



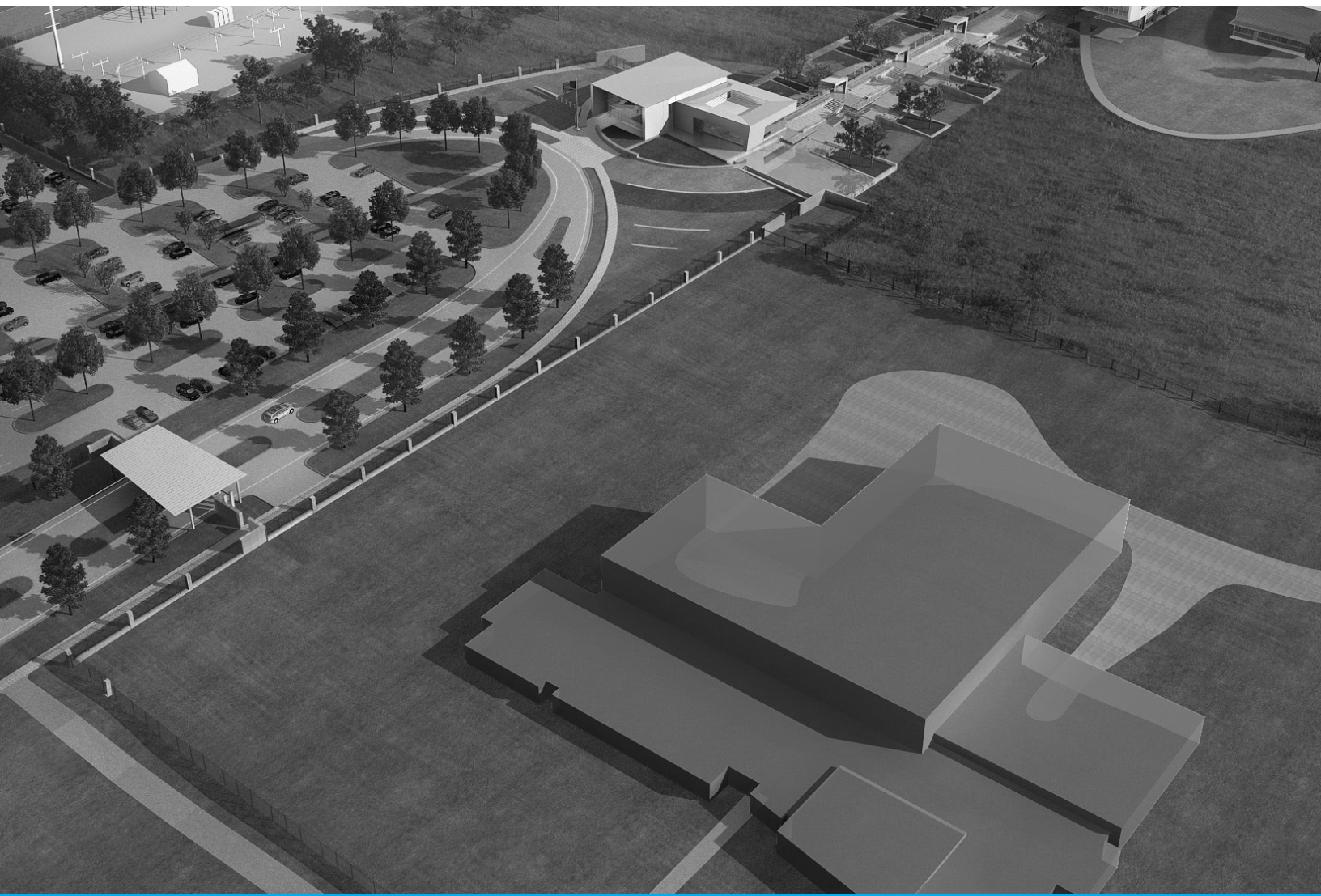
CREATING A NATIONAL ASSET FOR AMERICA'S BIOSECURITY INFRASTRUCTURE



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1

EXECUTIVE SUMMARY



CREATING A NATIONAL ASSET
FOR AMERICA'S BIOSECURITY
INFRASTRUCTURE



PROTECTING OUR NATION'S AGRICULTURE

NBAF
will be the
only large-
animal,
maximum-
containment
health
laboratory in
the country.

The National Bio and Agro-Defense Facility (NBAF) will be the premier center of scientific excellence for the study of transboundary, emerging, and zoonotic animal diseases (those transmitted between animals and humans) that threaten U.S. agriculture economy, food supply, and public health. This state-of-the-art facility will be a national asset that helps protect our nation's agriculture and its citizens against the threat and potential impact of serious animal diseases.

NBAF will ultimately replace the existing Plum Island Animal Disease Center (PIADC) and all its essential functions, as well as provide additional capabilities for early development of veterinary medical countermeasures.

Bio and agro-defense are essential. According to the World Health Organization (WHO), approximately 75 percent of new and emerging infectious diseases are zoonotic diseases which may be transmitted from animals to humans. Biological and agricultural defense is not just about protecting America; it is also about supporting global public health and food security.

Agriculture, food, and food processing contribute more than \$3.9 trillion to the U.S. economy per year, representing 22 percent of the domestic economy.¹ NBAF will be a critical component of a key United States Department of Agriculture (USDA) priority – the development of vaccines and other countermeasures for diseases that threaten livestock and other animals and food from our nation's farms. NBAF will specifically facilitate transboundary animal disease research to provide solutions to problems associated with the control, eradication, and recovery of priority diseases. NBAF will maintain a portfolio of expertise that will allow it to rapidly respond to new and unforeseen disease threats. Since transboundary animal diseases and/or new emerging diseases cause disease outbreaks worldwide every year, priority setting requires a flexible and rapid system to ensure the scientific program at NBAF can effectively respond to any disease outbreak that may threaten the United States.

Once NBAF becomes fully operational, it will provide several "firsts" for the U.S., including a maximum containment large animal Biosafety Level (BSL) 4 facility to study particularly dangerous zoonotic agents in large animals and a Biologics Development Module (BDM) to enhance and expedite the transition from research to commercially viable countermeasures. This will place NBAF at the nexus of the biodefense and agro-defense domains and establish NBAF as a leader among biocontainment laboratories.

¹ Kansas Department of Agriculture, 2017

NBAF MISSION

Provide an enduring capability to enable the United States to conduct comprehensive research, develop vaccines, and provide enhanced diagnostic and training capabilities to protect against transboundary, emerging, and zoonotic animal diseases that threaten our nation's food supply, agricultural economy, and public health.

NBAF VISION

A safer and more resilient America through a world-class, connected science facility for large animal agricultural research, training, and diagnostics.

To accomplish NBAF's mission, USDA will have strong relationships with stakeholders to set the priorities of the program and develop collaborative partnerships regionally, nationally, and internationally. USDA is a willing partner and will look to leverage our resources and expertise with partners from academia, the private sector, other Federal agencies, livestock and veterinary associations, and partner countries.

“USDA’S most important responsibility is ensuring the safety of the food we eat, because it is undeniably true that food security is national security.”

*Sonny Perdue,
U.S. Secretary Of Agriculture*

This document provides a vision of how NBAF will be operated and how scientists will work to protect our food supply and global health. It is intended to create a big-picture understanding of the NBAF facility. USDA encourages citizens' and stakeholders' interest in NBAF and USDA looks forward to serving the U.S. and contributing to global animal and public health with this new, state-of-the-art facility.

2 CREATING A NATIONAL BIOSECURITY ASSET



CREATING A NATIONAL ASSET
FOR AMERICA'S BIOSECURITY
INFRASTRUCTURE



PROVIDING A SAFER, MORE RESILIENT AMERICA

NBAF will greatly expand USDA's contribution to protecting the U.S. from dangerous threats and economic consequences of animal diseases.

Located in Manhattan, Kansas, NBAF will be one of the most advanced biocontainment facilities in the world, providing a safer, more resilient America through a state-of-the-art, connected science center for large animal agricultural research, training, and diagnostics.

NBAF will protect U.S. agriculture, farmers, and the American public from transboundary animal and dangerous, exotic zoonotic diseases by facilitating research, developing vaccines, performing diagnostic testing, and training researchers and veterinarians to respond to biothreats.

USDA is a world leader in animal disease research and diagnostics. Protecting the American public and U.S. agricultural production from transboundary animal and dangerous zoonotic diseases is a core mission of USDA. USDA will create a culture of collaboration and cooperative decision-making that enhances and advances the science of NBAF. NBAF will realize the synergy of multi-agency and multi-collaborator contribution to the Federal mission.



THE IMPORTANCE OF NBAF

To understand the need for NBAF, consider the consequences of an animal disease outbreak. In 2011, Iowa State University performed an economic analysis of the possibility of an outbreak of foot-and-mouth disease (FMD) in the U.S. The study described “enormous” losses that spread well beyond the pork and beef sectors. The report showed significant revenue reductions for poultry, corn, and soybean producers, as well as impacts to employment in rural areas as the U.S. pork and beef sectors are forced to downsize. Revenue losses in the combined U.S. pork and beef industries fall by an average of \$12.9 billion per year. The removal of this level of value-added activity is equivalent to the loss of as many as 58,000 full-time jobs.¹

¹ Dermot Hayes, Jacinto Fabiosa et al., “Economy Wide Impacts of a Foreign Animal Disease in the United States,” November 2011.

Agriculture, food & food processing contribute \$3.9+ trillion to the U.S. economy per year, or 22% of the domestic economy.

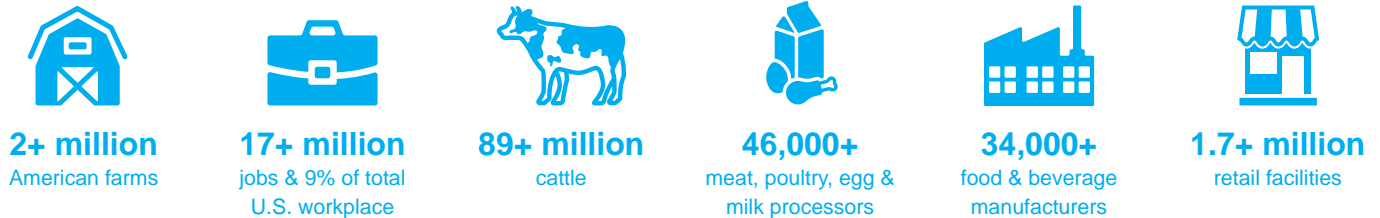


Figure 1: NBAF is essentially an insurance policy against a catastrophic risk to a critical sector of U.S. infrastructure.

If a FMD outbreak were to occur in the Midwest and no emergency vaccination program was implemented, the research found estimated losses to producers and consumers at approximately \$188 billion U.S. dollars (USD) and additional government losses at \$11 billion USD due to controlling livestock movement and depopulating infected livestock.

However, if an aggressive emergency vaccination program was implemented, such as a 50-kilometer (31-mile) vaccination zone where livestock were vaccinated at a rate of 50 herds per day at day 22 and 80 herds per day at day 40 from the onset of an outbreak, the economic losses would be reduced significantly to \$56 billion for producers and consumers and \$1.1 billion in governmental costs.² Generating this sort of response capability is a central part of NBAF's mission.

In the past, outbreaks of FMD in the United Kingdom (cost of about \$11 billion³), South Korea (cost of about \$2.88 billion⁴), and elsewhere have led to the culling of entire herds of cattle. Such threats have grave implications for the economic health of the U.S. agriculture industry, and more importantly, could affect the country's ability to produce affordable food for the nation and for export. Secondary and tertiary effects could include long-term environmental problems (e.g. consequences of disposing destroyed animals) and social and political impacts such as reduced confidence in government, reduced confidence in food safety, and economic and social disruption resulting from fear of tainted food.

² Ted Schroeder, Dustin Pendell, "Economic Impact of Alternative FMD Emergency Vaccination Strategies in Midwestern United States," July 2015.

³ D. Thompson, P. Muriel et al., "Economic costs of the foot and mouth disease outbreak in the United Kingdom in 2001." *Rev Sci Tech*, 2002 Dec, 21(3): 675–687.

⁴ T.J.D. Knight-Jones, J. Rushton, "The economic impacts of foot and mouth disease – What are they, how big are they and where do they occur?," *Preventive Veterinary Medicine*, 2013, Vol. 112,3-4: 161-73.

HISTORY OF NBAF



The decades-long work at PIADC in foreign animal disease research and diagnostic activities produced a number of significant achievements, such as the determination of the chemical structure of foot-and-mouth disease virus (FMDV).

NBAF modernizes and expands the mission of the highly successful PIADC, which has been in operation since 1954. Scientists at PIADC produced a number of significant achievements, such as the determination of the chemical structure of foot-and-mouth disease virus (FMDV); development of a thermostable vaccine for rinderpest virus critical to its eradication; and the creation of a non-replicating molecular vaccine for FMDV, as well as validation of diagnostic tools for deployment to the U.S. National Animal Health Laboratory Network (NAHLN).

Due to the age and condition of PIADC, as well as the need to expand capabilities of the scientific programs, a recapitalization to support of the activities at PIADC was necessary. Accordingly, Homeland Security Presidential Directive (HSPD) 9: Defense of U.S. Agriculture and Food, released in 2004, directed the Department of Homeland Security (DHS) and USDA to develop a plan to provide “safe, secure, and state-of-the-art” agriculture biocontainment capabilities for research and diagnostics. The result will be NBAF — with a coordinated homeland defense strategy that aligns with DHS and USDA missions. NBAF will directly support the mission by providing the necessary integrated infrastructure to improve our understanding of potential bioterrorism employing foreign animal and zoonotic disease pathogens against U.S. targets, and by developing abilities to improve countermeasures against such threats so that we may better anticipate, prevent, and mitigate the consequences of attacks on U.S. animal agriculture. Underscoring the significance of the interagency mission of bio and agro-defense, HSPD-9 also required the establishment of a National Veterinary Stockpile (NVS), later initiated by USDA Animal and Plant Health Inspection Service (APHIS), housing “sufficient amounts of animal vaccine, antiviral, or therapeutic products to appropriately respond to the most damaging animal diseases affecting human health and the economy and that will be capable of deployment within 24 hours of an outbreak.”

At full operational capability (FOC), all programs now performed at PIADC will be relocated to NBAF and the existing PIADC facility will be closed. NBAF will meet the specific requirements described in HSPD-9 as it provides an enduring capability for the U.S. to conduct comprehensive research, develop vaccines, and provide enhanced training and diagnostic capabilities to address foreign animal, emerging, and zoonotic diseases which threaten the U.S. food supply, agricultural economy, and general public. The facility will augment the existing biodefense complex by adding BSL-4 and BDM capabilities, which are presently lacking. These capabilities will enhance the related risk-characterization and forensics capacity. The combination of these capabilities will ensure that our nation has the infrastructure required to develop promising bio and agro-defense countermeasures, assess their safety and effectiveness, expedite their development, and provide test and evaluation capacity to support rapid licensure.

NBAF allows USDA to expand its scientific mission and its connectedness with academia, the Kansas City Animal Health Corridor (KCAHC) and other USDA laboratories, including the National Veterinary Services Laboratories (NVSL), National Animal Disease Center (NADC), and Center for Grain and Animal Health Research (CGAHR). USDA Agricultural Research Service (ARS) will be able to conduct research to defend against especially dangerous disease agents they currently cannot study, as well as emerging diseases. APHIS will be able to conduct diagnostic testing on samples of unknown zoonotic potential, increase testing capabilities for outbreaks, increase its ability to validate tests for the NAHLN, enhance training facilities for veterinarians in the detection of foreign animal diseases, and increase its capacity to monitor worldwide disease trends and threats. NBAF facilities greatly expand USDA's contribution to protecting U.S. people and animals from dangerous threats and the economic consequences of those diseases.

NBAF R&D WILL HAVE EXPANDED CAPABILITIES

	PIADC	NBAF
Biosafety Level 2	5,300 sq ft	9,700 sq ft
Biosafety Level 3 (3Ag + 3E)	72,000 sq ft	81,000 sq ft
Biosafety Level 4		13,400 sq ft
Biologics Development Module		8,300 sq ft
Research:		
Foot-and-Mouth Disease	●	●
African Swine Fever	●	●
Classical Swine Fever	●	●
Japanese Encephalitis		●
Rift Valley Fever		●
Nipah Virus		●
Ebola Virus		●
Emerging Pathogens (unknown)		●
Testing of Potential Vaccines to Shorten Development Timeline		●
Diagnostics for Foreign Animal Diseases	●	●
Foreign Animal Disease Training	●	●
Diagnostics for Foreign Animal and Zoonotic Diseases		●
North American Foot-and-Mouth Disease Vaccine Bank	●	●

Figure 2: NBAF Mission Area: R&D, Diagnostics, Training, and Vaccine Development

3

BUILDING AND OPERATING A STATE-OF-THE-ART LABORATORY



CREATING A NATIONAL ASSET
FOR AMERICA'S BIOSECURITY
INFRASTRUCTURE



A NEXT-GENERATION LABORATORY

NBAF will include the nation's only maximum biocontainment space capable of housing cattle and other large livestock.

NBAF's purpose is to provide all necessary capabilities to accomplish the overarching mission to carry out basic and applied research, diagnostics, training, and development of countermeasures for transboundary animal and zoonotic diseases in a safe, secure, and sustainable biocontainment facility. The facility's Basis of Design (BOD) was finalized on January 20, 2015 and provides detailed information on design intent and describes the facility capacity to meet scientific mission needs. The documented scope for operational requirements and the approach for steady-state operations are based on nationally and internationally recognized standards and have been benchmarked with peer institutions.

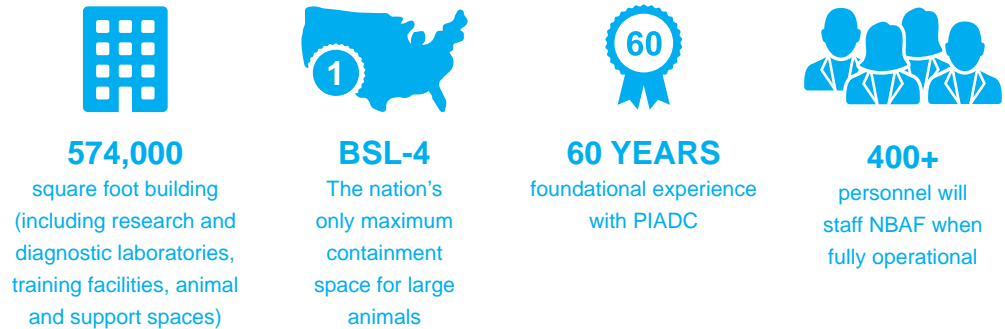


Figure 3: The completed NBAF site will be over 700,000 square feet.

In close collaboration with USDA, DHS led the funding, site selection, design, and construction of NBAF. The successful partnership between USDA and DHS has resulted in the creation of a facility that will set the standard for a secure, high-quality laboratory capable of providing the needed science to protect the nation's agriculture and its citizens against the threat and potential impact of serious animal diseases.

To manage the high-consequence pathogens to be studied within NBAF, the facility is designed as a self-contained operation. The completed site will be over 700,000 square feet. The main laboratory building provides 574,000 square feet of integrated laboratory space, animal spaces, support areas, and required safety systems. Other structures total 135,000 square feet, including the central utility plan (CUP), visitor center, transshipping building, and wastewater treatment plant.

The main NBAF building provides administrative and training space along with specialized laboratory space differentiated by the biosafety level required to perform the activities intended to occur within that area. The laboratories and animal spaces at NBAF will allow for the mission areas of research and countermeasure

development, diagnostics, and training to be met with efficiency and effectiveness, and offers the capability to partner with industry, academia, and other stakeholders. New capacities are noted below and explained further in the chapters for science and partnerships.

The main laboratory building provides 574,000 square feet of integrated laboratory space, animal space, support areas, and required safety systems.

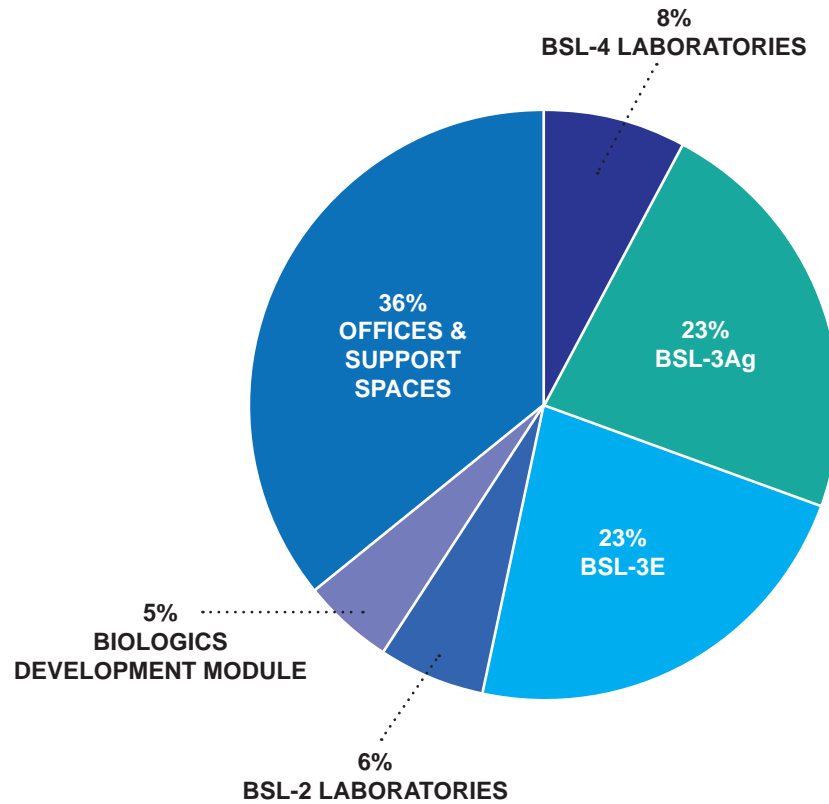


Figure 4: Percentage Allotment of Primary NBAF Areas

BSL-2

The BSL-2 laboratories at NBAF will maintain and provide cell lines cultured for use in the diagnostic and research laboratories. These cell lines provide the necessary substrate for growth of viruses in order to develop methods to quickly diagnose and control the spread of animal diseases. Scientists work in carefully controlled areas to ensure cell lines are maintained clean and pathogen-free prior to use within the containment laboratories.

Materials used for proficiency testing of the NAHLN are also made in BSL-2 laboratories. This testing ensures that government and academic laboratorians are trained and validated to handle samples should a foreign animal disease outbreak occur within the U.S. By having this coordinated capability, NBAF will be a reference laboratory for specific viruses within the U.S. for large animal populations.

BSL-3E

The BSL-3E (Enhanced) spaces are the laboratories where assays for disease detection are conducted and developed, and research for discrete identification of the infectious agents, disease epidemiology, and disease origin is conducted. After learning about each virus, vaccines can then be formulated to further protect livestock through vaccination. These activities require dedicated space for research and diagnostics performed by dedicated and experienced microbiologists, veterinarians, and molecular biologists.

BSL-3Ag

The BSL-3Ag (Agriculture) spaces are the prime work space to understand how animal diseases spread within and among large livestock populations in order to best learn how to diagnose and control the disease within the animals themselves. This is also the space that the APHIS Vaccine Bank uses to periodically test stockpiled vaccines for efficacy. The BSL-3Ag spaces house the animals where trained veterinarians and animal care staff attend to the animals' needs. With the increased containment space, more studies will be carried out simultaneously and more diseases will be studied and tested. In addition, a specifically designed training suite will allow enhanced training opportunities.

INSECTARY
(NEW CAPABILITY)

NBAF will have the capacity to house insects for insect studies in high containment. This is an important new capacity considering that many of the new emerging diseases are transmitted by insects. This space will allow scientists for the first time to be able to study these high containment diseases in the vector as well as in the host and conduct transmission studies which will provide novel control solutions.

BSL-4
(NEW CAPABILITY)

NBAF will have the first large animal BSL-4 capability in the United States. BSL-4 is the highest level of biocontainment and biosafety precautions. This new laboratory capability for USDA will allow disease work to be done with pathogens that could cause severe to fatal disease in humans. For NBAF, the work in this laboratory will involve zoonotic animal diseases or diseases that are transmissible to humans. For this reason, special procedures and equipment (e.g. fully contained suits with dedicated air supply) are necessary to work within this space and all veterinarians, animal handlers, and scientist must train for months before working in the BSL-4 laboratory. The BSL-4 suite includes BSL-4 laboratory space, Animal Biosafety Level (ABSL) 4 small animal space, BSL-4 large animal space, and necropsy space.

BDM
(NEW CAPABILITY)

The NBAF BDM will possess the capability to rapidly produce experimental biologicals, diagnostics, and vaccine-related products for potential use by USDA in an outbreak of an emerging animal disease. The facility mission will therefore directly support and accelerate technology transfer to commercial veterinary biologic manufacturers (e.g., vaccines, diagnostics, veterinary medical countermeasures [MCMs], and biotherapeutics).

BIORISK MANAGEMENT

The laboratories are where the frontline work in transboundary animal, emerging, and zoonotic diseases is advanced. All biocontainment spaces in the facility are designed to meet or exceed national and international standards and guidelines for the respective containment levels. The remainder of the facility, in excess of 80 percent by square footage, is carefully designed to ensure that disease agents are fully contained with redundant biocontainment controls and decontamination procedures.

Biorisk management is important for safely handling infectious agents at NBAF and for ensuring that containment is maintained while performing all aspects of the work. For these reasons and more, the facility is designed with multiple redundancies to ensure all containment systems always operate at peak efficiency. Training is a critical part of biorisk management and will be part of everyone’s daily routine throughout the facility.

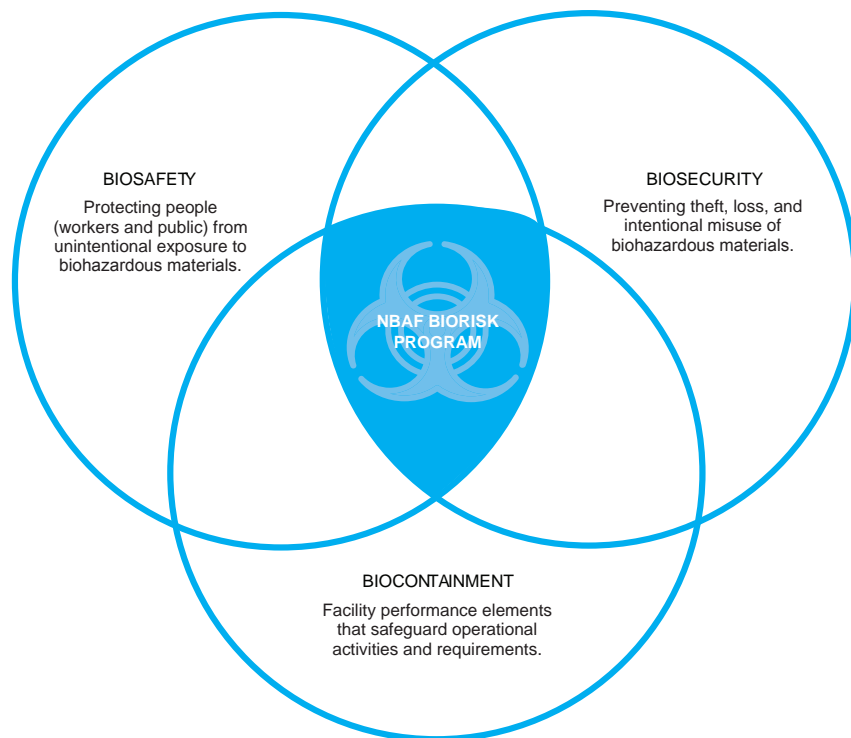


Figure 5: Biorisk Program Elements & Definitions

Safety is a predominant driver for the design and construction of NBAF. Critical facility systems have 100 percent backup and redundancy. Security design incorporates the concepts for multiple layers and graded protection that help to provide real-time and automated safeguards. Entry and exit points from security zones maintain multiple points of physical and electronic screening. The design approach includes general procedures and process flow descriptions for entry/ exit and movement of people, wastes, supplies, animals, etc. Cybersecurity risk assessments and protective measures have been considered and incorporated into all aspects of NBAF’s telecommunications and information technology (IT) infrastructure systems planning and operations.

SUPPORTING THE LABORATORIES

NBAF’s central facilities services organization provides excellence in operational and technical services in support of science missions at NBAF. This support is delivered with effective solutions through customized operational models and by a comprehensive management approach matching proper technical applications with engineering design and functional performance expectations to meet or exceed biocontainment and biosecurity requirements.





 GENERAL FACILITY	 LABORATORY SPECIFIC	 WASTE MANAGEMENT	 UTILITY INFRASTRUCTURE
HVAC SYSTEMS	BIOSEAL DOORS	AUTOCLAVES	ELECTRICAL POWER
BUILDING AUTOMATION SYSTEMS	CONTAINMENT BARRIERS	FUMIGATION CHAMBERS	STEAM
HVAC ALARMS	BIOSAFETY CABINETS	INCINERATORS	CHILLED WATER
FIRE SUPPRESSION & ALARMING	FUME HOODS	CARCASS TREATMENT SYSTEMS	POTABLE WATER
LIGHTING	BSL-4 SUITS	EFFLUENT DECONTAMINATION SYSTEM	WASTEWATER
COMMUNICATIONS	BSL-4 BREATHING AIR	WASTEWATER PRETREATMENT	STORMWATER
SECURITY	BSL-4 CHEMICAL SHOWERS		PLUMBING
	COMPRESSED GAS SYSTEM		
	LIQUID NITROGEN SYSTEM		
	BSL-3 SHOWER-OUT		

Figure 6: Critical Building Systems Example

The facilities services organization supports the scientific programs at NBAF while providing a safe, secure, productive, and environmentally responsible work environment to ensure compliance with regulations, standards, codes, and agreements. This is accomplished by utilizing the leadership and skills of highly qualified professional engineering staff and trades personnel and taking advantage of the latest technologies available. Adherence to operational protocols, policies, and procedures and implementation of preventive and predictive maintenance programs ensure continuous safe operations with a minimum disruption to the scientific programs.

NBAF uses a full-scale computerized maintenance management system (CMMS) which fully incorporates detailed facility design and operating data for critical infrastructure and support systems. It is used to schedule, organize, and prioritize the sequence and management of maintenance and repairs at NBAF. The capabilities of the CMMS provide long-term capture of metrics on the maintenance and repair activities that relate to labor management, expense, materials and supplies inventory, budget planning, and expenditures.

The CMMS tracks reactive and proactive maintenance and repair activities and provides analytic tools for evaluating efficiencies and resources associated with high performance operations. The CMMS will also support identifying process improvements to ensure operational excellence.

4 PREDICTING, PREVENTING, AND RESPONDING TO THREATS TO U.S. AGRICULTURE



CREATING A NATIONAL ASSET
FOR AMERICA'S BIOSECURITY
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EMPOWERING U.S. AGRICULTURAL DEFENSE

USDA will take on a critical role in the animal health, public health, and One Health domains.

USDA has a long and successful history of protecting U.S. agriculture and the food supply from both intentional and unintentional threats. In support of these efforts, USDA maintains networks of dedicated animal health professionals and scientists, and operates sophisticated scientific facilities across the country. In its projected 50+ year lifespan, NBAF will take on a critical role in the animal health, public health, and One Health (human, animal, and environmental health) domains.

In an increasingly interconnected world, disease threats are arising at an alarming rate and long-term social, cultural, and environmental trends may only serve to increase these threats. For example, climate changes have led to an expanded range of some vector-borne diseases that thrive in warmer climates. The rise in population density, changes in human migration patterns, and an overall growth in movement of goods, people, and animals has brought people and animals into closer proximity, increasing the chances of disease transmission.

Of particular concern are zoonotic animal diseases: diseases that can spread from animals to people. It is estimated that at least 75 percent of emerging infectious diseases affecting humans have an animal origin.¹ The U.S. currently does not have a laboratory facility to study zoonotic diseases that affect livestock and other large animals. To address this threat, it is essential that the U.S. possesses the capability to develop countermeasures that will reduce human exposure to these potentially lethal diseases. The best protection of the human population may be the early detection of the agent in animals and development of animal vaccines to prevent its spread.



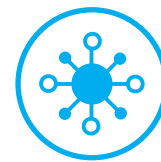
AGRO-TERRORISM

Intent to cause economic and social disruption. May also threaten public health, depending on agent used.



FOREIGN ANIMAL DISEASES

Non-domestic diseases, endemic overseas, may affect food, animals, horses, wildlife. Threat increasing due to large-scale movement of animals, illicit trade, climate change, and vector movement.



EMERGING ANIMAL DISEASES AND ZOOSES

Number of emerging infectious disease events increasing over time.

Figure 7: Categories of Disease Threats

¹ World Organisation for Animal Health, "Biological Threat Reduction Strategy: Strengthening Global Biological Security," October 2015

TYPES OF THREATS

NBAF will collaborate across government, academia, and private industry to predict, prevent, and respond to both unintentional and intentional threats. Unintentional threats are outbreaks that occur naturally or accidentally.

NBAF will also play a prominent role to enable APHIS animal health officials to identify “high-consequence” transboundary animal diseases and pests. These are serious diseases and pests that do not currently exist in the United States. If introduced here, they pose a severe threat to U.S. animal health and, in some cases, the economy and human health as well. These diseases and pests are divided into tiers according to risk level, as described below in Figure 8.

These high-consequence transboundary animal diseases and pests are of primary importance to APHIS emergency preparedness officials, guiding many of our

TIER 1 DISEASES	TIER 2 DISEASES	TIER 3 DISEASES
<p>Tier 1 diseases are those of national concern. They pose the most significant threat to animal agriculture in the United States, as they have the highest risks and consequences. This category includes:</p> <ul style="list-style-type: none"> • <i>African swine fever</i>² • <i>Classical swine fever</i>² • <i>Foot-and-mouth disease</i>² • <i>Avian influenza (any strain that is highly pathogenic or has zoonotic significance)</i>² • <i>Virulent Newcastle disease</i>² 	<p>Tier 2 diseases are transmitted primarily by pests. How quickly these diseases spread and APHIS’ ability to control or eradicate an outbreak depends largely on whether these pests are present in the environment and whether they can transmit the disease between animals. This category includes:</p> <ul style="list-style-type: none"> • <i>Heartwater</i> • <i>New World screwworm</i> • <i>Rift Valley fever</i>² • <i>Venezuelan equine encephalitis</i>² 	<p>Tier 3 diseases and pests pose less risk and fewer consequences than those in Tiers 1 and 2, but still rise to the level of inclusion because of their potential negative impact on animal or human health. This category includes:</p> <ul style="list-style-type: none"> • <i>African horse sickness</i> • <i>Contagious bovine pleuropneumonia and contagious caprine pleuropneumonia</i> • <i>Glanders and melioidosis</i> • <i>Henipaviruses (Hendra and Nipah)</i>² • <i>Rinderpest² and peste des petits ruminants²</i> • <i>Tropical bont tick</i>

Figure 8: APHIS list of priority diseases

² APHIS has identified these diseases as biological threats that need to be considered in program priorities and countermeasure stockpile requirements. — APHIS Veterinary Services Fact Sheet, “High-Consequence Foreign Animal Diseases and Pests,” July 2013

PREDICTING THREATS

program priorities. For example, the list will help inform decisions on how we procure countermeasures to address a disease outbreak and, potentially, funding for research and response activities.

Intentional or deliberate biological threats are introduced with the intent to cause damage to human and animal health and well-being, cause economic devastation, or erode trust in public institutions. While initial responses to intentional and unintentional types of incidents may be similar, USDA remains vigilant and closely collaborates with its partners to identify all threats and develop the tools to efficiently distinguish between the two types of threats.

NBAF will be a unique national security asset because it will establish critical relationships between the intelligence community, human biodefense community, universities, stakeholders, and international consortia to have a complete survey of the existing and emerging biological threats against animal agriculture. These relationships will inform NBAF's research, disease surveillance priorities, and animal health first responder training. As part of its responsibilities as a critical asset for national security, NBAF will be capable of performing classified research and diagnostics if needed.

A key member of the USDA team collaborating on the transition of NBAF is the USDA Office of Homeland Security (OHS), which mitigates risk and safeguards USDA personnel, customers, assets, and information by leading Government-wide initiatives and championing USDA's equities in homeland and national security. OHS is responsible for Departmental emergency operations, continuity of operations, security clearances, classified information, physical security policy, safety of ionizing radiation, and coordinating all homeland and national security policy, planning, and preparedness activities for USDA. OHS is responsible for an oversight process that includes the development of directives to USDA subcomponents concerning the prevention, detection, and response to agricultural biosecurity threats. OHS also provides USDA's direct link to and coordination with the Intelligence Community (IC), ensuring both that agriculture-related requirements are understood and appreciated by the IC and that agriculture threat information is shared with the appropriate USDA agencies. This information exchange will be critical to driving operations at NBAF.

Furthermore, with regard to international threats, USDA engages with multiple cross-agency workgroups and reaches out directly to the intelligence community. For example, USDA leads the Defense Against Agroterrorism Working Group (DAAWG), which is tasked with developing a clear understanding of threats, avoiding duplication of efforts, and increasing information sharing. Members include Health and Human Services (HHS), the Department of Energy (DOE), the Department of Commerce (DOC) and the Environmental Protection Agency (EPA), combined with key intelligence officials from DHS, the Department of Justice (DOJ), the Department

of State (DOS), the Department of Defense (DOD); the Office of the Director of National Intelligence, and the Central Intelligence Agency (CIA). Through this group and the embedded intelligence analysts that USDA has in the National Center for Medical Intelligence (NCMI), NBAF will be interconnected with the appropriate agencies and receive necessary information on high priority threats. In addition, USDA's intelligence analysts communicate regularly with the Kansas Intelligence Fusion Center (KIFC).

For unintentional threats, USDA is engaged with international working groups and global animal health communities to gain insight into the diseases affecting world communities and anticipate how these diseases could be introduced into the U.S. For example, USDA is a member of the World Organisation for Animal Health (OIE). The organization asks all its member countries to report on animal diseases it detects, disseminates that information to other countries, and encourages international solidarity in the control of animal diseases.

PREVENTING THREATS

Using both unintentional and intentional threat analyses, recommendations of the scientific community, and gap analyses as a guide, science leaders at NBAF will select diseases that represent the classes of the viral families that are most likely to cause a disease outbreak. One of these diseases will always be FMD because NBAF will be the only laboratory in the U.S. that is allowed to handle the live virus. USDA will focus on having the right diagnostic tools to do surveillance, having trained animal health first responders, and having the right vaccines available for control and eradication. USDA continues to develop collaborations and partnerships that will lead to preparedness and innovation.

RESPONDING TO THREATS

NBAF will be central to USDA's efforts to respond to an outbreak event involving transboundary and zoonotic animal disease agents of livestock, be it from intentional or unintentional sources. Since APHIS and ARS are cohoused in the facility, task forces around disease threats involving the two agencies will be formed to coordinate research and diagnostic activities and information sharing. The main response aspects of work at NBAF will include quickly diagnosing what the disease is; performing research to ensure that diagnostics are effective; evaluating whether any existing countermeasure for the disease is protective or if vaccines need to be developed; monitoring the disease outbreak through continually evolving diagnostics; and researching proper decontamination and disposal procedures. For APHIS, an additional responsibility may be to work with the Federal Bureau of Investigation (FBI) to perform diagnostics and ancillary testing for forensic and attribution purposes.

5

EXPANDING THE SCIENCE OF MANAGING AGRICULTURAL THREATS



CREATING A NATIONAL ASSET
FOR AMERICA'S BIOSECURITY
INFRASTRUCTURE



SCIENCE MISSION AND PROGRAM MANAGEMENT

NBAF is established with a unique scientific mission to study the most dangerous livestock and zoonotic pathogens.

NBAF will promote science programs aligned with the needs of the U.S. food supply, agricultural economy, animal health, and public health. Implementing effective collaboration and facilitating use of NBAF's unique biocontainment capacity, expertise, and the BDM to accelerate development of vaccines, diagnostic tools, and other veterinary MCMs will achieve this vision.

NBAF will develop and enact program management systems that lower barriers to efficient and effective scientific research and testing, and empower scientists to collaborate and to integrate end-to-end Research, Development, Test, and Evaluation (RDT&E).

NBAF aligns the strengths of ARS and APHIS. Each agency has specific and complementary roles. The NBAF management system allows each agency to best use its skills, strengths, and capabilities to develop diagnostics and disease countermeasures, conduct training, and provide maintenance of vaccine banks and repositories. NBAF will continue the legacy of the PIADC mission of cutting-edge transboundary animal disease research and diagnostic capabilities.

NBAF provides an enduring capability to enable the U.S. to conduct comprehensive research, develop vaccines, and provide enhanced diagnostic and training capabilities to protect our country against transboundary animal, emerging, and zoonotic diseases that threaten our nation's food supply, the nation's agricultural economy, and public health.

The NBAF science plan highlights key capabilities of NBAF and addresses mechanisms through which they can be best utilized. In support of NBAF scientific programs, the science plan demonstrates the approach USDA will take to understand and prioritize resource needs required to effectively coordinate a comprehensive national scientific agenda, while meeting the strategic objectives of USDA.

Transboundary animal diseases, as well as emerging and/or re-emerging diseases, represent a major threat to U.S. agriculture and public health. Introduction of these agents has the potential of resulting in devastating social and economic effects, not only in the country's agricultural systems, but also in a wide range of economic activities.

NBAF SCIENCE
GOALS & NATIONAL
MANDATES

The NBAF scientific mission includes four primary performance domains:

1. Emergency Response
2. Training
3. Diagnostics
4. Research and Development

Each area is enabled by unique NBAF capabilities and is curated through strategic approaches to technology management, such as periodic technology assessments and user engagement, to ensure alignment of priorities and appropriateness of investment.

Through the use of these primary performance domains the NBAF Science Program will ensure protection of our nation's food security, agricultural economy, and public health through the following tactics:

- Confirmatory Diagnostics
- Countermeasure Development
- Knowledge – International Reference Center
- Partnerships
- Technology Transfer

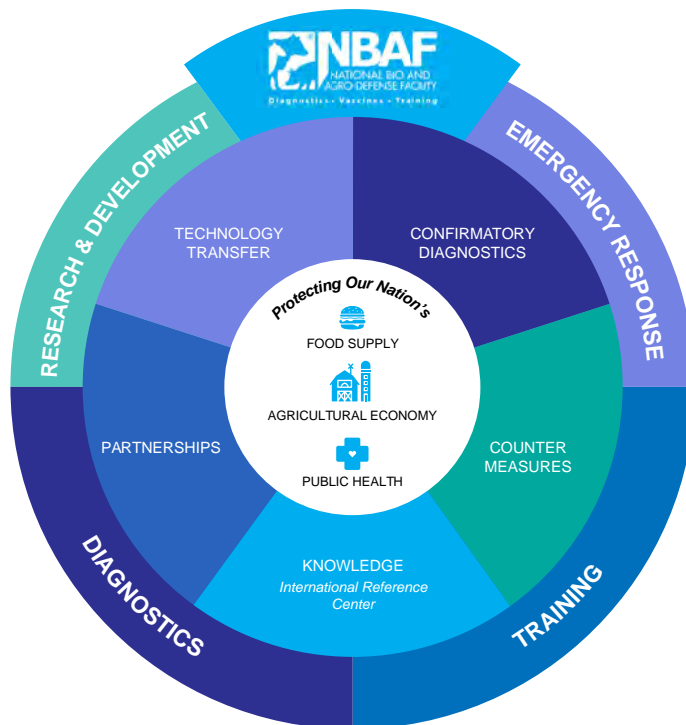


Figure 9: NBAF Science Goals and National Mandates

CONFIRMATORY DIAGNOSTICS

The diagnostic capability at NBAF will include capacity to safely handle zoonotic or BSL-4 agents of livestock, such as Nipah, Hendra, Ebola, and Rift Valley fever virus. Similarly, NBAF will enable scientists to safely manipulate unknown or newly emerging diseases that may be zoonotic. NBAF will enhance the USDA's ability to:

- Conduct diagnostic work on high risk or unknown samples.
- Open international packages containing unknown or high-risk materials.
- Split specimens for diagnostic accessions outside of biocontainment (glovebox capacity). This is critical for samples needing diagnostic work-up in multiple laboratories between agencies or handling of international submissions.

An additional role of the Foreign Animal Disease Diagnostic Laboratory (FADDL) is to provide diagnostic support, including forensics for attribution for the FBI. NBAF will allow additional staff to be trained and exercised on how to support this program.

COUNTER- MEASURES

NBAF will also enable discovery, proof-of-concept studies, and early phase veterinary MCMs (e.g., vaccine candidates, monoclonal antibodies) development. An aim of early-phase veterinary MCM development is to facilitate technology transfers to public and private sector partners. In the context of biodefense and the core mission of NBAF, the products derived from research outcomes include scientific information and/or veterinary MCMs needed to prevent and effectively respond to infectious disease threats.

Furthermore, research on disease acquisition and presentation, progression of disease, incubation periods, and disease transmission will be a key role of scientists at NBAF. These studies will form the foundation of research that informs countermeasure development.

KNOWLEDGE – INTERNATIONAL REFERENCE CENTER

NBAF will be home to internationally recognized animal disease experts in ARS and APHIS who will be called upon to assist other countries in addressing significant animal disease situations and to partner with public health officials when needed to protect animal and human health.

The FADDL at NBAF will continue to serve as international reference laboratories for OIE and the Food and Agriculture Organization of the United Nations (FAO). In this role, NBAF will accept diagnostic samples from other countries, provide training to laboratorians from other countries, and participate in epidemiological investigations when requested to do so. In addition, FADDL will continue to provide high quality diagnostic reagents to other laboratories to aid in their diagnostic work and, as the custodian of a national repository for transboundary animal disease agents, will provide historical isolates as needed by other laboratories.

PARTNERSHIPS

The goal of NBAF technology transfer is to make research outcomes publicly available and accelerate the development of veterinary medical countermeasures.

Since many of the most dangerous animal pathogens do not exist in the U.S., disease research must extend to countries where the diseases exist. Partnerships with research organizations in other countries are essential in implementing a biodefense research program against animal disease outbreaks. The program must include research on how a disease agent survives outside of the host, how the organism moves between susceptible hosts, how the pathogen attacks the animal, and how it then escapes from the host.

Increased research on how pathogens move between countries and between farms will allow prevention programs to enhance biosecurity and reduce the chance of pathogen introductions. In order to respond to a disease incursion, research must provide tools for accurate and continuous surveillance and vaccination programs. To counter an animal disease, research programs must also consider ways to manipulate the animal's immunological resistance to infection and ways to increase disease resistance through genetic selection, which may be the best way to minimize economic loss and disease spread. To ensure producers are able to return to full production and export their products as soon as possible, research must also provide the means to prove that animals are free of the disease. The Manhattan, Kansas location places NBAF in proximity to NBAF-mission related research in veterinary, agriculture, and biosecurity topics, and in the midst of expertise and resources for performing such research.

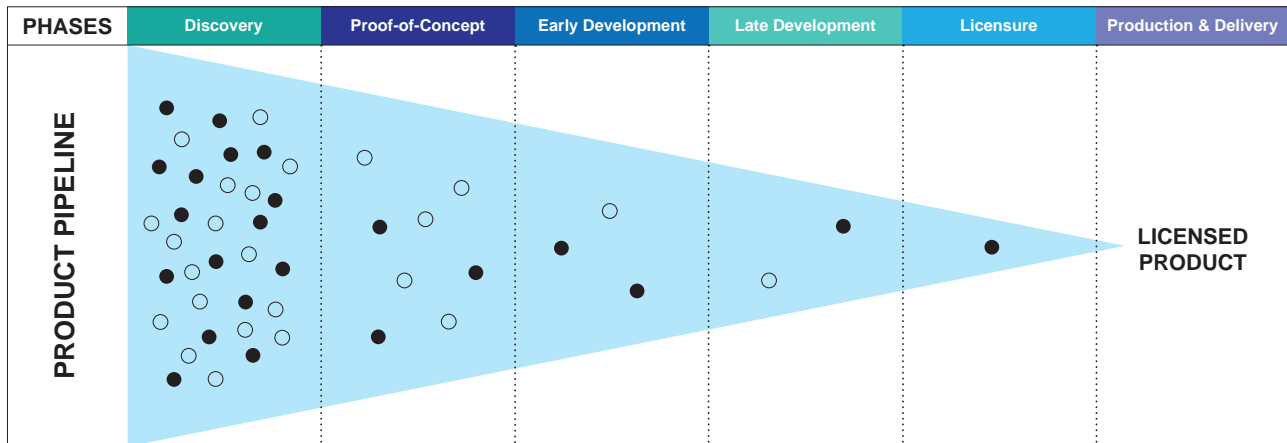


Figure 10: NBAF RDT&E pipeline

TECHNOLOGY TRANSFER

The NBAF scientific strategy will align with its primary mission and RDT&E approach to accelerate technology platform technologies and countermeasure candidates through the early development stage. Candidates that meet predefined threshold criteria will be transitioned to industry partners for further development. Strategically, the overarching goal is to increase the technology readiness level of early-stage veterinary countermeasure candidates for emerging and zoonotic infectious diseases that fall within the animal and public health 'One Health' domain.

6

FOSTERING INNOVATIVE RESEARCH WITH REGIONAL, NATIONAL, AND INTERNATIONAL PARTNERS



CREATING A NATIONAL ASSET
FOR AMERICA'S BIOSECURITY
INFRASTRUCTURE



BUILDING A COMMUNITY OF COLLABORATION

NBAF will create an active group of partners and collaborators as a means of building an essential presence in animal health bio and agro-defense research space.

There are multiple stakeholders involved in the biodefense and agro-defense domain, including Federal, State and local agencies, and other academic, industrial, and international collaborators. NBAF will proactively engage with a broad variety of stakeholders to understand their needs, requirements, and ideas for innovation, and to communicate the status of NBAF scientific programs.

All mission areas involved in prediction, preparation, and response to foreign, emerging, and zoonotic animal disease threats require dynamic outreach and partnerships. The types of partnerships will range from student scientific training and diagnostic training to pharmaceutical and biological collaborations for vaccine product development to international capacity building. A Partnerships and Communication Office in NBAF will coordinate much of the work.

Establishment and maintenance of robust stakeholder relationships are critical in the strategic approach for the facility. The bio and agro-defense mission domain is complex and involves coordinated efforts of multiple government agencies and private partners, particularly for the development of veterinary MCM technologies, knowledge products, and policies/practices necessary for emergency preparedness and response.

Within the NBAF structure, the Partnerships and Communication Office, a first for a USDA laboratory facility, recognizes the unique and special role that NBAF partnerships will play. This office will be the first point of contact for the use of several mechanisms to enhance collaborative opportunities and outcomes. Partnership intermediary agreements (PIAs), collaborative research agreements (CRAs) such as cooperative research and development agreements (CRADAs), material transfer research agreements (MTRAs), data transfer research agreements (DTRAs), other transaction authorities (OTAs), cooperative agreements, and prize/challenges are potentially a few of the mechanisms that may be used.

Alignments across NBAF and the stakeholder network will guide partnership formation and strengthen animal and public health protection while also promoting economic growth.

The types of partnerships engaged by both USDA agencies are:

- Regional Partnerships
- U.S. Partnerships
- Global Alliances

ASPIRE

Agrosecurity Partnerships for Innovative Research (ASPIRE) is the conceptual framework to engage creative partners and collaborators well beyond the walls of NBAF and stimulate the entire bio and agro-defense sector. Building on the partnering success that DHS initiated, NBAF will leverage its proximity to the KCAHC, Kansas State University (KSU) and BioNexus KC, and work to attract collaborators from across the U.S. and internationally.

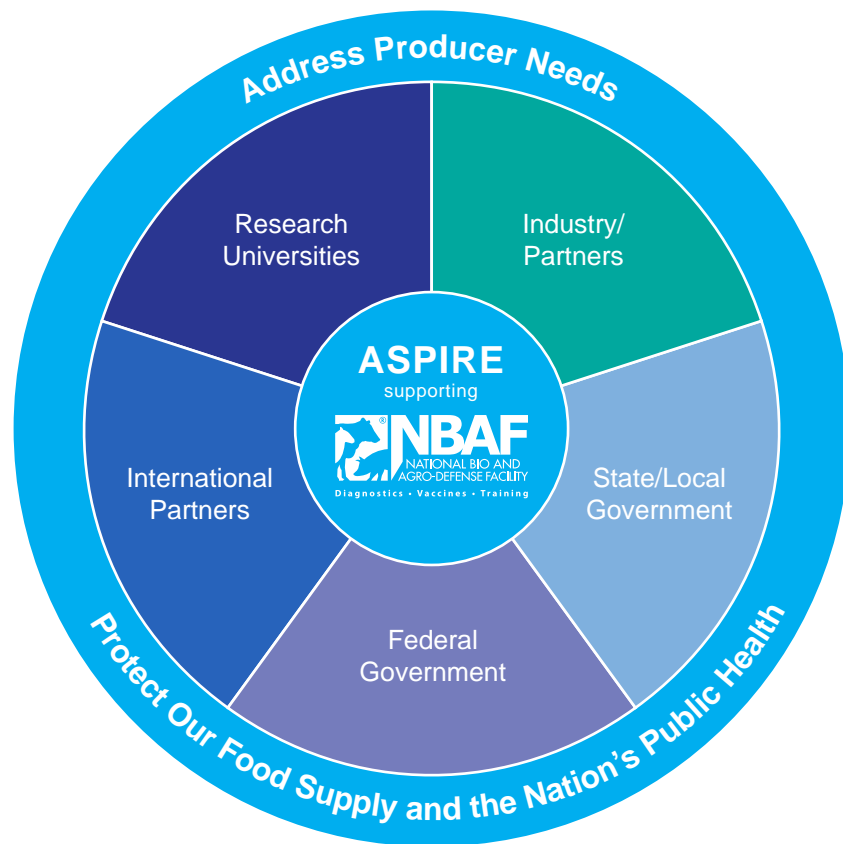


Figure 11: ASPIRE framework for innovative partnerships nurtured through NBAF

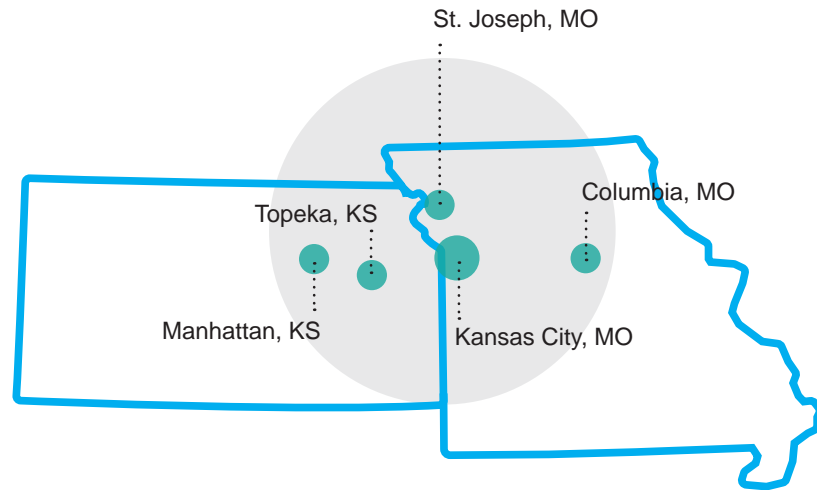


Figure 12: The Kansas City Animal Health Corridor

VETERINARY MCM DEVELOPMENT PARTNERSHIPS AND THE BDM

NBAF provides an opportunity to enhance USDA's engagement with external partners as potential veterinary MCM products and knowledge products enter the advanced development pipeline. Capitalization of these features is necessary to achieve this vision at NBAF. The NBAF BDM will enable stronger collaboration with the veterinary biopharmaceutical industry and help accelerate veterinary MCM development and transition.

The BDM will support customers from all NBAF user groups (ARS and APHIS) and commercial partners with an interest in the development of technologies and products that are key to the USDA mission. The facility mission will therefore directly support and accelerate technology transfer to commercial veterinary biologic (e.g., vaccines, diagnostics, and biotherapeutics) manufacturers. The development of qualified master cell and seed stocks for manufacturing viral and bacterial vaccines will be a critical activity to accomplish the mission. In addition, the facility will support the evolution of existing countermeasures (vaccine and diagnostic) programs by providing small-scale production of experimental test articles, such as monoclonal antibodies, for use in the clinical and analytical components of late-stage discovery and early-stage development NBAF projects.

The design of the BDM will support clinical investigations focusing on product safety, purity, potency, and efficacy geared toward development of licensed products using validated cell lines. The BDM has also been designed to support the growth, collection, and purification of reagents in individual production and diagnostic reagent production suites in support of the FADDL and the NAHLN.

Case Study: Foot and Mouth Disease Research

The scale and complexity of the decades-long research on FMD cannot be overemphasized. Research efforts with live virulent FMD virus is currently allowed only at PIADC and this ability will transfer to NBAF. Experiments are difficult and slow. Also, many of the various FMD strains and vaccines are not cross-protective.

First, several vaccine candidates were developed and tested. A promising candidate was developed by ARS scientists, where by deleting one of the viral proteins called leader, the virus was rendered non-virulent in cattle or pigs (the most sensitive animal to FMD). This vaccine candidate, known as “leaderless,” was unable to cause disease or grow in animals, but could be grown in large quantity in cell cultures.

In 2008 ARS scientists at PIADC developed an attenuated vaccine platform based on the leaderless virus — a system that can be used to generate vaccines against multiple strains. It was shown to be effective at laboratory scale.

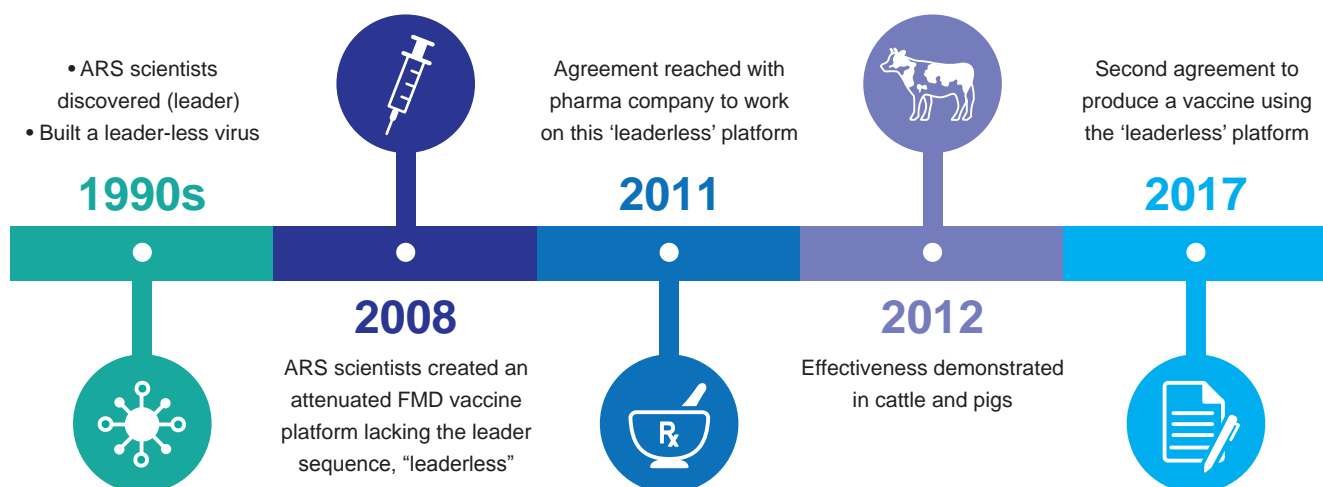


Figure 13: Timeline of research pipeline to defend against FMD

There are existing FMDV vaccines based on killed/inactivated virus antigen. These vaccines are effective and are the basis of the North American FMD Vaccine Bank, developed by the U.S., Mexico, and Canada and held at PIADC for the last 30 years. Because current vaccines are produced using virulent FMDV and are not allowed on the U.S. mainland, the U.S. depends on foreign manufacturers to source its vaccines. PIADC has developed two vaccine platforms that allow U.S. manufacturing: the licensed Ad5-FMD and the LL3B3D vaccines. When their development is completed by industry and production in the U.S. is possible, they can provide advantageous alternatives for vaccine stockpiling. Some animal pharmaceutical companies have estimated this would be possible within three to five years.

REGIONAL PARTNERSHIPS

Scientists at NBAF will be able to leverage the facility's physical location next to KSU — a major land-grant university with a considerable agricultural focus and a top veterinary school, with close proximity to the KCAHC, and to additional universities with animal and public health focused research programs.

The KCAHC is an established innovation corridor with national and global networks. The KCAHC is focused on animal health and has the highest concentration of animal health companies and assets in the world. Within the KCAHC, partners at KSU are leading development of a more localized innovation district in Manhattan, Kansas where NBAF is located. Its anchor institutions include NBAF, the KSU Veterinary Medicine Complex, along with a new \$11 million Partnership Office Park, and other assets.

USDA will partner with KSU and other academic institutions by collaborating in research, developing diagnostics, and workforce development. USDA is already collaborating on research with KSU at the Biosecurity Research Institute (BRI), as well as coordinating with the NAHLN at KSU for diagnostic testing and providing opportunities for KSU students.

APHIS is already working with KSU and multiple other universities on the APHIS NBAF Scientist Training Program to develop the workforce for the APHIS FADDL. APHIS is partnering with the universities by providing funding to DVM/PhD program candidates and MS and PhD microbiology graduate students who focus on foreign animal and zoonotic disease topics and will become scientists at FADDL. ARS will continue to collaborate with KSU and other universities by providing stipends and research funds to eligible students with the goal of developing the future NBAF workforce.

U.S. PARTNERSHIPS

Fulfilling the vision of NBAF requires leveraging U.S. partnerships across the Federal Science and Technology Enterprise and with academia, private companies, and non-profits. USDA will enhance its existing relationships with DHS, HHS, DOE, DOJ, and DOD science organizations and laboratory systems and build new Federal partnerships to realize the full potential of the expanded science capabilities at NBAF.

NBAF will foster and maintain strong relationships with other biocontainment facilities within the U.S., particularly those engaged in complementary activities within the bio and agro-defense mission domain. The USDA National Centers for Animal Health (NCAH), in Ames, Iowa, maintains a closely aligned portfolio of scientific activities on domestic animal diseases, and sustains engagement with NBAF programs in research and diagnostic activities. Engagement is expected with the ARS's CGAHR, also located in Manhattan, Kansas. The CGAHR's Arthropod-Borne Animal Diseases Research Unit (ABADRU), with its mission involving arthropod transmitted viral diseases of domestic animals, is a natural partner for NBAF.

APHIS will leverage its three diagnostic laboratories in Ames, Iowa that have expertise in bacteriology, virology, and bioanalytics to closely coordinate the NBAF program with the other NVSL laboratories. APHIS will also leverage the NAHLN (state and academic laboratories within the U.S.) and the North American Animal Health Laboratory Network (NAAHLN), consisting of laboratories in Canada, Mexico and the U.S.

One of the FADDL's core missions is to train and disseminate foreign animal disease (FAD) knowledge and expertise to both national and international partners and stakeholders. For example, in the Foreign Animal Disease Diagnostician School (FADD School) and the International Transboundary Animal Diseases (ITAD) course, participants learn how to identify the diseases clinically and during postmortem examinations.

USDA will work through interagency groups such as DAAWG and Foreign Animal Disease Threats (FADT) Working Group with participants from DHS, HHS, DOS, Department of the Interior (DOI), DOD, DOJ, Office of the Director of National Intelligence, and CIA to identify and prioritize research gaps. In addition to their own cooperative agreements and training programs, APHIS and ARS will leverage existing partnerships with USDA National Institute of Food and Agriculture (NIFA) to develop complementary extramural research, extension, and education programs that enhance efforts in NBAF and further develop partnerships with land-grant and other agricultural universities. In the One Health sphere, USDA will continue to coordinate with HHS and their Centers for Disease Control and Prevention (CDC).

Since 2004, USDA and DHS maintained a key partnership at PIADC. This productive relationship will continue at NBAF. Given NBAF's role as a critical asset for national security, as relevant to both animal and public health, DHS and USDA are developing a process to address homeland security mission priorities and collaborative evaluation of programmatic needs to advance bio and agro-security. Examples of areas through which these joint USDA-DHS initiatives will take place include:

- USDA and DHS will hold annual joint 'homeland security' meetings that include the National Biodefense Analysis and Countermeasure Center (NBACC), KIFC, and representatives from other federal partners involved in the bio and agro-defense domain, in order to maintain awareness regarding NBAF programmatic activities and aligned USDA priorities.
- DHS will continue to provide input to the international gap analysis of animal disease countermeasures conducted by USDA.
- DHS will participate in annual NBAF stakeholder meetings to gather input and to provide guidance regarding NBAF research priorities.

GLOBAL ALLIANCES

Beyond engagement with domestic entities, NBAF partnership efforts also involve international partners in the bio and agro-defense community. Partnerships established by PIADC with other high biocontainment research facilities in Canada, the United Kingdom, Australia, and Germany, will continue with aligned scientific programs. Engagement with such partners is formalized through NBAF’s membership in international networks such as the BSL-4 Zoonotic Laboratory Network (BSL4ZNet), with the secretariat sponsored by the Canadian government, and the International Veterinary Biosafety Workgroup (IVBW) founded by ARS and the Australian Commonwealth Scientific and Industrial Research Organisation (CSIRO).

Importantly, the following strategic global research alliances established and supported by USDA will continue at NBAF:

- Global Strategic Alliances for the Coordination of Research on the Major Infectious Diseases of Animals and Zoonoses (STAR-IDAZ)
- Global Foot-and-Mouth Disease Research Alliance (GFRA)
- Global African Swine Fever Research Alliance (GARA)

Moreover, USDA scientists will continue to lead global research communities with expertise on priority transboundary animal diseases by conducting research gap analyses on high consequence diseases, such as Nipah virus, African swine fever, and FMD.

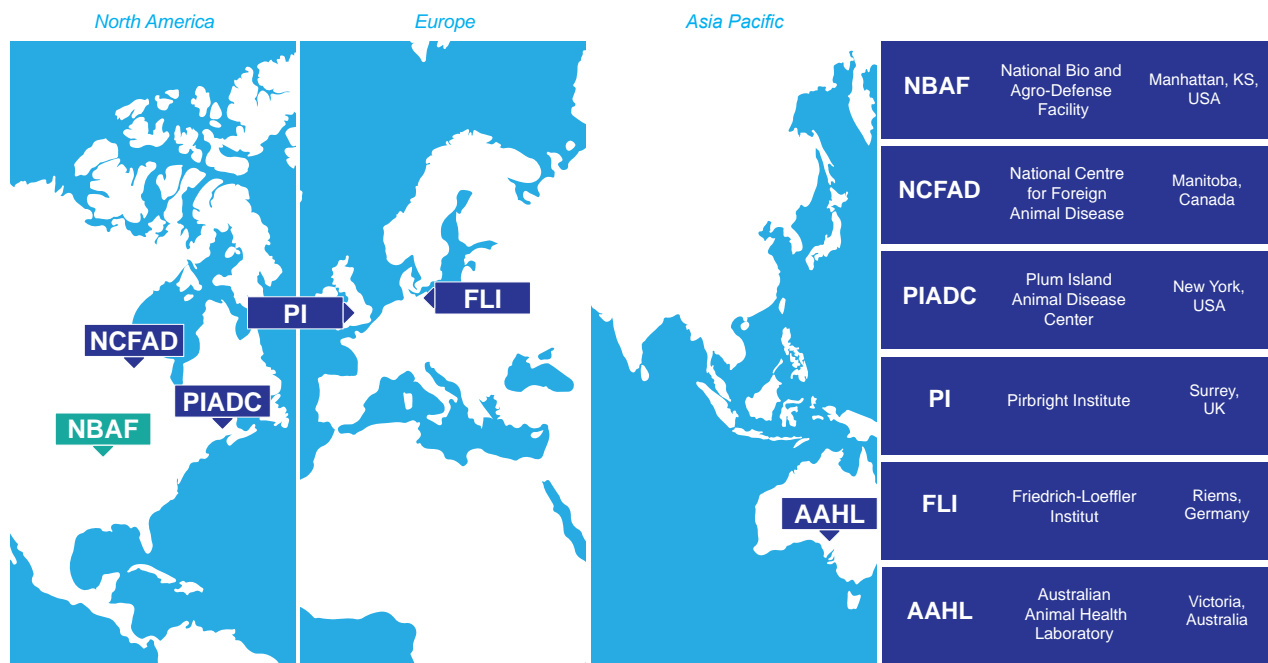


Figure 14: International network of large animal maximum containment research facilities participating in BSL4Znet

As one of the world's leading biocontainment facilities, NBAF will play an active role in global outreach and international initiatives relevant to the bio and agro-defense domain. NBAF may provide direct technical support through involvement of personnel; provision of subject matter expertise; or performance of (RDT&E) countermeasures.

FADDL has established a long tradition of training international veterinarians, scientists, and students. The FADDL mission at NBAF will include detection, diagnosis, and reagent production for an expanded repertoire of new/emerging transboundary and zoonotic animal diseases; increased outbreak response capabilities; and increased international outreach as a reference laboratory. Enhancements to training of FADDL staff, as well as external partners, veterinarians, scientists, and students will be an important part of the FADDL mission at NBAF. FADDL will continue as custodian and manager of the North American Foot-and-Mouth Vaccine Bank and as coordinator of the NAAHLN with Canada and Mexico.

NBAF will support global efforts to address emerging infectious diseases and is uniquely suited to address those occurring at the wildlife-livestock-human interface. Such efforts may involve engagement and coordination with WHO, FAO, OIE, U.S. Governmental organizations, and BSL4ZNet, among others.

7 STANDING UP A WORLD-CLASS LABORATORY



CREATING A NATIONAL ASSET
FOR AMERICA'S BIOSECURITY
INFRASTRUCTURE



A CULTURE OF RESPONSIBILITY & ACCOUNTABILITY

NBAF leadership is committed to the safety and health of employees, the public, and the environment, including U.S. agriculture.

USDA is committed to the successful stand-up and implementation of the vision for NBAF. To ensure effective, efficient, and secure inter- and intra-departmental planning, oversight, and management transition of all aspects of NBAF, USDA has formed an NBAF Executive Council with leadership from the Office of the Secretary, and the mission areas of Research, Education, and Economics and Marketing and Regulatory Programs. NBAF stand-up activities are overseen by the Executive Steering Committee, staffed by USDA and DHS top executives, and the USDA NBAF Transition Leadership Team (UNTLT), which is comprised of top leaders in both ARS and APHIS capable of making key decisions and providing guidance needed to move forward with the NBAF stand-up process. USDA also formed NBAF stand-up working groups comprised of USDA, DHS, and contractor support personnel:

- Animal Care & Use
- Biorepository Transfer
- Biorisk Management
- Budget
- Communications
- Contracting/Procurement
- Leadership Team
- Facilities
- Human Resources (HR)
- HR-Personnel Security
- IT
- Management/Lab Administration
- Security
- Room Data Sheets/Master Equipment Lists
- Science Program
- Secure Communications
- Safety, Health & Environmental Monitoring
- Technology Transfer
- Training
- Transshipping
- Laboratory Support Services

These working group members serve as the primary implementers of ongoing and immediate NBAF stand-up activities and will be supported in their execution of stand-up activities as new NBAF staff are hired. Each of the working groups represents a major functional, technical, or support area needed for the stand-up of NBAF.

THE VISION FOR OPERATIONS

The NBAF Operational Model (NOM) provides the vision for NBAF at a steady-state, FOC. The NOM is a foundational, yet living document that describes the idealized steady-state operation of NBAF. The NOM describes an operational framework with consideration of needs specific to ARS and APHIS, industry-best practices, and an appreciation for future technologies and methods to deliver a holistic recommendation for the best model in which to operate NBAF. Since technologies, practices, and regulations are constantly changing, the NOM provides the best possible operating strategy given knowledge and expertise that exists at that time. After NBAF is fully operational, the NOM will undergo periodic reviews and updates to account for foreseeable and unforeseeable changes in the scientific and technical communities, as well as any new policy or regulatory guidance.

THE NBAF CULTURE OF RESPONSIBILITY AND ACCOUNTABILITY

NBAF is critical to the protection of our nation’s food supply, agricultural economy, and public health and safety. To fulfill the mission, NBAF requires a Culture of Responsibility and Accountability. This Culture of Responsibility and Accountability speaks to the personal internalization of NBAF’s vision, mission, values, and practices. Adoption of this culture is achieved when all members of the NBAF team accept personal responsibility and commit to the successful completion of the mission; the security of the facility, its information, and its biological agents; and the identification and management of safety and ethical risks. This culture is supported by three core values:

Safety – We are committed to developing and maintaining a Culture of Safety through visible and active commitment by all levels of management to programs, policies, and procedures that support and enable open exchange of safety information among employees, contractors, and stakeholders.

Security – We are dedicated to a Culture of Security that will drive strategies to mitigate the risk of biosecurity failures that can impact the safety and security of our community and the nation’s animal and public health, economic, and critical infrastructure.

Quality – We embrace a Culture of Quality through individual quality programs and requirements of partner agencies and contractor counterparts.

NBAF PROGRAM TIMELINE

The following timeline (Figure 15) represents major construction and operational milestones to achieve steady state operations for NBAF.



Figure 15: Important NBAF milestones

THE INTEGRATED MASTER SCHEDULE

The USDA NBAF Stand-Up Integrated Master Schedule (IMS) captures and monitors the individual activities required to usher NBAF to steady-state operations. The IMS provides the granular level detail of all known activities required to achieve FOC at NBAF. The IMS is the roadmap and timetable for execution of all NBAF operational stand-up activities, many of which are underway and have been underway for years. As new information is learned, activities evolve, or durations change, the IMS will be updated as activities are added or completed.

Since many activities within the IMS are linked via interdependent relationships to form a critical path of activities, the IMS describes how any delays or accelerations of certain activities may have downstream impacts to other stand-up activities' completion dates. NBAF stand-up, and achievement of FOC, will be accomplished through the completion of all activities contained within the IMS. Some of the broader, overarching activities encompass many individual steps and range from establishing the security program at NBAF (personnel, physical, controlled entry space set-up, etc.), the installation of IT equipment (from switches and routers to office computing and laboratory equipment IT support), the hiring of animal caretakers, and the transfer of biological materials from PIADC to NBAF.

HIRE THE BEST AND BRIGHTEST WORKFORCE

Given NBAF's critical mission to protect America's food supply, cutting-edge design, modern equipment and facilities, and the opportunity to engage with the broader bio and agro-defense community, USDA is confident it will attract and incorporate the best and brightest minds to this state-of-the-art facility.

To accomplish its mission, USDA will transfer many of the experts from PIADC, then expand its workforce by acquiring entry-level and world-class scientists, technicians, and other support staff from the Manhattan, Kansas commuting area and across the nation.

The scientists and support staff who come to NBAF will also be attracted to the wide range of opportunities to accommodate and host partners and visiting collaborators (research fellows and graduate students) and to reinvest in the scientific communities and generations of today and tomorrow. The BDM will allow for the sharing of ideas, best practices, and staff resources to ensure the best possible science will be developed at NBAF.

8 CONCLUSION



CREATING A NATIONAL ASSET
FOR AMERICA'S BIOSECURITY
INFRASTRUCTURE



A KEY NATIONAL ASSET

NBAF will be the premier resource for vital research on transboundary and emerging animal diseases.

Furthering and expanding the mission of PIADC, NBAF is dedicated to the study of diseases that threaten both America's livestock industry and public health. As a next-generation laboratory, NBAF is crucial to the protection of our nation's food supply, agricultural economy, and public health and safety. NBAF will close capability gaps in animal disease research and response that will help this country's preparedness and response well into 21st century. This will help position NBAF as a provider of enduring capabilities in homeland security and establish it as one of the foremost research and diagnostic laboratory facilities in the world.

A critical national asset for America's biosecurity infrastructure, NBAF will be the gold standard for diagnosis, research, training, and containment of all types of emerging and zoonotic animal pathogens. It will be a premier resource for vital research on transboundary and emerging animal diseases. Collaboration with national and international entities are important parts of the mission.

NBAF takes this important work to a world-class level that further expands and extends its mission as America's buffer against catastrophic transboundary animal diseases. NBAF will play a crucial role in One Health, a collaborative, multisectoral, and transdisciplinary approach with the goal of achieving optimal health outcomes recognizing the interconnection between people, animals, plants, and their shared environment.

A STATE-OF-THE-ART FACILITY

NBAF will serve as the first animal BSL-4 facility designed to house and accommodate large livestock (principally cattle, swine, sheep, and goats) infected with high consequence zoonotic agents within the highest biocontainment envelope. This is a critical capability that does not currently exist within the U.S.

NBAF will also house the BDM, which offers the capability for small-scale production of standardized biological reagents needed for basic and applied research, as well as biological test materials for supporting proof-of-concept safety and efficacy studies, and early-phase veterinary MCM development. Furthermore, PIADC facilities are over 60 years old and no longer represent the most innovative and advanced equipment and design aspects for a biocontainment facility

NEW, UNIQUE CAPACITIES

NBAF will serve as a domestic and international resource for training, research and development, diagnostics, prevention, and response to transboundary, emerging, and zoonotic animal diseases. USDA will be better positioned to respond to sudden and emerging threats to U.S. agriculture.

INCREASED COLLABORATION AND INNOVATION

Through its robust partnerships, NBAF will establish an active group of NBAF partners and collaborators as a means of building an essential presence in the animal health and bio and agro-defense research space. NBAF will be the focus for concentrated knowledge and world-leading bio and agro-security infrastructure.

9 APPENDIX 1: GLOSSARY OF ACRONYMS AND ABBREVIATIONS



CREATING A NATIONAL ASSET
FOR AMERICA'S BIOSECURITY
INFRASTRUCTURE



ACRONYM**DEFINITION****A**

AAHL	Australian Health Laboratory
ABADRU	Arthropod-Borne Animal Diseases Research Unit
ABSL	Animal Biosafety Level
APHIS	Animal and Plant Health Inspection Service
ARS	Agricultural Research Service
ASPIRE	Agrosecurity Partnerships for Innovative Research

B

BDM	Biologics Development Module
BOD	Basis of Design
BRI	Biosecurity Research Institute
BSL	Biosafety Level
BSL-3Ag	Biosafety Level 3 Agriculture
BSL-3E	Biosafety Level 3 Enhanced
BSL4ZNet	Biosafety Level 4 Zoonotic Laboratory Network

C

CDC	Centers for Disease Control and Prevention
CGAHR	Center for Grain and Animal Health Research
CIA	Central Intelligence Agency
CMMS	Computerized Maintenance Management System
CRA	Collaborative Research Agreement
CRADA	Cooperative Research and Development Agreement
CSIRO	Commonwealth Scientific and Industrial Research Organisation
CUP	Central Utility Plan

D

DAAWG	Defense Against Agroterrorism Working Group
DHS	Department of Homeland Security
DOC	Department of Commerce
DOD	Department of Defense
DOE	Department of Energy
DOI	Department of the Interior
DOJ	Department of Justice
DOS	Department of State
DTRA	Data Transfer Research Agreement

E

EPA Environmental Protection Agency

F

FAD Foreign Animal Disease
 FADDL Foreign Animal Disease Diagnostic Laboratory
 FADD School Foreign Animal Disease Diagnostician School
 FADT Foreign Animal Disease Threats
 FAO Food and Agriculture Organization of the United Nations
 FBI Federal Bureau of Investigation
 FLI Friedrich-Loeffler Institut
 FMD Foot-and-Mouth Disease
 FMDV Foot-and-Mouth Disease Virus
 FOC Full Operational Capability

G

GARA Global African Swine Fever Research Alliance
 GFRA Global Foot-and-Mouth Disease Research Alliance

H

HHS Health and Human Services
 HSPD Homeland Security Presidential Directive
 HSADL High Security Animal Disease Laboratory

I

IC Intelligence Community
 IMS Integrated Master Schedule
 IT Information Technology
 ITAD International Transboundary Animal Diseases
 IVBW International Veterinary Biosafety Workgroup
 IVI Institute of Virology and Immunophyaxis

K

KCAHC Kansas City Animal Health Corridor
 KIFC Kansas Intelligence Fusion Center
 KSU Kansas State University

M

MCM Medical Countermeasures
 MTRA Material Transfer Research Agreement

N

NADC	National Animal Disease Center
NAAHLN	North American Animal Health Laboratory Network
NAHLN	National Animal Health Laboratory Network
NBACC	National Biodefense Analysis and Countermeasure Center
NBAF	National Bio and Agro-Defense Facility
NCAH	National Centers for Animal Health
NCFAD	National Centre for Foreign Animal Disease
NCMI	National Center for Medical Intelligence
NIFA	National Institute of Food and Agriculture
NOM	NBAF Operational Model
NVS	National Veterinary Stockpile
NVSL	National Veterinary Services Laboratories

O

OHS	Office of Homeland Security
OIE	World Organisation for Animal Health
OTA	Other Transaction Authority

P

PI	Pirbright Institute
PIA	Partnership Intermediary Agreement
PIADC	Plum Island Animal Disease Center

R

RDT&E	Research, Development, Test, and Evaluation
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S

STAR-IDAZ	Global Strategic Alliances for the Coordination of Research on the Major Infectious Diseases of Animals and Zoonoses
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U

UNTLT	USDA NBAF Transition Leadership Team
USD	U.S. Dollar
USDA	United States Department of Agriculture

W

WBR	Wageningen Bioveterinary Research
WHO	World Health Organization

