454-61. <http://onlinelibrary.wiley.com/doi/10.1002/jps.23422/abstract>
10. Del Favero G, Beltramo D, Sciancalepore M, Lorenzon P, Coslovich T, Poli M, Testai E Sosa S, Tubaro A. Toxicity of palytoxin after repeated oral exposure in mice and in vitro effects on cardiomyocytes. *Toxicon*. 2013 Dec 1; 75:3-15. <http://www.sciencedirect.com/science/article/pii/S0041010113002158#>
11. Duncan DD, Vogler AJ, Wolcott MJ, Li F, Sarovich DS, Birdsall DN, Watson LM, Hall TA, Sampath R, Housley R, Blyn LB, Hofstadler SA, Ecker DJ, Keim P, Wagner DM, Eshoo MW. Identification and typing of *Francisella tularensis* with a highly automated genotyping assay. *Lett Appl Microbiol*. 2013 Feb; 56(2):128-34. <http://onlinelibrary.wiley.com/doi/10.1111/lam.12022/full>
12. Felciano RM, Bavari S, Richards DR, Billaud JN, Warren T, Panchal R, Krämer A. Predictive systems biology approach to broad-spectrum, host-directed drug target discovery in infectious diseases. *Pac Symp Biocomput*. 2013:17-28. [http://www.worldscientific.com/doi/abs/10.1142/9789814447973\\_0003](http://www.worldscientific.com/doi/abs/10.1142/9789814447973_0003)

13. Fernandez S, Cisney ED, Ulrich RG. Enhancement of serum and mucosal immune responses to a *Haemophilus influenzae* Type B vaccine by intranasal delivery. *Clin Vaccine Immunol*. 2013 August 28; 20(11):1690-6. <http://cvi.asm.org/content/20/11/1690.abstract>
14. Fernández DA, Louzao MC, Vilariño N, Espiña B, Fraga M, Vieytes MR, Román A, Poli M, Botana LM. The kinetic, mechanistic and cytomorphological effects of palytoxin in human intestinal cells (Caco-2) explain its lower-than-parenteral oral toxicity. *FEBS J*. 2013 July 5; 280(16):3906-19. <http://onlinelibrary.wiley.com/doi/10.1111/febs.12390/pdf>
15. Garrison AR, Radoshitzky SR, Kota KP, Pegoraro G, Ruthel G, Kuhn JH, Altamura LA, Kwilas SA, Bavari S, Haucke V, Schmaljohn CS. Crimean-Congo hemorrhagic fever virus utilizes a clathrin- and early endosome-dependent entry pathway. *Virology*. 2013 Jun 19; 444(1-2):45-54. <http://www.sciencedirect.com/science/article/pii/S0042682213003115>
16. Grubaugh ND, McMenamy SS, Turell MJ, Lee JS. Multi-gene detection and identification of mosquito-borne RNA viruses using an oligonucleotide microarray. *PLoS Negl Trop Dis*. 2013 Aug 15; 7(8):e2349. <http://www.plosntds.org/article/info%3Adoi%2F10.1371%2Fjournal.pntd.0002349>
17. Herbert AS, Kuehne AI, Barth JF, Ortiz RA, Nichols DK, Zak SE, Stonier SW, Muhammad MA, Bakken RR, Prugar LI, Olinger GG, Groebner JL, Lee JS, Pratt WD, Custer M, Kamrud KI, Smith JF, Hart MK, Dye JM. Venezuelan equine encephalitis virus replicon particle vaccine protects nonhuman primates from intramuscular and aerosol challenge with ebola virus. *J Virol*. 2013 Feb 13; 87(9):4952-64. <http://jvi.asm.org/content/87/9/4952.long>
18. Hogan M, Bahta M, Cherry S, Lountos GT, Tropea JE, Zhao BM, Burke TR Jr, Waugh DS, Ulrich RG. Biomolecular Interactions of small-molecule inhibitors affecting the YopH protein tyrosine phosphatase. *Chem Biol Drug Des*. 2013 Mar; 81(3):323-33. <http://onlinelibrary.wiley.com/doi/10.1111/cbdd.12097/abstract>
19. Hooper JW, Josleyn M, Ballantyne J, Brocato R. A novel Sin Nombre virus DNA vaccine and its inclusion in a candidate pan-hantavirus vaccine against hantavirus pulmonary syndrome (HPS) and hemorrhagic fever with renal syndrome (HFRS). *Vaccine*. 2013 July 24; 31(40):4314-21. <http://www.sciencedirect.com/science/article/pii/S0264410X13009523>
20. Hu X, Compton JR, Abdulhameed MD, Marchand CL, Robertson KL, Leary DH, Jadhav A, Hershfield JR, Wallqvist A, Friedlander AM, Legler PM. 3-substituted indole inhibitors against *Francisella tularensis* FabI identified by structure-based virtual screening. *J Med Chem*. 2013 Jul 1; 56(13):5275-87. <http://pubs.acs.org/doi/abs/10.1021/jm4001242>
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22. Jaiani E, Kokashvili T, Mitaishvili N, Elbakidze T, Janelidze N, Lashkhi N, Kalandadze R, Mikashavidze E, Natroshvili G, Whitehouse CA, Huq A, Tediashvili M. Microbial water quality of recreational lakes near Tbilisi, Georgia. *J Water Health*. 2013 Jun; 11(2):333-45. <http://www.ncbi.nlm.nih.gov/pubmed/23708580>
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27. Kota KP, Eaton B, Lane D, Ulrich M, Ulrich R, Peyser BD, Robinson CG, Jaissle JG, Pegoraro G, Bavari S, Panchal RG. Integrating high-content imaging and chemical genetics to probe host cellular pathways critical for *Yersinia pestis* infection. *PLoS One.* 2013; 8(1):e55167. Epub 2013 Jan 30. <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0055167>
28. Krakauer T, Buckley M. Efficacy of two FDA approved drug combination in a mouse model of staphylococcal enterotoxin B-induced shock. *Mil Med.* 2013 Sep; 178(9):1024-28. <http://www.ncbi.nlm.nih.gov/pubmed/24005553>
29. Krakauer T, Stiles BG. The staphylococcal enterotoxin (SE) family: SEB and siblings. *Virulence.* 2013 Apr 19; 4(7):759-73. <https://www.landesbioscience.com/journals/virulence/article/23905/?nocache=1053947934>
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33. Kuhn JH, Bao Y, Bavari S, Becker S, et al. Virus nomenclature below the species level: a standardized nomenclature for laboratory animal-adapted strains and variants of viruses assigned to the family Filoviridae. *Arch Virol.* 2013 Jun; 158(6):1425-32. <http://link.springer.com/article/10.1007%2Fs00705-012-1594-2>
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- Wells JB, Moos WH, Burke RL, Tanga MJ. A systematic screen of FDA-approved drugs for inhibitors of biological threat agents. *PLoS One*. 2013; 8(4):e60579. Epub 2013 Apr 5. <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0060579>
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<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3690431/>

**5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms\* and/or toxins studied, as well as outdoor studies of biological aerosols.**

**Objectives:** To develop medical countermeasures, including candidate vaccines, diagnostic tests and drug or immunological therapies for biological agents. To perform exploratory studies and advanced development of protective and therapeutic countermeasures and agent identification technologies.

**Microorganisms and/or toxins studied:** Select Agents (HHS, Overlap) and Toxins, NIAID Category A pathogens

**Outdoor Studies:** None

**National biological defence research and development programmes: Facilities**

**1. What is the name of the facility?**

Brookhaven National Laboratory

**2. Where is it located (provide both address and geographical location)?**

Brookhaven National Laboratory, Biology Department, Upton, NY 11973  
(located on William Floyd Parkway, County Road 46, 1.5 mi. north of Long Island Expressway Exit 68)

**3. Floor area of laboratory areas by containment level:**

BSL-2: 18 m<sup>2</sup>

BSL-3: 0 m<sup>2</sup>

BSL-4: 0 m<sup>2</sup>

Total laboratory area 18 m<sup>2</sup>

**4. Organizational structure of each facility:**

**(i) Total number of personnel** 3

**(ii) Division of personnel:**

Military 0

Civilian 3

**(iii) Division of personnel by category:**

Scientists 3

Engineers 0

Technicians 0

Admin and Support Staff 0

**(iv) List the scientific disciplines represented in the scientific/engineering staff.**

Biochemistry, Structural Biology

**(v) Are contractor staff working in the facility? If so, provide an approximate number.**

No

**(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

Department of Defense – partly

Department of Health & Human Services

**(vii) What are the funding levels for the following program areas:**

Research \$1,250,000

Development \$0

Test and evaluation \$0

Total \$1,250,000

**(viii) Briefly describe the publication policy of the facility:**

As a Department of Energy/National Nuclear Security Administration (DOE/NNSA) facility, BNL is required to make scientific and technical information broadly available, within applicable laws and Departmental requirements, to accomplish mission objectives and strategic goals, promote scientific advancement, satisfy statutory dissemination requirements, and ensure a fair return on Departmental and

taxpayer investment. BNL has a mandate to ensure that scientific and technical information is identified, processed, disseminated, and preserved to enable the scientific community and the public to locate and use the unclassified and unlimited-distribution information resulting from DOE research and related endeavors. BNL also has procedures in place to manage and protect classified, sensitive controlled unclassified, and export-controlled scientific and technical information, yet make it accessible for appropriate access by the Department, its contractors, and others. Reviews are conducted prior to publication to determine availability of information, or restrictions thereto. These reviews include, but are not limited to, the following: 1) classification/declassification, 2) copyrighted materials or other intellectual property, 3) export controls or distribution restrictions, and 4) sensitive content that limits access. [US Department of Energy, Scientific and Technical Information Management: <https://www.directives.doe.gov/directives/0241.1-BOrder-b/view>]

**(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)**

1. Mizanur, R. M., Frasca, V., Swaminathan, S., Bavari, S., Webb, R., Smith, L. A., and Ahmed, S. A. The C terminus of the catalytic domain of type A Botulinum neurotoxin may facilitate product release from the active site. *Journal of Biological Chemistry*. 2013 Aug; 288(33): 24223-24233. <http://www.jbc.org/content/288/33/24223>.
2. Swaminathan, S. Structure-based drug discovery for botulinum neurotoxins. *Current Topics in Microbiology and Immunology: Botulinum Neurotoxins*. 2013 Jan; A. Rummel and Th. Binz, Editors, Vol. 364, pp. 197-218, Springer Life Science/Biomedicine Europe, Heidelberg, Germany. <http://www.ncbi.nlm.nih.gov/pubmed/?term=Swaminathan%2C+S.+Structure-based+drug+discovery+for+botulinum+neurotoxins.+Current+Topics+in+Microbiology+and+Immunology%3A+Botulinum+Neurotoxins.+2013>.

**5. Briefly describe the biological defense work carried out at the facility, including type(s) of microorganisms and/or toxins studied, as well as outdoor studies of biological aerosols.**

**Objectives:** The specific aim of the projects is to determine the three-dimensional structures of biowarfare agents. Purified toxin proteins are crystallized using standard crystallization techniques and brought to the National Synchrotron Light Source (also located at Brookhaven National Laboratory) for x-ray diffraction studies.

**Microorganisms and/or toxins studied:** HHS Select Toxins

**Outdoor studies:** None

**National biological defence research and development programmes: Facilities**

**1. What is the name of the facility?**

Lawrence Livermore National Laboratory (LLNL)

**2. Where is it located (provide both address and geographical location)?**

7000 East Avenue, Livermore, California 94550 (62 km east-southeast of San Francisco, California)

**3. Floor area of laboratory areas by containment level:**

BL2 (sqM)	1604.7
BL3 (sqM)	59.5
BL4 (sqM)	0
Total (sqM)	1664.2

**4. The organizational structure of each facility.**

**(i) Total number of personnel 94**

**(ii) Division of personnel:**

Military	0
Civilian	94

**(iii) Division of personnel by category:**

Scientists	55
Engineers	10
Technicians	10
Admin and Support Staff	19

**(iv) List the scientific disciplines represented in the scientific/engineering staff.**

Aerosol Science, Analytical Biochemistry, Analytical Mass Spectrometry, Bacteriology, Biochemistry, Bioinformatics, Biomedical Engineering, Biomedical Science, Biotechnology, Computational Biology, Computer Science, Environmental Science, Epidemiology, Genomics, Immunology, Mass Spectrometry, Microbial Forensics, Microbiology, Molecular Biology, Molecular Diagnostics, Nanotechnology, Proteomics, Toxinology, Virology

**(v) Are contractor staff working in the facility? If so, provide an approximate number.**

No

**(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

Department of Defense – partly  
Department of Health & Human Services  
Department of Homeland Security  
Environmental Protection Agency (EPA)  
Department of Agriculture (USDA)  
Universities  
Private-sector companies

**(vii) What are the funding levels for the following program areas:**

Research	\$14,782,000
Development	\$1,349,000
Test and evaluation	\$2,031,000

Total

\$18,162,000

**(viii) Briefly describe the publication policy of the facility:**

As a DOE/NNSA facility, LLNL is required to make scientific and technical information broadly available, within applicable laws and Departmental requirements, to accomplish mission objectives and strategic goals, promote scientific advancement, satisfy statutory dissemination requirements, and ensure a fair return on Departmental and taxpayer investment. LLNL has a mandate to ensure that scientific and technical information is identified, processed, disseminated, and preserved to enable the scientific community and the public to locate and use the unclassified and unlimited-distribution information resulting from DOE research and related endeavors. LLNL also has procedures in place to manage and protect classified, sensitive controlled unclassified, and export-controlled scientific and technical information, yet make it accessible for appropriate access by the Department, its contractors, and others. Reviews are conducted prior to publication to determine availability of information, or restrictions thereto. These reviews include, but are not limited to, the following: 1) classification/declassification, 2) copyrighted materials or other intellectual property, 3) export controls or distribution restrictions, and 4) sensitive content that limits access. [US Department of Energy, Scientific and Technical Information Management: <https://www.directives.doe.gov/directives/0241.1-BOrder-b/view>]

**(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)**

1. Borucki MK, Chen-Harris H, Lao V, Vanier G, Wadford DA, Messenger s, Allen JE. Ultra-Deep Sequencing of Intra-host Rabies Virus Populations during Cross-species Transmission. PLoS Negl Trop Dis. 2013 Nov; 7: DOI: 10.1371/journal.pntd.0002555. <http://www.plosntds.org/article/info%3Adoi%2F10.1371%2Fjournal.pntd.0002555>
2. Borucki MK, Allen JE, Chen-Harris H, Zemla A, Vanier G, Mabery S, Torres C, Hullinger P, Slezak T. The Role of Viral Population Diversity in Adaptation of Bovine Coronavirus to New Host Environments. PLoS ONE. 2013 Jan; DOI: 10.1371/journal.pone.0052752. <http://dx.doi.org/10.1371%2Fjournal.pone.0052752>
3. Chen-Harris H, Borucki M, Torres C, Slezak T, Allen J. Ultra-deep mutant spectrum profiling: improving sequencing accuracy using overlapping read pairs. BMC Genomics. 2013; 14: 96.<http://www.biomedcentral.com/1471-2164/14/96>
4. Kane S, Shah S, Létant S, Murphy G, Alfaro T, Avila J, Salazar E, Mullins M, Nichols T. Operational evaluation of the Rapid Viability PCR method for post-decontamination clearance sampling. J Bioterr Biodef. 2013 Jun 6; S3-016. <http://www.omicsonline.org/operational-evaluation-of-the-rapid-viability-pcr-method-for-post-decontamination-clearance-sampling-2157-2526.S3-016.pdf>
5. Be NA, Thissen JB, Gardner SN, McLoughlin KS, Fofanov VY, Koshinsky H, Ellingson SR, Brettin TS, Jackson PJ, Jaing CJ. Detection of Bacillus anthracis DNA in complex soil and air samples using next-generation sequencing. PLoS One. 2013 Sep 9; 8(9):e73455. <http://dx.plos.org/10.1371/journal.pone.0073455>.
6. Chromy BA, Eldridge A, Forsberg J, Brown TS, Kirkup BC, Jaing C, Be NA, Elster E, Luciw PA. Wound outcome in combat injuries is associated with a unique set of protein biomarkers. J Transl Med. 2013 Nov 6; 11(1):281. <http://www.translational-medicine.com/content/11/1/281>.
7. Wheeler EK, Baker BR, Piggott WT, Mabery SL, Hara CA, DeOtte J, Benett W, Mukerjee EV, Dzenitis J, Beer NR. On-chip laser-induced DNA dehybridization. Analyst. 2013 Jul 7; 138(13): 3692-6.<http://dx.doi.org/10.1039/C3AN00288H>

8. Gardner SN, Jaing CJ. Bioinformatics for microbial genotyping of equine encephalitis viruses, orthopoxviruses, and hantaviruses. *Journal of Virological Methods*. 2013 Oct; 193(1):112-20. <http://dx.doi.org/10.1016/j.jviromet.2013.04.019>.
9. Gardner SN, Thissen JB, McLoughlin KS, Slezak T, Jaing CJ. Optimizing SNP microarray probe design for high accuracy microbial genotyping. *Journal of Microbiological Methods*. 2013; 94(3):303-10. <http://dx.doi.org/10.1016/j.mimet.2013.07.006>.
10. Zapata J, Poonia B, Bryant J, Davis H, Ateh E, George L, et al. An attenuated Lassa vaccine in SIV-infected rhesus macaques does not persist or cause arenavirus disease but does elicit Lassa virus-specific immunity. *Virology Journal*. 2013; 10(1):52. doi:10.1186/1743-422X-10-52. <http://www.virologyj.com/content/10/1/52>
11. Zhang X, Wong SE, Lightstone FC. Toward Fully Automated High Performance Computing Drug Discovery: A Massively Parallel Virtual Screening Pipeline for Docking and Molecular Mechanics/Generalized Born Surface Area Rescoring to Improve Enrichment. *J. Chem. Inf. Model*. 2013 Dec; Article ASAP. <http://pubs.acs.org/doi/abs/10.1021/ci4005145>
12. Tari LW, Li X, Trzoss M, Bensen DC, Chen Z, Lam T, Zhang J, Lee SJ, Hough G, Phillipson D, Akers-Rodriguez S, Cunningham ML, Kwan BP, Nelson KJ, Castellano A, Locke JB, Brown-Driver V, Murphy TM, Ong VS, Pillar CM, Shinabarger DL, Nix J, Lightstone FC, Wong SE, Nguyen TB, Shaw KJ, Finn J. Tricyclic GyrB/ParE (TriBE) Inhibitors: A New Class of Broad-Spectrum Dual-Targeting Antibacterial Agents. *PLoS ONE*. 2013 Dec; 8(12): e84409. <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0084409>
13. Weilhammer DR, Blanchette CD, Fischer NO, Alam S, Loots GG, Corzett M, Thomas C, Lychak C, Dunkle AD, Ruitenberg JJ, Ghanekar SA, Sant AJ, Rasley A. Nanolipoprotein delivery enhances immunostimulatory properties of innate immune agonists and provides protection against lethal influenza challenge. *Biomaterials*. 2013; Dec; 34(38):10305-18. <http://www.sciencedirect.com/science/article/pii/S0142961213011216>
14. Bennion BJ, Lau EY, Fattebert J-L, Huang P, Schwegler E, Corning W, Lightstone FC. Modeling the Binding of CWAs to AChE and BuChE. *Military Medical Science Letters*. 2013; 82(3):102-114. [http://mmsl.cz/viCMS/soubory/pdf/MMSL\\_2013\\_3\\_2\\_WWW.pdf](http://mmsl.cz/viCMS/soubory/pdf/MMSL_2013_3_2_WWW.pdf)
15. Chaudhury S, Abdulhameed MDM, Singh N, Tawa NG, D'haeseleer PM, Zemla AT, Navid A, Zhou CE, Franklin MC, Cheung J, Rudolph MJ, Love J, Graf JF, Rozak DA, Dankmeyer JL, Amemiya K, Daefler S, Wallqvist A. Rapid Countermeasure Discovery against *Francisella tularensis* Based on a Metabolic Network Reconstruction. *PLoS ONE*. 2013 May; 8(5), e63369. <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0063369>
16. Trzoss M, Bensen DC, Li X, Chen Z, Lam T, Zhang J, Creighton CJ, Cunningham ML, Kwan B, Stidham BM, Nelson K, Brown-Driver V, Castellano A, Shaw KJ, Lightstone FC, Wong SE, Nguyen TB, Finn J, Tari LW. Pyrrolopyrimidine inhibitors of DNA gyrase B (GyrB) and topoisomerase IV (ParE), Part II: Development of inhibitors with broad spectrum, Gram-negative antibacterial activity. *Bioorg. Med. Chem. Lett*. 2013 Mar; 23:1537-43. <http://www.sciencedirect.com/science/article/pii/S0960894X12015259>
17. Tari LW, Trzoss M, Bensen MDC, Li X, Chen Z, Lam T, Zhang J, Creighton CJ, Cunningham ML, Kwan B, Stidham M, Shaw KJ, Lightstone FC, Wong SE, Nguyen TB, Nix J, Finn J. Pyrrolopyrimidine inhibitors of DNA gyrase B (GyrB) and topoisomerase IV (ParE). Part I: Structure guided discovery and optimization of dual targeting agents with potent, broad-spectrum enzymatic activity. *Bioorg. Med. Chem. Lett*. 2013 Mar; 23(5):1529-36. <http://www.sciencedirect.com/science/article/pii/S0960894X12014758>
18. Wang W-B, Jiang T, Gardner S. Detection of Homologous Recombination Events in Bacterial Genomes. *PLoS One*. 2013 Oct 7; 8(10): e75230. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3792089/>
19. Carpenter T, Lau EY, Lightstone FC. (2013) Identification of a Possible Secondary Picrotoxin-Binding Site on the GABAA-Receptor. *Chemical Research in Toxicology*. 2013; 26(10):1444-54. <http://pubs.acs.org/doi/abs/10.1021/tx400167b>

20. Ames SK, Hysom DA, Gardner SN, Lloyd GS, Gokhale MB, Allen JE. Scalable metagenomic taxonomy classification using a reference genome database. *Bioinformatics* (Oxford). 2013 Sep; 29(18):2253-60. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3753567/>
21. Kirshner DA, Nilmeier JP, Lightstone FC. Catalytic site identification-a web server to identify catalytic site structural matches throughout PDB. *Nucleic Acids Research*. 2013 Jul; 41:W256. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3692059/>
22. Nilmeier JP, Kirshner DA, Wong SE, Lightstone FC. Rapid Catalytic Template Searching as an Enzyme Function Prediction Procedure. *PLoS One*. 2013; 8(5):e62535. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3651201/>
23. Fischer NO, Rasley A, Corzett M, Hwang M, Hoeprich PD, Blanchette CD. Colocalized delivery of adjuvant and antigen using nanolipoprotein particles enhances the immune response to recombinant antigens. *J Am Chem Soc*. 2013 Feb 13; 135(6):2044-7. <http://pubs.acs.org/doi/abs/10.1021/ja3063293>
24. Hodge DR, Willner KM, Ramage JG, Prezioso S, Swanson T, Hastings R, Basavanna U, Datta S, Sharma S, Garber E, Staab A, Petit D, Drumgoole R, Swaney E, TXDPH ; Estacio PL, Hovatt S, Anders DL, Elder IA, Kovacs G, Morse B, Kellogg R, Stanker L, Morse S, Avila J, Pillai S. Comprehensive Laboratory Validation of a Highly Specific Lateral Flow Assay for the Detection of Ricin in Suspicious White Powders and Environmental Samples. *Biosecur Bioterror*. 2013 Dec; 11(4):237-50. doi: 10.1089/bsp.2013.0053 <http://www.ncbi.nlm.nih.gov/pubmed/24320219>

**5. Briefly describe the biological defense work carried out at the facility, including type(s) of microorganisms and/or toxins studied, as well as outdoor studies of biological aerosols.**

**Objectives:** Biological agent detection, therapeutics development, virulence mechanism elucidation, structural characterization, agent viability testing, response planning, assay development for monitoring for biological decontamination/response, and bioforensics. Development of diagnostic platforms that use a variety of techniques, such as PCR, immunoassay, mass spectrometry and genomic sequencing to gather useful information about the species present in the sampling environment. Development of microbial forensic assays to help determine geographic origin and attribution. Beyond detection, response, recovery, and attribution, LLNL also has ongoing research projects to elucidate mechanisms of host-pathogen interactions.

**Microorganisms and/or toxins studied:** Select Agents (HHS, Overlap), NIAID Category A pathogens

**Outdoor studies:** There were no outdoor studies.

**National biological defence research and development programmes: Facilities**

**1. What is the name of the facility?**

Los Alamos National Laboratory (LANL)

**2. Where is it located (provide both address and geographical location)?**

Bikini Atoll Road SM-30, P. O. Box 1663, Los Alamos, NM 87545  
(approximately 45 miles west of Santa Fe, New Mexico)

**3. Floor area of laboratory areas by containment level:**

BL2 (sqM)	322
BL3 (sqM)	0
BL4 (sqM)	0
Total (sqM)	322

**4. The organizational structure of each facility.**

**(i) Total number of personnel 41**

**(ii) Division of personnel:**

Military	0
Civilian	41

**(iii) Division of personnel by category:**

Scientists	23
Engineers	1
Technicians	17
Admin and Support Staff	0

**(iv) List the scientific disciplines represented in the scientific/engineering staff.**

Bacteriology, Cell Biology, Molecular Biology, Bioinformatics, Biological Science, Genetics, Genomics, Microbial Forensics, Microbiology, Molecular Diagnostics, Analytical Biochemistry, Biochemistry, Biotechnology, Environmental Science, Virology, Chemistry

**(v) Are contractor staff working in the facility? If so, provide an approximate number.**

No

**(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

Department of Defense – partly

Department of Energy

Department of Homeland Security

Internal (Laboratory Directed Research and Development, LDRD)

State of California Department of Public Health

**(vii) What are the funding levels for the following program areas:**

Research	\$9,395,000
Development	\$1,500,000
Test and evaluation	\$1,200,000
Total	\$12,095,000

**(viii) Briefly describe the publication policy of the facility:**

As a DOE/NSA facility, LANL is required to make scientific and technical information broadly available, within applicable laws and Departmental requirements, to accomplish mission objectives and strategic goals, promote scientific advancement, satisfy statutory dissemination requirements, and ensure a fair return on Departmental and taxpayer investment. LANL has a mandate to ensure that scientific and technical information is identified, processed, disseminated, and preserved to enable the scientific community and the public to locate and use the unclassified and unlimited-distribution information resulting from DOE research and related endeavors. LANL also has procedures in place to manage and protect classified, sensitive controlled unclassified, and export-controlled scientific and technical information, yet make it accessible for appropriate access by the Department, its contractors, and others. Reviews are conducted prior to publication to determine availability of information, or restrictions thereto. These reviews include, but are not limited to, the following: 1) classification/declassification, 2) copyrighted materials or other intellectual property, 3) export controls or distribution restrictions, and 4) sensitive content that limits access. [US Department of Energy, Scientific and Technical Information Management: <https://www.directives.doe.gov/directives/0241.1-BOrder-b/view>]

**(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)**

1. Micheva-Viteva S, Shou Y, Nowak-Lovato K, Rector KD, and Hong-Geller E. (2013) c-KIT-EGR1 signaling is targeted by Yersinia during infection. BMC Microbiology. 13: 249.  
<http://www.biomedcentral.com/1471-2180/13/249>
2. Harris JF, Micheva-Viteva S, Li N, and Hong-Geller E. (2013) Small-RNA-mediated regulation of host-pathogen interactions. Virulence. 4: 785-795.  
<https://www.landesbioscience.com/journals/virulence/2012VIRULENCE0112R.pdf>
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4. Nowak-Lovato K, Alexandrov LB, Banisadr A, Bauer AL, Bishop AR, Usheva A, Mu F, Hong-Geller E, Rasmussen K, Hlavacek WS, and Alexandrov BS. (2013) Binding of Nucleoid-associated Protein Fis to DNA is Regulated by DNA Breathing Dynamics. PLoS Comp. Biol.,9(1):e1002881. doi: 10.1371/journal.pcbi.1002881. <http://www.ploscompbiol.org/article/fetchObject.action?uri=info%3Adoi%2F10.1371%2Fjournal.pcbi.1002881&representation=PDF>
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6. Song J, Wolinsky M, Wren M, Burr T, Li P-E, and Doggett N. (2013) Forensic Signatures for Marburgviruses. Forensic Sci Int. 233:1-3, 338-347.  
<http://www.sciencedirect.com/science/article/pii/S0379073813004441>
7. Hill, K.K. and Smith, T.J. (2013) Genetic diversity within Clostridium botulinum serotypes, botulinum neurotoxin gene clusters and toxin subtypes. Curr Top Microbiol and Immunol 364:1-20. <http://www.ncbi.nlm.nih.gov/pubmed/23239346>
8. Dover, N. Barash, J., Hill, K., Davenport, K., Teshima, H., Xie, G. and Arnon, S. (2013) Clostridium botulinum strain Af84 contains three neurotoxin gene clusters: bont/A2, bont/F4 and bont/F5. PLoS ONE 8(4): e61205. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3625220/>
9. Dover, N. Barash, J., Hill, K., Xie, G. and Arnon, S. Molecular characterization of a novel botulinum neurotoxin type H gene. JID October 2013. 209 (2): 192-202.  
<http://jid.oxfordjournals.org/content/209/2/192>
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- common evolutionary lineage with *Escherichia coli* O157:H7. *BMC Genomics*. 2014 Jan 10;15(1):17. <http://www.ncbi.nlm.nih.gov/pubmed/24410921>
11. Mitter B, Petric A, Shin MW, Chain PS, Hauberg-Lotte L, Reinhold-Hurek B, Nowak J, Sessitsch A. Comparative genome analysis of *Burkholderia phytofirmans* PsJN reveals a wide spectrum of endophytic lifestyles based on interaction strategies with host plants. *Front Plant Sci*. 2013 Apr 30;4:120. doi: 10.3389/fpls.2013.00120. <http://www.ncbi.nlm.nih.gov/pubmed/23641251>
  12. Sharma PK, Fu J, Zhang X, Fristensky BW, Davenport K, Chain PS, Sparling R, Levin DB. Draft Genome Sequence of Medium-Chain-Length Polyhydroxyalkanoate-Producing *Pseudomonas putida* Strain LS46. *Genome Announc*. 2013 Apr 18;1(2):e0015113. doi: 10.1128/genomeA.00151-13. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3630404/>
  13. Fitzsimons MS, Novotny M, Lo C-C, Dichosa AEK, Yee-Greenbaum JL, Snook JP, Gu W, Chertkov O, Davenport KW, McMurtry K, Gleasner CD, Wills PL, Parson-Quintana B, Chain PS, Detter JS, Lasken RS, Han CS. Nearly finished genomes produced using gel microdroplet culturing reveals substantial intraspecies diversity within the human microbiome. *Genome Research*. 2013 Mar 14; 23(5):878-888. doi: 10.1101/gr.142208.112. <http://genome.cshlp.org/content/23/5/878.full>
  14. Wang D, Han CS, Dichosa AEK, Gleasner CD, Johnson SL, Daligault HE, Davenport KW, Li P-E, Pierson E, Pierson III LS. Draft Genome Sequence of *Pseudomonas putida* Strain S610, a Seedborne Bacterium of Wheat. *Genome Announcements*. 2013 Nov/Dec; 1(6):e0104-13. doi: 10.1128/genomeA.01048-13. <http://genomea.asm.org/content/1/6/e01048-13.full>
  15. Close DW, Ferrara F, Dichosa AEK, Kumar S, Daughton AR, Daligault HE, Reitenga KG, Velappan N, Sanchez TC, Iyer S, Kiss C, Han CS, Bradbury ARM. Using phage display selected antibodies to dissect microbiomes for complete de novo genome sequencing of low abundance microbes. *BMC Microbiology*. 2013 Nov 27; 13:270. doi: 10.1186/1471-2180-13-270. <http://www.biomedcentral.com/1471-2180/13/270>

**5. Briefly describe the biological defense work carried out at the facility, including type(s) of microorganisms and/or toxins studied, as well as outdoor studies of biological aerosols.**

**Objectives:** The biological defense research and development activities at the Los Alamos National Laboratory include pathogen characterization, host-pathogen interaction studies, and pathogen detection and analysis technology development. The main objectives for the studies are to: understand molecular mechanisms of host-pathogen interaction; study molecular, chemical, and physical characteristics of biothreat agents, including bacteria, viruses and toxins, for detection, characterization, assay design and improvement; evaluate detection assay and platform performance; assess commercial techniques for pathogen detection on environmental monitoring procedures; develop DNA, RNA and protein based bioforensics assays; develop next generation high throughput microbial sequencing, finishing and analysis capabilities; perform viral and bacterial pathogen sequencing for characterization, comparative genomic analysis, and metagenomic analysis; develop high throughput assays for host-pathogen protein interactions screening; develop and validate assays to improve the ability to identify and characterize bioterrorism incident; and identify host molecular targets as potential therapeutic candidates.

**Microorganisms and/or toxins studied:** Select Agents (HHS, Overlap), NIAID Category A pathogens

**Outdoor studies:** There were no outdoor studies.

**National biological defence research and development programmes: Facilities**

**1. What is the name of the facility?**

Pacific Northwest National Laboratory (PNNL)

**2. Where is it located (provide both address and geographical location)?**

Richland campus: 902 Battelle Boulevard, Richland, Washington 99352 (located 146 miles southwest from Spokane, WA, and 203 miles southeast from Seattle, WA)

Sequim campus: 1529 West Sequim Bay Road, Sequim, Washington 98382 (located 304 miles northwest from the PNNL Richland, WA campus and 66 miles west from Seattle, WA)

[Note: Personnel and budget are shared between Richland and Sequim campuses.]

**3. Floor area of laboratory areas by containment level (m<sup>2</sup>):**

Richland campus:	BSL-2:	697 m <sup>2</sup>
	BSL-3:	0 m <sup>2</sup>
	BSL-4:	0 m <sup>2</sup>
	Total laboratory floor area:	697 m <sup>2</sup>

Sequim campus:	BSL-2:	154 m <sup>2</sup>
	BSL-3:	0 m <sup>2</sup>
	BSL-4:	0 m <sup>2</sup>
	Total laboratory floor area:	154 m <sup>2</sup>

**4. The organizational structure of each facility:**

<b>(i) Total number of personnel:</b>	Richland campus:	49
	Sequim campus:	7

<b>(ii) Division of personnel:</b>	<b>Military</b>	0
	<b>Civilian</b>	56

<b>(iii) Division of personnel by category:</b>	<b>Scientists</b>	48
	<b>Engineers</b>	0
	<b>Technicians</b>	1
	<b>Admin and Support Staff</b>	7

**(iv) List the scientific disciplines represented in the scientific/engineering staff:**

Analytical Mass Spectrometry, Bacteriology, Biochemistry, Biological Science, Cell Biology, Chemistry, Genetics, Genomics, Mass Spectrometry, Microbial Forensics, Microbiology, Molecular Biology, Nanotechnology, Proteomics, Structural Biology

**(v) Are contractor staff working in the facility? If so, provide an approximate number:**

No

**(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

Department of Defense (DoD) – partly  
 Department of Health and Human Services (HHS)  
 Department of Homeland Security (DHS)  
 Other Government Agencies  
 Internal (Laboratory Directed Research & Development, LDRD)

Technology Maturation (funds generated from previous PNNL licensing returns)

**(vii) What are the funding levels for the following program areas:**

<b>Research</b>	\$3,426,000
<b>Development</b>	\$0
<b>Test and evaluation</b>	\$1,494,000
<b>Total</b>	\$4,920,000

**(viii) Briefly describe the publication policy of the facility:**

As a Department of Energy/National Nuclear Security Administration (DOE/NNSA) facility, PNNL and its facilities are required to make scientific and technical information broadly available, within applicable laws and Departmental requirements, to accomplish mission objectives and strategic goals, promote scientific advancement, satisfy statutory dissemination requirements, and ensure a fair return on Departmental and taxpayer investment. PNNL has a mandate to ensure that scientific and technical information is identified, processed, disseminated, and preserved to enable the scientific community and the public to locate and use the unclassified and unlimited-distribution information resulting from DOE research and related endeavors. PNNL also has procedures in place to manage and protect classified, sensitive controlled unclassified, and export-controlled scientific and technical information, yet make it accessible for appropriate access by the Department, its contractors, and others. Reviews are conducted prior to publication to determine availability of information, or restrictions thereto. These reviews include, but are not limited to, the following: 1) classification/declassification, 2) copyrighted materials or other intellectual property, 3) export controls or distribution restrictions, and 4) sensitive content that limits access. [Department of Energy, Scientific and Technical Information Management: <https://www.directives.doe.gov/directives/0241.1-BOrder-b/view>]

**(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.):**

1. Ansong C, Wu S, Meng D, Liu X, Brewer HM, Kaiser BLD, Nakayasu ES, Cort JR, Pevzner PA, Smith RD, Heffron F, Adkins JN, Pasa-Tolic L. Top-down proteomics reveals a unique protein S-thiolation switch in *Salmonella Typhimurium* in response to infection-like conditions. *Proc Nat Acad Sci USA*. 2013 June 18; 110(25):10153-10158. doi:10.1073/pnas.1221210110  
<http://www.pnas.org/content/110/25/10153.full>
2. Ansong C, Rutledge AC, Mitchell HD, Chauhan S, Jones MB, Kim YM, Mcateer K, Deatherage BL, DuBois JL, Brewer HM, Frank BC, McDermott JE, Metz TO, Peterson SN, Smith RD, Motin VL, Adkins, JN. A multi-omic systems approach to elucidating *Yersinia* virulence mechanisms. *Mol Biosys*. 2013 Oct 24; 9(1):44-54. doi:10.1039/C2MB25287B  
<http://pubs.rsc.org/en/content/articlehtml/2013/mb/c2mb25287b>
3. Clowers BH, Wunschel DS, Kreuzer HW, Engelmann HE, Valentine NB, Wahl, KB. Characterization of Residual Medium Peptides from *Yersinia pestis* Cultures. *Anal Chem*. 2013 April 3; 85(8):3933-3939. doi:10.1021/ac3034272 <http://pubs.acs.org/doi/full/10.1021/ac3034272>
4. Kaiser BLD, Li J, Sanford JA, Kim YM, Kronewitter SR, Jones MB, C Peterson C, Peterson SN, Frank BC, Purvine SO, Brown JN, Metz TO, Smith RD, Heffron F, Adkins NJ. A Multi-Omic View of Host-Pathogen-Commensal Interplay in *Salmonella*-Mediated Intestinal Infection. *PLoS One*. 2013 June 26; 8(6): e67155. doi:10.1371/journal.pone.0067155  
<http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0067155>
5. Kim YM, Schmidt B, Kidwai AS, Jones MB, Deatherage BL, Brewer HM, Mitchell HD, Palsson BO, McDermott JE, Heffron F, Smith RD, Peterson SN, C Ansong C, Hyduke DR, Metz TO, Adkins JN. *Salmonella* Modulates Metabolism During Growth under Conditions that Induce Expression of Virulence Genes. *Molecular Biosys*. 2013 March 22; 9(6):1522-1534. doi:10.1039/C3MB25598K.  
<http://pubs.rsc.org/en/content/articlehtml/2013/mb/c3mb25598k>

6. Merkley ED, Baker ES, Crowell KL, Orton DJ, Taverner T, Ansong C, Ibrahim YM, Burnet MC, Cort JR, Anderson GA, Smith RD, Adkins JN. Mixed-Isotope Labeling with LC-IMS-MS for Characterization of Protein-Protein Interactions by Chemical Cross-Linking . J Am Soc Mass Spectrom. 2013 Feb 20; 24(3):444-449. doi:10.1007/s13361-012-0565-x <http://link.springer.com/article/10.1007%2Fs13361-012-0565-x/fulltext.html>
7. Merkley ED, Cort JR, Adkins JN. Cross-Linking and Mass Spectrometry Methodologies to Facilitate Structural Biology: Finding a Path through the Maze. J Struct Funct Genomics. 2013 Aug 7; 14(3):77-90. doi:10.1007/s10969-013-9160-z <http://link.springer.com/article/10.1007/s10969-013-9160-z/fulltext.html>
8. Sadler NC, Melnicki MR, Serres MH, Merkley ED, Chrisler WB, Hill EA, Romine MF, Kim S, Zink EM, Datta S, Smith RD, Beliaev AS, Konopka A, Wright AT. Live Cell Chemical Profiling of Temporal Redox Dynamics in a Photoautotrophic Cyanobacterium. ACS Chem Biol. 2013 Oct 29; doi:10.1021/cb400769v. <http://pubs.acs.org/doi/full/10.1021/cb400769v>
9. Seiner DR, Colburn HA, Baird CL, Bartholomew RA, Straub TM, Victry KD, Hutchison JR, Valentine NB, Bruckner-Lea CJ. Evaluation of the FilmArray® system for detection of Bacillus anthracis, Francisella tularensis, and Yersinia pestis. J Appl Microbiol. 2013 Jan 31; 114(4):992-1000. doi:10.1111/jam.12107 <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3617465/>
10. Straub TM, Baird CL, Bartholomew RA, Colburn HA, Seiner DR, Victry KD, Zhang L, Bruckner-Lea CJ. Estimated Copy Number of Bacillus anthracis Plasmids pXO1 and pXO2 using Digital PCR. J Microbiol Methods. 2013 January; 9(1): 9–10. <http://www.sciencedirect.com/science/article/pii/S0167701212003466> <http://dx.doi.org/10.1016/j.mimet.2012.10.013>
11. Zhang Y, Gardberg A, Edwards TE, Sankaran B, Robinson H, Varnum SM, Buchko, GW. Structural Insights into the Functional Role of the Hcn Sub-domain of the Receptor-Binding Domain of the Botulinum Neurotoxin Mosaic Serotype C/D. Biochimie. 2013; 95(7):1379-1385. doi:10.1016/j.biochi.2013.03.006. <http://www.sciencedirect.com/science/article/pii/S0300908413000928>

**5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms<sup>5</sup> and/or toxins studied, as well as outdoor studies of biological aerosols:**

**Objectives:** PNNL is involved in biodefense-related activities, such as agent characterization (e.g., knock out experiments and investigation of infectious properties of agents) and the development of detection methods (e.g., nucleic acid, toxin, and proteomic signatures), testing and evaluation of commercial off the shelf equipment for agent detection as well as investigation of next generation biodetection equipment, biological and chemical forensics, investigation of natural history of agents, and interrogating DNA sequencing data and related analysis tools. No outdoor studies of biological aerosols were collected.

**Microorganisms and/or toxins studied:** HHS Select Toxins, Simulants

**Outdoor Studies:** There were no outdoor studies.

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<sup>5</sup> Including viruses and prions.

**National biological defence research and development programmes: Facilities**

**1. Name of the facility:**

Sandia National Laboratories (SNL)

**2. Where is it located?**

New Mexico Campus: P. O. Box 5800, Albuquerque, NM 87185 (located on Kirtland Air Force Base, in southeastern Albuquerque)

California Campus: 7011 East Avenue, Livermore, California (located in Livermore, CA.)

[Note: Personnel and budget are shared between New Mexico and California campuses.]

**3. Floor area of laboratory areas by containment level (m<sup>2</sup>):**

New Mexico campus:	BSL-2:	894.5 m <sup>2</sup>
	BSL-3:	0 m <sup>2</sup>
	BSL-4:	0 m <sup>2</sup>
	Total laboratory floor area:	894.5 m <sup>2</sup>

California campus:	BSL-2:	590 m <sup>2</sup>
	BSL-3:	0 m <sup>2</sup>
	BSL-4:	0 m <sup>2</sup>
	Total laboratory floor area:	590 m <sup>2</sup>

**4. Organizational structure of each facility:**

<b>(i) Total number of personnel:</b>	New Mexico campus:	54
	California campus:	40

<b>(ii) Division of personnel:</b>	<b>Military</b>	0
	<b>Civilian</b>	94

<b>(iii) Division of personnel by category:</b>	<b>Scientists</b>	53
	<b>Engineers</b>	7
	<b>Technicians</b>	30
	<b>Admin and Support Staff</b>	4

**(iv) Scientific discipline(s) that best describes field of work:**

Aerosol Science, Biochemistry, Biomedical Engineering, Biotechnology, Chemical Engineering, Materials Science, Medicine, Nanotechnology, Aerobiology, Bioinformatics, Biological Science, Cell Biology, Immunology, Molecular Biology, Virology, Molecular Diagnostics, Biophysics, Chemistry, Physics, Analytical Biochemistry, Analytical Chemistry, Analytical Mass Spectrometry, Bacteriology, Bioinorganic Chemistry, Biomedical Science, Computational Biology, Computer Engineering, Computer Science, Electrical Engineering, Environmental Engineering, Environmental Science, Genetics, Genomics, Mass Spectrometry, Mathematics, Mechanical Engineering, Microbial Forensics, Microbiology, Neuroscience, Operations Research Analysis, Optical Spectroscopy, Pathology, Physiology, Polymer Science, Protein Engineering, Proteomics, Structural Biology, Toxicology

**(v) Are Contractor staff working in the facility?**

Yes

Number: 6 (New Mexico campus)

**(vi) What is (are) the source(s) of funding for the work conducted in the facility?**

Department of Defense – partly

Department of Homeland Security

Internal (Laboratory Directed Research & Development, LDRD)

**(vii) What are the funding levels for Research and Development and Testing and Evaluation as of the most recent calendar year?**

Research	\$16,369,000
Development	\$2,110,000
Test and Evaluation	\$1,537,000
Total	\$20,016,000

**(viii) Briefly describe the publication policy of the facility:**

As a Department of Energy/National Nuclear Security Administration (DOE/NNSA) facility, Sandia National Laboratories is required to make scientific and technical information broadly available, within applicable laws and Departmental requirements, to accomplish mission objectives and strategic goals, promote scientific advancement, satisfy statutory dissemination requirements, and ensure a fair return on Departmental and taxpayer investment. SNL has a mandate to ensure that scientific and technical information is identified, processed, disseminated, and preserved to enable the scientific community and the public to locate and use the unclassified and unlimited-distribution information resulting from DOE research and related endeavors. SNL also has procedures in place to manage and protect classified, sensitive controlled unclassified, and export-controlled scientific and technical information, yet make it accessible for appropriate access by the Department, its contractors, and others. Reviews are conducted prior to publication to determine availability of information, or restrictions thereto. These reviews include, but are not limited to, the following: 1) classification/declassification, 2) copyrighted materials or other intellectual property, 3) export controls or distribution restrictions, and 4) sensitive content that limits access. [Department of Energy, Scientific and Technical Information Management:

<https://www.directives.doe.gov/directives/0241.1-BOrder-b/view>]

**(ix) Provide a list of publicly available papers and reports resulting from work during the previous 12 months:**

1. Harmon B, Kozina C, Maar D, Carpenter TS, Branda CS, Negrete OA, Carson BD., Identification of critical amino acids within the nucleoprotein of Tacaribe virus, important for anti-interferon activity. J Biol Chem. 2013 Mar 22;288(12):8702-11., doi: 10.1074/jbc.M112.444760. Epub 2013 Feb 4. PubMed PMID: 23382389; PubMed, Central PMCID: PMC3605688.  
<http://www.jbc.org/content/288/12/8702.abstract> <http://www.jbc.org/content/288/12/8702.long>,
2. Mai J, Abhyankar W, Piccini ME, Olano JP, Willson R, Hatch AV. Rapid Detection of Trace Bacteria in Biofluids Using Porous Monoliths in Microchannels. Biosens Bioelectron. 2013 Nov 12; 54:435-41. <http://www.sciencedirect.com/science/article/pii/S0956566313007902>,
3. Bent ZW, Branda SS, Young, GM. The Yersinia enterocolitica Ysa type III secretion system is expressed during infections both in vitro and in vivo. MicrobiologyOpen. 2013 Dec; 2(6): 962-75. <http://onlinelibrary.wiley.com/doi/10.1002/mbo3.136/abstract;jsessionid=DCF4F5927DF9A46C103F65B2CB8FD317.f02t02>,
4. Bent ZW, Brazel DM, Tran-Gyamfi MB, Hamblin RY, VanderNoot VA, Branda SS. Use of a Capture-Based Pathogen Transcript Enrichment Strategy for RNA-Seq Analysis of the Francisella Tularensis LVS Transcriptome during Infection of Murine Macrophages. PLOS ONE 2013 Oct 14; 8(10): e77834. <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0077834;jsessionid=92887B34479627D028C8EB7EF10FD4B3>,

5. Sinha A, Jebrail MJ, Kim H, Patel KD, Branda SS. A versatile automated platform for micro-scale cell stimulation experiments, J. Vis. Exp. 2013; 78: e50597. <http://www.jove.com/video/50597/a-versatile-automated-platform-for-micro-scale-cell-stimulation>
6. Tarn D, Ashley CE, Xue M, Carnes EC, Zink JJ, Brinker CJ. Mesoporous Silica Nanoparticle Nanocarriers: Biofunctionality and Biocompatibility. Accts Chem Res. 2013 Feb 13; 46(3): 792-801. <http://pubs.acs.org/doi/abs/10.1021/ar3000986>
7. Dengler EC, Liu J, Kerwin A, Torres S, Olcott CM, Bowman BN, Armijo L, Gentry K, Wilkerson K, Wallace J, Jiang X, Carnes EC, Brinker CJ, Milligan ED. Mesoporous silica-supported lipid bilayers (protocells) for DNA cargo delivery to the spinal cord. J. Control Release 2013 Mar 18; 168(2): 209-224. <http://www.sciencedirect.com/science/article/pii/S0168365913001521>,

**5. Briefly describe the biological defense work carried out at the facility, including type(s) of microorganisms and/or toxins studied, as well as outdoor studies of biological aerosols.**

**Objectives:** To improve our nation's ability to anticipate and defend against biological threats, our multidisciplinary research team is applying Sandia's traditional strengths in engineering and technology development to achieve the following goals:

1. Gain basic knowledge regarding the fundamental molecular processes of pathogenesis, including the dynamic interactions between microbial pathogens and their hosts.
2. Develop assays, novel materials, and platforms to detect and diagnose traditional and unknown pathogens, as well as to discover novel therapeutic targets.
3. Obtain an understanding of the microbiome's effects on human health in the absence or in the presence of an infectious disease.

**Microorganisms and/or toxins studied:** NIAID Category A pathogens, Simulants

**Outdoor studies:** There were no outdoor studies.

**National biological defence research and development programmes: Facilities**

**1. What is the name of the facility?**

CDC, National Center for Environmental Health (NCEH), Division of Laboratory Sciences (DLS)

**2. Where is it located (provide both address and geographical location)?**

4770 Buford Highway, Mail stop F-47, Atlanta, Georgia 30341

**3. Floor area of laboratory areas by containment level:**

BSL-2: 454 m<sup>2</sup>

BSL-3: 114 m<sup>2</sup>

BSL-4: 0 m<sup>2</sup>

Total laboratory floor area -568 m<sup>2</sup>

**4. The organizational structure of each facility:**

**(i) -Total number of personnel** 19

**(ii) Division of personnel:**

Military 0

Civilian 19

**(iii) Division of personnel by category:**

Scientists 19

Engineers 0

Technicians 0

Administrative and support staff 0

**(iv) List the scientific disciplines represented in the scientific/engineering staff:**

Analytical Biochemistry, Analytical Chemistry, Analytical Mass Spectrometry, Biochemistry, Biology, Chemistry, Mass Spectrometry, Proteomics

**(v) Are contractor staff working in the facility? If so, provide an approximate number:**

Yes Number: 5

**(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

Department of Health and Human Services

**(vii) -What are the funding levels for the following program areas: -**

Research \$1,026,190

Development \$350,000

Test and evaluation \$934,126

Total \$2,310,316

**(viii) Briefly describe the publication policy of the facility: -**

After review for dual use determination, scientists are encouraged to publish their results in the peer reviewed scientific literature and to present their work at national and international professional meetings. The clearance policy for information products disseminated outside CDC for public use is available online at: <http://www.cdc.gov/od/science/policies>

**(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)**

1. Abney CW, Knaack JL, Ali AA, Johnson RC. Novel dual-mode immunomagnetic method for studying reactivation of nerve agent-inhibited butyrylcholinesterase. *Chem Res Toxicol*. 2013 May 20;26(5):775-82. <http://www.ncbi.nlm.nih.gov/pubmed/23656164>
2. Andacht TM, Pantazides BG, Crow BS, Fidler A, Noort D, Thomas JD, Blake TA, Johnson RC. An enhanced throughput method for quantification of sulfur mustard adducts to human serum albumin via isotope dilution tandem mass spectrometry. *J Anal Toxicol*. 2014 Jan;38(1):8-15. <http://jat.oxfordjournals.org/content/38/1/8.long>
3. Carter MD, Crow BS, Pantazides BG, Watson CM, Thomas JD, Blake TA, Johnson RC. Direct quantitation of methyl phosphonate adducts to human serum butyrylcholinesterase by immunomagnetic-UHPLC-MS/MS. *Anal Chem*. 2013 Nov 19;85(22):11106-11. <http://pubs.acs.org/doi/abs/10.1021/ac4029714>
4. Carter MD, Crow BS, Pantazides BG, Watson CM, Decastro BR, Thomas JD, Blake TA, Johnson RC. Profiling cholinesterase adduction: a high-throughput prioritization method for organophosphate exposure samples. *J Biomol Screen*. 2014 Feb;19(2):325-30. <http://www.ncbi.nlm.nih.gov/pubmed/23954929>
5. Hamelin EI, Bragg W, Shaner RL, Swaim LL, Johnson RC. Comparison of high-resolution and tandem mass spectrometry for the analysis of nerve agent metabolites in urine. *Rapid Commun Mass Spectrom*. 2013 Aug 15;27(15):1697-04. <http://www.ncbi.nlm.nih.gov/pubmed/23821563>
6. Lautenschlager M, Maslanka SE, Paul PA, Kalb SR, Barr JR, Raphael BR. Recovery and Detection of Botulinum Neurotoxins from a Nonporous Surface. *Journal of Microbiological Methods*. 2013 92(3): 278-280. <http://www.sciencedirect.com/science/article/pii/S0167701212004162>
7. Kalb SR, Barr JR. Mass Spectrometric Identification and Differentiation of Botulinum Neurotoxins through Toxin Proteomics. *Reviews in Analytical Chemistry*. 2013 32(3): 189-96. <http://www.degruyter.com/view/j/revac.2013.32.issue-3/revac-2013-0013/revac-2013-0013.xml>
8. Knaack JS, Zhou Y, Magnuson M, Silvestri E, Johnson RC. Performance of a novel high throughput method for the determination of VX in drinking water samples. *Anal Chem*. 2013 Mar 5;85(5):2611-6. <http://pubs.acs.org/doi/abs/10.1021/ac3036102>
9. Pittman CT, Guido JM, Hamelin EI, Blake TA, Johnson RC. Analysis of a ricin biomarker, ricinine, in 989 individual human urine samples. *J Anal Toxicol*. 2013 May;37(4):237-40. <http://jat.oxfordjournals.org/content/37/4/237.long>
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**5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms\* and/or toxins studied, as well as outdoor studies of biological aerosols.**

**Objectives:** The CDC National Center for Environmental Health, Division of Laboratory Science has successfully developed toxin assays that are critical for better detection and diagnosis during a public health response to biological toxins.

**Microorganisms and/or toxins studied:** U.S. Select Agents and Toxins, NIAID Category A pathogens

**Outdoor Studies:** Outdoor studies of biological aerosols were not conducted at the facility or off-site by facility personnel.

**National biological defence research and development programmes: Facilities**

**1. What is the name of the facility?**

CDC, Office of Infectious Diseases (OID)

**2. Where is it located (provide both address and geographical location)?**

1600 Clifton Road Northeast, Atlanta, Georgia 30333

**3. Floor area of laboratory areas by containment level:**

BL2	294 (sqM)
BL3	2143 (sqM)
BL4	543 (sqM)
Total laboratory floor area	2980 (sqM)

**4. The organizational structure of each facility.**

**(i) Total number of personnel** 266

**(ii) Division of personnel:**

Military	5
Civilian	261

**(iii) Division of personnel by category:**

Scientists	227
Engineers	1
Technicians	20
Administrative and support staff	18

**(iv) List the scientific disciplines represented in the scientific/engineering staff.**

Animal Science, Biochemistry, Bioinformatics, Biology, Biological Science, Cell Biology, Chemistry, Clinical Immunology, Ecology, Entomology, Epidemiology, Genetics, Genomics, Immunology, Medicine, Microbiology, Molecular Biology, Molecular Diagnostics, Public Health, Statistics, Veterinary Medicine, Virology

**(v) Are contractor staff working in the facility? If so, provide an approximate number.**

Yes Number: 65

**(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Agency for International Development (USAID) , Department of Defense (DOD) – partly, Department of Health and Human Services (HHS), Department of Homeland Security (DHS), Department of State

**(vii) What are the funding levels for the following program areas:**

Research	\$ 14,007,196
Development	\$ 5,259,067
Test and evaluation	\$ 5,260,085
Total	\$ 24,526,348

**(viii) Briefly describe the publication policy of the facility:**

After review for dual use determination, scientists are encouraged to publish their results in the peer reviewed scientific literature and to present their work at national and international professional meetings. The clearance policy for information products disseminated outside CDC for public use is available online at: <http://www.cdc.gov/od/science/policies>.

**(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)**

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**5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms\* and/or toxins studied, as well as outdoor studies of biological aerosols.**

**Objectives:** Activities at this facility include developing diagnostic assays for public health, developing and validating methods to differentiate and characterize organisms and the toxins that they produce, developing environmental sampling methods for recovery of agents from porous and nonporous surfaces for public health, routine reference antimicrobial susceptibility testing of clinical isolates, conducting molecular and antigenic characterization of organisms, determining pathogenicity and virulence of infectious agents, determining the natural history of infectious organisms, and conducting epidemiologic studies and surveillance for diseases.

**Microorganisms and/or toxins studied:** Select Agents (HHS, Overlap) and Toxins, NIAID Category A pathogens

**Outdoor Studies:** Outdoor studies of biological aerosols were not conducted at the facility or off-site by facility personnel.

**National biological defence research and development programmes: Facilities**

**1. What is the name of the facility?**

CDC, OID, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Vector Borne Diseases (DVBD) - Ft. Collins

**2. Where is it located (provide both address and geographical location)?**

3156 Rampart Road, Fort Collins, Colorado 80521

**3. Floor area of laboratory areas by containment level:**

BSL-2: 66 m<sup>2</sup>

BSL-3: 1142 m<sup>2</sup>

BSL-4: 0 m<sup>2</sup>

Total laboratory floor area 1208 m<sup>2</sup>

**4. -The organizational structure of each facility:**

**(i) -Total number of personnel** 54

**(ii) -Division of personnel:**

Military 0

Civilian 54

**(iii) -Division of personnel by category:**

Scientists 27

Engineers 0

Technicians 10

Administrative and support staff 17

**(iv) List the scientific disciplines represented in the scientific/engineering staff:**

Animal Science, Bacteriology, Bioinformatics, Biological Science, Cell Biology, Ecology, Entomology, Environmental Science, Epidemiology, Genomics, Immunology, Medicine, Microbiology, Molecular Biology, Molecular Diagnostics, Pathology, Public Health, Structural Biology, Veterinary Medicine, Virology

**(v) Are contractor staff working in the facility? If so, provide an approximate number:**

Yes Number: 6

**(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

Agency for International Development (USAID)

Department of Health & Human Services

Department of Defense (DoD) – partly

Department of State (DoS)

**(vii) What are the funding levels for the following program areas: -**

Research \$1,123,562

Development \$1,123,562

Test and evaluation \$1,072,997

Total \$3,320,120

**(viii) Briefly describe the publication policy of the facility:**

After review for dual use determination, scientists are encouraged to publish their results in the peer-reviewed scientific literature and to present their work at national and international professional meetings. Publication is encouraged and managed by editorial and clearance policies conducted at all levels of the CDC. The clearance policy for information products disseminated outside CDC for public use is available online at: <http://www.cdc.gov/od/science/policies>.

**(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)**

1. Eisen RJ, Ensore RE, Atiku LA, Zielinski-Gutierrez E, Mpanga JT, Kajik E, Andama V, Mungujakisa C, Tibo E, MacMillan K, Borchert JN, and Gage KL. 2013. Evidence that rodent control strategies ought to be improved to enhance food security and reduce the risk of rodent-borne illnesses within subsistence farming villages in the plague-endemic West Nile region, Uganda. *International Journal of Pest Management*. 2013 Oct;59(4):245-258.  
<http://www.tandfonline.com/doi/full/10.1080/09670874.2013.845321>
2. Graham CB, Borchert JN, Black WC, Atiku LA, Mpanga JT, Boegler KA, Moore SM, Gage KL, Eisen RJ. Blood meal identification in off-host cat fleas (*Ctenocephalides felis*) from a plague-endemic region of Uganda. *Am J Trop Med Hyg*. 2013 Feb;88(2):381-389.  
<http://www.ajtmh.org/content/88/2/381.long>
3. Jones RT, Vetter SM, Gage KL. Short report: Exposing laboratory-reared fleas to soil and wild flea feces increases transmission of *Yersinia pestis*. *Amer J Trop Med Hyg*, 2013 Oct;89(4):784-787.  
<http://www.ajtmh.org/content/89/4/784.long>
4. Jones RT, Vetter SM, Montenieiri J, Holmes J, Bernhardt SA, Gage KL. *Yersinia pestis* infection and laboratory conditions alter flea-associated bacterial communities. *ISME J*. 2013 Jan;7(1):24-28. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3526169/>
5. Kading R, Crabtree M, Miller B. Inactivation of infectious virus and serological detection of virus antigen in Rift Valley fever virus-exposed mosquitoes fixed with paraformaldehyde. *J Virol Methods*. 2013 Apr;189(1):184-8. doi: 10.1016/j.jviromet.2013.01.014. Epub 2013 Feb 4.  
<http://www.sciencedirect.com/science/article/pii/S0166093413000190>
6. Nelson C, Kugeler K, Petersen J, Mead P. Tularemia – United States, 2001-2010. *MMWR Morbidity Mortality Weekly Report*. 2013 Nov 29;62(47):963-6  
[http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6247a5.htm?s\\_cid=mm6247a5\\_w](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6247a5.htm?s_cid=mm6247a5_w)
7. Tularemia - United States, 2001-2010. *MMWR Morb Mortal Wkly Rep*. 2013 Nov 29;62(47):963-6.  
<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6247a5.htm>
8. Williams SK, Schotthoefer AM, Monteneri JA, Holmes JL, Vetter SM, Gage KL, Bearden. Effects of low temperature flea maintenance on the transmission of *Yersinia pestis* by *Oropsylla montana*. *Vector Borne Zoonotic Dis*. 2013 Jul;13(7):468-478.  
<http://online.liebertpub.com/doi/pdf/10.1089/vbz.2012.1017>

**5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms<sup>4</sup> and/or toxins studied, as well as outdoor studies of biological aerosols.**

**Objectives:** CDC's Division of Vector Borne Diseases (DVBD) has the primary responsibility for research on tularemia, plague and alphaviruses. This research involves development of assays for surveillance, detection, and molecular and antigenic characterization.

**Microorganisms and/or toxins studied:** Select Agents (HHS, Overlap), NIAID Category A pathogens

**Outdoor Studies:** No outdoor studies of biological aerosols were conducted at the facility or off-site by facility personnel.

**National biological defence research and development programmes Facilities**

**1. What is the name of the facility?**

Integrated Research Facility at Rocky Mountain Laboratories (IRF - RML)

**2. Where is it located (provide both address and geographical location)?**

903 South 4th Street, Hamilton, Montana 59840

**3. Floor area of laboratory areas by containment level:**

BSL-2: 1361 m<sup>2</sup>

BSL-3: 407 m<sup>2</sup>

BSL-4: 1145 m<sup>2</sup>

Total laboratory floor area 2913 m<sup>2</sup>

**4. The organizational structure of each facility.**

**(i) Total number of personnel** 103

**(ii) Division of personnel:**

Military 0

Civilian 103

**(iii) Division of personnel by category:**

Scientists 73

Engineers 0

Technicians 25

Administrative and support staff 5

**(iv) List the scientific disciplines represented in the scientific/engineering staff.**

Aerobiology, Animal Science, Bacteriology, Biochemistry, Biological Science, Cell Biology, Entomology, Genetics, Genomics, Immunology, Microbiology, Microscopy, Molecular Biology, Pathology, Proteomics, Veterinary Medicine, Virology

**(v) Are contractor staff working in the facility? If so, provide an approximate number.**

Yes Number: 5

**(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

Department of Health and Human Services (HHS)

**(vii) What are the funding levels for the following program areas:**

Research \$22,416,073

Development \$0

Test and evaluation \$0

Total \$22,416,073

**(viii) Briefly describe the publication policy of the facility:**

All researchers are encouraged to publish results in peer-reviewed open literature. The NIH Public Access Policy (<http://publicaccess.nih.gov/policy.htm>) ensures that the public has access to the published results of NIH-funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the National Library of Medicine's digital archive, PubMed Central, upon acceptance for publication. To help advance science and improve human health, the policy requires that these papers are accessible to the public on PubMed Central no later than 12 months after publication.

**(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)**

1. Best SM. Viruses PLAY DEAD to TAME interferon responses. *Cell Host Microbe*. 2013 Aug 14;14(2):117-8. doi: 10.1016/j.chom.2013.07.014. PubMed PMID: 23954149; PubMed Central PMCID: PMC3780386. <http://www.sciencedirect.com/science/article/pii/S193131281300262X>
2. Bukreyev AA, Chandran K, Dolnik O, Dye JM, Ebihara H, Leroy EM, Mühlberger E, Netesov SV, Patterson JL, Paweska JT, Saphire EO, Smither SJ, Takada A, Towner JS, Volchkov VE, Warren TK, Kuhn JH. Discussions and decisions of the 2012-2014 International Committee on Taxonomy of Viruses (ICTV) Filoviridae Study Group, January 2012-June 2013. *Arch Virol*. 2013 Oct 13. [Epub ahead of print] PubMed PMID: 24122154. <http://link.springer.com/article/10.1007%2Fs00705-013-1846-9/fulltext.html>
3. Case ED, Chong A, Wehrly TD, Hansen B, Child R, Hwang S, Virgin HW, Celli J. The Francisella O-antigen mediates survival in the macrophage cytosol via autophagy avoidance. *Cell Microbiol*. 2013 Nov 29. doi: 10.1111/cmi.12246. [Epub ahead of print] PubMed PMID: 24286610. <http://onlinelibrary.wiley.com/doi/10.1111/cmi.12246/abstract>
4. Celli J, Zahrt TC. Mechanisms of Francisella tularensis intracellular pathogenesis. *Cold Spring Harb Perspect Med*. 2013 Apr 1;3(4):a010314. doi: 10.1101/cshperspect.a010314. Review. PubMed PMID: 23545572. <http://perspectivesinmedicine.cshlp.org/content/3/4/a010314.long>
5. Changula K, Yoshida R, Noyori O, Marzi A, Miyamoto H, Ishijima M, Yokoyama A, Kajihara M, Feldmann H, Mweene AS, Takada A. Mapping of conserved and species-specific antibody epitopes on the Ebola virus nucleoprotein. *Virus Res*. 2013 Sep;176(1-2):83-90. doi: 10.1016/j.virusres.2013.05.004. Epub 2013 May 20. PubMed PMID: 23702199; PubMed Central PMCID: PMC3787873. <http://www.sciencedirect.com/science/article/pii/S016817021300169X>
6. Cheung GY, Kretschmer D, Queck SY, Joo HS, Wang R, Duong AC, Nguyen TH, Bach TH, Porter AR, Deleo FR, Peschel A, Otto M. Insight into structure-function relationship in phenol-soluble modulins using an alanine screen of the phenol-soluble modulin (PSM)  $\alpha 3$  peptide. *FASEB J*. 2014 Jan;28(1):153-61. doi: 10.1096/fj.13-232041. Epub 2013 Sep 5. PubMed PMID: 24008753; PubMed Central PMCID: PMC3868839. <http://www.fasebj.org/content/28/1/153.long>
7. Choi YP, Priola SA. A specific population of abnormal prion protein aggregates is preferentially taken up by cells and disaggregated in a strain-dependent manner. *J Virol*. 2013 Nov;87(21):11552-61. doi: 10.1128/JVI.01484-13. Epub 2013 Aug 21. PubMed PMID: 23966386; PubMed Central PMCID: PMC3807341. <http://jvi.asm.org/content/87/21/11552.long>
8. Chong A, Child R, Wehrly TD, Rockx-Brouwer D, Qin A, Mann BJ, Celli J. Structure-Function Analysis of DipA, a Francisella tularensis Virulence Factor Required for Intracellular Replication. *PLoS One*. 2013 Jun 26;8(6):e67965. Print 2013. PubMed PMID: 23840797; PubMed Central PMCID: PMC3694160. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3694160/>
9. Crane DD, Griffin AJ, Wehrly TD, Bosio CM. B1a cells enhance susceptibility to infection with virulent Francisella tularensis via modulation of NK/NKT cell responses. *J Immunol*. 2013 Mar 15;190(6):2756-66. doi: 10.4049/jimmunol.1202697. Epub 2013 Feb 1. PubMed PMID: 23378429; PubMed Central PMCID: PMC3594638. <http://www.jimmunol.org/content/190/6/2756.long>
10. Crane DD, Ireland R, Alinger JB, Small P, Bosio CM. Lipids derived from virulent Francisella tularensis broadly inhibit pulmonary inflammation via toll-like receptor 2 and peroxisome proliferator-activated receptor  $\alpha$ . *Clin Vaccine Immunol*. 2013 Oct;20(10):1531-40. doi: 10.1128/CVI.00319-13. Epub 2013 Aug 7. PubMed PMID: 23925884; PubMed Central PMCID: PMC3807199. <http://cvi.asm.org/content/20/10/1531.long>
11. DeBuysscher BL, de Wit E, Munster VJ, Scott D, Feldmann H, Prescott J. Comparison of the pathogenicity of Nipah virus isolates from Bangladesh and Malaysia in the Syrian hamster. *PLoS Negl Trop Dis*. 2013;7(1):e2024. doi: 10.1371/journal.pntd.0002024. Epub 2013 Jan 17. PubMed PMID: 23342177; PubMed Central PMCID: PMC3547834. <http://www.plosntds.org/article/info%3Adoi%2F10.1371%2Fjournal.pntd.0002024>

12. de Jong MF, Starr T, Winter MG, den Hartigh AB, Child R, Knodler LA, van Dijk JM, Celli J, Tsolis RM. Sensing of bacterial type IV secretion via the unfolded protein response. *MBio*. 2013 Feb 19;4(1):e00418-12. doi: 10.1128/mBio.00418-12. PubMed PMID: 23422410; PubMed Central PMCID: PMC3624511. <http://mbio.asm.org/content/4/1/e00418-12.long>
13. de Wit E, Munster VJ. MERS-CoV: the intermediate host identified? *Lancet Infect Dis*. 2013 Oct;13(10):827-8. doi: 10.1016/S1473-3099(13)70193-2. Epub 2013 Aug 9. PubMed PMID: 23933068. <http://www.sciencedirect.com/science/article/pii/S1473309913701932>
14. de Wit E, Prescott J, Baseler L, Bushmaker T, Thomas T, Lackemeyer MG, Martellaro C, Milne-Price S, Haddock E, Haagmans BL, Feldmann H, Munster VJ. The Middle East respiratory syndrome coronavirus (MERS-CoV) does not replicate in Syrian hamsters. *PLoS One*. 2013 Jul 2;8(7):e69127. doi: 10.1371/journal.pone.0069127. PubMed PMID: 23844250; PubMed Central PMCID: PMC3699510. <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0069127>
15. de Wit E, Rasmussen AL, Falzarano D, Bushmaker T, Feldmann F, Brining DL, Fischer ER, Martellaro C, Okumura A, Chang J, Scott D, Benecke AG, Katze MG, Feldmann H, Munster VJ. Middle East respiratory syndrome coronavirus (MERS-CoV) causes transient lower respiratory tract infection in rhesus macaques. *Proc Natl Acad Sci U S A*. 2013 Oct 8;110(41):16598-603. doi: 10.1073/pnas.1310744110. Epub 2013 Sep 23. PubMed PMID: 24062443; PubMed Central PMCID: PMC3799368. <http://www.pnas.org/content/110/41/16598.full>
16. Elder AM, Henderson DM, Nalls AV, Wilham JM, Caughey BW, Hoover EA, Kincaid AE, Bartz JC, Mathiason CK. In vitro detection of prionemia in TSE-infected cervids and hamsters. *PLoS One*. 2013 Nov 1;8(11):e80203. doi: 10.1371/journal.pone.0080203. eCollection 2013. PubMed PMID: 24224043; PubMed Central PMCID: PMC3815098. <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0080203>
17. Escaffre O, Borisevich V, Carmical JR, Prusak D, Prescott J, Feldmann H, Rockx B. Henipavirus pathogenesis in human respiratory epithelial cells. *J Virol*. 2013 Mar;87(6):3284-94. doi: 10.1128/JVI.02576-12. Epub 2013 Jan 9. PubMed PMID: 23302882; PubMed Central PMCID: PMC3592112. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3592112/>
18. Falzarano D, de Wit E, Martellaro C, Callison J, Munster VJ, Feldmann H. Inhibition of novel  $\beta$  coronavirus replication by a combination of interferon- $\alpha$ 2b and ribavirin. *Sci Rep*. 2013;3:1686. doi: 10.1038/srep01686. PubMed PMID: 23594967; PubMed Central PMCID: PMC3629412. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3629412/>
19. Falzarano D, de Wit E, Rasmussen AL, Feldmann F, Okumura A, Scott DP, Brining D, Bushmaker T, Martellaro C, Baseler L, Benecke AG, Katze MG, Munster VJ, Feldmann H. Treatment with interferon- $\alpha$ 2b and ribavirin improves outcome in MERS-CoV-infected rhesus macaques. *Nat Med*. 2013 Oct;19(10):1313-7. doi: 10.1038/nm.3362. Epub 2013 Sep 8. PubMed PMID: 24013700. <http://www.nature.com/nm/journal/v19/n10/full/nm.3362.html>
20. Falzarano D, Feldmann H. Vaccines for viral hemorrhagic fevers--progress and shortcomings. *Curr Opin Virol*. 2013 Jun;3(3):343-51. doi: 10.1016/j.coviro.2013.04.007. Epub 2013 Jun 15. Review. PubMed PMID: 23773330; PubMed Central PMCID: PMC3743920. <http://www.sciencedirect.com/science/article/pii/S187962571300062X>
21. Feldmann F, Feldmann H. Ebola: facing a new transboundary animal disease? *Dev Biol (Basel)*. 2013;135:201-9. doi: 10.1159/000190049. Epub 2013 May 14. PubMed PMID: 23689898. <http://www.ncbi.nlm.nih.gov/pubmed/23689898>
22. Gherardini FC. *Borrelia burgdorferi* HtrA may promote dissemination and irritation. *Mol Microbiol*. 2013 Oct;90(2):209-13. doi: 10.1111/mmi.12390. Epub 2013 Sep 16. PubMed PMID: 23998919. <http://onlinelibrary.wiley.com/doi/10.1111/mmi.12390/abstract>
23. Gilk SD, Cockrell DC, Luterbach C, Hansen B, Knodler LA, Ibarra JA, Steele-Mortimer O, Heinzen RA. Bacterial colonization of host cells in the absence of cholesterol. *PLoS Pathog*. 2013 Jan;9(1):e1003107. doi: 10.1371/journal.ppat.1003107. Epub 2013 Jan 24. PubMed PMID: 23358892; PubMed Central PMCID: PMC3554619. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3554619/>

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82. van Doremalen N, Bushmaker T, Munster VJ. Stability of Middle East respiratory syndrome coronavirus (MERS-CoV) under different environmental conditions. *Euro Surveill*. 2013 Sep 19;18(38). pii: 20590. PubMed PMID: 24084338. <http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=20590>
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85. Zivcec M, Safronetz D, Scott D, Robertson S, Ebihara H, Feldmann H. Lethal Crimean-Congo hemorrhagic fever virus infection in interferon  $\alpha/\beta$  receptor knockout mice is associated with high viral loads, proinflammatory responses, and coagulopathy. *J Infect Dis*. 2013 Jun 15;207(12):1909-21. doi: 10.1093/infdis/jit061. Epub 2013 Feb 15. PubMed PMID: 23417661; PubMed Central PMCID: PMC3654741. <http://jid.oxfordjournals.org/content/207/12/1909.long>

**5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms<sup>4</sup> and/or toxins studied, as well as outdoor studies of biological aerosols.**

**Objectives:** The Integrated Research Facility at Rocky Mountain Laboratories hosts research dedicated to understanding the mechanisms of pathogenesis of microbial agents associated with or likely to cause serious or lethal human diseases, including NIAID Category A pathogens and U.S. select agents, using molecular methods and animal model systems. Research activities include pathogenesis studies, vaccinology, and the development of therapeutic countermeasures and rapid diagnostic assays in support of the civilian biodefense program.

**Microorganisms and/or toxins studied:** Select Agents (HHS, Overlap, USDA), NIAID Category A pathogens, Simulants

**Outdoor Studies:** No outdoor studies of biological aerosols were conducted.

**National biological defence research and development programmes: Facilities**

**1. What is the name of the facility?**

Integrated Research Facility at Fort Detrick (IRF – Frederick)

**2. Where is it located (provide both address and geographical location)?**

8200 Research Plaza, Frederick, Maryland 21702

**3. Floor area of laboratory areas by containment level:**

BSL-2: 878 m<sup>2</sup>

BSL-3: 0 m<sup>2</sup>

BSL-4: 1305 m<sup>2</sup>

Total laboratory floor area 2,183 m<sup>2</sup>

**4. The organizational structure of each facility:**

**(i) Total number of personnel** 66

**(ii) Division of personnel:**

Military 0

Civilian 66

**(iii) Division of personnel by category:**

Scientists 20

Engineers 3

Technicians 42

Administrative and support staff 1

**(iv) List the scientific disciplines represented in the scientific/engineering staff:**

Aerobiology, Aerosol Science, Analytical Biochemistry, Biochemistry, Biological Science, Cell Biology, Immunology, Medicine, Microbiology, Microscopy, Molecular Biology, Molecular Diagnostics, Pathology, Public Health, Veterinary Medicine, Virology

**(v) Are contractor staff working in the facility? If so, provide an approximate number:**

Yes Number: 60

**(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

Department of Health and Human Services (HHS)

**(vii) What are the funding levels for the following program areas:**

Research \$18,733,082

Development \$0

Test and evaluation \$0

Total \$18,733,082

**(viii) Briefly describe the publication policy of the facility:**

All researchers are encouraged to publish results in peer-reviewed open literature. The NIH Public Access Policy (<http://publicaccess.nih.gov/policy.htm>) ensures that the American public has access to the published results of NIH-funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the National Library of Medicine's digital archive, PubMed Central, upon acceptance for publication. To help advance biomedical science and improve human health,

the policy requires that these papers are accessible to the public on PubMed Central no later than 12 months after publication.

**(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)**

1. Blaney JE, Marzi A, Willet M, Papaneri AB, Wirblich C, Feldmann F, Holbrook M, Jahrling P, Feldmann H, Schnell MJ. Antibody quality and protection from lethal Ebola virus challenge in nonhuman primates immunized with rabies virus based bivalent vaccine. *PLoS Pathog.* 2013;9(5):e1003389. doi: 10.1371/journal.ppat.1003389. Epub 2013 May 30. PubMed PMID: 23737747; PubMed Central PMCID: PMC3667758.  
<http://www.plospathogens.org/article/info%3Adoi%2F10.1371%2Fjournal.ppat.1003389>
2. Cai Y, Yú S, Mazur S, Dong L, Janosko K, Zhang T, Müller MA, Hensley LE, Bavari S, Jahrling PB, Radoshitzky SR, Kuhn JH. Nonhuman transferrin receptor 1 is an efficient cell entry receptor for Ocozocautla de Espinosa virus. *J Virol.* 2013 Dec;87(24):13930-5. doi: 10.1128/JVI.02701-13. Epub 2013 Oct 9. PubMed PMID: 24109228; PubMed Central PMCID: PMC3838296.  
<http://jvi.asm.org/content/87/24/13930.long>
3. Hart BJ, Dyall J, Postnikova E, Zhou H, Kindrachuk J, Johnson RF, Olinger GG Jr, Frieman MB, Holbrook MR, Jahrling PB, Hensley L. Interferon-beta and mycophenolic acid are potent inhibitors of Middle East respiratory syndrome coronavirus in cell-based assays. *J Gen Virol.* 2013 Dec 9. doi: 10.1099/vir.0.061911-0. [Epub ahead of print] PubMed PMID: 24323636.  
<http://vir.sgmjournals.org/content/early/2013/12/09/vir.0.061911-0.long>
4. Kuhn JH, Bào Y, Bavari S, Becker S, et al. Virus nomenclature below the species level: a standardized nomenclature for filovirus strains and variants rescued from cDNA. *Arch Virol.* 2013 Nov 5. [Epub ahead of print] PubMed PMID: 24190508.  
<http://link.springer.com/article/10.1007%2Fs00705-013-1877-2>
5. Kuhn JH, Bao Y, Bavari S, Becker S, et al.. Virus nomenclature below the species level: a standardized nomenclature for laboratory animal-adapted strains and variants of viruses assigned to the family Filoviridae. *Arch Virol.* 2013 Jun;158(6):1425-32. doi: 10.1007/s00705-012-1594-2. Epub 2013 Jan 29. PubMed PMID: 23358612; PubMed Central PMCID: PMC3669655.  
<http://link.springer.com/article/10.1007%2Fs00705-012-1594-2>
6. Kuhn JH, Bekal S, Cai Y, Clawson AN, Domier LL, Herrel M, Jahrling PB, Kondo H, Lambert KN, Mihindikulasuriya KA, Nowotny N, Radoshitzky SR, Schneider U, Staeheli P, Suzuki N, Tesh RB, Wang D, Wang LF, Dietzgen RG. Nyamiviridae: proposal for a new family in the order Mononegavirales. *Arch Virol.* 2013 Oct;158(10):2209-26. doi: 10.1007/s00705-013-1674-y. Epub 2013 May 1. PubMed PMID: 23636404; PubMed Central PMCID: PMC3857105.  
<http://link.springer.com/article/10.1007%2Fs00705-013-1674-y>
7. Kuhn JH, Radoshitzky SR, Bavari S, Jahrling PB. The International Code of Virus Classification and Nomenclature (ICVCN): proposal for text changes for improved differentiation of viral taxa and viruses. *Arch Virol.* 2013 Jul;158(7):1621-9. doi: 10.1007/s00705-012-1582-6. Epub 2013 Feb 16. PubMed PMID: 23417351; PubMed Central PMCID: PMC3689849.  
<http://link.springer.com/article/10.1007%2Fs00705-012-1582-6>
8. Song H, Janosko K, Johnson RF, Qin J, Josleyn N, Jett C, Byrum R, St Claire M, Dyall J, Blaney JE, Jennings G, Jahrling PB. Poxvirus antigen staining of immune cells as a biomarker to predict disease outcome in monkeypox and cowpox virus infection in non-human primates. *PLoS One.* 2013;8(4):e60533. doi: 10.1371/journal.pone.0060533. Epub 2013 Apr 5. PubMed PMID: 23577120; PubMed Central PMCID: PMC3618230.  
<http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0060533>
9. Song H, Josleyn N, Janosko K, Skinner J, Reeves RK, Cohen M, Jett C, Johnson R, Blaney JE, Bollinger L, Jennings G, Jahrling PB. Monkeypox virus infection of rhesus macaques induces massive expansion of natural killer cells but suppresses natural killer cell functions. *PLoS One.* 2013

Oct 17;8(10):e77804. doi: 10.1371/journal.pone.0077804. eCollection 2013. PubMed PMID: 24147080; PubMed Central PMCID: PMC3798392.

<http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0077804>

10. Song H, Sidney J, Wiseman RW, Josleyn N, Cohen M, Blaney JE, Jahrling PB, Sette A. Characterizing monkeypox virus specific CD8+ T cell epitopes in rhesus macaques. *Virology*. 2013 Dec;447(1-2):181-6. doi: 10.1016/j.virol.2013.09.003. Epub 2013 Sep 28. PubMed PMID: 24210113. <http://www.sciencedirect.com/science/article/pii/S0042682213005126>
11. Taylor SL, Wahl-Jensen V, Copeland AM, Jahrling PB, Schmaljohn CS. Endothelial cell permeability during hantavirus infection involves factor XII-dependent increased activation of the kallikrein-kinin system. *PLoS Pathog*. 2013;9(7):e1003470. doi: 10.1371/journal.ppat.1003470. Epub 2013 Jul 18. PubMed PMID: 23874198; PubMed Central PMCID: PMC3715459. <http://www.plospathogens.org/article/info%3Adoi%2F10.1371%2Fjournal.ppat.1003470>

**5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms<sup>4</sup> and/or toxins studied, as well as outdoor studies of biological aerosols.**

**Objectives:** The Integrated Research Facility at Fort Detrick in Frederick, Maryland manages, coordinates, and facilitates the conduct of emerging infectious disease and biodefense research to develop vaccines, countermeasures, and improved medical outcomes for patients. Battelle Memorial Institute facilitates research performed at the IRF-Frederick with direction from the IRF Scientific Steering Committee. Research emphasis is placed on elucidating the nature of high consequence infections, including NIAID Category A priority pathogens and newly emerging infectious disease microbes. In 2013, IRF-Frederick began to conduct research involving microbial agents associated with or likely to cause serious or lethal human diseases. No research with U.S. select agent microorganisms was conducted in 2013.

**Microorganisms and/or toxins studied:** NIAID Category A pathogens

**Outdoor Studies:** No outdoor studies of biological aerosols were conducted.

**National biological defence research and development programmes: Facilities**

**1. What is the name of the facility?**

C.W. Bill Young Center for Biodefense and Emerging Infectious Diseases

**2. Where is it located (provide both address and geographical location)?**

9000 Rockville Pike, Bethesda, Maryland 20892

**3. Floor area of laboratory areas by containment level:**

BSL-2: 2493 m<sup>2</sup>

BSL-3: 1091 m<sup>2</sup>

BSL-4: 0 m<sup>2</sup>

Total laboratory floor area 3584 m<sup>2</sup>

**4. The organizational structure of each facility:**

**(i) Total number of personnel** 124

**(ii) Division of personnel:**

Military 0

Civilian 124

**(iii) Division of personnel by category:**

Scientists 91

Engineers 0

Technicians 27

Administrative and support staff 6

**(iv) List the scientific disciplines represented in the scientific/engineering staff:**

Aerobiology, Analytical Biochemistry, Animal Science, Bacteriology, Biochemistry, Biological Science, Cell Biology, Immunology, Microbiology, Microscopy, Molecular Biology, Veterinary Medicine, Virology

**(v) Are contractor staff working in the facility? If so, provide an approximate number:**

Yes Number: 6

**(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

Department of Health and Human Services (HHS)

**(vii) What are the funding levels for the following program areas:**

Research \$36,109,469

Development \$0

Test and evaluation \$0

Total \$36,109,469

**(viii) Briefly describe the publication policy of the facility:**

All researchers are encouraged to publish results in peer-reviewed open literature. The NIH Public Access Policy (<http://publicaccess.nih.gov/policy.htm>) ensures that the public has access to the published results of NIH-funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the National Library of Medicine's digital archive, PubMed Central, upon acceptance

for publication. To help advance science and improve human health, the policy requires that these papers are accessible to the public on PubMed Central no later than 12 months after publication.

**(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)**

1. Abrami L, Brandi L, Moayeri M, Brown MJ, Krantz BA, Leppla SH, van der Goot FG. Hijacking multivesicular bodies enables long-term and exosome-mediated long-distance action of anthrax toxin. *Cell Rep*. 2013 Nov 27;5(4):986-96. doi: 10.1016/j.celrep.2013.10.019. Epub 2013 Nov 14. PubMed PMID: 24239351; PubMed Central PMCID: PMC3866279. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3866279/>
2. Ambroggio XI, Dommer J, Gopalan V, Dunham EJ, Taubenberger JK, Hurt DE. HASP server: a database and structural visualization platform for comparative models of influenza A hemagglutinin proteins. *BMC Bioinformatics*. 2013 Jun 18;14:197. doi: 10.1186/1471-2105-14-197. PubMed PMID: 23777206; PubMed Central PMCID: PMC3693987. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3693987/>
3. Americo JL, Sood CL, Cotter CA, Vogel JL, Kristie TM, Moss B, Earl PL. Susceptibility of the wild-derived inbred CAST/Ei mouse to infection by orthopoxviruses analyzed by live bioluminescence imaging. *Virology*. 2014 Jan 20;449:120-32. doi: 10.1016/j.virol.2013.11.017. Epub 2013 Nov 28. PubMed PMID: 24418545; PubMed Central PMCID: PMC3902144. <http://www.sciencedirect.com/science/article/pii/S0042682213006302>
4. Andrade BB, Hullsiek KH, Boulware DR, Rupert A, French MA, Ruxrungtham K, Montes ML, Price H, Barreiro P, Audsley J, Sher A, Lewin SR, Sereti I; INSIGHT Study Group. Biomarkers of inflammation and coagulation are associated with mortality and hepatitis flares in persons coinfecting with HIV and hepatitis viruses. *J Infect Dis*. 2013 May 1;207(9):1379-88. doi: 10.1093/infdis/jit033. Epub 2013 Jan 18. PubMed PMID: 23335804; PubMed Central PMCID: PMC3610421. <http://jid.oxfordjournals.org/content/207/9/1379.long>
5. Andrade BB, Pavan Kumar N, Mayer-Barber KD, Barber DL, Sridhar R, Rekha VV, Jawahar MS, Nutman TB, Sher A, Babu S. Plasma heme oxygenase-1 levels distinguish latent or successfully treated human tuberculosis from active disease. *PLoS One*. 2013 May 6;8(5):e62618. doi: 10.1371/journal.pone.0062618. Print 2013. PubMed PMID: 23671613; PubMed Central PMCID: PMC3646008. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3646008/>
6. Bachran C, Morley T, Abdelazim S, Fattah RJ, Liu S, Leppla SH. Anthrax toxin-mediated delivery of the *Pseudomonas* exotoxin A enzymatic domain to the cytosol of tumor cells via cleavable ubiquitin fusions. *MBio*. 2013 Apr 30;4(3):e00201-13. doi: 10.1128/mBio.00201-13. PubMed PMID: 23631917; PubMed Central PMCID: PMC3648902. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3648902/>
7. Balinsky CA, Schmeisser H, Ganesan S, Singh K, Pierson TC, Zoon KC. Nucleolin interacts with the dengue virus capsid protein and plays a role in formation of infectious virus particles. *J Virol*. 2013 Dec;87(24):13094-106. doi: 10.1128/JVI.00704-13. Epub 2013 Sep 11. PubMed PMID: 24027323; PubMed Central PMCID: PMC3838225. <http://jvi.asm.org/content/87/24/13094.long>
8. Barouch DH, Stephenson KE, Borducchi EN, Smith K, Stanley K, McNally AG, Liu J, Abbink P, Maxfield LF, Seaman MS, Dugast AS, Alter G, Ferguson M, Li W, Earl PL, Moss B, Giorgi EE, Szinger JJ, Eller LA, Billings EA, Rao M, Tovanabutra S, Sanders-Buell E, Weijtens M, Pau MG, Schuitemaker H, Robb ML, Kim JH, Korber BT, Michael NL. Protective efficacy of a global HIV-1 mosaic vaccine against heterologous SHIV challenges in rhesus monkeys. *Cell*. 2013 Oct 24;155(3):531-9. doi: 10.1016/j.cell.2013.09.061. Epub 2013 Oct 24. PubMed PMID: 24243013; PubMed Central PMCID: PMC3846288. <http://www.sciencedirect.com/science/article/pii/S0092867413012804>
9. Baz M, Paskel M, Matsuoka Y, Zengel J, Cheng X, Jin H, Subbarao K. Replication and immunogenicity of swine, equine, and avian h3 subtype influenza viruses in mice and ferrets. *J Virol*. 2013 Jun;87(12):6901-10. doi: 10.1128/JVI.03520-12. Epub 2013 Apr 10. PubMed PMID:

- 23576512; PubMed Central PMCID: PMC3676140.  
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3676140/>
10. Baz M, Luke CJ, Cheng X, Jin H, Subbarao K. H5N1 vaccines in humans. *Virus Res.* 2013 Dec 5;178(1):78-98. doi: 10.1016/j.virusres.2013.05.006. Epub 2013 May 28. PubMed PMID: 23726847; PubMed Central PMCID: PMC3795810. <http://www.ncbi.nlm.nih.gov/pubmed/23726847>
  11. Boonnak K, Vogel L, Orandle M, Zimmerman D, Talor E, Subbarao K. Antigen-activated dendritic cells ameliorate influenza A infections. *J Clin Invest.* 2013 Jul 1;123(7):2850-61. doi: 10.1172/JCI67550. Epub 2013 Jun 24. PubMed PMID: 23934125; PubMed Central PMCID: PMC3696566. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3696566/>
  12. Carroll MW, Jeon D, Mountz JM, Lee JD, Jeong YJ, Zia N, Lee M, Lee J, Via LE, Lee S, Eum SY, Lee SJ, Goldfeder LC, Cai Y, Jin B, Kim Y, Oh T, Chen RY, Dodd LE, Gu W, Dartois V, Park SK, Kim CT, Barry CE 3rd, Cho SN. Efficacy and safety of metronidazole for pulmonary multidrug-resistant tuberculosis. *Antimicrob Agents Chemother.* 2013 Aug;57(8):3903-9. doi: 10.1128/AAC.00753-13. Epub 2013 Jun 3. PubMed PMID: 23733467; PubMed Central PMCID: PMC3719751. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3719751/>
  13. Chen GL, Lamirande EW, Cheng X, Torres-Velez F, Orandle M, Jin H, Kemble G, Subbarao K. Evaluation of three live attenuated H2 pandemic influenza vaccine candidates in mice and ferrets. *J Virol.* 2013 Dec 26. [Epub ahead of print] PubMed PMID: 24371061. <http://jvi.asm.org/content/early/2013/12/20/JVI.01829-13.long>
  14. Cho E, Shamputa IC, Kwak HK, Lee J, Lee M, Hwang S, Jeon D, Kim CT, Cho S, Via LE, Barry CE 3rd, Lee JS. Utility of the REBA MTB-rifa® assay for rapid detection of rifampicin resistant *Mycobacterium Tuberculosis*. *BMC Infect Dis.* 2013 Oct 15;13:478. doi: 10.1186/1471-2334-13-478. PubMed PMID: 24128118; PubMed Central PMCID: PMC3852947. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3852947/>
  15. Dartois V, Barry CE 3rd. A medicinal chemists' guide to the unique difficulties of lead optimization for tuberculosis. *Bioorg Med Chem Lett.* 2013 Sep 1;23(17):4741-50. doi: 10.1016/j.bmcl.2013.07.006. Epub 2013 Jul 12. PubMed PMID: 23910985; PubMed Central PMCID: PMC3789655. <http://www.sciencedirect.com/science/article/pii/S0960894X13008408>
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  17. Dong B, Moore AR, Dai J, Roberts S, Chu K, Kapranov P, Moss B, Xiao W. A concept of eliminating nonhomologous recombination for scalable and safe AAVvector generation for human gene therapy. *Nucleic Acids Res.* 2013 Jul;41(13):6609-17. doi: 10.1093/nar/gkt404. Epub 2013 May 15. PubMed PMID: 23677609; PubMed Central PMCID: PMC3711426. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3711426/>
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21. Fouchier RA, García-Sastre A, Kawaoka Y, Barclay WS, Bouvier NM, Brown IH, Capua I, Chen H, Compans RW, Couch RB, Cox NJ, Doherty PC, Donis RO, Feldmann H, Guan Y, Katz JM, Kiselev OI, Klenk HD, Kobinger G, Liu J, Liu X, Lowen A, Mettenleiter TC, Osterhaus AD, Palese P, Peiris JS, Perez DR, Richt JA, Schultz-Cherry S, Steel J, Subbarao K, Swayne DE, Takimoto T, Tashiro M, Taubenberger JK, Thomas PG, Tripp RA, Tumpey TM, Webby RJ, Webster RG. Transmission studies resume for avian flu. *Science*. 2013 Feb 1;339(6119):520-1. doi: 10.1126/science.1235140. Epub 2013 Jan 23. PubMed PMID: 23345603; PubMed Central PMCID: PMC3838856.  
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  79. Via LE, Weiner DM, Schimel D, Lin PL, Dayao E, Tankersley SL, Cai Y, Coleman MT, Tomko J, Paripati P, Orandle M, Kastenmayer RJ, Tartakovsky M, Rosenthal A, Portevin D, Eum SY, Lahouar S, Gagneux S, Young DB, Flynn JL, Barry CE 3rd. Differential virulence and disease progression following *Mycobacterium tuberculosis* complex infection of the common marmoset (*Callithrix jacchus*). *Infect Immun.* 2013 Aug;81(8):2909-19. doi: 10.1128/IAI.00632-13. Epub 2013 May 28. PubMed PMID: 23716617; PubMed Central PMCID: PMC3719573. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3719573/>
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  81. Wan H, Gao J, Xu K, Chen H, Couzens LK, Rivers KH, Easterbrook JD, Yang K, Zhong L, Rajabi M, Ye J, Sultana I, Wan XF, Liu X, Perez DR, Taubenberger JK, Eichelberger MC. Molecular basis for broad neuraminidase immunity: conserved epitopes in seasonal and pandemic H1N1 as well as H5N1 influenza viruses. *J Virol.* 2013 Aug;87(16):9290-300. doi: 10.1128/JVI.01203-13. Epub 2013 Jun 19. PubMed PMID: 23785204; PubMed Central PMCID: PMC3754050. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3754050/>

82. Wang R, Taubenberger JK. Characterization of the Noncoding Regions of the 1918 Influenza A H1N1 Virus. *J Virol*. 2014 Feb;88(3):1815-8. doi: 10.1128/JVI.03098-13. Epub 2013 Nov 13. PubMed PMID: 24227852. <http://jvi.asm.org/content/88/3/1815.long>
83. Wang R, Xiao Y, Taubenberger JK. Rapid sequencing of influenza A virus vRNA, cRNA and mRNA non-coding regions. *J Virol Methods*. 2014 Jan;195:26-33. doi: 10.1016/j.jviromet.2013.09.005. Epub 2013 Oct 4. PubMed PMID: 24096269. <http://www.sciencedirect.com/science/article/pii/S0166093413003923>
84. Wong SY, Javid B, Addepalli B, Piszczek G, Strader MB, Limbach PA, Barry CE 3rd. Functional role of methylation of G518 of the 16S rRNA 530 loop by GidB in *Mycobacterium tuberculosis*. *Antimicrob Agents Chemother*. 2013 Dec;57(12):6311-8. doi: 10.1128/AAC.00905-13. Epub 2013 Oct 7. PubMed PMID: 24100503; PubMed Central PMCID: PMC3837903. <http://aac.asm.org/content/57/12/6311.long>
85. Xiao YL, Kash JC, Beres SB, Sheng ZM, Musser JM, Taubenberger JK. High-throughput RNA sequencing of a formalin-fixed, paraffin-embedded autopsy lung tissue sample from the 1918 influenza pandemic. *J Pathol*. 2013 Mar;229(4):535-45. doi: 10.1002/path.4145. PubMed PMID: 23180419; PubMed Central PMCID: PMC3731037. <http://onlinelibrary.wiley.com/doi/10.1002/path.4145/abstract>
86. Yang Z, Maruri-Avidal L, Sisler J, Stuart CA, Moss B. Cascade regulation of vaccinia virus gene expression is modulated by multistage promoters. *Virology*. 2013 Dec;447(1-2):213-20. doi: 10.1016/j.virol.2013.09.007. Epub 2013 Oct 3. PubMed PMID: 24210117; PubMed Central PMCID: PMC3840034. <http://www.sciencedirect.com/science/article/pii/S0042682213005230>

**5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms<sup>4</sup> and/or toxins studied, as well as outdoor studies of biological aerosols.**

**Objectives:** At the C.W. Bill Young Center for Biodefense and Emerging Infectious Diseases, the Laboratory of Infectious Diseases (LID) focuses on viral vaccine development, host immune response to viruses, and viral molecular biology and genetics. The Laboratory of Bacterial Diseases (LBD) focuses on the development of diagnostics, vaccines, and therapeutics for biodefense. Specific research concerns the identification and analysis of bacterial virulence factors and their genetic regulation; structure-function analysis of bacterial proteins and other factors; and disease pathogenesis. The Laboratory of Viral Diseases (LVD) studies the basic mechanisms of viral entry into cells, regulation of viral gene expression, viral DNA replication, assembly and transport of viral proteins and particles, viral virulence, and humoral and cellular immunity for DNA and RNA viruses. Applied research includes development of recombinant expression vectors, candidate vaccines, and antiviral agents.

**Microorganisms and/or toxins studied:** Select Agents (HHS, Overlap, USDA) and Toxins, NIAID Category A pathogens

**Outdoor Studies:** No outdoor studies of biological aerosols were conducted.

**National biological defence research and development programmes: Facilities**

**1. What is the name of the facility?**

Dale and Betty Bumpers Vaccine Research Center

**2. Where is it located (provide both address and geographical location)?**

9000 Rockville Pike, Bethesda, Maryland 20892

**3. Floor area of laboratory areas by containment level:**

BSL-2: 89 m<sup>2</sup>

BSL-3: 0 m<sup>2</sup>

BSL-4: 0 m<sup>2</sup>

Total laboratory floor area 89 m<sup>2</sup>

**4. The organizational structure of each facility:**

**(i) Total number of personnel** 9

**(ii) Division of personnel:**

Military 0

Civilian 9

**(iii) Division of personnel by category:**

Scientists 9

Engineers 0

Technicians 0

Administrative and support staff 0

**(iv) List the scientific disciplines represented in the scientific/engineering staff:**

Biological Science

**(v) Are contractor staff working in the facility? If so, provide an approximate number:**

Yes Number: 2

**(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

Department of Health and Human Services (HHS)

**(vii) What are the funding levels for the following program areas:**

Research \$739,364

Development \$0

Test and evaluation \$0

Total \$739,364

**(viii) Briefly describe the publication policy of the facility:**

All researchers are encouraged to publish results in peer-reviewed open literature. The NIH Public Access Policy (<http://publicaccess.nih.gov/policy.htm>) ensures that the public has access to the published results of NIH-funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the National Library of Medicine's digital archive, PubMed Central, upon acceptance for publication. To help advance science and improve human health, the policy requires that these papers are accessible to the public on PubMed Central no later than 12 months after publication.

**(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)**

1. Kuhn JH, Bào Y, Bavari S, Becker S, et al. Virus nomenclature below the species level: a standardized nomenclature for filovirus strains and variants rescued from cDNA. Arch Virol. 2013 Nov 5. [Epub ahead of print] PubMed PMID: 24190508.  
<http://link.springer.com/article/10.1007%2Fs00705-013-1877-2>
2. Kuhn JH, Bao Y, Bavari S, Becker S, et al. Virus nomenclature below the species level: a standardized nomenclature for laboratory animal-adapted strains and variants of viruses assigned to the family Filoviridae. Arch Virol. 2013 Jun;158(6):1425-32. doi: 10.1007/s00705-012-1594-2. Epub 2013 Jan 29. PubMed PMID: 23358612; PubMed Central PMCID: PMC3669655.  
<http://link.springer.com/article/10.1007%2Fs00705-012-1594-2>

**5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms<sup>4</sup> and/or toxins studied, as well as outdoor studies of biological aerosols.**

**Objectives:** The research focus of the Biodefense Research Laboratory, Vaccine Research Center (VRC) comprises three areas: development of vaccines and antivirals against hemorrhagic fever viruses such as Ebola, Marburg and Lassa; studies of the mechanism of vaccine-induced immune protection; and basic research to understand the mechanism of virus replication (entry) and neutralization.

**Microorganisms and/or toxins studied:** No Select Agents or Toxins, NIAID Category A pathogens, nor applicable simulants were used.

**Outdoor Studies:** No outdoor studies of biological aerosols were conducted.

**National biological defence research and development programmes: Facilities**

**1. What is the name of the facility?**

Foreign Disease-Weed Science Research Unit

**2. Where is it located (provide both address and geographical location)?**

1301 Ditto Avenue, Fort Detrick, Maryland 21702

**3. Floor area of laboratory areas by containment level:**

BSL-2: 105 m<sup>2</sup>

BSL-3: 950 m<sup>2</sup>

BSL-4: 0 m<sup>2</sup>

Total: 1055 m<sup>2</sup>

BSL-2 laboratories are enhanced by HEPA air filtration. BSL-3 plant pathogen containment facility has HEPA air filtration, steam sterilization of wastewater, and personnel shower-out procedures.

**4. The organizational structure of each facility:**

**(i) Total number of personnel** 35

**(ii) Division of personnel:**

Military 0

Civilian 35

**(iii) Division of personnel by category:**

Scientists 12

Engineers 0

Technicians 16

Administrative/Support 7

**(iv) List the scientific disciplines represented in the scientific/engineering staff:**

Agronomy, Biological Control, Horticulture, Plant Biochemistry, Plant Molecular Biology, Plant Pathology, Plant Physiology, Plant Virology, Weed Science

**(v) Are contractor staff working in the facility? If so, provide an approximate number.**

No

**(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

Department of Agriculture (USDA)

**(vii) What are the funding levels for the following program areas:**

Research \$3,300,000

Development \$0

Test and evaluation \$0

Total \$3,300,000

**(viii) Briefly describe the publication policy of the facility:**

All scientific research data is available for publication in peer-reviewed publications after review for dual use determination. All scientists are required to have a minimum of two peer-reviewed publications per year. They are encouraged to present research at scientific conferences and to publish in books and proceedings.

**(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)**

1. Berner, D.K., Smallwood, E.L., Cavin, C.A., Lagopodi, A., Kashefi, J., Kolomiets, T., Pankratova, L., Mukhina, Z., Cripps, M., Bourdot, G. Successful establishment of epiphytotics of *Puccinia punctiformis* for biological control of *Cirsium arvense*. *Biological Control*. 2013; 67:350-360. <http://www.sciencedirect.com/science/article/pii/S1049964413002077>
2. Bonde, M.R., Nester, S.E., Berner, D.K. Effects of frequency of extreme temperature highs on development of soybean rust. *Phytopathology*. 2013; 103:708-716. <http://www.ncbi.nlm.nih.gov/pubmed/?term=Effects+of+frequency+of+extreme+temperature+highs+on+development+of+soybean+rust>
3. Bonde, M.R., Palmer, C.L., Luster, D.G., Nester, S.E., Revell, J., Berner, D.K. Sporulation capacity and longevity of *Puccinia horiana* teliospores in infected chrysanthemum leaves. *Plant Health Progress*. 2013; doi:10.1094/PHP-2013-0823-01-RS. <https://www.plantmanagementnetwork.org/php/elements/sum2.aspx?id=10672> [This site requires a subscription to access the full article.]
4. Bruckart, W.L., Eskandari, F., Coombs, E.M., Rossman, A.Y., Palm, M.E. First report of *Pilidium concavum* causing leaf necrosis on *Fallopia japonica* in the United States. *Plant Dis*. 2013; 97(1):146. <http://handle.nal.usda.gov/10113/56829>
5. Damsteegt, V.D., Stone, A.L., Smith, O.P., Mcdaniel, L., Sherman, D.J., Dardick, C.D., Hammond, J., Jordan, R.L., Schneider, W.L. A previously undescribed potyvirus isolated and characterized from arborescent *Brugmansia*. *Arch Virol*. 2013; 158:1235-1244. <http://link.springer.com/article/10.1007%2Fs00705-012-1600-8>
6. Debacker, M., Bonants, P., Pedley, K.F., Maes, M., Roldan-Ruiz, I., Van Bockstaele, E., Heugens, K., Van Der Lee, T. Genetic relationships in an international collection of *Puccinia horiana* isolates based on newly identified molecular markers and demonstration of recombination. *Mol Ecol*. 2013; <http://dx.doi.org/10.1094/PHYTO-01-13-0007-R>
7. Diers, B.W., Kim, K., Frederick, R.D., Hartman, G.L., Unfried, J.R., Schultz, S.J., Cary, T.R. Registration of eight soybean germplasm lines resistant to soybean rust. *Journal of Plant Registrations*. 2013; DOI: 10.3198/jpr2012.11.0052crg. <https://www.crops.org/publications/jpr/abstracts/8/1/96?search-result=1>
8. Preuett, J.A., Collins, D.J., Luster, D.G., Widmer, T.L. Screening selected Gulf Coast and Southeastern forest species for susceptibility to *Phytophthora ramorum*. *Plant Health Progress*. 2013; PHP 2013-0730-01-RS. <http://handle.nal.usda.gov/10113/57160>
9. Tooley, P.W., Browning, M.E., Leighty, R.M. Inoculum density relationships for infection of some Eastern forest species by *Phytophthora ramorum*. *Journal of Phytopathology*. 2013; 161:595-603. <http://onlinelibrary.wiley.com/doi/10.1111/jph.12107/abstract>
10. Wang, X., Zhu, X., Tooley, P.W., Zhang, X. Cloning and functional analysis of three genes encoding polygalacturonase-inhibiting proteins from *Capsicum annuum* and transgenic CaPGIP1 in tobacco in relation to increased resistance to two fungal pathogens. *Plant Molecular Biology*. 2013; 81:379-400. <http://link.springer.com/article/10.1007%2Fs11103-013-0007-6>
11. Widmer, T.L., Dodge, S.C. Can fungal epiphytes reduce disease symptoms caused by *Phytophthora ramorum*? *Biological Control*. 2013; 65:135-141. <http://handle.nal.usda.gov/10113/55999>

**5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms\* and/or toxins studied, as well as outdoor studies of biological aerosols.**

**Objectives:** The USDA, Agricultural Research Service, Foreign Disease-Weed Science Research Unit has two distinct missions united by a common relationship to plant pathology and the unit's unique BL-3 plant pathogen laboratory and greenhouse containment facilities.

The mission of the foreign disease program is to develop techniques for the rapid detection and identification of new and emerging crop pathogens, and to provide fundamental information on emerging pathogens for risk assessment and the development of practical phytosanitary regulations for the import and export of agricultural commodities and germplasm.

The mission of the weed biological control program is to collect foreign pathogens overseas from weeds in their native habitat, and to evaluate, characterize and release the pathogens in the U.S. for biological control of introduced weeds, leading to improved, sustainable weed control practices in agricultural systems with reduced dependence on chemical herbicides.

**Microorganisms and/or toxins studied:** Select Agents (PPQ)

**Outdoor studies:** None

**National biological defence research and development programmes: Facilities**

**1. What is the name of the facility?**

National Animal Disease Center (NADC)

**2. Where is it located (provide both address and geographical location)?**

1920 Dayton Avenue, Ames, Iowa 50010

**3. Floor area of laboratory areas by containment level.**

BSL-2: 4410 m<sup>2</sup>

BSL-3: 2489 m<sup>2</sup>

BSL-4: 0 m<sup>2</sup>

Total 6899 m<sup>2</sup>

In addition NADC has unique animal biocontainment facilities ranging from ABSL-2 to ABSL-3Ag (highest biocontainment level available in the U.S. that can accommodate food producing animals and various wildlife species). Biocontainment enhancements include HEPA-filtered supply air; dual HEPA filtered exhaust; air-tight doors; shower-in/out of each animal room; heat-treated waste; steam-treated rendering for carcasses; stainless steel penning and gating systems; epoxy-coated floors; and epoxy-covered surfaces. NADC also has two large biocontainment buildings that are considered ABSL-2-enhanced.

ABSL-2: 3467.7 m<sup>2</sup>

ABSL-3: 160.5 m<sup>2</sup>

ABSL-3Ag: 1581.6 m<sup>2</sup>

Total: 5209.8 m<sup>2</sup>

**4. The organizational structure of each facility:**

**(i) Total number of personnel** 274

**(ii) Division of personnel:**

Military 0

Civilian 274

**(iii) Division of personnel by category:**

Scientists 40

Engineers 1

Technicians 79

Administrative/Support 154

**(iv) List the scientific disciplines represented in the scientific/engineering staff:**

Agricultural Engineering, Animal Science, Biochemistry, Bioinformatics, Biology, Biotechnology, Cell Biology, Clinical Immunology, Computational Biology, Ecology, Genetics, Genomics, Immunology, Infectious Disease, Mass Spectrometry, Microbiology, Molecular Biology, Pathogenesis, Pathology, Physiology, Prionology, Proteomics, Statistics, Structural Biology, Vaccine Evaluation, Veterinarian, Veterinary Clinical Research, Veterinary Medicine, Virology

**(v) Are contractor staff working in the facility? If so, provide an approximate number.**

Yes Number: 2

**(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

Department of Agriculture

Department of Defense – partly  
 Health and Human Services  
 Universities  
 Private sector companies

**(vii) What are the funding levels for the following program areas:**

Research	\$4,300,000
Development	\$0
Test and evaluation	\$0
Total	\$4,300,000

**(viii) Briefly describe the publication policy of the facility:**

All scientific research data is available for publication in peer-reviewed publications after review for dual use determination. All scientists are required to have a minimum of two peer-reviewed publications per year. They are encouraged to present research at scientific conferences and to publish in books and proceedings.

**(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)**

1. Bannantine, J.P., Olsen, S.C., Kehrli Jr, M.E., Stanton, T.B., Casas, E., Whipple, D.L., Zuelke, K.A. High-impact animal health research conducted at the USDA's National Animal Disease Center. *Vet Microbiol.* 2013; 165(2013):224-233.  
<http://www.sciencedirect.com/science/article/pii/S0378113513002125>
2. Epperson, S., Jhung, M., Richards, S., Quinlisk, P., Ball, L., Moll, M., Boulton, R., Haddy, L., Biggerstaff, M., Brammer, L., Trock, S., Burns, E., Gomez, T., Wong, K.K., Katz, J., Lindstrom, S., Klimov, A., Bresee, J.S., Jernigan, D.B., Cox, N., Finelli, L. Influenza A(H3N2)v Virus Investigation Team (Vincent, A.L.). Human infections with influenza A(H3N2) variant virus in the United States, 2011-2012. *Clin Infect Dis.* 2013; 57(S1):S4-S11.  
[http://cid.oxfordjournals.org/content/57/suppl\\_1/S4.long](http://cid.oxfordjournals.org/content/57/suppl_1/S4.long)
3. Gauger, P.C., Loving, C.L., Lager, K.M., Janke, B.H., Kehrli Jr, M.E., Roth, J.A., Vincent, A.L. Vaccine-associated enhanced respiratory disease does not interfere with the adaptive immune response following challenge with pandemic A/H1N1 2009. *Viral Immunol.* 2013; 26(5):314-321.  
<http://online.liebertpub.com/doi/abs/10.1089/vim.2013.0018> [This site requires a subscription to access the full article.]
4. Khurana, S., Loving, C.L., Manischewitz, J., King, L.R., Gauger, P.C., Henningson, J., Vincent, A.L., Golding, H. Vaccine-induced anti-HA2 antibodies promote virus fusion and enhance influenza virus respiratory disease. *Sci Transl Med.* 2013; 5(200):200ra114.  
<http://stm.sciencemag.org/content/5/200/200ra114>
5. Killian, M.L., Swenson, S.L., Vincent, A.L., Landgraf, J.G., Shu, B., Lindstrom, S., Xu, X., Klimov, A., Zhang, Y., Bowman, A.S. Simultaneous infection of pigs and people with triple-reassortant swine influenza virus H1N1 at a U.S. county fair. *Zoonoses Public Health.* 2013; 60(3):196-201.  
<http://onlinelibrary.wiley.com/doi/10.1111/j.1863-2378.2012.01508.x/abstract>
6. Kitikoon, P., Gauger, P.C., Anderson, T.K., Culhane, M.R., Swenson, S., Loving, C.L., Perez, D.R., Vincent, A.L. Swine influenza virus vaccine serologic cross-reactivity to contemporary US swine H3N2 and efficacy in pigs infected with an H3N2 similar to 2011-2012 H3N2v. *Influenza Other Respir Viruses.* 2013; 7(Suppl. 4):32-41. <http://onlinelibrary.wiley.com/doi/10.1111/irv.12189/pdf>
7. Kitikoon, P., Nelson, M.I., Killian, M.L., Anderson, T.K., Koster, L., Culhane, M.R., Vincent, A.L. Genotype patterns of contemporary reassorted H3N2 virus in US swine. *J Gen Virol.* 2013; 94 (Pt 6):1236-1241. [http://vir.sgmjournals.org/content/94/Pt\\_6/1236.abstract](http://vir.sgmjournals.org/content/94/Pt_6/1236.abstract) [This site requires a subscription to access the full article.]

8. Kudva, I.T., Hovde, C.J., John, M. Adherence of non-O157 Shiga-toxin Escherichia coli to bovine recto-anal junction squamous epithelial cells appears to be mediated by mechanisms distinct from those used by O157. Foodborne Pathog Dis. 2013; 10(4):375-381.  
<http://www.ncbi.nlm.nih.gov/pubmed/23510495>
9. Kudva, I.T., Smole, S., Griffin, R.W., Garren, J., Kalia, N., Murray, M., John, M., Timperi, R., Calderwood, S.B. Polymorphic amplified typing sequences (PATs) strain typing system accurately discriminates a set of temporally and spatially disparate Escherichia coli (O157) isolates associated with human infection. The Open Microbiology Journal. 2013; 7:123-129.  
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3837366/>
10. Kudva, I.T., Stasko, J.A. Bison and bovine rectoanal junctions exhibit similar cellular architecture and Escherichia coli O157 adherence patterns. BMC Vet Res. 2013; 9(266).  
<http://www.biomedcentral.com/1746-6148/9/266>
11. Loving, C.L., Lager, K.M., Vincent, A.L., Brockmeier, S.L., Gauger, P.C., Anderson, T.K., Kitikoon, P., Perez, D.R., Kehrli, Jr., M.E. Efficacy in pigs of inactivated and live attenuated influenza virus vaccines against infection and transmission of an emerging H3N2 similar to the 2011-2012 H3N2v. J Virol. 2013; 87(17):9895-903. <http://jvi.asm.org/content/87/17/9895.long>
12. Olsen, S.C. Recent developments in livestock and wildlife brucellosis vaccination. World Organization for Animal Health Scientific and Technical Review. 2013; 32(1):207-217.  
[http://iapreview.ars.usda.gov/research/publications/publications.htm?seq\\_no\\_115=283928](http://iapreview.ars.usda.gov/research/publications/publications.htm?seq_no_115=283928)
13. Olsen, S.C. Biosafety considerations for in vivo work with risk group 3 pathogens in large animals and wildlife in North America. Anim Health Res Rev. 2013; 14(1):2-10.  
[http://journals.cambridge.org/download.php?file=%2FAHR%2FAHR14\\_01%2FS1466252312000217a.pdf&code=3c155f83e330dfb26dc05fe2f918880a](http://journals.cambridge.org/download.php?file=%2FAHR%2FAHR14_01%2FS1466252312000217a.pdf&code=3c155f83e330dfb26dc05fe2f918880a)
14. Register, K.B., Woodbury, M.R., Davies, J.L., Trujillo, J.D., Perez-Casal, J., Burrage, P.H., Clark, E.G., Windeyer, C. Systemic mycoplasmosis with dystocia and abortion in North American bison (Bison bison) herd. J Vet Diagn Invest. 2013; 25(4):541-545.  
<http://vdi.sagepub.com/content/25/4/541>
15. Sharma, V.K., Bearson, B.L. Hha controls Escherichia coli O157:H7 biofilm formation by differential regulation of global transcriptional regulators FlhDC and CsgD. Appl Environ Microbiol. 2013; 79(7):2384-2396. <http://aem.asm.org/content/79/7/2384.long>
16. Sharma, V.K., Bearson, S.M. Evaluation of the impact of quorum sensing transcriptional regulator SdiA on long-term persistence and fecal shedding of Escherichia coli O157:H7 in weaned calves. Microb Pathog. 2013; 57:21-26.  
<http://www.sciencedirect.com/science/article/pii/S0882401013000223>
17. Stoffregen, W.C., Johnson, C.S., Olsen, S.C. Immunogenicity and safety of a natural rough mutant of Brucella suis as a vaccine for swine. Res Vet Sci. 2013; 95(2013):251-258.  
<http://www.sciencedirect.com/science/article/pii/S0034528813001409>

**5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms<sup>4</sup> and/or toxins studied, as well as outdoor studies of biological aerosols.**

**Objectives:** Support the control and eradication of national and international exotic, emerging, zoonotic, and endemic infectious diseases of animals through a comprehensive research program emphasizing basic and applied research in diagnostics, prevention, and control strategies, prediction of disease outbreaks, molecular epidemiology, and understanding disease pathogenesis. Specifically, the research programs aim to produce new research knowledge and technology to:

- prevent, reduce or eliminate losses from impaired performance, and increased deaths and condemnations;
- develop more sensitive, specific and faster diagnostic tests;
- develop vaccines designed for the control and, when feasible, the eradication of disease;
- improve our understanding of the ecology and epidemiology of pathogens at the domestic animal-wildlife interface; and

- improve our understanding of the genetic and pathophysiologic basis of disease and pathogen virulence. This research provides government regulatory agencies and the livestock industries with improved intervention strategies against priority diseases.

**Microorganisms and/or toxins studied:** Select Agents (Overlap, USDA)

**Outdoor Studies:** No research work is done outdoors with infectious organisms.

**National biological defence research and development programmes: Facilities**

**1. What is the name of the facility?**

Southeast Poultry Research Laboratory

**2. Where is it located (provide both address and geographical location)?**

934 College Station Road, Athens, Georgia 30605

**3. Floor area of laboratory areas by containment level:**

BSL-2: 1138 m<sup>2</sup>

BSL-3: 624 m<sup>2</sup>

BSL-4: 0 m<sup>2</sup>

Total: 1762 m<sup>2</sup>

**4. The organizational structure of each facility:**

**(i) Total number of personnel 37**

**(ii) Division of personnel:**

Military 0

Civilian 37

**(iii) Division of personnel by category:**

Scientists 11

Engineers 0

Technicians 13

Administrative/Support 13

**(iv) List the scientific disciplines represented in the scientific/engineering staff:**

Animal Science, Biochemistry, Biology, Biotechnology, Cell Biology, Clinical Immunology, Computational Biology, Genetics, Genomics, Immunology, Infectious Disease, Microbiology, Molecular Biology, Pathology, Proteomics, Public Health, Statistics, Veterinarian, Veterinary Clinical Research, Veterinary Medicine, Virology

**(v) Are contractor staff working in the facility? If so, provide an approximate number:**

Yes Number: 3

**(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Agriculture (USDA)

Department of Health and Human Services

U.S. Department of Defense (DOD) – partly

Non-profit Associations

Private Sector Companies

Department of State

**VII What are the funding levels for the following program areas:**

Research \$3,700,000

Development \$0

Test and evaluation \$0

Total \$3,700,000

**(vii) What are the funding levels for the following program areas:**

All scientific research data is available for publication in peer-reviewed publications after review for dual use determination. All scientists are required to have a minimum of two peer-reviewed publications per year. They are encouraged to present research at scientific conferences and to publish in books and proceedings.

**(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)**

1. Afonso, C.L., Miller, P.J. Newcastle Disease: Progress and gaps in the development of vaccines and diagnostic tools. *Dev Biol.* 2013; 135:95-106. <http://www.karger.com/Article/Abstract/178459> [This site requires a subscription to access the full article.]
2. Bertran, K., Sa E Silva, M., Pantin Jackwood, M.J., Swayne, D.E. Protection against H7N3 high pathogenicity avian influenza in chickens immunized with a recombinant fowlpox and an inactivated avian influenza vaccines. *Vaccine.* 2013; 33:3572-3576. <http://www.sciencedirect.com/science/article/pii/S0264410X13006270>
3. Cardenas-Garcia, S., Navarro, R., Morales, R., Olvera, M., Marquez, M., Merino, R., Miller, P.J., Afonso, C.L. Epidemiological and phylogenetic characterization of Newcastle disease viruses isolated from exotic, wild and commercial birds in Mexico between 2008 and 2011. *Appl Environ Microbiol.* 2013; 79(16):4985-4992. <http://handle.nal.usda.gov/10113/57936>
4. Chmielewski, R.A., Beck, J.R., Juneja, V.K., Swayne, D.E. Inactivation of low pathogenicity notifiable avian influenza virus and lentogenic Newcastle disease virus following pasteurization in liquid egg products. *LWT.* 2013; 52(1):27-30. <http://www.sciencedirect.com/science/article/pii/S0023643813000030>
5. Chmielewski, R.A., Beck, J.R., Swayne, D.E. Evaluation of the USDA's egg pasteurization processes on the inactivation of high-pathogenicity avian influenza virus and velogenic Newcastle disease virus in processed egg products. *J Food Prot.* 2013; 76(4):640-645. <http://www.ncbi.nlm.nih.gov/pubmed/?term=The+evaluation+of+the+USDA+egg+pasteurization+processes+on+the+inactivation+of+high+pathogenicity+avian+influenza+virus+and+velogenic+Newcastle+disease+virus+in+processed+egg+products>.
6. Courtney, S.C., Gomez, D., Hines, N.L., Pedersen, J.C., Miller, P.J., Afonso, C.L., Susta, L., Brown, C. Highly divergent virulent isolates of newcastle disease virus from the Dominican Republic are members of a new genotype that may have evolved unnoticed for over two decades. *J Clin Microbiol.* 2013; 51(2):508-517. <http://jcm.asm.org/content/51/2/508.long>
7. Cornax, I., Diel, D.G., Rue, C.A., Estevez, C., Miller, P.J., Yu, Q., Afonso, C.L. Newcastle disease virus fusion and haemagglutinin-neuraminidase proteins contribute to its macrophage host range. *Virus Res.* 2013; 94:1189-1194. [http://vir.sgmjournals.org/content/94/Pt\\_6/1189.long](http://vir.sgmjournals.org/content/94/Pt_6/1189.long)
8. Faulkner, O.B., Estevez, C., Yu, Q., Suarez, D.L. Passive antibody transfer in chickens to model maternal antibody after avian influenza vaccination. *Vet Immunol Immunopathol.* 2013; 152(3-4):341-347. <http://www.sciencedirect.com/science/article/pii/S0165242713000275>
9. Hualei, L., Lv, Y., Afonso, C.L., Ge, S., Zheng, D., Zhao, Y., Wang, Z. Complete genome sequences of new emerging Newcastle disease virus strains isolated from China. *Genome Announc.* 2013; 1(1):e00129-12. doi:10.1128/genomeA.00129-12. <http://genomea.asm.org/content/1/1/e00129-12.long>
10. Kapczynski, D.R., Afonso, C.L., Miller, P.J. Immune responses of poultry to newcastle disease virus. *Dev Comp Immunol.* 2013; 41. <http://dx.doi.org/10.1016/j.dci.2013.04.012>.
11. Miller, P.J., Afonso, C.L., El Attrache, J., Dorsey, K.M., Courtney, S.C., Guo, Z., Kapczynski, D.R. Effects of Newcastle disease virus vaccine antibodies on the shedding and transmission of challenge viruses. *Dev Comp Immunol.* 2013; DOI:S0145-305X(13)00170-5. 10.1016/j.dci.2013.06.007. <http://www.sciencedirect.com/science/article/pii/S0145305X13001705>
12. Nemeth, N.M., Brown, J.D., Stallknecht, D.E., Howerth, E.W., Newman, S.H., Swayne, D.E. Experimental infection of bar-headed geese (*Anser indicus*) and ruddy shelducks (*Tadorna*

- ferruginea) with a clade 2.3.2 H5N1 highly pathogenic avian influenza virus. *Vet Pathol.* 2013; Nov;50(6):961-70. doi: 10.1177/0300985813490758. <http://vet.sagepub.com/content/50/6/961>
13. Pantin Jackwood, M.J., Smith, D.M., Shepherd, E.M., Swayne, D.E. Effect of species, breed and route of virus inoculation on the pathogenicity of H5N1 highly pathogenic influenza (HPAI) viruses in domestic ducks. *Vet Res.* 2013; 44(1):62. <http://www.veterinaryresearch.org/content/44/1/62>
  14. Pantin Jackwood, M.J., Suarez, D.L. Vaccination of domestic ducks against H5N1 HPAI: A review. *Virus Res.* 2013; <http://dx.doi.org/10.1016/j.virusres.2013.07.012>.
  15. Ramey, A.M., Reeves, A.B., Ogawa, H., Ip, H.S., Imai, K., Bui, V., Yamaguchi, E., Silko, N.Y., Afonso, C.L. Genetic diversity and mutation of avian paramyxovirus serotype 1 (Newcastle disease 2 virus) in migratory birds and evidence for intercontinental spread. *Arch Virol.* 2013; 158(12):2495-2503. <http://link.springer.com/article/10.1007%2Fs00705-013-1761-0>
  16. Ramey, A., Spackman, E., Yeh, J., Fujita, G., Konishi, K., Reed, J., Wilcox, B., Brown, J., Stallknecht, D. Antibodies to H5 subtype avian influenza virus and Japanese encephalitis virus in northern pintails (*Anas acuta*) sampled in Japan. *Jpn J Vet Res.* 2013; 61(3):117-123. <http://eprints.lib.hokudai.ac.jp/dspace/bitstream/2115/53135/3/%E5%86%8D%E6%A0%A1%E3%80%80023.p117-123%20NOTE%20RAMEY.pdf>
  17. Sa E Silva, M., Ellis, A., Karaca, K., Minke, J., Nordgren, R., Wu, S., Swayne, D.E. Domestic goose as a model for West Nile virus vaccine efficacy. *Vaccine.* 2013; 31(7):1045-1050. <http://www.sciencedirect.com/science/article/pii/S0264410X12018294>
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  19. Spackman, E., Pedersen, J.C., McKinley, E.T., Gelb, J. Optimal specimen collection and transport methods for the detection of avian influenza virus and Newcastle disease virus. *BMC Vet Res.* 2013; 9(35). DOI: 10.1186/1746-6148-9-35. <http://www.biomedcentral.com/1746-6148/9/35>
  20. Susta, L., Cornax, I., Diel, D.G., Cardenas, S., Miller, P.J., Brown, C.C., Afonso, C.L. Expression of interferon gamma by a highly virulent Newcastle disease virus decreases its pathogenicity in chickens. *Microb Pathog.* 2013; 62:73-83. <http://www.sciencedirect.com/science/article/pii/S0882401013000867>
  21. Swayne, D.E., Spackman, E. Current status and future needs in diagnostics and vaccines for high pathogenicity avian influenza. *Dev Biol.* 2013; 135:79-94. <http://www.ncbi.nlm.nih.gov/pubmed/?term=Current+status+and+future+needs+in+diagnostics+and+vaccines+for+high+pathogenicity+avian+influenza>.
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  23. Zhao, W., Hu, H., Zsak, L., Yu, Q., Yang, Z. HN gene c-terminal extension of newcastle disease virus is not the determinant of the enteric tropism. *Virus Genes.* 2013; 47(1):27-33. <http://link.springer.com/article/10.1007%2Fs11262-013-0903-5>

**5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms\* and/or toxins studied, as well as outdoor studies of biological aerosols.**

**Objectives:** Provide scientific solutions to national and international exotic, emerging and endemic poultry viral diseases through a comprehensive research program emphasizing basic and applied research in diagnostics, prevention, and control strategies; prediction of disease outbreaks; molecular epidemiology; and understanding of disease pathogenesis. Produce new research knowledge and technology to:

- prevent, reduce or eliminate losses from impaired performance and increased deaths and condemnations;
- develop more sensitive, specific and faster diagnostic tests;
- develop vaccines designed for the control and, when feasible, the eradication of disease;

- improve our understanding of the ecology and epidemiology of viruses at the wild bird-domestic poultry interface; and
- improve our understanding of the genetic and pathobiological basis of virulence.

This research provides government regulatory agencies and the poultry industries with improved intervention strategies against poultry viral diseases. The Laboratory has two research units: 1) Exotic and Emerging Avian Viral Diseases Research Unit, and 2) Endemic Poultry Viral Diseases Research Unit.

**Microorganisms and/or toxins studied:** Select Agents (USDA)

**Outdoor Studies:** No research work is done outdoors with infectious organisms.

**Form B**

**BWC - Confidence Building Measure**

**Exchange of information on outbreaks of infectious diseases  
and similar occurrences caused by toxins**

United States of America

April 15, 2014

**Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern<sup>6</sup>**

**1. Time of cognizance of the outbreak**

The US National Focal point was notified of an extremely drug-resistant (XDR) tuberculosis case with extensive travel from Nepal through South Asia, South America, Central America and Mexico to Texas, U.S. on January 31<sup>st</sup>.

**2. Location and approximate area affected**

Case traveled from Nepal to the United States (Texas), through 13 countries by the different modes of transportation (plane, bus, car, by foot) over a period of 3 months (08/31/2012 to 11/26/2012)

**3. Type of disease/intoxication**

Extremely drug resistant (XDR) cavity tuberculosis

**4. Suspected source of disease/intoxication**

Not identified

**5. Possible causative agent(s)**

*Mycobacterium tuberculosis*

**6. Main characteristics of systems**

Pulmonary Tuberculosis – affecting the lungs

**7. Detailed symptoms, when applicable**

General symptoms include fever, chills, night sweats, loss of appetite, weight loss, fatigue chest pain and prolonged cough.

**8. Deviation(s) from the normal pattern as regards type, etc.**

Antimicrobial susceptibility tests found the isolate to be resistant to all first-line TB drugs, a fluoroquinolone, and all three second-line injectable drugs. This particular TB genotype has only once before been found in a patient in the United States, who was also of Nepalese origin.

**9. Approximate number of primary cases**

1 – this case

**10. Approximate number of total cases**

2 (within the US, including previous case)

**11. Number of deaths**

0

**12. Development of the outbreak**

Upon arrival in the U.S. he was found to be sputum smear positive with *Mycobacterium tuberculosis*. Treatment initiation is pending further laboratory tests and medication procurement.

**13. Measures taken**

Contact investigation is still ongoing to identify at risk contacts with sufficient information to initiate follow up. One notification for a flight of >8 hours duration has been made to Brazil to date.

US NFP notified this as a potential PHEIC to WHO on February 1, 2013

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<sup>6</sup> See paragraph 2 of the chapeau to Confidence-Building Measure B.

**Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern**<sup>7</sup>

**1. Time of cognizance of the outbreak**

March 28, 2013

**2. Location and approximate area affected**

Affected entire United States. Additionally, less than 400 pounds total of these products was distributed internationally to Bermuda, Trinidad and Peru.

**3. Type of disease/intoxication**

Shigellosis

**4. Suspected source of disease/intoxication**

Rich Products Corporation recall included all products produced at its Waycross, Georgia plant between July 1, 2011 and March 29, 2013 due to possible contamination with *E. coli* O121

**5. Possible causative agent(s)**

Shiga toxin-producing *Escherichia coli* O121

**6. Main characteristics of systems**

Shigellosis – affecting the gastrointestinal system

**7. Detailed symptoms, when applicable**

Fever, tiredness, watery or bloody diarrhea, nausea and vomiting, abdominal pain

**8. Deviation(s) from the normal pattern as regards type, etc.**

Food product contamination with Shiga toxin-producing *Escherichia coli* O121 (STEC O121) is not normal

**9. Approximate number of primary cases**

A total of 27 individuals infected with the outbreak strain of STEC O121 have been reported from 15 states. The number of ill persons identified in each state is as follows: Alabama (1), Arkansas (1), Illinois (2), Indiana (2), Michigan (3), Mississippi (1), New York (4), Ohio (3), Pennsylvania (1), South Dakota (1), Texas (3), Utah (1), Virginia (1), Washington (1), and Wisconsin (2)

**10. Approximate number of total cases**

27

**11. Number of deaths**

No death reported

**12. Development of the outbreak**

Among persons for whom information is available, illness onset dates range from December 30, 2012 to March 18, 2013. Ill persons range in age from 2 years to 75 years, with a median age of 17 years. Eighty-one percent of ill persons are 21 years of age or younger. Fifty-six percent of ill persons are female. Among 23 persons with available information, 8 (35%) reported being hospitalized. Two ill people developed hemolytic uremic syndrome (HUS), a type of kidney failure, and no deaths have been reported. Illnesses that occurred after March 13, 2013 might not be reported yet due to the time it takes between when a person becomes ill and when the illness is reported.

In interviews, ill persons answered questions about food consumed and other exposures during the week before becoming ill. Twenty (100%) of 20 ill persons interviewed reported consuming frozen food products. Ten (63%) of 16 ill persons reported consuming Farm Rich brand frozen food products. Investigations are ongoing to determine the specific types and sources of frozen food that might be linked with illness, as well as to determine which particular ingredients or components of these products may be contaminated.

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<sup>7</sup> See paragraph 2 of the chapeau to Confidence-Building Measure B.

### 13. Measures taken

The Centers for Disease Control and Prevention collaborated with public health officials in multiple states, the U.S. Department of Agriculture's Food Safety and Inspection Service (USDA-FSIS), and the U.S. Food and Drug Administration (FDA) to investigate a multistate outbreak of Shiga toxin-producing *Escherichia coli* O121 (STEC O121) infections.

On March 28, 2013, Rich Products Corporation, a Buffalo, New York firm, recalled approximately 196,222 pounds of Farm Rich brand frozen chicken quesadillas and several other frozen mini meals and snack items because they might be contaminated with *E. coli* O121 ([http://www.fsis.usda.gov/News\\_&\\_Events/Recall\\_025\\_2013\\_Release/index.asp](http://www.fsis.usda.gov/News_&_Events/Recall_025_2013_Release/index.asp)). The products subject to recall were produced between November 12, 2012 and November 19, 2012, and distributed for retail sale nationwide.

On April 4, 2013, Rich Products Corporation expanded its recall to include all products produced at its Waycross, Georgia plant between July 1, 2011 and March 29, 2013 due to possible contamination with *E. coli* O121 ([http://www.fsis.usda.gov/News\\_&\\_Events/Recall\\_025\\_2013\\_Expanded/index.asp](http://www.fsis.usda.gov/News_&_Events/Recall_025_2013_Expanded/index.asp)). The expanded recall is in addition to products recalled on March 28, 2013. The Farm Rich, Market Day, and Schwan's brand frozen food products included in the recall had "Best By" dates ranging from January 1, 2013 to September 29, 2014.

Rich Products Corporation has notified its distributors and customers who have received the recalled products, and has directed them to remove and destroy the affected product. All other affected product under Rich's control has been quarantined and will be destroyed.

Less than 400 pounds total of these products has been distributed internationally to Bermuda, Trinidad and Peru. FDA has notified the ministries of health and other pertinent government authorities of these countries. FDA has also notified the Canada and Mexico government counterparts in case of any potential cross-border movement of these products. The best available information collected by FSIS to date is that there have been no exports of FSIS-regulated products.

US NFP notified this as a potential PHEIC to WHO on April 13, 2013.

**Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern<sup>8</sup>**

**1. Time of cognizance of the outbreak**

On June 5 the US National Focal Point was notified of a multistate outbreak of *Salmonella* Montevideo and *Salmonella* Mbandaka infections from Krinos brand tahini sesame paste

**2. Location and approximate area affected**

Eight individuals infected with the outbreak strain of *Salmonella* Montevideo or *Salmonella* Mbandaka have been reported from six states. The number of ill persons identified in each state is as follows: California (1), Minnesota (2), North Dakota (1), New York (1), Texas (2), and Wisconsin (1).

**3. Type of disease/intoxication**

Salmonellosis

**4. Suspected source of disease/intoxication**

Krinos brand tahini sesame paste

**5. Possible causative agent(s)**

*Salmonella* Montevideo and *Salmonella* Mbandaka

**6. Main characteristics of systems**

Salmonellosis - affecting GI system

**7. Detailed symptoms, when applicable**

Diarrhea, fever, and abdominal cramps

**8. Deviation(s) from the normal pattern as regards type, etc.**

Food product contamination with *Salmonella* Montevideo and *Salmonella* Mbandaka is not normal

**9. Approximate number of primary cases**

8

**10. Approximate number of total cases**

8

**11. Number of deaths**

0

**12. Development of the outbreak**

A total of eight individuals infected with the outbreak strain of *Salmonella* Montevideo or *Salmonella* Mbandaka have been reported from six states. Among persons for whom information is available, illness onset dates range from March 4, 2013, to April 30, 2013. Among four ill persons with available information, none (0 percent) reported being hospitalized. No deaths have been reported. Illnesses that occurred after May 10, 2013, might not be reported yet due to the time it takes between when a person becomes ill and when the illness is reported. However, the recalled tahini sesame paste has a long shelf-life and may still be in people's homes, and illnesses may still continue to be reported. In interviews, ill persons answered questions about foods eaten and other exposures during the week before becoming ill. Four (100%) of four ill persons interviewed reported eating homemade hummus made with Krinos brand tahini sesame paste.

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<sup>8</sup> See paragraph 2 of the chapeau to Confidence-Building Measure B.

### 13. Measures taken

The U.S. Centers for Disease Control and Prevention (CDC) is collaborating with public health officials in multiple states and the U.S. Food and Drug Administration (FDA), to investigate a multistate outbreak of *Salmonella* Montevideo and *Salmonella* Mbandaka infections.

A notification of the outbreak and an inquiry for additional matches was sent to members of the European Centers for Disease Control and PulseNet International. Through this inquiry, the CDC was notified of an outbreak of *Salmonella* Mbandaka, *Salmonella* Montevideo, and *Salmonella* Maastricht in New Zealand at the end of 2012 that matched the outbreak strains in the U.S. investigation. Illnesses were also linked to tahini imported from Gesas Genel Gıda Sanayi Ve Ticaret A.Ş., Konya, Turkey. All three outbreak strains were isolated from unopened tubs of tahini sesame paste sourced from the warehouse of the New Zealand distributor.

In addition, during routine product testing at a retail store, the Michigan Department of Agriculture isolated *Salmonella* Montevideo from Krinos brand tahini sesame paste. Additional testing by the FDA isolated *Salmonella* Mbandaka from imported tahini sesame paste collected from shipments arriving in the U.S for distribution by Krinos Foods. Testing conducted by a state health department isolated *Salmonella* Maastricht and the outbreak strains of *Salmonella* Montevideo and *Salmonella* Mbandaka from an opened jar of Krinos brand tahini sesame paste.

Traceback of this tahini paste determined that the product was part of a consignment of tahini imported directly from Turkey with arrival in the United States on October 12, 2012.

On April 28, 2013, Krinos Foods, LLC of Long Island City, New York, recalled its tahini sesame paste. Sesame paste imported from Turkey was repackaged and relabeled under the Krinos brand. The product was distributed nationwide. (<http://www.fda.gov/Safety/Recalls/ucm350163.htm>). On May 9, 2013, Krinos Foods expanded its recall to include additional expiration dates. The recalled lots have expiration dates from January 1, 2014, to June 8, 2014, and from October 16, 2014, to March 15, 2015. (<http://www.fda.gov/Safety/Recalls/ucm351630.htm?source=govdelivery>)

Krinos Foods only distributed products domestically in the United States. Currently, FDA is not aware of any international distribution under the Krinos brand name. A photo of the product label can be found in FDA's website at: <http://www.fda.gov/Safety/Recalls/ucm350163.htm>

US NFP notified this as a potential PHEIC to WHO on June 5, 2013

**Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern<sup>9</sup>**

**1. Time of cognizance of the outbreak**

June 7, 2013

**2. Location and approximate area affected**

Corpus Christie, Texas was the diagnosis location however, the geographic scope is large or spread over a large area (multiple countries) and in an area of high population density due to the number of individuals exposed to case while in detention center.

**3. Type of disease/intoxication**

Rabies

**4. Suspected source of disease/intoxication**

The rabies virus is a canine variant similar to those found in southern Mexico, Honduras, and El Salvador; however, it is possible that he was infected in Guatemala.

**5. Possible causative agent(s)**

Rabies virus

**6. Main characteristics of systems**

Rabies – inflammation of the brain

**7. Detailed symptoms, when applicable**

General weakness/discomfort, fever, headache and cerebral dysfunction, anxiety, confusion, agitation progressing to delirium, abnormal behavior, hallucinations, and insomnia.

**8. Deviation(s) from the normal pattern as regards type, etc.**

No

**9. Approximate number of primary cases**

1

**10. Approximate number of total cases**

1

**11. Number of deaths**

1

**12. Development of the outbreak**

The infectious period is estimated to have begun on May 2 and ended on June 11<sup>th</sup> when patient died; this period includes the entire time the patient was in the U.S., during which the case was in close contact with other persons who have already returned to their countries of origin.

**13. Measures taken**

The contact tracing investigation was carried out with international collaboration to prevent potential further rabies virus transmission. Risk assessments of those who had contact with the patient during his infectious period were necessary to determine if post-exposure prophylaxis was necessary. Person-to-person transmission by bite, and non-bite exposures to secretions of an infected human could theoretically transmit rabies, but no such cases have been laboratory-confirmed.

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<sup>9</sup> See paragraph 2 of the chapeau to Confidence-Building Measure B.

**Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern**<sup>10</sup>

**1. Time of cognizance of the outbreak**

June 24, 2013

**2. Location and approximate area affected**

Indiana, U.S. – followed by Illinois, Indiana, Iowa, Michigan and Pennsylvania in 2013.

**3. Type of disease/intoxication**

Influenza

**4. Suspected source of disease/intoxication**

Swine at a local agriculture fair

**5. Possible causative agent(s)**

H3N2v Influenza virus

**6. Main characteristics of systems**

Respiratory Illness

**7. Detailed symptoms, when applicable**

General Influenza Symptoms

**8. Deviation(s) from the normal pattern as regards type, etc.**

H3N2v has not been defined by the CDC as a “Seasonal Influenza” yet and continues to be notified to WHO as a potential PHEIC upon the first case presented each year, with a referral to CDC flu view for subsequent cases that season.

**9. Approximate number of primary cases**

1

**10. Approximate number of total cases**

19

**11. Number of deaths**

0

**12. Development of the outbreak**

This is the first report of a human infection with influenza A (H3N2)v in the United States in 2013. The total number of human infections with influenza A (H3N2)v virus reported in the United States was 12 in 2011 and 309 in 2012 and 19 in 2013. In 2013 cases were seen in Illinois, Indiana, Iowa, Michigan and Pennsylvania. There was no change in severity of the disease caused by the variant.

**13. Measures taken**

On June 18, 2013, a person <18 years old became ill with influenza-like illness, and on June 20, 2013, the individual sought care at a local healthcare provider, where a respiratory specimen was collected for influenza testing. Reverse transcription-polymerase chain reaction (RT-PCR) testing conducted at the Indiana State Department of Health Laboratory indicated a presumptive influenza A (H3N2) variant [(H3N2)v] virus, and the sample was forwarded to CDC for additional testing. On June 24, 2013, genome sequencing confirmed influenza A (H3N2)v virus with the M gene from the influenza A (H1N1)pdm09 virus similar to cases detected previously in 2011 and 2012 in the United States.

The case was not hospitalized and recovered from the illness. Swine contact at an agricultural fair was reported in the week preceding illness onset, and a joint human-animal investigation to evaluate illness among other fair attendees and community members is ongoing. Information about this case has been released through Epi-X and the Indiana Health Alert Network.

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<sup>10</sup> See paragraph 2 of the chapeau to Confidence-Building Measure B.

**Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern**<sup>11</sup>

**1. Time of cognizance of the outbreak**

20 May 2011 first case; 27 June 2013 potential PHEIC assessed/notified

**2. Location and approximate area affected**

Belgium, China, Croatia, Czech Republic, Germany, Guatemala, Hong Kong, Hungary, Italy, Japan, Kenya, Mexico, Netherlands, Portugal, Republic of Korea (South), Singapore, Spain, Turkey, United Kingdom, Venezuela

**3. Type of disease/intoxication**

Salmonellosis

**4. Suspected source of disease/intoxication**

Traceback investigations of turtles purchased from Florida souvenir shops in Outbreak 3 identified two turtle farms in Louisiana as the source of those turtles. The Louisiana Department of Agriculture and Forestry issued cease and desist orders in March 2013 for the source farms; therefore, turtles with a shell length of less than 4 inches from these farms are no longer being sold domestically. The source of turtles in other outbreaks could not be identified because of the challenges of tracing small turtles that are sold illegally by transient vendors.

**5. Possible causative agent(s)**

Salmonella

**6. Main characteristics of systems**

Salmonellosis

**7. Detailed symptoms, when applicable**

Diarrhea, fever, and abdominal cramps

**8. Deviation(s) from the normal pattern as regards type, etc.**

Turtles smaller than US regulatory requirement were being sold. No deviation with regard to disease severity or pathogenicity.

**9. Approximate number of primary cases**

Initial notification to state and local health departments

**10. Approximate number of total cases**

471 (U.S.) currently

**11. Number of deaths**

0

**12. Development of the outbreak**

A total of 473 (391 at the time of notification as a potential PHEIC to WHO) persons infected with the outbreak strains of *Salmonella* were reported from 41 states, the District of Columbia, and Puerto Rico. 29% of ill persons were hospitalized, and no deaths were reported. 70% of ill persons were children 10 years of age or younger, and 31% of ill persons were children 1 year of age or younger. 44% of ill persons were of Hispanic ethnicity. Twenty-nine percent of ill persons have been hospitalized, and no deaths have been reported. Seventy-one percent of ill persons are children 10 years of age or younger, and 33% of ill persons are children 1 year of age or younger. Forty-five percent of ill persons are of Hispanic ethnicity. The earliest illness associated with these eight outbreaks began on May 20, 2011 and illnesses continue to be reported as of July 2013. Four of these outbreaks remain under active investigation.


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<sup>11</sup> See paragraph 2 of the chapeau to Confidence-Building Measure B.

### 13. Measures taken

CDC and FDA continue investigating the eight overlapping, multistate outbreaks of human *Salmonella* infections linked to exposure to small turtles (those with a shell length of less than 4 inches/10 centimeters).

Results of the epidemiologic and environmental investigations indicate exposure to turtles or their environments (e.g., water from a turtle habitat) is the cause of these outbreaks. The majority of small turtles were purchased from transient vendors such as flea markets or street vendors. Traceback investigations identified two turtle farms in Louisiana as the source of some of the turtles. The Louisiana Department of Agriculture and Forestry issued cease and desist orders for the source turtle farms, but small turtles continue to be distributed internationally to 20 different countries. Based on available export records from the U.S. Fish and Wildlife Service, turtles were shipped to the affected countries (#2 above)

Since 1975, the [Food and Drug Administration has banned the sale and distribution of turtles with a shell length of less than 4 inches in size as pets](#). These small turtles should not be purchased as pets or given as gifts.

The numbers of new cases have declined substantially since the peak of the outbreak, but illnesses are still being reported among people who have contact with small turtles. The outbreak is expected to continue at a low level for the next several months since consumers might be unaware of the risk of *Salmonella* infection from reptiles including small turtles. If properly cared for, small turtles have a long life expectancy.

On 27 July 2013, the US IHR NFP notified this as a potential PHEIC to WHO

**Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern<sup>12</sup>**

**1. Time of cognizance of the outbreak**

July 29 the US National Focal Point was notified by CDC and subsequently notified this as a potential PHEIC to WHO

**2. Location and approximate area affected**

10 states: Arizona (23), California (79), Colorado (28), Hawaii (8), New Hampshire (1), New Jersey (1), New Mexico (11), Nevada (6), Utah (3), and Wisconsin (2)

**3. Type of disease/intoxication**

Hepatitis

**4. Suspected source of disease/intoxication**

Epidemiological investigation by FDA and CDC have determined that the most likely vehicle for the hepatitis A virus appears to be a common shipment of pomegranate seeds from a company in Turkey, Goknur Foodstuffs Import Export Trading.

**5. Possible causative agent(s)**

Viral Hepatitis A

**6. Main characteristics of systems**

Hepatitis A is an acute liver disease caused by the hepatitis A virus (HAV), lasting from a few weeks to several months. It does not lead to chronic infection.

**7. Detailed symptoms, when applicable**

Cases presented with various general hepatitis symptoms: Fever, Fatigue, Loss of appetite, Nausea, Vomiting, Abdominal pain, Dark urine, Clay-colored bowel movements, Joint pain, Jaundice (a yellowing of the skin or eyes)

**8. Deviation(s) from the normal pattern as regards type, etc.**

Food product contamination with hepatitis A is not normal. The major outbreak strain of hepatitis A virus, belonging to genotype 1B, was found in clinical specimens of 117 people in nine states: AZ, CA, CO, HI, NH, NJ, NM, NV, and WI. This genotype is rarely seen in the Americas but circulates in North Africa and the Middle East. This genotype was identified in a 2013 outbreak of hepatitis A virus infections in Europe linked to frozen berries and a 2012 outbreak in British Columbia related to a frozen berry blend with pomegranate seeds from Egypt. However, there is no evidence at this time that these outbreaks are related to the ongoing U. S. outbreak.

**9. Approximate number of primary cases**

155 (case count as of July 29 2013 when notified as a potential PHEIC to WHO)

**10. Approximate number of total cases**

162 (155 at time of notification as a potential PHEIC to WHO)

**11. Number of deaths**

0

**12. Development of the outbreak**

As of September 20, 2013, 162 people were confirmed to have become ill from hepatitis A after eating 'Townsend Farms Organic Antioxidant Blend' in 10 states: Arizona (23), California (79), Colorado (28), Hawaii (8), New Hampshire (1), New Jersey (1), New Mexico (11), Nevada (6), Utah (3), and Wisconsin (2). [Note: The cases reported from Wisconsin resulted from exposure to the product in California, the cases reported from New Hampshire reported fruit exposure during travel to Nevada, and the case reported in New Jersey was a household contact of a confirmed case from Colorado.] Six of the confirmed cases were household contacts of confirmed cases (secondary cases). 90 (55%) ill people were women; Ages ranged from 1 – 84 years; 94 (58%) of those ill were between 40 – 64 years of age. 11 children age 18 or under were also ill. None were previously vaccinated. Illness onset dates ranged from

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<sup>12</sup> See paragraph 2 of the chapeau to Confidence-Building Measure B.

3/31/2013 – 7/26/2013; 71 (44%) ill people were hospitalized, and no deaths were reported. All ill people who reported eating this product purchased it from Costco markets; however, the product was also sold at Harris Teeter stores. No ill people were identified that bought the product at Harris Teeter.

### **13. Measures taken**

By combining information gained from FDA's traceback and traceforward investigations and the CDC's epidemiological investigation, FDA and CDC have determined that the most likely vehicle for the hepatitis A virus appears to be a common shipment of pomegranate seeds from a company in Turkey, Goknur Foodstuffs Import Export Trading. FDA detained shipments of pomegranate seeds from Goknur when they are offered for import into the United States. These pomegranate seeds were used by Townsend Farms to make the Townsend Farms and Harris Teeter Organic Antioxidant Blends and by Scenic Fruit Company to make the Woodstock Frozen Organic Pomegranate Kernels. FDA worked with the firms that have distributed pomegranate seeds from this shipment from Turkey to help ensure that all recipients of these seeds were notified.

On June 4, 2013, [Townsend Farms, Inc. of Fairview, Oregon voluntarily recalled certain lots of its frozen Organic Antioxidant Blend](#) because of potential hepatitis A virus contamination.

On June 28, 2013, [Townsend Farms, Inc. of Fairview, Oregon, expanded its voluntary limited lot recall of frozen Organic Antioxidant Blend, 3 lb](#) because of potential hepatitis A virus contamination.

On June 26, 2013, [Scenic Fruit Company of Gresham, Oregon recalled specific lots of Woodstock Frozen Organic Pomegranate Kernels](#) because of potential hepatitis A virus contamination.

Additional information regarding these recalls was updated regularly at: [FDA Investigates Multistate Outbreak of Hepatitis A Illnesses Associated with Pomegranate seeds from Turkish Importer](#).

Additionally, the FDA inspectional and traceback activities revealed the pomegranate seeds (arils) used in the Townsend Farms Organic Antioxidant Blend were imported from Turkey and were not used in any other products produced by Townsend Farms. Traceback activities included but were not limited to review of invoices, purchase orders, and production records for each point in the supply chain.

The FDA selected four confirmed clinical cases for traceback. These cases were chosen for traceback legs based on the case-patient's food history indicating exposure to the suspect product, shopper card information, and laboratory results confirming that the case-patient matched the Hepatitis A/1B genotype outbreak strain. All four traceback leg investigations conducted by FDA identified a single lot and source of frozen imported pomegranate seeds (arils) originating from Turkey in all Townsend Farms products known to be purchased by confirmed case patients. No other pomegranate lots or sources were identified or associated with case patients.

The FDA has been conducting specialized product testing of sealed and unsealed bags of the Townsend Farms Organic Antioxidant Blend product that have been obtained from patients. While no positive microbiological samples have been identified yet, the epidemiological link has been made and additional extensive product testing is ongoing.

There is concern that the pomegranate seeds (arils) from the supplier in Turkey may have been distributed internationally and could impact other countries. The FDA is collaborating with the Turkey's Ministry of Food, Agriculture and Livestock (MFAL) in their investigation at the supplier. Further investigation is pending.

Currently, the US is unaware of any export of recalled products by Townsend Farms or Scenic Fruit, the two firms that have recalled products.

**Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern**<sup>13</sup>

**1. Time of cognizance of the outbreak**

September 9, 2013 (Hawaii Department of Health was notified of initial 9 cases). On November 1, 2013 the US National Focal Point was notified of 56 cases by CDC and subsequently notified this as a potential PHEIC to the WHO.

**2. Location and approximate area affected**

As of 31 October 2013, there have been 56 cases identified in 13 USA states (42 of these cases are in Hawaii; Arizona-1, California-2, Kentucky-1, Maine-1, Minnesota-1, Missouri-1, New York-1, Ohio-1, Pennsylvania-1, Rhode Island-1, Virginia-2, and Washington-1)

A few other cases have been identified in other countries as well: New Zealand and Japan.

**3. Type of disease/intoxication**

Hepatitis

**4. Suspected source of disease/intoxication**

Associated with ingestion of OxyELITE Pro™ (OEP) products, dietary supplements marketed for energy boost, body building, and weight loss.

**5. Possible causative agent(s)**

Non-viral hepatitis

**6. Main characteristics of systems**

Hepatitis A is an acute liver disease caused by the hepatitis A virus (HAV), lasting from a few weeks to several months. It does not lead to chronic infection.

**7. Detailed symptoms, when applicable**

All presented with general hepatitis symptoms. Twenty two cases have been hospitalized with acute hepatitis; two cases have received liver transplants, and one person has died.

**8. Deviation(s) from the normal pattern as regards type, etc.**

Among these cases, testing for viral hepatitis was negative, and other explicative etiologies for liver injury were ruled out.

**9. Approximate number of primary cases**

9 (Hawaii)

**10. Approximate number of total cases**

56

**11. Number of deaths**

1

**12. Development of the outbreak**

Acute hepatitis and in some instances, liver failure, among otherwise healthy adults has been associated with ingestion of OxyELITE Pro™ (OEP) products, dietary supplements marketed for energy boost, body building, and weight loss. As of 10/31/13, there have been 56 cases in 13 states of acute hepatitis with an unknown cause subsequent to use of a weight loss or muscle building dietary supplement identified nationally, with most of these being from the State of Hawaii (42 of these cases are in Hawaii; Arizona-1, California-2, Kentucky-1, Maine-1, Minnesota-1, Missouri-1, New York-1, Ohio-1, Pennsylvania-1, Rhode Island-1, Virginia-2, and Washington-1). 47 of these used OEP during the 60 days prior to illness. Twenty two cases have been hospitalized with acute hepatitis; two cases have received liver transplants, and one person has died. Among these cases, testing for viral hepatitis was negative, and other explicative etiologies for liver injury were ruled out.

The investigation is ongoing and the data presented are preliminary. Thus far, clinicians have reported 45 patients to the Hawaii DOH in response to a public health alert. Of those, 29 patients, including the

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<sup>13</sup> See paragraph 2 of the chapeau to Confidence-Building Measure B.

original seven, were confirmed to have acute hepatitis after using a nutritional supplement for weight loss or muscle building. The median age of the 29 patients is 33 years; 14 (48%) are male. The date of the first reported laboratory test was used as a proxy for illness onset and ranged from May 10 through October 3, 2013. The most commonly reported symptoms included loss of appetite, light-colored stools, dark urine, and jaundice. Median laboratory values reported at the peak of illness were the following:

- aspartate aminotransferase (AST) 1,128 IU/L;
- alanine transaminase (ALT) 1,793 IU/L;
- alkaline phosphatase 150 IU/L; and
- total bilirubin 12.6 mg/dL.

Ten patients had liver biopsy data available as of October, 8 2013. Seven had histology consistent with hepatitis from drug/toxic injury, with findings including hepatocellular necrosis and cholestasis. Three patients had liver biopsy findings of acute hepatitis associated with other etiologies such as autoimmune hepatitis. Eleven (38%) patients were hospitalized, with a median duration of seven days. One patient died, and two patients received liver transplants. Two remain hospitalized, and all other hospitalized patients have been discharged.

Of the 29 identified patients, 24 (83%) reported using OxyELITE Pro during the 60 days prior to illness onset. There was no other dietary supplement or medication use reported in common by more than two patients.

### **13. Measures taken**

The United Kingdom, Spain, New Zealand, Australia, Singapore, Japan and Denmark have issued consumer warnings about OEP, and CDC has provided epidemiologic data collection tools to Australia and Singapore. Laboratory analysis of the product to date has not identified a causal etiologic agent, and more specific testing is ongoing. OEP products are distributed to various retailers and are on Internet marketing sites.

National case finding efforts have identified several individuals from states outside Hawaii with reported OxyELITE Pro or other weight loss or muscle building dietary supplement use prior to the development of acute hepatitis of unknown cause. CDC, in collaboration with state health departments, is collecting additional clinical and epidemiologic information from these individuals to determine if this outbreak is national in scope.

There were three World Organization for Animal Health (OIE) immediate reports for animal disease events in 2013 (deviations from normal pattern), and four ongoing reports from previous years. Event summaries can be found on the OIE website: <http://web.oie.int/wahis/public.php>

**Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern**<sup>14</sup>

**Summary of Reports:** There were three World Organization for Animal Health (OIE) immediate reports for animal disease events in 2013 (deviations from normal pattern), and four ongoing reports from previous years. Event summaries can be found on the OIE website: <http://web.oie.int/wahis/public.php>.

**1) Contagious Equine Metritis – Two outbreaks detected in 2013 (OIE Immediate Report February 12, 2013 – Open).** Contagious equine metritis is an inflammation of the endometrium of mares caused by *Taylorella equigenitalis*, which usually results in temporary infertility. It is a nonsystemic infection, the effects of which are restricted to the reproductive tract of the mare. *T. equigenitalis* is most frequently transmitted by sexual contact with carrier stallions, which are always asymptomatic.

**California** - On February 6, 2013, a 17-year-old Lusitano mare in California was confirmed positive for *T. equigenitalis*, the bacterium that causes contagious equine metritis (CEM), during a pre-breeding health examination. The epidemiological investigation identified an additional two stallions and one mare infected with *T. equigenitalis*, and 18 exposed horses. All four positive horses have been treated, re-tested with negative results, treated again, and released from quarantine. Of the 18 exposed horses, 13 have been tested with negative results, treated, and released from quarantine. Five mares remain quarantined until completion of CEM testing and treatment protocols. There is currently no known relationship between these positive horses and any other horses associated with previous U.S. cases of CEM. This California CEM event is ongoing.

**Puerto Rico** - On May 2, 2013 a two-year-old Thoroughbred mare in Puerto Rico was confirmed positive by the National Veterinary Services Laboratories (NVSL) for *T. equigenitalis*, the bacterium that causes contagious equine metritis (CEM). The mare had moved to Puerto Rico and was tested for *T. equigenitalis* relative to the move. A thorough epidemiological investigation of the positive horse was completed. No additional positive horses were detected and no relationship was found between the positive mare and any horses associated with previous U.S. cases of CEM. The positive mare was treated, retested with negative test results for *T. equigenitalis*, and released from quarantine. The Puerto Rico CEM event is considered closed.

**2) Infection with *Bonamia exitiosa* - One new event in 2013 and one continuing event from 2012.**

*Bonamia exitiosa* is a *Haplosporidia* protozoan parasite (Carnegie & Cochenec-Laureau, 2004) infecting haemocytes of several oyster species and inducing physiological disorders and eventually death of the animal (Cranfield *et al.*, 2005; Dinamani *et al.*, 1987).

**North Carolina** (OIE Immediate Report August 28, 2012 – Resolved February 15, 2013). *Bonamia exitiosa* was found infecting hatchery-produced *C. virginica* seed at 93.8% prevalence. No elevated mortality in the affected stock was observed. *C. virginica* was thought to be refractory from *B. exitiosa* and the impact on production or wild populations of *C. virginica* is unknown. The farmed species were in open water with *B. exitiosa* susceptible wild species. The impact of *B. exitiosa* on commercial and wild populations of *C. virginica* is unknown. Current information indicates there is not widespread infection of *C. virginica* with *B. exitiosa*. Follow-up sampling and laboratory testing of the *B. exitiosa*-affected hatchery indicates the prevalence of the infections was significantly reduced from initial testing. No infections were heavy and no mortality was noted. It appears that the reductions in prevalence represent regression of infection rather than the disappearance through mortality. Additional sampling and studies are to be conducted but no official action in relation to the infection with *B. exitiosa* event is planned at this time. This *B. exitiosa* event is considered closed.

**Massachusetts** (OIE Immediate Report September 9, 2013 – Resolved August 29, 2013) *Bonamia exitiosa* infection was detected through routine testing of a farmed *Crassostrea virginica* (Eastern

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<sup>14</sup> See paragraph 2 of the chapeau to Confidence-Building Measure B.

American oyster) seed located in Massachusetts coastal waters. This was the first reported occurrence of *B. exitiosa* in Massachusetts. The 2-month-old *C. virginica* seed were in open water and showed no increased morbidity or mortality. The *C. virginica* seed were hatchery-produced and tested negative for *Bonamia* infection prior to placement at the nursery site when they were 1 month old. Additional sampling and studies are to be conducted, but no official action in relation to the infection with the *B. exitiosa* event is planned. This *B. exitiosa* event is considered closed.

**3) Low Pathogenic Notifiable Avian Influenza (OIE Immediate Report June 19, 2013 – Resolved August 6, 2013).** H5 and H7 avian influenza in its low pathogenic form in poultry is a notifiable disease as per Chapter 10.4 on avian influenza of the OIE Terrestrial Animal Health Code (2013):

[http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre\\_1.10.4.htm](http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_1.10.4.htm)

Low pathogenic notifiable avian influenza (LPNAI) H7N7 was detected in a 44-week-old commercial broiler breeder flock in Arkansas after the birds exhibited a drop in egg production. Egg production started to return to normal and the birds appeared healthy at the time of inspection. No increased mortality or respiratory signs were noted. The USDA Animal Plant Health Inspection Service (APHIS) and the Arkansas Livestock & Poultry Commission conducted a comprehensive epidemiological investigation of the event. Enhanced surveillance was conducted on all flocks within a 10 km (6.2 mile) zone and on all flocks epidemiologically linked to the affected premises. No additional avian influenza-positive flocks were detected. The infected flock was depopulated and the index premises was cleaned and disinfected (C&D). Post C&D environmental samples were negative for avian influenza virus. The comprehensive epidemiological investigation of this LPNAI event is considered closed.

**4) Equine piroplasmiasis** - Three OIE Ongoing Reports in 2013. Equine piroplasmiasis is a tick-borne protozoal disease of horses, mules, donkeys, and zebra. The aetiological agents are blood parasites named *Theileria equi* and *Babesia caballi*.

**National Outbreak** (2 ongoing OIE reports: *T. equi* and *B. caballi*):

Testing for interstate movement and movement to equine events in response to the recent equine piroplasmiasis (EP) outbreaks continues in many States. The USDA Animal Plant Health Inspection Service (APHIS) and the State Departments of Agriculture are conducting comprehensive epidemiological investigations of these events.

From November 2009 to September 1, 2013, more than 231,664 U.S. horses were tested for equine piroplasmiasis (*T. equi* and *B. caballi*). As of September 1, 2013, 205 *T. equi* and 10 *B. caballi*-positive horses were detected in 22 States: AL, AZ, CA, CO, FL, GA, IL, IN, IA, KY, LA, MA, MI, MN, MS, NM, NC, OH, OK, SC, TN, and TX. Unlike the South Texas outbreak, transmission of the organism likely resulted from management practices (use of shared needles or substances between horses) rather than by a tick vector. Additionally, some of the EP-positive horses detected were imported prior to August 2005 when the official import test became the competitive enzyme-linked assay (cELISA). These imported horses are considered to have acquired their infections prior to arrival in the United States. Individual State movement testing for equine piroplasmiasis continues in 2014.

**South Texas Outbreak** (Ongoing OIE report)

Equine piroplasmiasis (*Theileria equi*) was identified in South Texas on October 19, 2009. During the outbreak investigation, 2,500 horses were tested and 413 *T. equi*-positive horses were detected. *T. equi*-positive horses were identified in 17 States: AL, CA, CO, FL, GA, IN, LA, MN, MO, NM, NC, NJ, OK, TX, TN, UT, and WI. The *T. equi*-positive horses were either moved back to the index ranch in Texas to be managed under long-term quarantine, euthanized, or enrolled in research programs. Approximately 220 quarantined horses are undergoing treatment for research purposes. The results of the epidemiological investigation indicate that infection was likely present on the index ranch prior to 1990. Extensive tick studies on the index premises found one known experimental tick vector for *T. equi*, *Dermacentor variabilis*, and determined via testing that a second tick species, *Amblyomma cajennense*, was also capable of transmitting *T. equi*. The epidemiological investigation has concluded for this outbreak but the OIE report is still open.

**Form C**

**BWC - Confidence Building Measure**

**Encouragement of Publication of Results and Promotion of Use of Knowledge**

United States of America

April 15, 2014

<b>Department of Health and Human Services (HHS) Open Government Plan</b> <a href="http://www.hhs.gov/open/plan/opengovernmentplan/openplanversion2.pdf">http://www.hhs.gov/open/plan/opengovernmentplan/openplanversion2.pdf</a>	The key principles of Open Government are transparency, collaboration, and participation.
<b>Centers for Disease Control and Prevention (CDC) Policy on Releasing and Sharing Data</b> <a href="http://www.cdc.gov/maso/Policy/ReleasingData.pdf">http://www.cdc.gov/maso/Policy/ReleasingData.pdf</a>	Public health and scientific advancement are best served when data are shared with public health agencies and academic researchers in an open, timely, and appropriate way.
<b>The Journal <i>Emerging Infectious Diseases</i></b> <a href="http://wwwnc.cdc.gov/eid/">http://wwwnc.cdc.gov/eid/</a>	Emerging Infectious Diseases is an open access, peer-reviewed journal published by the Centers for Disease Control and Prevention (CDC).
<b>The Morbidity and Mortality Weekly Report (MMWR)</b> <a href="http://www.cdc.gov/mmwr/">http://www.cdc.gov/mmwr/</a>	CDC's primary vehicle for scientific publication of reliable, authoritative, objective, and useful public health information and recommendations; open access.
<b>Advancing Excellence and Integrity of CDC Science</b> <a href="http://www.cdc.gov/od/science/">http://www.cdc.gov/od/science/</a>	The Office of the Associate Director for Science's mission is to strengthen the quality, integrity, and relevance of CDC's science and health impact
<b>Office of Scientific Integrity (OSI)</b> <a href="http://www.cdc.gov/od/science/integrity/">http://www.cdc.gov/od/science/integrity/</a>	OSI ensures that CDC science and research activities comply with various federal laws, regulations, and policies; coordinates the agency's 301(d) and 308(d) confidentiality protections; ensures leadership in public health ethics; and provides trainings to promote a well-educated and ethical domestic and international workforce at CDC.
<b>Public Health Image Library (PHIL)</b> <a href="http://phil.cdc.gov/">http://phil.cdc.gov/</a>	The PHIL offers an organized, electronic gateway to CDC images for reference, teaching, presentation, and public health messages; open access.
<b>U.S. Food and Drug Administration (FDA) Publications</b> <a href="http://www.accessdata.fda.gov/scripts/publications/">http://www.accessdata.fda.gov/scripts/publications/</a>	An actively updated and searchable research publications database for all FDA publications.
<b>PubMed Central (PMC)</b> <a href="http://www.ncbi.nlm.nih.gov/pmc/">http://www.ncbi.nlm.nih.gov/pmc/</a>	PMC is the National Library of Medicine's digital archive. Final peer-reviewed manuscripts that arise from NIH funds are accessible to the public on PMC no later than twelve months after publication; open access.
<b>The National Institutes of Health (NIH) Public Access Policy</b> <a href="http://publicaccess.nih.gov/policy.htm">http://publicaccess.nih.gov/policy.htm</a>	The NIH Public Access Policy ensures that the public has access to the published results of NIH funded research.
<b>Agricultural Research Magazine</b> <a href="http://www.ars.usda.gov/is/AR/">http://www.ars.usda.gov/is/AR/</a>	The Agricultural Research Magazine is the USDA's science magazine published by the Agricultural Research Service (ARS); open access.

<b>National Science Foundation (NSF) Research Spending and Results</b> <a href="https://www.research.gov/research-portal/appmanager/base/desktop?_nfpb=true&amp;_eventName=viewQuickSearchFormEvent_so_rsr">https://www.research.gov/research-portal/appmanager/base/desktop?_nfpb=true&amp;_eventName=viewQuickSearchFormEvent_so_rsr</a>	Research funded in whole or in part by NSF is required to be made available to the public in electronic format in a timely manner; open access.
<b>Environmental Protection Agency (EPA) Scientific Integrity Policies</b> <a href="http://www.epa.gov/research/htm/scientific-integrity.htm">http://www.epa.gov/research/htm/scientific-integrity.htm</a>	The EPA strongly encourages and supports transparency and active, open communication including publication in peer-reviewed journals, conference papers and presentations, media interviews, web postings, and news releases.
<b>Environmental Protection Agency (EPA) Homeland Security Research Publications</b> <a href="http://www.epa.gov/nhsr/pubs.html">http://www.epa.gov/nhsr/pubs.html</a>	All EPA Homeland Security Research publications are openly available online, organized by topic.
<b>Department of Energy (DOE) Biological and Environmental Research (BER) Program</b> <a href="http://genomicscience.energy.gov/datasharing/">http://genomicscience.energy.gov/datasharing/</a>	The DOE BER Program requires that all publishable data, metadata, and software resulting from research funded by the Genomic Science Program must be deposited in a public access database(s) appropriate for the research.

**Form E**

**BWC - Confidence Building Measure**

**Declaration of legislation, regulations and other measures**

United States of America

April 15, 2014

**Declaration of legislation, regulations and other measures**

	Legislation	Regulations	Other <sup>15</sup>	Amended since last year
(a) Development, production, stockpiling, acquisition or retention of microbial or other biological agents, or toxins, weapons, equipment and means of delivery specified in Article I	YES	YES	YES	NO
(b) Exports of Micro-Organisms <sup>16</sup> and Toxins	YES	YES	YES	YES
(c) Imports of Micro-Organisms and Toxins	YES	YES	NO	NO
(d) Biosafety <sup>17</sup> and biosecurity <sup>18</sup>	YES	YES	YES	YES

**(b) Exports of Micro-Organisms and Toxins: Changes to Regulations****Implementation of the Understandings Reached at the 2012 Australia Group (AG) Plenary Meeting and the 2012 AG Intersessional Decisions; Changes to Select Agent Controls.**

This regulation was published in the June 5, 2013 Federal Register (78 FR 33692) to amend the Export Administration Regulations by removing ten “select agents” from the Commerce Control List that are no longer listed by the Centers for Disease Control and Prevention (U.S. Department of Health and Human Services) or by the Animal and Plant Health Inspection Service (U.S. Department of Agriculture), while adding three bacteria (botulinum neurotoxin producing strains of *Clostridium argentinense*, *Clostridium baratii*, and *Clostridium butyricum*), two fungi (*Tilletia indica* and *Thecaphora solani*), and two viruses (SARS-associated coronavirus (SARS-CoV) and tickborne encephalitis virus, Siberian subtype). Additionally the rule clarified controls for three bacteria (*Escherichia coli* and other verotoxin producing serotypes, *Xanthomonas campestris* pv. *citri* and *Ralstonia solanacearum*), two fungi (*Puccinia graminis* and *Magnaporthe grisea*), one virus (Andean potato latent virus), and the toxins produced by *Staphylococcus aureus*. Finally, this rule expanded the scope of the EAR controls that apply to dual-use spray-drying equipment capable of drying toxins or pathogenic microorganisms.

(<http://www.bis.doc.gov/index.php/regulations/federal-register-notice#78fr33692>)

**(d) Biosafety and Biosecurity: Changes to Regulations****Import Regulations for Infectious Biological Agents, Infectious Substances, and Vectors**

Section 361 of the Public Health Service Act (PHS Act) (42 U.S.C. 264) authorizes the Secretary of HHS (Secretary) to make and enforce regulations for preventing the introduction, transmission, and spread of communicable diseases from foreign countries into the United States and from one state or possession into another. Section 361 of the PHS Act also provides for the inspection and destruction of articles found to be infected or so contaminated as to be sources of dangerous infection to humans and for other measures, as the Secretary deems necessary. The Foreign Quarantine Regulations (42 CFR Part 71) set forth provisions to prevent the introduction, transmission, and spread of communicable disease into the United States. Subpart F – Importations - contains provisions for importation of etiologic agents, hosts, and vectors (42 CFR Part 71.54), requiring persons that import or distribute after importation these materials to obtain a permit issued by CDC.

<sup>15</sup> Including guidelines.

<sup>16</sup> Micro-organisms pathogenic to man, animals and plants in accordance with the Convention.

<sup>17</sup> In accordance with the latest version of the WHO Laboratory Biosafety Manual or equivalent national or international guidance.

<sup>18</sup> In accordance with the latest version of the WHO Laboratory Biosecurity Guidance or equivalent national or international guidance.

The Centers for Disease Control and Prevention (CDC)'s Import Permit Program located within the Division of Select Agents and Toxins (DSAT) amended the regulations regarding the importation of infectious biological agents, infectious substances, and vectors to clarify regulatory definitions, ensure adequate biosafety measures, increase oversight through inspections, address permit exemptions, transportation requirements and to describe an appeal process. The final rule contains provisions that apply to a variety of entities including academic institutions and biomedical centers, commercial manufacturing facilities, federal, state, and local laboratories, including clinical and diagnostic laboratories, and research facilities. (Final Action February 2013)

(d) Biosafety and Biosecurity: **Changes to Regulations**

**New Select Agent Regulations in Full Effect in April 2013** – The U.S. Departments of Health and Human Services (HHS) and Agriculture (USDA) published final rules (42 C.F.R. Part 73, 7 C.F.R. Part 331, and 9 C.F.R. Part 121) in the Federal Register on October 05, 2012. The new regulations were the result of a robust process guided by two Executive Orders (EO 13486 and EO 13546) and involving key stakeholders within and outside the federal government. Updated regulations were published in October 2012, phased in through early 2013, and came into full effect in April 2013. The result of this process was the designation of a subset of the U.S. select agent and toxin list (Tier 1) that identifies those agents and toxins of highest risk to the U.S. public and provides additional security measures to prevent the misuse of these materials. Updates to the Select Agent Regulations were described in detail in BWC/MSP/2013/MX/WP.4.

(d) Biosafety and Biosecurity: **Other measures**

**FBI Biosecurity Outreach**

During 2013, the FBI conducted ten biosecurity outreach events to research institutions across the United States. These outreach events provided an environment where law enforcement and the academic science communities (research students, professors/researchers, biosafety officers, etc.) could engage in mutually beneficial dialogue. During these events, the FBI aimed to: 1) improve situational awareness of biosecurity threats, and 2) foster a mechanism for academia to report suspicious activities. The FBI works to enhance the science community's awareness of threats and vulnerabilities, both internal and external, as scientists can be exploited because of their expertise, access to biological material/technologies, and dual-use potentials. Additionally, the FBI educates the science community of the FBI's roles and responsibilities in the biosecurity arena and provides resources that can be used to mitigate suspicious activities observed, such as contacting their local FBI WMD Coordinator, the point of contact in every FBI Field Office across the U.S. The WMD Coordinator can in turn offer expertise and resources from Federal, State, and local agencies for mitigation. Law enforcement and science collaboration also fosters better understanding of what type of biosecurity policies are needed to suit both FBI and science research needs. This understanding allows the FBI to advise policymakers on policy that improves security without impeding research.

During 2013, the FBI conducted one biosecurity outreach event with the amateur biology community in the United States. Amateur biology groups believe that opportunities to develop advances in science and biotechnology, just like the early computer revolution, should be made available outside of traditional academic and industrial settings, e.g., community laboratories. The FBI has developed partnerships with the amateur biology community in order to garner their assistance in preventing, detecting, and responding to incidents of misuse, particularly for nefarious purposes. FBI efforts focus primarily on outreach and awareness of potential threats. This outreach includes attendance at amateur biology conferences and regional meetings, FBI-sponsored national workshops, assistance in the development of a safety and security framework, and dissemination of education materials. By hosting an outreach workshop, the FBI continued to foster the development of a culture of responsibility and to open lines of communication between members of the amateur biology community and their local FBI WMD Coordinators to facilitate the reporting of suspicious activity.

During 2013, the FBI conducted four Joint Criminal and Epidemiological Investigations training courses across the United States. These 2-day courses focused on improving local response plans and information-sharing protocols, educating participants on the benefits of the joint investigation and interview models and fostering relationships between the law enforcement and public health communities to rapidly assess whether the origin of an unusual outbreak was natural or intentional. Through this effort, law enforcement and public health officials gain familiarity with criminal and epidemiological investigations and learn how each agency can support the other through the sharing of information, expertise and resources. The training initiative also encourages participants to develop a Memorandum of Understanding to codify joint response plans and information sharing protocols. The FBI and CDC also released an updated edition of the FBI/CDC Criminal and Epidemiological Joint Investigation Handbook in 2011. This handbook serves as a joint investigation reference for personnel with potential involvement in a bioterrorism investigation.

(d) Biosafety and Biosecurity: **Other measures**

**Publication of A Framework for Guiding U.S. Department of Health and Human Services Funding Decisions about Research Proposals with the Potential for Generating Highly Pathogenic Avian Influenza H5N1 Viruses that are Transmissible among Mammals by Respiratory Droplets** – The full text of the Framework is available at <http://phe.gov/s3/dualuse/documents/funding-hpai-h5n1.pdf>.

**Form F**

**BWC - Confidence Building Measure**

**Declaration of Past Activities in Offensive and/or Defensive  
Biological Research and Development Programmes**

United States of America

April 15, 2014

**Declaration of Past Activities in Offensive and/or Defensive Biological Research and Development Programmes**

- 1. Date of entry into force of the Convention for the State party.**

26 March 1975

- 2. Past offensive biological research and development programmes:**

Nothing new to declare

**Form G**

**BWC - Confidence Building Measure**

**Declaration of Vaccine Production Facilities**

United States of America

April 15, 2014

**Declaration of vaccine production facilities**

The U.S. Food and Drug Administration publishes a current list of human vaccines licensed in the United States, including associated production facilities. This list is available at:

<http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm>.

Data provided on CBM Form G are excerpted from the publicly available website listed above (as accessed on January 31, 2014). Trade names are included when provided by the manufacturer. Specific and current information about a vaccine, and contact information for the manufacturer, are available by following the hyperlinks provided on the above website.

**1. Name of facility**

Barr Laboratories, Inc.

**2. Location (Mailing Address)**

1235 Mays Mill Road, Forrest, VA 24551

**3. General description of the types of diseases covered:**

Acute respiratory disease caused by Adenovirus Type 4 and Type 7 Vaccine, Live, Oral

Vaccines: Adenovirus Type 4 and Type 7 Vaccine, Live, Oral

**1. Name of facility**

Emergent BioDefense Operations Lansing, Inc.

**2. Location (Mailing Address)**

3500 N. Martin Luther King Jr. Boulevard, Lansing, Michigan 48906

**3. General description of the types of diseases covered:**

Anthrax disease caused by *Bacillus anthracis*

Vaccines: Anthrax Vaccine Adsorbed - [BioThrax]

**1. Name of facility**

MassBiologics

**2. Location (Mailing Address)**

University of Massachusetts Medical School, Boston, Massachusetts 02130

**3. General description of the types of diseases covered:**

Diphtheria and tetanus caused by *Corynebacterium diphtheriae* and *Clostridium tetani*.

Vaccines: Tetanus and Diphtheria Toxoids Adsorbed

**Declaration of vaccine production facilities****1. Name of facility**

MedImmune, LLC

**2. Location (Mailing Address)**

One MedImmune Way, Gaithersburg, Maryland 20878

**3. General description of the types of diseases covered:**

Influenza disease caused by influenza virus subtypes A and B.

**Vaccines:**

Influenza Vaccine Live, Intranasal - [FluMist]

Influenza Vaccine Live, Intranasal (FluMist Quadravalent)

**1. Name of facility**

Merck Sharp &amp; Dohme Corp.

**2. Location (Mailing Address)**

PO Box 1000, UG2D-68, West Point, Pennsylvania 19486-0004

**3. General description of the types of diseases covered:**

Invasive disease caused by *Haemophilus influenzae* type b; infection caused by all known subtypes of hepatitis B virus; Hepatitis A disease; cervical, vulvar and vaginal cancer and certain other diseases caused by Human Papillomavirus (HPV) Types 6, 11, 16, and 18; Measles (rubeola); Mumps; diseases caused by *Streptococcus pneumoniae*; Rotavirus disease; Rubella (German measles) disease; Varicella disease caused by the varicella-zoster virus (VZV); Herpes zoster (shingles) disease.

**Vaccines:**

Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate) - [PedvaxHIB]

Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate) &amp; Hepatitis B (Recombinant) Vaccine - [COMVAX]

Hepatitis A Vaccine, Inactivated - [VAQTA]

Hepatitis B Vaccine (Recombinant) - [Recombivax HB]

Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Vaccine, Recombinant - [Gardasil]

Measles, Mumps, and Rubella Virus Vaccine, Live - [M-M-R II]

Measles, Mumps, Rubella and Varicella Virus Vaccine Live - [ProQuad]

Pneumococcal Vaccine, Polyvalent - [Pneumovax 23]

Rotavirus Vaccine, Live, Oral, Pentavalent - [RotaTeq]

Varicella Virus Vaccine Live - [Varivax]

Zoster Vaccine, Live, (Oka/Merck) - [Zostavax]

**Declaration of vaccine production facilities**

**1. Name of facility**

Organon Teknika Corporation, LLC

**2. Location (Mailing Address)**

100 Rodolphe Street, Building 1300, Durham, North Carolina 27712

**3. General description of the types of diseases covered:**

For the prevention of tuberculosis

Vaccines: BCG Live (BCG Vaccine

**1. Name of facility**

Protein Sciences Corporation

**2. Location (Mailing Address)**

1000 Research Parkway, Meriden, Connecticut 06450-7159

**3. General description of the types of diseases covered:**

For active immunization against disease caused by influenza virus subtypes A and B

Vaccines: Influenza vaccine for subtypes A and B, (Flublok)

**1. Name of facility**

Sanofi Pasteur Biologics Co.

**2. Location (Mailing Address)**

38 Sidney Street, Cambridge, Massachusetts 02139

**3. General description of the types of diseases covered:** Smallpox disease

Vaccines: Smallpox (Vaccinia) Vaccine, Live - [ACAM2000]

**Declaration of vaccine production facilities****1. Name of facility**

Sanofi Pasteur, Inc

**2. Location (Mailing Address)**

Discovery Drive, Swiftwater, Pennsylvania 18370

**3. General description of the types of diseases covered:**

Diphtheria caused by *Corynebacterium diphtheria*; tetanus caused by *Clostridium tetani*; pertussis (whooping cough) caused by *Bordetella pertussis*; influenza disease caused by pandemic (H1N1) 2009 virus; influenza disease caused by H5N1 subtype; influenza disease caused by influenza virus subtypes A and B; invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y and W-135; meningitis and meningococcemia caused by *N. meningitidis*; and Yellow fever acute viral illness caused by a mosquito-borne flavivirus.

**Vaccines:**

Diphtheria & Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed - [Tripedia; Daptacel]

Diphtheria and Tetanus Toxoids Adsorbed USP (For Pediatric Use) (DT)

Influenza Virus Vaccine (Fluzone, Fluzone High-Dose, Fluzone Intradermal and Fluzone Quadrivalent)

Influenza Virus Vaccine, H5N1

Meningococcal Polysaccharide (Serogroups A, C, Y and W-135) Diphtheria Toxoid Conjugate Vaccine [Menactra]

Meningococcal Polysaccharide Vaccine, Groups A, C, Y and W-135 Combined - [Menomune®-A/C/Y/W-135]

Tetanus and Diphtheria Toxoids Adsorbed for Adult Use - [DECAVAC]

Tetanus Toxoid Adsorbed

Tetanus Toxoid for Booster Use Only

Yellow Fever Vaccine - [YF-VAX®]

**1. Name of facility**

Wyeth Pharmaceuticals, Inc

**2. Location (Mailing Address)**

Pfizer, Inc., 401 N. Middletown Road, Pearl River, NY 10965

**3. General description of the types of diseases covered:**

Invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F and otitis media caused by *Streptococcus pneumoniae* serotypes 4, 6B, 9V, 14, 18C, 19F and 23F.

**Vaccines:**

Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein) - [Prevnam 13]

Pneumococcal 7-valent Conjugate Vaccine (Diphtheria CRM197 Protein)

**Biological Select Agents and Toxins**

Biological Select Agents and Toxins are biological pathogens and toxins that the United States has determined have the potential to pose a severe threat to public health and safety, animal and plant health, or animal and plant products. The possession, use, and transfer of these agents is regulated by the U.S. Department of Health and Human Services (HHS) Centers for Disease Control and Prevention and the U.S. Department of Agriculture Animal and Plant Health Inspection Service under the Select Agent Regulations found in Part 73 of Title 42 of the Code of Federal Regulations, Part 331 of Title 7 of the Code of Federal Regulations, and Part 121 of Title 9 of the Code of Federal Regulations. Information on Biological Select Agents and Toxins can be found on the National Select Agent Registry website: <http://www.selectagents.gov>.

**HHS Select Agents and Toxins**

Abrin  
Botulinum neurotoxins  
Botulinum neurotoxin-producing species of *Clostridium*  
Cercopithecine herpesvirus 1 (Herpes B virus)  
*Clostridium perfringens* epsilon toxin  
*Coccidioides posadasii/Coccidioides immitis*  
Conotoxins  
*Coxiella burnetii*  
Crimean-Congo haemorrhagic fever virus  
Diacetoxyscirpenol  
Eastern Equine Encephalitis virus  
Ebola virus  
*Francisella tularensis*  
Lassa fever virus  
Marburg virus  
Monkeypox virus  
Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)  
Ricin  
*Rickettsia prowazekii*  
*Rickettsia rickettsii*  
Saxitoxin  
Shiga-like ribosome inactivating proteins  
Shigatoxin  
South American Haemorrhagic Fever viruses: Flexal, Machupo, Guanarito, Sabia, Junin  
Staphylococcal enterotoxins  
T-2 toxin  
Tetrodotoxin  
Tick-borne encephalitis complex (flavi) viruses: Central European Tick-borne encephalitis, Far Eastern Tick-borne encephalitis, Kyasanur Forest disease, Omsk Hemorrhagic Fever, Russian Spring and Summer encephalitis  
Variola major virus (Smallpox virus)  
Variola minor virus (Alastrim)  
*Yersinia pestis*

**OVERLAP Select Agents and Toxins**

*Bacillus anthracis*

*Brucella abortus*

*Brucella melitensis*

*Brucella suis*

*Burkholderia mallei* (formerly *Pseudomonas mallei*)

*Burkholderia pseudomallei* (formerly *Pseudomonas pseudomallei*)

Hendra virus

Nipah virus

Rift Valley fever virus

Venezuelan Equine Encephalitis virus

**USDA Select Agents and Toxins**

African horse sickness virus

African swine fever virus

Akabane virus

Avian influenza virus (highly pathogenic)

Bluetongue virus (exotic)

Bovine spongiform encephalopathy agent

Camel pox virus

Classical swine fever virus

*Ehrlichia ruminantium* (Heartwater)

Foot-and-mouth disease virus

Goat pox virus

Japanese encephalitis virus

Lumpy skin disease virus

Malignant catarrhal fever virus (Alcelaphine herpesvirus type 1)

Menangle virus

*Mycoplasma capricolum* subspecies *capripneumoniae* (contagious caprine pleuropneumonia)

*Mycoplasma mycoides* subspecies *mycoides* small colony (*Mmm* SC) (contagious bovine pleuropneumonia)

Peste des petits ruminants virus

Rinderpest virus

Sheep pox virus

Swine vesicular disease virus

Vesicular stomatitis virus (exotic): Indiana subtypes VSV-IN2, VSV-IN3

Virulent Newcastle disease virus 1

**USDA PLANT PROTECTION AND QUARANTINE (PPQ) Select Agents and Toxins**

*Peronosclerospora philippinensis* (*Peronosclerospora sacchari*)

*Phoma glycinicola* (formerly *Pyrenochaeta glycines*)

*Ralstonia solanacearum* race 3, biovar 2

*Rathayibacter toxicus*

*Sclerophthora rayssiae* var *zeae*

*Synchytrium endobioticum*

*Xanthomonas oryzae*

*Xylella fastidiosa* (citrus variegated chlorosis strain)

## **Appendix A**

### **NIAID Category A, B, and C Priority Pathogens**

The National Institute of Allergy and Infectious Disease (NIAID) categorization of pathogens identifies specific pathogens as priorities for additional research efforts as part of the NIAID biodefense research agenda.

Additional information on NIAID Category A, B, and C Priority Pathogens is available at:

<http://www.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/research/Pages/CatA.aspx>

<http://www.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/Documents/categorybandc.pdf>

Category A pathogens are those organisms/biological agents that pose the highest risk to national security and public health because they

- Can be easily disseminated or transmitted from person to person
- Result in high mortality rates and have the potential for major public health impact
- Might cause public panic and social disruption
- Require special action for public health preparedness

### **Category A Priority Pathogens**

*Bacillus anthracis* (anthrax)

*Clostridium botulinum* toxin (botulism)

*Yersinia pestis* (plague)

Variola major (smallpox) and other related pox viruses

*Francisella tularensis* (tularemia)

Viral hemorrhagic fevers

Arenaviruses (LCMV, Junin virus, Machupo virus, Guanarito virus, Lassa virus)

Bunyaviruses (Hantaviruses, Rift Valley Fever virus)

Flaviruses (Dengue virus)

Filoviruses (Ebola, Marburg viruses)

Category B pathogens are the second highest priority organisms/biological agents. They

- Are moderately easy to disseminate
- Result in moderate morbidity rates and low mortality rates
- Require specific enhancements for diagnostic capacity and enhanced disease surveillance

### **Category B Priority Pathogens**

*Burkholderia pseudomallei*

*Coxiella burnetii* (Q fever)

*Brucella* species (brucellosis)

*Burkholderia mallei* (glanders)

*Chlamydia psittaci* (Psittacosis)

Ricin toxin (from *Ricinus communis*)

Epsilon toxin of *Clostridium perfringens*

Staphylococcus enterotoxin B

Typhus fever (*Rickettsia prowazekii*)

Food- and Waterborne Pathogens

- Bacteria: Diarrheagenic *E.coli*, Pathogenic *Vibrio*, *Shigella* species, *Salmonella*, *Listeria monocytogenes*, *Campylobacter jejuni*, *Yersinia enterocolitica*
- Viruses: Caliciviruses, Hepatitis A virus

- Protozoa: *Cryptosporidium parvum*, *Cyclospora cayatanensis*, *Giardia lamblia*, *Entamoeba histolytica*, Toxoplasma
- Fungi: Microsporidia

Additional viral encephalitides: West Nile Virus, LaCrosse virus, California encephalitis virus, Venezuelan equine encephalitis virus, Eastern equine encephalitis virus, Western equine encephalitis virus, Japanese Encephalitis Virus, Kyasanur Forest Virus

Category C pathogens are the third highest priority and include emerging pathogens that could be engineered for mass dissemination in the future because of

- Availability
- Ease of production and dissemination
- Potential for high morbidity and mortality rates and major health impact

### **Category C Priority Pathogens**

Emerging infectious disease threats such as Nipah virus and additional hantaviruses

Tickborne hemorrhagic fever viruses (Crimean-Congo Hemorrhagic fever virus)

Tickborne encephalitis viruses

Yellow fever

Tuberculosis, including drug-resistant TB

Influenza

Other Rickettsias

Rabies

Prions

Chikungunya virus

Severe acute respiratory syndrome associated coronavirus (SARS-CoV)

*Coccidioides immitis*

*Coccidioides posadasii*

Antimicrobial resistance, excluding research on sexually transmitted organisms<sup>19</sup>

- Research on mechanisms of antimicrobial resistance
- Studies of the emergence and/or spread of antimicrobial resistance genes within pathogen populations
- Studies of the emergence and/or spread of antimicrobial-resistant pathogens in human populations
- Research on therapeutic approaches that target resistance mechanisms
- Modification of existing antimicrobials to overcome emergent resistance

Antimicrobial research, as related to engineered threats and naturally occurring drug-resistant pathogens, focused on development of broad-spectrum antimicrobials

Innate immunity, defined as the study of nonadaptive immune mechanisms that recognize, and respond to, microorganisms, microbial products, and antigens

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<sup>19</sup> NIAID Category C Antimicrobial Resistance—Sexually Transmitted Excluded Organisms: Bacterial vaginosis, Chlamydia trachomatis, Cytomegalovirus, Granuloma inguinale, Hemophilus ducreyi, Hepatitis B virus, Hepatitis C virus, Herpes Simplex virus, Human immunodeficiency virus, Human papillomavirus, Neisseria gonorrhea, Treponema pallidum, Trichomonas vaginalis

**Appendix B****Compiled list of biological agents and toxins used for biodefense research**

<b>MICROORGANISM</b>	<b>CATEGORY</b>
Abrin	HHS Select Toxin
African horse sickness virus	USDA Select Agent
African swine fever virus	USDA Select Agent
Alpha conotoxins	HHS Select Toxin
Avian influenza virus	USDA Select Agent
<i>Bacillus anthracis</i>	Overlap Select Agent/NIAID Category A
<i>Bacillus anthracis</i> Pasteur strain	Overlap Select Agent
Botulinum neurotoxins	HHS Select Toxin
<i>Brucella abortus</i>	Overlap Select Agent
<i>Brucella melitensis</i>	Overlap Select Agent
<i>Brucella suis</i>	Overlap Select Agent
<i>Burkholderia mallei</i>	Overlap Select Agent
<i>Burkholderia mallei</i> (killed)	Simulant
<i>Burkholderia pseudomallei</i>	Overlap Select Agent
Chapare virus	HHS Select Agent
Classical swine fever virus	USDA Select Agent
<i>Clostridium</i> species producing botulinum neurotoxin	HHS Select Agent/NIAID Category A
<i>Coxiella burnetti</i>	HHS Select Agent
<i>Coxiella burnetti</i> (killed)	Simulant
Crimean-Congo hemorrhagic fever virus	HHS Select Agent
Dengue virus	NIAID Category A
Diacetoxyscirpenol	HHS Select Toxin
Eastern equine encephalitis virus	HHS Select Agent
Ebola virus	HHS Select Agent/NIAID Category A
Escherichia coli O157:H7 (killed)	Simulant
Foot-and-mouth disease virus	USDA Select Agent
<i>Francisella philomiragia</i>	Simulant
<i>Francisella tularensis</i>	HHS Select Agent/NIAID Category A
<i>Francisella tularensis</i> (killed)	Simulant
Goatpox virus	USDA Select Agent
Guanarito virus	HHS Select Agent/NIAID Category A
Hantaviruses	NIAID Category A
Hendra virus	Overlap Select Agent
Influenza A virus, reconstructed replication-competent pandemic 1918 strains	HHS Select Agent
Junin virus	HHS Select Agent/NIAID Category A
Kyasanur Forest Disease virus	HHS Select Agent
Lassa virus	HHS Select Agent/NIAID Category A
Lujo virus	HHS Select Agent
Lumpy skin disease virus	USDA Select Agent
Lymphocytic choriomeningitis virus	NIAID Category A
Machupo virus	HHS Select Agent/NIAID Category A
Marburg virus	HHS Select Agent/NIAID Category A
Monkeypox virus	HHS Select Agent
<i>Mycoplasma mycoides</i>	USDA Select Agent
Newcastle disease virus	USDA Select Agent
Nipah virus	Overlap Select Agent
Omsk hemorrhagic fever virus	HHS Select Agent

<i>Peronosclerospora philippinensis</i>	PPQ Select Agent
Peste-des-petits-ruminants virus	USDA Select Agent
<i>Phoma glycinicola</i>	PPQ Select Agent
<i>Rathayibacter toxicus</i>	PPQ Select Agent
Ricin	HHS Select Toxin
<i>Rickettsia prowazekii</i>	HHS Select Agent
Rift Valley fever virus	Overlap Select Agent/NIAID Category A
Sabia virus	HHS Select Agent
<i>Salmonella typhimurium</i> (killed)	Simulant
Saxitoxin	HHS Select Toxin
Severe acute respiratory syndrome-related coronavirus	HHS Select Agent
Sheep pox virus	USDA Select Agent
<i>Shigella dysenteriae</i> (killed)	Simulant
Staphylococcal enterotoxins A, B, C, D, E subtypes	HHS Select Toxin
Swine vesicular disease virus	USDA Select Agent
T-2 toxin	HHS Select Toxin
Tetrodotoxin	HHS Select Toxin
Tick-borne encephalitis complex flavivirus, Far Eastern subtype	HHS Select Agent
Tick-borne encephalitis complex flavivirus, Siberian subtype	HHS Select Agent
Venezuelan equine encephalitis virus	Overlap Select Agent
<i>Vibrio cholerae</i> (killed)	Simulant
<i>Yersinia pestis</i>	HHS Select Agent/NIAID Category A
<i>Yersinia pestis</i> (killed)	Simulant