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

Barrett D Slenning

Department of Population Health and Pathobiology
College of Veterinary Medicine
NC State University
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Topics

What is the NBAF and site selection process?

What are Biosafety Levels and NBAF issues?

Broader National Biocontainment Facility Issues

One Medicine, One Health
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

One Medicine, One Health
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
### 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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**Federal Register**

**Vol. 71, No. 12 / Thursday, January 19, 2006 / Notices**

### 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. DHS also is requiring the U.S. airports post a notice of the determination, in accordance with statutory requirements.

**FURTHER INFORMATION CONTACT:** Richard H. Steinauer, General Manager, International, Transportation Security Administration, 601 South 12th Street, Arlington, VA 22202–4220, Telephone: (703) 227–2774, e-mail: Richard.Steinauer@tsa.dot.gov.

**Notice**

Pursuant to 49 U.S.C. 44707(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 servicing the United States or that may pose a “high risk of introducing danger to international air travel.” The notice defines 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 standards used * * * in making the assessment.” 49 U.S.C. 44007(c).

Further, the Secretary must: (a) Publish the identity of the foreign airport in the Federal Register, (b) provide the identity of such airport at all U.S. airports that regularly provide scheduled air carrier operations, and notify the news media of the identity of the airport. 49 U.S.C. 44007(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 in or with the ticket, to all passengers purchasing transportation between the United States and the airport. 49 U.S.C. 44007(b)(1)(B).

On December 23, 2005, the Secretary of Homeland Security notified the Government of Indonesia that, under 49 U.S.C. 44007, he had determined that Bandara Ngurah Rai International Airport (IAP), Denpasar, Bali, Indonesia, does 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).

The Department of Homeland Security (DHS) is issuing this document, pursuant to 49 U.S.C. 44007(b)(1), to inform the public of this determination. DHS directs that all U.S. airports with regularly scheduled air carrier operations prominently display a notice of the determination. Further, DHS is notifying the news media of this determination. In addition, as a result of this determination, 49 U.S.C. 44007(d)(1)(B) requires that each U.S. and foreign air carrier (and their agents) providing transportation between the United States and DPS provide notice of the Department’s determination to each passenger buying a ticket for transportation between the United States and DPS, with such notice to be made by written material included on or with such ticket.

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**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 20,000 SF 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**

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One Medicine, One Health
North Carolina Consortium for the National Bio and Agro-Defense Facility

One Medicine, One Health

NC Ag & Tech University
approx 70 mi

Duke University
approx 17 mi

NC Central University
approx 19 mi

UNC-Chapel Hill
approx 30 mi

NC State University
approx 30 mi

NC Dept Ag
NC Dept Health
USDA/APHIS East
approx 32 mi

Research Triangle Park
approx 23 mi

RDU Intl Airport
approx 27 mi

Proposed NBAF Site

Umstead 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

One Medicine, One Health
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

“No Decision Alternative” (PIADC)

Five “Alternates” (GA, KS, MS, NC, TX)
**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

One Medicine, One Health
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)*

One Medicine, One Health
BIOSAFETY FACILITY ‘FLOOR’ DIAGRAMS

<table>
<thead>
<tr>
<th>HVAC Floor</th>
<th>LAB Floor</th>
<th>WASTE Floor</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Air Supply System and Air Exhaust System</td>
<td>Thermal/Chemical waste treatment system</td>
</tr>
<tr>
<td></td>
<td>Impermeable walls, ceiling, floor</td>
<td></td>
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</tbody>
</table>

**BSL 2**
- Environmental air in
- Unfiltered air out
- Access controls
- Special training
- Standard lab coat, nitrile/latex gloves, face shield/goggles

**BSL 3 Enhanced**
- 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

**BSL 3 Ag or BSL 4**
- HEPA filtered air in/out
- Negative pressure lab room
- Access control, background checks, special training
- Lab space encased in 2° 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
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


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

• Diagnoses for foreign animal diseases & zoonotics

- **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

- 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]
Broader National Biosafety Issues

Oversight and proliferation of high biocontainment facilities

Learning from recent incidents and experiences

One Medicine, One Health
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
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...”
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

One Medicine, One Health
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**
Barrett D Slenning

Department of Population Health and Pathobiology

College of Veterinary Medicine

NC State University

919.513.6324

barrett_slenning@ncsu.edu