I. EXECUTIVE SUMMARY

This report presents the background, study methods, and results of additional reviews that were conducted to determine what risks might arise from a National Biocontainment Laboratory (NBL) operated by Boston University. These reviews, conducted voluntarily in response to concerns raised in a Federal court proceeding, used computer models and fictitious scenarios to assess 1) the potential for various exotic infectious agents to be released into the community and cause disease, and 2) the suitability of three different sites for the location of the laboratory.

BACKGROUND

The National Institutes of Health (NIH), awarded a grant to Boston University in 2003 to partially fund the design and construction of an NBL. This advanced biomedical research laboratory will include biosafety level 2, 3, and critically needed biosafety level 4 (BSL-4) research space. BSL-4 laboratories, which are designed, constructed, and operated to be the safest, most secure laboratories in the world, allow research with exotic agents that pose a high risk of life-threatening disease to the laboratory worker handling them and for which there are no vaccines or therapies. BSL-4 laboratories are essential to perform the research required to develop medical countermeasures to protect the American public against emerging and re-emerging infectious diseases that may either occur naturally or be deliberately introduced. Research conducted in this NBL will aid the national effort to develop new diagnostics, vaccines, and therapeutics for these agents, as well as for diseases such as pandemic influenza.

To date, there has not been a laboratory-acquired infection in the United States resulting from work in a BSL-4 laboratory. The stringent precautions taken to protect the laboratory workers' health and to reduce their individual risk also serve to protect the surrounding communities and the environment as well. Indeed, the numerous safety precautions in the design and operation of a BSL-4 laboratory result in a negligible risk of release of infectious agent into the surrounding community.

As required by the National Environmental Policy Act (NEPA), the NIH completed and published a Final Environmental Impact Statement (FEIS) for the Boston University NBL on December 9, 2005, and a Record of Decision on February 2, 2006. Public input and comments were solicited and received throughout this process. Construction of the Boston University NBL – known as the National Emerging Infectious Diseases Laboratories (NEIDL) – is underway at the BioSquare II Research Park on Albany Street in Boston, adjacent to the Boston University Medical Center (BUMC).

In preparing the Final EIS, the NIH thoroughly reviewed the possible impacts of the NEIDL on the public and the environment. That review demonstrated that the construction and operation of the NEIDL did not pose a risk to the community in which the laboratory was sited or to the surrounding communities.

PURPOSE OF THE SUPPLEMENTAL REVIEWS

In response to concerns raised in a Federal court proceeding, the NIH completed additional reviews of the potential impacts of the NEIDL, as described in this report. These additional reviews included

1. *additional risk assessments*: efforts were undertaken to determine if a quantitative assessment of potential risks of the release of various exotic infectious agents into the community could be made under realistic conditions
2. *comparative risk assessments*: a quantitative comparison of the potential risk of infectious disease posed by the release of various exotic infectious agents into the community was evaluated by simulating fictitious scenarios
3. *alternative site analyses*: sites in three communities -- Boston-BUMC, Albany Street; Tyngsborough, MA; and Peterborough, NH -- were considered as potential locations for construction and operation of the NEIDL (all three sites are owned by Boston University)

These reviews were designed to answer three questions:

1. What risks, if any, would be posed by an accident involving an infectious disease agent during operation of the NEIDL?
2. Does location of the NEIDL in an urban, suburban, or rural setting represented by Boston-BUMC, Tyngsborough, and Peterborough, respectively, affect the incidence of disease or transmission of disease as a result of the introduction of an infectious agent through each scenario?
3. Are Environmental Justice communities (i.e., low-income and minority communities), if present, subjected to disproportionate health impacts as a result of siting the NEIDL near these communities in the unlikely event that an infectious agent was released?

METHODS

The NIH engaged the State University of New York at Buffalo to develop a model that used advanced techniques to simulate scenarios involving infectious disease releases or laboratory accidents in order to predict (1) who would become infected, (2) where they would be infected, (3) when the infection would occur, and (4) the outcome of the infection. This technique, known as Agent-Based Explicit Spatial and Temporal (A-BEST) Modeling, simulated fictitious scenarios for the potential spread of selected exotic infectious diseases in each of the three communities. The scenarios involved four disease agents -- Ebola virus, Sabia virus, monkeypox virus, and Rift Valley fever (RVF) virus – and the risk of infectious disease should such an exotic agent be released into the community through an infected laboratory worker, laboratory accident, or other mishap. An additional simulation approach -- Multilayer Agent Based-Simulation Tool (MLAB-ST) -- was used to investigate further the spread of a mosquito-borne disease (RVF) in each of the three communities.

Initially, NIH determined that it would not be possible to attempt a quantitative assessment of risk resulting from an accident involving an infectious disease agent studied at the NEIDL, because any modeling based on realistic -- even if conservative -- assumptions would lead to a conclusion of essentially negligible risk. In hundreds of thousands of person-hours of work in BSL-4 laboratories in the United States, there has not been even one laboratory-acquired infection, let alone any cases of infection in the community.

Given the absence of any predicted risk to the community based on reasonable assumptions, and in order to generate quantitative comparisons of the relative risks among the three communities, the scenarios developed by NIH were accordingly designed to exaggerate and amplify any risks in order to "force" an infection beyond the laboratory so that the relative effects on the three communities could be compared. In other words, unrealistic assumptions were made solely to generate quantitative risk estimates that could be used to compare risks among the communities.

For example, the probability that the initial accident in the NEIDL would lead to an infection was set at one (1), even though this is inconsistent with actual experience, because if a NEIDL researcher is not infected, then, by definition, no disease would result in the community. Throughout the scenarios, other similarly unrealistic assumptions were made to ensure that the model would result in the occurrence of disease in the three communities.

The scenarios modeled included situations suggested by interested citizens during public meetings and written submissions. The scenarios also took into account the complex social, work, and home interactions and networks approximating daily life in three communities. The additional analyses also compared each of the three sites on a number of important variables such as facility location, noise and air quality impacts, and transportation and access.

The scenarios describe the events that would have to happen, in the correct sequence, to produce possible risks to the community. In addition, the models were designed such that each event or step within a scenario occurred all the time, which would be extremely unlikely to occur in real life. Results from these simulations also far overstate the probability of disease in the community because the model did not allow for the use of common public health or medical interventions (for example, vaccination of livestock for RVF, use of insect repellents, medical interventions, or supportive therapy). Thus, the scenarios grossly exaggerate any real risks that may be posed by construction and operation of the NBL.

RESULTS

As noted above, NIH first concluded that, under realistic conditions, infectious diseases would not occur in the communities as a result of an accident in the NEIDL. In the fictitious scenarios in which risks were exaggerated in order to "force" an infection beyond the laboratory, allowing a comparison of the effects on the three communities, results indicate that

- There was no difference in simulated disease transmission among the urban, suburban, or rural environments of Boston-BUMC, Tyngsborough, MA, or Petersborough, NH, respectively, for Ebola, monkeypox, or Sabia virus.
- The population size in each community did not affect the rate of transmission of Ebola, Sabia, monkeypox, or Rift Valley fever in the communities.
- The Environmental Justice communities near Boston-BUMC were not disproportionately affected by the presence of the NEIDL on Albany Street.

The simulations also indicated that RVF (a mosquito-borne disease) would not be sustained in the Boston population. However, in the Tyngsborough and Peterborough communities, livestock helped carry and spread the RVF virus, resulting in significant human disease and even death. In fact, the nature of the communities surrounding Boston-BUMC (i.e., urban environment, lack of livestock virus carriers, etc.) places citizens of these communities at much less risk of RVF infection than persons living in Tyngsborough or Peterborough.

Based on the results of the site analyses for the three communities and the additional risk assessments, the Boston-BUMC, Albany Street site was determined to be the best site for construction and operation of the NBL.