

# NBAF Biotechnology Development Module (BDM)

## Preparation Information for Workshop

Office of National Laboratories  
Science and Technology Directorate



**Homeland  
Security**

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Science and Technology



- 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 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**



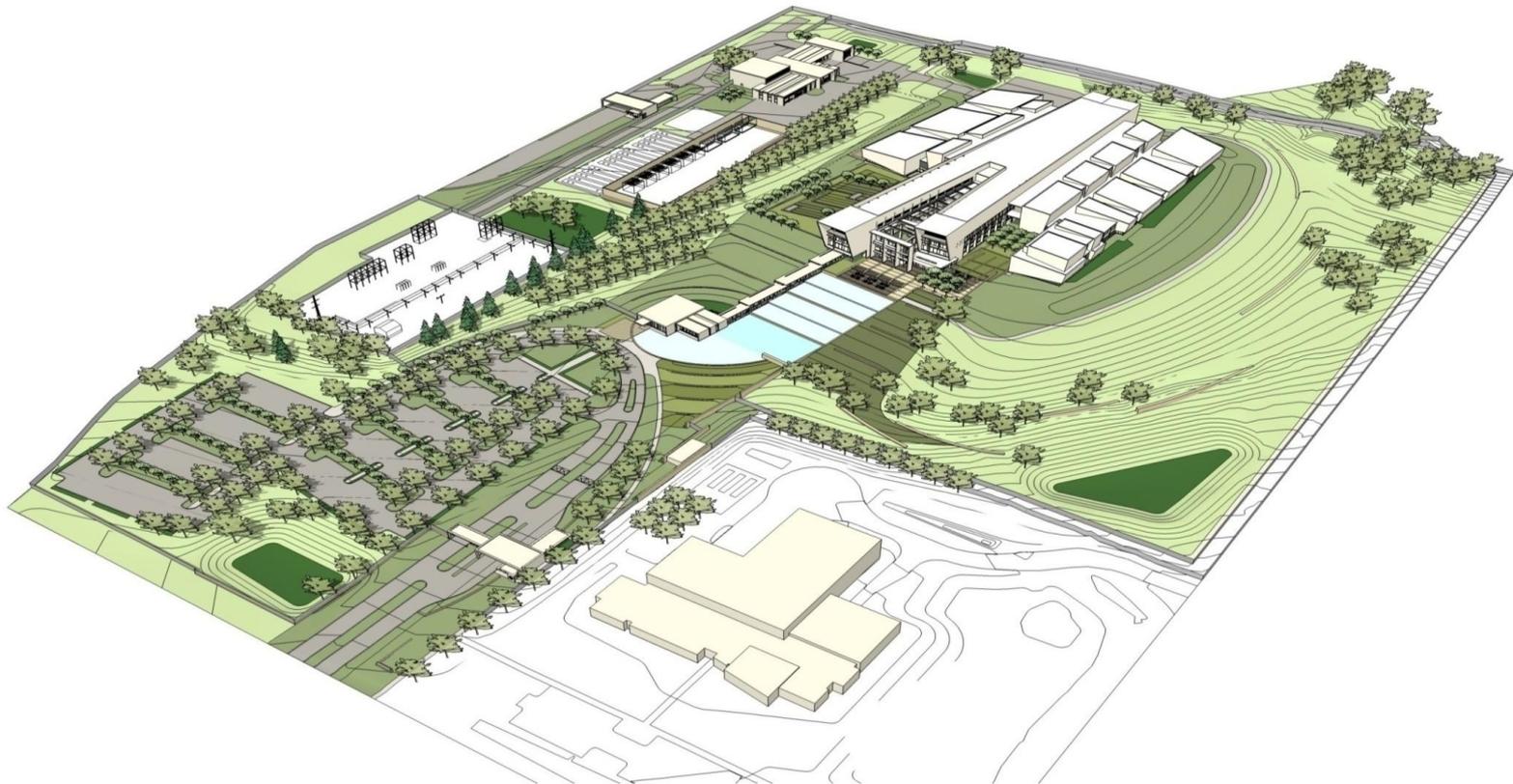
# NBAF Capabilities

**NBAF is a 574,000 sq. ft. BSL-3Ag and Large Animal BSL-4 biocontainment laboratory that is designed to:**

- 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**
- Perform maintenance of the vaccine bank**
- Train 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**



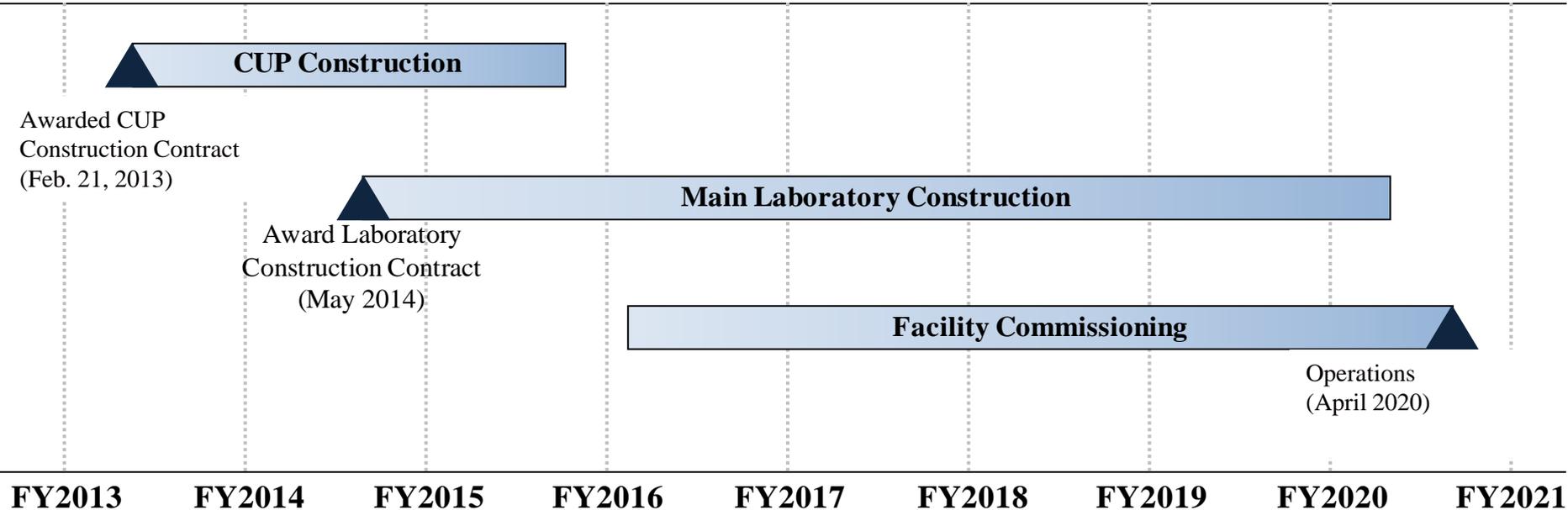
# NBAF Site Concept Design



- 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 Schedule



**Construction will begin for the NBAF (and BDM) upon Congressional approval and provision of funding**



# 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





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

- ❑ The NBAF Biotechnology Development Module (BDM) will provide small scale production of biological reagents for basic research, and biological countermeasure materials for supporting efficacy studies and early phase clinical trials.**
  
- ❑ Processes and production areas will include the ability to support:**
  - 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**
  - Monoclonal antibodies and diagnostic reagents**
  - Plasmid DNA products, recombinant proteins and natural antigens**
  - Small scale viral and bacterial (attenuated or inactivated) vaccines**
  - Dedicated formulation/aseptic fill areas and processes**

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



# NBAF BDM – Building Features

- The BDM is 8,300 ft<sup>2</sup> and consists of production suites and general support spaces
- BSL-2 containment with BSL-3 enhanced production area for development of inactivated and attenuated viral products (no live FMD virus)
- Meets USDA APHIS Center for Veterinary Biologics requirements; compliant with 9 CFR 101-123
- Flexibility to operate under current Good Manufacturing Practices (cGMP) as per 21 CFR Parts 210/211/600 and 610
- BDM will be utilized 24 hours per day, based on annual production needs
- Adjacent to NBAF
- Close proximity to BRI, USDA ABADRU, KSU and College of Veterinary Medicine, Animal Health Research Corridor

***Is the BDM right-sized  
for capacity?***

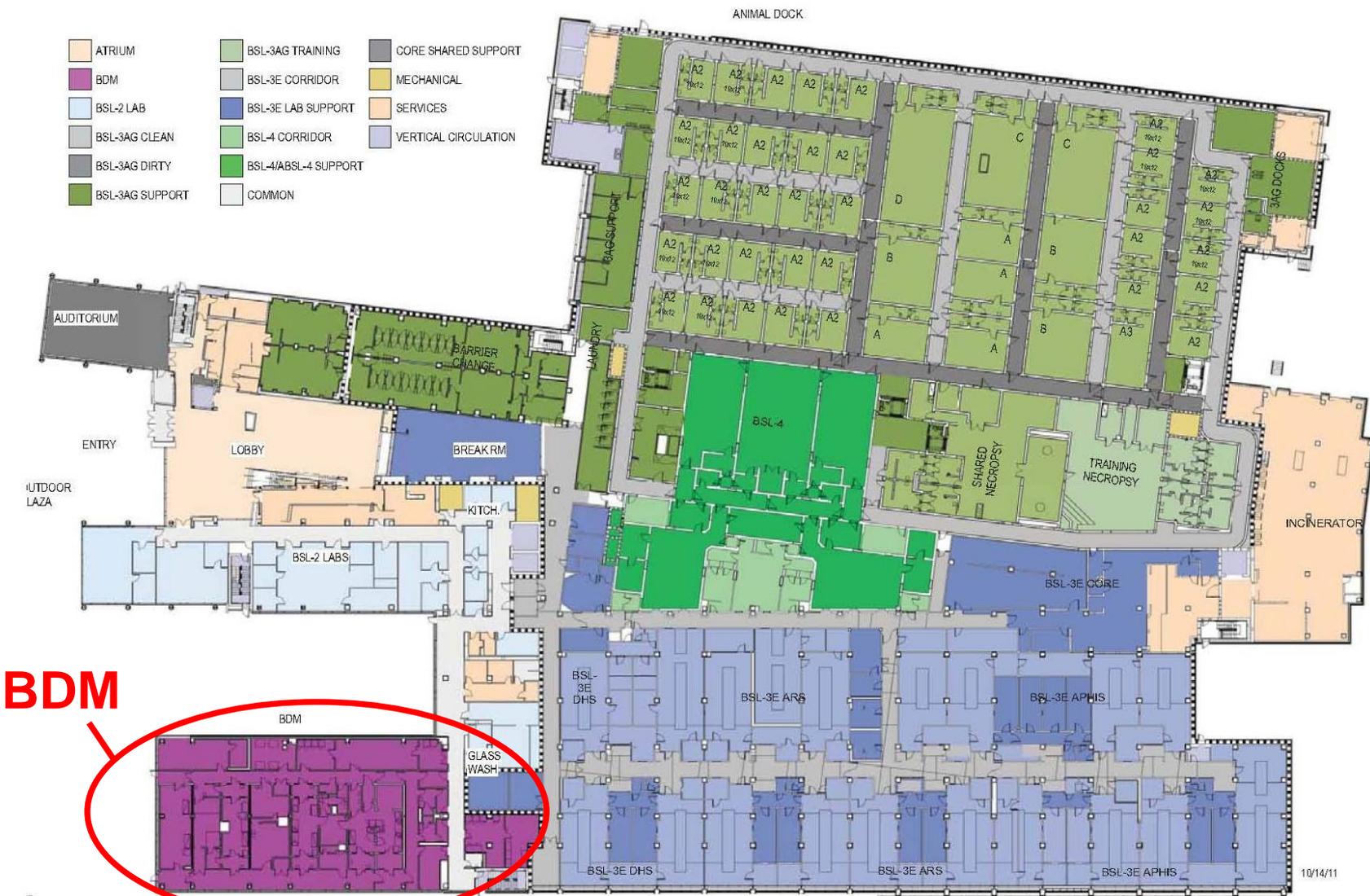


# NBAF BDM – Design Objectives

- ❑ **BDM spaces can accommodate a number of equipment combinations that may be utilized for the manufacturing process**
- ❑ **Layouts were compared with industry standards and benchmarking configurations**
- ❑ **Rooms were sized for an approximate batch size of 30L for infectious materials, with potential for increasing to 100L for post-development work**
- ❑ **Personnel, materials, product and equipment flow concepts have been developed**
- ❑ **Design Guidelines:**
  - Code of Federal Regulations Title 9 - Animals and Animal Products
  - Code of Federal Regulations Title 21 - Food and Drugs; cGMP (current Good Manufacturing Practices)
  - USDA ARS 242.1 Guide - ARS Facility Design Standards
  - CDC (Centers for Disease Control and Prevention) guidelines
  - NIH (National Institutes of Health) guidelines
  - Rules Governing Medicinal Products in the European Union - Volume 4 - EU Guidelines to Good Manufacturing Practice: Medicinal Products for Human and Veterinary Use
  - BMBL (Biosafety in Microbiological and Biomedical Laboratories), 5th Edition



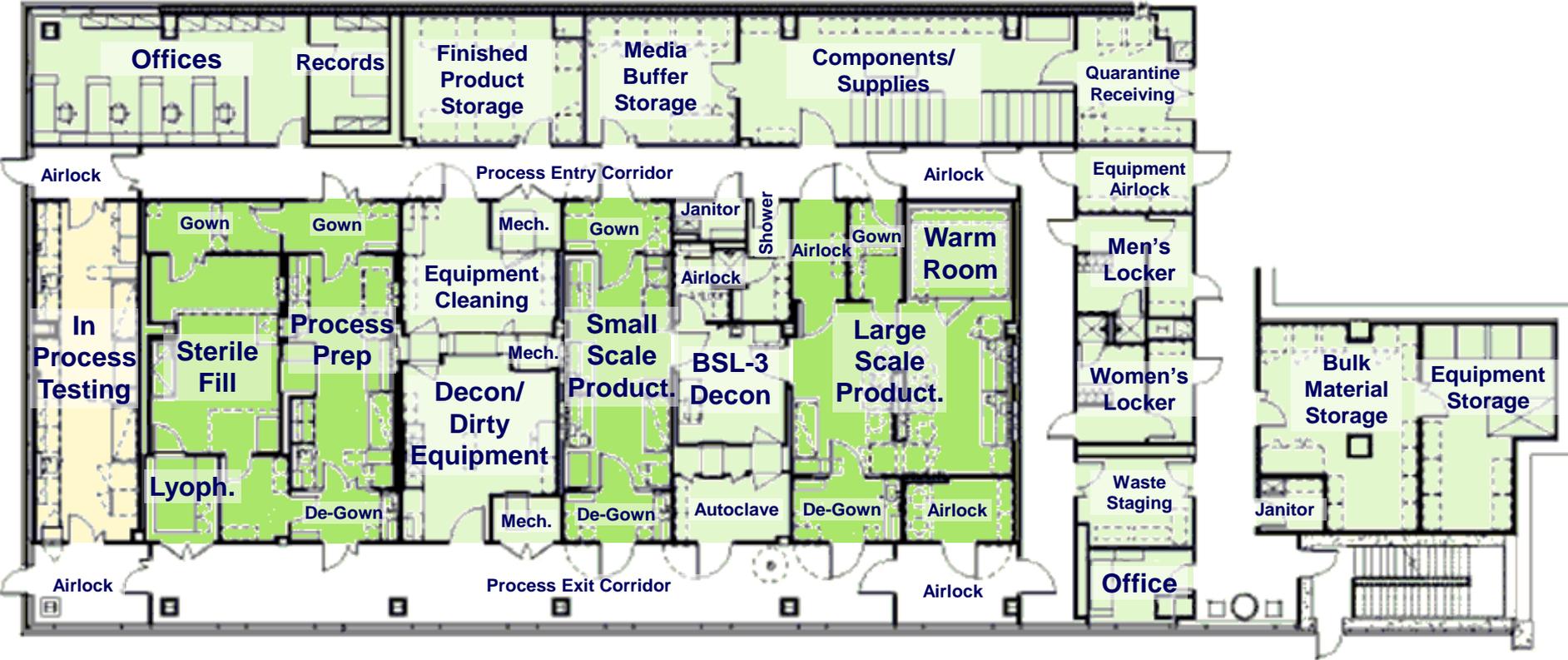
# BDM Location in NBAF



**BDM**



# NBAF BDM Schematic Design



Legend	
<span style="display:inline-block; width:15px; height:15px; background-color:#90EE90;"></span>	PRODUCTION
<span style="display:inline-block; width:15px; height:15px; background-color:#E0FFE0;"></span>	PRODUCTION SUPPORT
<span style="display:inline-block; width:15px; height:15px; background-color:#FFFACD;"></span>	LABORATORY

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

This document contains pre-decisional and/or deliberative process information exempt from mandatory disclosure under the Freedom of Information Act, 5 U.S.C.552(b) (5). Do not release without prior approval of the Department of Homeland Security.



# NBAF BDM – Operational Requirements

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- The BDM is designed to be flexible and accommodate various needs of government and industry**
- The BDM will operate as an Unclassified facility**
- Card/Access Security Control will be established to maintain access control to the manufacturing suites and access corridors**
- Access established to ensure that only properly trained personnel can enter appropriate areas**



## **NBAF BDM Operating Models – Considerations**

**□ Examples of criteria that the USG needs to consider in addressing these potential operating models:**

- Facility and Scientific Oversight**
- Ability to Respond to Changing Mission**
- Facility Availability**
- Ability to Establish Collaborations**
- Safety & Security**
- Technology Transfer**
- Cost Effectiveness**
- Outside Funding**
- Risk of Failure/Bankruptcy**
- Liability**

***Are there other criteria to consider?***



# Benchmark Comparisons

## ❑ Lessons learned from other BDM-like operations

- **Dedicated, well-trained personnel are needed to staff the BDM**
  - **Need to manage the paradigm shift in changing the way staff work**
  - **NBAF core fundamental laboratory research versus a highly documented mode of product development and scale-up in GMP production operations**
- **QC/QA effort and documentation burden is often underestimated**
- **High initial capital and start-up costs (animal health industry services may partially mitigate)**
- **Operations/validation personnel must be engaged early in the project**
- **Sufficient funds are needed to complete and sustain GMP effort (beyond initial financing and start-up). A commitment is necessary to build and grow/market BDM operations, raise the profile and build networks.**
- **Expectations of BDM promoters cannot differ, e.g. is it a core facility, for profit, etc.?**
- **Feedback during design, construction and operation from USDA (CVB, etc.) will be crucial**

# NBAF BDM – Enhancing Collaboration

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- DHS and USDA envision the BDM as a mechanism for collaboration with animal health industry**
- It will foster technology transfer to partners, both nationally and overseas, and also allow rapid transfer to contract manufacturers for scale-up and commercialization**
- Various mechanisms exist for government-industry collaboration: direct procurements, Broad Agency Announcements, Small Business Innovation Research (SBIR) programs, Grants, etc.**
- DHS/USDA are seeking input regarding mechanisms to utilize the BDM to enhance collaboration with industry, in accordance with the NBAF mission**
- Training facility for intra/extramural programs**

***Other mechanisms for USG-Industry  
collaboration?***



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# NBAF Intellectual Property Context



# NBAF Intellectual Property Context

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- ❑ **Intellectual Property Considerations whether work performed by Government or Contractor Scientists.**
  - **Inventions**
  - **Rights in Data**
  - **Copyright**
  - **Trademark**

## ❑ Treatment of Inventions where Inventor is Government Employee

- Assignment to the Government
- Non-exclusive License – No public notice. 37 CFR § 404.6
- Exclusive License-Public Notice and determination. 37 CFR § 404.7

- ❑ **Treatment of Data where produced by Federal Employee.**
  - **Work of Federal employees is Work of the United States Government and may not be copyrighted. 17 U.S.C. § 105.**
  - **Subject to public disclosure pursuant to the Freedom of Information Act (FOIA). 5 U.S.C. § 552.**

# NBAF Intellectual Property Context

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## □ Treatment of Inventions under Federal Contracts.

### ➤ Bayh-Dole Act, 35 U.S.C. §§ 200-212.

**“It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.”**

## ❑ Bayh-Dole Act:

- **For small businesses and non-profits, including universities.**
- **Contractor may elect to take title to each subject invention.**
- **Each such invention is subject to domestic manufacturing preferences and march-in rights.**
- **Government retains non-exclusive worldwide license “to practice or have practiced for or on its behalf. . .”**

# NBAF Intellectual Property Context

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- ❑ Presidential Memorandum, dated Feb. 18, 1983 expanded the benefits of Bayh-Dole to large businesses.**
- ❑ All Federal agencies that do not have a statutory patent policy (e.g., DHS and USDA) use contract patent clauses designed to provide all contractors the right to elect to retain title, subject to the limitations of the Act. See Federal Acquisition Regulation (FAR) 52.227-11 and Defense Federal Acquisition Regulation Supplement 252.227-7038.**

# NBAF Intellectual Property Context

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- ❑ **Generally, the Federal government uses procurement contracts to acquire goods and services. See Federal Acquisition Regulation, 48 CFR Part 1.**
- ❑ **It uses “assistance instruments” to undertake actions that fulfill a public purpose.**
  - **Grants.**
  - **Cooperative Agreements.**
- ❑ **See 31 U.S.C. § 6303-05.**

- ❑ **Basic Principle of Government Contract Law is Full and Open Competition. 41 U.S.C. § 3301.**
  - **Exceptions at 41 U.S.C. § 3304. FAR Subpart 6.3:**
    - **Available from Only One Source**
    - **Unusual and Compelling Urgency**
    - **Specific Circumstances, generally relating to maintaining industrial base**
    - **International Agreement**
    - **Specifically Authorized by Law**
    - **Compromise National Security**
    - **Determined by Agency Head to be Necessary in the Public interest**

- ❑ **Treatment of Rights in Data under Federal Contracts.**
  - **DHS and USDA are subject to the FAR Rights in Data clauses. Generally, civilian agencies use clause at FAR 52.227-14. See 41 U.S.C. § 2302.**
    - **Government acquires “unlimited rights” in all data first produced under the contract.**
    - **Absent contract provision to the contrary, contractor acquires right to use such data, subject to classification, markings, export controls, for private purposes.**

# NBAF Intellectual Property Context

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- Generally, Contractor may not Assert its Copyright in Data First Produced absent Contracting Officer (CO) Permission, except academic purposes. If permission granted, Clause provides Government a Government purpose license. FAR 52.227-14(c).**
- May not include in deliverables data copyrighted by third parties without acquiring specified license for Government or CO permission.**

## ❑ **Additional Relationships:**

- **Cooperative Research and Development Agreements (CRADAs). 15 U.S.C. § 3710a.**
  - **Allows Agencies to Authorize Director of Government-Owned, Government-Operated (GOGO) and Government-Owned, Contractor-Operated (GOCO) laboratories to enter into this statutorily created instrument.**
  - **Purposes at 15 U.S.C. § 3701, e.g., “Increased industrial and technological innovation would reduce trade deficits, stabilize the dollar, increase productivity gains, increase employment, and stabilize prices. . .”**

# NBAF Intellectual Property Context

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**(Cont'd)**

- **“The Federal laboratories and other performers of federally funded research and development frequently provide scientific and technological developments of potential use to State and local governments and private industry. These developments, which include inventions, computer software, and training technologies, should be made accessible to those governments and industry. There is a need to provide means of access and to give adequate personnel and funding support to these means.**

# NBAF Intellectual Property Context

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- Collaborator given first right of refusal for exclusive or non-exclusive license to inventions made in whole or in part by a Federal employee under the CRADA.**
- Collaborator's inventions are subject to Government-purpose research license.**
- Government does not pay collaborator.**
- Collaborator may reimburse the GOGO or GOCO.**

# NBAF Intellectual Property Context

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- The Government may protect data that results from the research and development activities from disclosure pursuant to FOIA for a period of up to 5 years. 15 U.S.C. § 3710a(c)(7)(B).**
- Proprietary data received from the Collaborator is protected from disclosure pursuant to FOIA.**

## □ Use of Trademark

- **DHS will register the NBAF trademark.**
- **DHS may, subject to other developments, register the trademark in BDM.**
- **DHS uses trademarks in software, particularly to license and protect dissemination.**



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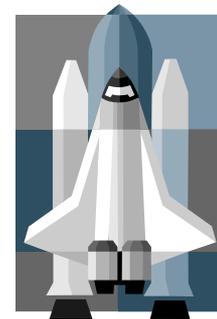
# Technology Transfer Program

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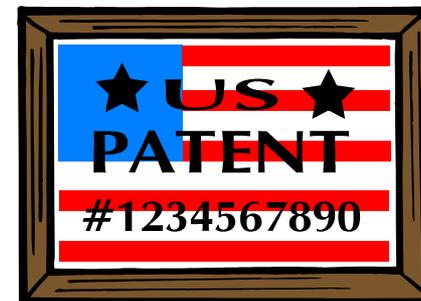


# Delegation of Technology Transfer at DHS

- ❑ **Delegation from Secretary Chertoff to the Under Secretary for Science and Technology to Facilitate Technology Transfer (Signed in Fall 2005)**
- ❑ **Delegate Authority to the Under Secretary for S&T to:**
  - **Establish a Technology Transfer Office (*i.e.*, ORTA) to establish, coordinate, and implement technology transfer policies for the DHS laboratories.**
  - **Permit the director of any DHS GOGO laboratory and the director of any DHS GOCO laboratory to enter into cooperative research and development agreements (CRADAs) and licensing agreements.**
  - **Permit the director of a DOE national laboratory to enter into CRADAs or to negotiate licensing agreements in connection with DHS's utilization of such DOE national laboratory.**



# What is Technology Transfer?



Technology transfer is the process by which existing knowledge, facilities or capabilities developed under federal research and development (R&D) funding are utilized to fulfill public and private needs.

- New Products
- New Services
- New Businesses





# Technology Transfer: WHY?

- ❑ **Facilitates the transfer of technology/innovation for the benefit of the nation**
- ❑ **Enhances the research experience of laboratory scientists and engineers**
- ❑ **Promotes economic development by leveraging DHS innovations**
- ❑ **Provides financial incentives to DHS scientists and engineers to stimulate technological innovations**
- ❑ **Congress and the President have made it the responsibility of every scientist and engineer (Technology Transfer Act of 1986 (P.L. 99-502) and Executive Order 12591 (Facilitating Access to Science and Technology))**





# Technology Transfer Mechanisms

- Cooperative Research and Development Agreement (CRADA)**
- Special Purpose CRADA (Material Transfer Agreement)**
- Licensing Agreement**
- Memorandum of Understanding (MOU)/Memorandum of Agreement (MOA)**
- Partnership Intermediary Agreement (PIA)**
- Work-for-Others Agreement**
- Commercial Test Agreement or User Facility Agreement (future)**
- Education Partnership Agreement (future)**





# Cooperative Research & Development Agreements (CRADAs)

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- Legal agreement between a government R&D laboratory and interested partners**
- Allows partners to collaborate in mutually beneficial R&D in specific technical areas consistent with laboratory mission**
- Partners can provide facilities, equipment, and personnel in support of CRADA**
- The non-government partner can provide funds to the government laboratory to perform tasks under the CRADA**
- The government laboratory CANNOT provide funds to their partners**

# CRADA Characteristics

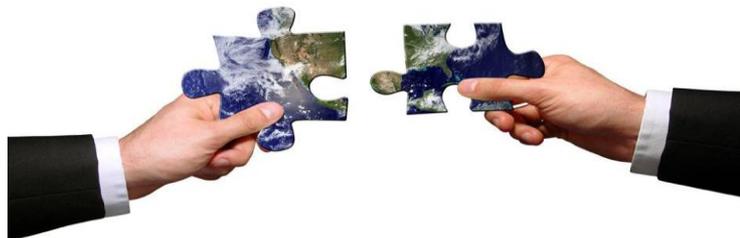
- ❑ Gives special consideration to small businesses, consortia involving small business, and business located in the United States that agree to manufacture products resulting from the CRADA substantially within the nation
- ❑ Provides the government the ability to retain a nonexclusive, nontransferable, irrevocable, paid-up license to inventions developed under the CRADA



# CRADA Characteristics

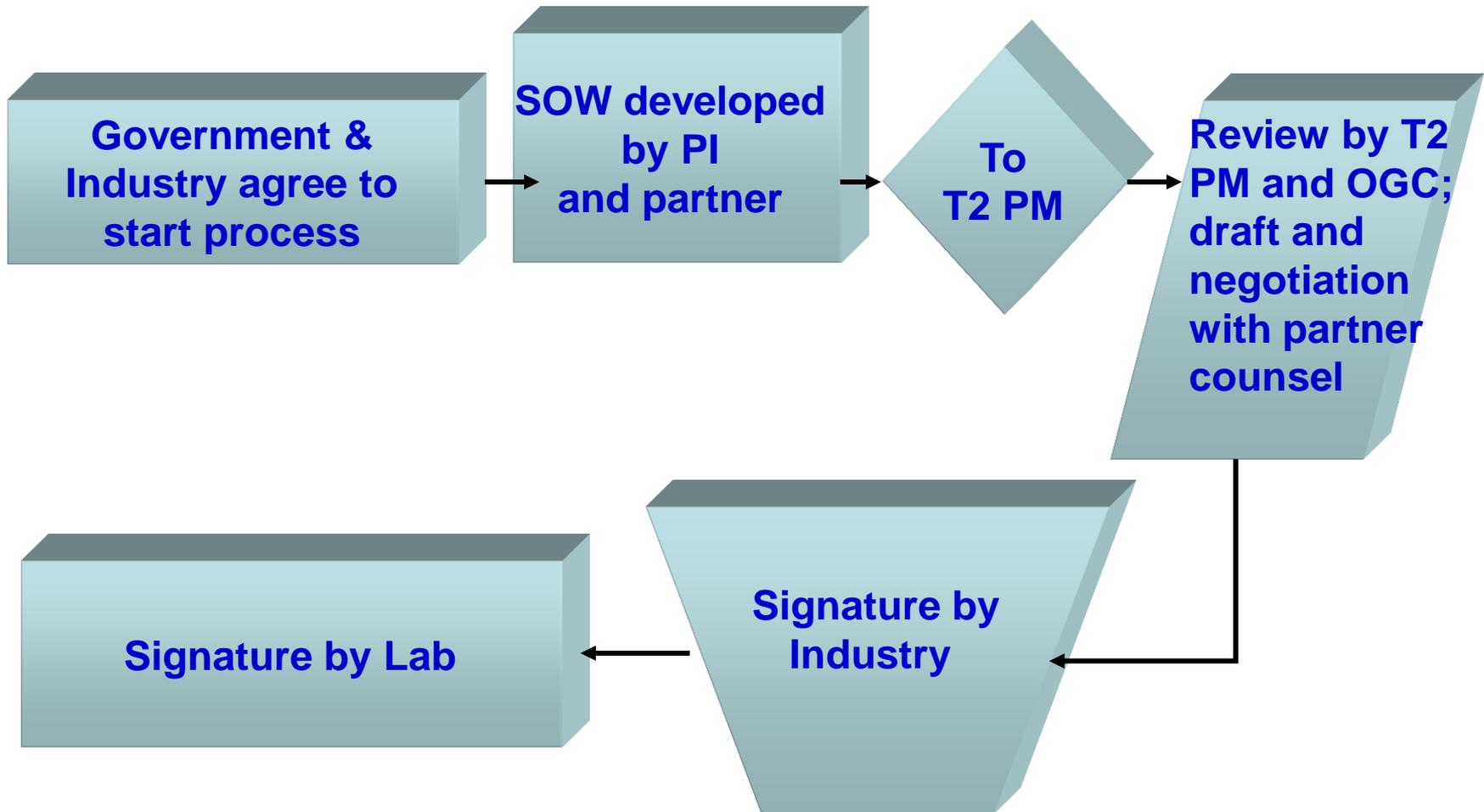
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- ❑ **CRADAs are sensitive to the needs of business organizations to protect commercially valuable information**
- ❑ **Privileged information that develops during the course of a CRADA can be protected from disclosure for up to 5 years**





# CRADA Process



# Licensing Agreements

**A contract between the owner or lawful user of intellectual property (IP) (licensor) and another party (licensee) that permits the licensee to use the IP in accordance with the terms of the contract**

- Nonexclusive license**
- Exclusive license**





# Non-Disclosure Agreements

- A non-disclosure agreement is typically used when lab personnel are going to receive proprietary information from external organizations**
- Non-disclosure agreement defines the treatment of this proprietary information under terms that are acceptable to both parties' cooperative agreements**
- An NDA protecting incoming information creates an obligation for federal employees.**
- By signing a non-disclosure agreement, you are making yourself personally liable for breach of the agreement**
- Seek help from the Office of the General Counsel**
- Generally, we can get some arrangement with a company to accomplish our mission**



# User Facility Agreements

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- Makes unique equipment and facilities accessible to private industry**
- Provides laboratory services for testing materials, equipment, and systems to outside parties for a prescribed fee**
- Agreements with individuals, partnerships, corporations, state or local government, or other government agency**



# Educational Partnerships

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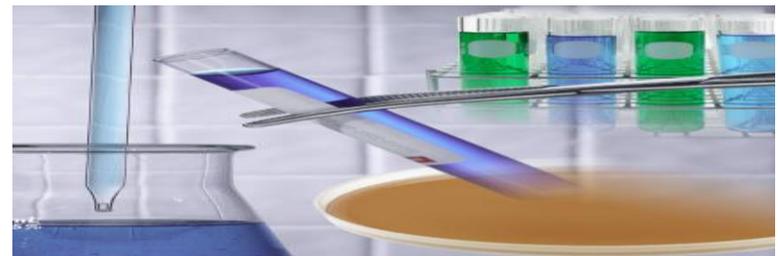
- Formal agreement with educational institution to transfer technology applications at all levels of education**
- Equipment can be donated or loaned to an educational institute for any length of time**



# Partnership Intermediaries

**Section 3710 of Title 15 (15 U.S.C. § 3710) defines a partnership intermediary as an agency or affiliate of a state or local government that assists, counsels, advises, evaluates, or otherwise cooperates with small business firms, institutions of higher education or educational institutions that need or can productively use technology-related assistance from a federal laboratory. PIAs are agreements between DHS and the agency of such a state or local government or a nonprofit entity to allow the partnership intermediary to:**

- Identify new technologies in the private sector that can be utilized by DHS**
- Facilitate joint projects between DHS and private companies, as well as between agencies and academic institutions, in order to accelerate delivery of technological capabilities to the nation**



# Partnership Intermediaries

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- ❑ **Some examples of PIAs helping businesses:**
  - **Assistance in finding federal technologies and federal partners**
  - **Assistance with access to facilities, equipment and research expertise**
  - **Assistance with business plans and commercialization**
  
- ❑ **How PIAs help federal laboratories**
  - **Identify potential research/commercialization partners**
  - **Increase access to potential non-federal partners**
  - **Increase likelihood of success by providing assistance to non-federal partner**
  - **Expand customer interactions with private sector**
  - **Conduct outreach**

# Bottom Line...

Technology Transfer will *accelerate delivery* of technological capabilities to meet the needs of our customers and nation by:

- ❑ **Assisting DHS Laboratories in conducting Research and Development for technology that can be transferred to industry in support of the DHS mission**
- ❑ **Establishing partnerships to transfer cutting-edge technology to the nation's marketplace**





# Homeland Security

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