THE NATIONAL ACADEMIES
REPORT IN BRIEF

Summary

Evaluation of the Health and Safety Risks of the New USAMRIID High Containment Facilities at Fort Detrick, Maryland

The U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) is expanding and renovating its existing biocontainment facilities at Fort Detrick in Frederick, Maryland. These facilities are and will be designed to handle infectious agents (pathogens) that cause serious or potentially lethal diseases, which require that research performed on them be contained in specialized laboratory suites.

As part of the decision process for the expansion, and to comply with the National Environmental Policy Act (NEPA) of 1969 and associated regulations, the Army prepared an Environmental Impact Statement (EIS), required for Federal Government agency actions significantly affecting the quality of the human environment. The final EIS was issued in December 2006, and the Record of Decision to construct and operate the new USAMRIID facilities was issued in February 2007. However, residents of Frederick County, Maryland have questioned whether the potential public health and safety risks, and strategies to mitigate those risks, were adequately considered in the decision to go forward with the expansion. To address these concerns, Congress directed the Secretary of Defense to commission an independent review by the National Research Council (NRC) of certain aspects of the EIS relating to risks from work with infectious agents (P.L. 110-329). The NRC assembled a multidisciplinary committee of individuals with expertise in biosafety, infectious

Illustration courtesy of the U.S. Army

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diseases, industrial hygiene, environmental engineering, risk assessment, epidemiology, and stakeholder participation. The committee was asked to evaluate the scientific adequacy and credibility of the analyses of health and safety risks associated with exposure to pathogen research, and the proposed strategies to mitigate those risks, as presented in the final EIS. The committee also was asked to examine USAMRIID's current procedures and regulations for reducing exposure to pathogens to determine whether they are comparable to those in place at other facilities and whether they meet accepted standards established by the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) and by other rules and guidance. USAMRIID's records on laboratory-acquired infections were also to be considered, as well as measures being taken for ensuring the prevention and mitigation of risks to the health and safety of laboratory workers and the public.

The committee held public meetings to gather information to address its task. It met with USAMRIID and Fort Detrick medical and safety officials, contractors involved in the development of the EIS, members of the Frederick County Board of Commissioners, and members of the general public. The committee also had separate meetings with the medical and security staff of Frederick Memorial Hospital, officials from Frederick County's emergency management and health departments, and representatives from the community.

Assessment of the Environmental Impact Statement

EISs are documents required under NEPA to identify probable environmental impacts (including health effects) from programs and actions of the Federal Government. They are required to provide full and fair discussion of significant potential environmental and health impacts and consider reasonable alternatives that would avoid or minimize adverse environmental impacts or enhance the quality of the human environment. However, there is no specific guidance for considering some of the unusual infectious disease risks from biocontainment facilities.

The hazard assessment included in the USAMRIID EIS explored a range of possible consequences that could result from a mishap at the new USAMRIID facilities. The maximum credible event analyses (required in an EIS) involved simulation of biological aerosol releases from Biosafety Level (BSL)-3 and BSL-4 laboratories. In the scenarios, *Coxiella burnetii* (requiring BSL-3 containment) and *Ebola Zaire* virus (requiring BSL-4 containment) were released to the surrounding environment from an exhaust stack after vials in a centrifuge leaked and air filters failed to filter the pathogens. The EIS estimates that ground concentrations would be insignificant and would not pose a hazard to the nearby community. However, the committee was unable to verify this prediction, because the modeling performed in support of the scenarios was not transparent, could not be reproduced, and was incomplete. Specifically, the data and parameterizations used in the computerized simulation scenarios were not provided in the EIS and the model software (Hazard Prediction and Assessment Capability model) is a closed-source system not available for independent review. The committee attempted to verify the calculations using common alternative models. The committee's calculations indicated the potential for significantly higher doses of infectious agents following puff releases than was described in the EIS.

Other problems with the maximum credible event (MCE) scenarios were the use of inappropriate scenarios and inadequate enumeration and characterization of risks. EIS guidance specifies that hazard scenarios should be "reasonably foreseeable," but the ones used in the USAMRIID EIS required multiple failures, such as human errors (e.g., failure to use O-rings to seal the centrifuge tubes) and safety failures (e.g., inoperable high-efficiency particulate air [HEPA] filter). Results appear to present only peak concentrations, rather than total infectious agent dose, which is the most appropriate measure of per-person risk. The EIS contained no documentation of an individual's risk of infection under the prescribed conditions or any description of the effect of population density and population size on the number of cases expected for any of the pathogens of interest. Furthermore, the scenarios only

Scientists preparing to enter a BSL-4 laboratory.

Credit: CDC

considered exposures beyond the Fort Detrick fence line, with no consideration of exposure to USAMRIID workers or other people on the base. Despite the committee's estimation that an exceptionally large aerosol release might pose a human health risk, there are no reasonably foreseeable scenarios where such a release could occur.

The EIS does not provide a systematic characterization of exposure risks and consequences associated with the scenarios. Nor does it document the effects of mitigation measures on scenarios or how risks would vary under alternative actions. For example, a systematic review would have identified arthropod escape as an exposure scenario, in addition to those characterized in the EIS of escape of an infected animal, mishaps during biological material shipments, terrorist acts, external acts (such as natural disaster or mechanical failures), spread by an infected worker, and cumulative impacts. Several biological agents likely to be studied at the new USAMRIID facility are transmitted by arthropod vectors (such as fleas, mosquitoes, and ticks), and the vectors may be used in the course of research. Consideration of such a scenario in the EIS would have shown that there are significant ecological barriers that make associated relative risks small. Another scenario that was not considered was the threat of an insider with malicious intent. Although such a situation is difficult to predict or quantify, it is clearly of concern to the citizens of Frederick County.

The EIS does not provide scenarios describing potential exposure risks involving pathogens to USAMRIID laboratory personnel, but does cite a brief history of cases of laboratory-acquired infections occurring between 1989 and 2002. Review of these cases illustrates both means of transmission and procedures in place to address identification and treatment of affected laboratory workers. Common risks to workers are needle- or sharps-stick accidents, inadvertent aerosol generation that leads to inhalation or ocular/mucosal exposure, and contact with infected laboratory animals.

The EIS explained that the new USAMRIID facility will be part of the National Interagency Biodefense Campus, which Congress directed to be located at Fort Detrick. However, the EIS fell short of its NEPA requirements as it did not attempt to provide a reasonable alternative location for the laboratory. Such an exercise might have illustrated how risks differ between locations and could have provided guidance on whether changes or improvements might be needed at the mandated site.

Findings:

- The analyses in the EIS of the risks and the mitigation measures to address them were not comprehensive and there was insufficient documentation for a fully comprehensive independent assessment of the risks to the community posed by biological agents. The problem was compounded by the fact that the MCE scenarios were not reasonably foreseeable accidents.
- The epidemiologic characteristics, including transmission pathways, natural reservoirs, geographic distributions, and clinical outcomes of the pathogens, were not systematically documented
- There was incomplete consideration of some of the possible routes through which the general public might be exposed to pathogens.

- Although the congressional mandate placing the National Interagency Biodefense Campus at Fort Detrick precludes siting the new USAMRIID facility elsewhere, it would have been appropriate for the EIS to include consideration of an alternative location, such as one in a less populated area. Such an exercise could have provided a comparison that identified advantages and disadvantages specific to each location, and guided preventive strategies and mitigation efforts if differential risks were found.
- Despite the problems identified with the EIS, the committee judged that it would not be useful to propose specific revisions to the EIS or supplementary analyses given that the Record of Decision to construct the new USAMRIID facility was issued and construction has begun on the project.

Recommendation:

- The committee recommends that the Army 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.

Regulations and Operating Requirements of the New Laboratory

The guidelines, procedures, and regulations that govern the operations of biocontainment facilities at USAMRIID were reviewed by the NRC committee. The new USAMRIID biocontainment laboratories are required to be constructed and operated under the most current standards and guidelines for such facilities established by CDC and NIH. Before work with BSL-3 and BSL-4 pathogens (serious and high-risk infectious agents) can be performed in these laboratories, they must be independently inspected and approved by CDC/NIH. The operations of the containment laboratories are governed by biosafety guidelines established by CDC that prescribe engineering controls, personal protective equipment, work practices, and administrative controls (such as immunizations, medical surveillance, and training). In addition, the Army has its own laboratory-specific standard operating procedures, regulations, and guidelines for USAMRIID.

The Department of Defense and the Army also developed regulations and guidance related to biosurety. Biosurety involves establishing systems and procedures to safeguard biological select agents and toxins (BSAT; select agents are agents and toxins that have the potential to pose a severe threat to public, animal, or plant health, or to animal or plant products) against theft, loss, diversion, or unauthorized access or use, and to operate the laboratory in a safe, secure, and reliable manner. Because the laboratory will be on an Army base, the level of physical security is even greater than that found at other biocontainment facilities. The new USAMRIID facilities also will be subject to announced and unannounced inspections by CDC, which will include scrutiny of the receipt, storage, use, and transfer of BSAT.

Personnel reliability is another important aspect of biosurety. It involves systems and procedures to ensure that individuals with access to BSAT meet high standards of reliability. The Army has taken the lead in establishing a robust biosecurity program, which has been fully adopted by USAMRIID. However, it is the consensus of the committee that no program can stop all threats of theft or misuse of BSAT. The solution to preventing such incidents is not in stopping all work with BSAT, but rather in identifying means to further strengthen biosecurity programs, such as by formalized training for laboratory workers on their individual and collective responsibilities and accountability and paying increased attention to behavior signals that may identify personnel as "at risk." Because insider threats are a significant concern of the citizens of Frederick County, it will be important for USAMRIID to develop a means for addressing their concerns (possible options are discussed below).

It is also noteworthy that the Army has been a leader in developing cutting-edge requirements for high- and maximum-containment facilities. For example, the institute was involved in the development of biological safety cabinets, establishing the scientific basis for packaging and shipping infectious agents, applying HEPA filtration technology, and vaccinating its workers. When these and other related developments are placed in context with the history of laboratory-acquired infections at USAMRIID, it is clear that lessons

learned from past incidents have improved safety practices and significantly reduced the incidence of laboratory-acquired infections. It is expected that any future incidents will continue to guide improved safety practices.

Findings:

- USAMRIID's current procedures and regulations for its biocontainment facilities meet or exceed the standards of NIH and CDC for such facilities and other accepted rules and guidance for handling and containing pathogens during use, inventorying, and storage; treating and safely disposing of laboratory solid waste; and handling and decontaminating wastewater.
- Measures have been taken to improve safety at USAMRIID when problems have been identified. The new facilities will be operated under even more stringent guidelines than were in place previously regarding physical security, engineering infrastructure and redundancies, biosafety, and biosecurity. Thus, 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 to protect its workers and the public from exposures to pathogens, and any new pathogens, studied in its laboratories.
- USAMRIID has strived to improve safety procedures. Lessons learned from exposure and/or disease incidents have directed some of the improvements, as indicated by the decrease in laboratory-acquired infections from the 1940s to the present, so that laboratory-acquired infections are now infrequent.

Recommendations:

- USAMRIID should continue to set high standards for advancing security, operational, and biosurety measures.
- 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. The circumstances surrounding the laboratory-acquired infections also should be carefully evaluated to determine what lessons can be learned for preventing future cases.

Medical and Emergency Management Response

USAMRIID has a special immunizations program (SIP) clinic that serves as the occupational health provider for laboratory personnel and an outpatient research facility for investigational vaccines. It is staffed with infectious disease specialists and laboratory staff with experience

Training exercise with ambulance transport isolation system.
Courtesy of the U.S. Army

in testing for the agents under study at USAMRIID. Although the SIP clinic should be the first place to go when seeking medical care for symptoms suspected to be work-related, it is incumbent on the individual worker to report laboratory incidents and to go through the appropriate channels for care.

In the event of an incident requiring medical care, a formal agreement is in place between USAMRIID and Frederick Memorial Hospital for patients to be transported and treated at the hospital. In addition, the two organizations have an understanding on providing mutual support to deal with a public health emergency or terrorist attack. The understanding calls for USAMRIID to provide quarterly training for hospital staff and for the director of safety and security at the hospital to receive annually updated material on USAMRIID's

medical management of biological casualties. To facilitate care, each USAMRIID staff member is provided with a contact card identifying him or her as an employee to expedite notification by clinicians of infectious disease experts for consultation.

The Barquist Army Health Clinic at Fort Detrick also has an ongoing and good relationship with Frederick County's Health Department, such that the county has confidence that it will be informed of any reportable medical incidents of which the clinic is aware. However, there is no guarantee that USAMRIID workers will report incidents or seek medical care at the Barquist or SIP clinics. Since 2000, there have been two known cases in which USAMRIID workers failed to seek medical attention at the SIP clinic and also appeared to have failed to disclose that they were USAMRIID employees to the off-base physicians from whom they sought medical care. These failures delayed prompt diagnosis and treatment, and have raised community concerns about the potential for secondary transmission (that is, infection of others through contact).

A primary concern of the committee focuses on medical response and whether clinicians with specialized training in the clinical diagnosis and treatment of unusual infectious diseases are readily available. The committee was informed that, at present, there are only a few physicians in the community who regularly consult on infectious disease problems and none are believed to have had substantial training in dealing with diseases caused by the organisms being studied at USAMRIID. Efforts have been made by USAMRIID to provide education to some of the Frederick Memorial Hospital physicians through quarterly training. However, it is unrealistic to expect many of the physicians in the county to avail themselves of such educational efforts or to know when and whom to consult when confronted with a patient with an unknown infectious disease.

The Fort Detrick Garrison has on-base fire and emergency services equipped to deal with medical and fire emergencies at USAMRIID. Formal agreements also are in place between Fort Detrick and Frederick County's Division of Emergency Management to provide mutual aid in dealing with fire, hazardous materials problems, and other disasters, including biological incidents. The Garrison team conducts regular drills at the USAMRIID facility, including rescue drills involving BSL-3 and BSL-4 laboratories. Procedures and appropriate equipment are in place to ensure proper decontamination of a exposed person before transport to Frederick Memorial Hospital.

Findings:

- USAMRIID, Fort Detrick, and Frederick County have the resources and partnerships in place to address medical and emergency situations at the containment laboratories. There are several concerns, however, that need to be addressed.
- A primary concern is the lack of readily available clinicians with the necessary specialized training to consult on the clinical diagnosis and treatment of unusual infectious diseases.

Recommendations:

- Given the unique nature of USAMRIID's mission in dealing with special pathogens, 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. Such physicians should also serve to provide continuing communication and coordination between USAMRIID scientists and community physicians and public health personnel.
- 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 National Interagency Biodefense Campus, 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.

Communication and Cooperation with the Public

A variety of views have been expressed by the Frederick community about the planned expansion of USAMRIID. Some citizens hold views that no research that requires containment should be performed there at all, while others are fully supportive of USAMRIID's expansion. Views that fall between those extremes include the belief that biocontainment facilities should be built in remote locations or that if the work must be done in populated areas, assurances that the work will be done in a safe manner and that plans are in place to deal with any potential exposure are needed. The underlying theme of these concerns has to do with *trust* that USAMRIID will act promptly and openly regarding any safety breaches. To date, USAMRIID's interactions with the community have been perceived by some to be perfunctory and not performed in a way that merits public trust. Community leaders have stated that information presented by the Army to this committee during its public meetings is the type of information that would help them better understand the potential public health risks. Such information involved discussions about USAMRIID's operations, regulations and guidelines, training, history of laboratory exposures and illnesses, and details about the institute's agreements with Frederick County and Frederick Memorial Hospital on emergency response and health incidents. To date, such information had not been adequately shared with the public.

While the committee does not believe that improved communication with the public in these areas will eliminate all opposition to USAMRIID's expansion, a more proactive communication program could build trust, alleviate concerns about community safety, and provide an opportunity for community involvement. USAMRIID should go beyond demonstrating that it is following

Work in a BSL-4 laboratory using a negatively pressurized laminar flow hood.
Credit: CDC

the rules and procedures that govern its operations and more directly answer the specific concerns raised by its critics. This would involve a public dialogue between citizens and Army officials with authority at USAMRIID, and not just press releases and announcements.

Findings:

- A segment of the local population around Fort Detrick is not satisfied that the Army is doing everything it can to protect them from infection by pathogens being studied at USAMRIID.
- Communication between USAMRIID and the Frederick community has not been adequate to address community concerns. The community has not been made aware of the details of the many safeguards already in place at USAMRIID, the requirements governing the operation of biocontainment facilities, and the Army's ongoing commitment to improving safety and security.

Recommendations:

- USAMRIID should expand its two-way communications with the public. Examples of possible communication efforts are:
  - Promptly disclosing laboratory incidents to the public,
  - Providing fact sheets about pathogens being studied, to include information on their

natural reservoirs and how they are transmitted, and

  - Holding an open house prior to activation of the new USAMRIID facility or opening a visitors' center.

- 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.
- 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 (which reviews research involving biohazardous risks) or other relevant committees.
- 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.

In summary, although the EIS failed to provide adequate and credible technical analyses, current procedures, regulations, physical security, and biosurety guidelines at USAMRIID meet or exceed accepted standards and practices. Furthermore, the Army and Frederick County have the resources and the partnerships in place to address medical and emergency situations at the containment laboratories. Thus, the committee has a high degree of confidence that policies and procedures are in place to provide appropriate protections for workers and the public. Nonetheless, no program can fully stop all threats resulting from human error (for example, laboratory-acquired infections), or from theft or misuse of select agents. In going forward, the Army and USAMRIID should review its methods and procedures for preparing an EIS (including consideration of human health issues), more actively train personnel regarding accountability and responsibility, and more proactively reach out to the local community to inform it of its safety and security policies and procedures and to constructively design approaches for communicating timely information should an adverse incident occur.

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The National Academies appointed the above committee of experts to address the specific task requested by the U.S. Army. The members volunteered their time for this activity; their report is peer-reviewed and signed off by both the committee members and the National Academies.

For more information, contact the Board on Life Sciences at (202) 334-2187 or visit http://dels.nas.edu/bls. Copies of *Evaluation of the Health and Safety Risks of the New USAMRIID High Containment Facilities at Fort Detrick, Maryland* are available from the National Academies Press, 500 Fifth Street, NW, Washington, D.C. 20001; (800) 624-6242; www.nap.edu.