

# NBAF: National Bio and Agro-Defense Facility & Biocontainment Issues



*One Medicine, One Health*

**Barrett D Slenning**  
*Department of Population  
Health and Pathobiology  
College of Veterinary Medicine  
NC State University  
12 December 2007*



# Topics



- **What is the NBAF and site selection process?**
- **What are Biosafety Levels and NBAF issues?**
- **Broader National Biocontainment Facility Issues**



# The National Bio and Agro-Defense Facility and its mission

 **USA lacks facilities to address animal and public health defense needs.**

 **Diseases shared by humans and animals are being missed**

 **In response, the federal government initiated plans for **National Bio and Agro-Defense Facility****

 **Major player in USA's research complex with**

- *Homeland Security,*
- *Agriculture,*
- *Health-Human Services*

**to**

- *Be a major national diagnostic laboratory*
- *Study diseases affecting humans and animals*
- *Develop tests, vaccines, and other tools*



# Process Timeline – Start-Up



## 19Jan06 – DHS call for NBAF Expressions of Interest

- **Three fold mission:**
  - [1] Foreign Animal Disease research,
  - [2] Study diseases shared between animals and humans,
  - [3] Develop & evaluate tests & vaccines
- **Minimum 30 acres**
- **500K s.f. biocontainment building**

Dated: January 5, 2005.  
**Stephen Long,**  
 Executive Officer, NIAAA.  
 [FR Doc. 05-490 Filed 1-18-05; 8:45 am]  
 BILLING CODE 4140-01-M

### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### National Institutes of Health

#### National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Initial Review Group, Subcommittee G—Education.

Date: February 13–14, 2006.  
 Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Double Tree Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Sonya Roberson, PhD, Scientific Review Administrator, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Blvd., Room 8045, Bethesda, MD 20892, (301) 594-1182, [robersons@ncl.nih.gov](mailto:robersons@ncl.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS.)

Dated: January 9, 2006.  
**Anna Snouffer,**  
 Acting Director, Office of Federal Advisory Committee Policy.  
 [FR Doc. 05-489 Filed 1-18-06; 8:45 am]  
 BILLING CODE 4140-01-M

### DEPARTMENT OF HOMELAND SECURITY

#### Security of Aircraft and Safety of Passengers Transiting Denpasar, Bali, Indonesia

AGENCY: Department of Homeland Security.  
 ACTION: Notice.

**SUMMARY:** This document informs the public that the Department of Homeland Security (DHS) has determined that Bandara Ngurah Rai International Airport, Denpasar, Bali, Indonesia, does not maintain and carry out effective security measures. Pursuant to this determination, the Department of Homeland Security is directing all U.S. and foreign air carriers (and their agents) providing service between the U.S. and Bandara Ngurah Rai International Airport to provide notice of this determination to any passenger purchasing a ticket for transportation between the United States and Bandara Ngurah Rai International Airport. DHS also is requiring that U.S. airports post a notice of the determination, in accordance with statutory requirements.

**FOR FURTHER INFORMATION CONTACT:** Richard H. Stein, General Manager, International, Transportation Security Administration, 601 South 12th Street, Arlington, VA 22202-4220, Telephone: (571) 227-2764, e-mail: [Richard.Stein@dhs.gov](mailto:Richard.Stein@dhs.gov).

#### Notice

Pursuant to 49 U.S.C. 44907(a), the Secretary of Homeland Security (the Secretary) is authorized to assess periodically the effectiveness of the security measures maintained by foreign airports that handle air carriers serving the United States or that may pose a "high risk of introducing danger to international air travel." If the Secretary determines that a foreign airport does not maintain and carry out effective security measures, the Secretary is required to "notify the appropriate authorities of the government of the foreign country of the decision and recommend the steps necessary to bring the security measures up to the standard used \* \* \* in making the assessment." 49 U.S.C. 44907(c).

Further, the Secretary must: (a) Publish the identity of the foreign airport in the *Federal Register*, (b) post the identity of such airport at all U.S. airports that regularly provide scheduled air carrier operations, and (c) notify the news media of the identity of the airport. 49 U.S.C. 44907(d). In addition, the statute requires all air carriers providing service between the

United States and the airport to provide written notice of the determination, either on or with the ticket, to all passengers purchasing transportation between the United States and the airport. 49 U.S.C. 44907(d)(1)(B).

On December 23, 2005, the Secretary of Homeland Security notified the Government of Indonesia that, under 49 U.S.C. 44907, he had determined that Bandara Ngurah Rai International Airport (DPS), Denpasar, Bali, Indonesia, did not maintain and carry out effective security measures. He based the determination on Transportation Security Administration (TSA) assessments that security measures used at DPS did not meet the standards established by the International Civil Aviation Organization (ICAO).

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Dated: December 23, 2005.

**Michael Chertoff,**  
 Secretary.  
 [FR Doc. 05-523 Filed 1-18-06; 8:45 am]  
 BILLING CODE 4910-02-P

### DEPARTMENT OF HOMELAND SECURITY

#### National Bio and Agro-Defense Facility (NBAF); Notice of Request for Expression of Interest for Potential Sites for the NBAF

AGENCY: Science and Technology Directorate (Office of Research & Development), DHS.

**SUMMARY:** The U.S. Department of Homeland Security (DHS) is exploring potential sites for a proposed new national research and development (R&D) asset, the National Bio and Agro-Defense Facility (NBAF), which is in the planning phase. The proposed facility size is approximately 500,000 ft<sup>2</sup> and its site will require a minimum of 30 acres.



# Process Timeline – Start-Up

## Selection Criteria –

- Research environment and capacity
- Workforce training and availability
- Infrastructure and acquisition issues
- Acceptance by stakeholder communities

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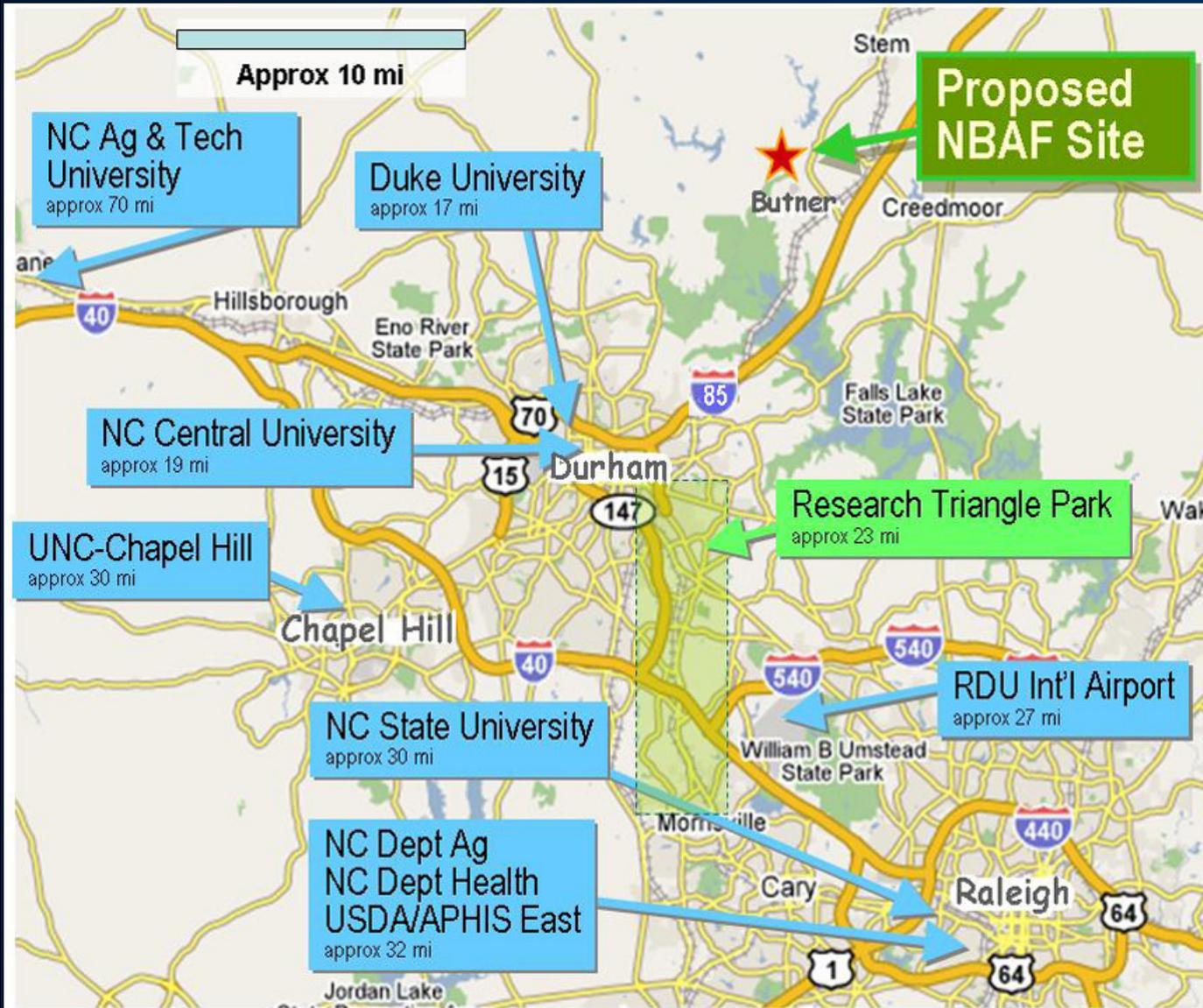
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**SUMMARY:** The U.S. Department of Homeland Security (DHS) is exploring potential sites for a proposed new national research and development (R&D) asset, the National Bio and Agro-Defense Facility (NBAF), which is in the planning phase. The proposed facility size is approximately 500,000 ft<sup>2</sup> and its site will require a minimum of 30 acres.



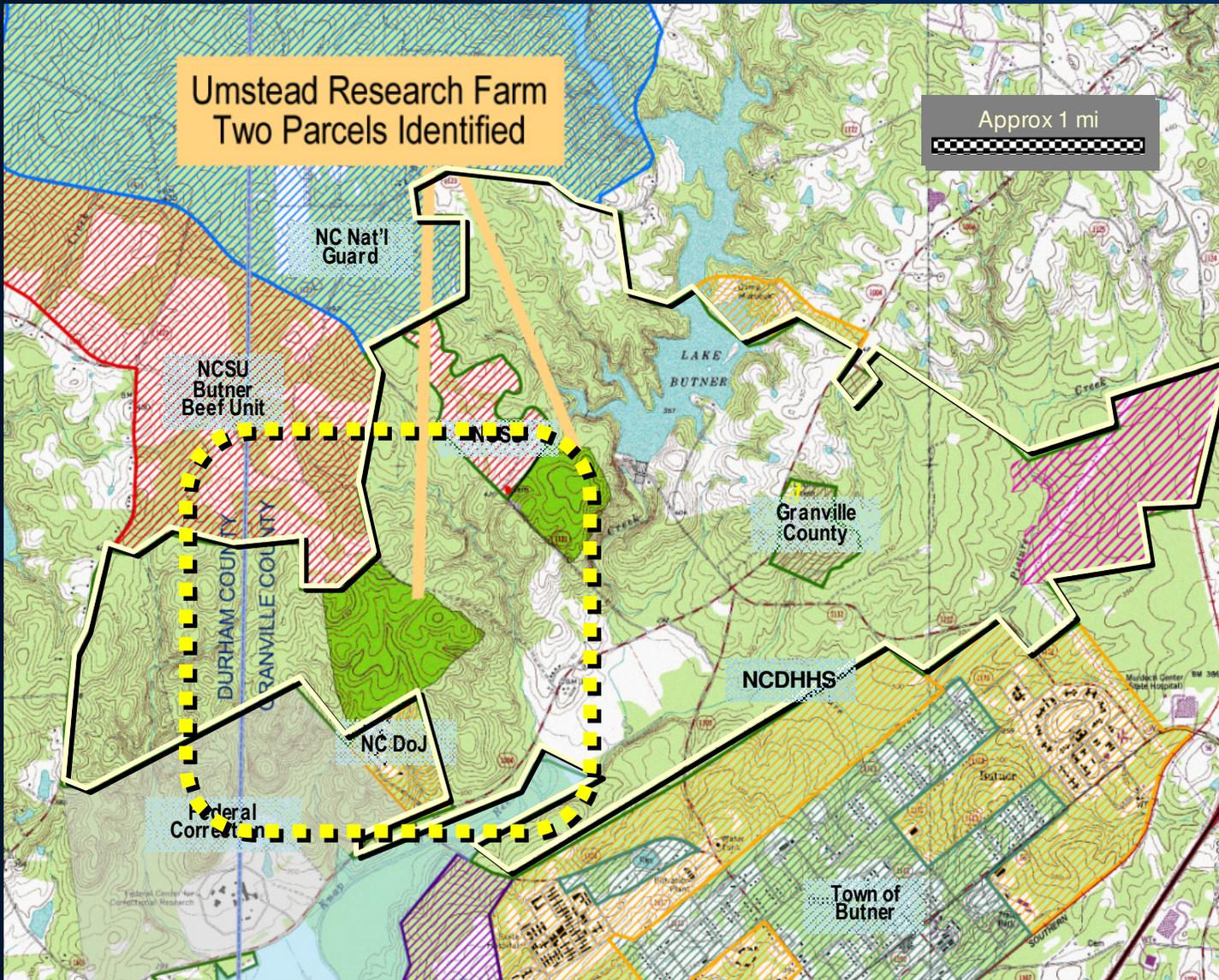
## NC Process Timeline – State Survey

- Feb 2006 - Gov Easley directed NC Commerce to canvas the Charlotte-Triad-Triangle corridor for interest
  - *Responders proposed sites to meet the 4 criteria*
- NCC Core Team evaluated proposed sites
  - *Local opinion maker/gov't acceptance*
  - *Enviro, cultural, infrastructure, logistical issues*
- Advanced six sites; one picked for EOI



### Unstead Research Farm

- *Use: Since 1950's NC Dept Agric Research farm for animal and crop agriculture*
- *4035 A pastures & forest*
- *282 A in 2 high ground parcels*



**Outside of 100, 500 yr floodplain**

**Access to freeways, rail, bus, air**

**Utilities on and around site**

**No public interest areas**

**State and federal neighbors**

**Within 30 miles of the Research Triangle assets**

**Inspected for enviro and culturally sensitive issues '90s**

**State resourced for Public Safety**

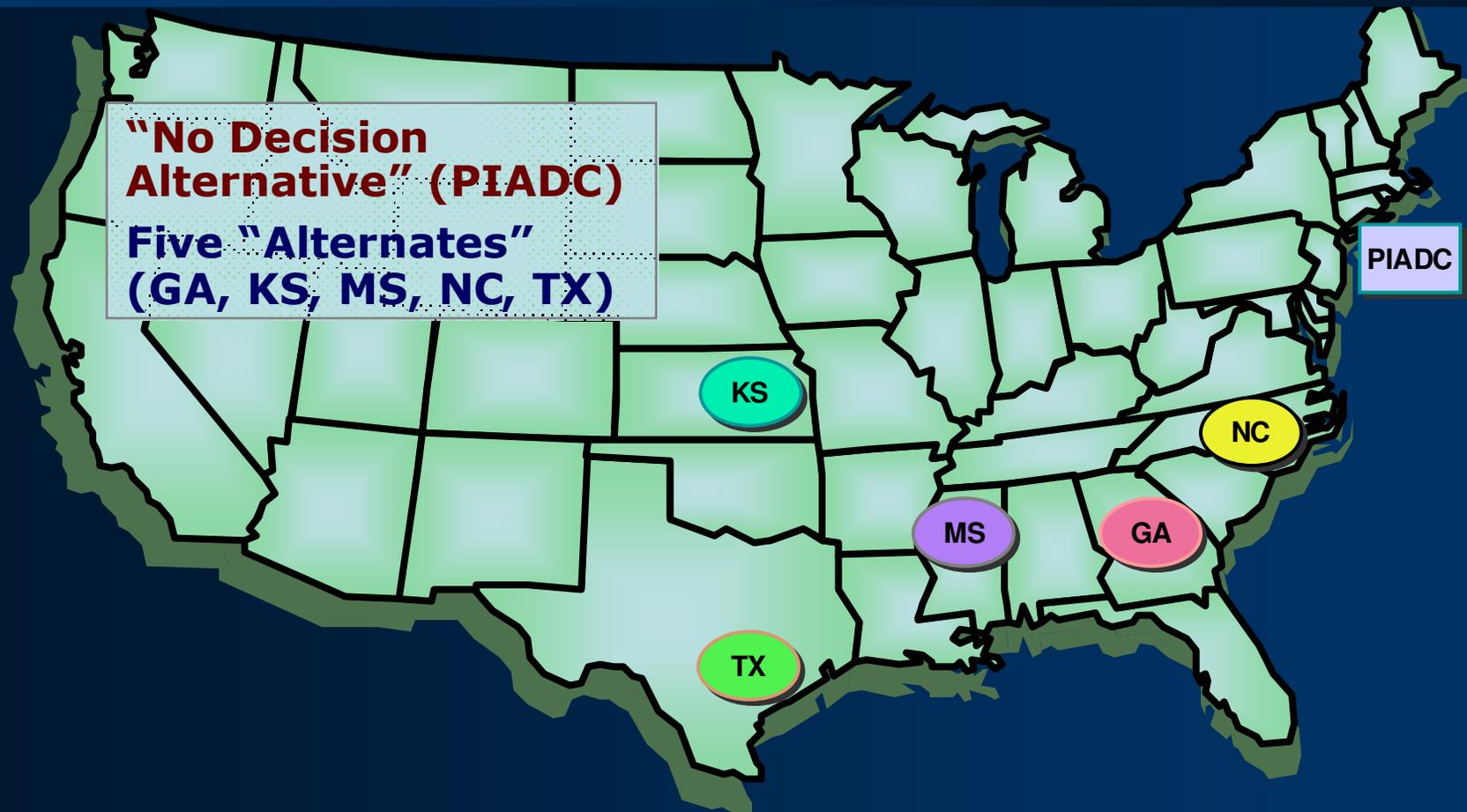


## The NBAF Competition

- March 2006:** 29 EOIs from across the country submitted
  - AL, AR/LA, AZ, CA, FL, GA(2), IA, KS(2), KY/TN, MD, MO, MS(3), NC, ND, NY, NM, OK, PA, TX(4), WI(2), DC*
- August 2006:** List cut to 14 consortia (18 sites)
  - CA, GA(2), KS(2), KY/TN, MD, MO, MS(3), NC, OK, TX(4), WI*
- July 2007:** Downselect to 'final five' was made



# NBAF Competition, as of July 2007





## NBAF Next Steps

-  **NEPA Environmental Impact Study –**  
*Evaluate/confirm physical, cultural,  
biological, economic impacts & limits*
  - **Scoping Meetings – Aug-Sep 2007**
  - **Data Development – Winter 2007**
  - **Draft Report – Spring 2008**
  - **Final Report – Late Summer 2008**
-  **Site Selection – Autumn 2008**
-  **Construction – Through 2012-2013**
-  **Operational – 2013-2014**



# Biocontainment Facility Categories

(Since late 70's - early 80's)

## Biosafety level 1, 2, 3, 3Ag, and 4 laboratories

- ***BSL1 – School biology & city water testing labs; no risk to healthy adults (>1000 in NC)***
- ***BSL2 – Hospital and diagnostic labs; some risk to healthy adults (hundreds in NC)***
- ***BSL3 – Hospital research labs; possible high risk via air transmission (dozens in NC)***
- ***BSL4 – High security labs; likely high risk via poor treatment options (none in NC)***

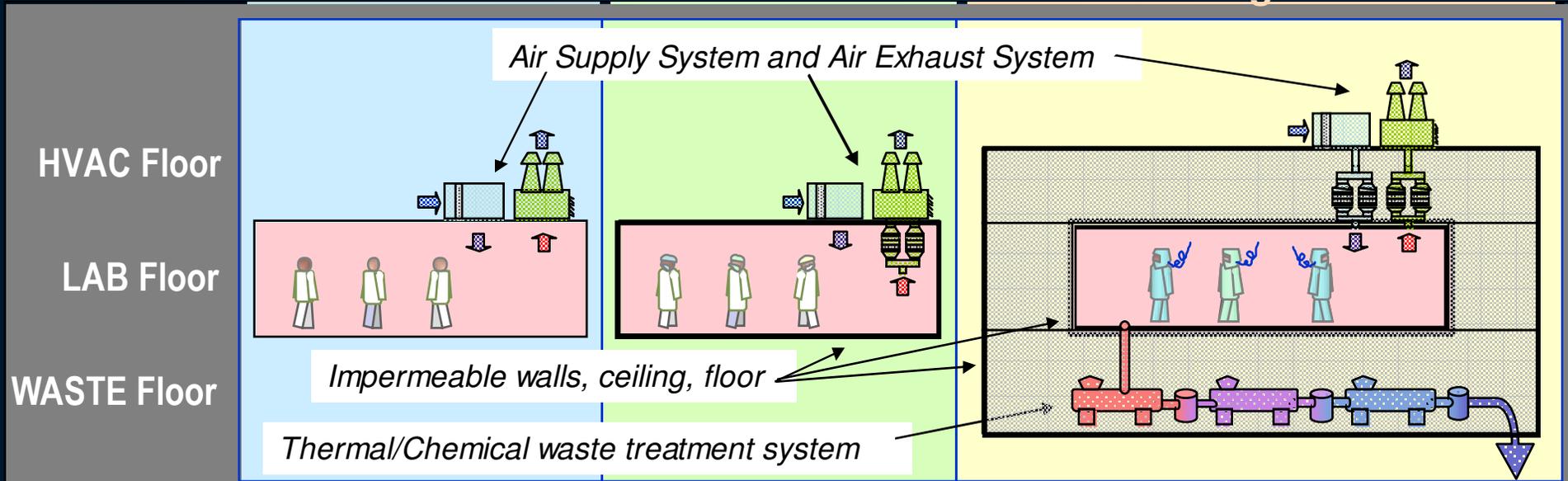


## BIOSAFETY FACILITY 'FLOOR' DIAGRAMS

BSL 2

BSL 3 Enhanced

BSL 3 Ag or BSL 4



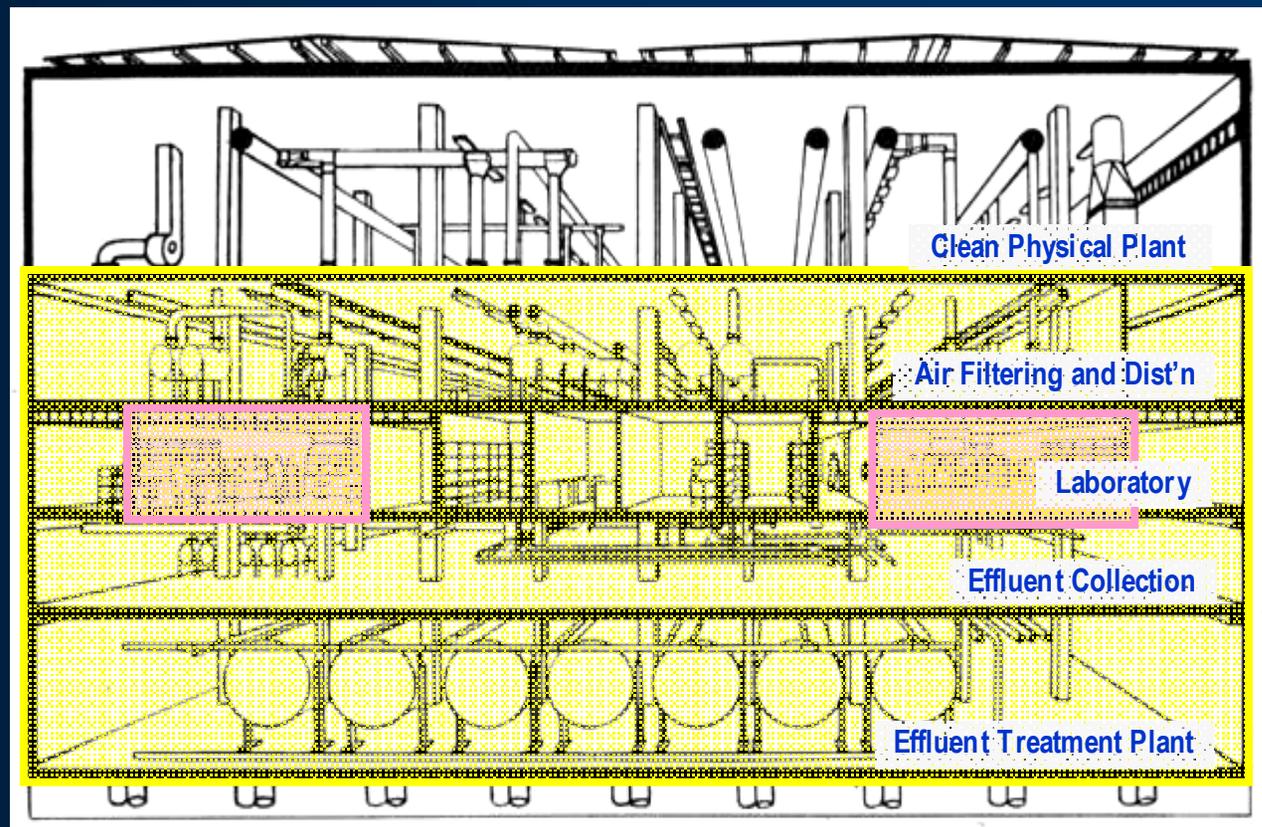
- Environmental air in
- Unfiltered air out
- Access controls
- Special training
- Standard lab coat, nitrile/latex gloves, face shield/goggles

- Environmental air in, HEPA (Hi Effic Particul Air) filtered air out
- Neg pressure lab room
- Access control, background checks, special training
- Surgical-style gown, cap & booties, double gloves, safety goggles, mask/respirator

- HEPA filtered air in/out
- Negative pressure lab room
- Access control, background checks, special training
- Lab space encased in 2<sup>o</sup> containment envelope
- Effluent decontaminated in redundant process
- Clothing as per BSL3e, or pressurized body suit and powered respirator

# Cross-Section of a BSL3-Ag or BSL-4

-  **Five floors shown**
-  **Lab space is usually less than 25% of total space**
  - *Yellow box is containment area*
  - *Pink boxes are containment labs*



Adapted from Edwards SF, Lamb B, Maurer D. 'Design and Operation of a High Containment Sewage Treatment Facility'. Geelong, Victoria, Australia



# NCC NBAF Issues/Opportunities

## Correcting Errors from the Media:

- Will be a diagnostic and health research facility (like CDC), NOT a “bioweapons” lab
- Only unclassified research with community oversight
- Will research 8 diseases for now [1. African and 2. Classical Swine Fevers, 3. Bov Pleuropneumonia, 4. Foot & Mouth; 5. Hendra virus, 6. Japanese Encephalitis, 7. Nipah virus, 8. Rift Valley Fever]

*Note smallpox, ebola, anthrax, avian influenza, mad cow, etc., are not listed*

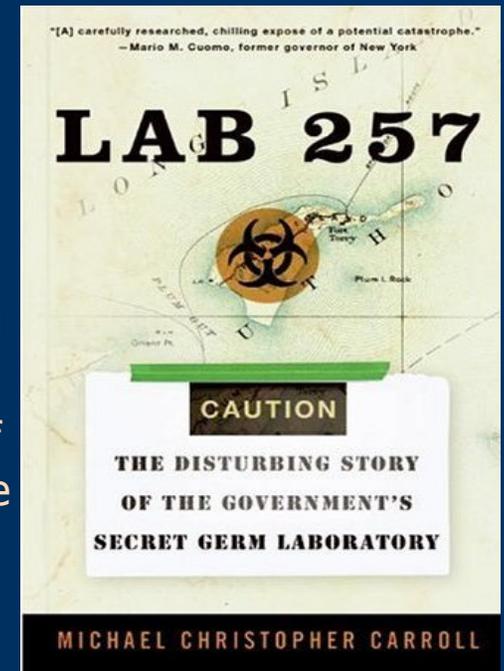
- Diagnoses for foreign animal diseases & zoonotics



## NCC NBAF Issues/Opportunities

### Correcting Errors from the Media: "Lab 257" Michael C Carroll (2004)

- **Claims a late 1970s FMD outbreak affected animals outside the laboratory**
  - **True, but misleading.** Was 30 yr ago, when construction disabled some biocontainment and susceptibles were brought to building door
    - The event was partially responsible for creation of the new biosafety rules we now live under. Is one reason why facilities don't house animals outside.
- **Claims Anthrax, Lyme, and West Nile came from Plum Island (PI)**
  - **False.** Anthrax is common in US and so is not worked on at PI
  - **False.** Lyme called "Montauk Knee" in 1880's, renamed 1970's
  - **False.** West Nile work at PI started on request by NY, after the 1999 outbreak started



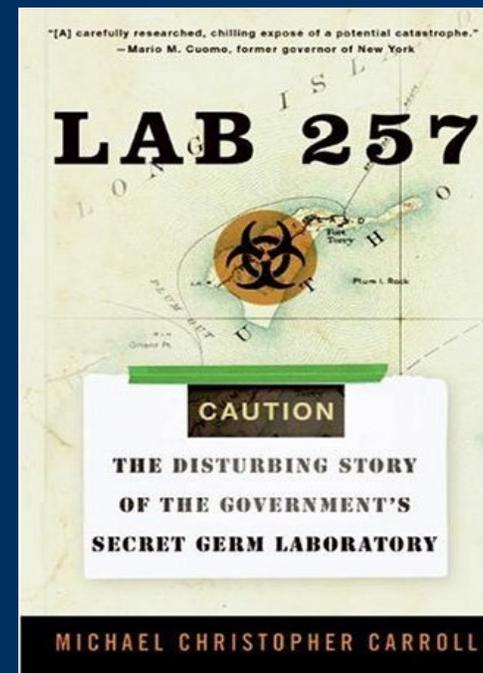


## NCC NBAF Issues/Opportunities

### Correcting Errors from the Media: "Lab 257" Michael C Carroll (2004)

#### ▪ *Quotes from officials and experts –*

- "... You don't sell many books by concluding that federal officials are doing a really good job... These are claims that are completely untrue..." [*R Breeze, former PI Dir.*]
- "... I believe we have a fairly good handle on what's going on there and that the administrators are pretty open about it..." [*T Bishop, Representative for PI district*]
- "... I have been comfortable with Plum Island since Day 1..." [*D Kapell, Mayor of Greenport CT, where many PI employees live*]
- "... I personally just don't think that has any merit..." [*D Weld, Exec Dir., American Lyme Disease Foundation*]



Rather J. Heaping more dirt on Plum I. NY Times. 15Feb04  
Dunn A. The mysterious lab off New York's shore. CNN.com 2Apr04



# Broader National Biosafety Issues



## Oversight and proliferation of high bio-containment facilities



## Learning from recent incidents and experiences

United States Government Accountability Office

**GAO**

Testimony  
Before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

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For Release on Delivery Expected at 10:00 a.m. EDT Thursday, October 4, 2007

**HIGH-CONTAINMENT BIOSAFETY LABORATORIES**

Preliminary Observations on the Oversight of the Proliferation of BSL-3 and BSL-4 Laboratories in the United States

**THE NATIONAL ACADEMIES**  
*Advisers to the Nation on Science, Engineering, and Medicine*

555 Fifth Street, NW  
Washington, DC 20001  
Phone: 202-334-2107  
Fax: 202-334-1289

November 21, 2007

**Ian A. Bowles**  
Secretary, Executive Office of Energy and Environmental Affairs  
100 Cambridge Street, Suite 900  
Boston, MA 02114

Dear Secretary Bowles,

At your request, the National Research Council (NRC) established an expert Committee to provide technical input on the document *Draft Supplementary Risk Assessments and Site Suitability Analyses for the National Emerging Infectious Diseases Laboratory, Boston University* (hereafter referred to as the

**Independent Review of the safety of UK facilities handling foot-and-mouth disease virus**

Chairman: Prof. Brian G Spratt FRS FMedSci

Presented to the Secretary of State for Environment, Food and Rural Affairs and the Chief Veterinary Officer

31 August 2007

Health and Safety Executive

**Final report on potential breaches of biosecurity at the Pirbright site 2007**

HSE



# GAO Report on High Biocontainment Facility (HBF) Issues

(Oct07)

## Concern 1: Lack of information on high biocontainment facilities (HBF)

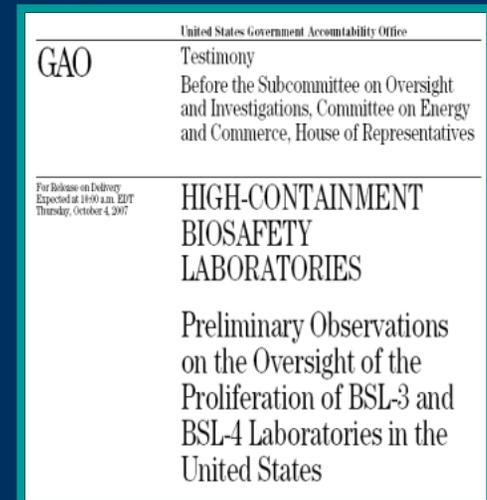
- *Federally funded/registered facilities have sufficient info on them*

## Concern 2: No one federal agency has authority to monitor HBFs

- *Federally funded/registered facilities have sufficient info on them*

## Concern 3: Six specific lessons from past incidents at non-federal HBFs

- *Federal agencies have precedents for meeting five of the six*





# NRC Report: NIH Draft Supplemental Risk Assessment for the Boston HBF (Nov07)

- 
**A member of the NC Consortium was also a on this NRC Committee**
- 
**Found NIH Draft Supplemental Risk Assessment (DSRA) --**
  - *was not credible,*
  - *had poor 'worst-case' evaluation, and*
  - *was not transparent enough to compare risks of alternate sites.*
- 
**"... the Committee was asked to provide only a technical review of the [DSRA, and] did not carry out an independent assessment of the risks associated with the proposed facility or possible alternative locations..."**

**THE NATIONAL ACADEMIES**  
*Advisers to the Nation on Science, Engineering, and Medicine*

885 Fifth Street, NW  
Washington, DC 20001  
Phone: 202-334-2187  
Fax: 202-334-1289

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# Lessons Learned: UK's Pirbright HBF and FMD

(Aug-Sep '07)

- 🍷 03 & 06 Aug 2 farms ~ 4 mi from Pirbright FMD+
  - *Virus only is in labs in Belgium and Pirbright*
- 🍷 Starting mid-Sep, 6 more farms found; the last finding was on 30 Sep.
  - *Same virus*
  - *Under 500 animals destroyed*
    - Farm 3 may face civil charges for hiding disease
- 🍷 Pirbright 2 parts
  - *Gov't Animal Health Inst*
  - *Private vaccine plant*
    - Both used the FMD strain in late July
- 🍷 On 07 Sep two independent investigations found
  - *An old buried iron waste pipe from Merial plant had been damaged by tree roots*
  - *Recent floods likely brought virus to surface*
  - *Contractors traveled over the areas and past the affected farms*
- 🍷 In mid-Oct, another in-depth investigation was ordered – results by end of year
- 🍷 As of early November animal movement and export restrictions were eased



## Pirbright and FMD, September 2007

### Differences between NBAF and Pirbright

- ***NBAF will not have a vaccine plant and the complications resulting therefrom***
- ***NBAF will not pipe raw effluent out of the building – all treatments are w/in facility***
  - **Will not use buried cast iron pipes; observable double-wall welded stainless steel will be used**
- ***Pirbright is decades old and needs extensive maintenance lending it to construction-related incidents***
- ***8 cases were Dx'd within hours - showing we can respond to a break, and that having lab resources at hand is vital to do so***



**NCC NBAF**

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**Barrett D Slenning**

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