United States of America

Confidence Building Measure Return covering 2014

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, 2015
Declaration form on Nothing to Declare or Nothing New to Declare for use in the information exchange

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Date: April 15, 2015

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:

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Form A, Part 1

BWC - Confidence Building Measure

Exchange of data on research centres and laboratories

United States of America

April 15, 2015
Exchange of data on research centres and laboratories

1. Name(s) of facility
   National Biodefense Analysis and Countermeasures Center (NBACC)
   [Declared in accordance with Form A, Part 2 (iii)]

2. Responsible public or private organization or company
   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
   U.S. Department of Homeland Security (DHS)
   U.S. Department of Defense (DOD) - partly
   U.S. Department of Justice (DOJ)

5. Number of maximum containment units within the research centre and/or laboratory, with an indication of their respective size (m²)
   BSL 4 Laboratory = 980 m²

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.
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 21702-5011

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 Defense (DoD) – partly
   Department of Homeland Security (DHS)
   Department of Health and Human Services (DHHS)
   Department of Agriculture (USDA)
   Universities
   Private sector companies

5. Number of maximum containment units within the research centre and/or laboratory, with an indication of their respective size (m²)
   BSL-4 Laboratory = 1186 m²

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

1. Name(s) of facility
   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 (CDC), 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)
   U.S. Agency For International Development (USAID)
   Department of State (DOS)
   Department of Defense (DOD) – partly

5. Number of maximum containment units within the research centre and/or laboratory, with an indication of their respective size (m$^2$)
   BSL-4 Laboratory = 136 m$^2$
   BSL-4 Laboratory = 271 m$^2$
   BSL-4 Laboratory = 136 m$^2$

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. (The select agent list is available at http://www.selectagents.gov/SelectAgentsandToxinsList.html.)
Exchange of data on research centres and laboratories

1. Name(s) of facility
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 within the research centre and/or laboratory, with an indication of their respective size (m²)
BSL 4 Laboratory = 1305 m²

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 newly emerging infectious disease microbes. Additional information can be found at:
http://www.niaid.nih.gov/about/organization/dir/irf/Pages/default.aspx.
Exchange of data on research centres and laboratories

1. **Name(s) of facility**
   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 within the research centre and/or laboratory, with an indication of their respective size (m\(^2\))**
   BSL-4 Laboratory = 1145 m\(^2\)

6. **Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate.**
   The Integrated Research Facility at Rocky Mountain Laboratories (RML) 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 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

1. Name(s) of facility
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)
Department of Health and Human Services (HHS)

5. Number of maximum containment units within the research centre and/or laboratory, with an indication of their respective size (m$^2$)
BSL-4 Laboratory = 186 m$^2$ (Shope Laboratory)
BSL-4 Laboratory = 1022 m$^2$ (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/](http://www.utmb.edu/gnl/).
Exchange of data on research centres and laboratories

1. Name(s) of facility
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
Department of Health and Human Services
Department of Defense (DOD) - partly
Department of Homeland Security (DHS)
Private Sector Companies
Private Donors

5. Number of maximum containment units within the research centre and/or laboratory, with an indication of their respective size (m$^2$)
BSL 4 Laboratory = 114 m$^2$

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/about/extraordinary-resources/biosafety-level-4-laboratory.
Exchange of data on research centres and laboratories

1. **Name(s) of facility**
   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**
   Department of Health and Human Services
   Georgia Research Alliance
   Immunology Core Support
   Elizabeth R. Griffin Research Foundation

5. **Number of maximum containment units within the research centre and/or laboratory, with an indication of their respective size (m²)**
   BSL 4 Laboratory = 60 m²

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](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, 2015
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.
National biological defence research and development programmes - Description

United States of America

April 15, 2015
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:

- 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, toxicology, physical protection, decontamination and other related research.

   The Department of Defense Chemical and Biological Defense Program develops capabilities to enable the U.S. Armed Forces to deter, prevent, protect from, mitigate, respond to, and recover from the effects of chemical, biological, and radiological (CBR-) threats, as well as emerging infectious diseases, as part of a layered, integrated defense. The Program is an integral contributor to a global and systems approach for Countering Weapons of Mass Destruction (CWMD), Global Health Security, and other pertinent mission areas.

   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; capabilities for pre- and post-exposure therapeutics for biological select agents and novel threats; testing battlefield detection and identification methods, protective systems, and decontamination systems; the development of rapid and deployable detection assays for force 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.
   $655,211,000 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?
   57%

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 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).

This chart reflects funding relationships. Organizational relationships may differ.

```
Department of Defense

OSD(AT&L)
  DTRA
    Joint Science and Technology Office
    Universities and Contractors

Secretary of the Army
(Executive Agent)
  DARPA
    Universities and Contractors
    Program Analysis and Integration Office

Military Services
  Chem Bio Defense Program Test and Evaluation
    Joint Program Executive Office, Chemical and Biological Defense
    Universities and Contractors

Joint Staff
  Joint Requirements Office CBRN Defense

In the 2014 U.S. CBM return, the Department of Defense reported one additional lab, Air Force Research Laboratory (AFRL), Molecular Signatures (RHXBC). This lab did not conduct biodefense research in 2014.
```

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.

In accordance with Form A part 2 (iii):
- 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 (USAMRDEC)
- U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)
- U.S. Army Edgewood Chemical and Biological Center

In the 2014 U.S. CBM return, the Department of Defense reported one additional lab, Air Force Research Laboratory (AFRL), Molecular Signatures (RHXBC). This lab did not conduct biodefense research in 2014.
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 characterization and containment of contamination, and in the remediation of sites following terrorist attacks.

2. State the total funding for the programme and its source.
$8,000,000     U.S. 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 each programme is expended in these contracted or other facilities?
   37 %

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

To address capabilities related to EPA’s indoor/outdoor remediation mission, NHSRC, through intramural and extramural avenues, conducts research related to characterization methods, risk assessment, decontamination methods, and waste management. Specifically the program develops and evaluates 1) sampling and analytical methods for environmental matrices, 2) decontamination methods for complex environments, and 3) treatment methods for solid and liquid waste. Supporting such capabilities, NHSRC has been addressing the fate and transport of biological agents and developing exposure assessment information and methods to support risk assessment decisions.
6. Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in this programme.)

```
Environmental Protection Agency
     /           \
  Office of Research & Development
     /           \
National Homeland Security Research Center
     /           \
Decontamination & Consequence Management Division
     /           \
Threat & Consequence Assessment Division
     /           \
Water Infrastructure Protection Division
```

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.

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.
$66,377,065  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?
20%

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 Integrated Research Facility-Frederick, including refinement of animal models to facilitate countermeasure development, with direction from 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 (NCEH), 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?

Not applicable

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

Not applicable

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, toxicology, 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. OID includes the National Center for Emerging Zoonotic Infectious Diseases (NCEZID) and the National Center for Immunization and Respiratory Diseases (NCIRD). The select agents list is available at: http://www.selectagents.gov/SelectAgentsandToxinsList.html

2. State the total funding for each programme and its source.
$28,291,434 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, CO
- 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 diseases of plants and animals 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 wheat rust, Foot-and-Mouth Disease, Avian Influenza, Rift Valley Fever, Classical Swine Fever, African Swine Fever, Exotic Newcastle disease, Vesicular stomatitis, and Exotic Bluetongue.

Plant and Animal health officials define an exotic or foreign plant or animal disease as important infectious diseases of crops, livestock or poultry believed to be absent from the U.S. and its territories that has a potential significant health or economic impact. In addition, 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 crops or animals, resulting in loss of foods, 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 prevention, control, management, and recovery from foreign disease outbreaks. These factors include free trade agreements, free trade blocks, regionalization, increased international passenger travel, intensification of plant and 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 plant and animal diseases are inadequate or not currently available. Our understanding of pathogenesis, transmission, and host responses is insufficient to rapidly control and eradicate disease outbreaks resulting from foreign plant and animal diseases incursions. Effective countermeasures to prevent, control and eradicate foreign plant and 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 program providing alternatives to animal drugs
- 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
Determine basic knowledge of the biology, pathology, and epidemiology of selected Oomycete pathogens as the basis for development of improved control/management strategies

**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 in host range 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 and cost of recovery from disease outbreaks (DIVA compatible) 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 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
- Indepth knowledge of pathogen biology, taxonomy, genetics, ecology, and pathology of emerging Oomycete pathogens that can be used to develop novel and effective exclusion, control and management strategies

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.**
   $16,700,000  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.

In accordance with Form A part 2 (iii):
- 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.

   Preventing terrorism and enhancing security, including protection against biological terrorism, is one of the five key Department of Homeland Security (DHS) mission areas. This includes efforts to: prevent terrorist attacks, including biological attacks; prevent the unauthorized acquisition, importation, movement, or use of, inter alia, biological materials and capabilities within the United States; and reduce the vulnerability of critical infrastructure to terrorist attacks and other hazards. These efforts are further guided by the Homeland Security Presidential Directive – 10, “Biodefense for the 21st Century,” which outlines the four guiding pillars of the DHS Biodefense program: Threat Awareness, Prevention and Protection, Surveillance and Detection, and Response and Recovery.

   The goal of the DHS biodefense program is to leverage emerging technologies to protect against biological attacks targeting the U.S. population, agriculture, or infrastructure. The DHS biodefense program focuses on scenario modeling, agent release detection, training in responding to biological events, 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 2014 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 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.
   $91,007,895 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.
   Identical to answer provided in question 1.
6. Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in this programme).

![Organizational Structure Diagram](image)

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. In accordance with Form A Part 2(iii):
   - 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, 2015
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.9), “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.
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 (m²):
BSL-2: 1,282 m²
BSL-3: 2,564 m²
BSL-4: 980 m²
Total laboratory floor area: 4,826 m²

4. The organizational structure of each facility:
   (i) Total number of personnel: 170
   (ii) Division of personnel:
       Military 0
       Civilian 170
   (iii) Division of personnel by category:
       Scientists 32
       Engineers 38
       Technicians 58
       Administrative and support staff 42
   (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:
       Number: 170
   (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 Defense (DoD) – partly
       U.S. Department of Justice (DoJ)
   (vii) What are the funding levels for the following program areas:
       Research $4,261,917
       Development $9,622,356
       Test and evaluation $0
       Total $13,884,273
(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 (FFRDC) 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 Export Administration Regulations (EAR), International Traffic in Arms Regulations (ITAR), the Biological Weapons Convention (BWC), 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):**


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 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 (HHS, Overlap), NIAID Category A pathogens, Simulants

**Outdoor Studies:** No outdoor studies performed
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 (m$^2$):  
- BSL-2: 292 m$^2$
- BSL-3: 18,046 m$^2$
- BSL-4: 0 m$^2$
Total laboratory floor area: 18,338 m$^2$

4. The organizational structure of each facility:  
   (i) Total number of personnel: 412
   
   (ii) Division of personnel:  
         Military 0  
         Civilian 412
   
   (iii) Division of personnel by category:  
         Scientists 103  
         Engineers 5  
         Technicians 26  
         Administrative and support staff 278
   
   (iv) List the scientific disciplines represented in the scientific/engineering staff:  
        Biological Science, Chemistry, 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: 279
   
   (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)  
        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 $4,953,257  
        Total $23,453,257
   
   (viii) Briefly describe the publication policy of the facility:  
        DHS scientific research staffs are expected to publish papers in open literature. Papers are peer reviewed and approved by PIADC and 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; and

(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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22. Stenfeldt C, Pacheco JM, Rodriguez LL, Arzt J. Early events in the pathogenesis of foot-and-mouth disease in pigs; identification of oropharyngeal tonsils as sites of primary and
http://dx.plos.org/10.1371/journal.pone.0106859
http://dx.doi.org/10.1016/j.virol.2013.10.025

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: 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: USDA Select Agents
Outdoor Studies: No outdoor studies performed
1. What is the name of the facility?
Lothar Salomon Test Facility (LSTF)

2. Where is it located (provide both address and geographical location)?
2029 Burns Road, TEDT-DPW-LS MS#6, Dugway, Utah 84022

3. Floor area of laboratory areas by containment level (m²):
   - BSL-2: 710 m²
   - BSL-3: 336 m²
   - BSL-4: 0 m²
   Total laboratory floor area: 1,046 m²

4. The organizational structure of each facility:
   (i) Total number of personnel: 47
   (ii) Division of personnel:
        Military: 0
        Civilian: 47
   (iii) Division of personnel by category:
        Scientists: 35
        Engineers: 2
        Technicians: 8
        Administrative and support staff: 2
   (iv) List the scientific disciplines represented in the scientific/engineering staff:
        Aerobiology, Bacteriology, Biochemistry, Engineering, Immunology, Microbiology, Molecular Biology, Toxicology, Virology
   (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?
        Department of Defense (DoD) – partly
        Department of Homeland Security (DHS)
        Department of Justice (DoJ)
   (vii) What are the funding levels for the following program areas:
        Research: $ 0
        Development: $ 0
        Test and evaluation: $ 3,450,000
        Total: $ 3,450,000
   (viii) Briefly describe the publication policy of the facility:
Lothar Salomon’s unique facilities and experienced staff of scientists, test officers, engineers, and technicians provide a full range of chemical and biological testing services, including the development of one-of-a-kind test capabilities, to meet customer requirements for new or developmental products. The results from testing are documented in government publications, and their distribution is controlled by the test customer or sponsor. These results are not generally suitable for publication in peer-reviewed journals.

(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. Additional information can be found at: http://www.dugway.army.mil/.

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

Outdoor Studies: Yes - using simulants
National biological defence research and development programmes: Facilities

1. What is the name of the facility?
Naval Medical Research Center (NMRC)

2. Where is it located (provide both address and geographical location)?
8400 Research Plaza, Fort Detrick, Maryland 21702

3. Floor area of laboratory areas by containment level (m²):
   BSL-2: 2,000 m²
   BSL-3: 0 m²
   BSL-4: 0 m²
   Total laboratory floor area: 2,000 m²

4. The organizational structure of each facility:
   (i) Total number of personnel: 61
   (ii) Division of personnel:
       Military 13
       Civilian 48
   (iii) Division of personnel by category:
       Scientists 19
       Engineers 0
       Technicians 35
       Administrative and support staff 7
   (iv) List the scientific disciplines represented in the scientific/engineering staff:
       Biochemistry, Computational Biology, Immunology, Microbiology, Molecular Biology
   (v) Are contractor staff working in the facility? If so, provide an approximate number:
       Yes Number: 43
   (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 – wholly
   (vii) What are the funding levels for the following program areas:
       Research $ 4,725,008
       Development $ 0
       Test and evaluation $ 0
       Total $ 4,725,008
   (viii) Briefly describe the publication policy of the facility:
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.):


http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4239345/

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4263729/

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 forces. During 2014, we continued studying clinical cases of sepsis in austere environments with the ultimate goal of understanding host-pathogen interactions, development of new diagnostic assays and better treatment strategies against relevant infectious diseases. Additional information is available at http://www.med.navy.mil/sites/nmrc/Pages/bd_main.htm.

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 (m²):
   - BSL-2: 1,186 m²
   - BSL-3: 0 m²
   - BSL-4: 0 m²
   Total laboratory floor area: 1,186 m²

4. The organizational structure of each facility:
   (i) Total number of personnel: 36
   (ii) Division of personnel:
        Military 1
        Civilian 35
   (iii) Division of personnel by category:
        Scientists 29
        Engineers 1
        Technicians 6
        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: 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?
        U.S. Department of Defense (DoD) – partly
        Department of Health and Human Services
   (vii) What are the funding levels for the following program areas:
        Research $6,593,000
        Development $1,519,000
        Test and evaluation $0
        Total $8,112,000
   (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. Release of DoD publications is guided by DoD Directive 5230.09,

(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.):


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. Additional information is available at http://www.nrl.navy.mil/chemistry/research/6106.

**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 (m²):

   - BSL-2: 190 m²
   - BSL-3: 26 m²
   - BSL-4: 0 m²

   Total laboratory floor area: 216 m²

4. The organizational structure of each facility:

   (i) Total number of personnel: 193

   (ii) Division of personnel:

   - Military: 0
   - Civilian: 193

   (iii) Division of personnel by category:

   - Scientists: 67
   - Engineers: 44
   - Technicians: 15
   - Administrative and support staff: 67

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

   - Aerospace Engineering
   - Biology
   - Chemical Engineering
   - Chemistry
   - Computer Engineering
   - Computer Science
   - Electronic Engineering
   - General Engineering
   - Industrial Engineering
   - Mathematics
   - Mechanical Engineering
   - Microbiology
   - Molecular Biology
   - Operations Research Analysis
   - Physical Science
   - Software Engineering
   - Toxicology

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

   - Yes
   - Number: 42

   (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: $1,603,000
   - Development: $7,076,800
   - Test and evaluation: $5,669,500
   - Total: $14,349,300
(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.):**


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. Additional information is available at http://www.navsea.navy.mil/nswc/dahlgren/ET/CBRD/CBRD.aspx.

**Microorganisms and/or Toxins Studied:** Overlap Select Agent, NIAID Category A pathogen, Simulants

**Outdoor Studies:** Performance testing of currently deployed biosurveillance system using a biological simulant.
National biological defence research and development programmes: Facilities

1. What is the name of the facility?
U.S. Army Edgewood Chemical and Biological Center (ECBC)

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 (m²):
   - BSL-2: 532 m²
   - BSL-3: 177 m²
   - BSL-4: 0 m²
   - Total laboratory floor area: 709 m²

4. The organizational structure of each facility:
   (i) Total number of personnel: 252
   (ii) Division of personnel:
       - Military: 0
       - Civilian: 252
   (iii) Division of personnel by category:
       - Scientists: 154
       - Engineers: 38
       - Technicians: 18
       - Administrative and support staff: 42
   (iv) List the scientific disciplines represented in the scientific/engineering staff:
       Aerobiology, Aerospace Engineering, Biochemistry, Biology, Biomedical Engineering, Biotechnology, Chemical Engineering, Chemistry, Computer Engineering, Electronic Engineering, General Engineering, Immunology, Mathematics, Mechanical Engineering, Microbiology, Molecular Biology, Operations Research Analysis, Physical Science, Physics, Physiology, Toxicology, Toxinology, Virology
   (v) Are contractor staff working in the facility? If so, provide an approximate number:
       - Yes
       - Number: 150
   (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: $1,250,000
       - Development: $22,900,000
       - Test and evaluation: $0
       - Total: $24,150,000
   (viii) Briefly describe the publication policy of the facility:
       It is Army policy to encourage scientific and technical personnel to publish research procedures and results in recognized professional journals as well as present their work at national and
international professional meetings. Such publication is an important part of the Army’s research and development program.

Publications are prepared and published in accordance with Army regulations. The regulations governing the publication of research findings include:
AR 70-14 “Publications and Reprints of Articles in Professional Journals.”
AR 70-31 “Standards for Technical Reporting”
AR 360-1 “The Army Public Affairs Program”
AR 530-1 “Operations Security”

(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.):

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. Additional information is available at http://www.ecbc.army.mil/research/index.html.

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

Outdoor Studies: None
1. What is the name of the facility?
U.S. Army Medical Research Institute of Chemical Defense (USAMRICD)

2. Where is it located (provide both address and geographical location)?
3100 Ricketts Point Road, Aberdeen Proving Ground, Maryland 21010

3. Floor area of laboratory areas by containment level (m$^2$):
   - BSL-2: 300 m$^2$
   - BSL-3: 0 m$^2$
   - BSL-4: 0 m$^2$
   - Total laboratory floor area: 300 m$^2$

4. The organizational structure of each facility:
   (i) Total number of personnel: 12
   (ii) Division of personnel:
      - Military: 0
      - Civilian: 12
   (iii) Division of personnel by category:
      - Scientists: 7
      - Engineers: 0
      - Technicians: 5
      - Administrative and support staff: 0
   (iv) List the scientific disciplines represented in the scientific/engineering staff:
      Biochemistry, Biology, Molecular Biology, Pharmacology, Physiology
   (v) Are contractor staff working in the facility? If so, provide an approximate number:
      Yes
      Number: 8
   (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: $2,017,755
      - Development: $0
      - Test and evaluation: $0
      - Total: $2,017,755
   (viii) Briefly describe the publication policy of the facility:
      It is Army policy to encourage scientific and technical personnel to publish research procedures and results in recognized professional journals as well as present their work at national and international professional meetings. Such publication is an important part of the Army’s research and development program.
Publications are prepared and published in accordance with Army regulations. The regulations governing the publication of research findings include:
AR 70-14 “Publications and Reprints of Articles in Professional Journals”
AR 70-31 “Standards for Technical Reporting”
AR 360-1 “The Army Public Affairs Program”
AR 530-1 “Operations Security”
(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.):


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: Discover and develop medical products and knowledge solutions against chemical and toxin threats through research, education and training, and consultation. USAMRICD performs comprehensive, basic scientific research using established and emerging technologies that support the transition of products to advanced development; develops education and training capabilities for military, interagency, domestic, and international personnel in the medical management of chemical casualties; and provides a venue for mutually beneficial collaboration with external investigators and interagency partners to conduct medical chemical defense research against chemical warfare agents and toxins. http://chemdef.apgea.army.mil/
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 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 (m²):
   - BSL-2: 26,026 m²
   - BSL-3: 3,139 m²
   - BSL-4: 1,186 m²
   Total laboratory floor area: 30,351 m²

4. The organizational structure of each facility:
   (i) Total number of personnel: 862
   (ii) Division of personnel:
        - Military: 206
        - Civilian: 656
   (iii) Division of personnel by category:
        - Scientists: 275
        - Engineers: 9
        - Technicians: 335
        - Administrative and support staff: 243
   (iv) List the scientific disciplines represented in the scientific/engineering staff:
        Aerobiology, Biochemistry, Biology, Chemistry, Clinical Immunology, Entomology, Genetics,
        Immunology, Infectious Disease, Internal Medicine, Microbiology, Molecular Biology,
        Preventive Medicine, Toxicology, Veterinary Medicine, Virology
   (v) Are contractor staff working in the facility? If so, provide an approximate number:
        Yes
        Number: 376
   (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
        - U.S. Department of Homeland Security (DHS)
        - U.S. Department of Health and Human Services (DHHS)
        - U.S. Department of Agriculture (USDA)
        - Universities
        - Private sector companies
   (vii) What are the funding levels for the following program areas:
        - Research: $5,688,960
        - Development: $50,227,228*
        - Test and evaluation: $5,899,000
        - Total: $61,815,188
*Includes reimbursables from Cooperative Research and Development Agreements and other Departments

(viii) Briefly describe the publication policy of the facility:
It is Army policy to encourage scientific and technical personnel to publish research procedures and results in recognized professional journals as well as present their work at national and international professional meetings. Such publication is an important part of the Army’s research and development program.

Publications are prepared and published in accordance with Army regulations. The regulations governing the publication of research findings include:
AR 70-14 “Publications and Reprints of Articles in Professional Journals”
AR 70-31 “Standards for Technical Reporting”
AR 360-1 “The Army Public Affairs Program”
AR 530-1 “Operations Security”

(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.):


60. Jelacic TM, Chabot DJ, Bozue JA, Tobery SA, West MW, Moody K, Yang D, Oppenheim JJ, Friedlander AM. Exposure to Bacillus anthracis capsule results in suppression of human


127. Wanja E, Parker ZF, Oduasami O, Rowland T, Davé K, Davé S, Turell MJ. Immuno-chromatographic wicking assay for the rapid detection of dengue viral antigens in mosquitoes
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 and to perform exploratory studies and advanced development of protective and therapeutic countermeasures and agent identification technologies. Additional information is available at [http://www.usamriid.army.mil/](http://www.usamriid.army.mil/).

**Microorganisms and/or Toxins Studied:** Select Agents (HHS, USDA, 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)?
Biology Department, Upton, New York 11973
(Located on William Floyd Parkway, County Road 46, 1.5 miles north of Long Island Expressway Exit 68)

3. Floor area of laboratory areas by containment level (m²):
   BSL-2: 18 m²
   BSL-3: 0 m²
   BSL-4: 0 m²
   Total laboratory floor area: 18 m²

4. The 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
        Administrative 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 (DoD) – partly
        Department of Health and Human Services
   (vii) What are the funding levels for the following program areas:
        Research  $ 1,359,000
        Development $ 0
        Test and evaluation $ 0
        Total $ 1,359,000
   (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-BO/Order-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.):

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 overall objective of the work is to develop countermeasures for biowarfare agents. The specific aims of the projects are to determine the three-dimensional structures of the agents. The purified agents 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. These results can lead to vaccine development, treatment, and/or diagnosis.
Microorganisms and/or Toxins Studied: HHS Select Toxin
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 (m$^2$):
   - BSL-2: 1,604.7 m$^2$
   - BSL-3: 59.5 m$^2$
   - BSL-4: 0 m$^2$
   - Total laboratory floor area: 1,664.2 m$^2$

4. The organizational structure of each facility:
   (i) Total number of personnel: 70

   (ii) Division of personnel:
      - Military: 0
      - Civilian: 70

   (iii) Division of personnel by category:
      - Scientists: 40
      - Engineers: 8
      - Technicians: 11
      - Administrative and support staff: 11

   (iv) List the scientific disciplines represented in the scientific/engineering staff:
      Aerosol Science, Analytical Biochemistry, Analytical Mass Spectrometry, Bacteriology
      Biochemistry, Bioinformatics, Biomedical Engineering, Biotechnology
      Computational Biology, Computer Science, Environmental Science, Epidemiology, Genomics
      Immunology, Mass Spectrometry, Microbial Forensics, Microbiology, Molecular Biology,
      Molecular Diagnostics, Nanotechnology, Proteomics, Toxicology, 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—partially
      Department of Health & Human Services
      Department of Homeland Security
      Department of Homeland Security
      Environmental Protection Agency

   (vii) What are the funding levels for the following program areas:
      - Research: $19,986,000
      - Development: $1,806,000
(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.):


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: 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. Additional information is available at https://missions.llnl.gov/biosecurity.

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, Los Alamos, NM 87545 (Approximately 45 miles west of Santa Fe, New Mexico)

3. Floor area of laboratory areas by containment level (m$^2$):
BSL-2: 320 m$^2$
BSL-3: 0 m$^2$
BSL-4: 0 m$^2$
Total laboratory floor area: 320 m$^2$

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 17
   Engineers 1
   Technicians 15
   Administrative and support staff 8
(iv) List the scientific disciplines represented in the scientific/engineering staff:
   Bacteriology, Biological Science, Chemistry, Cell Biology, Microbiology, Molecular Biology, Bioinformatics, Genomics, Environmental Science, Plant Pathology, Analytical Biochemistry, Molecular Diagnostics, Public Health, Biotechnology, Biochemistry, Genetics, 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 (DoD) – partly
   Department of Health & Human Services
   Department of Homeland Security (DHS)
   Internal (Laboratory Directed Research and Development)
   State of California Department of Public Health
   Other Government Agencies
(vii) What are the funding levels for the following program areas:
   Research $11,667,000
   Development $2,810,000
   Test and evaluation $3,310,000
   Total $17,787,000
(viii) **Briefly describe the publication policy of the facility:**

As a DOE/NNSA 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](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):**


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 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. Additional information is available at http://www.lanl.gov/science-innovation/capabilities/bioscience-biosecurity-health/biosecurity-health/index.php.

Microorganisms and/or Toxins Studied: Select Agents (Overlap + HHS), 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

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 (m²):
Richland campus:
- BSL-2: 750 m²
- BSL-3: 0 m²
- BSL-4: 0 m²
Total laboratory floor area: 750 m²

Sequim campus:
- BSL-2: 130 m²
- BSL-3: 0 m²
- BSL-4: 0 m²
Total laboratory floor area: 130 m²

4. The organizational structure of each facility:
(i) Total number of personnel:
Richland campus: 55
Sequim campus: 4

(ii) Division of personnel:
Military 0
Civilian 59

(iii) Division of personnel by category:
Scientists 55
Engineers 0
Technicians 0
Admin and Support Staff 4

(iv) List the scientific disciplines represented in the scientific/engineering staff:
Analytical Mass Spectrometry, Bacteriology, Biochemistry, Biological Science,
Cell Biology, Chemistry, Computational Biology, Genetics, Genomics, Mass Spectrometry,
Microbial Forensics, Microbiology, Molecular Biology, Nanotechnology, Pathology, Proteomics,
Structural Biology, Systems Biology, 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-partially
What are the funding levels for the following program areas:

<table>
<thead>
<tr>
<th>Program Area</th>
<th>Funding Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research</td>
<td>$7,314,000</td>
</tr>
<tr>
<td>Development</td>
<td>$0</td>
</tr>
<tr>
<td>Test and evaluation</td>
<td>$1,971,000</td>
</tr>
<tr>
<td>Total</td>
<td>$9,285,000</td>
</tr>
</tbody>
</table>

Briefly describe the publication policy of the facility:
As a DOE/NNSA facility, PNNL 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. 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. [US Department of Energy, Scientific and Technical Information Management: https://www.directives.doe.gov/directives/0241.1-BOrder-b/view]

For this location, a searchable database of materials published since 1988 is available at http://www.pnnl.gov/publications/.

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.):

   http://pubs.rsc.org/en/Content/ArticleLanding/2014/AN/C4AN01270D#divAbstract

   http://journals.plos.org/plosgenetics/article?id=10.1371/journal.pgen.1004872


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: 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, pathogenesis studies, and interrogating DNA sequencing data and related analysis tools

Microorganisms and/or toxins studied: No work using Select Agents or NIAID Category A pathogens during 2014.

Outdoor Studies: No outdoor studies of biological aerosols were conducted.
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 (m²):

New Mexico campus:
- BSL-2: 326.6 m²
- BSL-3: 0 m²
- BSL-4: 0 m²
- Total laboratory floor area: 326.6 m²

California campus:
- BSL-2: 230 m²
- BSL-3: 0 m²
- BSL-4: 0 m²
- Total laboratory floor area: 230 m²

4. Organizational structure of each facility:
(i) Total number of personnel:
- New Mexico campus: 140
- California campus: 78

(ii) Division of personnel:
- Military: 0
- Civilian: 218

(iii) Division of personnel by category:
- Scientists: 101
- Engineers: 30
- Technicians: 76
- Admin and Support Staff: 11

(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: 1 (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)
Private sector

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

<table>
<thead>
<tr>
<th>Category</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research</td>
<td>$9,847,999.70</td>
</tr>
<tr>
<td>Development</td>
<td>$2,690,483.00</td>
</tr>
<tr>
<td>Test and Evaluation</td>
<td>$0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$12,538,482.70</strong></td>
</tr>
</tbody>
</table>

(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:


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http://scitation.aip.org/content/aip/journal/apl/104/11/10.1063/1.4869105.

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; and 3) Obtain an understanding of the microbiome’s effects on human health in the absence or in the presence of an infectious disease. Available at: http://bio.sandia.gov/solutions/biodefense/

**Microorganisms and/or toxins studied**: No work using Select Agents or NIAID Category A pathogens at SNL/NM or SNL/CA during 2014.

**Outdoor studies**: There were no outdoor studies.
1. **What is the name of the facility?**
Centers for Disease Control and Prevention (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:**
   - BL2: 568 sqM
   - BL3: 0 sqM
   - BL4: 0 sqM
   - Total laboratory floor area: 568 sqM

4. **The organizational structure of each facility.**
   (i) **Total number of personnel** = 20
   (ii) **Division of personnel:**
      - Military = 0
      - Civilian = 20
   (iii) **Division of personnel by category:**
      - Scientists = 20
      - 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
      Contractor staff = 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?**
      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:**
      Scientists are encouraged to publish their results in the peer reviewed scientific literature as well as 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](http://www.cdc.gov/od/science/policies). CDC Policy on “Oversight and clearance of dual use research of concern,” is available online at: [http://aops-mas-iis.cdc.gov/Policy/Doc/policy516.pdf](http://aops-mas-iis.cdc.gov/Policy/Doc/policy516.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.)


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.

**Agents Microorganisms and/or toxins studied:** HHS Select Agent and Toxins, NIAID Category A pathogen

**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?
Centers for Disease Control and Prevention (CDC), Office of Infectious Diseases (OID)

2. Where is it located (provide both address and geographical location)?
1600 Clifton Road N.E., Atlanta, Georgia 30333

3. Floor area of laboratory areas by containment level:

<table>
<thead>
<tr>
<th>Containment Level</th>
<th>Floor Area</th>
</tr>
</thead>
<tbody>
<tr>
<td>BL2</td>
<td>294 sqM</td>
</tr>
<tr>
<td>BL3</td>
<td>2143 sqM</td>
</tr>
<tr>
<td>BL4</td>
<td>543 sqM</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>2980 sqM</strong></td>
</tr>
</tbody>
</table>

4. The organizational structure of each facility
(i) Total number of personnel = 225
(ii) Division of personnel: Military = 2
     Civilian = 223
(iii) Division of personnel by category:

<table>
<thead>
<tr>
<th>Category</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scientists</td>
<td>183</td>
</tr>
<tr>
<td>Engineers</td>
<td>0</td>
</tr>
<tr>
<td>Technicians</td>
<td>22</td>
</tr>
<tr>
<td>Administrative and support staff</td>
<td>20</td>
</tr>
</tbody>
</table>

(iv) List the scientific disciplines represented in the scientific/engineering staff.
Bioinformatics, Epidemiology, Genetics, Medicine, Microbiology, Molecular Biology, Public Health, Statistics, Veterinary Medicine, Virology

(v) Are contractor staff working in the facility? If so, provide an approximate number.
Yes Contractor staff = 69

(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)
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:

<table>
<thead>
<tr>
<th>Program Area</th>
<th>Funding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research</td>
<td>$15,502,299</td>
</tr>
<tr>
<td>Development</td>
<td>$4,989,837</td>
</tr>
<tr>
<td>Test and evaluation</td>
<td>$4,368,625</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$24,860,871</strong></td>
</tr>
</tbody>
</table>

(viii) Briefly describe the publication policy of the facility:
Publication is encouraged and managed by editorial and clearance policies conducted at all levels of the Agency. The clearance policy for information products disseminated outside CDC for public use is
(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.)


http://www.ncbi.nlm.nih.gov/pubmed/?term=Genetic+characterization+of+clade+2.3.2.1+avian+influenza+A(H5N1)+viruses%2C+Indonesia

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6325a4.htm


http://www.ncbi.nlm.nih.gov/pubmed/?term=Kyasanur+Forest+disease+virus+infection+in+mice+is+associated+with+higher+morbidity+and+mortality+than+infection+with+the+closely+related+Alkhurma+hemorrhagic+fever+virus

http://www.ncbi.nlm.nih.gov/pubmed/?term=Rift+valley+Fever+virus+encephalitis+is+associated+with+an+ineffective+systemic+immune+response+and+activated+T+cell+infiltration+into+the+CNS+in+an+immunocompetent+mouse+model


http://www.ncbi.nlm.nih.gov/pubmed/?term=Brucella+placentitis+and+seroprevalence+in+northern+fur+seals+%28Callorhinus+ursinus%29+of+the+Pribilof+Islands%2C+Alaska


adapted+master+donor+virus+A%2FLeningrad%2F134%2F17%2F57+(H2N2)+and+reassortants+with+H5N1+surface+genes+in+a+mouse+model


http://wwwnc.cdc.gov/eid/article/20/2/13-0860_article


protective immunity of the neuraminidase between human influenza A(H1N1) virus and highly pathogenic avian influenza A(H5N1) virus


   http://www.ncbi.nlm.nih.gov/pubmed/?term=Characterizing+wild+bird+contact+and+seropositivity+to+highly+pathogenic+avian+influenza+A-(H5N1)+virus+in+Alaskan+residents+%2C+Influenza+Other+Respir+Viruses


   http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6311a6.htm


anas%2C+California%2C

105. Zemtsova GE, Watkins NE, Levin ML. Multiplex qPCR assay for identification and 
differentiation of *A. americanum, A. cajennense* and *A. maculatum* tick species in the Eastern US. 

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, USDA, 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?
Centers for Disease Control and Prevention (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:

- BL2: 66 sqM
- BL3: 1142 sqM
- BL4: 0 sqM

Total laboratory floor area: 1208 sqM

4. The organizational structure of each facility
(i) Total number of personnel = 53
(ii) Division of personnel:
   - Military = 0
   - Civilian = 53
(iii) Division of personnel by category:
   - Scientists = 27
   - Engineers = 0
   - Technicians = 10
   - Administrative and support staff = 16
(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, Contractor staff = 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?
   - U.S. Agency for International Development (USAID)
   - Department of Health & Human Services
   - Department of Defense (DoD)
   - Department of State
(vii) What are the funding levels for the following program areas:
   - Research: $1,234,004
   - Development: $1,123,562
   - Test and Evaluation: $1,072,997
   - Total: $3,430,563
(viii) Briefly describe the publication policy of the facility:
Publication is encouraged and managed by editorial and clearance policies conducted at all levels of the Agency. The clearance policy for information products disseminated outside CDC for public use is available online at: http://www.cdc.gov/od/science/policies. 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.)


http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3923427/


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: CDC’s Division of Vector Borne Diseases (DVBD) possesses many of the select agents that are on the Department of Health and Human Services (HHS) and HHS/U.S. Department of Agriculture overlap lists. Within CDC, DVBD has the primary responsibility for research on tularemia, plague and alphaviruses. This research involves development of assays for surveillance and detection of each agent 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:
   - BL2: 1361 sqM
   - BL3: 407 sqM
   - BL4: 1145 sqM
   - Total laboratory floor area: 2913 sqM

4. The organizational structure of each facility
   (i) Total number of personnel = 115
   (ii) Division of personnel:
       Military = 0
       Civilian = 115
   (iii) Division of personnel by category:
       Scientists = 79
       Engineers = 0
       Technicians = 31
       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 Contractor staff = 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: $20,129,117
       Development: $0
       Test and evaluation: $0
       Total: $20,129,117
   (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/) 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.)


http://www.jbc.org/content/289/18/12245.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 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 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 studies:** Select Agents (HHS, Overlap, USDA), 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?
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:
   
<table>
<thead>
<tr>
<th>Level</th>
<th>Area (sqM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BL2</td>
<td>878</td>
</tr>
<tr>
<td>BL3</td>
<td>0</td>
</tr>
<tr>
<td>BL4</td>
<td>1,305</td>
</tr>
<tr>
<td>Total</td>
<td>2,183</td>
</tr>
</tbody>
</table>

4. The organizational structure of each facility
   (i) Total number of personnel = 76

   (ii) Division of personnel:  
       Military = 0
       Civilian = 76

   (iii) Division of personnel by category:  
       Scientists = 19
       Engineers = 2
       Technicians = 54
       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

   (v) Are contractor staff working in the facility? If so, provide an approximate number.
       Yes  
       Contractor staff = 69

   (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:
       
       | Program          | Funding Level |
       |------------------|---------------|
       | Research         | $13,326,889   |
       | Development      | $0            |
       | Test and evaluation | $0       |
       | Total            | $13,326,889   |

   (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/) 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.)


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 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. Batelle 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.

**Microorganisms and/or toxins studied:** Select Agents (HHS, Overlap, USDA), 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:
   - BL2: 2493 m²
   - BL3: 1091 m²
   - BL4: 0 m²
   - Total laboratory floor area: 3584 m²

4. The organizational structure of each facility.
   (i) Total number of personnel = 116
   (ii) Division of personnel: Military = 0, Civilian = 116
   (iii) Division of personnel by category: Scientists = 85, Engineers = 0, Technicians = 25, Administrative and support staff = 6
   (iv) List the scientific disciplines represented in the scientific/engineering staff.
       Bacteriology, Biological Science, Chemistry, Immunology, Medicine, Microbiology, Molecular Biology, Parasitology, Pathogenesis, Toxicology, Vaccine Evaluation, Virology
   (v) Are contractor staff working in the facility? If so, provide an approximate number.
       Yes, Contractor staff = 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?
       Department of Health and Human Services
   (vii) What are the funding levels for the following program areas:
       - Research: $32,176,511
       - Development: $0
       - Test and evaluation: $0
       - Total: $32,176,511
   (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/) 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.)


http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4154137/


http://jid.oxfordjournals.org/content/211/3/352.long


http://onlinelibrary.wiley.com/doi/10.1002/path.4432/abstract;jsessionid=32F1EFFB22B983A79F5653D227EA63FA.f01t03


http://journals.plos.org/plospathogens/article?id=10.1371/journal.ppat.1003971


http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4139342/

40. Laliberte JP, Moss B. A novel mode of poxvirus superinfection exclusion that prevents fusion of the lipid bilayers of viral and cellular membranes. J Virol. 2014 Sep 1;88(17):9751-68. doi:


http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4097805/


http://www.nature.com/nature/journal/v511/n7507/full/nature13489.html

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3987803/

http://cid.oxfordjournals.org/content/early/2014/12/14/cid.ciu924.long


http://jid.oxfordjournals.org/content/early/2014/11/12/infdis.jiu530.long

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4054442/


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:** 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. Newer programs focus on developing vaccines – from basic research to clinical trials. The Laboratory of Parasitic Diseases (LPD) conducts basic and clinical studies to prevent, control, and treat diseases caused by parasitic protozoa. Research includes basic aspects of host-pathogen interaction in humans, animal models, and invertebrate vectors of important parasites. 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. The Laboratory of Clinical Infectious Diseases (LCID) conducts clinical and basic studies of important mycobacterial, bacterial, viral, and fungal infections and of immune disorders associated with infection susceptibility and resistance. LCID’s patient-oriented approach promotes a comprehensive understanding of the natural history, pathogenesis, and management of diseases. Training of physicians and scientists is central to LCID’s mission.

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

**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 (VRC)

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:
<table>
<thead>
<tr>
<th>Containment Level</th>
<th>Floor Area</th>
</tr>
</thead>
<tbody>
<tr>
<td>BL2</td>
<td>89 m²</td>
</tr>
<tr>
<td>BL3</td>
<td>0 m²</td>
</tr>
<tr>
<td>BL4</td>
<td>0 m²</td>
</tr>
<tr>
<td>Total</td>
<td>89 m²</td>
</tr>
</tbody>
</table>

4. The organizational structure of each facility
(i) Total number of personnel = 8
(ii) Division of personnel:
   - Military = 0
   - Civilian = 8
(iii) Division of personnel by category:
   - Scientists = 8
   - 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
   Contractor staff = 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?
   Department of Health and Human Services
(vii) What are the funding levels for the following program areas:

<table>
<thead>
<tr>
<th>Program Area</th>
<th>Funding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research</td>
<td>$774,548</td>
</tr>
<tr>
<td>Development</td>
<td>$0</td>
</tr>
<tr>
<td>Test and evaluation</td>
<td>$0</td>
</tr>
<tr>
<td>Total</td>
<td>$774,548</td>
</tr>
</tbody>
</table>

(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/) 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.)


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 research focus of the Vaccine Research Center (VRC), Biodefense Research Section 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; basic research to understand the mechanism of virus replication (entry) and neutralization.

Microorganisms and/or toxins studied: No U.S. Select Agents, 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 (m²):
   - BSL-2: 105 m²
   - BSL-3: 950 m²
   - BSL-4: 0 m²
   Total laboratory floor area: 1,055 m²

4. The organizational structure of each facility:
   (i) Total number of personnel: 28
   (ii) Division of personnel:
        - Military: 0
        - Civilian: 28
   (iii) Division of personnel by category:
        - Scientists: 10
        - Engineers: 
        - Technicians: 13
        - Administrative and support staff: 5
   (iv) List the scientific disciplines represented in the scientific/engineering staff:
        Agronomy, Biological Control, Horticulture, Plant Bacteriology, 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:
        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?
        U.S. Department of Agriculture (USDA)
   (vii) What are the funding levels for the following program areas:
        - Research: $4,000,000
        - Development: $0
        - Test and evaluation: $0
        - Total: $4,000,000
   (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. The USDA Agricultural Research Service (ARS) maintains a searchable online database of publications by scientists at this location (available at http://www.ars.usda.gov/services/services.htm?modecode=80-44-05-00&locpubs=yes).
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.):

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 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. 1) 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. 2) 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. Additional information about research projects conducted at this location is available at http://www.ars.usda.gov/research/projects_programs.htm?modecode=80-44-05-00.
Microorganisms and/or Toxins Studied: Select Agents (Plant Protection and Quarantine, 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 (m²):
   BSL-2: 4,410 m²
   BSL-3: 2,489 m²
   BSL-4: 0 m²
   Total laboratory floor area: 6,899 m²

   In addition NADC has unique animal biocontainment facilities ranging from ABSL-2 to ABSL-3Ag (highest biocontainment level 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: 3,467.7 m²
   ABSL-3: 160.5 m²
   ABSL-3Ag: 1,581.6 m²
   Total biocontainment facility floor area: 5209.8 m²

4. The organizational structure of each facility:
   (i) Total number of personnel: 48
   (ii) Division of personnel:
        Military 0
        Civilian 48
   (iii) Division of personnel by category:
        Scientists 8
        Engineers 1
        Technicians 10
        Administrative and support staff 29
   (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:
        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?

U.S. Department of Agriculture (USDA)
Department of Defense (DoD) – partly
Department of Health and Human Services (HHS)
Universities
Private Sector Companies

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

<table>
<thead>
<tr>
<th>Program Area</th>
<th>Funding Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research</td>
<td>$4,900,000</td>
</tr>
<tr>
<td>Development</td>
<td>$0</td>
</tr>
<tr>
<td>Test and evaluation</td>
<td>$0</td>
</tr>
<tr>
<td>Total</td>
<td>$4,900,000</td>
</tr>
</tbody>
</table>

(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. The USDA Agricultural Research Service (ARS) maintains a searchable online database of publications by scientists at this location (available at http://www.ars.usda.gov/services/services.htm?modecode=50-30-20-00&locpubs=yes).

(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):


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: 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. Additional information about research projects conducted at this location is available at http://www.ars.usda.gov/research/projects_programs.htm?modecode=50-30-20-00.

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 (m²):
- BSL-2: 1,138 m²
- BSL-3: 624 m²
- BSL-4: 0 m²
Total laboratory floor area: 1,762 m²

4. The organizational structure of each facility:
   (i) Total number of personnel: 23
   (ii) Division of personnel:
        Military
        Civilian 23
   (iii) Division of personnel by category:
        Scientists 11
        Engineers 0
        Technicians 8
        Administrative and support staff 4
   (iv) List the scientific disciplines represented in the scientific/engineering staff:
        Animal Science, Biology, Biotechnology, Cell Biology, Computational Biology, Genetics, Genomics, Immunology, Infectious Disease, Microbiology, Molecular Biology, Pathology, Public Health, Statistics, Veterinarian, Veterinary Medicine, Virology
   (v) Are contractor staff working in the facility? If so, provide an approximate number:
        Yes Number: 0
   (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 (HHS)
        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
(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. The USDA Agricultural Research Service (ARS) maintains a searchable online database of publications by scientists at this location (available at http://www.ars.usda.gov/services/services.htm?modecode=60-40-07-00&locpubs=yes).

(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.):


   http://www.veterinaryresearch.org/content/pdf/1297-9716-45-60.pdf


   http://jvi.asm.org/content/88/18/10556.short


   http://jcm.asm.org/content/52/5/1382.full.pdf+html

   http://vet.sagepub.com/content/early/2014/02/06/0300985814521247.full.pdf+html


http://tct.sagepub.com/content/13/2/169.full.pdf+html


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 one research unit that conducts biological defense work: Exotic and Emerging Avian Viral Diseases Research Unit. Additional information about research projects conducted at this location is available at http://www.ars.usda.gov/research/projects_programs.htm?modecode=60-40-07-00.

**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, 2015
Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern\(^1\)

1. **Time of cognizance of the outbreak**: On May 2, 2014, the U.S. National Focal Point was notified of a case of Middle Eastern Respiratory Syndrome Coronavirus (MERS-CoV).

2. **Location and approximate area affected**: One individual in Indiana was diagnosed with MERS-CoV. The case lived and worked in Riyadh, Saudi Arabia, and had returned to the U.S. from Riyadh to Chicago on April 24 via London Heathrow, with travel from Chicago to Indiana by bus.

3. **Type of disease/intoxication**: Viral respiratory syndrome

4. **Suspected source of disease/intoxication**: Not identified, presumably travel associated

5. **Possible causative agent(s)**: MERS-CoV (confirmed)

6. **Main characteristics of systems**: Hospital-based severe acute respiratory illness surveillance

7. **Detailed symptoms, when applicable**: Shortness of breath, cough, increasing fever and mild runny nose. A chest x-ray showed infiltrates in the right lung base. A chest computed tomography (CT) scan on April 29 showed bilateral lung infiltrates.

8. **Deviation(s) from the normal pattern**: Not applicable

9. **Approximate number of primary cases**: 1

10. **Approximate number of total cases**: 1

11. **Number of deaths**: 0

12. **Development of the outbreak**: On April 28, patient was seen in an emergency room; chest x ray showed infiltrates in the right lung base, patient was admitted to hospital and placed in a private room. Negative pressure room and airborne precautions were reportedly implemented on April 29 and full isolation (standard, contact, airborne) precautions on April 30.

13. **Measures taken**: A standard PCR respiratory panel run on a nasopharyngeal (NP) swab collected on April 29 was negative for several viruses (adenovirus, CoVx4, HMPV, RV/EV, Flu A, A H1N1, A/H1, A/H3, PIV1-4 and RSV). On May 1, a NP swab and serum collected on April 30 were tested at the Indiana state public health laboratory for MERS-CoV using the CDC rRT-PCR MERS-CoV assay and MERS-CoV was detected in both specimens. On May 2, this result was confirmed by CDC. U.S. National Focal Point notified this as a potential PHEIC to WHO on May 2, 2014.

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\(^1\) See paragraph 2 of the chapeau to Confidence-Building Measure B.
Form B

Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern

1. **Time of cognizance of the outbreak:** The U.S. National Focal Point was notified of a case of Middle Eastern Respiratory Syndrome Coronavirus (MERS-CoV) on May 12, 2014.

2. **Location and approximate area affected:** The patient was diagnosed in Orlando, Florida, but lived and worked in Jeddah, Saudi Arabia. Patient travelled to the U.S. from Jeddah on May 1 on commercial flights via London Heathrow with travel from London to Boston, Massachusetts, from Boston to Atlanta Georgia, from Atlanta to Orlando, Florida. [Note: This case is not linked to the first case of MERS-CoV reported in the U.S. described above.]

3. **Type of disease/intoxication:** Viral respiratory syndrome

4. **Suspected source of disease/intoxication:** Not identified, presumably travel associated

5. **Possible causative agent(s):** MERS-CoV (confirmed)

6. **Main characteristics of systems:** Hospital-based severe acute respiratory illness surveillance

7. **Detailed symptoms, when applicable:** Not available

8. **Deviation(s) from the normal pattern:** Not applicable

9. **Approximate number of primary cases:** 1

10. **Approximate number of total cases:** 1

11. **Number of deaths:** 0

12. **Development of the outbreak:** Patient began feeling unwell on May 1 with a low-grade fever, chills, and a slight cough. On May 9, patient was seen in an emergency room and admitted to hospital. The patient recovered fully.

13. **Measures taken:** A nasopharyngeal (NP) swab collected on May 9 was negative for standard pathogens. An induced sputum collected on May 10 tested positive at the Florida State Public Health Laboratory was positive for MERS-CoV using the CDC rRT-PCR MERS-CoV assay. On May 11, this result was confirmed by CDC. U.S. National Focal Point notified this as a potential PHEIC to WHO on May 12, 2014.
Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern

1. **Time of cognizance of the outbreak**: The U.S. National Focal Point was notified of a case of locally acquired Chikungunya virus on June 3, 2014.

2. **Location and approximate area affected**: The Commonwealth of Puerto Rico

3. **Type of disease/intoxication**: Viral fever, mosquito borne

4. **Suspected source of disease/intoxication**: *Aedes aegypti* mosquitoes

5. **Possible causative agent(s)**: Chikungunya virus (confirmed)

6. **Main characteristics of systems**: Health care facility-based fever surveillance

7. **Detailed symptoms, when applicable**: Fever and polyarthritis

8. **Deviation(s) from the normal pattern**: This 2014 case was the first case of locally acquired Chikungunya ever reported in the Commonwealth of Puerto Rico.

9. **Approximate number of primary cases**: 1

10. **Approximate number of total cases**: 26,336 suspected (including 4,315 laboratory confirmed) cases in Puerto Rico through January 7, 2015.

11. **Number of deaths**: 13

12. **Development of the outbreak**: The original case, a 16 year old resident of the municipality of San Juan, was treated at an emergency room and referred to supportive therapy at home as her condition did not require hospitalization. On May 29, the Department of Health, in collaboration with CDC, confirmed the diagnosis of chikungunya fever through PCR lab testing. Tens of thousands of additional cases were reported through routine public health surveillance programs through the remainder of the year.

13. **Measures taken**: Vector control efforts by the Department of Environmental Health, including inspections to identify mosquito breeding sites, is underway. The public is being urged to take preventive measures to avoid mosquito bites. Local mosquito control programs continue both routine and targeted pesticide application in order to reduce transmissions.

Household investigations conducted by Puerto Rico Department of Health and CDC in June-August demonstrated that ~90% of individuals that had laboratory evidence of chikungunya virus infection and had sought medical care had not been reported as a suspected case. This suggests that the number of reported chikungunya cases may be a large underestimate of the actual number of cases. Efforts by Puerto Rico Department of Health have since focused on improving cases reporting by making chikungunya a reportable health condition in Puerto Rico.

U.S. National Focal Point notified this as a potential PHEIC to WHO on June 3, 2014.
Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern

1. **Time of cognizance of the outbreak:** On May 6, 2014, PulseNet identified a cluster of gastrointestinal infections (diarrheal disease) in the U.S. caused by *Salmonella enterica* serotype Newport that was subsequently linked to cases in Canada exposed to the same source (chia seed powder). In June 2014, infections caused by *S. enterica* serotypes Hartford and Oranienburg were also associated with the same source.

2. **Location and approximate area affected:** A total of 31 persons infected with the outbreak strains of *Salmonella* serotypes Newport (20 persons), Hartford (7 persons), or Oranienburg (4 persons) were reported from 16 states: AZ (1), CA (4), CO (1), CT (3), FL (1), IL (2), MD (1), MA (1), MI (1), NY (7), OH (1), RI (1), TX (2), UT (1), WA (1) and WI (3).

3. **Type of disease/intoxication:** Bacterial infection due to *Salmonella* serotypes Newport, Hartford, and Oranienburg.

4. **Suspected source of disease/intoxication:** Associated with the consumption of contaminated organic sprouted chia powder of variable brand names traced back to one firm as the common supplier.

5. **Possible causative agent(s):** *Salmonella* serotypes Newport, Hartford, and Oranienburg

6. **Main characteristics of systems:** PulseNet, the national molecular subtyping network for foodborne disease surveillance, detected a cluster of *Salmonella* Newport. Epidemiologic, traceback, and laboratory investigations led to the addition of two more *Salmonella* serotypes, Hartford and Oranienburg, in the case definition.

7. **Detailed symptoms, when applicable:** Common symptoms of salmonellosis: diarrhea, fever, and abdominal cramps. Of the 31 case-patients with known clinical outcome, 22% (5/23) were hospitalized, and no deaths were reported.

8. **Deviation(s) from the normal pattern:** Human salmonellosis has not previously been linked to consumption of chia-containing products.

9. **Approximate number of primary cases:** 31

10. **Approximate number of total cases:** 31 from 16 U.S. states

11. **Number of deaths:** 0

12. **Development of the outbreak:** A cluster of *Salmonella* Newport infections with a novel pulsed field gel electrophoresis (PFGE) pattern was initially detected by PulseNet, the national subtyping network of public health and food regulatory agency laboratories coordinated by CDC. Subsequent patient interviews identified chia-containing products as a common exposure among cases. An outbreak in Canada linked to the same products was associated with a strain of *Salmonella* Hartford; a query of PulseNet identified additional persons infected with the *Salmonella* Hartford strain associated with the Canadian outbreak. Testing of leftover product and product obtained from retail locations in the U.S. identified a strain of *Salmonella* Oranienburg; a query of PulseNet identified additional ill persons infected with this strain.
Thirty-one cases were identified from 16 states: AZ (1), CA (4), CO (1), CT (3), FL (1), IL (2), MD (1), MA (1), MI (1), NY (7), OH (1), RI (1), TX (2), UT (1), WA (1) and WI (3). Twenty cases were Salmonella Newport, seven cases were Salmonella Hartford, and four cases were Salmonella Oranienburg. Isolation dates range from January 29–July 25, 2014. The median age is 48 years with a range of 1 to 81 years. Nineteen (61%) are female. Eighty-four percent of isolates were from stool, 10% from urine, and 3% from blood. For cases with available information, five (22%) of 22 were hospitalized; no deaths were reported. Ninety percent (19/21) of case-patients reported consuming chia seeds or powder; 79% (15/19) of those specifically reported consuming chia seed powder of variable brand names. Although sprouted chia seeds are a novel Salmonella outbreak vehicle, this investigation highlights the well-documented risks for foodborne illness associated with the sprouting process.

13. **Measures taken:** As a result of this investigation, several recalls of products containing organic sprouted chia powder and chia seeds were issued. Traceback identified a Canadian firm as the common supplier for the sprouted chia seed powder. Multiple products containing sprouted chia seed powder from this firm were recalled and FDA denied admission of these products into the US though an Import Alert on June 11, 2014 until testing could confirm the products were no longer contaminated.

The first U.S. recall occurred May 28, followed by recalls on June 4, June 5, June 6, June 26, and July 1, 2014. Several recalls of products containing chia powder and chia seeds were also announced by the Canadian Food Inspection Agency. Some of these products were available for purchase online.

Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern

1. **Time of cognizance of the outbreak:** On July 18, 2014, the U.S. National Focal Point was notified of local transmission of confirmed cases of Chikungunya virus.

2. **Location and approximate area affected:** Florida

3. **Type of disease/intoxication:** Viral syndrome, mosquito borne

4. **Suspected source of disease/intoxication:** *Aedes aegypti* or *Ae. albopictus* mosquitoes

5. **Possible causative agent(s):** Chikungunya virus

6. **Main characteristics of systems:** Community-based surveillance (routine)

7. **Detailed symptoms, when applicable:** Acute onset of fever and polyarthralgia

8. **Deviation(s) from the normal pattern:** Second and third autochthonous cases in the U.S.

9. **Approximate number of primary cases:** 2

10. **Approximate number of total cases:** 11 confirmed cases of autochthonous transmission in the continental United States (all in Florida)

11. **Number of deaths:** 0

12. **Development of the outbreak:** The first patient was treated at an outpatient clinic on June 13, 2014 with fever and joint pain and received supportive therapy. The patient returned to the clinic on June 15 and a serum sample was sent to a commercial diagnostic laboratory, producing a CHIKV positive serological test. The sample was forwarded to the Florida Department of Health, where it tested positive for chikungunya virus IgM antibodies. This result was later confirmed by the CDC. In addition, a convalescent serum sample tested positive for IgG chikungunya virus antibodies at the Florida Department of Health laboratory. Despite prior overseas travel to an area with ongoing chikungunya cases, the timing of symptom onset and laboratory test result indicate that the infection occurred while the patient was in Florida.

    The second patient presented to the emergency room on July 3. The patient was hospitalized from July 3-6 and a serum sample obtained on July 4 that was tested for dengue by a commercial lab was PCR positive for chikungunya virus in testing performed by the Florida Department of Health. The specimen was forwarded to the CDC where it was confirmed PCR positive for chikungunya virus. In addition, a convalescent sample tested at the Florida Department of Health was positive for IgG antibodies to the virus on July 17.

13. **Measures taken:** Epidemiological investigations were implemented to determine the source of exposure and to identify possible additional cases. The local vector control agencies conducted inspections to identify mosquito breeding sites and applied control measures to reduce the abundance of vector mosquitoes in the area. The public was being urged to take preventive measures to avoid mosquito bites.

    U.S. National Focal Point notified this as a potential PHEIC to WHO on July 18, 2014.
Form B

Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern

1. **Time of cognizance of the outbreak**: On August 21, 2014, the U.S. National Focal Point was notified of an outbreak of human infection with variant influenza A virus H3N2.

2. **Location and approximate area affected**: Ohio

3. **Type of disease/intoxication**: Viral syndrome, respiratory

4. **Suspected source of disease/intoxication**: Swine at a local agricultural fair

5. **Possible causative agent(s)**: H3N2v Influenza virus

6. **Main characteristics of systems**: Hospital-based severe acute respiratory illness surveillance

7. **Detailed symptoms, when applicable**: Severe influenza-like syndrome

8. **Deviation(s) from the normal pattern**: No

9. **Approximate number of primary cases**: 1

10. **Approximate number of total cases**: 2 (not epidemiologically linked)

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 2014. Swine contact at an agricultural fair was reported in the week preceding illness onset and a joint human-animal investigation to evaluate illness in the community is ongoing. Additional information about this investigation has been released through Epi-X. The total number of human infections with influenza A (H3N2)v virus reported in the United States was 309 in 2012 and 19 in 2013. In 2014, there were three cases reported. There was no change in severity of the disease caused by the variant.

    The sentinel case patient (a toddler) was hospitalized in Ohio on August 4, 2014 and discharged on August 6, 2014 with no subsequent disability. No other family members were ill and no increase in influenza-like illness was seen in the surrounding community.

    On August 20, 2014, RT-PCR testing at CDC confirmed H3N2v virus, and subsequent partial genome sequencing identified the NP and M genes from the influenza A (H1N1)pdm09 virus. This is the first influenza A (H3N2)v virus containing only the NP and M genes from influenza A (H1N1)pdm09 virus identified in the United States, although this genome composition has been seen previously in H3N2 influenza viruses in swine. Complete genome sequencing is pending.

13. **Measures taken**: Routine influenza surveillance is ongoing. The U.S. National Focal Point notified this as a potential PHEIC to WHO on August 21, 2014.
Form B

Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern

1. **Time of cognizance of the outbreak**: On September 30, 2014, the U.S. National Focal Point was notified of a single case of Ebola virus disease (Texas). An additional imported case was reported on October 23, 2014 (New York).

2. **Location and approximate area affected**: Texas and New York

3. **Type of disease/intoxication**: Viral syndrome, gastrointestinal

4. **Suspected source of disease/intoxication**: Associated with international travel to affected region

5. **Possible causative agent(s)**: Ebola virus

6. **Main characteristics of systems**: Hospital-based surveillance and response with State and Federal public health supplementation

7. **Detailed symptoms, when applicable**: Not available

8. **Deviation(s) from the normal pattern**: The case reported on September 30 was the first recognized case of Ebola imported into the United States (when persons previously known to be infected/exposed are excluded).

9. **Approximate number of primary cases**: 1

10. **Approximate number of total cases**: 3 (1 primary, plus 2 cases associated with the primary)

11. **Number of deaths**: 1

12. **Development of the outbreak**: Two healthcare workers contracted the virus from the case in Texas. The total number of human Ebola infections in the United States was 4 in 2014. Of these, three were related.

13. **Measures taken**: The person sought medical care at Texas Health Presbyterian Hospital of Dallas after developing symptoms consistent with Ebola and was admitted and isolated on September 28. Based on the person’s travel history and symptoms, CDC recommended testing for Ebola. The medical facility isolated the patient and sent specimens for testing at CDC and at a Texas lab participating in the CDC’s Laboratory Response Network on September 30. CDC and the Texas Health Department reported positive PCR laboratory test results to the medical center to inform the patient later that afternoon. Local public health officials identified close contacts of the person for further daily monitoring for 21 days after exposure. CDC sent a team to Texas at the request of Texas health officials.

   U.S. National Focal Point notified this imported case, as it was related to a declared PHEIC, to WHO on September 30, 2014.
Form B

Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern

Summary of Reports: In 2014, the United States submitted six World Organization for Animal Health (OIE) immediate reports for animal disease events that deviated from the normal pattern. These included 2 low pathogenic notifiable avian influenza reports, 1 novel swine enteric coronavirus report, 1 vesicular stomatitis report, and 2 highly pathogenic avian influenza (HPAI) reports. In addition, there were two reports of disease events that occurred in 2013 that were resolved in 2014. These include contagious equine metritis and equine piroplasmosis. Event summaries can be found on the OIE website: http://web.oie.int/wahis/public.php. Summaries are organized by the year of their occurrence.

2013 reports resolved in 2014:
Contagious Equine Metritis
Two outbreaks in 2013 (OIE Immediate Report February 12, 2013 – Resolved February 27, 2014)

Equine piroplasmosis
Three OIE Ongoing Reports in 2013 (Resolved May 20, 2014)

2014 immediate reports:
Low Pathogenic Notifiable Avian Influenza
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 (2014): http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_avian_influenza_viruses.htm. Avian influenza (AI) is caused by influenza type A viruses which can infect poultry (such as chickens, turkeys, pheasants, quail, domestic ducks, geese, and guinea fowl) and are carried by free flying waterfowl such as ducks, geese, and shorebirds. AI viruses are classified by a combination of two groups of proteins: hemagglutinin or “H” proteins, of which there are 16 (H1-H16), and neuraminidase or “N” proteins, of which there are 9 (N1-N9). Many different combinations of “H” and “N” proteins are possible. Each combination is considered a different subtype, and can be broken down in different strains. AI viruses are classified by their pathogenicity (low or high)—the ability of a particular virus strain to produce disease in domestic chickens.

Low Pathogenic Notifiable Avian Influenza, H7N3
OIE Immediate Report August 27, 2014—Resolved September 25, 2014
Low pathogenic notifiable avian influenza H7N3 was detected through routine AI testing on a breeding farm and hunting preserve containing approximately 44,000 mallard ducks and approximately 7,200 pheasants. There were no clinical signs of illness or increased mortality in birds on the premises. The USDA Animal Plant Health Inspection Service (APHIS) and the New Jersey Department of Agriculture conducted a comprehensive epidemiological investigation of this event. Enhanced surveillance and multiple testing did not detect any AI.

Low Pathogenic Notifiable Avian Influenza, H5N8
OIE Immediate Report, April 22, 2014—Resolved July 15, 2014
Low pathogenic notifiable avian influenza H5N8 was detected in a commercial Japanese quail (Coturnix japonica) layer flock consisting of 116,000 birds. The USDA Animal Plant Health Inspection Service (APHIS) and the California Department of Food and Agriculture (CDFA) conducted a comprehensive epidemiological investigation of this event. All birds on the premises were destroyed and cleaning and disinfection (C&D) was completed.

Novel Swine Enteric Coronavirus
**OIE Immediate Report-Emerging Disease April 21, 2014—Final Report, April 30, 2014**

Novel Swine Enteric Coronavirus Disease(s) (SECoV) is disease in swine caused by emerging porcine coronaviruses, including porcine epidemic diarrhea virus (PEDV) and porcine delta coronavirus (PDCoV). SECoV affects swine causing diarrhea, vomiting, and 50-100% mortality of infected piglets. The clinical presentation of SECoV infections in growing pigs can be variable in its severity and not readily distinguishable from many other causes of diarrhea in growing pigs. While adult pigs can become infected, mortality is low. SECoV is now considered endemic and is clinically indistinguishable from transmissible gastroenteritis (TGE), another swine disease caused by a coronavirus that is endemic in the United States.

**Vesicular stomatitis virus (VSV)**


Vesicular stomatitis is an insect-transmitted acute disease, primarily of horses, cattle, and pigs, with less frequent infections of sheep and goats, and characterized by the formation of vesicles, on the snout, mouth, udder, and feet. The causative agent is vesicular stomatitis virus (VSV), a member of the genus *Vesiculovirus* in the family Rhabdoviridae. The OIE removed VSV from its OIE-listed diseases for 2015. Vesicular stomatitis will continue to be a reportable disease in the U.S. because of its clinical similarity with foot and mouth disease (FMD) in cloven-hoofed animals. The 2014 outbreak of VSV, New Jersey serotype involved 433 premises in three states: Texas, Colorado, and Nebraska. The outbreak of VSV identified 584 equine cases and 60 cases in cattle — no cases of VSV were identified in any other domestic species. Colorado and Texas were the primary focus of VSV activity in 2014 with Colorado—370 premises; Texas—62 premises; and Nebraska—1 premises. Positive premises are eligible for quarantine release 21 days after lesions have healed in all affected animals. NOTE: As part of the 2014-2015 incident one premises in Arizona was confirmed with VSV New Jersey serotype in two horses after the U.S. closed the OIE report.

**Highly Pathogenic Avian Influenza (HPAI)**

Avian influenza (AI) is caused by influenza type A viruses which can infect poultry (such as chickens, turkeys, pheasants, quail, domestic ducks, geese, and guinea fowl) and are carried by free flying waterfowl such as ducks, geese, and shorebirds. AI viruses are classified by a combination of two groups of proteins: hemagglutinin or “H” proteins, of which there are 16 (H1-H16), and neuraminidase or “N” proteins, of which there are 9 (N1-N9). Many different combinations of “H” and “N” proteins are possible. Each combination is considered a different subtype, and can be broken down in different strains. AI viruses are classified by their pathogenicity (low or high)—the ability of a particular virus strain to produce disease in domestic chickens.

The U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS), U.S. Geological Survey (USGS) National Wildlife Health Center (NWHC), and state departments of agriculture have announced several detections of highly pathogenic avian influenza (HPAI) H5N8, H5N2, and novel H5N1-reassortant in avian species along the Pacific Flyway in counties in Washington, Oregon, California, Utah, and Idaho in December 2014 and January 2015. The primary concern with AI, especially HPAI, is the potential for human infection and economic consequence from infection in domestic poultry, particularly commercial flocks. AI is zoonotic but no human infections have been recognized in association with this outbreak and there is no immediate human public health concern.

The USDA Animal and Plant Health Inspection Service (APHIS), in conjunction with state departments of agriculture and wildlife, are continuing to conduct a comprehensive epidemiological investigation and enhanced surveillance (including wild bird surveillance of hunter harvested birds) in response to the HPAI H5N8 and H5N2 wild bird related events. Novel avian influenza virus of Eurasian origin (EA-H5N8 clade 2.3.4.4) spread rapidly along wild bird migratory pathways during 2014. Introduction of this EA-H5N8 virus into the Pacific Flyway sometime during 2014 has allowed mixing with North American
(AM) lineage viruses and generated new combinations with genes from both EA and AM origin (or “reassortant” viruses) such as the EA/AM H5N2-reassortant detected in Canada and the US. These findings are not unexpected as the EA-H5N8 virus continues to circulate. The EA H5 clade 2.3.4.4 viruses are highly pathogenic for poultry.

- **Highly Pathogenic Avian Influenza (HPAI) H5N8**
  OIE Immediate Report December 16, 2014—Open
  H5N8 was initially identified in a captive wild gyrfalcon that was fed hunter killed wild birds from Whatcom County, Washington and H5N2 was initially identified in a wild pintail duck also from Whatcom County, Washington. HPAI H5N8 has been identified as of January 19, 2015 in wild birds in the states of Washington, California, Utah, and Idaho; in backyard birds on one premises in Oregon; and in commercial turkeys on one premises in California. The detection of the HPAI H5N8 in the commercial turkey flock is considered to be related to the recent avian influenza events in wild birds.

- **Highly Pathogenic Avian Influenza (HPAI) H5N2**
  OIE Immediate Report December 16, 2014—Open
  H5N8 was initially identified in a captive wild gyrfalcon that was fed hunter killed wild birds from Whatcom County, Washington and H5N2 was initially identified in a wild pintail duck also from Whatcom County, Washington. The HPAI H5N2 has been identified, as of January 22, 2015, in wild birds in the states of Washington and Oregon; and in two backyard premises in the state of Washington and one backyard premises in Idaho. The HPAI EA/AM H5N2-reassortant virus has NOT been found in commercial poultry anywhere in the United States.
Form C
BWC - Confidence Building Measure

Encouragement of Publication of Results and Promotion of Use of Knowledge

United States of America
April 15, 2015
<p>| Department of Health and Human Services (HHS) Open Government Plan | The key principles of Open Government are transparency, collaboration, and participation. |
| National Institutes of Health (NIH) Data Sharing Policy and Implementation Guide | This guidance provides the National Institutes of Health (NIH) policy statement on data sharing and additional information on the implementation of this policy. |
| Centers for Disease Control and Prevention (CDC) Policy on Releasing and Sharing Data | 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. |
| The Journal <em>Emerging Infectious Diseases</em> | Emerging Infectious Diseases is an open access, peer-reviewed journal published by the Centers for Disease Control and Prevention (CDC). |
| The Morbidity and Mortality Weekly Report (MMWR) | CDC’s primary vehicle for scientific publication of reliable, authoritative, objective, and useful public health information and recommendations; open access. |
| The Excellence in Science Committee (EISC) at the CDC | The EISC fosters, supports, and protects an environment for the promotion of scientific integrity, quality assurance, and the rapid dissemination of scientific innovations, technology, and information with the ultimate goal of improving public health. |
| CDC Office of Science Quality (OSQ) | The OSQ is responsible for increasing the impact of CDC research and science by promoting standards and recommended practices for scientific quality, relevance, credibility, transparency, and utility within the agency and throughout the public health community (e.g., authorship, scientific clearance, peer review, and extramural research policies). |
| Advancing Excellence and Integrity of CDC Science | 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. |
| Office of Scientific Integrity (OSI) | 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. |
| Public Health Image Library (PHIL) | The PHIL offers an organized, electronic gateway to CDC images for reference, teaching, presentation, and public health messages; open access. |
| U.S. Food and Drug Administration (FDA) | An actively updated and searchable research database. |</p>
<table>
<thead>
<tr>
<th><strong>Publications Database</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>publications database for all FDA publications.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>FDA Office of Science and Engineering Laboratories (OSEL) Annual Report</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm109778.htm">http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm109778.htm</a></td>
</tr>
<tr>
<td>The OSEL Annual Report provides current information about the Office's organization and intramural science activities; provides a summary of the Office's direct laboratory support for pre-market review and compliance cases; and provides a bibliography of scientific publications, presentations, and research seminars for the fiscal year.</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th><strong>FDA Center for Biologics Evaluation and Research (CBER)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="http://www.fda.gov/BiologicsBloodVaccines/ScienceResearch/default.htm">http://www.fda.gov/BiologicsBloodVaccines/ScienceResearch/default.htm</a></td>
</tr>
<tr>
<td>This CBER website provides links to the strategic plan for regulatory science and research, general information about research programs, as well as highlights from selected research publications.</td>
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<tr>
<th><strong>PubMed Central (PMC)</strong></th>
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<tbody>
<tr>
<td>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.</td>
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</table>

<table>
<thead>
<tr>
<th><strong>The National Institutes of Health (NIH) Public Access Policy</strong></th>
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<tbody>
<tr>
<td>The NIH Public Access Policy ensures that the public has access to the published results of NIH funded research.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Agricultural Research Magazine</strong></th>
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</thead>
<tbody>
<tr>
<td><a href="http://www.ars.usda.gov/is/AR/">http://www.ars.usda.gov/is/AR/</a></td>
</tr>
<tr>
<td>The Agricultural Research Magazine is the USDA’s science magazine published by the Agricultural Research Service (ARS); open access.</td>
</tr>
<tr>
<td><strong>National Science Foundation (NSF) Research Spending and Results</strong>&lt;br&gt;<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></td>
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<tr>
<td><strong>Environmental Protection Agency (EPA) Scientific Integrity Policies</strong>&lt;br&gt;<a href="http://www.epa.gov/research/htm/scientific-integrity.htm">http://www.epa.gov/research/htm/scientific-integrity.htm</a></td>
</tr>
<tr>
<td><strong>Department of Energy (DOE) Biological and Environmental Research (BER) Program</strong>&lt;br&gt;<a href="http://genomicscience.energy.gov/datasharing/">http://genomicscience.energy.gov/datasharing/</a></td>
</tr>
</tbody>
</table>
Form E

BWC - Confidence Building Measure

Declaration of legislation, regulations and other measures

United States of America

April 15, 2015
**Declaration of legislation, regulations and other measures**

<table>
<thead>
<tr>
<th></th>
<th>Legislation</th>
<th>Regulations</th>
<th>Other</th>
<th>Amended Since Last year</th>
</tr>
</thead>
<tbody>
<tr>
<td>(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</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>(b) Exports of Micro-Organisms(^3) and Toxins</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES[1]</td>
</tr>
<tr>
<td>(c) Imports of Micro-Organisms and Toxins</td>
<td>YES</td>
<td>YES</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>(d) Biosafety(^4) and biosecurity(^5)</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES[2]</td>
</tr>
</tbody>
</table>

[1] Amendment to Regulations: (b) Exports of Micro-Organisms and Toxins

**Implementation of the Understandings Reached at the June 2013 Australia Group (AG) Plenary Meeting and the December 2012 AG Intersessional Decisions.** This regulation was published in the March 26, 2014 Federal Register (79 FR 16664) to amend the Export Administration Regulations (EAR) by revising the description of controlled fermenters, adding components designed for those fermenters, and clarifying a Technical Note to include all types of bioreactors, including single-use (disposable) bioreactors, as well as chemostats and continuous-flow systems. The list of controlled animal pathogens was amended to clarify that the Rabies virus listing includes all other members of the Lyssavirus genus. The list of zoonotic pathogens and toxins was amended to clarify that Clostridium perfringens toxins mean only the alpha, beta 1, beta 2, epsilon, and iota toxins and to clarify the eligibility requirements for the use of License Exception STA for the export of small quantities of any toxins not also controlled for chemical weapons reasons. Technical Note 1, to the list of genetic elements associated with pathogenicity, was amended to include those chromosomes, genomes, plasmids, transposons, and vectors that have been chemically synthesized in whole or in part. In addition to the changes related to the Australia Group this rule also reflected the addition of Mexico as a participating country in the Australia Group. ([http://www.gpo.gov/fdsys/pkg/FR-2014-03-26/html/2014-06406.htm](http://www.gpo.gov/fdsys/pkg/FR-2014-03-26/html/2014-06406.htm) or [http://www.bis.doc.gov/index.php/regulations/federal-register-notices#79fr16664](http://www.bis.doc.gov/index.php/regulations/federal-register-notices#79fr16664))

[2] Updates to Other measures: (d) Biosafety and biosecurity

**Federal Select Agent Program:** The White House National Security and Technology Council (NSTC) established an interagency group to conduct a comprehensive review of the impact that the Select Agent Regulations (SAR) have had on science, technology, and national security and should include in its review an analysis of benefits, costs, and limitations of the SAR, as well as offer recommendations to address any identified challenges or gaps. NSTC has convened multiple public meetings of SAR stakeholders to inform and support the NSTC-led process.

\(^2\) Including guidelines.
\(^3\) Micro-organisms pathogenic to man, animals and plants in accordance with the Convention.
\(^4\) In accordance with the latest version of the WHO Laboratory Biosafety Manual or equivalent national or international guidance.
\(^5\) In accordance with the latest version of the WHO Laboratory Biosecurity Guidance or equivalent national or international guidance.
“Safety Stand-Down” to Enhance Biosafety and Biosecurity: In the aftermath of three biosafety and biosecurity incidents (see Appendix C), the White House released a memorandum on August 18, 2014 entitled, “Enhancing Biosafety and Biosecurity in the United States.” [https://www.whitehouse.gov/sites/default/files/microsites/ostp/enhancing_biosafety_and_biosecurity_19aug2014_final.pdf] This memorandum reiterated the government’s responsibility to ensure that infectious disease research is conducted safely and securely. To maximize the positive effect of lessons learned from these incidents, United States Government departments and agencies that that work with infectious agents were urged to take immediate and long-term steps to enhance safety and security of research to minimize the potential for future incidents. By September 18, 2014, all departments and agencies operating facilities that possess, use, or transfer human, animal, or plant infectious agents or toxins were urged to perform a "Safety Stand-Down." Senior leaders were to: devote significant, dedicated time to review laboratory biosafety and biosecurity best practices and protocols; develop and implement plans for sustained inventory monitoring; confer with local and agency management and staff to identify opportunities for improving research safety and local oversight systems; and kick-off an immediate sweep of their facilities that possess, use, or transfer human, animal, or plant infectious agent or toxin holdings to identify BSAT. Extramural facilities receiving U.S. government funding that possess, use, or transfer human, animal, or plant infectious agents or toxins were encouraged to hold similar events. The results of the Safety Stand-Down are available at http://www.cdc.gov/about/lab-safety/factsheet.html.

Federal Experts Security Advisory Panel: The White House National Security Council (NSC) staff tasked the Federal Experts Security Advisory Panel (FESAP) in September 2014 to: 1) identify needs and gaps and make recommendations to optimize biosafety, biosecurity, oversight, and inventory management and control for Biological Select Agents and Toxins (BSAT); 2) identify actions and any regulatory changes to improve biosafety and biosecurity; and 3) identify an approach to determine the appropriate number of high-containment U.S. laboratories required to possess, use, or transfer BSAT. Information regarding this effort is available at http://www.phe.gov/s3/Pages/biosafety-stewardship.aspx.

Dual Use Research of Concern (DURC): On September 24, 2014, the United States Government released the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (Institutional DURC Policy). The policy addresses institutional oversight of DURC, which includes policies, practices, and procedures to ensure DURC is identified and risk mitigation measures are implemented, where applicable. Institutional oversight of DURC is the critical component of a comprehensive oversight system because institutions are most familiar with the life sciences research conducted in their facilities and are in the best position to promote and strengthen the responsible conduct and communication of DURC. This Policy complements the March 2012 United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern in emphasizing a culture of responsibility by reminding all involved parties of the shared duty to uphold the integrity of science and prevent its misuse. Like the March 2012 DURC Policy, the scope of the Institutional DURC Policy is limited to a well-defined subset of life sciences research involving 15 agents and toxins and seven categories of experiments. The U.S. Government will solicit feedback on the experience of institutions in implementing the Policy; evaluate the impact of DURC oversight on the life sciences research enterprise; assess the benefits and risks of expanding the scope of the Policy to encompass additional agents and toxins and/or categories of experiments; and update the Policy as warranted. The Institutional DURC Policy, along with a suite of educational and training tools, is available at http://www.phe.gov/s3/dualuse/Pages/default.aspx.

Deliberative Process and Research Funding Pause on Selected Gain-of-Function Research: On October 16, 2014, the White House announced that the U.S. Government will launch a deliberative process in order to assess the risks and benefits of certain gain-of-function (GOF) experiments. During this deliberative process, U.S. government departments and agencies will pause the release of federal
funding for GOF studies that enhances the pathogenicity or transmissibility among mammals by respiratory droplets of influenza, MERS, or SARS. The pause will allow the U.S. Government, in partnership with the life sciences community and stakeholders, to conduct a comprehensive assessment of gain-of-function research with the explicit goal of developing a new federal policy framework to guide future investments in this area of research. The White House announcement, along with frequently asked questions, is available at http://www.phe.gov/s3/dualuse/Pages/default.aspx.

**USDA Announces Funding, Issues Federal Order to Combat PEDv:** Washington, D.C., June 5, 2014

In response to the significant impact porcine epidemic diarrhea virus (PEDv) and porcine deltacoronavirus (PDCoV) are having on U.S. pork producers, the United States Department of Agriculture (USDA) announced $26.2 million in funding to combat these diseases. Additionally, USDA issued a Federal Order requiring the reporting of new detections of these viruses to its Animal and Plant Health Inspection Service (APHIS) or State animal health officials. These viruses do not pose any risk to human health or food safety, and they are commonly detected in countries around the world. "In the last year, industry has estimated PEDv has killed some 7 million piglets and caused tremendous hardship for many American pork producers," said Agriculture Secretary Vilsack. "The number of market-ready hogs this summer could fall by more than 10 percent relative to 2013 because of PEDv. Together with industry and our State partners, the steps we will take through the Federal Order will strengthen the response to PEDv and these other viruses and help us lessen the impact to producers, which ultimately benefit the consumers who have seen store pork prices rise by almost 10 percent in the past year." The international animal health governing body, the OIE, believes that cases of PEDv and these other swine enteric coronavirus diseases shouldn’t be the basis for countries to restrict exports of pork and pork products from the U.S.

**National Institutes of Health (NIH) Review Mechanism for Dual Use Research Manuscripts:** The NIH has established a review mechanism for manuscripts which may involve dual use research of concern. The Publication and Abstract Clearance Form is available online at: http://www1.od.nih.gov/oir/sourcebook/oversight/pub-clear-form.htm. The Dual Use Questionnaire is available online at: http://sourcebook.od.nih.gov/oversight/Dual%20Use%20Questionnaire-4-2010.pdf.

**National Institutes of Health (NIH) Instruction in the Responsible Conduct of Research:** The NIH requires responsible conduct of research (RCR) instruction for all trainees, fellows, participants, and scholars receiving support through NIH training, career development award (individual or institutional), research education grant, and dissertation research grant. RCR is defined as the practice of scientific investigation with integrity. It involves the awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific research. The NIH Policy is available online at: http://grants1.nih.gov/grants/guide/notice-files NOT-OD-10-019.html. NIH materials for Research Conduct and Ethics Instruction, including case studies for the 2012 theme (Mentoring) are available online at: http://sourcebook.od.nih.gov/resethicscases/cases-doc.htm.
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, 2015
Form F

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, 2015

Page 160 of 171
**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](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, 2015). 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.

<table>
<thead>
<tr>
<th>1. Name of facility</th>
<th>Barr Laboratories, Inc.</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Location (Mailing Address)</td>
<td>1235 Mays Mill Road, Forrest, Virginia 24551</td>
</tr>
<tr>
<td>3. General description of the types of diseases covered:</td>
<td>Acute respiratory disease caused by Adenovirus Type 4 and Type 7 Vaccine, Live, Oral</td>
</tr>
<tr>
<td>Vaccines:</td>
<td>Adenovirus Type 4 and Type 7 Vaccine, Live, Oral</td>
</tr>
</tbody>
</table>

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</thead>
<tbody>
<tr>
<td>2. Location (Mailing Address)</td>
<td>3500 N. Martin Luther King Jr. Boulevard, Lansing, Michigan 48906</td>
</tr>
<tr>
<td>3. General description of the types of diseases covered:</td>
<td>Anthrax disease caused by <em>Bacillus anthracis</em></td>
</tr>
<tr>
<td>Vaccines:</td>
<td>Anthrax Vaccine Adsorbed - [BioThrax]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>1. Name of facility</th>
<th>MassBiologics</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Location (Mailing Address)</td>
<td>University of Massachusetts Medical School, Boston, Massachusetts 02130</td>
</tr>
<tr>
<td>3. General description of the types of diseases covered:</td>
<td>Diphtheria and tetanus caused by <em>Corynebacterium diphtheriae</em> and <em>Clostridium tetani</em></td>
</tr>
<tr>
<td>Vaccines:</td>
<td>Tetanus and Diphtheria Toxoids Adsorbed</td>
</tr>
</tbody>
</table>
# 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

<table>
<thead>
<tr>
<th>Vaccines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Influenza Vaccine Live, Intranasal - [FluMist]</td>
</tr>
<tr>
<td>Influenza Vaccine Live, Intranasal (FluMist Quadravalent)</td>
</tr>
</tbody>
</table>

## 1. Name of facility
Merck Sharp & 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); Measles; 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.

<table>
<thead>
<tr>
<th>Vaccines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate) - [PedvaxHIB]</td>
</tr>
<tr>
<td>Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate) &amp; Hepatitis B (Recombinant) Vaccine - [COMVAX]</td>
</tr>
<tr>
<td>Hepatitis A Vaccine, Inactivated - [VAQTA]</td>
</tr>
<tr>
<td>Hepatitis B Vaccine (Recombinant) - [Recombivax HB]</td>
</tr>
<tr>
<td>Human Papillomavirus 9-valent Vaccine, Recombinant - [GARDASIL 9]</td>
</tr>
<tr>
<td>Measles, Mumps, and Rubella Virus Vaccine, Live - [M-M-R II]</td>
</tr>
<tr>
<td>Measles, Mumps, Rubella and Varicella Virus Vaccine Live - [ProQuad]</td>
</tr>
<tr>
<td>Pneumococcal Vaccine, Polyvalent - [Pneumovax 23]</td>
</tr>
<tr>
<td>Rotavirus Vaccine, Live, Oral, Pentavalent - [RotaTeq]</td>
</tr>
<tr>
<td>Varicella Virus Vaccine Live - [Varivax]</td>
</tr>
<tr>
<td>Zoster Vaccine, Live, (Oka/Merck) - [Zostavax]</td>
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</tbody>
</table>
### Declaration of vaccine production facilities

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<thead>
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<th>1. Name of facility</th>
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<tbody>
<tr>
<td>Organon Teknika Corporation, LLC</td>
<td></td>
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<table>
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<tr>
<th>2. Location (Mailing Address)</th>
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</tr>
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<tbody>
<tr>
<td>100 Rodolphe Street, Building 1300, Durham, North Carolina 27712</td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. General description of the types of diseases covered:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>For the prevention of tuberculosis</td>
<td></td>
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</tbody>
</table>

**Vaccines:** BCG Live (BCG Vaccine)

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<table>
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</thead>
<tbody>
<tr>
<td>Protein Sciences Corporation</td>
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</table>

<table>
<thead>
<tr>
<th>2. Location (Mailing Address)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1000 Research Parkway, Meriden, Connecticut 06450-7159</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. General description of the types of diseases covered:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>For active immunization against disease caused by influenza virus subtypes A and B</td>
<td></td>
</tr>
</tbody>
</table>

**Vaccines:** Influenza vaccine for subtypes A and B (Flublok)

---

<table>
<thead>
<tr>
<th>1. Name of facility</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Sanofi Pasteur Biologics Co.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. Location (Mailing Address)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>38 Sidney Street, Cambridge, Massachusetts 02139</td>
<td></td>
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<table>
<thead>
<tr>
<th>3. General description of the types of diseases covered:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Smallpox disease</td>
<td></td>
</tr>
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</table>

**Vaccines:** Smallpox (Vaccinia) Vaccine, Live - [ACAM2000]
### Declaration of vaccine production facilities

<table>
<thead>
<tr>
<th><strong>1. Name of facility</strong></th>
<th>Sanofi Pasteur, Inc</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2. Location (Mailing Address)</strong></td>
<td>Discovery Drive, Swiftwater, Pennsylvania 18370</td>
</tr>
<tr>
<td><strong>3. General description of the types of diseases covered:</strong></td>
<td>Diphtheria caused by <em>Corynebacterium diphtheriae</em>; tetanus caused by <em>Clostridium tetani</em>; pertussis (whooping cough) caused by <em>Bordetella pertussis</em>; 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 <em>Neisseria meningitidis</em> serogroups A, C, Y and W-135; meningitis and meningococcemia caused by <em>N. meningitidis</em>; and Yellow fever acute viral illness caused by a mosquito-borne flavivirus.</td>
</tr>
<tr>
<td><strong>Vaccines:</strong></td>
<td>Diphtheria &amp; Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed - [Tripedia; Daptacel]</td>
</tr>
<tr>
<td></td>
<td>Diphtheria and Tetanus Toxoids Adsorbed USP (For Pediatric Use) (DT)</td>
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<tr>
<td></td>
<td>Influenza Virus Vaccine (Fluzone, Fluzone High-Dose, Fluzone Intradermal and Fluzone Quadrivalent)</td>
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<tr>
<td></td>
<td>Influenza Virus Vaccine, H5N1</td>
</tr>
<tr>
<td></td>
<td>Meningococcal Polysaccharide (Serogroups A, C, Y and W-135) Diphtheria Toxoid Conjugate Vaccine - [Menactra]</td>
</tr>
<tr>
<td></td>
<td>Meningococcal Polysaccharide Vaccine, Groups A, C, Y and W-135 Combined - [Menomune®-A/C/Y/W-135]</td>
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<tr>
<td></td>
<td>Tetanus and Diphtheria Toxoids Adsorbed for Adult Use - [DECAVAC]</td>
</tr>
<tr>
<td></td>
<td>Tetanus Toxoid Adsorbed</td>
</tr>
<tr>
<td></td>
<td>Tetanus Toxoid for Booster Use Only</td>
</tr>
<tr>
<td></td>
<td>Yellow Fever Vaccine - [YF-VAX®]</td>
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</table>

<table>
<thead>
<tr>
<th><strong>1. Name of facility</strong></th>
<th>Wyeth Pharmaceuticals, Inc</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2. Location (Mailing Address)</strong></td>
<td>Pfizer, Inc., 401 N. Middletown Road, Pearl River, NY 10965</td>
</tr>
<tr>
<td><strong>3. General description of the types of diseases covered:</strong></td>
<td>Invasive disease caused by <em>Streptococcus pneumoniae</em> serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F and otitis media caused by <em>Streptococcus pneumoniae</em> serotypes 4, 6B, 9V, 14, 18C, 19F and 23F; and invasive disease caused by <em>Neisseria meningitides</em> serogroup B.</td>
</tr>
<tr>
<td><strong>Vaccines:</strong></td>
<td>Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein) - [Prevnar 13]</td>
</tr>
<tr>
<td></td>
<td>Pneumococcal 7-valent Conjugate Vaccine (Diphtheria CRM197 Protein)</td>
</tr>
<tr>
<td></td>
<td>Meningococcal Group B Vaccine - (TRUMENBA)</td>
</tr>
</tbody>
</table>
Appendix A

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 (Reconstructed1918 Influenza virus)
Rcin
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 Pyrenoachaeta glycinus)
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

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
  • 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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6 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
### Compiled list of microorganisms and toxins used for biodefense research

<table>
<thead>
<tr>
<th>MICROORGANISM</th>
<th>CATEGORY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abrin</td>
<td>HHS Select Toxin</td>
</tr>
<tr>
<td>African horse sickness virus</td>
<td>USDA Select Agent</td>
</tr>
<tr>
<td>African swine fever virus</td>
<td>USDA Select Agent</td>
</tr>
<tr>
<td>Alpha conotoxins</td>
<td>HHS Select Toxin</td>
</tr>
<tr>
<td>Avian influenza virus (highly pathogenic)</td>
<td>USDA Select Agent</td>
</tr>
<tr>
<td><em>Bacillus anthracis</em></td>
<td>Overlap Select Agent/NIAID Category A</td>
</tr>
<tr>
<td><em>Bacillus anthracis</em> Pasteur strain</td>
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</tr>
<tr>
<td>Botulinum neurotoxins</td>
<td>HHS Select Toxin</td>
</tr>
<tr>
<td><em>Brucella abortus</em></td>
<td>Overlap Select Agent</td>
</tr>
<tr>
<td><em>Brucella melitensis</em></td>
<td>Overlap Select Agent</td>
</tr>
<tr>
<td><em>Brucella suis</em></td>
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</tr>
<tr>
<td><em>Burkholderia mallei</em></td>
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</tr>
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</tr>
<tr>
<td><em>Burkholderia pseudomallei</em></td>
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<td>Chapare virus</td>
<td>HHS Select Agent</td>
</tr>
<tr>
<td>Classical swine fever virus</td>
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</tr>
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<td><em>Clostridium</em> species producing botulinum neurotoxin</td>
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<td><em>Coxiella burnetti</em></td>
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</tr>
<tr>
<td><em>Coxiella burnetti</em> (killed)</td>
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<tr>
<td>Crimean-Congo hemorrhagic fever virus</td>
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</tr>
<tr>
<td>Dengue virus</td>
<td>NIAID Category A</td>
</tr>
<tr>
<td>Diacetoxyscirpenol</td>
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<td>Eastern equine encephalitis virus</td>
<td>HHS Select Agent</td>
</tr>
<tr>
<td>Ebola virus</td>
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</tr>
<tr>
<td>Escherichia coli O157:H7 (killed)</td>
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</tr>
<tr>
<td>Foot-and-mouth disease virus</td>
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<tr>
<td><em>Francisella philomiragia</em></td>
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</tr>
<tr>
<td><em>Francisella tularensis</em></td>
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</tr>
<tr>
<td><em>Francisella tularensis</em> (killed)</td>
<td>Simulant</td>
</tr>
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<td>Goatpox virus</td>
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</tr>
<tr>
<td>Guanarito virus</td>
<td>HHS Select Agent/NIAID Category A</td>
</tr>
<tr>
<td>Hantaviruses</td>
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</tr>
<tr>
<td>Hendra virus</td>
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<tr>
<td>Influenza A virus, reconstructed replication-competent pandemic 1918 strains</td>
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</tr>
<tr>
<td>Junin virus</td>
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<tr>
<td>Kyasanur Forest Disease virus</td>
<td>HHS Select Agent</td>
</tr>
<tr>
<td>Lassa virus</td>
<td>HHS Select Agent/NIAID Category A</td>
</tr>
<tr>
<td>Lujo virus</td>
<td>HHS Select Agent</td>
</tr>
<tr>
<td>Lumpy skin disease virus</td>
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<tr>
<td>Lymphocytic choriomeningitis virus</td>
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</tr>
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<td>Machupo virus</td>
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<tr>
<td>Marburg virus</td>
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<tr>
<td>Monkeypox virus</td>
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</tr>
<tr>
<td><em>Mycoplasma capricolum</em></td>
<td>USDA Select Agent</td>
</tr>
<tr>
<td><em>Mycoplasma mycoides</em></td>
<td>USDA Select Agent</td>
</tr>
<tr>
<td>Newcastle disease virus</td>
<td>USDA Select Agent</td>
</tr>
<tr>
<td>Nipah virus</td>
<td>Overlap Select Agent</td>
</tr>
<tr>
<td>Omsk hemorrhagic fever virus</td>
<td>HHS Select Agent</td>
</tr>
<tr>
<td><strong>Peronosclerospora phillipinensis</strong></td>
<td>PPQ Select Agent</td>
</tr>
<tr>
<td><strong>Peronosclerospora sacchari</strong></td>
<td>PPQ Select Agent</td>
</tr>
<tr>
<td>Peste-des-petits-ruminants virus</td>
<td>USDA Select Agent</td>
</tr>
<tr>
<td><strong>Phoma glycinicola</strong></td>
<td>PPQ Select Agent</td>
</tr>
<tr>
<td><strong>Rathayibacter toxicus</strong></td>
<td>PPQ Select Agent</td>
</tr>
<tr>
<td>Ricin</td>
<td>HHS Select Toxin</td>
</tr>
<tr>
<td><strong>Rickettsia prowazekii</strong></td>
<td>HHS Select Agent</td>
</tr>
<tr>
<td>Rift Valley fever virus</td>
<td>Overlap Select Agent/NIAID Category A</td>
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<tr>
<td>Sabia virus</td>
<td>HHS Select Agent</td>
</tr>
<tr>
<td><strong>Salmonella typhimurium</strong> (killed)</td>
<td>Simulant</td>
</tr>
<tr>
<td>Saxitoxin</td>
<td>HHS Select Toxin</td>
</tr>
<tr>
<td>Severe acute respiratory syndrome-related coronavirus</td>
<td>HHS Select Agent</td>
</tr>
<tr>
<td>Sheep pox virus</td>
<td>USDA Select Agent</td>
</tr>
<tr>
<td><strong>Shigella dysenteriae</strong> (killed)</td>
<td>Simulant</td>
</tr>
<tr>
<td>Staphylococcal enterotoxins A, B, C, D, E subtypes</td>
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<td>Swine vesicular disease virus</td>
<td>USDA Select Agent</td>
</tr>
<tr>
<td>T-2 toxin</td>
<td>HHS Select Toxin</td>
</tr>
<tr>
<td>Tetrodotoxin</td>
<td>HHS Select Toxin</td>
</tr>
<tr>
<td>Tick-borne encephalitis complex flavivirus, Far Eastern subtype</td>
<td>HHS Select Agent</td>
</tr>
<tr>
<td>Tick-borne encephalitis complex flavivirus, Siberian subtype</td>
<td>HHS Select Agent</td>
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<tr>
<td>Variola major virus</td>
<td>HHS Select Agent</td>
</tr>
<tr>
<td>Variola minor virus</td>
<td>HHS Select Agent</td>
</tr>
<tr>
<td>Venezuelan equine encephalitis virus</td>
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<td><strong>Vibrio cholerae</strong> (killed)</td>
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<tr>
<td><strong>Yersinia pestis</strong></td>
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</tr>
<tr>
<td><strong>Yersinia pestis</strong> (killed)</td>
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</tr>
</tbody>
</table>
Appendix C

Biosafety and Biosecurity Incidents in the United States in 2014

To maintain a high level of transparency to States Parties, the U.S. makes available below reports regarding three biosafety and biosecurity incidents that occurred in federal laboratory facilities in 2014. None of these events resulted in any case of infection or illness.

On June 19, 2014, the U.S. National Focal Point was notified of possible anthrax exposures sometime during between June 6 and June 13, 2014 at a U.S. Centers for Disease Control and Prevention (CDC) laboratory and in turn notified WHO on June 20, 2014 (under Article 7 of the IHR). Approximately 75 Atlanta-based CDC staff were monitored or provided antibiotics because they may have been unintentionally exposed to live Bacillus anthracis (bacterium causing anthrax) after established safety practices were not followed. Early reports showed that a biosafety level 3 (BSL3) laboratory was preparing B. anthracis samples for research in other CDC labs at lower biosafety levels to yield new methods of detecting dangerous pathogens in environmental samples. However, the lab used an unvalidated procedure that did not adequately inactivate the samples. Internal reviews of this incident remain ongoing and CDC will review its safety protocols with all employees working in this area. On July 11, 2014, CDC published a Report on the Potential Exposure to the Anthrax (available at http://www.cdc.gov/od/science/integrity/). Included in this report are actions taken and plans for the future.

On July 8, 2014, the U.S. National Focal Point was notified that vials labelled “variola,” (the virus causing smallpox) had been discovered and in turn notified WHO on July 9, 2014 (under Article 7 of the IHR). On July 1, Food and Drug Administration (FDA) employees discovered vials labelled “variola,” in an unused portion of a cold storage room in a FDA laboratory located on the National Institutes of Health Bethesda campus. There was no evidence that any of the vials had been breached. On July 7, the vials were transported safely and securely with the assistance of federal and local law enforcement agencies in a U.S. government aircraft to CDC’s high containment facility in Atlanta. CDC notified WHO about the discovery and WHO was invited to participate in the investigation. On February 24, 2015, WHO personnel witnessed the destruction of these smallpox materials. The public was first notified of this incident in a July 8, 2014, CDC press release (http://www.cdc.gov/media/releases/2014/s0708-NIH.html), and more information was provided in a July 16, 2014, FDA press release (http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm405434.htm).

By request, CDC shipped an aliquot of H9N2 virus to Southeast Poultry Research Laboratory (SEPRL) on March 12, 2014. The material was shipped overnight by commercial courier service using a USDA Animal and Plant Health Inspection Service (APHIS) permit for low pathogenicity avian influenza (LPAI) H9N2 virus. On May 23, 2014, SEPRL notified CDC that it identified highly pathogenic avian influenza (HPAI) H5N1 virus (a select agent) in the H9N2 sample. The same day, CDC confirmed by rRT-PCR that the sample sent to SEPRL had been contaminated with the HPAI H5N1 virus. It was determined that the contamination occurred at a CDC Biosafety Level 3 with enhancements (BSL3-E) laboratory prior to its transfer to the SEPRL Animal Biosafety Level 3 with enhancements (ABSL3-E) laboratory. USDA Animal and Plant Health Inspection Service (APHIS) received notification of this incident by SEPRL and the CDC, conducted an investigation, and issued a public report (http://www.cdc.gov/about/pdf/lab-safety/investigationcdch5n1contaminationeventaugust15.pdf). The investigation determined that the incident did not pose a safety risk because the virus was handled under the appropriate containment for HPAI H5N1 virus (BSL3-E or ABSL3-E) by both CDC and USDA SEPRL, respectively.