



Review of the National Academy of Sciences Report: Recommendations and USAMRIID Response

Colonel John P. Skvorak, Commander

***US Army Medical Research Institute of Infectious
Diseases (USAMRIID)***

john.skvorak@us.army.mil





Background

USAMRIID - PROTECT, PROJECT, SUSTAIN

Congressionally Directed—September 2008

“The National Research Council will convene a committee of experts to evaluate:

- The scientific adequacy and credibility of the analyses of health and safety risks associated with exposure to pathogen research in the proposed new USAMRIID high containment labs.”
- The study did not concentrate on National Environmental Policy Act (NEPA) compliance.

“The focus of the study is:

- The safety of both the general public and the laboratory workers
 - ✓ USAMRIID’s record on laboratory acquired infections (LAIs)
 - ✓ The measures being taken for ensuring the prevention and mitigation of risks to the health and safety of workers and the public.”

The Environmental Impact Statement was conducted in accordance with existing guidelines.

NRC report published March 2010





NAS Recommendations/Responses:

1. Assessment of the EIS

USAMRIID - PROTECT, PROJECT, SUSTAIN

“The Army [should] consider developing detailed and practical guidance for conducting hazard assessments of infectious agents for inclusion in its guidance for implementing NEPA to improve future EIS processes and products.”

- ✓ USAMRMC recommendations regarding hazard assessments forwarded to ASA(I&E) for Army-wide consideration (memo signed by MG Gilman on 6 July 2010)
- ✓ USAMRMC will incorporate NAS recommendations on hazard assessments into future EIS involving BSL-3 and BSL-4 labs
 - Formal working relationship with NAS to review proposed risk assessment approach for Medical Countermeasures Test and Evaluation Facility (MCT&EF) EIS
 - NAS meeting 21 March 2011 in Frederick to hear proposed approach; public comment period included





NAS Recommendations/Responses: 2. Lab Regulations and Operating Requirements

USAMRIID - PROTECT, PROJECT, SUSTAIN

A. *“USAMRIID should continue to set high standards for advancing security, operational, and biosurety measures.”*

✓ Has been and remains USAMRIID’s highest priority

“...the committee has a high degree of confidence that the new USAMRIID facility will have the appropriate and effective physical security, biosurety program, and biosafety operating practices and procedures in place...”

B. *“Although USAMRIID has sought to set high standards for biosurety and biosafety, recent examples of laboratory-acquired infections (glanders and tularemia) and breaches in containment (B. anthracis spores) point to human error or deliberate misuse. The committee recommends further formalized training in responsibility and accountability at USAMRIID, similar to that required for NIH-sponsored training programs.”*

✓ Responsible Conduct of Research quarterly seminar series began
29 April 2010





NAS Recommendations/Responses:

2. Lab Regulations and Operating Requirements

USAMRIID - PROTECT, PROJECT, SUSTAIN

Responsible Conduct of Research Seminar Series:

29 April 2010. Introductory Lectures

"Ethical Decision Making Primer;" Dr. Arthur O. Anderson, USAMRIID

"Research Misconduct: How to Recognize It - What Can Be Done About It?" Dr. Anderson, USAMRIID

(A copy of the NAS Book "On Being A Scientist: A Guide to Responsible Conduct in Research, 3rd Edition" was given to each attendee)

28 July 2010. Research Misconduct

"The Statutory Basis and Procedures used in Investigating Research Misconduct." Mr. Stephen Maleson, Ft. Detrick JAG

"Building a Culture of Research Integrity," Dr. Anderson, USAMRIID

28 October 2010. Responsible Handling of Numerical and Image Data

"What Would Gauss Do?: Ethical Guidelines for Data Analysis," Ms. Sarah Norris, USAMRIID

"Observational Integrity: Responsible Use of Image Data," Dr. Anderson, USAMRIID

28 January 2011. Conflict of Interest and Intellectual Property

"How Intellectual Property & Other Legal Issues Impact on the Perception of Ethical Conduct of Research," Peter Weinstein, PhD, JD, Chief Counsel, Baxter Healthcare

28 April 2011. Philosophy of Science

Dr. Michael Weisberg, University of Pennsylvania

28 July 2011. Human Research Protection Programs

Dr. Greg Koski, Harvard Medical School





NAS Recommendations/Responses:

2. Lab Regulations and Operating Requirements

USAMRIID - PROTECT, PROJECT, SUSTAIN

C. *“The circumstances surrounding the laboratory-acquired infections (LAI) also should be carefully evaluated to determine what lessons can be learned for preventing future cases.”*

- ✓ Institute Accident Investigation Board assembled to review the tularemia LAI; report is complete and actions taken
 - New absence reporting policy signed and in effect
 - Task Force formed to review the use of personal protective equipment with *F. tularensis*
 - USAMRIID Policy for the use of respirators
 - Special Immunizations Program reevaluated and revised Tularemia vaccine guidelines; all individuals working with *F. tularensis* will be offered the vaccine regardless of pre-existing titers
 - Retraining on illness reporting was accomplished at a USAMRIID Safety Day (SAFE Campaign) March 2010; 100 percent employee participation either in-person or through online training

“...it is clear that lessons learned from past incidents have improved safety practices and significantly reduced the incidence of laboratory-acquired infections.”



NAS Recommendations/Responses:

2. Lab Regulations and Operating Requirements

USAMRIID - PROTECT, PROJECT, SUSTAIN

- Improved communication between SIP/Occupational Health and the Competent Medical Authority in potential Occupational Exposure (OE) cases
- SIP/CMA put together an OE card that summarizes OE reporting, sick call and leave reporting for employees



Occupational Exposures Card (OE)

Occupational Infectious Agent Exposure Reporting:

1. Address immediate first aid requirements (i.e., wound flushing)
2. Report Incident immediately to:
 - your supervisor or technical advisor;
 - Special Immunizations Program (SIP); and
 - your Competent Medical Authority (CMA)
3. Report to SIP clinic immediately for further evaluation.
4. If you go to the hospital, please present this card (or your USAMRIID Medical Alert Card) and have medical staff call the SIP during duty hours and Security after duty hours for further assistance in your diagnosis and management.

Contact Numbers During Duty Hours:

- Special Immunizations Program [REDACTED]
- Chief CMA [REDACTED]
- Alternate CMA [REDACTED]
- Chief CMA [REDACTED]

Contact Numbers After Duty Hours:

- Security [REDACTED]
- Chief CMA [REDACTED]
- Alternate CMA [REDACTED]
- Chief CMA [REDACTED]



Occupational Exposures Card (OE)

Sick Call/Sick Leave Reporting (USAMRIID Policy 10-113):

- **Soldiers:** Notify chain of command of illness; report to Barquist AHC on sick call; if placed on quarters, provide DD 689 to chain of command prior to returning to quarters.
- **Govt Civilian employees:** Notify first line supervisor within 2 hours of duty start time
- **Contractors:** Notify USAMRIID Technical Advisor comply with company personnel procedures
- **ALL PERSONNEL WHO HAVE ESCORTED/ UNESCORTED ENTRY INTO BSL-3 or BSL-4 LABS MUST NOTIFY SIP OF THEIR ILLNESS, AFTER CONTACTING THEIR SUPERVISOR.**
- **IF THEY ARE ENROLLED IN BPRP, THEY MUST ALSO NOTIFY THE CMA OF THEIR ILLNESS AND ANY PRESCRIBED MEDICATIONS OR TREATMENT.**

Contact Numbers During Duty Hours:

- Special Immunizations Program [REDACTED]
- Chief CMA [REDACTED]
- Alternate CMA [REDACTED]
- Chief CMA [REDACTED]

Contact Numbers After Duty Hours:

- Security [REDACTED]
- Chief CMA [REDACTED]
- Alternate CMA [REDACTED]
- Chief CMA [REDACTED]





NAS Recommendations/Responses: 3. Medical and Emergency Response

USAMRIID - PROTECT, PROJECT, SUSTAIN

A. *“...additional measures should be taken to provide assurance that experienced medical professionals are readily available to consult on unusual infectious diseases. Serious consideration should be given to support an initiative that would provide experienced specialist physicians knowledgeable of diseases caused by organisms studied at the laboratories. This would include consultation as needed on a 24/7 schedule to see patients from the community.”*

✓ Current MOA between USAMRIID and FMH

– Mutual support for acute care

– USAMRIID provides quarterly professional medical training

Feb 2010: Travel Medicine, MAJ Rivard

May 2010: Overview of SIP/Barquist Biosurety Program, COL Wadding & Dr. McIntosh

Sep 2010: Tularemia, Dr. Goldberg

Jan 2011: Rickettsial Diseases, MAJ Mody

Upcoming June 2011: Anthrax, LTC Vietri

✓ POC for consultation provided

– 24/7 availability of Infectious Diseases specialist for consultation

✓ USAMRIID’s Medical Management of Biological Casualties Course is available to civilian medical personnel as well as those in military service.





NAS Recommendations/Responses:

3. Medical and Emergency Response

USAMRIID - PROTECT, PROJECT, SUSTAIN

B. “Such physicians should also serve to provide continuing communication and coordination between USAMRIID scientists and community physicians and public health personnel.”

- ✓ USAMRIID/Barquist Army Health Clinic/Competent Medical Authority participation in existing medical groups primarily to increase familiarity with staff and capabilities
 - FMH Emergency Department
 - Barquist and USAMRIID attended and briefed on 4 May 2010
 - Future FMH ED meetings provide a viable mechanism to disseminate information
 - Occupational Health Services WG
 - Barquist and Ft. Detrick Garrison actively participate
 - New subgroup formed with Medical Directors associated with Campus labs to discuss occupational health issues, emergency transportation, and protocols for handling after-hours calls related to potential OEs
 - First meeting 12 April 2011 at USAMRIID
 - Frederick County Public Health Officer added to distribution of mishap reports (CDC Form 3)





**NAS Recommendations/Responses:
3. Medical and Emergency Response
(US Army Garrison, Ft. Detrick)**

USAMRIID - PROTECT, PROJECT, SUSTAIN

C. *“For medical and emergency response mechanisms, a senior authoritative management system is needed to ensure that USAMRIID works effectively with county government agencies, the local medical community, emergency preparedness and response initiatives, and Frederick Memorial Hospital. Such a system would include a clear chain of command with designated personnel to work directly with partners in the county and community. The Army should consider the use of permanent civilian staff for these positions to ensure continuity of relationships. Because USAMRIID will be part of the NIBC, which will include biocontainment facilities of two other agencies, consideration should be given to delineating and coordinating emergency and medical response plans and resources for all facilities on the campus.”*

- ✓ Multiple mutual support agreements in place
- ✓ USAG Directorate of Emergency Services provides full-time staff for coordination
- ✓ Ongoing coordination as a member of the Frederick County Emergency Management Policy Advisory Committee (EMPAC), ensuring integration with Frederick County and City First Responders, Emergency Planners, local medical community





**NAS Recommendations/Responses:
3. Medical and Emergency Response
(US Army Garrison, Ft. Detrick)**

USAMRIID - PROTECT, PROJECT, SUSTAIN

- ✓ Includes reciprocal participation in both county/city and Fort Detrick sponsored annual emergency response exercises
- ✓ Member of Local Emergency Planning Committee (LEPC)
- ✓ Detrick Emergency Preparedness Plan (EPP) applies to all tenants
- ✓ Increased coordination with both the Frederick County and MD Public Health Offices
 - USAMRIID Emergency Management Plan review and approval
 - Involved in exercises

“...the Army and Frederick County have the resources and the partnerships in place to address medical and emergency situations at the containment laboratories.”





NAS Recommendations/Responses: 3. Medical and Emergency Response

USAMRIID - PROTECT, PROJECT, SUSTAIN

Planned* and Completed Exercises:

- SEPT 2011** Capstone Exercise, Bomb threat, shelter in place, EOC Activation (USAMRIID, Fort Detrick EMS, US Army Garrison)*
- AUG 2011** Power outage/water loss exercise – Generator backup and water availability exercise (USAMRIID, FD-EMS, USAG)*
- JUL 2011** Fire Evacuation Exercise (All USAMRIID Buildings)*
- JUN 2011** EOC Activation Exercise (USAMRIID, MRMC, USAG)*
- MAY 2011** Patient Evacuation Exercise (USAMRIID, FD-EMS, USAG)*
- APR 2011** Phone Recall Exercise (USAMRIID)*
- FEB 2011** Anaphylactic Emergency SIP (USAMRIID and Fort Detrick EMS)
- AUG 2010** Medical Defender Exercise, DAIG (USAMRIID, USAG, MRMC, FD EMS, USN)
- JUL 2010** Communications Exercise with VHF Radios (USAMRIID)
- JUL 2010** Fire Evacuation Exercise, bldg 1425 (USAMRIID)
- JUL 2010** Tornado Drill Exercise, bldg 1425 (USAMRIID)





NAS Recommendations/Responses:

3. Medical and Emergency Response

USAMRIID - PROTECT, PROJECT, SUSTAIN

- JUN 2010** Phone Recall Exercise during normal duty hours (ALL USAMRIID STAFF)
- JUN 2010** Training Exercise, Autoclave/medical emergency/centrifuge (USAMRIID)
- MAY 2010** Fire Evacuation Exercise, bldg 1425 (USAMRIID)
- MAY 2010** Tabletop Exercise, BSL-3 Insectary (USAMRIID)
- APR 2010** Tabletop Exercise, Biological Safety Cabinet (USAMRIID)
- APR 2010** Fire Evacuation Exercises, Bldgs 1443, 1414, 1408, 1412, 1416 (USAMRIID)
- MAR 2010** Phone Recall after normal duty hours (ALL USAMRIID STAFF)
- MAR 2010** Medical Information Request Exercise (USAMRIID)
- OCT 2009** Renovated BSL-3/BSL-4 Walk-through Training Exercise (USAMRIID)
- JUN 2009** Medical emergency in BSL-3 laboratory (USAMRIID and FD-EMS)
- APR 2009** Fire Evacuation Exercise, bldg 1412 (USAMRIID)
- NOV 2008** Fire Evacuation Exercise, bldg 1425 (USAMRIID)





NAS Recommendations/Responses:

4. Communication/Cooperation with the Public

USAMRIID - PROTECT, PROJECT, SUSTAIN

A. *“USAMRIID should expand its two-way communication with the public. Examples of possible communication efforts are: (1) Promptly disclosing laboratory incidents to the public, (2) providing fact sheets about pathogens being studied, to include information on their natural reservoirs and how they are transmitted, and (3) holding an open house prior to activation of the new USAMRIID facility or opening a visitors' center.”*

- ✓ Coordinated release of information to public, media, health and local officials and safety reporting chain of command regarding tularemia case in Nov-Dec 2010
 - Summary of internal report shared with media
 - Safety mishap information presented at Community Liaison Council meetings
 - Currently developing an up-to-date mishap reporting mechanism for the USAMRIID public website
- ✓ Detailed biological pathogen fact sheets available on www.cdc.gov (and through link on USAMRIID website)
- ✓ Tours of new USAMRIID building planned (local officials, media, others to be considered)
- ✓ Visitors' center concept also being explored at Fort Detrick





NAS Recommendations/Responses:

4. Communication/Cooperation with the Public

USAMRIID - PROTECT, PROJECT, SUSTAIN

B. *“USAMRIID should consider strategies that have been used by other containment laboratories to enhance community understanding and facilitate integration into the community. If possible, such communication strategies could be coordinated with the two other laboratories of the National Interagency Biodefense Campus.”*

- ✓ BSL-4 Directors Group (nation-wide)
 - Consulted with other BSL-4 labs including NIAID-RML, Galveston NL, and Canadian Science Center in Winnipeg
 - Establishment of community board/committee and safety mishap reporting to local public health officials considered the two most important elements (both implemented)
- ✓ Relevant NICBR committees and subcommittees, such as the Public Affairs/Community Relations Subcommittee, are briefed on USAMRIID communications activities





NAS Recommendations/Responses:

4. Communication/Cooperation with the Public

USAMRIID - PROTECT, PROJECT, SUSTAIN

- ✓ Continuous requirement to increase community understanding of safety and security measures—**process is ongoing**
- ✓ Maintained **media outreach** to local outlets (Frederick News Post, Frederick Gazette, AP) and explored new ones (270 Inc. magazine, “Frederick’s Forum” on WFMD radio)
- ✓ Developed a “**USAMRIID 101**” **presentation** and new pop-up displays for use at **several completed and planned meetings and events** (see list on next slide)





NAS Recommendations/Responses:

4. Communication/Cooperation with the Public

USAMRIID - PROTECT, PROJECT, SUSTAIN

Completed and Planned Meetings/Events:

| | | | |
|---------------------|-----------------------------------|--------------------|--|
| 7 Jun 2010 | Community Liaison Council Meeting | 27 Jan 2011 | USAMRIID Overview Brief & Tour for CLCAC |
| 21 Jun 2010 | Ft. Detrick Community Meeting | 31 Jan 2011 | Ft. Detrick Town Hall Meeting |
| 13 Sept 2010 | Community Liaison Council Meeting | 7 Feb 2011 | USAMRIID Biosurety Brief for CLCAC |
| 23 Sept 2010 | NAC 5 Meeting * | 28 Mar 2011 | Frederick Rotary Open House |
| 26 Oct 2010 | Clover Hill Residents Meeting | 29 Mar 2011 | Kiwanis Club Meeting |
| 2 Nov 2010 | Hood College Students | 12 Apr 2011 | Ft. Detrick Alliance Open House |
| 3 Nov 2010 | NAC 1 Meeting * | 27 Apr 2011 | Spring Research Festival (2-day event) |
| 8 Nov 2010 | NAC 3 Meeting * | 15 Jun 2011 | Ft. Detrick Alliance Community Event |
| 17 Nov 2010 | NAC 6 & 9 Meeting * | (TBD) 2011 | Media Tour of Renovated BSL-4 Lab |

**Initial outreach efforts focused on the 5 Neighborhood Advisory Councils that border Ft. Detrick; others to be covered*





NAS Recommendations/Responses: 4. Communication/Cooperation with the Public

USAMRIID - PROTECT, PROJECT, SUSTAIN

C. *“USAMRIID should involve the Frederick community in ongoing activities related to improving safety at the laboratory. For example, it might be useful to include community members on the Institutional Biosafety Committee or other relevant committees.”*

NIH Guidelines require institutions to establish an IBC specifically for the review of recombinant DNA research. The IBC must have at least five members with appropriate experience in recombinant research. The IBC must also include two members nonaffiliated with the institution.

- ✓ USAMRIID is in **full compliance** with nonaffiliated member requirement for IBC
- ✓ Newly formed Containment Laboratory Community Advisory Committee (CLCAC) is **key mechanism** for hearing and addressing community concerns about laboratory safety at USAMRIID





NAS Recommendations/Responses:

4. Communication/Cooperation with the Public

USAMRIID - PROTECT, PROJECT, SUSTAIN

D. *“USAMRIID should create a community advisory board, with a broad representation of community views. This board should meet regularly to learn about successes, problems, and improvements in policies and practices; encourage public suggestions for improvements; and help shape the laboratory's public communications and activities-including the development of guidelines for reporting incidents to the public.”*

- ✓ **4 Mar 2010—Initial recommendation made in NRC report**
- ✓ **17 June 2010—USAMRIID briefs City/County on progress**
- ✓ **29 July 2010—USAMRIID presents plan for proposed advisory committee to small City/County working group**
 - Plan developed with extensive input from similar functioning committees at other BSL-4 facilities in U.S. and Canada
 - City/County recommends committee not be limited to USAMRIID but address containment labs at Ft. Detrick





NAS Recommendations/Responses:

4. Communication/Cooperation with the Public

USAMRIID - PROTECT, PROJECT, SUSTAIN

- ✓ **18 Aug 2010—USAMRIID communicates its plan for proposed organization to Ft. Detrick Interagency Coordinating Committee (FDICC)**
 - Scope changed to all containment labs in Frederick County
- ✓ **26 Aug 2010—USAMRIID presents proposal to joint meeting of City/County/Municipalities**
 - Proposed objectives, membership application and guidelines accepted as working draft, subject to revision and final approval by committee members and local officials
- ✓ **28 Sept 2010—City/County/Ft. Detrick hold joint press conference to announce committee formation and call for applications**
 - City and County form search committee
 - Ft. Detrick/USAMRIID not involved in selection process
- ✓ **18 Nov 2010—Members of CLCAC announced**
- ✓ **2 Dec 2010—First meeting of CLCAC**
 - 1 non-voting liaison is from USAMRIID/Ft. Detrick





Summary

USAMRIID - PROTECT, PROJECT, SUSTAIN

- USAMRIID has made **significant progress** in implementing the March 2010 recommendations from the National Research Council.
- There is no “endpoint” – rather, this is a **continuous requirement** to maintain a **safe** and **secure** operation, be **prepared** for contingencies, and **keep lines of communication open** with the public, emergency responders, local health professionals, and elected officials.
- The **Containment Laboratory Community Advisory Committee** will be key to USAMRIID’s ongoing effort to implement the recommendations.

