

# **NBAF Biotechnology Development Module (BDM) Webinar**

**James Johnson  
Director, Office of National Laboratories  
Science & Technology Directorate  
U.S. Department of Homeland Security**

**April 2013**



**Homeland  
Security**

# Agenda

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9:00 a.m. – 9:15 a.m.

**Welcome and Introduction**

Jamie Johnson, Director, Office of National Laboratories, DHS

Steven Kappes, Deputy Administrator, Animal Production and Protection, USDA

Beth Lautner, Director, National Veterinary Services Laboratories, USDA

9:15 a.m. – 10:00 a.m.

**NBAF Program Overview**

Jamie Johnson, Director, Office of National Laboratories , DHS

10:00 a.m. – 10:45 a.m.

**BDM Design, Operational Requirements, and Utilization Plans**

Julie Brewer, Chief, Construction Branch, Office of National Laboratories, DHS

Joanne Jones-Meehan, Biosurety Officer, Office of National Laboratories, DHS

Michelle M. Colby, Agriculture Defense Branch Chief, Chemical Biological Defense Division, DHS

10:45 a.m. – 12:00 p.m.

**General Q&A**

12:00 p.m.

**Closing Comments**

Jamie Johnson, Director, Office of National Laboratories, DHS

# Welcome and Introduction

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## Key Participants:

### DHS:

- Jamie Johnson, Director, Office of National Laboratories (ONL)
- Julie Brewer, Construction Branch Chief, ONL
- Tim Barr, Construction Project Manager, ONL
- Joanne Jones-Meehan, Biosurety Officer, ONL
- Eugene Cole, NBAF Technical Manager, ONL
- Michelle M. Colby, Agriculture Defense Branch Chief, Chemical Biological Defense Division (CBD)
- Mary Goobic, Program Analyst, ONL

### USDA Agricultural Research Service (ARS):

- Steven Kappes, Deputy Administrator, Animal Production and Protection

### USDA Animal and Plant Health Inspection Service (APHIS):

- Beth Lautner, Director, National Veterinary Services Laboratories

# Goals of Webinar

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- Overview and update on the NBAF
- Overview of the planned mission requirements of the BDM
- Present the proposed BDM design
- Review analogous current and planned biological counter-measure development initiatives
- Gauge industry interest in the utilization of the BDM to enhance collaboration
- Answer questions

**Note: DHS will hold meeting in Kansas in June 2013 to provide feedback on RFI submissions and hold panel discussions**



# NBAF Mission



*The NBAF, a new, state-of-the-art biosafety level 3 & 4 facility, located in Manhattan, KS, will enable the U.S. to conduct comprehensive research, develop vaccines and antivirals, and provide enhanced diagnostic capabilities to protect our country from numerous foreign animal, emerging and zoonotic diseases.*

# Agricultural Threats and Economic Impacts

❑ Large-scale threat to agriculture sector might arise via many routes, but the main routes are:

➤ **Agroterrorism**

- Intent to cause economic and social disruption
- May also threaten public health, depending upon 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 Zoonoses**

- Number of emerging infectious disease events increasing over time



**Agriculture and the food industry contributes more than \$1 trillion to the economy per year and one-sixth of the our gross national product (GDP)**



- Protect the nation's animal agriculture and public health against numerous foreign animal and emerging zoonotic diseases
- Conduct research, diagnostics, vaccine development and testing, and training for veterinary and animal agricultural specialists in preparedness and response
- Strategic partnership between DHS and USDA to set research priorities based on threats to animal agriculture, conduct risk assessments, gap analysis and other necessary evaluations to protect the U.S. from threats to agriculture.
- Fills the capability gap in HSPD-9: *Defense of U.S. Agriculture and Food* (paragraph 24) to “develop a plan to provide safe, secure, and state-of-the-art agriculture biocontainment laboratories... for foreign animal and zoonotic diseases.”
- Currently 8 foreign animal and zoonotic diseases planned for study (listed below), which require BSL-3 Ag and BSL-4 laboratory capabilities:

**FMD Virus, Classical Swine Fever, African Swine Fever, Rift Valley Fever, Contagious Bovine Pleuropneumonia, and Japanese Encephalitis Virus, Nipah Virus and Hendra Virus**

# NBAF Capabilities

**NBAF will provide expanded mission and capacity from the current Plum Island mission to better prepare the labs to detect and respond to FAD, emerging and zoonotic diseases.**

- Support basic and applied research for early detection of foreign animal and zoonotic diseases
- Provide concurrent development of multiple vaccines or biotherapeutics
- Lead acceleration and expansion of countermeasures for response to a high consequence foreign animal disease outbreak
- Perform diagnostic development and operational testing
- Pilot production of vaccines for proof of concept and further developmental testing
- Maintenance of the vaccine bank
- Provide enhanced training for veterinarians and other animal health professionals in foreign animal diseases to establish U.S. rapid response capability
- Provide Large Livestock BSL-4 space for research on foreign animal, emerging and zoonotic diseases

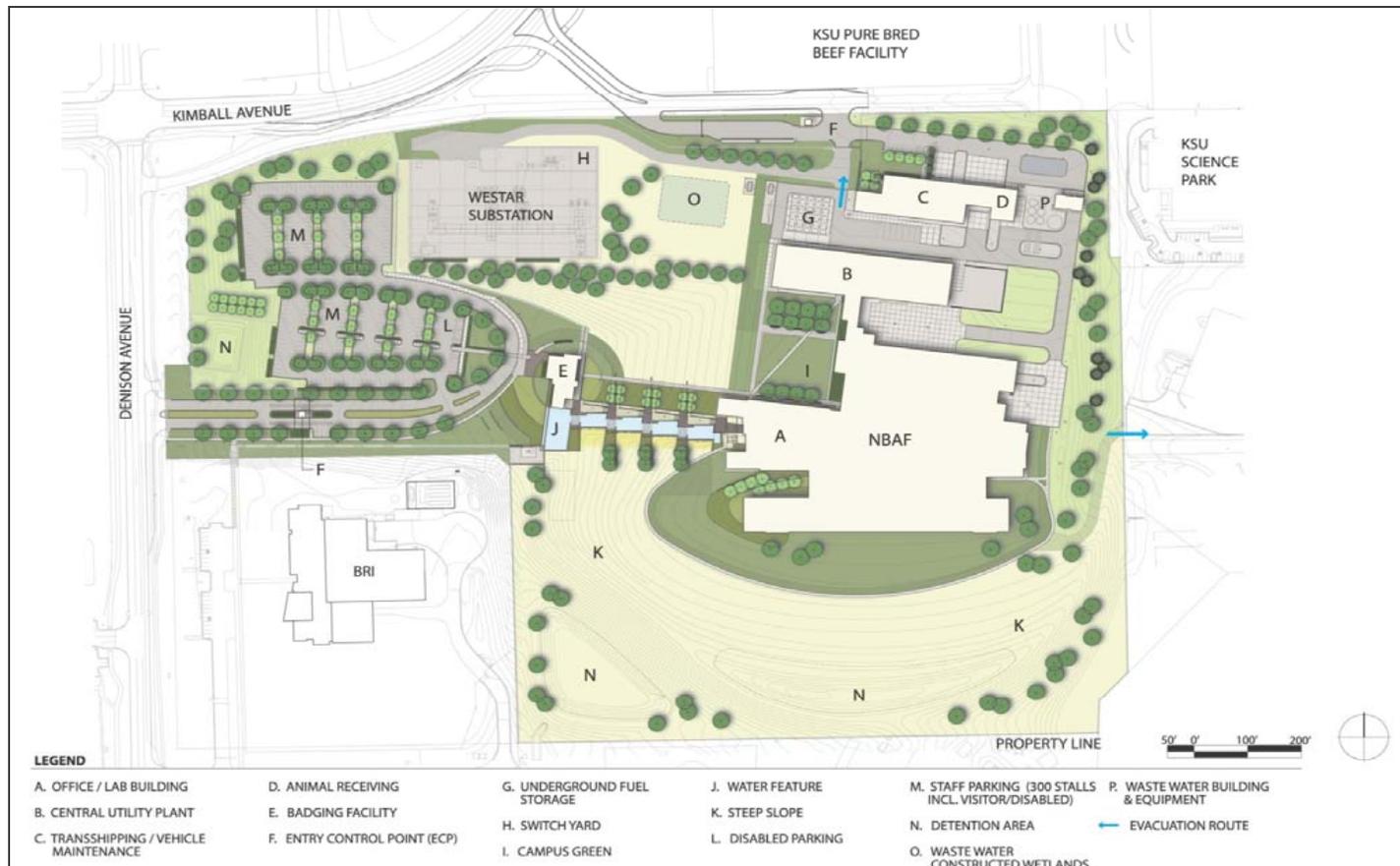
# NBAF Design Concept



- ❑ First BSL-4 facility in the U.S. for large animal research
- ❑ 574,000 gross square feet of research, animal holding and laboratory support spaces
- ❑ Hoteling concept and shared research space to provide optimum utilization of space and facility resources
- ❑ Space for vaccine development
- ❑ Entry Control Center, Central Utility Plant, transshipping and storage facilities
- ❑ Planning basis is to operate NBAF as a Government-Owned/Government-Operated (GOGO) Facility

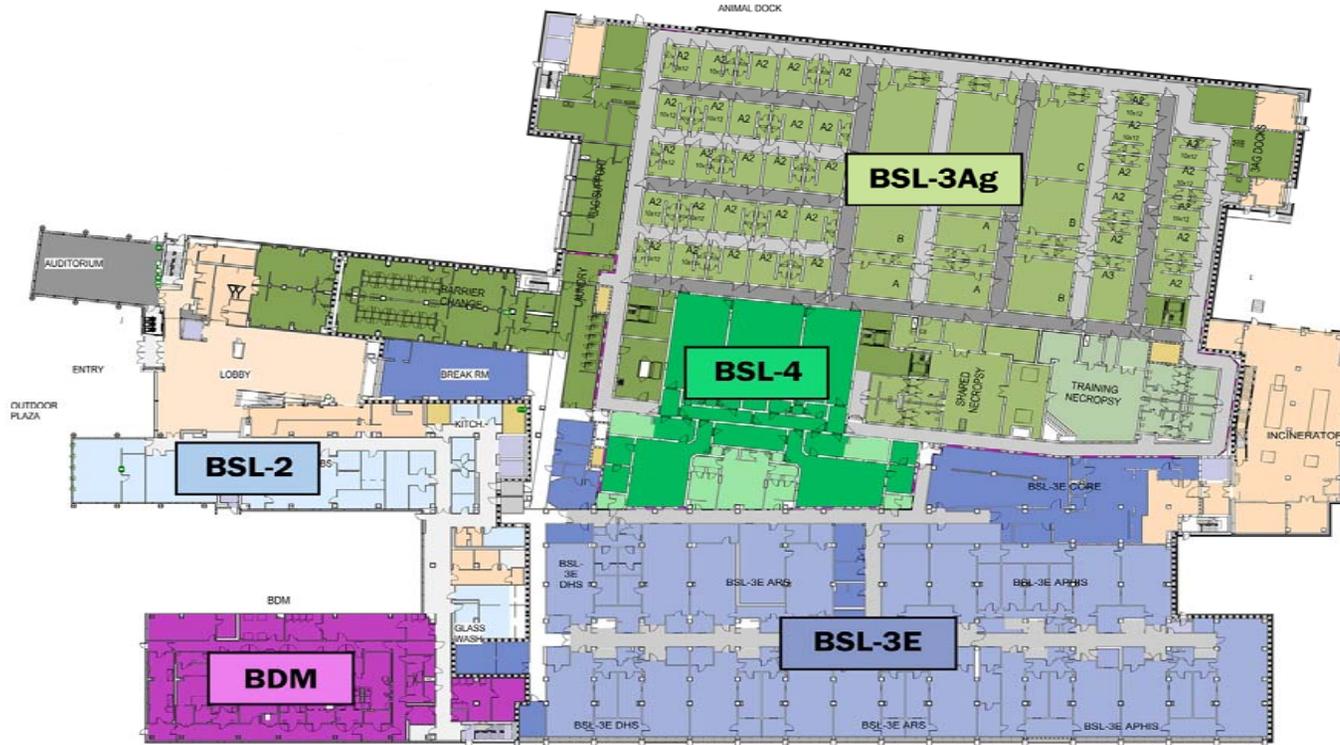
# NBAF Site Plan

- ❑ The Kansas State Biosecurity Research Institute (BRI) will be leveraged for training, complementary research and administration
- ❑ NBAF strategically positioned to leverage proximity to animal health corridor





# NBAF Laboratory Design



Type of Space	NBAF NSF
BSL-4 Laboratories	13,400
BSL-3Ag + BSL-3E Laboratories	81,100
BSL-2 Laboratories	9,700
Biotechnology Development Module	8,300
Office & Support Space	63,500
<b>Main Building Total NSF</b>	<b>176,000</b>
<b>Main Building Total GSF</b>	<b>580,200</b>

# Completed Activities to Date

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- ✓ **Design 100% complete by world class architecture engineering firm (NBAF Design Partnership)**
- ✓ **Completed peer reviews of NBAF design, construction and operations plans**
- ✓ **McCarthy-Mortenson selected as construction manager for entire NBAF project**
- ✓ **Site-Specific Risk Assessment (SSRA) was completed and outputs incorporated into the design and operations planning**
- ✓ **Land transferred to DHS in December 2012**
- ✓ **Activities to prepare the site for construction are complete**
- ✓ **Awarded the Central Utility Plant (CUP) construction contract in February 2013**

# NBAF Site Ready to Support Construction



- General grading of site complete
- Installation of sanitary and storm sewer
- Installation of water lines
- Installation of storm water retention ponds
- Installation of paved and gravel parking areas
- Installation of entrance off Kimball Ave.
- Installation and set up of construction trailers
- Installation of permanent perimeter fence

# NBAF Governance Model Has Been Determined

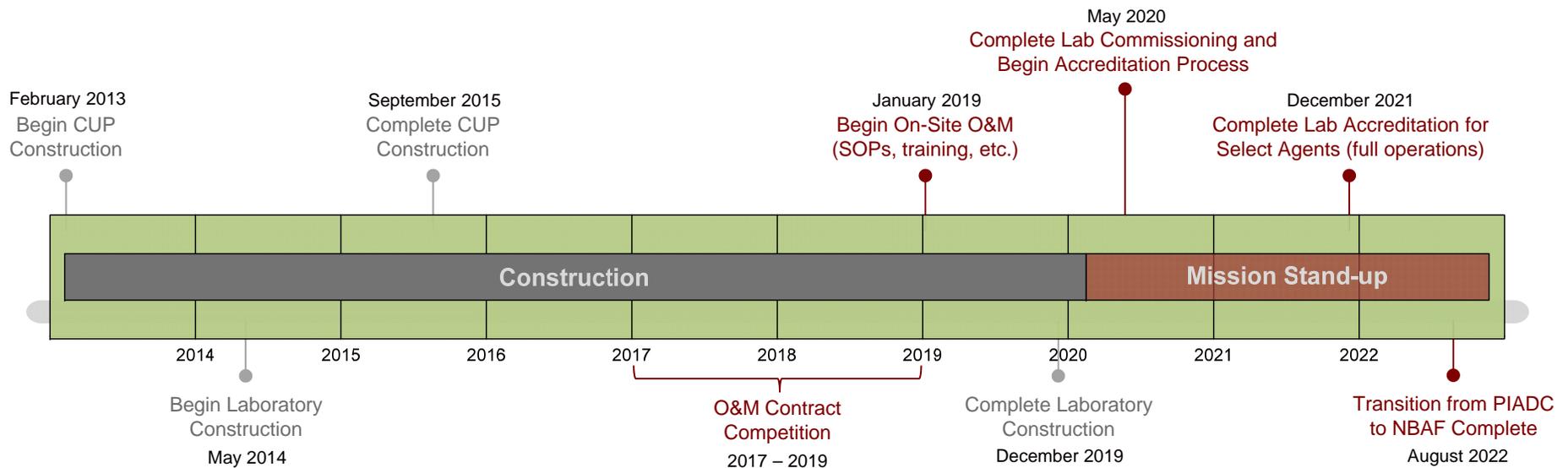
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- ❑ **As currently planned, the NBAF governance model will be Government Owned and Government Operated (GOGO) with contractor support**
  - **Leverages the 60+ years of operations at Plum Island Animal Disease Center (PIADC)**
  - **Offers the opportunity to draw more effectively upon private sector experience**
  - **Federal employees provide direction to the contractor(s) for the research mission and O&M of the facility**
  - **U.S. Government (USG) has full control over the facility to meet mission needs including during emergency situations**
  - **USG determines which facility, security, and biocontainment upgrades are needed**
  - **Promotes International/Federal agency collaborations**
  - **Reduce contract steps for work for others (WFOs)**
  - **Liability coverage**

# Doing Business with DHS S&T

<b>TYPE</b>	<b>GRANT</b>	<b>CONTRACT</b>	<b>Cooperative Research and Development Agreement (CRADA)</b>
<b>Funding</b>	Advance payment allowed if appropriate	Pay for delivery after receipt	No funding from gov't to collaborator, but collaborator can provide funding to gov't
<b>Competition</b>	Competed based on technical/ programmatic merits	Price must be considered, technical/ programmatic merits considered as well	Agency may put out Notice of CRADA intent, or either party can approach the other to initiate
<b>Termination</b>	Grantee can terminate	No contractor right to terminate	Either party can terminate
<b>Deliverable</b>	Publication, report or completion of a project	Product or service required	Products or services agreed to on both sides
<b>Legal Authority</b>	OMB Circulars	Federal Acquisition Regulation	15 USC § 3710a

# NBAF Integrated Project Timeline



- Construction will begin for the NBAF laboratory facility upon Congressional approval and appropriation in FY 2014.**
- A preliminary transition plan was developed to plan and coordinate initiating operations at NBAF.**
- Full operations are expected to begin in 2021.**

# Mission and Vision of the NBAF BDM

- ❑ Provide a key enabling resource for the defense of U.S. agriculture by enhancing efficacy and timeliness of biological countermeasure development
- ❑ Address critical needs to develop pilot manufacturing processes to transfer technology and reagents to veterinary pharmaceutical and bio tech industries
- ❑ Address Homeland Security Presidential Mandate (HSPD-9, paragraph 23) to “accelerate and expand” countermeasures for agriculture
- ❑ Serve to attract animal industry involvement and encourage public-private partnerships as biological countermeasure candidates emerge from the NBAF



**BDM Enhances NBAF Mission**

# Background

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- ❑ **BDM provides capabilities that we do not have at Plum Island**
- ❑ **Right sized to meet government requirements**
  - **Currently, larger global veterinary biologics companies with U.S.-based production facilities operate under cGMP for global marketed products in order to meet the regulatory requirements of EU, Japan, etc.**
- ❑ **DHS and USDA desire to explore partnerships and collaborations with animal health industry to provide supplemental GMP capabilities**
- ❑ **Requesting animal health industry input on ways to foster collaboration for countermeasure development**
  - **Explore need for additional GMP space on adjacent NBAF property or other locations**
  - **Modify current design layout**
  - **GMP is important for manufacture of veterinary countermeasures**

## **NBAF BDM – Planned Scope/Services Available**

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- Provide small scale production of biological reagents for basic research, and biological countermeasure materials for supporting efficacy studies and early phase clinical trials**
- Designed to support early development and eventual license of vaccines/products/reagents discovered at NBAF**
- Enable federal government to implement early product initiatives in partnership with the private sector to increase rate of technology transfer success**
- Support key processes and production areas:**
  - **Technology transfer to potential future commercial manufacturers**
  - **Biological development activities (process development, scale up, etc.)**
  - **Master cells for production**
  - **Attenuated viral and bacterial master seed**

***Are there other perceived needs for the BDM?***

# DHS Seeking Feedback Regarding...

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- Are there additional or different perceived needs for the BDM?
- How much interest is there for utilizing the BDM?
- Is the BDM right sized for capacity?
- What are the proposed utilization alternatives for the BDM?
- What are the possible mechanisms to enhance collaboration between the BDM and the animal health biologics industry?
- Provide lessons learned for DHS to consider regarding design and operational planning for the BDM.
- Need for GMP capabilities adjacent to NBAF or other locations

***Input will be used by DHS and USDA  
to better plan the **scope, capacity,** and  
**utilization alternatives** for the BDM  
facility***

# **BDM Facility Design**

**Julie Brewer**

**Chief, Construction Branch, ONL  
Science & Technology Directorate  
U.S. Department of Homeland Security**

**April 2013**



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# The BDM enhances the NBAF mission

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- ❑ The BDM satisfies HSPD-9 paragraph 23 by helping “***accelerate and expand development of current and new countermeasures against the intentional introduction or natural occurrence of catastrophic animal, plant, and zoonotic diseases.***”
- ❑ The BDM is designed to support the development and eventual license of products/reagents discovered and developed at the NBAF.
- ❑ The BDM will foster collaboration with the veterinary biopharmaceutical industry.
- ❑ The BDM mission space adds cGMP capabilities to the NBAF mission that are not present at PIADC.

# The BDM will produce vaccines and reagents on a small scale

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## ❑ The BDM will provide capability for:

- Small scale production of biological countermeasure materials for supporting efficacy studies and early phase clinical trials responding to DHS programs
- Small scale production of biological reagents for DHS, ARS, and APHIS programs.

## ❑ The BDM is designed as follows:

- The facility was designed to meet containment and cross contamination control requirements set forth in various guidelines and federal regulations.
- The production suites and general support areas for the individual suites are designed as a BSL-2 containment facility with a BSL 3 Enhanced production area for the development of inactivated and attenuated viral products.
- While BSL 4 vaccine capability will not be provided for the initial program, the layout was designed with potential for contiguous expansion for this function.

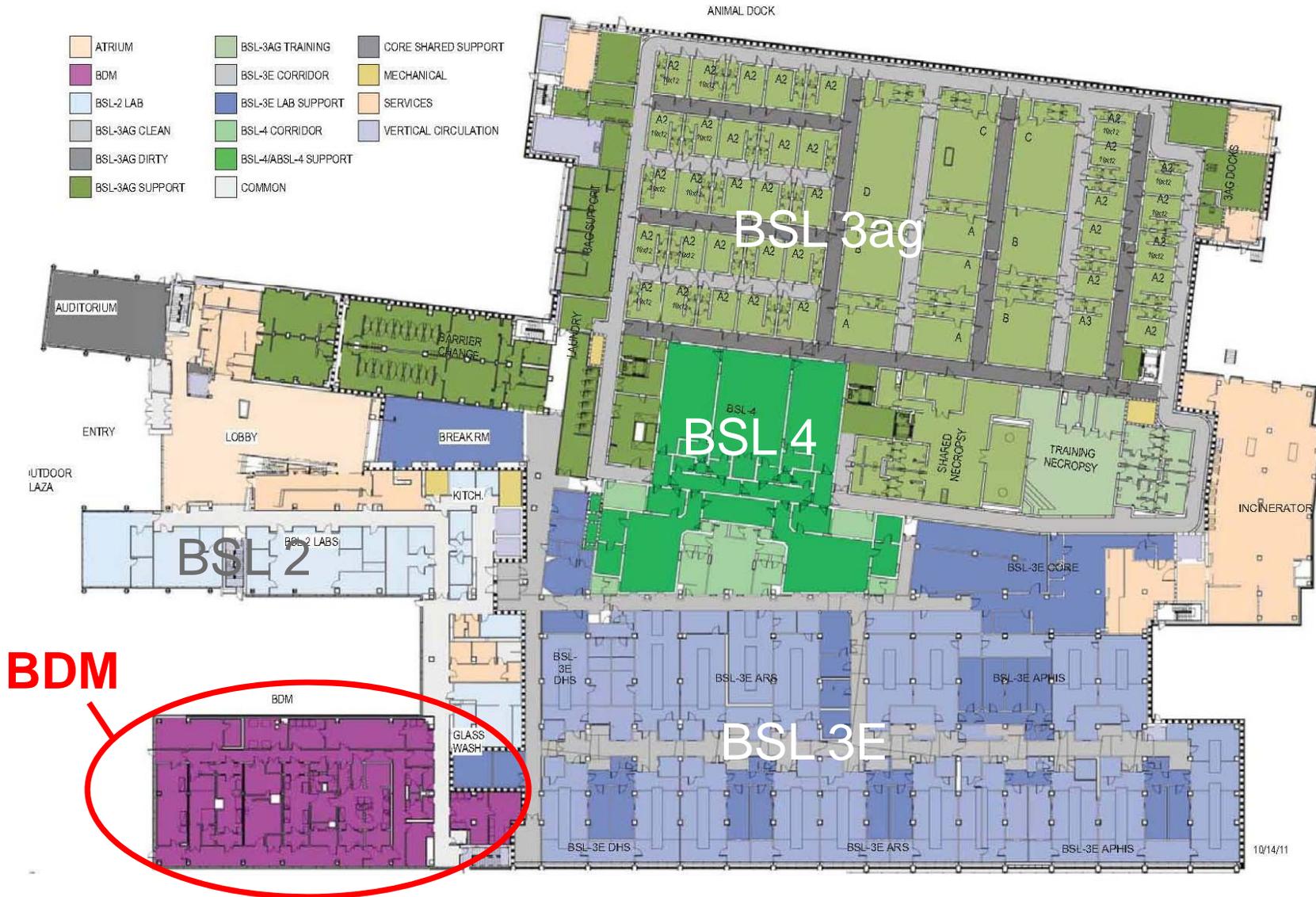
# The BDM will be physically segregated from other NBAF missions

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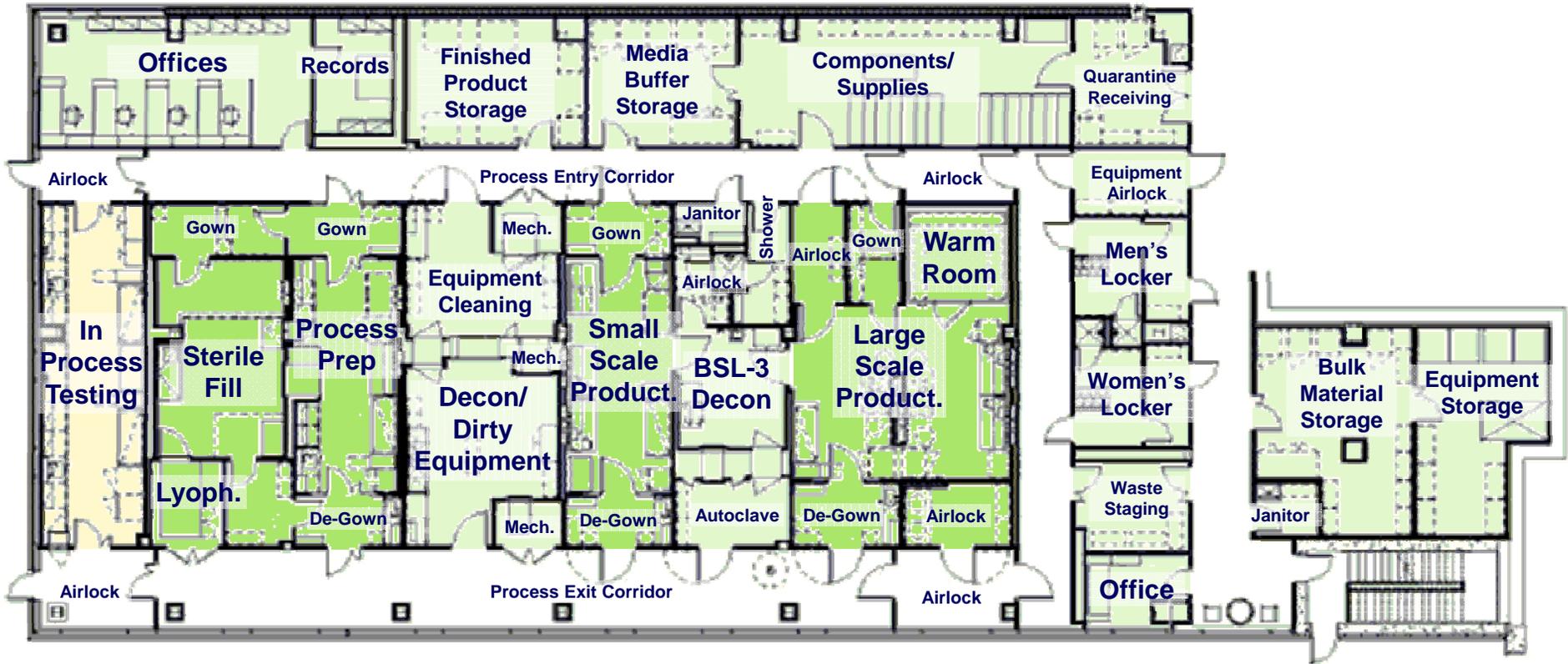
- ❑ **The BDM follows current Good Manufacturing Practices (cGMP) protocol requirements for the prevention of contamination and cross-contamination of products.**
  - Segregated areas of production
  - Strict cleaning and validation protocols
  - Air supply and exhaust segregation of the main lab and separate processes
- ❑ **The BDM was designed to be used 24 hours a day on a year round schedule once operational.**
- ❑ **The facility is designed as an 8,300-square foot mixed use space**
  - Space allocated for BSL-3 capabilities, quality control laboratories, office space, storage and warehousing and utilites.



# BDM Location in NBAF



# BDM Schematic Design



Legend	
<span style="display: inline-block; width: 15px; height: 15px; background-color: #008000; border: 1px solid black;"></span>	PRODUCTION
<span style="display: inline-block; width: 15px; height: 15px; background-color: #90EE90; border: 1px solid black;"></span>	PRODUCTION SUPPORT
<span style="display: inline-block; width: 15px; height: 15px; background-color: #FFD700; border: 1px solid black;"></span>	LABORATORY

Net Square Feet (Estimated)	
<b>Total BDM</b>	<b>8300</b>
PRODUCTION	2040
PRODUCTION SUPPORT	4350
LABORATORY	400
CIRCULATION	1510

# **DHS Science Mission: PIADC to NBAF**

**Michelle Colby, DVM, MS  
Agricultural Defense Branch Chief  
Science & Technology Directorate  
U.S. Department of Homeland Security**

**April 2013**

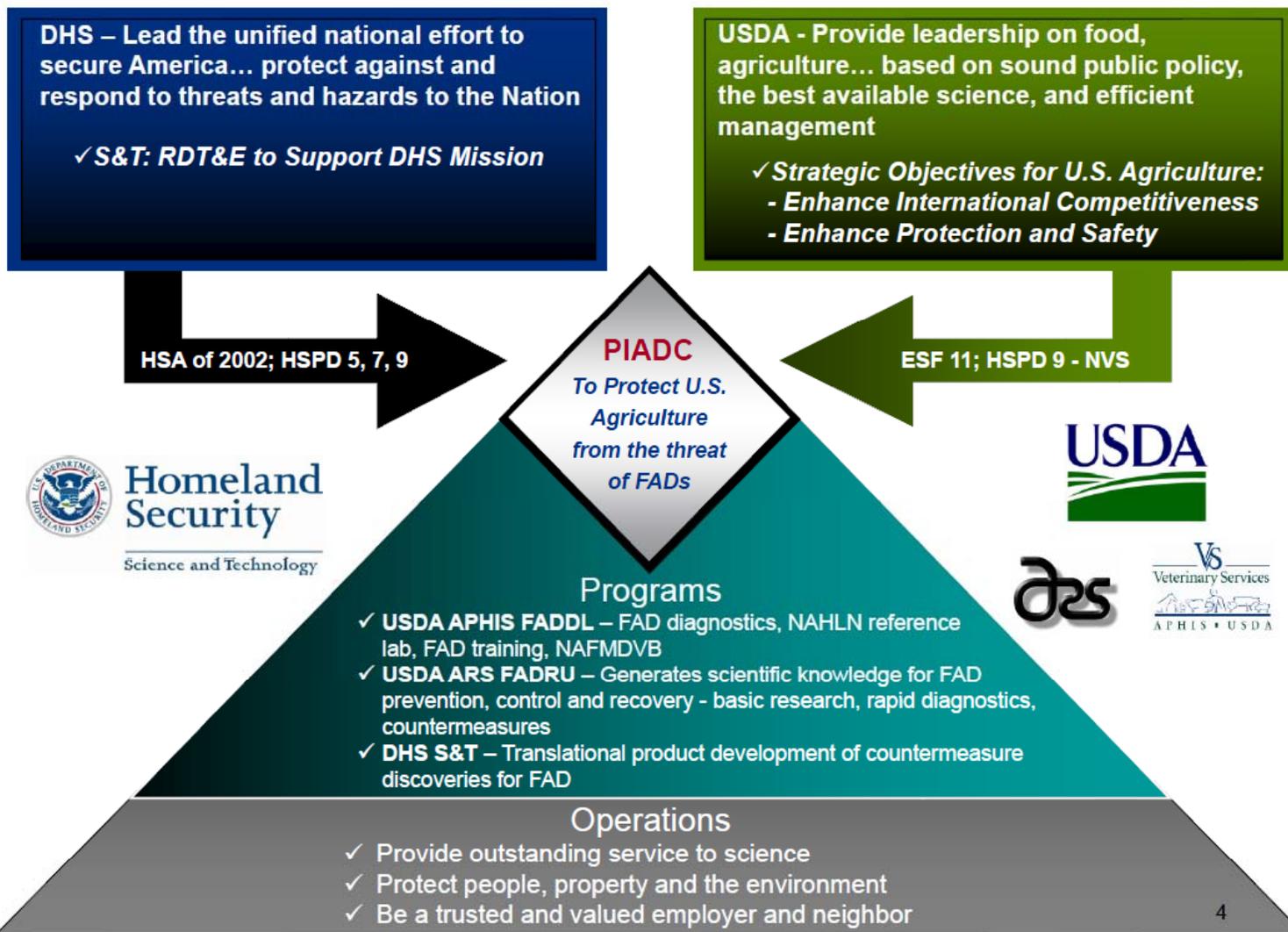


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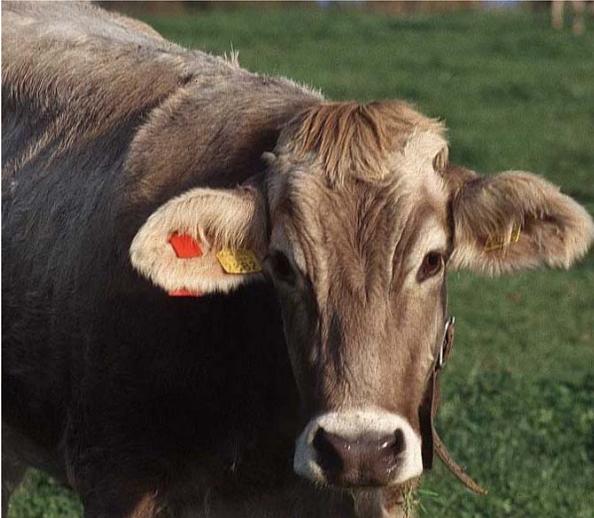
The Agricultural Defense mission is to conduct risk-based agricultural threat countermeasure development; to accelerate and expand the development of current and new medical and diagnostic countermeasures to detect, and prevent the spread of, an intentional introduction or natural occurrence of a catastrophic foreign animal disease in coordination with internal and external stakeholders.

HSPD-9 Paragraph 23: *The Secretaries of [DHS, USDA, HHS & EPA]...in consultation with the Director of the Office of Science and Technology Policy, will **accelerate and expand development of current and new countermeasures** against the intentional introduction or natural occurrence of catastrophic animal, plant, and zoonotic diseases. The Secretary of Homeland Security will coordinate these activities.*

# Integrated FAD Missions



# FAD Vaccines and Diagnostics Project



Develop more effective vaccines and diagnostic countermeasures for high priority FAD, in partnership with the USDA and industry.

## FMD Vaccines (initiated 2005)

- Near term - Enhanced characterization of current vaccine antigens (N. American FMD Vaccine Bank) and commercial FMD vaccines
- Mid term – Enhanced characterization and import permits for ‘Off the shelf’ foreign-manufactured, inactivated FMD vaccines
- Long term - New serotype- and subtype-specific, marked, molecular vaccines (pipeline) \*Conditional License May 2012

## Countermeasures for Other FAD

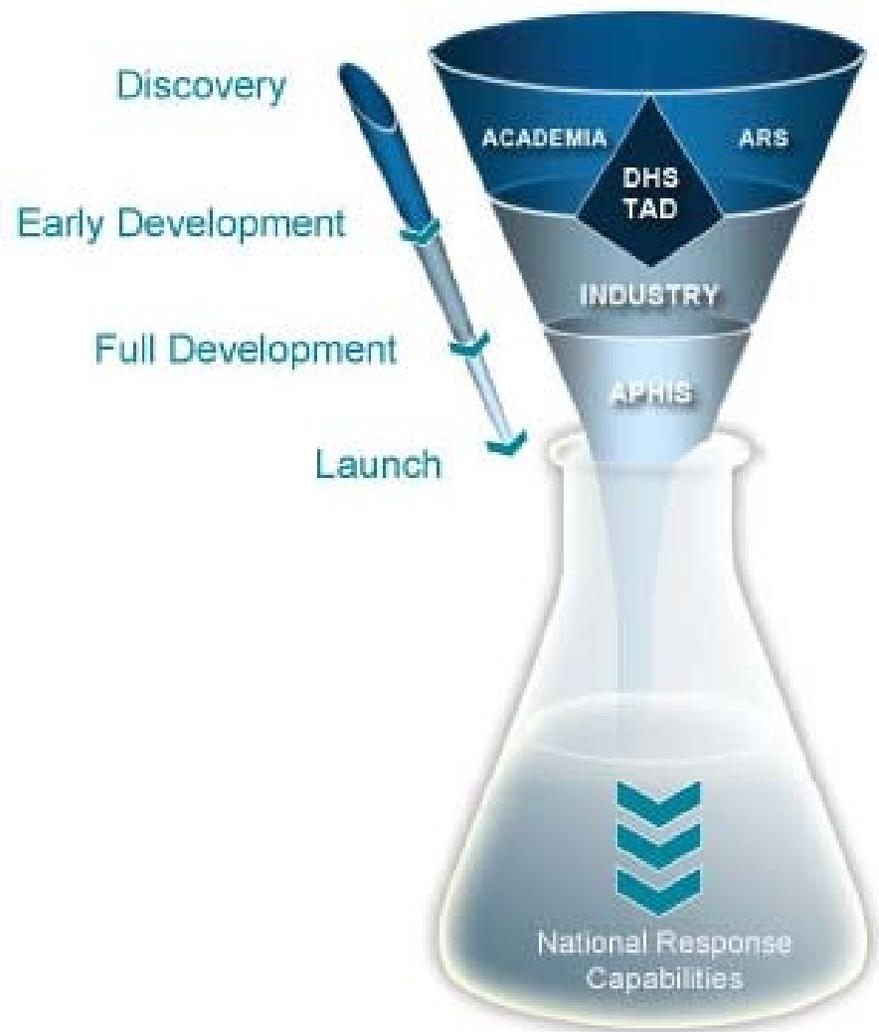
- Prioritized agents identified by key customer (USDA-APHIS Emergency Management – NVS) and interagency working groups (FADT)
- Includes near term, mid term and long term R&D funding projects for swine (CSF, ASF) and zoonotic (RVF) FADs

## Diagnostics

- Next-generation high-throughput and molecular-based technologies for surge in National Animal Health Laboratory Network (NAHLN)

# Overview of Vaccine and Diagnostic Countermeasure Product Candidate Pipeline

1. FMD molecular vaccine candidates – 8 platforms
2. CSF live, attenuated vaccines – 2 candidates
3. ASF molecular vaccine candidates – 3 platforms
4. Henipavirus molecular vaccines – 2 candidates
5. RVF live, rationally attenuated vaccine – 2 candidate



- ❑ **Expand the development of countermeasures for multiple FAD and zoonotic diseases; developing, testing, and evaluating novel delivery methods of those product types**
  - **Current lack of capacity limits the testing, evaluation and development of vaccine candidates for FMD and other FAD's**
  - **PIADC can support three vaccine efficacy trials concurrently**
    - **As current off-island investments in African Swine Fever, Classical Swine Fever and alternative FMD vaccine platforms mature, we will begin to outgrow the space available at PIADC and have to prioritize/delay on-island proof-of-concept (POC) and efficacy studies**
    - **We are funding Rift Valley Fever and Henipavirus platforms that cannot undergo POC or efficacy testing at PIADC, but this could be done in NBAF**

- ❑ **Enhance opportunities for industry engagement in the advanced development pipeline and improve probability of successful technology transitions**
  - **NBAF is located very close to the K-State Veterinary School, the Animal Health Biotechnology Corridor, and several agricultural/land grant universities**
  - **NBAF Biotechnology Development Module will enable stronger collaboration with the veterinary biopharmaceutical industry**
  - **BSL-4 livestock capability may foster collaborative opportunities with other federal agencies (i.e., DOD, HHS)**

- **The NBAF will include a unique pilot production facility which will accelerate existing countermeasure development efforts**
  - **Current facility plans include a Biotechnology Development Module (BDM), which will be capable of vaccine master seed production (pilot scale\*) and scaling up production of small lots of candidate countermeasures**
  - **This new space will eliminate the need for DHS to contract out to private industry for some parts of the countermeasure development process and will allow DHS and USDA researchers to develop countermeasure technologies to a point attractive as an investment to the animal biologics industry**
  - **To facilitate downstream regulatory processes, the BDM is planned to operate in accordance with concepts of quality design consistent with current Good Manufacturing Practice (cGMP), allowing countermeasure production to be conducted within the framework of regulatory guidelines and requirements for veterinary biologics**

\* This will not include vaccines that require the use of live FMD virus

## Next Steps

- ✓ RFI Issued – March 4
- ✓ BDM Webinar – April 22
- ✓ RFI Written Responses Due **May 3, 2013**
- ✓ Follow-Up Meeting June 2013

### Request for Information (RFI)

Are there additional or different perceived needs for the BDM?

How much interest is there for utilizing the BDM?

Is the BDM right sized for capacity?

What are the proposed utilization alternatives for the BDM?

What are the possible mechanisms to enhance collaboration between the BDM and the animal health biologics industry?

Provide lessons learned for DHS to consider regarding the BDM.

### Questions?

**Contact: [nbafprogrammanager@dhs.gov](mailto:nbafprogrammanager@dhs.gov)**

*Updates Posted on DHS website ([www.dhs.gov/nbaf](http://www.dhs.gov/nbaf))*