



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 1
1 CONGRESS STREET, SUITE 1100
BOSTON, MASSACHUSETTS 02114-2023

OFFICE OF THE
REGIONAL ADMINISTRATOR

January 13, 2006

Valerie Nottingham
National Institutes of Health
NIH B13/2W64
9000 Rockville Pike
Bethesda, Maryland 20892

Re: Final Environmental Impact Statement for National Emerging Infectious Diseases
Laboratories, Boston, Massachusetts, CEQ # 20050514

Dear Ms. Nottingham:

In accordance with our responsibilities under the National Environmental Policy Act (NEPA) and Section 309 of the Clean Air Act, we have reviewed the National Institutes of Health's (NIH) Final Environmental Impact Statement (FEIS) for the National Emerging Infectious Diseases Laboratory (NEIDL) at the Boston University Medical Center Campus in Boston, Massachusetts.

The FEIS describes the proposed construction of a 194,000 square foot biosafety lab facility at the BioSquare Research Park in Boston. EPA commented on the SDEIS for this project in May 2005. Our comments on the FEIS focus on the responses provided to those comments.

In general, while we do not object to the project, we continue to note several areas of concern that have not been fully addressed in the FEIS. We suggest that they be addressed in the Record of Decision. The attachment to this letter provides our comments on the FEIS. Please contact Timothy Timmermann (617-918-1025) of EPA's Office of Environmental Review with any questions.

Sincerely,



Robert W. Varney
Regional Administrator

attachment

617-918-1010

Internet Address (URL) • <http://www.epa.gov/region1>

Recycled/Recyclable • Printed with Vegetable Oil Based Inks on Recycled Paper (Minimum 30% Postconsumer)

Additional Detailed Comments on the FEIS for the National Emerging Infectious Diseases Laboratories (NEIDL), Boston, Massachusetts

Air Quality

The FEIS has responded to our request that measures be implemented to reduce diesel exhaust from construction. The FEIS commitment to the use of electric welders and the use of low sulfur diesel fuel in all diesel powered equipment will help reduce diesel emissions on site. The FEIS also commits to the use of scrubbers in all heavy duty construction equipment (including cranes and excavators) if used on site for more than two months. The NIH should clarify what is meant by “scrubbers” and confirm that they would add advanced pollution controls, such as a diesel oxidation catalyst, to the equipment. Further, EPA believes the two month minimum represents a very high threshold, and recommends that the NIH require the use of advanced pollution controls on equipment that is on site for thirty days or longer--a threshold that is more protective of human health among the at-risk population in the surrounding communities. This is the threshold used by the CT DOT in the Q Bridge re-construction project. In Connecticut, this requirement has effectively led to the retrofit of approximately 200 pieces of equipment, helped to reduce air pollution, and has had no negative impact on the progress of the construction project.

Comments on Responses to Building Design and Fault-tree Analysis Requests

EPA requested a fault-tree analysis; however, the FEIS did not include one. Instead it refers to a graphical analysis that evaluates all possible failure modes and design components for the building in a procedure similar to fault-tree analysis (Appendix 10-2). Although the FEIS refers to this graphical analysis, it was not provided to EPA for review.

The FEIS states that the design of the facility had been reviewed multiple times throughout the design development but it is not clear in reading the FEIS how all the individual safety features are being collectively reviewed. For example, in one part of the FEIS, there is a response to a comment regarding an air crash that all BSL-4 organisms would be consumed in the ensuing fire and not be released; yet, in another section there is a description of the redundancies in the fire suppression system that should combat such a fire. We continue to believe that a comprehensive review of all building safety and environmental features should be provided and that such an analysis would increase the understanding of how the facility will be designed and operated to reduce community and environmental risks.

Comments on the Risk Assessment and Conclusions of Social Resources Impact

Qualitative Risk Assessment

Appendix 4 is cited as the qualitative risk assessment and includes a summary of work in all BSL-4 laboratories. While the reviews in Appendix 4 show that there has not been a release to a

community, there is an update showing a total of 3 reported laboratory-acquired infections with BSL-4 viruses. Therefore, in the absence of a definition of “negligible risk” it is difficult to understand the statement in the FEIS that “the qualitative risk assessment demonstrates that not only is the community risk resulting from the potential release of infectious agents negligible, the risk to a researcher working within a BSL-4 laboratory is negligible as well”, p.4-9.

Worst Case Scenario

Our comments on the DEIS and SDEIS worst case scenario analysis requested that all routes of exposure, not just the inhalation pathway, be evaluated in the quantitative worst-case risk analysis of release of anthrax spores. The FEIS notes in response that cutaneous anthrax is easily treated by antibiotics, that GI anthrax is not a likely outcome of an accidental release and that inhalation exposure to anthrax represents the worst case in terms of public health impact. Both dermal and ingestion routes are likely exposure routes and should be used as complete exposure pathways. Even if dermal or GI anthrax exposure may be treatable and generally not cause death, we believe that a more thorough response should address preventing harm to the public health, not just preventing death.

The risk assessments described in Chapter 4 contain a mix of highly conservative assumptions, such as the use of the maximum possible risk (MPR) model, and of less than protective assumptions, such as the use of a published LD2 dose which is a lethal effect as a health benchmark. We have the following comments on the worst case scenarios:

- We continue to believe that the risk assessment should consider a broader range of health benchmarks when assessing the human health impact of the facility.
- The calculated Maximum Possible Risk (MPR) worst case release of 1,255,396 respirable particles from one gram of technical powder was not used in the risk assessments in Appendix 9 described as Maximum Possible Risk (MPR) scenarios.
- Our previous comments recommended that fractions of spores be rounded up to one since spore fractions were not biologically plausible. This change was not made.
- All exposure pathways were not used, only the inhalation pathway was evaluated after we had recommended that both dermal and GI routes be evaluated. The population exposure estimates were also not provided as requested. Therefore, it is not clear to us at this time that the modeled exposures represent the worst cases and that "the risk of public harm is so minute that it may be described as negligible" (FEIS page 4-8).

Environmental Justice

We appreciate that the FEIS responded to our requests to expand the area of impact studied, conduct broader public participation and implement measures to reduce diesel exhaust from

construction (with the exceptions noted in the air quality comments above that are more protective of human health). The stated commitments to reduce diesel exhaust from construction will help mitigate the harmful effects of diesel exposure among the high number of residents in the surrounding communities who have asthma.

Other Comments

The FEIS does not respond to several of our other requests for additional information. For example in our "Other Comments" section of our comments on the SDEIS, EPA suggested that the analysis of alternative locations should evaluate the benefits of physical isolation of a BSL-4 laboratory; such an analysis was not included. Rather, this comment was answered by a narrow definition of the terms separation and isolation. Similarly, no additional information was provided regarding the filtration of general laboratory air exhaust. In addition, we note that:

- EPA's comments on the DSEIS made recommendations about the use of the SLAB model for the dispersion of Anthrax Spores following an accidental release. The FEIS includes the ISC-prime analysis suggested. Although the result is still acceptable, the number of inhaled spores increases by almost 2 orders of magnitude (from .0024 to .1755). This makes the assumption that 400,000 spores will become airborne more critical.
- There is a discrepancy about the number of spores in a 15cc tube. In Appendix 12, the number is 700 billion, with 1,255,396 being respirable, while in Appendix 9, the equivalent numbers are 10 billion and 400,000 spores.

captured and disposed of after use. This is important to ensure that the NEIDL has a safe and environmentally sound method for capturing potentially toxic releases.

The safety assessment conducted for the proposed laboratory does not mention whether a fault-tree analysis was performed on the design components of the building.¹ A fault-tree analysis would reveal potential health and safety considerations for the facility. Such an analysis is a more comprehensive way to identify potential points of vulnerability in the building design than risk assessment of a single release.

Risk Assessment – Worst Case Scenario Analysis

Chapter four of the DEIS includes a worst case scenario analysis assessing the impact of a loss of containment systems and a release of anthrax within the facility. The risk assessment is incomplete in that it only examines the inhalation risk, and no other exposure risks, such as risk from touching spores. In addition, it uses just one inhalation dose as the health benchmark to assess the impact of this accidental release on human health. The risk assessment in the FEIS should consider a range of health benchmarks, including that recommended by the Journal of the American Medical Association in 2002 (one spore or less), when assessing the human health impact of such an accidental release.

We also recommend that the FEIS provide more information on the eventual fate of the spores. For example, additional analysis of the deposition of the spores is necessary to identify any potential adverse environmental impacts to the air, water, or to human health. Similarly, the DEIS assumes that if 10 billion spores are released, only 400,000 will become airborne. The basis for this assumption and the predicted fate of all the spores should be explained in the FEIS.

Transportation Related Air Pollution Impacts

The DEIS indicates that the NEIDL will create an additional 660 jobs in the area. The DEIS indicates that, currently, 48 percent of employees in the area arrive in single occupancy vehicles and the rest walk, ride transit, or carpool. In order to maintain this relatively high level of commuters and others using means other than a single occupancy vehicle, we suggest that other commuting alternatives, such as walking, biking, carpooling and the use of transit be actively promoted by the NEIDL. The plan proposed in the DEIS to meet the transportation needs of commuters and others who will come to the facility includes all of the important elements of a strong transportation demand management program, but lacks any specific commitments by the NEIDL beyond membership in the local Transportation Management Association (TMA). The FEIS should present the transportation demand management plan to which the NEIDL has committed through the Commonwealth's Massachusetts Environmental Policy Act (MEPA)

¹ A fault-tree analysis is a risk assessment technique that provides a systematic prediction of the combination of possible occurrences in a system which can result in undesirable outcomes. Each step of the analysis presents a probability for the potential for failure. Conducting such an analysis makes it easier to determine which safety features of a facility should be over engineered in construction.