NBAF
NATIONAL BIO AND AGRO-DEFENSE FACILITY
Vaccines • Diagnostics • Countermeasures

Site-Specific Biosafety and Biosecurity Mitigation Risk Assessment

October 2010

Final Report Executive Summary

Homeland Security
Science and Technology Directorate

Defending America Against Foreign Animal Diseases

Acknowledgements

This report was reviewed in draft form by a U.S. government employee panel selected for their diverse knowledge and technical expertise. We wish to thank the Panel for their review.

Steve Bennett, Ph.D.,
Assistant Director for Risk Analytics, Office of Risk Management and Analysis National Protection Programs Directorate, Department of Homeland Security

Michelle M. Colby, DVM,
Chief Agriculture Branch, Chem/Bio Division, Science and Technology Directorate, Department of Homeland Security

Cyril Gerard Gay, DVM/Ph.D.,
Senior National Program Leader, Animal Production and Protection, Agricultural Research Service, United States Department of Agriculture

Bruce Harper, Ph.D.,
Director of Science, Plum Island Animal Disease Center, Science and Technology Directorate, Department of Homeland Security

Joanne Jones-Meehan, Ph.D.,
Biosurety Officer, Office of National Labs, Science and Technology Directorate, Department of Homeland Security

Ali S. Khan, M.D., MPH
Office of Public Health Preparedness and Response, Center for Disease Control and Prevention, Department of Health and Human Services

Randall Levings,
Scientific Advisor, Animal and Plant Health Inspection Service, Veterinary Services, Emergency Management and Diagnostics, United States Department of Agriculture

Stuart T. Nichol, Ph.D.,
Chief, Special Pathogens Branch, Division of Viral and Rickettsial Diseases, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) (proposed), Centers for Disease Control and Prevention, Department of Health and Human Services

Nicki Pesik, M.D.,
Associate Director for Biosecurity; Epidemiology Team Lead Bacterial Zoonoses Branch, National Center for Emerging and Zoonotic Diseases (NCEZID) (proposed), Centers for Disease Control and Prevention, Department of Health and Human Services

The National Academy of Sciences (NAS), an honorific society of distinguished scholars engaged in scientific and engineering research, has been charged with the responsibility of conducting a formal review of the Site-Specific Biosafety and Biosecurity Mitigation Risk Assessment (SSRA) for the DHS-planned National Bio and Agro-Defense Facility (NBAF) in Manhattan, Kansas. The NAS Committee was convened during the development of the SSRA to provide an initial review of the SSRA workplan. The NAS Committee provided DHS and the SSRA contractor with several recommendations that were communicated in a preliminary letter report and during their initial review of the SSRA. Recommendations and comments provided by the NAS Committee in the preliminary letter report and during subsequent review of the draft SSRA were incorporated into the SSRA.

The NAS Committee is composed of the following members:

Ronald M. Atlas, Ph.D., Chair, Professor of Biology and Public Health; and Co-director, Center for Health Preparedness, University of Louisville, KY

Thomas W. Armstrong, Ph.D., Principal Investigator, TWA8HR Occupational Hygiene Consulting, LLC, Branchburg, NJ

Michael S. Ascher, M.D., Visiting Researcher, University of California, Davis, CA

Mark T. Hernandez, Ph.D., Professor of Environmental Engineering, University of Colorado, Boulder, CO

Barbara Johnson, Ph.D., Consultant for Biosafety & Biosecurity, Johnson and Associates, LLC, Herndon, VA

Brendan McCluskey, Executive Director, University of Medicine and Dentistry of New Jersey, Newark, NJ

Kishor C. Mehta, Ph.D., P.W. Horn Professor of Civil Engineering, Texas Technical University, Lubbock, TX

Frederick A. Murphy, Professor of Pathology, University of Texas Medical Branch at Galveston, Galveston, TX

Philip L. Paarlberg, Professor of Agricultural Economics, Purdue University, West Lafayette, IN

Timothy C. Reluga, Ph.D., Assistant Professor of Mathematics, Pennsylvania State University, University Park, PA

James A. Roth, Ph.D., Professor, Clarence Hartley Covault Distinguished Professor, Iowa State University, Ames, IA

Mark C. Thurmond, DVM/Ph.D., Professor Emeritus, School of Veterinary Medicine, University of California, Davis, CA

International and domestic peers in science, engineering, and administration from other high-containment laboratories provided valuable insight, and experience-based observations and recommendations while extending every courtesy and addressing many questions from the SSRA team. The following individuals were responsible for coordinating the involvement and cooperation:

Pattie Gillespie, Executive Services Officer, Public Health Agency of Canada

John Copps, BSc.Ag., DVM, DVSc., Deputy Director, National Centre for Foreign Animal Disease (NCFAD), Winnipeg, Canada

Kelly Keith, Senior Communications Officer, Public Health Agency of Canada, Canadian Science Centre for Human and Animal Health, Winnipeg, Canada

Catherine Robertson, MSc., Head, Safety and Environmental Services, Public Health Agency of Canada, Canadian Science Centre for Human and Animal Health, Winnipeg, Canada

Stefan Wagener, Ph.D., CBSP, Scientific Director, Biosafety and Environment, Canadian Science Centre for Human and Animal Health, Winnipeg, Canada

Less Wittmeier, Manager, Technical Services, Public Health Agency of Canada, Canadian Science Centre for Human and Animal Health, Winnipeg, Canada

Uwe U. Muller-Doblies, DVM, MRCVS, Dipl. ECFPH, Head of Biosecurity, Institute for Animal Health, Pirbright, United Kingdom

Steve Copping, Head of Compliance, Regulatory Affairs & Risk, Institute for Animal Health, Pirbright, United Kingdom

Scott Rusk, Director, Pat Roberts Hall, Biosecurity Research Institute, Manhattan, Kansas

Thomas Sawicki, Biological Safety Officer, Plum Island Animal Disease Center

Larry Barrett, DVM, Director, Plum Island Animal Disease Center

A team of over 130 federal employees, contractors, and subject matter experts contributed directly to the development and writing of the SSRA. A complete list of individuals can be found in Section 8. The major contributors include:

- Prime Contractor: Signature Science, LLC

- Sub-Contractors: Gryphon Scientific and Science and Technology in Atmospheric Research (STAR) Institute
- SSRA Subject Matter Experts
- NBAF Design Partnership: Perkins + Will (Prime), Flad Architects, Merrick & Company, CCRD Partners, Affiliated Engineers, Inc., and Sandia National Laboratories
- NBAF Project Management Office: Booz Allen Hamilton, Inc.

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Glossary of Acronyms and Terms

AAALAC	Association for Assessment and Accreditation for Laboratory Animal Care
AAHL	Australian Animal Health Laboratory (AAHL)
ACL	Arthropod Containment Levels
ADEQ	Arkansas Department of Environmental Quality
APHIS	Animal and Plant Health Inspection Service
AR	Arkansas
ARF	Airborne Release Fraction
ARS	Agricultural Research Service
ASF	African Swine Fever
ASFv	African Swine Fever virus
AUSVETPLAN	Australian Veterinary Emergency Plan
AVMA	American Veterinary Medical Association
BDM	Biotechnology Development Module
BEA	Bureau of Economic Analysis
BMBL	Biosafety in Microbiological and Biomedical Laboratories
BRI	Biosecurity Research Institute
BSAT	Biological Select Agents and Toxins
BSC	Biological Safety Cabinet
BSL	Biosafety Level
CA	California
CAFO	Concentrated animal feeding operation
CBPP	Contagious Bovine Pleuropneumonia
CDC	Center for Disease Control (aka CDCP)
CDCP	Center for Disease Control and Prevention (aka CDC)
CEAH	Centers for Epidemiology and Animal Health
CEPR	Commission on Emergency Planning and Response [Kansas Division of Emergency Management]
cGMP	current Good Manufacturing Practices
CO	Colorado
COI	Cost of Illness
CRDF	Cumulative Risk Distribution Function
CSCHAH	Canadian Science Centre for Human and Animal Health
CSF	Classical Swine Fever
CSFv	Classical Swine Fever virus
CUP	Central Utility Plant
Cwt	hundredweight
D&B	Dunn and Bradstreet
DADS	Davis Animal Disease Simulation
DBT	Design Based Threat

DEFRA	United Kingdom, Department of Environment, Food and Rural Affairs
DHS	Department of Homeland Security
DNR	Department of Natural Resources
DNRE	Michigan Department of Natural Resources and Environment
DOI	Department of Interior
DOT	Department of Transportation
DP	NBAF Design Partnership
DR	Damage Ratio
DSAT	Division of Select Agent and Toxins
DTRA	Defense Threat Reduction Agency
EDS	Effluent Decontamination System
EIS	Environmental Impact Statement
EMAC	Emergency Management Assistance Compact
EOPs	Emergency Operations Plans
EPCRA	Emergency Planning Community Right-to-Know Act
EPZ	Emergency Planning Zone
ERP	Emergency Response Plan
ERS	Economic Research Service
EU	European Union
FAD	Foreign Animal Disease
FADD	Foreign Animal Disease Diagnostician
FADDL	Foreign Animal Disease Diagnostic Laboratory
FADRU	Foreign Animal Disease Research Unit
FDEP	Florida Department of Enviromental Protection
FEMA	Federal Emergency Management Agency
FL	Florida
FMD	Foot and Mouth Disease
FMDv	Foot and Mouth Disease virus
GAO	General Accounting Office [of US Congress]
GEP	Google Earth Pro
GIS	Geographic Information System
GMP	Good Manufacturing Practices
GNL	Galveston National Laboratory
GSF	Gross Square Feet
HAN	Health Alert Network (KDHE)
HEPA	High Efficiency Particulate Air
Hev	Hendra virus
HHS	Health and Human Services
HSPD	Homeland Security Presidential Directive
HVAC	Heating, Ventilation and Air Conditioning
IA	Iowa
IACUC	Institutional Animal Care and Use Committee
IAH	Institute of Animal Health

IAHER	International Animal Health Emergency Reserve
IATA	International Air Transport Association
IBC	International Building Codes
ICC	International Code Council
ID	Infectious Dose
IL	Illinois
ILAR	Institute for Laboratory Animal Research
IN	Indiana
IRB	Institutional Review Board
ISC	Interagency Security Commission
ISO	International Standards Organization
JE	Japanese Encephalitis
JEv	Japanese Encephalitis virus
KDHE	Kansas Department of Health and Environment
KOH	Potassium Hydroxide
KS	Kansas
KSU	Kansas State University
LAI	Laboratory Acquired Infection
LEPCs	Local Emergency Planning Committees
LMIC	Livestock Marketing Information Center
LPF	Leak Path Factor
MAR	Material at Risk
MESA	Multiscale Epidemiological/Economic Simulation and Analysis
MFD	Manhattan Fire Department
MHK	Manhattan Regional Airport
MI	Michigan
MID	Minimum Infectious Dose
MN	Minnesota
MO	Missouri
MOU	Memorandum of Understanding
MP	Military Police
MRHC	Mercy Regional Health Clinic
MTV	Minute Tidal Volume
NAADSM	North American Animal Disease Spread Model
NAHLN	National Animal Health Laboratory Network
NaOH	Sodium Hydroxide
NAS	National Academy of Sciences
NASS	National Agricultural Statistics Service
NBACC	National Biodefense Analysis and Countermeasures Center
NBAF	National Bio and Agro-Defense Facility
NCAH	National Centers for Animal Health
NCEZID	National Center for Emerging and Zoonotic Diseases
NCFAD	National Center for Foreign Animal Disease

NE	Nebraska
NEHRP	National Earthquake Hazards Reduction Program
NIH	National Institute of Health
NIMS	National Incident Management System
Niv	Nipah virus
NOAA	National Oceanic and Atmospheric Administration
NRC	National Research Council
NRC	Nuclear Regulatory Commission
NSF	Net Square Feet
O&M	Operation and Maintenance
OHS	Occupation Health Services
OIE	World Organisation for Animal Health
OK	Oklahoma
OSHA	Occupational Safety and Health Administration
OSTP	Office of Science and Technology Policy (White House)
pdf	probability density function
pfu	plaque-forming units
PHS	Public Health Service
PIADC	Plum Island Animal Disease Center
PPE	personal protective equipment
PReP	Preparedness and Response Plan
R&D	Research and Development
RCEM	Riley County Emergency Management
RIMS	Regional Input/Output Modeling System
RVF	Rift Valley Fever
RVFv	Rift Valley Fever virus
S&T	Science and Technology
SARA	Superfund Amendments and Reauthorization Act
SCIPUFF	Second-order Closure Integrated PUFF (model)
SME	Subject Matter Expert
SOMs	Self Organizing Maps
SOP	Standard Operating Procedure
SPC	Storm Prediction Center
SSO	Sanitary Sewer Overflow
SSRA	Site-Specific Risk Assessment
STAR	Science and Technology in Atmospheric Research (Institute)
T&D	Transport and Dispersion (modeling)
TAD	Targeted Advanced Development
TCID	Tissue Culture Infectious Dose
TD	Tissue Digester
TRA	Threat and Risk Assessment
U.S.	United States
UFC	Unified Facilities Criteria (Department of Defense)

UK	United Kingdom
ups	uninterrupted power supply
USBLS	United States Bureau of Labor Statistics
USDA	United States Department of Agriculture
USDHHS	United States Department of Health and Human Services
USEPA	United States Environmental Protection Agency
USGS	U.S. Geological Survey
VA	Virginia
VBA	Visual Basic for Applications
VSL	Value of a Statistical Life
VSv	Vesicular Stomatitis Virus
WHO	World Health Organization
WI	Wisconsin
WTP	Willingness to Pay
WWTP	Wastewater Treatment Plant

Executive Summary

ES1 SSRA Overview and Conclusions

The Site-Specific Biosafety and Biosecurity Mitigation Risk Assessment (SSRA) has provided the Department of Homeland Security (DHS) with conclusions and recommendations for the optimization of biosafety and biosecurity at the proposed National Bio and Agro-Defense Facility (NBAF) that will be built in Manhattan, Kansas. Results from this highly-integrated multi-disciplinary data gathering, modeling, and assessment process are intended to assist DHS by providing input on design strategies, operational considerations, and mitigation and response planning at the early stages of the facility development program. Since there are inherent risks associated with basic research, diagnostics testing, and countermeasures development of exotic and emerging infectious diseases, DHS has concluded that a proactive approach to the management of these risks is the best solution for the long-term interests of the United States. DHS requirements for the performance of the SSRA are consistent with this approach and with legislative guidance. In addition to the SSRA, DHS has incorporated other techniques for the management of NBAF risks, including: the use of interagency teams of government experts that have provided input and review; the selection of a highly-qualified and experienced design team; and the development of international partnerships that have enabled exchanges of relevant experiences and expertise.

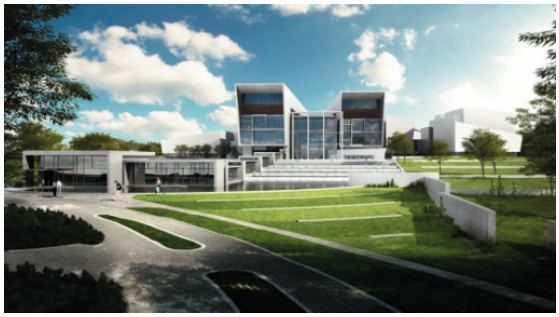
The NBAF biocontainment strategy is predicated on modern facility design, specialized technologies and equipment, and the use of good laboratory practice. Based on quantitative analyses and qualitative assessments performed during the SSRA, the greatest NBAF risks are the consequences of an animal disease (Foot and Mouth Disease—FMD) outbreak resulting from human errors that violate the overall biocontainment strategy. The highest risk-ranked cases assessed during the SSRA are 1) the inadvertent loss of biocontainment via an inanimate object (shoes, personal effects, or other items) removal from the laboratory by a staff member or visitor, and 2) the unintentional removal and distribution of a pathogen carried on/in a person that has been in a containment area. These results include the assumptions that the facility and its supporting infrastructure are properly specified, constructed, and installed in a manner consistent with the current design strategy, adjusted in accordance with DHS consideration of the SSRA recommendations, and enhanced, when appropriate, by additional best practices information.

This principal conclusion would indicate that DHS should continue and accelerate the development of protocols, procedures, and other operational management, mitigation, and response planning tools as the facility design matures under the continued guidance of government, academia, and private-sector subject matter experts. NBAF's operational plans will require the close cooperation and aggregation of regulations and best practices from two technical communities (human disease research and animal disease research) that have many similar requirements but different cultures and practices. An accelerated integration program will help manage these identified risks.

Given the combination of proven biocontainment design, robust operational procedures, and response planning for NBAF, the facility introduces extremely low risk relative to the greater risk the country faces if FMD is intentionally or accidentally introduced. The purpose of this SSRA was not to assess the risk or impact of an intentional or accidental release of FMD by an external source. However, it is because of this National vulnerability that DHS believes there is a pressing need for a facility with the NBAF's capabilities in Manhattan, Kansas specifically aimed at enhanced surveillance, rapid identification, and countermeasures development to foreign animal diseases.

The remainder of the Executive Summary describes the purpose and benefits of the proposed facility, summarizes the NBAF risk management strategy and SSRA conclusions and recommendations, and presents an overview of the path forward.

ES2 NBAF Purpose and Benefits



The U.S. food and agriculture industry is a highly integrated, global, and complex system that relies on a sophisticated agricultural infrastructure. These characteristics make the industry inherently vulnerable to foreign animal, emerging, and zoonotic disease outbreaks that could threaten the stability of the economy, food security, and the Nation's public health. DHS has the responsibility and the national stewardship mandate to detect, prevent, protect against, and respond to terrorist attacks within the U.S. (Homeland Security Act of 2002, 6 U.S.C 182). DHS shares these responsibilities, as they apply to the defense of animal agriculture, with the U.S. Department of Agriculture (USDA); hence, a coordinated, multi-agency strategy is required to adequately protect the Nation.

Consultations between DHS and USDA regarding the coordinated agricultural research strategy, as called for in the Homeland Security Act of 2002 and Homeland Security Presidential Directive 9 (HSPD-9), "Defense of U.S. Agriculture and Food," January 30, 2004, revealed a capability gap in the development of new countermeasures against the introduction or natural occurrence of animal and zoonotic diseases. HSPD-9 also specifically identified the need for "safe, secure, and state-of-the-art agriculture biocontainment laboratories that research and develop diagnostic capabilities for foreign animal and zoonotic diseases." To address the capability gap and need for modern biocontainment facilities, DHS is building the National Bio and Agro-Defense Facility (NBAF) to conduct advanced research, diagnostic testing, and biologic countermeasure development for high-threat foreign animal diseases affecting livestock.

In December 2003, the White House Office of Science and Technology Policy (OSTP) organized a Blue Ribbon Panel to examine research and development requirements to support efforts to mitigate the potential threat of bioterrorism directed against agricultural livestock. This panel presented a series of recommendations including a prioritization of pathogens requiring study [Kelly, 2003]. DHS and USDA

have since partnered to identify the following high-consequence diseases that threaten the U.S. for research in the NBAF: Foot-and-Mouth Disease, African Swine Fever, Classical Swine Fever, Japanese Encephalitis, Rift Valley Fever, and Contagious Bovine Pleuropneumonia. These diseases were identified for study based on the threats and consequences of their introduction into the U.S. In addition, the NBAF will be the first facility of its kind in the U.S. to conduct critical studies on Nipah and Hendra and other emerging zoonotic viruses in large livestock (*e.g.,* cattle and swine).

Foreign animal diseases (FADs) affect livestock, poultry, and wildlife and are not indigenous to the U.S. For the past 50 years, much of the Nation's FAD research has been conducted off the coast of Long Island, New York, at the Plum Island Animal Disease Center (PIADC). Because the food and agriculture industries are significant contributors to U.S. economic prosperity, any disruptions from a deliberate or natural FAD introduction that caused a significant loss in the agro business chain, would have significant economic consequences. In addition, FADs that also result in zoonoses (transmission from animals to humans) may cause a human health crisis. Since June 2003, PIADC has been operated by DHS with two tenant USDA institutes: The Foreign Animal Disease Diagnostic Laboratory (FADDL), which is a part of the Animal and Plant Health Inspection Service (APHIS); and the Foreign Animal Disease Research Unit (FADRU), a unit in the Agricultural Research Service (ARS). The NBAF will replace the PIADC and expand the research that is currently available. Facilities at the PIADC have limited laboratory space, antiquated infrastructure, and do not include Biosafety Level 4 (BSL-4) laboratories, which are required to safely conduct research on emerging and high-threat exotic pathogens, such as the Nipah and Hendra viruses.

The NBAF will enable DHS and USDA to conduct comprehensive research of high-threat foreign animal and zoonotic diseases within the U.S. and will therefore serve to protect the Nation's animal agriculture and public health against numerous foreign animal and emerging diseases. Specifically, the NBAF will provide:

- Capabilities to perform basic and advanced research;
- Enhanced means to perform laboratory diagnostic detection and response;
- Expanded capabilities for development of new vaccines against high-threat foreign animal diseases; and
- Facilities for training veterinarians in preparedness and response to high-consequence foreign animal disease outbreaks.

ES3 NBAF Risk Management Strategy

Safety and security are of paramount importance in the planning, design, construction, and operations of the NBAF. From selection of the site to the design of the facility and, finally, the operation of the NBAF, DHS is committed to understanding the associated safety and security risks and mitigating those risks through the necessary design, engineering, operational protocols, and response planning efforts. To date, DHS has completed an Environmental Impact Statement (EIS) including a Health and Safety Chapter [DHS, 2008], a Threat and Risk Assessment (December 2008) and a Site-Specific Threat and Risk

Assessment [Sandia, 2010] that considered intentional acts. In addition, as a necessary part of the design development process, DHS conducted this SSRA for the Manhattan, Kansas, site. Identifying and understanding the site-specific risks will assist DHS in developing appropriate risk mitigation strategies for NBAF and is a critical part of the planning process for the safe operation of large animal biocontainment laboratories.

The National Research Council (NRC) report "*Technical Input on Any Additional Studies to Assess Risk Associated with Operation of the National Emerging Infectious Diseases Laboratory*" [Boston University, 2008] suggests answering the following list of overarching questions as part of understanding risks for a high containment laboratory:

1. "What could go wrong? That is, what might be the sequence of events that could cause an infectious agent to escape the laboratory, set up a chain of transmission, and cause infectious disease in the surrounding community?
2. What are the probabilities of such a sequence of events?
3. What would be the consequences of such a sequence of events?"

This SSRA answers these questions based upon the known baseline design and response infrastructure. These answers lead to a better understanding of risks that, in turn, will be used to inform and enhance the design, operational protocols, and the emergency response planning to minimize the identified site-specific risks.

Another component of risk management is active engagement and transparent communication with state and local responders and the community stakeholders. There is a strong public and stakeholder interest in NBAF and, as such, DHS has and will continue to place significant emphasis on the importance of effective risk analysis and risk communication. DHS has developed a plan entitled the "*Stakeholder Engagement Plan*" (see Appendix A) to ensure that risks and mitigation strategies are communicated to the public and key stakeholders. Communication with the public includes publication of the results of this SSRA, as well as continuing communication throughout the design, construction, and operation of the NBAF.

ES3.1 NBAF Site-Specific Biosafety and Biosecurity Mitigation Risk Assessment

An integrated, strategic, and risk-based approach was used in the decision-making process to select a site for the NBAF that was in the best interests of protecting the Nation's agriculture, public health, and economy. Safety and security risks were major factors that DHS considered during the selection of the Manhattan, Kansas, location for NBAF. Following the NBAF site selection, DHS entered into a contract with Signature Science, LLC, to conduct the SSRA, recognizing that completion of the SSRA is an important step to establish confidence in NBAF design, operation, and mitigation strategies at the Manhattan location. The overall approach for the SSRA is to:

- Review the baseline design (based on the current design from the Architectural-Engineering Firm), baseline operational protocols, and baseline response strategies;

- Perform scenario modeling and risk analyses; and
- Provide recommendations to enhance the design, operational plans, and/or emergency response.

Additionally, the SSRA will serve as a tool for future and on-going risk assessments that will be conducted during the projected 50-year life-cycle of the NBAF as new information or risks are encountered (*e.g.,* advancements in engineering controls, knowledge about specific pathogens, and changes in mission requirements). NBAF design, construction, and operations will be directed by federal regulations and guidelines, local codes, and international standards that will provide opportunities for systematic safety and security reviews. This SSRA will establish a risk baseline and a consolidated approach that can be used to inform future risk assessment efforts. The transparent and detailed reporting of all data and methods in this SSRA for scenarios, pathways, event failure frequencies, source terms, initial conditions, meteorological conditions, fate and transport modeling parameters, and data source terms can be leveraged for future risk assessment efforts. In particular, the Scenario Database, a database housing relevant source term data and supporting references constructed as part of this SSRA, meets this objective and provides a dynamic and accessible tool that encourages future SSRA efforts (see Appendix B for Scenario Database details).

To effectively achieve the stated objectives, a multi-disciplinary, integrated SSRA team and process were developed to perform a qualitative assessment of all eight NBAF research pathogens; review baseline best practices; collect data on susceptible populations, vectors, or carriers; review scenarios and transportation pathways; perform quantitative epidemiological modeling of FMD and RVF; and execute economic impact analyses. Figure ES-1 illustrates how these components of the SSRA (each with unique and specific sub-objectives) are interrelated and how they serve the ultimate goal of informing design, operation, and mitigation response planning for the NBAF.

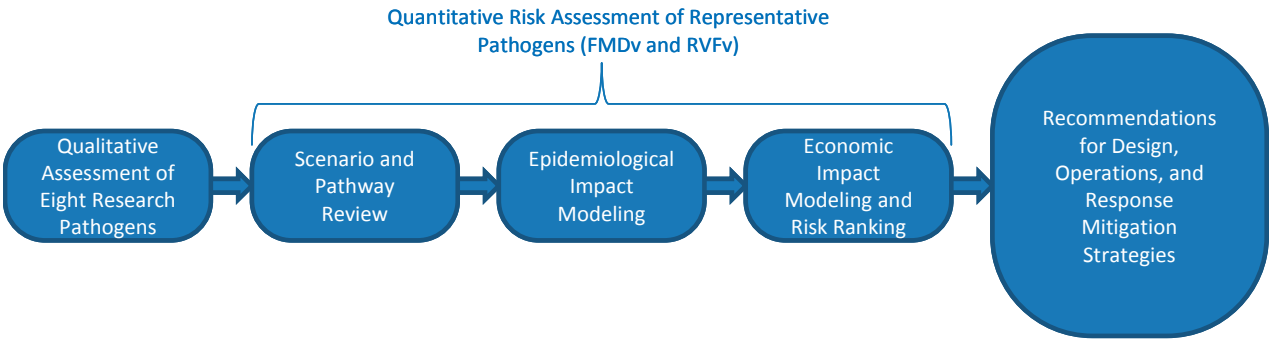


Figure ES-1: Components of the SSRA

ES3.2 Regional Considerations

This SSRA addresses specific local (Manhattan, Kansas) and regional (contiguous states) characteristics and uses high fidelity modeling techniques based on current NBAF design plans to generate a current and comprehensive assessment of safety and security risk. Properties unique to the Manhattan NBAF site such as location and density of susceptible human and animal populations, location of livestock transportation hubs, insect vector populations, sanitary sewer systems, solid waste-handling facilities, local meteorological conditions, and regional economics were factored into this evaluation of risk. An analysis of the meteorological conditions prevalent in the Manhattan, Kansas, region was performed using a 21-year (1985–2005) historical weather database, specifically developed to support aerosol transport modeling and simulation [Rife, 2010]. An example of the individual weather patterns that were used to calculate the aerosol plume and deposition patterns used in subsequent epidemiological modeling are shown in Figure ES-2.

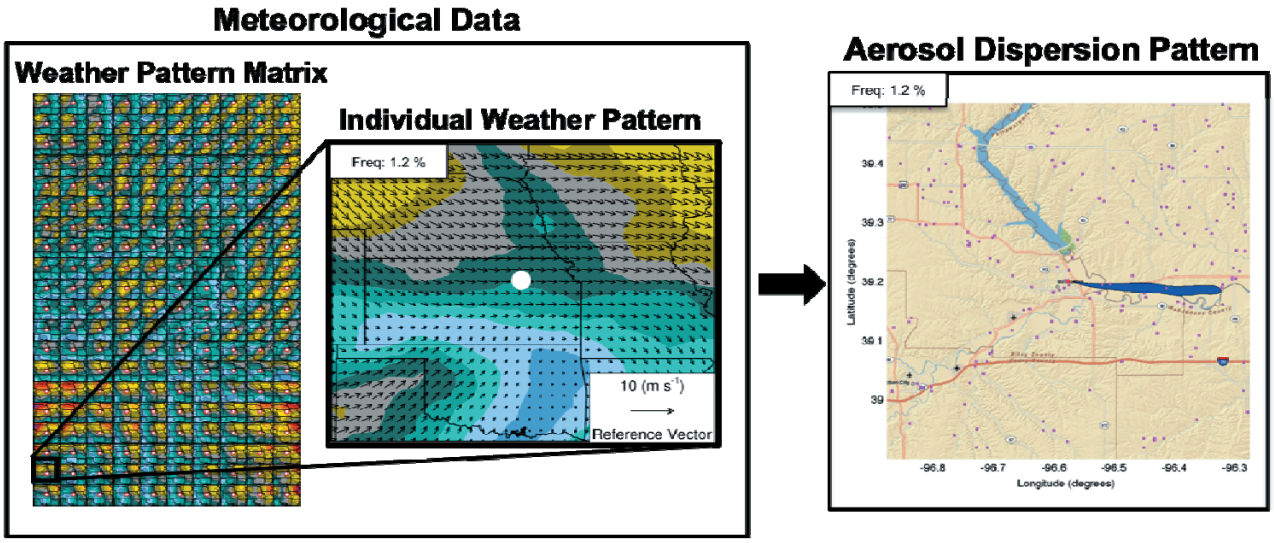


Figure ES-2: Conceptual Diagram of Aerosol Fate and Transport (Plume) Modeling Inputs/Outputs

Additionally, the total number of cattle in Kansas was estimated through detailed evaluation of Kansas-specific data sets. Figure ES-3 illustrates a sample of the level of fidelity that was developed by indicating the numerous susceptible livestock locations used in the modeling. Susceptible species were also identified (density, geographic location, and facility type) for other states of agricultural importance, including states that are contiguous to Kansas (Oklahoma, Colorado, Iowa, Missouri, Arkansas, and Nebraska) as well as others with significant numbers of livestock that could be impacted during a foreign animal disease outbreak.

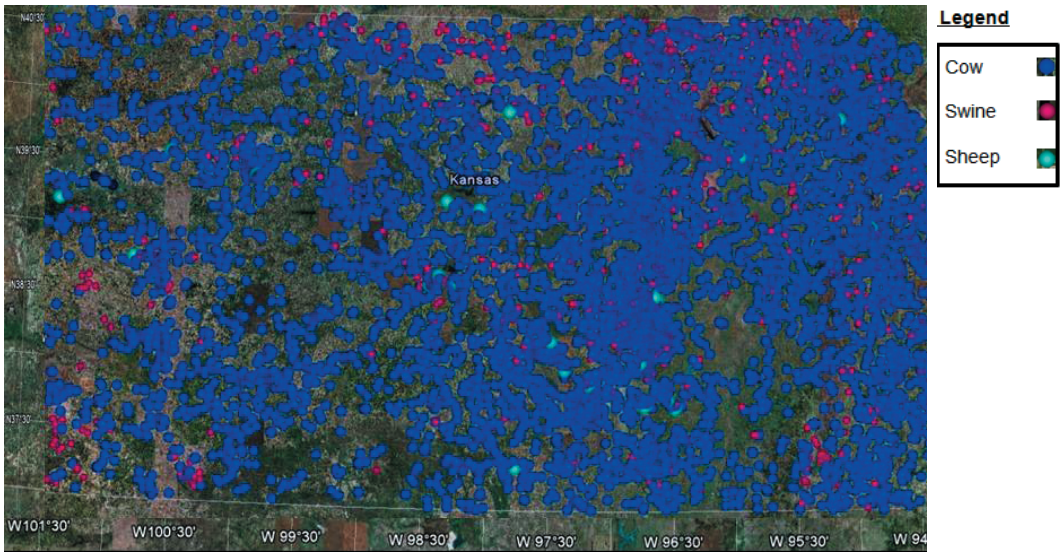


Figure ES-3: Susceptible Livestock Facility Locations in Kansas

The addition of facility type (cow-calf operation, dairy, sales barn, feedlot, etc.) and the compilation of animal movement trends in and out of Kansas to twenty other states in the primary and secondary modeling regions resulted in the ability to predict long-distance spread of disease and provide greater confidence in the modeling of the impact of a FAD outbreak (as illustrated in Figure ES-4). The addition of sales barns enhanced the ability of NAADSM (a computer program designed to simulate the spread and control of foreign animal diseases) to simulate disease spread while accounting for animal movement patterns.

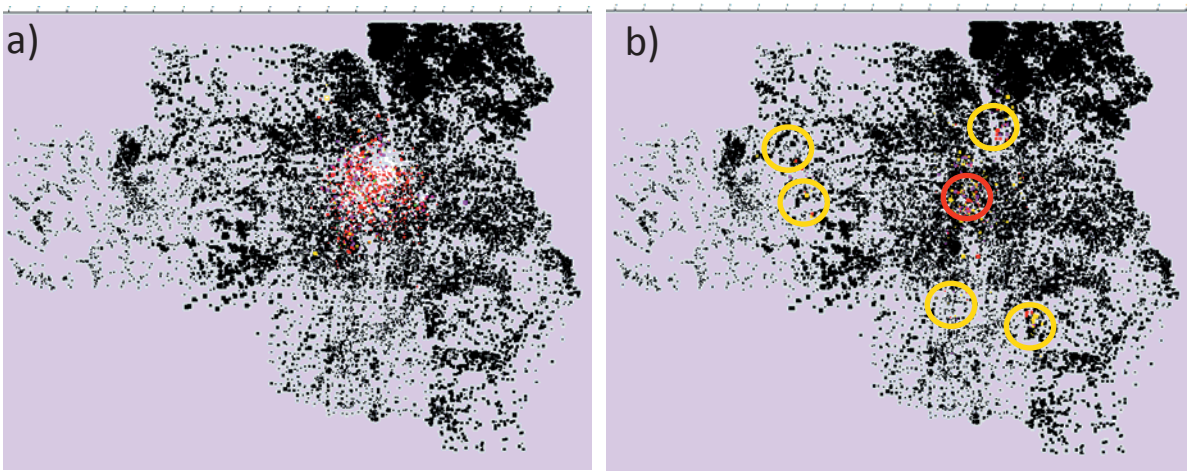


Figure ES-4: a) Spread of FMD without Sales Barns (original NAADSM), b) Spread of FMD with Sales Barns (SSRA-enhanced NAADSM)

As seen in Figure ES-4, the inclusion of the sales barns (livestock auction facilities) resulted in a wider geographical distribution of infected premises (compare ES-4a to ES-4b). Without sales barns (Figure ES-4a), the infection is more localized around the Manhattan, Kansas, area and grows in a more concentric fashion away from the source area. In comparison, ES-4b shows that multiple foci of FMD appear (yellow) well outside the Manhattan, Kansas, area (red) because of the animal shipment from sales barns.

ES3.3 Pathogens Evaluated

Eight pathogens have been proposed for the NBAF research mission in Manhattan, Kansas: African Swine Fever virus (ASFv), Classical Swine Fever virus (CSFv), Foot and Mouth Disease virus (FMDv), Rift Valley Fever virus (RVFv), Hendra virus (Hev), Japanese Encephalitis virus (JEv), Nipah virus (Niv), and *Mycoplasma mycoides* (the causative agent of Contagious Bovine Pleuropneumonia, or CBPP). All eight of these NBAF research pathogens were described in a Qualitative Hazard and Risk Assessment (QRA) entitled "*A Subject Matter Expert Panel Review of the Qualitative Assessment of Hazards and Risks Associated with Research on Eight (8) Specific Pathogens at the Planned National Bio- and Agro-Defense Facility (NBAF) in Manhattan, Kansas,*" (Appendix C) performed as part of this SSRA.

While the SSRA provides a comprehensive, qualitative evaluation of risk associated with these eight pathogens, FMDv and RVFv were selected for a more detailed quantitative assessment, which included epidemiological and economic impact modeling. Inclusion of FMDv in the SSRA was mandated by Congress in the Homeland Security Appropriation Act of 2010 (P. L. 111-83 §560). Additionally, FMDv was used because it is persistent as a dry virus in the environment, is highly contagious, is transmissible as an aerosol and in other modes, and has a sufficiently characterized etiology to be modeled effectively. Furthermore, The Food Conservation and Energy Act of 2008 (P.L. 110-246) specifically

amended a prohibition on FMDv research on the mainland in 121 U.S.C 113(a) to allow FMDv research at a designated facility on the U.S. mainland. Thus, an assessment of the economic impact from a potential outbreak of FMDv on the mainland was critical to understanding the risk and developing appropriate mitigation strategies. In an effort to expand the scope of the SSRA to include another representative risk, DHS included RVFv in the SSRA. RVFv was selected from among the seven other research pathogens because it is a zoonotic, vector-borne virus that is spread by several species of mosquito native to North America.

Based on the qualitative evaluation of the etiological, biosafety, biosecurity, and host range properties of all eight NBAF research pathogens, DHS and the QRA Subject Matter Expert (SME) panel determined that the magnitude of potential consequences and risks of a loss of containment/outbreak from the NBAF were well represented by the quantitative assessment of FMDv and RVFv (i.e., a highly contagious animal disease and a zoonotic, insect-borne pathogen) in this SSRA. Some NBAF priority research pathogens were not considered for additional scrutiny because they were not zoonotic and therefore did not provide an opportunity to model the risks to human health. In addition, although there is currently a lack of data on the etiology of other NBAF priority research pathogens, such as Nipah (Niv) and Hendra (Hev), and thus a lack of sufficient data for quantitative modeling, DHS remains committed to continuing the risk assessment process as more data and validated models become available for these pathogens.

ES3.4 Scenario and Pathway Review and Development

The SSRA modeled the NBAF risks by assessing thirteen different release scenarios. For all scenarios, whether accidental or intentional, the transport and fate of pathogenic materials could occur along one or more of four different transport mechanism pathways:

- Liquid (viable pathogen contamination of the NBAF sanitary sewerage);
- Solid (viable pathogen contamination of the NBAF solid waste disposal process);
- Fomite/Vector/Carrier (F/V/C); and
- Air and Deposition (viable pathogen release of aerosols that pose an inhalation threat to susceptible species and the deposition of such aerosols that pose ingestion or exposure threat).

Fomite: An inanimate object capable of transferring infectious material.

Vector: An arthropod or living organism that transmits an infectious agent.

Carrier: an individual that harbors infectious material but is not infected.

Eight of these scenarios were originally developed in the Health and Safety Chapter of the EIS [DHS, 2008]. Three additional scenarios were developed to provide specific consideration for additional types of accidents. Two intentional release scenarios were developed as a result of the Site-Specific Threat and Risk Assessment (TRA) [Sandia, 2010]. A panel of SSRA SMEs and the SSRA Interagency Government Review Team reviewed the scenarios and considered them to be representative of the risk-space.

The correlation between the transport mechanisms and scenarios evaluated in this SSRA is summarized in Table ES-1.

Table ES-1: Scenario and Transport Pathways

Scenario		Transport Pathway			
No.	Description	Liquid	Solid	F/V/C	Air and Deposition
1	Small/Medium Laboratory Spill with Creation of Aerosol				✓
2	Laboratory Acquired Infection			✓	
3	Lost or Escaped Vector			✓	
4	Loss of Containment by Liquid/Solid Waste	✓	✓		
5	Single Room Fire				✓
6	Single Room Deflagration/Overpressure				✓
7	Seismic (Earthquake) or High Wind (non Tornado) Event			✓	✓
8	Small Aircraft Crash Into Facility				✓
9	Human Carrier (non Infection)			✓	
10	Loss of Containment by Fomite			✓	
11	Tornado			✓	✓
12	Theft and Subsequent Intentional Pathogen Release			✓	
13	Sabotage of NBAF Systems or Processes with Subsequent Pathogen Release	✓	✓		✓

Each of the 13 scenarios listed above included multiple cases that were examined in the SSRA. A case identifier was created for each pathogen and for a specified set of conditions. The general methodology used for the estimation of case modeling parameters such as the source terms, initial conditions, and failure frequencies was derived from peer-reviewed literature and techniques used in the EIS that were reviewed by SSRA SMEs. Details regarding the development of the source terms and initial conditions (including assumptions and corresponding references) are provided in this report and are included in a Scenario Database (SD), a deliverable of the SSRA. The “splash” screen (initial screen) for the SD application is shown in Figure ES-5.

The SD allows for transparent and detailed reporting of all data and methods in the SSRA regarding scenarios, pathways, event failure frequencies, source terms, initial conditions, meteorological conditions, fate and transport modeling parameters, and data source terms. The SD will also provide a solid framework for future NBAF pathogen risk assessments. The scenario and pathway review and resulting SD documented the set of potential NBAF loss-of-biocontainment scenarios that were used to model epidemiological outcomes and economic consequences for the SSRA.

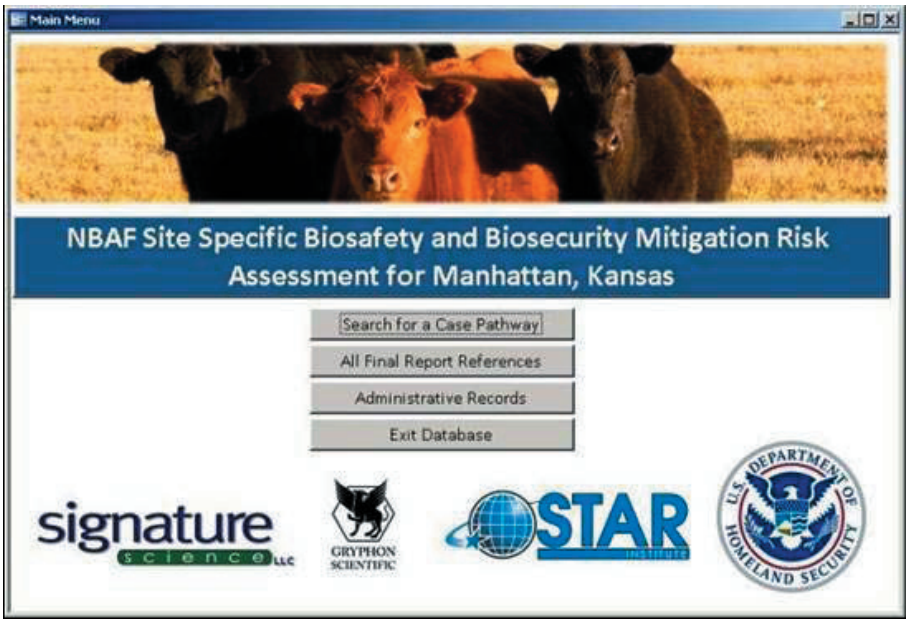


Figure ES-5: Scenario Database Splash Screen

ES3.5 Epidemiological and Economic Modeling

Epidemiological modeling was performed on the spread and subsequent control of FMD and RVF that may result from any of the loss-of-containment scenarios. Epidemiological modeling served to test various hypotheses on the relative value of risk mitigation measures and enabled the SSRA team to quantify (for risk-ranking applications) the overall impact (in terms of number of susceptible populations infected) of a release from the NBAF. The epidemiological modeling incorporated pathogen fate and transport modeling data that determined the extent to which agents such as FMDv and RVFv would be dispersed by the pathway mechanisms in the event of a containment loss. The output of the epidemiological models served as input for the economic models.

Based on epidemiological impact data, economic consequence assessments were performed to determine the economic effect of a pathogen release (e.g., FMDv or RVFv) on the susceptible populations and to project costs and disruptions to public and private trade activities (such as animal commodity flow, and collateral industry and workforce populations). The economic modeling included four market sectors of significance: beef, swine, dairy cattle, and grain at both the regional and national levels. This assessment served to provide cost-benefit analyses of proposed countermeasures and mitigation strategies (e.g., containment, clean up, and animal stock movement zones) that factored into the overall risk ranking and final recommended design, operations, and response mitigation strategies for NBAF.

ES4 Key Results of the SSRA

The highest risk-ranked loss of containment cases are ultimately assignable to human error. An overview of these results and a summary of SSRA recommendations are presented in ES4.1 and ES4.2.

ES4.1 Risks and Risk Rankings

The estimated frequencies and economic consequences of each of the 44 modeled cases were identified and the relative risk of each case ranked according to the overall risk (economic consequences multiplied by the case frequency to yield risk dollars) to provide prioritization for the principal NBAF recommendations. As illustrated in Figure ES-6, the majority (97%) of the risk space (as defined by risk dollars) was represented by the Fomite/Vector/Carrier transport pathway. The air and deposition transport pathway represented <3% of the overall risk space while the liquid effluent and solid waste pathways were minor contributors to the overall observed risk.

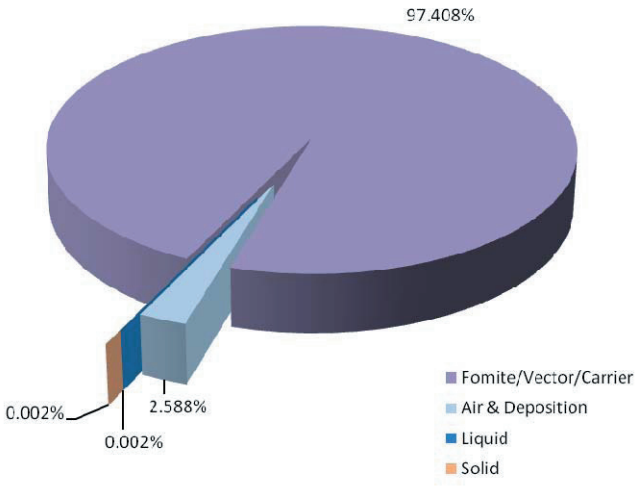


Figure ES-6: Percentage of Risk Consequences by Pathway

The results for several of the modeled cases indicated that a disease outbreak would not result from the modeled pathogen release. Other cases were found to be of low-medium risk because of a low accident frequency—even if the consequences were high. For example, an FMD outbreak occurring as a result of a failure in the liquid effluent decontamination system has very significant economic consequence (>$23B), but due to the many redundancies that are built into the engineering and operational protocols, this event had an estimated frequency of once every 2.1 million years. Thus, this is a medium risk case. Many of the cases that involved the accidental transfer of FMDv through a fomite or non-infected human carrier are considered high risk because of the relatively higher accident frequency and the substantial economic consequences.

Ultimately, the risk rankings were used to prioritize the recommendations presented in Section ES4.2. These recommendations were made to inform the current stage of the NBAF design and other planning activities. While in the process of collecting data to support the SSRA modeling processes and risk ranking, many other potentially useful observations were made and suggestions were developed that are documented in Section 7.3. While not directly correlated to the conclusions or ranked risks, they provide additional information that may be used to inform the NBAF development process.

ES4.2 SSRA Recommendations for Enhancements to Current Design, Operations, and Mitigation Strategies

DHS commissioned the SSRA early in the NBAF design and operational planning phase to purposefully solicit the best design, operations, and response strategies and to ensure that the NBAF is a safe and a secure agricultural research facility. This SSRA sought to validate design and operations best practices that are appropriate for NBAF and to identify enhanced design, operations, and response planning recommendations above and beyond the applicable standards—to further mitigate risks. The analyses from the SSRA conclude that the NBAF can be designed and operated in a safe and secure manner. Several of the recommendations developed from the results of the SSRA analyses were previously anticipated by DHS and will be addressed prior to commissioning of the NBAF. The conclusions of the SSRA are summarized in Table ES-2.

Table ES-2: SSRA Conclusions

1	The Fomite/Carrier/Vector pathway was found to be the pathway of greatest risk, provided that the evolution of the current NBAF schematic design (modified with SSRA recommendations) continues to be consistent with applicable regulations, appropriate standards, and best practices used in this assessment.
2	The current NBAF design strategy was found to be generally consistent with requirements and best practices for containment facilities used for animal **and** human pathogens.
3	DHS has developed and is successfully using an integrated NBAF planning team comprised of engineers, architects, scientific end-users, biosafety, biosecurity, and animal husbandry experts to inform the design, operational strategy development, and mitigation and response planning efforts.
4	The design and engineering strategies that are being used by the NBAF Design Partnership are consistent with current construction and engineering code requirements.
5	The SSRA assessment of the current NBAF design (90 mph design load with 1.15 Importance Factor and 1.6 Factor of Safety) indicated that an F2 or greater intensity tornado may cause a loss of biocontainment. DHS has specified that the NBAF should be able to maintain containment if struck by an F2 or lesser intensity tornado, and planning efforts are underway to modify the schematic design to be consistent with this requirement.
6	Security features included in the NBAF site layout, as recommended by the TRA, have been successfully integrated into the current plans.
7	NBAF's central location (Manhattan, Kansas) provides timely access to all parts of the country for sample receipt and handling while minimizing staff commuting demands and fostering advanced research opportunities with other government, academic, and private institutions.
8	NBAF operational strategies are in the early stages of development and are expected to produce comprehensive operational and management plans to provide NBAF with the highest levels of safety, security, animal care, and research capabilities.
9	NBAF mitigation and response strategies are being developed that will involve local, regional, state, and tribal governments as well as relevant academic and private entities. This integrated mitigation strategy serves several purposes and will provide another layer of biosafety and biosecurity for the NBAF.

Recommendations developed for the SSRA were prioritized using the risk ranking presented in Section 6. The prioritized recommendations are presented in Table ES-3. This table includes the recommendation number, a summary of the recommendation, a summary of the supporting rationale, and comments on the impact of the recommendation.

Table ES-3: Prioritized Recommendations			
No.	**Recommendation**	**Rationale**	**Impact**
1	DHS should initiate the development of NBAF staff training programs as soon as is practically possible. The control of fomites, vectors, carriers, and laboratory acquired infections is one of the most important elements of risk control for the facility.	The early development of training programs will facilitate the incorporation of best practices from facilities that perform research on animal and/or human pathogens. The aggregation of these different standards may highlight divergences in operational protocols, procedures, and training. It is important to identify such compatibility issues early to provide as much time as possible to adjust and validate new protocols, procedures, and training methodologies before the NBAF is commissioned.	When implemented, well-established training programs provide mitigation for the risk associated with containment loss by human error.
2	DHS should convene professionals from the design team and other subject matter experts to explore all of the options available to the NBAF for carcass disposal systems. Currently, incineration is the primary technology and alkaline hydrolysis is designated as a secondary process. (However, very recent developments have indicated that rendering might be considered as the primary technology.) This group should make a final recommendation to DHS before the schematic design evolves to the next level.	Each carcass disposal technology has inherent risks and benefits. The DHS/NDP strategy to use redundant technologies at NBAF is excellent. The selection of these technologies, however, may warrant a more detailed assessment and analysis than has been performed to date. Nearly every disposal option is constrained, to some extent, by technical limitations and regulatory requirements.	The safe and effective neutralization of pathogenic material in infected carcasses is a key element in the overall strategy to mitigate the risks associated with the release of fomites. Since these systems are inherently large, complicated, and integrated into the facility, the design should be informed with a high-confidence selection of carcass disposal systems.

Table ES-3: Prioritized Recommendations			
No.	**Recommendation**	**Rationale**	**Impact**
3	DHS should strictly limit access to the NBAF laboratory areas and minimize the potential for unauthorized visitors. When access to the containment block is required (FADD students), strict escort protocols must be followed and visitors must be provided with ingress/egress training and/or supervision.	Visitors and FADD school attendees will potentially have the least experience and familiarity with NBAF biosafety requirements and containment systems. For safety and security reasons, these individuals should be limited to specific laboratory areas—only those designated for training activities or other official business.	Limited access is an important aspect of the mitigation for the risk associated with containment loss by human error. Untrained, undertrained, or improperly trained persons enhance the risk of containment loss. In addition, biosecurity concerns and current regulations require strict access limitations.
4	The NBAF Biosafety Officer is responsible for developing respiratory protection guidelines with specific regard to staff and visiting researchers who work in a BSL-3Ag environment with large animals infected with non-zoonotic pathogens. The appropriate guidelines for evaluating respiratory protection should be prepared prior to completing the facility design.	While there are potential risks associated with the non-infected pathogen-carrying human, the safety and efficacy of working with large animals while wearing respiratory protection are problematic. Wearing respiratory protection may limit the field of vision or distract individuals while in the midst of performing high-risk procedures or animal transfers. Thus, the determination of need for respiratory protection for humans working in the BSL-3Ag area should be made after careful consideration by the Biosafety Officer of the animal pathogen (disease), animal species, and risk associated with the specific activity.	The SSRA assessed that the risks associated with the inadvertent transfer of viable pathogenic material from a containment area can be relatively high. The Biosafety Officer will be in the best position when working with researchers and other biosecurity professionals to make program or case-specific respiratory protection policies that will help mitigate these risks in accordance with federal and facility-specific guidelines.

Table ES-3: Prioritized Recommendations			
No.	**Recommendation**	**Rationale**	**Impact**
5	Non-operational containment integrity (static containment) should be maintained for up to an F2 event. DHS will implement this requirement in the schematic design and construction plan. This recommendation also applies to portions of the Central Utility Plant (CUP) that provide essential services to the laboratory facility while in "shut down" mode after a tornado strike. In addition, the design team should perform a technical assessment to determine if the F2 working loads would provide F3 static containment. If not, the design team should assess the marginal costs of satisfying F3 requirements for static containment and DHS should evaluate the cost/benefit analysis before finalizing the facility design.	Quantitative modeling of FMDv and RVFv indicated that there was the potential for FMD disease outbreak (models indicated no outbreak of RVF would follow a tornado strike) if NBAF were struck by a tornado with wind speeds above its design load. The estimated mean economic consequence of an FMD outbreak could exceed $5B.	Facility hardening will help mitigate the risks of biocontainment loss for an F2 (or F3) tornado event and provide mitigation for other natural disasters and intentional scenarios.
6	DHS should provide additional expertise to the design team to include an engineering organization that has extensive design experience in high-wind event mitigation practices. This additional resource would assist DHS in setting the most appropriate design specifications and reviewing the developments of the NBAF design as it evolves.	The current design team has done a very good job accommodating requirements that have been provided to them in a dynamic environment that is challenged by balancing mission needs, schedule issues, and budgetary concerns. An outside entity with wind engineering design expertise will enhance the real and perceived responsiveness of DHS to the tornado threat issue.	The expertise and focused discussion and design enhancements will help satisfy the requirements of Recommendation 5.

Table ES-3: Prioritized Recommendations			
No.	**Recommendation**	**Rationale**	**Impact**
7	DHS should consider adding a requirement to install an on-site underground sanitary sewage waste retention system. This system should be able to accommodate at least one day's worth of liquid effluent and incorporate the ability to be sanitized and/or bypassed as needed.	Although the SSRA indicates the risk of liquid waste effluent contamination is very low, the temporary wastewater retention capability adds another layer of protection to the facility and provides mitigation for several identified risks.	An onsite sanitary sewage retention system will provide additional response options for an accidental release and will provide mitigation for risks associated with the temporary loss or denial of municipal discharge capacity.
8	DHS should develop and implement a plan for identifying resources with local and regional entities to enhance and exercise Foreign Animal Disease (FAD) Emergency Response Plans. Observations and suggestions regarding implementation of this recommendation are provided in Section 7.3.3. DHS conducted a meeting with regional and state officials on May 25, 2010, to begin this exchange.	Albeit a very unlikely event, local and regional entities will be on the "front lines" of a response to any NBAF FAD issue. The ability of the initial responders to quickly and effectively execute response plans significantly reduces the potential consequences of an event and enhances the perception of response readiness—further reducing risks.	The integrated response team must be equipped with the appropriate tools and have the opportunity to exercise the plans in order to provide response actions that will minimize the impact of any containment loss—potentially preventing disease outbreak.
9	DHS should resolve details regarding the final disposition of solid waste removed from the high-containment areas. The current plans require double (series) autoclaving of solid waste, followed by temporary storage of sterilized waste in an uncontained area before transfer to an unidentified witnessed waste incineration provider in the Kansas City area.	Even though all solid waste will be serially autoclaved before removal from the containment block, it is important to maintain positive control until it can be destroyed or permanently stored in a controlled-access landfill. The motivation for the positive control is twofold: 1) prevent the release of sterilized but recognizable solid waste, and 2) provide a final level of protection in the unlikely case that the solid waste is not properly sterilized.	The resolution of this issue is part of the overall strategy to reduce the risks associated with releases from fomites/vectors/carriers.

Table ES-3: Prioritized Recommendations			
No.	**Recommendation**	**Rationale**	**Impact**
10	DHS should evaluate additional solid waste disposal options for non-containment waste located in close proximity to the NBAF. A dedicated site for disposition with controllable access and scavenger exclusion features would minimize this risk. It is recommended that DHS engage with Riley County officials to investigate the possibility of developing a local landfilling option (as a county function) that has limited access and practices/features that will minimize the potential of animal/insect/human contact with NBAF refuse.	Riley County does not currently have an operational landfill. There is some small potential for contaminated waste to errantly leave NBAF through the non-containment solid waste pathway.	The resolution of this issue is also part of the overall strategy to reduce the risks associated with releases from fomites/vectors/carriers.
11	DHS should consider adding an NBAF requirement to identify an emergency supplier for potable water (mobile provider) or install an on-site potable water supply reservoir. In either case, 1-3 days of potable water should be available in case normal potable water supplies are temporarily unavailable.	Having a source of guaranteed potable water would permit NBAF research to continue in a safe and normal mode unless the anticipated service interruption would cause exhaustion of the reserves or available supplies. A service interruption elevates risk levels because there may be fewer decontamination procedures, higher levels of animal culling (if the situation becomes critical) and less diluent (washdown water) introduced to the NBAF Effluent Decontamination System (EDS).	Continued access to potable water during a temporary denial of service will help mitigate the risks associated with the suspension of normal operational procedures and hygiene practices that are necessary to manage multiple containment risks.

Table ES-3: Prioritized Recommendations			
No.	**Recommendation**	**Rationale**	**Impact**
12	DHS should accommodate the permanent addition of a laboratory mock-up facility. A mock-up facility is critical to preliminary equipping of the facility and DHS has included a temporary mock-up as part of the NBAF development process. The recommendation is to provide an on-site location for the mock-up so that it can become a permanent non-operational fixture that may facilitate training and operational readiness exercises.	A permanent mock-up provides a useful resource to evaluate new systems or to determine how systems from different suppliers may be successfully integrated. The permanent facility can also be used for orientation training, public outreach, and media relations.	The permanent mock-up facility provides additional risk management opportunities for several of the identified risks, particularly during orientation, training, and development of procedures.
13	The NBAF should incorporate basic design features to facilitate the safe and humane movement of animals through the facility. Examples include rounded corners, adjustable penning, lighting considerations, and other features that will help maintain animal temperament and minimize animal agitation.	The current schematic design and BSL-3Ag and ABSL-4 layouts have not yet identified the design features that should ultimately be incorporated into the NBAF construction plans. While it is anticipated that large animal movement considerations will be included as the design matures, early consideration of these issues may drive changes to the facility layout. Such considerations are important because there are many risks associated with the movement of ill-tempered or agitated large animals.	Risks to personnel and biocontainment are minimized when the handling of large animals can be performed without the additional hazards associated with uncooperative livestock.

Table ES-3: Prioritized Recommendations			
No.	**Recommendation**	**Rationale**	**Impact**
14	Documentation and publications that describe NBAF activities and pathogens should identify the current capabilities associated with research, diagnostics and training demonstrations.	From some public documentation regarding the planned activities at NBAF, it could be inferred that the eight proposed research pathogens are the only pathogens that will be stored and manipulated at the facility. DHS' proactive inclusion of the pathogens associated with diagnostics and training, when referencing the research pathogen list, will prevent miscommunication and facilitate mitigation and response planning.	All persons and entities involved in design, operations, and response planning should be informed of the full potential suite of pathogens that will be used at the facility. Transparency and proactive communications are key to mitigating many identified risks.
15	The NBAF should develop a proactive maintenance program that includes preventative and predictive maintenance procedures.	Preventative and predictive maintenance programs not only extend the functional lifespan of the facility, but also decrease the overall operational costs and risks.	The assumptions used to develop the risk rankings are predicated on having a sound maintenance program. If a proactive maintenance program is not used, the risk ranking would need to be adjusted to reflect the higher probabilities of failures associated with engineered systems.
16	DHS should consider developing site-specific natural disaster and enhanced disease surveillance and response plans for inclusion in NBAF's operating procedures. Disease surveillance plans for local and regional facilities should also be developed in conjunction with public and private sectors.	In conjunction with other federal, state, and local agencies, several potentially-disruptive natural phenomena could be anticipated (blizzard, heavy snow, hail, high-wind, tornado, flooding, lightning, and potentially seismic events) and operational procedures may be temporarily adjusted or limited to minimize risks to staff, animals, and the public.	Information from natural disaster and disease surveillance are critical to facility response protocols and will minimize risks associated with these events. Local/regional disease surveillance is an important part of the risk reduction strategy because the spread of disease may be curtailed when disease is identified early in susceptible species outside of containment.

Table ES-3: Prioritized Recommendations			
No.	**Recommendation**	**Rationale**	**Impact**
17	DHS should implement all personnel screening requirements from the Employee Access program as well as security requirements currently in use at the PIADC, and consider adding personnel security requirements recommended by the Working Group on "Strengthening Laboratory Biosecurity in the United States" established by Executive Order 13386 on 9 January 2009, and the report "Responsible Research with Biological Select Agents and Toxins" prepared by the Committee on Laboratory Security and Personnel Reliability Assurance Systems for Laboratories Conducting Research on Biological Select Agents and Toxins of the National Research Council.	The findings of the SSRA indicate that a culture of personal responsibility and technical vigilance are important components of NBAF biosecurity and biosafety strategies. Personnel screening programs and security requirements provide significant risk mitigation for several of the identified risks and provide the foundation needed to cultivate a laboratory culture that is based on professionalism and mutual trust. Scientific peers at NBAF will have the flexibility to share data and laboratory observations with the assurance that all personnel and visitors are vetted, responsible, and trusted with information, findings, and materials that are critical to the NBAF mission.	Highly-selective personnel screening and security requirements for employees and authorized laboratory visitors may complicate the processes associated with hiring and vetting NBAF researchers and staff. However, the investment in this risk mitigation technique will help minimize the potential for a loss (intentional or unintentional) of biocontainment and the resulting economic and/or public health consequences. Long-term support of the NBAF's mission depends on avoiding incidents that have a negative impact on the economy, food security, and US public health. The complexities associated with stringent personnel security are considered to be minimal in comparison to the potential consequences.