UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

KLARE ALLEN et al.,	)	
Plaintiffs,	)	
v.	)	NO. 1:06–cv-10877-PBS
NATIONAL INSTITUTES OF HEALTH et al.,	)	
Defendants.	)	

MEMORANDUM AND ORDER

September 30, 2013

SARIS, U.S.D.J.

I. INTRODUCTION

This case involves a dispute over whether Defendant National Institutes of Health ("NIH") should be permitted to fund the new National Emerging Infectious Diseases Laboratories ("BioLab") at the Boston University Medical Center ("BUMC") in Boston's South End and Roxbury neighborhoods. If approved, the facility will house Biosafety Level-3 ("BSL-3") and Biosafety Level-4 ("BSL-4") laboratories designed to research extremely dangerous pathogens, such as the Ebola virus, for biodefense purposes. Plaintiffs Klare Allen, Melvin King, Joyce King, Carmen Nazario-Vega – residents of the South End and Roxbury – and the Conservation Law Foundation request that the Court enjoin federal funding of the BioLab on the ground that the NIH has failed to comply with the

National Environmental Policy Act ("NEPA"), 42 U.S.C. § 4321 et seq. The plaintiffs strongly oppose building the BioLab in their high density urban neighborhood, which they contend would be unsafe and disproportionately affect minority and low-income populations. The Trustees of Boston University ("BU"), who received the NIH grant in support of the BioLab, have intervened. All parties have moved for summary judgment. Plaintiffs have also moved to expand the administrative record.

After hearing and a review of the record, the Court finds that the NIH has met its obligation under NEPA to take a hard look at the environmental consequences of its decision to build the BioLab in Boston. While the community has understandable concerns about the wisdom of locating the facility in a highly populated urban area, the Final Supplementary Risk Assessment ("FSRA") reports that the risk of infections to the public resulting from accidents or malevolent acts "is extremely low, or beyond reasonably foreseeable," and the probability of secondary infections is so low that none is likely to occur for any of the pathogens over the proposed 50 year lifetime of the Biolab. See infra p. 29. The report acknowledges that the estimated likelihood of infections or fatalities is "generally slightly greater" at the Boston location than at the two alternative sites (one suburban, one rural). FSRA at 11-24. However, the differences among the three sites "are not substantial." Id.

This conclusion that the BioLab will pose low risk to the public is based, in part, on the security safeguards built into the facility, the low amounts of pathogens that will be present, and the culture of biosafety and training that will be integrated into every day practice at the BioLab.

Significantly, the methodology used in the FSRA for evaluating the risk to the public was scrutinized and approved by two sets of independent experts: the National Research Council, which in the past had been critical of the NIH's methodology, and a Blue Ribbon Panel of experts in infectious disease, epidemiology, and public health.

The NIH emphasizes that the benefits of having the BioLab in Boston include opportunities for efficient medical research collaboration and training with other institutions in Boston and Cambridge to advance critical research on biodefense and infectious diseases.

The Court **ALLOWS** defendants' motions for summary judgment (Doc. Nos. 83 & 90) and **DENIES** plaintiffs' motion for summary judgment and permanent injunctive relief (Doc. No. 87).

II. PROCEDURAL HISTORY

In October 2002, the NIH's National Institutes of Allergy and Infectious Disease ("NIAID") issued a request for proposals to construct a national biocontainment laboratory suitable to perform research on extremely dangerous pathogens. The mission

of the NIAID is to play a leading role in the nation's effort to develop diagnostics, vaccines, and therapeutics to combat emerging and re-emerging infectious diseases, including those that can be used as agents of terrorism.

The BUMC proposed building a laboratory on Albany Street in Boston's Roxbury and South End neighborhoods. On September 30, 2003, the NIAID granted BUMC $128 million to construct the BioLab. On December 2, 2005, the NIH issued an Environmental Impact Statement ("EIS"), and on February 2, 2006, approved the decision to fund the construction of the BioLab in Boston.

On May 18, 2006, the plaintiffs filed a complaint against the NIH, alleging that the EIS violated NEPA. On June 29, 2006, the plaintiffs moved for a preliminary injunction to enjoin federal funding of the BioLab. On August 2, 2006, in parallel litigation in state court, the Massachusetts Superior Court ruled that a separate environmental report prepared by University Associates, an affiliate of BU, was inadequate under the Massachusetts Environmental Policy Act ("MEPA"), Mass. Gen. Laws ch. 30 §§ 61–62H. See Ten Residents of Boston v. Boston Redevelopment Authority, 2006 WL 2440043, at *19 (Mass. Super. 2006). The Court found that the report violated MEPA because it "failed to consider any 'worst case' scenario that involved the risk of contagion arising from the accidental or malevolent release of a contagious pathogen, and . . . failed to analyze

whether that 'worst case' scenario would be materially less catastrophic if the Biolab were located in a feasible alternative location in a less densely populated area." Id. at *18.

As a result of the state court decision, University Associates was required to amend its report. On September 13, 2006, defendants in this case filed notice of their intention to perform additional risk assessments taking into account the public health consequences of the accidental release of dangerous pathogens; an alternatives analysis to determine whether siting the facility in a less-populated area would result in materially different public health consequences in the event of a pathogen release; and additional measures to identify and assess other risks associated with the BioLab. See Doc. No. 27. On October 20, 2006, this Court deferred a decision on plaintiffs' motion for a preliminary injunction until the NIH finished its supplemental report. See Doc. No. 36.

The supplemental report, entitled the "Final Supplementary Risk Assessment" ("FSRA"), was issued on July 6, 2012. On January 2, 2013, the NIH issued its decision approving the FSRA to fund the BioLab in Boston. The parties subsequently filed cross-motions for summary judgment.

III. FACTUAL BACKGROUND

A. The Experts

Soon after the order staying the development of the BioLab, the NIH began the process of amending the initial EIS by commissioning a team of expert independent scientists and engineers from the National Research Council ("NRC") of the National Academy of Sciences. The NRC is a private non-profit society of distinguished scholars established by an Act of Congress in 1863.

In July 2007, the NIH issued a draft report to respond to the concerns regarding the EIS. A committee of 11 experts from the NRC conducted a technical review of the draft report.[1] On November 21, 2007, the NRC Committee issued a letter on the draft

[1] The NRC committee consisted of: John Ahearne (Chair), Executive Director of Sigma Xi, the Scientific Research Society; Thomas W. Armstrong, Senior Scientific Associate in the Exposure Sciences Section of ExxonMobil Biomedical Sciences, Inc.; Gerardo Chowell, Assistant Professor at the School of Human Evolution and Social Change at Arizona State University; Margaret E. Coleman, Senior Microbiologist at Syracuse Research Corporation in the Environmental Science Center; Gigi Kwik Gronvall, Senior Associate at the Center for Biosecurity of University of Pittsburgh Medical Center; Eric Harvill, Associate Professor of Microbiology and Infectious Diseases at the Pennsylvania State University; Barbara Johnson, Ph.D., RBP, owner of consulting company Barbara Johnson & Associates, LLC focusing in the area of biosafety, biocontainment and biosecurity; Paul A. Locke, Associate Professor in the Department of Environmental Health Sciences at the Johns Hopkins Bloomberg School of Public Health; Warner North, President of NorthWorks, Inc.; Jonathan Richmond, CEO of Jonathan Richmond and Associates, a biosafety consulting firm with a global clientele; and Gary Smith, Chief of the Section of Epidemiology and Public Health in the School of Veterinary Medicine at University of Pennsylvania.

report and concluded that the draft "is not sound and credible." The Committee stated that the draft "has not adequately identified and thoroughly developed worst case scenarios [and] does not contain the appropriate level of information to compare the risks associated with alternative locations." AR Doc. 647 at 2.

In response, the NIH appointed a second set of experts, the Blue Ribbon Panel ("BRP"), in February 2008 to provide independent and scientifically based advice to the NIH regarding the scope of further risk assessments and site suitability analyses needed for the BioLab. The BRP was made up of 16 nationally recognized experts in infectious diseases, public health and epidemiology, risk assessment, modeling, risk communications, biodefense, biosafety, and environmental justice.[2] The NIH also requested the NRC Committee to reconvene

[2] The BRP consisted of: Adel A.F. Mahmoud, M.D., Ph.D. (Chair), Professor at the Woodrow Wilson School of Public and International Affairs and the Department of Molecular Biology at Princeton University; Steven P. Bennett, Ph.D., the Weapon of Mass Destruction (WMD) Terrorism Risk Assessment Program Manager in the U.S. Department of Homeland Security's Science and Technology Directorate; Donald S. Burke, M.D., Dean of the Graduate School of Public Health, Director of the Center for Vaccine Research, and Associate Vice Chancellor for Global Health at the University of Pittsburgh; Stephen Eubank, Ph.D., staff member at Los Alamos National Laboratory; Vicki S. Freimuth, Ph.D., Professor of Communication and Director of the Center for Health and Risk Communication at the University of Georgia; George Friedman-Jiménez, M.D., Medical Director of the Occupational and Environmental Medicine Clinic at Bellevue Hospital Center in New York City and Assistant Professor of Environmental Medicine and Medicine at the New York University

and provide independent review of the supplementary risk assessment.

B. The FSRA

The NIH hired the environmental consulting firm Tetra Tech, Inc. to prepare the FSRA. With the BRP and NRC's input, Tetra Tech and the NIH spent the next four years developing the supplementary risk assessment that resulted in the issuance of the FSRA in July 2012. The FSRA is a 2,700-page report that

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School of Medicine; Margaret A. Hamburg, M.D., Senior Scientist, Nuclear Threat Initiative/Global Health and Security Initiative (now Commissioner of the Food and Drug Administration); Karen A. Holbrook, Ph.D., Vice President for Research and Innovation at the University of South Florida; Dennis L. Kasper, M.D., William Ellery Channing Professor of Medicine and Professor of Microbiology and Molecular Genetics at Harvard Medical School; Rima F. Khabbaz, M.D., Director of the National Center for Preparedness, Detection, and Control of Infectious Diseases at the Centers for Disease Control and Prevention and Clinical Associate Professor of Medicine at Emory University; W. Ian Lipkin, M.D., Director of Center for Infection and Immunity, John Snow Professor of Epidemiology, and Professor of Neurology and Pathology in the Mailman School of Public Health and College of Physicians and Surgeons at Columbia University; Thomas H. Murray, Ph.D., President of The Hastings Center; Mary E. Northridge, Ph.D., M.P.H., Professor of Clinical Sociomedical Sciences at the Mailman School of Public Health of Columbia University; Jean Patterson, Ph.D., Chairman of the Department of Virology and Immunology at the Southwest Foundation for Biomedical Research; Mark Gregory Robson, Ph.D., M.P.H., Director of the New Jersey Agricultural Experiment Station and Professor of Entomology at Rutgers University and Professor of Environmental and Occupational Health at the University of Medicine and Dentistry of New Jersey School of Public Health; Samuel L. Stanley, Jr., M.D., Vice Chancellor for Research at Washington University in St. Louis and Director of the Midwest Regional Center of Excellence for Biodefense and Emerging Infectious Diseases Research; Wayne R. Thomann, Dr.P.H., M.S., Director of Occupational and Environmental Safety at Duke University Medical Center.

evaluates the risks of release and exposure to the public of 13 different pathogens expected to be handled at the BioLab's Boston location under multiple release scenarios including terrorist attacks, laboratory accidents, transportation accidents, and natural disasters such as an earthquake. These analyses are also applied to two different alternative sites in Tyngsborough, Massachusetts (the suburban site) and Peterborough, New Hampshire (the rural site). In addition, the report includes a sealed threat assessment for malevolent acts and addresses the impact of the BioLab's Boston location on low-income, minority, and medically vulnerable populations. The following is a chapter-by-chapter summary of the FSRA's analysis of the BioLab.

1. Chapter 1: Introduction

The FSRA begins by stating that the purpose of the BioLab is "to provide safe and secure laboratories dedicated to the study of disease-causing microorganisms (pathogens) to research the pathogenesis of emerging infectious diseases . . .; develop vaccines, therapeutics, and diagnostics for the pathogens; develop animal models for the comparative study of the pathogens; perform preclinical and clinical research in humans; train scientists and related support personnel in the requirements of the area of research; and support a national response if a biodefense emergency occurs." FSRA at 1-1.

The FSRA responds to the human health issues raised by the public and the Courts: "[T]he analyses [will] determine what, if any, adverse human health effects would occur from an accidental or malevolent release of a pathogen or infected insects/animals from biocontainment. It also [will] determine[] whether there are differences in the effects if the facility were in an area with a lower population density than the Boston site." Id.

The scope of the FSRA includes "qualitative and quantitative analyses of an array of pathogens and events leading to exposure of individuals to pathogens and probabilistic estimates of initial infections, subsequent secondary transmissions, and fatalities." Id. at 1-15. The FSRA "follows guidelines established by federal agencies for conducting and reporting risk assessments and has been performed by using available scientific data and established methods of analyses." Id. The report also "acknowledges the uncertainty associated with the data and the appropriate role of judgment (expert opinion) in estimating key parameters required for risk assessment." Id.

Thirteen pathogens were analyzed. A subset of pathogens that could be studied at the BioLab, these 13 pathogens were selected to cover a range of pathogen characteristics, "such as their ability to be spread from person to person . . ., the method by which they are spread from one person to the

next . . ., their ability to cause human disease . . . and their ability to cause deaths among those infected . . . ." Id.

Each pathogen is designated a BSL level, ranging from 1 to 4. The BSLs are designated by the degree of protection provided to personnel, the environment, and the community. BSL-1 pathogens are the safest to handle and require the most basic level of protections. Id. at 1-10 to 1-11. BSL-4 pathogens are highly fatal and require the most stringent protections. Id. Seven of the pathogens studied were BSL-3 and six were BSL-4.

Three questions guided the risk analysis in the FSRA:

> (1) What could go wrong? That is, what might be the sequence of events that could cause an infectious pathogen to escape the laboratory, set up a chain of transmission, and cause infectious disease in the surrounding community?
>
> (2) What are the probabilities of such a sequence of events?
>
> (3) What would be the consequences of such a sequence of events?

Id. at 1-19.

2. Chapter 2: Facility Design, Operations, and Site Description

Chapter 2 describes the facility's design specifications under federal and state law as well as the operational and security procedures and systems in place designed to mitigate potential risks associated with the release of pathogens due to an accident or malevolent act.

In addition to meeting the general requirements for earthquakes and severe weather events, the BSL-4 laboratory is located in the interior of the building, and is structurally isolated from the rest of the building, providing additional protection in the event of an incident which might otherwise compromise the physical integrity of the building. Id. at 2-4, 2-10. The BSL-4 space is separated from the rest of the BioLab using airlock doors that are interlinked to ensure that multiple doors cannot be opened simultaneously. Id. at 2-10. It is under constant negative air pressure (air flows from outside the laboratory space into it), and any air leaving the BSL-4 space must pass through two high-efficiency particulate air (HEPA) filters, which ensures clean air by removing at least 99.97 percent of particles having a diameter of 0.3 micrometer. Id. at 2-8.

Other safety measures of the facility include: (1) implementation of a "culture of safety," a BU safety program including training for laboratory staff, conditioning laboratory privileges on compliance with safety requirements, appointing a Laboratory Safety Coordinator for the BioLab, and creating a Safety Committee with ongoing responsibility to review all safety procedures; (2) Select Agent clearance: because the pathogens are "select agents" according to the CDC, researchers studying those agents must be adequately screened, trained, and registered with

the CDC; (3) the "two-person" rule: for any research involving BSL-3 or BSL-4 pathogens, no research may be conducted unless two researchers are present; and (4) physical security, consisting of barriers, electronic surveillance systems, and intrusion detection systems that form a comprehensive site-wide network of monitored alarms. The network includes security officers, biometric and card access devices, closed circuit television cameras, automatic door locking systems, and access alarms. The BioLab is also surrounded by an 8-foot-high security fence. Id. at 2-3.

Chapter 2 also compares the public safety and emergency response capabilities of the Boston site with the proposed Tyngsborough and Peterborough sites. The Boston location has considerably more law enforcement resources to handle an emergency than the other two sites. Boston is the only proposed site that has a dedicated Emergency Operation Center that serves as a centralized location from which large-scale emergency incidents are managed and an Office of Public Health Preparedness, responsible for developing plans to deliver mass prophylactic care in response to disease outbreaks. The chapter concludes, "Heavily populated metropolitan areas, such as Boston, have developed the public safety infrastructure and capabilities necessary to provide services across the spectrum of prevention, preparedness, response, and recovery." Id. at 2-26.

3. Chapter 3: Pathogen Characteristics

Chapter 3 describes the characteristics of the 13 pathogens chosen to be studied, why these pathogens were chosen for analysis, details about their biology, the kinds of infections that each causes and limits of the availability of information for each of the pathogens. The pathogens are summarized below.

The seven BSL-3 pathogens are (1) Bacillus anthracis, a bacterium that causes anthrax; (2) Francisella tularensis, the causative pathogen of tularemia or "rabbit fever"; (3) Yersinia pestis, a bacterium that causes the plague; (4) 1918 H1N1 Influenza Virus, the prototypical pandemic strain of influenza; (5) SARS-associated Coronavirus, which causes severe acute respiratory syndrome (SARS); (6) Rift Valley fever virus (RVFV), an RNA virus in the larger family of viral hemorrhagic fevers; and (7) Andes Virus, the major etiological pathogen of Hantavirus Pulmonary Syndrome (HPS) that occurs in South America. Of these pathogens, Bacillus anthracis, Yersinia pestis, 1918 H1N1 Influenza Virus, and SARS-associated Coronavirus can be spread through airborne transmission and not solely through direct person-to-person or person-to-animal contact. According to the NRC, "some agents handled in BSL-3 facilities may present more serious potential risks than BSL-4 agents." AR Doc. 647 at 8. "Agents are categorized for BSL-4 containment because they cause

deadly disease for which there is no treatment, not because they are highly infectious and cause widespread disease." Id. at 8-9.

The six BSL-4 pathogens are the (1) Ebola virus, causing highly fatal hemorrhagic fever that interferes with the blood's ability to clot, causes internal bleeding, and damages the body's vascular system; (2) Marburg virus, closely related to the Ebola virus, also causing highly fatal hemorrhagic fever; (3) Lassa virus, causing a viral hemorrhagic fever; (4) Junín virus, causing the Argentine hemorrhagic fever; (5) Tick-borne Encephalitis virus, causing encephalitis transmitted through the bite of an infected tick; and (6) Nipah virus, causing viral encephalitis.

These BSL-4 pathogens are among the most fatal known to mankind. All of them except the Junín virus are transmitted to humans through direct contact with infected animals or other humans. The Junín virus is transmitted to humans by inhaling the virus through the respiratory tract from rodent urine, feces, saliva, and contaminated fomites, which are inanimate substances carrying infectious organisms such as germs or parasites. FSRA at 3-63. The Ebola virus is transmissible as a blood-borne pathogen. AR Doc. 647 at 9. Scientists have hypothesized that the Ebola and Lassa viruses could be spread through airborne transmission; however, current evidence demonstrates that transmission of these viruses is associated with direct contact

with infected individuals, rather than spread between humans through airborne transmission. FSRA at 3-50, 3-60; see also AR Doc. 647 at 9 (stating that the Ebola virus "is extremely unlikely to be spread through the routes of transmission").

4. Chapter 4: Event Sequence Analysis

Chapter 4 describes the process of identifying, selecting, and analyzing maximum reasonably foreseeable[3] events that might occur at the BioLab to answer the question: what could go wrong that could cause a pathogen to escape from the laboratory and infect people in the surrounding community? The report considers more than 300 potential incidents. Because many of these incidents are similar to others, common incidents were consolidated and narrowed down into 34 categories of incident types. The 34 categories include aircraft crash, animal bite, centrifuge release, fire, flooding inside the laboratory, inadequate pathogen accountability, loss of power, malevolent act, earthquake, tornado, needlestick, spill, and transportation mishap. FSRA at 4-9. Likely frequencies were assigned to each category along with a description of the potential exposure of laboratory workers, other facility workers, and members of the

[3] A "maximum reasonably foreseeable accident is an accident with the most severe consequences that can reasonably be expected to occur for a given proposal . . ." FSRA at 4-2. Reasonably foreseeable events are defined as events "including low probability/high consequence accidents and higher probability/(usually) lower consequence accidents." Id. at 4-3.

public. Id. at 4-8 to 4-11. The 34 event types are further grouped into five scenarios that purport to represent all potential event types because the risks associated with these five scenarios provide the upper bounds for the risks posed by similar events.

The five scenarios are: (1) a centrifuge release, in which a centrifuge tube breaks and a pathogen is released into the air; (2) a needlestick, in which a lab worker breaks his skin with a needle so that the pathogen enters his body; (3) an earthquake, including the maximum reasonably foreseeable event that would cause total collapse of the BioLab building and release all of pathogens; (4) an aircraft crash into the BioLab; and (5) malevolent acts, such as a terrorist attack.

The analysis indicated that an earthquake, aircraft crash, and malevolent act could cause the greatest harm, with high exposure of pathogens to laboratory and facility workers and "moderate" exposure to the public. At the same time, the report calculates that the probability of an earthquake or aircraft crash strong enough to cause a dangerous pathogen release is only once in 10,000 to 1 million years.[4] Id. at 4-31, 4-48.

[4] Plaintiffs do not challenge the general mathematical methodology used to calculate these probability ratios, which is derived from the U.S. Department of Emergency Recommendation for Analyzing Accidents under the National Environmental Policy Act (DOE 2002). Therefore, the Court does not address how they were calculated.

Aerosolized pathogen particles could be dispersed beyond 300 meters, but concentrations would be extremely low beyond three kilometers.

The centrifuge release would cause moderate exposure to laboratory workers but no exposure to other facility workers or the public. Similarly, the needlestick would cause low exposure to laboratory workers but no exposure to other facility workers or the public. The probability of a centrifuge release or needlestick is once in 1 to 100 years. The likelihood of an undetected and unreported needlestick decreases to once in 100 to 10,000 years. The analysis also determined that the probabilities of these incidents would be the same at all three sites, except for an airplane crash, which is more likely to occur at the Boston site because of its proximity to Logan Airport.

According to United States Department of Energy guidance, the likelihood of a malevolent act (like terrorism) is "unknowable" and therefore the frequency of the event cannot be measured. While it is too speculative to calculate the risk of a malevolent act, Chapter 6 and the sealed threat assessment analyze various factors that could make a terrorist attack more likely or less likely at the three sites. See infra pp. 20-24.

Appendix D summarizes the reports of Dr. Karl Johnson who found, for the five BSL-4 facilities he reviewed from 1970 to

2009, "no infections occurred during 700,000 worker hours of facility operation." Id. at D-5. In addition, he surveyed three BSL-3 laboratories of the National Institute of Allergy and Infectious Diseases from 1982 to 2003 and found that only one clinical infection and four asymptomatic infections had occurred for 3.2 million worker hours of operation during those years. Id. The Johnson reports are viewed as having "the best data available for use in estimating frequency of infections in BSL-3 and BSL-4 facilities." Id. at D-6. The BSL-4 facilities surveyed represent the extent of the BSL-4 operation in the United States. However, the Johnson reports do not reflect all the BSL-3 facilities, which number in the hundreds. The FSRA summarizes:

> Airborne dispersion calculations for the [Maximum Reasonably Foreseeable] earthquake show that individual members of the public beyond the NEIDL exclusion fence (i.e., at least 30 m from the facility) would receive an average exposure that is smaller than any dose proven to cause infection in humans or animals via inhalation, with the possible exception of [Rift Valley Fever Virus]. While this is an extremely severe event that includes the loss of all biocontainment features and results in the maximum credible release amount, the public exposure estimates are still small due to the small quantities of pathogen in the laboratory, the limited potential for release of this inventory, and the dilution of any release in the atmosphere.

Id. at 4-51.

5. Chapter 5: Transportation Analysis

Chapter 5 addresses potential risks associated with transporting pathogens to and from the BioLab. A traffic

accident involving these shipments, in which packages containing pathogens might be damaged, may pose a risk to the surrounding community due to the risk of exposing members of the public to infectious materials. Because BSL-3 and BSL-4 pathogens are classified as Category A Infectious Substances under U.S. Department of Transportation regulations, they must be triple-packed, which includes a leakproof primary receptacle, a leakproof secondary packaging, and a rigid outer packaging of adequate strength for its capacity, mass, and intended use. Id. at 5-2. Because of the strength of the packaging used to transport these pathogens and the nature and amount of pathogens being transported, the report concludes that the likelihood of a public infection resulting from a transportation-related release is less than once in 1 million years. Id. at 5-28. Crash-related injuries and fatalities would be far more likely to occur. The report states that three sites would have the same probability because "the protocols followed for pathogen shipments would be similar for all sites." Id.

6. Chapter 6: Threat Assessment Methodology Overview

Chapter 6 summarizes the procedures used and the conclusions reached in performing the threat assessment for the BioLab. It addresses the likelihood of malevolent acts, threats to the public that stem from deliberate efforts to expose personnel at the BioLab or members of the public to the pathogens studied

there. Because of the sensitive nature of the threat assessment, it is considered a "Controlled Document" under the provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. Therefore, only an overview of the findings is described in the report.[5]

The threat assessment analyzes the threats to and vulnerabilities of the security systems in place at the BioLab, and examines the security and police personnel and procedures, electronic systems, BioLab policy and procedures, and facility design and construction. It attempts to identify and evaluate threats at each of the three sites, determine the likelihood of those threats occurring, assess the potential consequences associated with the impact if those threats occurred, and provide effective mitigation measures to ensure secure operations against the identified threats. Id. at 6-1 to 6-2.

In order to determine the types of threats at each site, the assessment analyzed crime statistics, determined the local threat environment by conducting interviews with federal, state, and local law enforcement agencies, collected and evaluated threat intelligence, and determined the target attractiveness (i.e., how suitable the target would be to a malevolent actor's primary goal). Id. at 6-4 to 6-5. The threat assessment identifies 11

[5] A copy of the threat assessment was provided under seal to the Court.

scenarios of potential threats, ranging from a disgruntled employee surreptitiously removing and releasing a pathogen to an extremist group blowing up the BioLab with an improvised explosive device ("IED"). Id. at 6-11 to 6-12.

According to Department of Energy guidance, it is too speculative to analyze the consequences of malevolent acts "because the potential number of scenarios is limitless." Id. at O-163. For example, the report describes the hypothetical scenario of a terrorist removing a pathogen from the facility and using a nebulizer and fans in a highly populated area to deliver high exposure levels to a large number of people. Because the release could be attempted at any location of the terrorist's choosing, the report states that "the potential consequences of such a release . . . would be speculative and is beyond the scope of this [report] to attempt to characterize the consequences of this type of scenario." Id. at 6-17 to 6-18.

Therefore, the threat assessment recommends that the consequences for malevolent acts "could be discussed by comparison to the consequences of a severe accident." Id. at O-163. The consequences resulting from the malevolent act scenarios (including the use of an IED to damage the containment boundary and the HVAC systems, including the HEPA filters), were analyzed in comparison to maximum reasonably foreseeable earthquake consequences. The threat assessment concludes that

all malevolent acts scenarios would necessarily be less consequential than an earthquake that would result in the complete collapse of the facility and a total loss of pathogens "because the inventory is less, the release fraction is less, and the release may be discharged [above ground level]," diluting the pathogen release and reducing the harm to the public. Id. at O-238; AR. Doc. 770 at 6-17.

The NIH filed under seal and ex parte the threat assessment, dated October 26, 2010. Because of its confidentiality, plaintiffs did not have an opportunity to review or challenge it. Among other things, the Tetra Tech threat assessment team used various methodologies in its analysis of the comparable risks at the three sites, which are used by the Department of Defense for offensive target analysis based on military objectives. One methodology is designed "to determine the most likely terrorist targets." Threat Assessment at 48. In a comparison of terrorist scenarios for the three sites, the Boston location scored the highest because of two criteria: population and proximity. Other methodologies were also used to evaluate target "attractiveness", for example by looking at other potential targets within three to five miles of the site and by looking at the accessibility, vulnerability and recognizability of a site from a criminal's point of view. Id. at 78-82. After examining the baseline physical and operational security, the threat assessment

concluded that the "systems being employed at the exterior of the [BioLab] provide a well defined perimeter and make this area a difficult environment for a malevolent act to be successfully carried out by an outsider." Id. at 102. Interior security systems were also described.

The Tetra Tech team developed the 11 "worst case" scenarios involving internal and external breaches of security by terrorists, extremists, criminals, malicious employees, and persons with psychopathic tendencies. Overall, the report ranked the threat from insiders (those working at the facility) as higher than the threats from other malevolent actors. Id. at 156.

The report explained that the first and primary response force for the vast majority of the scenarios were the protective service officers, and the onsite security features remain the same for each comparative location. Id. at 157. Significantly, the threat assessment identified and recommended additional, upgraded measures to mitigate the effects of deliberate actions by terrorists and other malevolent actors to destroy, incapacitate, or exploit the facility's mission, pathogens, and technology, which for obvious reasons I do not describe. With the recommended mitigation features, the threat assessment concluded that "no matter where the [BioLab] is located amongst the comparable sites, the risk from a malevolent act is

essentially the same, regardless of the differences associated with the current and projected threat spectrums at the three sites." Id. at 158.

On September 4, 2013, the Court issued an order requesting a supplemental filing regarding the status of the recommended mitigation features. In response, defendants filed the affidavits of Thomas G. Robbins, the Executive Director of Public Safety of Boston University, Kevin Tuohey, the Executive Director for Research Compliance of Boston University, and Alfred P. Johnson, Director of Research Services, NIH, who also serves as NIH's Chief Security Officer and the Designated Agency Safety and Health Official.[6] In these affidavits, defendants provide evidence that the mitigation recommendations in the threat assessment have been or will be addressed prior to the initiation of the NEIDL's operations. The defendants also provide evidence that the threat assessment is consistent with information gleaned by law enforcement after the Boston Marathon bombings.

7. Chapter 7: Potential for Released Pathogens to Become Established in the Environment

Chapter 7 considers whether, if any of the 13 pathogens were released from the BioLab, either by accident or malevolent act, a pathogen could become established in the environment in the New England area (in animals, insects, soil, or water). The analysis

[6] Three of the affidavits were under seal.

showed that four BSL-3 pathogens – Francisella tularensis, Yersinia pestis, 1918 H1N1 Influenza Virus, and Rift Valley fever virus – could become established in the environment if released from any of the three locations. Id. at 7-13 to 7-17. However, because the "intensively urbanized nature of the [Boston site] supports smaller populations of [disease-carrying animals]," it would be more difficult for these pathogens to become established in the local environment in Boston as compared to the rural and suburban sites. Id. at 7-22. One BSL-4 pathogen, Tick-borne Encephalitis Virus, could also become established, but this is unlikely to occur. The virus would have to adapt to a new host, since the tick which carries it is not endemic to New England. Id. at 7-17 to 7-22.

8. Chapter 8: Health Effects - Initial Exposure

Chapters 8 and 9 address what could happen if any of the 13 pathogens were released either inside the BioLab or outside in the community. In order to determine the probability of infection and death to laboratory workers, facility workers, and the public under a variety of scenarios, the report utilizes a methodology based on a review of the available literature and mathematical modeling exercises with both qualitative and quantitative components. Because information in the literature and sufficient quantitative data are not available for all

pathogens, NIH convened an additional expert panel,[7] using the modified Delphi methodology,[8] to fill in the missing gaps. Id. at H-2.

Chapter 8 looks at the likelihood of an infection or fatality occurring as the result of direct exposure to the pathogens from an accident inside the BioLab. The report analyzes the extent to which the scenarios causing the exposure of pathogens described in Chapter 4 – centrifuge release, needlestick, and maximum reasonably foreseeable earthquake – would result in infections or fatalities. The first step is to analyze the probabilities of how likely it is for an infection to

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[7] The experts were: Arturo Casadevall, M.D., Ph.D., Professor of Microbiology and Immunology and Medicine Chair at Albert Einstein College of Medicine; Charles N. Haas, Ph.D., L.D. Betz Chair Professor of Environmental Engineering at Drexel University; Joseph Kanabrocki, Ph.D., C.B.S.P., Assistant Dean for Biosafety at University of Chicago; James W. LeDuc, Ph.D., Professor, Microbiology and Immunology at Galveston National Laboratory, University of Texas Medical Branch; Alison D. O'Brien, Ph.D. Professor and Chair Department of Microbiology and Immunology Uniformed Services at University of the Health Sciences; and Jean Patterson, Ph.D., Scientist and Chair of the Department of Virology and Immunology at Southwest Foundation for Biomedical Research.

[8] The Delphi methodology is the most widely accepted forecasting method using a panel of experts and is common in biomedicine. Several rounds of questionnaires are sent out to the experts, and their anonymous responses are aggregated and shared with the group after each round. The experts are allowed to adjust their answers in subsequent rounds. Because multiple rounds of questions are asked and because each member of the panel is told what the group thinks as a whole, the Delphi method seeks to reach the "correct" response through consensus. Id. at H-6 to H-7.

occur after exposure to different amounts of each pathogen through the respiratory route, called the dose response assessment. As a result of the dose response assessments and modeling, the report concludes the following: A laboratory worker would become infected about once per 100 to 10,000 years as a result of an undetected and unreported needlestick, and would die about once per 200 to 1 million years. Id. at 8-10 to 8-14. A laboratory worker would become infected about once every 100 to 10,000 years as a result of a BSL-3 pathogen centrifuge release, and would die once every 5,000 to more than 2 million years, with the Rift Valley fever virus having the highest probability.[9] Id. at 8-20.

Regarding the maximum reasonably foreseeable earthquake scenario, resulting in the complete destruction of the building and release of all pathogens, the highest probability of infection to the public is associated with the Rift Valley fever virus at once per 100,000 years, then the Ebola virus at once per 6 million years, and all other pathogens at once per 10 million years. Id. at 8-25 to 8-32. With regard to medically vulnerable subpopulations – children under five years old, adults over 65 years old, people with diabetes, people with HIV/AIDS, and

[9] Because the event analysis in Chapter 4 found no plausible scenario in which a centrifuge release could result in an exposure to a BSL-4 pathogen, there is no likelihood of anyone being infected or dying in that situation.

pregnant women – there is no significant increase of risk to these populations at any of the three sites. Id. at 8-42 to 8-43.

9. Chapter 9: Secondary Transmission

Chapter 9 considers the likelihood of an infected laboratory worker or member of the public being able to transmit the pathogen to other members of the public and potentially causing a dangerous outbreak. All 13 pathogens were analyzed qualitatively and four of the pathogens that can be transmitted directly from person-to-person contact – Yersinia pestis, 1918 H1N1 influenza virus, SARS-associated coronavirus, and Ebola virus – were analyzed quantitatively as well. Id. at 9-2. The report concludes that the probability of secondary infections is so low that none is likely to occur for any of the pathogens over the proposed 50-year life of the BioLab. Of the BSL-3 pathogens, Yersinia pestis, 1918 H1N1 influenza virus, and SARS-associated coronavirus pose the highest risk for secondary transmission. Id. at 11-9. The Ebola virus represents the highest transmission risk among BSL-4 pathogens. Id. at 11-11. The pathogen with the highest likelihood of the public being infected through secondary transmission is the 1918 H1N1 influenza virus at once in 550 to 16,000 years. Id. at 9-6.

For the total number of infections and fatalities, the report states that there is no statistically significant

difference among the three sites. "The reason that the overall results from the suburban and rural sites are so similar to the urban site results is that there is a high estimated rate of commuting to and from the towns at those sites, so that a significant portion of transmissions occur among nonresidents and are not subject to local population constraints or to the estimates for decreased contact rates that were based on residents only." Id. at 9-15. When comparing local residents at each site, "[t]here tends to be a lower estimated chance of each consequence . . . at the suburban and rural sites compared to the urban site because of commuting and contact rate differences, although uncertainty ranges overlap in most cases. The differences suggest that a more substantial portion of the risk from an undetected/unreported laboratory worker infection at the suburban and rural sites would be borne by nonresidents, particularly areas with a strong connection with the local area via commuting." Id. For each medically vulnerable subpopulation, the estimated likelihood of infections and fatalities was not substantially different among sites. Id. at 9-15 to 9-16.

10. Chapter 10: Environmental Justice

Chapter 10 addresses NIH's compliance with Executive Order 12,898, *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations*, which "directs

federal agencies to develop environmental justice strategies to address disproportionately high and adverse human health or environmental effects of their programs on minority and low-income populations, and to focus federal attention on the environmental and human health conditions of minority and low-income populations with the goal of achieving environmental protection for all communities." Id. at 10-1. The order is also intended "to promote nondiscrimination in federal programs that affect human health and the environment and provide minority and low-income communities' access to public information and public participation in matters relating to human health and the environment." Id. at 10-1 to 10-2.

The report analyzes how the BioLab would affect low-income and minority populations at the three locations. It first compares the percentage of low-income and minority populations within a 10-kilometer (6-mile) radius[10] from the center of each site to ensure that all potential areas that could be affected by a release of pathogens are considered. At the Boston location, 51 percent of census tracts have a minority population greater than the national average, while 53 percent have a poverty level greater than the national average. Id. at 10-13. For the Tyngsborough suburban location, these numbers are 22 percent for

[10] The report also summarizes data within each 2-kilometer radius boundary within the 10-kilometer area. Id. at 10-13 to 10-14.

the minority population and 24 percent for the poverty level. Id. at 10-15. For the Peterborough rural location, they are 0 percent for both the minority population and the poverty level. Id. at 10-17.

The report acknowledges that low-income and minority populations would likely be more affected by a pathogen release at the Boston site compared to the other two locations because of its higher percentages of both minorities and low-income persons. It also states that "[t]here are reports of higher rates of infectious diseases such as HIV/AIDS, syphilis, hepatitis, and tuberculosis among racial and ethnic minorities. . . . Thus, health disparities along with chronic diseases have the potential to contribute to increased susceptibility to any of the pathogens being studied in this [report]." Id. at 10-23.

However, the report concludes that the risk of direct pathogen exposure to the low-income and minority populations within a 2-kilometer radius of the Boston location is extremely low. In the event of a maximum reasonably foreseeable release earthquake, the "public would receive an average exposure that is unlikely to cause infection," with the possible exception of the Rift Valley fever virus where the frequency is still very low. Id. at 10-20. With regard to secondary transmissions, "the potential for exposure extends well beyond the 10-km (6-mi) radius used for the demographic study, and those at greatest risk

will be the [infected person's] social contacts." Id. at 10-20. The extent to which individuals living closer to the Boston site "would bear the risk estimated under secondary transmission scenarios is not obvious, due to the unpredictability of where transmissions would occur among people traveling in and out of the local area." Id. at 10-21. Therefore, "the analysis did not determine that people in close proximity to the [Boston location] were at greater risk than people in the larger vicinity located farther away." Id. at 10-22.

11. Chapter 11: Risk Characterization

Chapter 11 provides the overall conclusions of the report. In summary, the FSRA concludes that the risk of infections or deaths resulting from accidents or malevolent acts at the BioLab are generally very low to only remotely possible. This is largely due to the safeguards and training at the facility and the low amounts of pathogens used.

The report states that based on experience at other BSL-3 and BSL-4 laboratories, "laboratory workers may be exposed to pathogens and [laboratory associated infections] are a real possibility" because of the likelihood of a needlestick or centrifuge release. Id. at 11-14. "The greatest potential risk identified in the analysis is to the people conducting research in the laboratories." Id. at 16. "Infections caused by 12 of the 13 pathogens are unlikely to occur in the lifetime of the

facility (estimated to be 50 years); only Rift Valley Fever Virus infection has a reasonable chance of causing infection in a lab worker." Id.

Comparing risks to the general public at the three locations, the report acknowledges that there are slightly smaller risks at the suburban and rural sites compared to the Boston site. The estimated likelihood of infections and fatalities resulting from secondary transmission among the public is "slightly greater" at the urban site because residents' contacts on average are fewer in the suburban (15 percent lower) and rural (50 percent lower) sites, and the populations are lower. Id. at 11-24. However, the difference was not substantial. Id. The report also acknowledges that the urban site has a relatively greater risk of a fatality from direct exposure to the Rift Valley fever virus following an earthquake because of Boston's higher population density.[11] Id. at 11-25.

However, regarding the overall risk to the public, the Reader's Guide to the FSRA concludes: "The risk to the general public is extremely low, or beyond reasonably foreseeable." Id. at 17. Regarding secondary transmissions, which pose a greater risk to the public, the Reader's Guide concludes that even

[11] For this event, Rift Valley fever virus was chosen as the representative pathogen because it has a greater direct exposure risk to the public than the other 12 pathogens. Reader's Guide at 11-24.

infections from a release of 1918 H1N1 influenza and SARS, which are the most likely to occur, "might occur over 500-5,000 years of operation, far beyond the facility lifetime of 50 years." Reader's Guide at 17.

C. Public Input

In addition to receiving comments from the NRC Committee and BRP experts, the NIH also solicited input from the public when drafting the FSRA. From 2008 to 2010, the BRP held seven meetings (four located in Boston) aimed at informing the public as well as receiving questions and comments from the public. In these meetings, Boston community members asked questions about and provided comments on the proposed work plan recommended by the BRP, environmental justice issues and how to effectively engage communities, planning and oversight of biocontainment laboratories, the report's design and methodology, the proposed approach to quantitative modeling, and initial and secondary infection rates. Id. at 10-11. On April 19, 2012, the NIH also held a 3-hour public hearing in Boston to receive comments on the final draft of the FSRA.

D. Conclusions of the Experts

The BRP and NRC Committee spent considerable time reviewing and critiquing the report to ensure it adequately addressed the risks of permitting research of BSL-3 and BSL-4 pathogens at the Boston site. Over the four years it took to draft the FSRA, the

BRP met nine times, held 25 teleconferences, met with the NRC Committee six times, and conveyed its findings to the NIH in four meetings with the NIH Advisory Committee to the Director of NIH. In reviewing the final report, the BRP concluded that:

> This study is unprecedented in its scope, breadth and complexity, and utilized widely accepted validated methods. The scenarios described in the risk assessment used real live data and experience to the maximum extent possible. With that in mind the Blue Ribbon Panel believes that this is the most scientifically sound rigorously conducted study that is possible at this point.

AR. Doc. 371 at 11-12.

Since its initial letter in 2007 finding the first draft of the FSRA to be "not sound and credible," the NRC Committee issued updated letter reports in 2008, April 2010, September 2010, and December 2011. The NRC Committee remained critical of the FSRA's methodology throughout the drafting process. For example, the September 2010 letter concluded that the NRC Committee "could not endorse as scientifically and technically sound the illustrative analyses presented." AR. Doc. 650 at 7. At that time, the committee found that the "the analyses presented did not represent a thorough assessment of the public health concerns." Id. However, in its final December 2011 letter, the NRC Committee concluded that the NIH responded to many of its concerns and stated:

> The [FSRA] is now closer to reaching its goal of being "scientifically and technically sound" and, in general, addresses the concerns raised in the original NRC

> review of the "DSRASSA" document in 2007. While there are many approaches to preparing a risk assessment and in some aspects the Committee would have used approaches other than those found in this draft, this is no reason to fault the document. It is clear that NIH and the Blue Ribbon Panel have gone to unprecedented lengths to improve the risk assessment for the [BioLab] and have made substantial advances. . . . It is the Committee's view that no further advice from this group would be useful nor should it be required.

Id. at 14.

IV. DISCUSSION

A. Standard of Review

Plaintiffs allege that the NIH violated NEPA and the Administrative Procedures Act ("APA") by issuing its decision allowing funding of the BioLab in the current Boston location.

NEPA provides:

> [A]ll agencies of the Federal Government shall . . . (C) include in every recommendation or report on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment, a detailed statement by the responsible official on—(i) the environmental impact of the proposed action, (ii) any adverse environmental affects which cannot be avoided should the proposal be implemented, [and] (iii) alternatives to the proposed action. . . .

42 U.S.C. § 4332. NEPA does not dictate whether a government agency may fund a project like the BioLab. Instead, "it simply prescribes the necessary process for preventing uninformed – rather than unwise – agency action." Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 333 (1989). NEPA's

procedural requirements are meant to "ensure both that an agency has information to make its decision and that the public receives information so it might also play a role in the issue." Dep't of Transportation v. Public Citizen, 541 U.S. 752, 768 (2004); see also 40 C.F.R. § 1500.1(c) ("The NEPA process is intended to help public officials make decisions that are based on an understanding of environmental consequences, and take actions that protect, restore, and enhance the environment."). "NEPA does not prevent agencies from then deciding that the benefits of a proposed action outweigh the potential environmental harms: NEPA guarantees process, not specific outcomes." Town of Winthrop v. FAA, 535 F.3d 1, 4 (1st Cir. 2008).

"Judicial review of a federal agency's compliance with NEPA is governed by [the APA]." Airport Impact Relief, Inc. v. Wykle, 192 F.3d 197, 202 (1st Cir. 1999). "[T]he reviewing court shall hold unlawful and set aside agency action, findings, and conclusions found to be 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" Id. (quoting 5 U.S.C. § 706(2)(A)). "While this is a highly deferential standard of review, it is not a rubber stamp." Id. at 203; see also Citizens Awareness Network v. U.S. NRC, 59 F.3d 284, 290 (1st Cir. 1995)("[D]eference is especially marked in technical or scientific matters within the agency's area of expertise."). "The reviewing court must undertake a thorough,

probing, in-depth review and a searching and careful inquiry into the record. Only by carefully reviewing the record and satisfying itself that the agency has made a rational decision can the court ensure that agency decisions are founded on a reasoned evaluation of the relevant factors." Wykle, 192 F.3d at 202 (internal quotations omitted). "NEPA requires an agency to take a 'hard look' at environmental consequences." Beyond Nuclear v. U.S. NRC, 704 F.3d 12, 19 (1st Cir. 2013).

Summary judgment is an appropriate procedure for resolving a challenge to a federal agency's administrative decision when review is based upon the administrative record. If the Court finds "the agency's determination procedurally adequate, summary judgment in [the agency's] favor [is] appropriate unless [the non-moving party has] raised a genuine issue of material fact as to whether its substantive decision was arbitrary and capricious or an abuse of discretion." Concerned Citizens on I-190 v. Secretary of Transportation, 641 F.2d 1, 7 (1st Cir. 1981). "[T]he real question is not whether the facts [can establish some dispute], but rather, whether the administrative record, now closed, reflects a sufficient dispute concerning the factual predicate on which [the agency] relied . . . to support a finding that the agency acted arbitrarily or capriciously." Commonwealth of Massachusetts v. Sec'y of Agric., 984 F.2d 514, 525 (1st Cir. 1993).

B. Plaintiffs' Challenges to the FSRA

Plaintiffs allege that the FSRA fails to adhere to NEPA's requirements in a number of respects. The Court addresses each of their arguments below.

1. Statement of Purpose

Plaintiffs contend that the NIH has violated NEPA by relying on an outdated statement of purpose and need for building the BioLab. A statement of purpose and need must "briefly specify the underlying purpose and need to which the agency is responding in proposing the alternatives including the proposed action." 40 C.F.R. § 1502.13. "Courts review purpose and need statements for reasonableness giving the agency considerable discretion to define a project's purpose and need." Alaska Survival v. Surface Transp. Bd., 705 F.3d 1073, 1084 (9th Cir. 2013). "A purpose and need statement will fail if it unreasonably narrows the agency's consideration of alternatives so that the outcome is preordained." Id. "Where an action is taken pursuant to a specific statute, the statutory objectives of the project serve as a guide by which to determine the reasonableness of objectives outlined in an [Environmental Impact Statement]." Id. at 1084-85.

Plaintiffs argue that the NIH's statement of purpose and need relies on an outdated 2002 report indicating that there was an "insufficient amount of [BSL]-3 and BSL-4 laboratory space . .

. [to] protect the United States from further bioterrorist attacks." FSRA at 1-4. Plaintiffs provided the NIH with an *Alternative Vision* document they prepared in 2010 suggesting that modern research techniques limit the need for live pathogen research. See id. at O-100. Others opposing the BioLab have noted the proliferation of bio-safety laboratory space in the United States since 2002. Id. at O-89, O-236.

The NIH's decision to construct the BioLab was part of its response to a Congressional mandate in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. In the aftermath of the September 11th terrorist attacks and "ongoing threats from new and emerging pathogens" – including anthrax letter attacks in 2001 and SARS and bird flu scares in 2002 – Congress mandated "a major expansion of research on such biological agents with an emphasis on the development of vaccines, therapeutics, and diagnostics to address these public health threats." AR. Doc. 804 at 1. Over the past decade, the continuing need to construct BSL-3 and BSL-4 laboratory space has been supported by the NIH's National Institutes of Allergy and Infectious Disease, the Institute of Medicine of the National Academy of Sciences, and the NRC Committee. See FSRA at 1-4, 1-7; AR. Doc. 650 at 6 (NRC Committee "acknowled[ing] and emphasiz[ing] the need for biocontainment laboratories, including BSL-4 laboratories"). Plaintiffs' claim fails because the NIH

has adequately and reasonably demonstrated the continuing need to build the BioLab pursuant to Congressional mandate. Its decision is entitled to deference. See Alaska Survival, 705 F.3d at 1086.

2. Alternatives to the Boston location

Plaintiffs contend that the FSRA does not adequately analyze the proposed alternatives to the Boston location, namely the suburban Tyngsborough and rural Peterborough sites. "The duty under NEPA is to study all alternatives that appear reasonable and appropriate for study at the time of drafting the EIS." Beyond Nuclear, 704 F.3d at 20 (internal quotations omitted). "[T]he consideration of alternatives is 'the heart of the environmental impact statement.'" Dubois v. U.S. Dep't of Agric., 102 F.3d 1273, 1286 (1st Cir. 1996)(quoting 40 C.F.R. § 1502.14). "The EIS [should] 'rigorously explore and objectively evaluate all reasonable alternatives, and for alternatives which were eliminated from detailed study, briefly discuss the reasons for their having been eliminated.'" Id. (quoting 40 C.F.R. § 1502.14(a)). "[T]he decisionmaker [must] be provided with a detailed and careful analysis of the relative environmental merits and demerits of the proposed action and possible alternatives." Id. at 1286-87 (internal quotations omitted). The First Circuit has characterized this requirement as "the linchpin of the entire impact statement." Id. at 1287 (internal quotations omitted). "The discussion of environmental effects of

alternatives need not be exhaustive. What is required is information sufficient to permit a reasoned choice of alternatives as far as environmental aspects are concerned." Id. (internal quotations omitted); see also Seacoast Anti-Pollution League v. Nuclear Regulatory Comm'n, 598 F.2d 1221, 1232 (1st Cir. 1979)("Alternative sites cannot be studied Ad infinitum, and the fact that a sampling of sites has been found not to be superior affords some basis for believing that other sites will fare no better.").

a. Alternatives Analysis Assumptions

In this case, the original EIS "failed to consider alternative locations for the Biolab." Allen v. Boston Redevelopment Auth., 450 Mass. 242, 259 (2007). The FSRA attempts to fix the problem by adding analysis of the suburban Tyngsborough and rural Peterborough sites. The plaintiffs maintain that the alternatives analysis is based on unsupported assumptions that favor a predetermined choice of the Boston location.

i. Structure of the BioLab

Plaintiffs first criticize the FSRA's assumption that the proposed laboratories in Tyngsborough and Peterborough would have the identical structure as the Boston BioLab. Plaintiffs contend that given the greater space available at the other locations (210 acres in Tyngsborough and 700 acres in Peterborough), a BSL-

4 laboratory could be built on those sites with different dimensions that could alter the risks associated with secondary transmissions or malevolent attacks. Defendants respond that the NIH's decision to assume the other sites had the same structure was reasonable because regardless of where the facility was located, it needed to conform to "the same high standards of biosafety containment protection, earthquake resistence, and external force protection." FSRA at O-102. Moreover, to adequately compare the risks at the three sites, "the alternatives [needed to] be developed to a comparable level" as the Boston site. Id. Finally, the FSRA adds that even if alternate designs were proposed for the other two locations, it "would not significantly alter the results" of the risk analysis. Id. at O-230. Specifically, the centrifuge release and needlestick scenarios would not be affected by a different structure because they only concern operations inside the facility. The MRF earthquake scenario would also not be affected because it assumes a total release of all pathogens which would not change due to the size or structure of the building. See id. Plaintiffs have not explained how a change in the structure of the BioLab would make a substantial difference.

ii. Commuting Methods

Plaintiffs also contend that the FSRA does not take into account the higher risk of secondary transmission of pathogens

based on the commuting methods to the Boston site as opposed to the rural and suburban sites. They argue that because many workers will commute to Boston using public transportation, the likelihood of an infected lab worker transmitting a disease to the public would be greater if he traveled to and from the Boston location by bus or subway than if he were commuting by car to the rural and suburban sites. This argument has greater force.

The NRC Committee's 2007 letter finding the draft supplementary risk assessment "not sound and credible" specifically criticized the draft's assumptions that "[t]ravel to and from the facility [would] be by privately operated vehicle for all three locations" and "use of public transportation (trains or buses) is unlikely in the case of the South End of Boston inner city location." AR. Doc. 647 at 14. The 2007 letter stated that lab workers would likely have more contacts with the public at the Boston site because of the use of public transportation, which would affect the secondary transmission analysis. The NRC suggested that the NIH analyze whether there would be "a higher potential for aerosol transmission of disease in such crowded microenvironments where aerosol transmission between humans may be very important as a mechanism for the spread of contagious diseases." Id.

The NIH acknowledges that it did not quantitatively consider how public transportation may affect secondary transmissions of

pathogens. The FSRA states: "Use of public transportation was not specifically addressed because assessment of potential links between public transit ridership and risk of acquiring infection is an open area of research and no clear correlations were found in the literature that could be used to support any further adjustments in assumed site-specific contact rates." FSRA at O-123; see id. at L-18 ("The formulation of quantitative models to address [issues including public transportation] is an open area of research, and at present there are no well established or validated methods for estimating the effects of these characteristics on rates of transmission for specific sites or populations.").

While the NIH concluded that public transportation data could not be incorporated into a quantitative analysis of the rate of secondary transmissions because of the lack of reliable scientific literature, the FSRA does address the risks associated with public transportation qualitatively. The report states that "[i]f there are secondary exposures due to an infected worker leaving the facility . . . those at greatest risk will be the worker's social contacts [which] include those individuals . . . that are encountered during routine commute to work, including those on mass transit." Id. at 10-20; see also id. at L-17 ("[A] person's . . . travel patterns . . . play [an] important role[] in determining the likelihood of transmission.").

The use of public transportation was also considered indirectly in the quantitative analysis of secondary transmissions. For example, to quantify secondary transmission rates for outbreaks of 1918 H1N1 influenza virus and SARS-associated Coronavirus in urban areas, the NIH used infection data from historical outbreaks from the published literature. Much of this data came from large cities around the world with mass transit systems, such as Beijing, Singapore, and Toronto. See id. at L-82, L.3.4.1, L.3.5.1; see also AR Doc. 246 at 179-80 ("The branching process model does consider the probability that one person could spread the pathogen to many others. Those probabilities that we're using for SARS Coronavirus are based on what actually happened in outbreaks that occurred. There were no outbreaks in Boston, but outbreaks did occur in large cities where public transportation exists.")(Comments of NIH modeling consultant Dr. Damon Toth).

The FSRA points out that the increased risk to Boston residents, due to the city's public transportation system and higher population density, depends on the transmissibility of the pathogens. "[P]athogens that are highly transmissible via an aerosol route" would be more dangerous to the public than "pathogens that require more intimate contact for transmission." FSRA at L-17. "For pathogens of the latter type, an increase in

the number of brief, casual contacts would have little to no effect on the rate of transmission." Id.

Of the 13 pathogens studied in the FSRA, all of the highly transmissible airborne ones, such as the 1918 H1N1 influenza virus and SARS-associated Coronavirus, are BSL-3 pathogens, and none are BSL-4. In other words, the most deadly viruses which understandably cause the greatest public concern are unlikely to be transmitted on public transportation through airborne contact, such as coughing or sneezing. Instead, according to the best current scientific knowledge about the BSL-4 pathogens discussed in the FSRA, it is believed that an infected person must have direct bodily contact with an individual to transmit the disease.

Based in part on the quantitative and qualitative analysis of the effect of public transportation on secondary transmission rates, the FSRA concludes that there would "be a lower estimated chance of each consequence among local residents at the suburban and rural sites compared to the urban site because of commuting and contact rate differences, although uncertainty ranges overlap in most cases." Id. at 9-15.

While the risk of secondary transmission on public transportation is troubling in an urban area, plaintiffs' challenge on this point fails because the NIH's decision not to include public transportation contact data when analyzing secondary transmissions was a result of the lack of such data in

the scientific literature, rather than a failure to consider the problem. See, e.g., Town of Winthrop v. FAA, 535 F.3d 1, 13 (1st Cir. 2008)("It is not unreasonable for an agency to decline to study in an [supplemental environmental impact statement] a pollutant for which there are not yet standard methods of measurement or analysis."); Lee v. U.S. Air Force, 354 F.3d 1229, 1244 (10th Cir. 2004)(Agency not required to conduct own studies where scientific information is scarce, despite concerns raised during the comment period). In order for the public and the Court to better understand why public transportation data was not analyzed in the FSRA, the NIH could have included a more detailed explanation about why the existing scientific literature is insufficient to understand the correlation between public transportation and secondary transmission. See 40 C.F.R. § 1502.22(b)(Where information is unavailable, agency required to state its relevance and summarize existing credible scientific evidence that could be used to replace it). However, plaintiffs have not provided any evidence to suggest that defendants ignored available data. Most significantly, the NIH's decision was supported by the expert BRP and NRC Committee, which both stated that analysis that is not supported by the scientific literature should be avoided. See AR Docs. 464 at 2, 648 at 7. After reviewing the final draft of the FSRA, the NRC Committee found "the modeling on secondary transmission to be satisfactory and

the assumptions made in the chapter are transparent." AR Doc. 650 at 12.

As this Court previously pointed out, because eleven BSL-3 laboratories already exist in the Boston area,[12] the BioLab only poses a unique risk to Boston residents due to its inclusion of BSL-4 pathogens. See Doc. No. 36 at 3 n.1, 4; see also Tri-Valley CAREs v. Dep't of Energy, 671 F.3d 1113, 1119 (9th Cir. 2012) ("There are more than 1,350 BSL-3 laboratories in the United States. Common examples of BSL-3 facilities include hospital surgical suites, laboratories associated with medical schools, and university research laboratories."). Therefore, even if Boston's mass transit system would increase the potential infection rate of the public, this risk would likely pertain primarily to the BSL-3 pathogens, which are already being studied elsewhere in Boston, and does not justify enjoining NIH's funding to construct the BioLab's BSL-3 or BSL-4 laboratory.

iii. Malevolent Acts

Plaintiffs also contend that the FSRA does not adequately address the consequences and probabilities of malevolent attacks

[12] According to the Boston Public Health Commission, there are 11 BSL-3 laboratories currently operating throughout the greater Boston area, including laboratories at Boston University, Brigham & Women's Hospital, Children's Hospital, Dana Farber Cancer Institute, and Harvard University. See Boston Public Health Commission, Biological Safety in Boston Research Laboratories, available at http://www.bphc.org/programs/cib/environmentalhealth/biologicalsafety/Forms_Documents/Biolab_fact_sheet.pdf.

at the three sites. A major shortcoming of the original EIS was that it failed to include analysis of malevolent attacks. See Allen v. Boston Redevelopment Auth., 450 Mass. at 256-57 ("The final [EIS] failed to analyze the likely damage to the environment caused by the release of a contagious pathogen . . . through . . . terrorism . . . which is a critical consideration in a densely populated urban area.").

Plaintiffs criticize the FSRA's comparison of the consequences of malevolent acts to the maximum reasonably foreseeable earthquake scenario because malevolent attacks purposefully inflict harm, while earthquakes do not. The threat assessment identifies 11 potential malevolent attack scenarios, ranging from a disgruntled employee releasing a pathogen to the public to an extremist blowing up the BioLab. The plaintiffs are correct that it does not separately analyze consequences of the scenarios and instead compares them to the consequences of an earthquake. The FSRA explains that it took this approach because all malevolent acts would have less impact than an earthquake that would result in the complete collapse of the facility and a total loss of all pathogens. See FSRA at O-238. Department of Energy NEPA guidance states that it is too speculative to analyze the consequences of malevolent acts "because the potential number of scenarios is limitless" and recommends that they "could be discussed by comparison to the consequences of a severe

accident." Id. at O-163. Plaintiffs' argument fails because the NIH reasonably followed the Department of Energy's guidance when analyzing consequences of malevolent acts.

Plaintiffs also challenge the FSRA's determination that the threat from malevolent acts would be the same at all three sites. The plaintiffs contend that the probability of a terrorist attack in Boston would be higher than in Tyngsborough or Peterborough, because Boston would be a more attractive target. At least one of the methodologies used in the sealed threat assessment would support that conclusion while recognizing that the overall threat from outsiders is low. The Department of Energy's NEPA guidance states that the "likelihood of [a terrorist] attack is unknowable," and that is why a "frequency estimate is not reported" for malevolent acts. Id.; see also Richard A. Posner, Catastrophe: Risk and Response 171 (2004)("We do not have the ability [to quantify the risk] with respect to terrorist attacks."). Despite this challenge, the threat assessment takes into consideration "site-specific threat and crime information" and "target attractiveness" for all three sites. The information includes the history of threats, activities, and attacks in the region and area; identifiable threat intelligence; potential adversarial or threat groups present in the region; motivation, intent, and capabilities of identified threats; and public safety response resources. FSRA at 6-6.

Because plaintiffs were not permitted to view the threat assessment, they necessarily based their challenge only on Chapter 6, the FSRA's summary of the threat assessment. When analyzing Chapter 6, the NRC Committee stated:

> The Committee is sympathetic to the difficulties of presenting a threat assessment but is concerned that this chapter will not alleviate public concern in its current form. It is frustrating to read because conclusions are not presented at the end. The chapter would benefit if it were to state clearly up front that the results of some calculations cannot be reported because of security concerns. This would at least spare the reader the frustration of finding no bottom line at the end of the chapter.

AR Doc. 650 at 11.

After an in camera review of the threat assessment, albeit without the benefit of public comment, the Court concludes that it adequately analyzes the risks of malevolent acts at the three locations, and recommends measures to mitigate the risks. Further, after reading defendants' supplemental briefing, the Court finds that the defendants have provided evidence that the mitigation measures have been or will be added prior to the initiation of the NEIDL's operations and that the threat assessment is consistent with information gleaned by law enforcement after the Boston Marathon bombings.

Finally, plaintiffs argue that the FSRA does not analyze the challenges Boston may face when responding to a malevolent attack as compared to the other sites, such as Boston's increased population density, criminal activity, and traffic. For example,

the Massachusetts Nursing Association opposes the BioLab in part because it believes that the Boston Medical Center ("BMC"), the closest hospital to the Boston site, has insufficient capacity to handle a pathogen outbreak. FSRA at O-137 to O-139. One Boston City Councilor also testified that police officers and fire fighters told him they are not prepared to respond to an emergency at the BioLab. Id. at O-225 to O-226.

The FSRA adequately addresses these concerns. The report states:

> Boston University, in conjunction with the Boston Public Health Commission, has provided extensive training for City of Boston emergency responders, including Boston Police, Boston Fire and Boston EMTs. These training sessions have familiarized the emergency responders with the specifics of the [BioLab] facility as well as the general response protocols for biological laboratory emergencies which could occur in any one of the hundreds of such laboratories located in Boston. In addition, Boston University provided a $200,000 grant for training programs coordinated by the Boston Public Health Commission to bring in outside trainers with national expertise on responding to biological laboratory emergencies. Boston University will offer ongoing training and support to the City's first responders so that they continue to be prepared to respond in the event of an emergency.

Id. at O-199. The executive director of the Boston Public Health Commission added that "[t]he City of Boston feels confident that our current regulations and our coordinated permitting, inspecting, and enforcement practices are sufficient to ensure the continued safety of Boston research laboratories." Id. at O-84. Moreover, the NRC Committee disagreed with the Massachusetts

Nursing Association's concerns about the BMC, stating that "[a] positive note with regard to the [BioLab's] current location is its affiliation with the Boston Medical Center, which has ample isolation space and provides an ability to bring point-of-care to the patient and minimize patient movement through the hospital." AR. Doc. 650 at 10; see also FSRA at O-104 (explaining the benefits of having the BMC close to the Boston BioLab site). The FSRA adequately justifies its conclusion that Boston's safety officials would be better able to respond to a malevolent attack than those at the suburban and rural sites. Chapter 2 details the increased resources available in Boston, including significantly more police officers, fire fighters, and emergency medical technicians, as well as a centralized emergency operation center and public health preparedness program. Id. at 2-23 to 2-26.

b. Changed Circumstances

The plaintiffs argue that the FSRA fails to consider two changed circumstances that affect its evaluation of the alternative rural and suburban locations. "[W]here changed circumstances affect the factors relevant to the development and evaluation of alternatives, [an agency] must account for such change in the alternatives it considers." NRDC v. U.S. Forest Serv., 421 F.3d 797, 813 (9th Cir. 2005). First, in 2010, the BMC withdrew its funding, leaving BU as the only private operator

of the BioLab. Second, BU sold the Tyngsborough site in 2008. Plaintiffs' claim fails because they have not adequately demonstrated that either of these two changes affect the bottomline of the FSRA's alternatives analysis.

BMC's divestment "has not caused any change in the [BioLab] leadership team, and there are no changes in the approvals and oversight required for the research that takes place in the [BioLab]. Boston Medical Center will continue to be available as needed to provide emergency medical care." Supplemental Final Environmental Impact Report 1-2 (2013), available at http://www.bu.edu/neidl/files/2013/01/SFEIR-Volume-I.pdf. With respect to the sale of the Tyngsborough site, the FSRA acknowledges that the Tyngsborough site formerly served as BU's Corporate Education Center and is now operated by the Innovation Academy Charter School. FSRA at F-26, F-30.

Even if the record were expanded to include the proffered evidence, plaintiffs have provided no persuasive evidence that the defendants purposefully misled the public regarding the sale of the Tyngsborough site in an attempt to force the BioLab's placement in Boston.[13] In any event, even though the site had

[13] Plaintiffs sought to expand the record to document these changed circumstances, but did not press this point at the hearing. A court "may (although it is not required to) supplement the record where there is a strong showing of bad faith or improper behavior by agency decision makers [or] where there is a failure to explain administrative action as to frustrate effective judicial review." Town of Winthrop v. FAA,

been sold, it was useful to consider a suburban site as an alternative, rather than just a rural site, in order to weigh the risks and benefits of the urban site. If the NIH had decided a suburban site was preferable for a BSL-4 lab, it could have denied funding to BU.

3. Environmental Consequences

a. Event Scenarios

Plaintiffs contend that the environmental analysis is based on questionable and unsupported assumptions regarding the probability and consequences of the risks created by the BioLab's placement in a densely populated urban area. The FSRA considers 300 potential incidents that might occur at the BioLab, narrowed down into 34 categories, and further grouped into five scenarios that provide the upper bounds for the risks posed by similar events. Plaintiffs argue that folding 300 incidents into five scenarios understates the actual risk to the public, and requests that the NIH analyze the frequencies of all 300 events, which would yield a higher overall risk. Even if analysis of the five scenarios is appropriate, the plaintiffs contend that the FSRA understates the total risk by analyzing the events in isolation, ignoring the possibility that multiple events could take place simultaneously or one event could make the others more likely. For example, if the BioLab were compromised by an earthquake, a

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535 F.3d 1, 14 (1st Cir. 2008)(internal quotations omitted).

terrorist could take advantage of the situation and release a pathogen to the public.

The NIH and BRP experts decided "that it is inappropriate to attempt to present total risk for this risk assessment." FSRA at O-155. "This risk assessment analyzed scenarios that are expected to pose the greatest risk to the public, but it is not possible to attempt to analyze all possible scenarios." Id. Because only the five scenarios were analyzed in detail, "[a] summation of these scenarios would present a misleading [total risk] that . . . would not serve the public interest." Id. The NIH contends that the estimates for the MRF earthquake and needlestick analyses "are reasonable approximations of the total public risk for direct and indirect exposures." Id. The FSRA does not take into account the possibility of multiple events taking place simultaneously because it "was considered beyond reasonably foreseeable and, therefore, beyond the scope of this analysis." Id. at O-123. Finally, the FSRA considers the possibility of a malevolent act following an earthquake "only one very low likelihood scenario out of a host of theft scenarios," addressed in Section 6.8 of the Draft Supplementary Risk Assessment. Id. The plaintiffs' challenge fails because the methodology used was reasonable and was supported by both the BRP and NRC Committee experts. See AR Doc. 648 at 7 ("The [FSRA]

provides a range of scenarios that meet the criteria the [NRC] committee recommended be examined.").

b. Secondary Transmissions

The plaintiffs also challenge assumptions made in the FSRA's secondary transmissions analysis. Because "contact rates are difficult to quantify through direct observation," the NIH determined the probability of secondary transmissions based on computer modeling. Id. at L-18. The FSRA created a synthetic resident population based on the specific zip codes of the three sites. "A simulation of the synthetic population on a single day (a weekday in the Spring) spending time in various activity locations, such as homes, offices, and schools, was used to estimate the number of contacts of at least 10-minute duration for each individual." Id. For the Boston site (using the zip code where the BioLab is located), the average number of contacts per person was 44.0. For the suburban site, there were 37.6 contacts, and for the rural site, there were 20.83 contacts. Id. at L-18 to L-19.

Plaintiffs contend this analysis is flawed in two ways. First, they argue that the synthetic populations should not have been based on zip code. Because the city of Boston has over 30 zip codes, contacts with individuals in other zip codes would be much higher in Boston than at the rural or suburban locations. Second, they claim that the modeling should have included

contacts between persons shorter than 10 minutes. Including briefer contacts, such as those on public transportation or a crowded urban sidewalk, would arguably increase the contact rate for the Boston location, which would in turn increase the likelihood of secondary transmissions as compared to the rural and suburban sites.

The computer modeling using the zip code and 10-minute contact assumptions was based on input from Dr. Stephen Eubank, a member of the BRP with expertise in using social networks to model the transmission of infectious diseases. Dr. Eubank did consider including shorter contacts but concluded that "focusing on rural/urban differences in these short contacts might be stretching the plausibility of the models they're based on." AR Doc. 485 at 1; see also FSRA at L-17 to L-18 ("Even for highly transmissible pathogens, the relative importance of brief, casual contacts compared to more intimate contacts during historical outbreaks has often been unclear. The formulation of quantitative models to address [this issue] is an open area of research, and at present there are no well established or validated methods. . ."). The NIH consultants concluded that "limiting the data to longer contact durations seems very reasonable to us, as it is likely that the vast majority of transmissions come from longer/more intimate contacts." AR Doc. 485 at 2. Therefore, they decided to "stick[] to the >10 minute

contacts for the quantitative comparison, and then discussing possible implications of other types of contacts (including mass transit) more qualitatively." Id. at 1. After reviewing this methodology, the NRC Committee concluded that "the modeling on secondary transmission [is] satisfactory and the assumptions made in the chapter are transparent." AR Doc. 650 at 12.

Plaintiffs' claim fails because the assumptions made in the secondary transmissions quantitative analysis using populations based on zip codes and contacts for at least 10 minutes are reasonable and supported by qualified scientific experts. Briefer contacts were addressed qualitatively. Moreover, as with the public transportation analysis, even if shorter contacts were included, the potential increased risk to the public at the Boston site would pertain primarily to the highly transmissible airborne BSL-3 pathogens.

c. Safety procedures

The plaintiffs allege that the FSRA analysis is flawed because it relies too much on safety procedures at the BioLab, and does not take into account inevitable human error. One of the NRC Committee's criticisms of the report was that "failure of protective equipment and failure to follow procedures on the part of personnel are underestimated in the analyses." AR. Doc. 650 at 13. The NIH counters that its assumption that safe working practices and equipment help prevent infections is reasonable,

based on the fact that no single clinical infection has occurred in over 700,000 hours of worker exposure at BSL-4 laboratories in the United States and South Africa. FSRA at D-62. Furthermore, the NIH did take into account human error. For example, the analysis of the likelihood of an undetected and unreported needlestick assumes that lab workers will be unable to detect, or forget to report, a needlestick. To address human error, NIH points to the "two-person" rule, requiring that two researchers must be present for any research involving BSL-3 or BSL-4 pathogens, to lower the risk of a needlestick being undetected and unreported. See id. at O-70 to O-72. While the NRC was concerned that human error may be underestimated in certain analyses, the NIH was cognizant of the risks associated with human error throughout the FSRA. Despite its criticism, the NRC Committee stated that the NIH and BU should emphasize its "clear commitment . . . to encouraging and maintaining a culture of safety at the [BioLab]." AR. Doc. 650 at 8. Therefore, the FSRA's reliance on the implementation of safety procedures and practices was not arbitrary and capricious.

The plaintiffs further contend that the FSRA underemphasizes the risk of pathogen release by failing to discuss high-profile cases of pathogen loss from other facilities around the United States. These cases of pathogen loss include an incident where 9,220 vials of pathogens had not been accounted for at a

biosafety laboratory in Fort Detrick, Maryland, and the 2001 anthrax attacks which killed five people and infected at least 22. The plaintiffs are wrong that these incidents were not adequately discussed or considered. Appendix D is a thorough 70-page report detailing incidents, exposures, and infections in BSL-3 and BSL-4 laboratory facilities across the United States. BRP expert Donald Burke called the tables of incidents in Appendix D "probably the single best location to find this kind of information in the world today." AR Doc. 371 at 108. Appendix D and Chapter 3 explicitly discuss the October 2001 anthrax attacks, stating that the FBI concluded that a scientist from the U.S. Army Medical Research Institute of Infectious Diseases acted alone when he deliberately stole and released anthrax spores in letters to media outlets and politicians. FSRA at D-16; id. at 3-10 to 3-11. Regarding the unaccounted for vials at Fort Detrick, the FSRA states that the incident "involved old working stock vials, some dating back to the Korean War, that had not been used for some time and had not been entered into the pathogen inventory database. There was not any actual loss of pathogens as a result of this event and it was considered a clerical error." Id. at O-115.

4. Effect on Minority and Low-Income Populations

Plaintiffs contend that the FSRA fails to comply with Executive Order 12,898 because it did not adequately analyze the

effects of the BioLab on the minority and low-income populations of the South End and Roxbury neighborhoods. Executive Order 12,898 requires that, "to the greatest extent practicable and permitted by law, . . . each Federal agency shall make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations." Exec. Order No. 12,898 § 1-101, 59 Fed. Reg. 7629 (1994). The order "shall not be construed to create any right to judicial review." Id. § 6-609, 59 Fed. Reg. at 7632-33; see Sur Contra la Contaminacion v. EPA, 202 F.3d 443, 449 (1st Cir. 2000) (declining to review claim that EPA's decision to grant environmental permit was in violation of Executive Order 12,898). However, the D.C. Circuit has held that when an agency includes an environmental justice analysis of the effects on minority and low-income populations in its environmental impact statement, that analysis is reviewed under NEPA and the APA. See Cmtys. Against Runway Expansion, Inc. v. FAA, 355 F.3d 678, 689 (D.C. Cir. 2004)(concluding that environmental justice claim "is properly before this court because it arises under NEPA and the APA, rather than [Executive Order 12,898]" and the agency "exercised its discretion to include the environmental justice analysis in its NEPA evaluation.").

"The purpose of an environmental justice analysis is to determine whether a project will have a disproportionately adverse effect on minority and low income populations." Mid States Coal. for Progress v. Surface Transp. Bd., 345 F.3d 520, 541 (8th Cir. 2003). "Where a potential environmental justice issue has been identified by an agency, the agency should state clearly in the EIS . . . whether, in light of all of the facts and circumstances, a disproportionately high and adverse human health or environmental impact on minority populations, low-income populations, or Indian tribe is likely to result from the proposed action and any alternatives." Council on Environmental Quality, Environmental Justice: Guidance under the National Environmental Policy Act 15 (Dec. 10, 1997). "This statement should be supported by sufficient information for the public to understand the rationale for the conclusion." Id.

Chapter 10 of the FSRA analyzes the effect of constructing the BioLab in the South End and Roxbury neighborhoods on low-income and minority populations. It also analyzes a smaller environmental justice community near the suburban site, while the rural site does not contain any environmental justice communities. When reviewing the penultimate draft of the FSRA, the NRC Committee stated that the report "has made substantial progress in addressing environmental justice and Chapter 10 and Appendix M set out a credible and thoughtful approach to

environmental justice based largely on federal and state environmental justice executive orders and policies." AR Doc. 650 at 13. But the NRC added that "one significant short-coming in the environmental justice analysis" was that it failed to address whether minority and low-income populations would be more susceptible to a release of the 13 pathogens than other members of the public. Id. Even if quantitative data does not exist on these issues, the NRC requested that "[q]uestions of increased morbidity and mortality, accessibility and utilization of health services, and secondary transmission in minority communities should at least be explored in a philosophical discussion. . ." Id.

The final draft of the report acknowledges that there are larger low-income and minority populations at the Boston location than at the rural and suburban sites. FSRA at 10-13 to 10-18. The FSRA also recognizes that "environmental justice communities most often are comprised of individuals that have lack of access to health services." Id. at 10-22. "There are disparities in life expectancy, morbidity, risk factors, and quality of life" that could make them more susceptible to the dangers of a pathogen release than other members of the public. Id. at 10-23. For example, there are "higher rates of infectious diseases such as HIV/AIDS, syphilis, hepatitis, and tuberculosis among racial and ethnic minorities." Id. Still, the report points out that

the likelihood of direct exposure to pathogens is extremely low to not reasonably foreseeable regardless of how close the public lives to the BioLab. Id. at 10-20. With regard to secondary transmissions, those greatest at risk will be the infected lab worker's social contacts, and not necessarily those living closer to the BioLab site. Id. at 10-21 to 10-22. Plaintiffs' claim fails because the FSRA considers the potential impact the BioLab may have on low-income and minority populations.[14]

5. Meaningful Community Input

Plaintiffs' final challenge is that the NIH developed the FSRA without meaningful input from the public, especially from the low-income and minority populations in the South End and Roxbury. One of NEPA's main goals is to "inform the public that [the agency] has indeed considered environmental concerns in its decisionmaking process." Baltimore Gas and Elec. Co. v. Natural

[14] Plaintiffs also criticize the NIH's decision to measure the effects on low-income and minority populations within 10 kilometers of each site. They contend this distance was used to artificially increase the minority and low-income population of the Tyngsborough suburban site by including the urban area of Lowell, Massachusetts. Plaintiffs are incorrect. "A guideline of 1-km radius study area within the city limits and a 2.4-km radius outside city limits is provided by the U.S. Regulatory Commission as generally sufficient for assessing potential environmental justice impacts associated with activities other than nuclear power plants." FSRA at M-4. The NIH used a 10-km radius "to ensure that all potentially affected areas are considered." Id. at 10-12. In a statement during a public meeting in April 2012, plaintiff Klare Allen acknowledged the importance of using a larger radius, stating, "If there is an incident in this community it will affect everyone within a ten mile radius." Id. at O-320.

Res. Def. Council, Inc., 462 U.S. 87, 97 (1983). To ensure public participation, NEPA regulations require a government agency to "[m]ake diligent efforts to involve the public in preparing and implementing their NEPA procedures" and to "[p]rovide public notice of NEPA-related hearings, public meetings, and the availability of environmental documents so as to inform those persons and agencies who may be interested or affected." 40 C.F.R. § 1506.6(a)-(b). The agency should also hold public hearings when there is "[s]ubstantial environmental controversy concerning the proposed action." Id. § 1506.6(c)(1). "After preparing a draft environmental impact statement and before preparing a final environmental impact statement, the agency shall [r]equest comments from the public, affirmatively soliciting comments from those persons or organizations who may be interested or affected." 40 C.F.R. § 1503.1(a)(4).

"Participation of low-income populations [and] minority populations . . . may require adaptive or innovative approaches to overcome linguistic, institutional, cultural, economic, historical, or other potential barriers to effective participation in the decision-making processes of Federal agencies under customary NEPA procedures." Council on Environmental Quality, Environmental Justice: Guidance under the National Environmental Policy Act 13 (Dec. 10, 1997). "These barriers may range from agency failure to provide translation of

documents to the scheduling of meetings at times and in places that are not convenient to working families." Id.

The initial Environmental Impact Statement was created with little public input and failed to address serious public concerns regarding the risks associated with the BioLab and potential alternative locations. However, the FSRA was designed to address these concerns, in particular to answer the question: "What . . . could cause an infectious pathogen to escape the laboratory, set up a chain of transmission, and cause infectious disease in the surrounding community?" FSRA at 1-19. The report also addresses the probabilities and consequences of a pathogen release and how these might change if the BioLab were moved to a rural or suburban location.

The NIH also became more engaged with the community throughout the drafting process of the FSRA. Because constructing the BioLab has generated substantial controversy among the public, the BRP held seven meetings with the public from 2008 to 2010. Four of these meetings were in Boston and were accessible to the affected communities. Two were in central Boston (at the Massachusetts State House and the Boston Marriott Copley Place) and two were in Roxbury (at Roxbury Community College and the Roxbury Center for the Arts). While one meeting started at 9 a.m., and might have been difficult for working families to attend, three other meetings started at 6:30 p.m.

Flyers for the meetings were also translated into Spanish. See AR Docs. 229, 247.

Throughout these meetings, many members of the public, especially those living in the South End and Roxbury neighborhoods close to the Boston location, expressed strong opposition to building the BioLab. Their main concerns surrounded the following issues: the cost, need, and purpose of the BioLab; constructing the BioLab in a high density urban area that would disproportionately affect minority populations; the risks of pathogen release; and the transparency of the process selecting the Boston location. See, e.g., AR. Nos. 234, 194-97.

On April 19, 2012, after the draft supplemental risk assessment was released but before the final report, the NIH held a public hearing at Roxbury Community College starting at 6:30 p.m. to receive public comments on the draft. More than 50 people spoke at the 3-hour long meeting, many of whom continued to voice their vehement opposition to building the BioLab in Boston. The NIH also received hundreds of written comments during the 67-day comment period.

To promote public participation and transparency of the activities at the BioLab, BU has also created a Community Liaison Committee, consisting of 10 members of the public, most of whom live in the South End and Roxbury, with "[o]utreach efforts made to have an ethnically, rationally, and demographically diverse

membership." Community Liaison Committee Guidelines, available at http://www.bu.edu/neidl/community/clc/guidelines/. The committee meets monthly, its meetings are open to the public, and its responsibilities are sharing information about the projects at the BioLab and advising the BioLab leadership on potential issues of concern between the laboratory and the community.

Plaintiffs' claim fails because these actions demonstrate that the NIH has met its public participation requirements under NEPA. By asking important and difficult questions about the BioLab, especially with regards to the risks associated with constructing a BSL-4 laboratory in an urban area, plaintiffs and other members of the public played an integral role in ensuring the NIH adhered to NEPA's requirements of considering alternatives and risks to the public, and adequately explaining its decision. Appendix O of the FSRA – 682 pages of comments received from the public along with the NIH's responses – in particular demonstrates the importance of community engagement, and the NIH's response to public concerns.

Plaintiffs also contend that the FSRA itself is too technical and long for the public to understand. The NRC Committee recognized that "the draft report is an extremely large and technically complex document" and recommended that the NIH include "an Executive Summary written for the lay audience and a summary of Chapter 11 that synthesizes and interprets the major

findings of the [FSRA] in plain language be developed to facilitate public understanding." AR. Doc. 650 at 8. The Court agrees that the FSRA is technical and difficult to read in a number of areas. However, in response to concerns from the public and the NRC Committee, the NIH did prepare a Reader's Guide for the FSRA and added conclusions and summaries to many of the chapters to make the report somewhat more accessible.

C. A Hard Look

After examining all of plaintiffs' challenges to the FSRA and conducting a comprehensive review of the report in its entirety, the Court concludes that the NIH has met its obligation under NEPA "to take a 'hard look' at environmental consequences" of its decision to build the BioLab in Boston. Beyond Nuclear, 704 F.3d at 19. The FSRA is a significantly improved document as compared with the initial EIS, which did not analyze alternative locations. The FSRA includes a detailed quantitative and qualitative analysis of five categories of incident types (needlestick, centrifuge release, earthquake, plane crash, and malevolent act) with 13 different BSL-3 and BSL-4 pathogens at three distinct locations.

Plaintiffs contend that the FSRA's analysis is biased in favor of the Boston site because the BioLab has already been constructed there. BSL-2 research is being conducted at the BioLab, and the Commonwealth approved BSL-3 research in March

2013. The BSL-4 lab is currently not operational. Although it would have been preferable to have taken a hard look before funding any research at the BioLab, there is no evidence the bottom line would have been different because the risk to the public is so low according to the methodology used by experts in the field. The report was vetted by two separate sets of highly qualified independent experts, the BRP and NRC Committee. The NRC has been very critical of the analysis in the past. The experts did not merely rubberstamp the FSRA, but instead made numerous critical comments over a five-year period, causing the NIH to continue to improve the document before it was released to the public.

The Court recognizes a shortcoming in the FSRA is its inability to analyze certain issues that could potentially increase the risk of transmitting dangerous pathogens among the public in a highly populated urban area. Specifically, the report's secondary transmission analysis does not have quantitative data regarding how the use of public transportation or contacts with individuals for less than 10 minutes would affect the BioLab's risk to residents of Boston as compared to those in suburban or rural areas. However, the NIH explained that the scientific literature did not support analyzing these issues quantitatively, and the Court must defer to the agency's scientific judgment, particularly since it is backed by such

highly qualified expert panels. See Tri-Valley CAREs, 671 F.3d at 1124. They were addressed qualitatively, and the FSRA recognizes that, in the event of a pathogen release, the infection rate would be slightly higher at the Boston location than at the suburban and rural locations. FSRA at 11-24. Even if public transportation and shorter contact rates were included in the analysis, the increased risk to the public in Boston would pertain primarily to highly transmissible airborne BSL-3 pathogens, not the BSL-4 pathogens. Since eleven BSL-3 laboratories already exist in Boston, this potential increased risk does not justify enjoining construction of the BioLab.

Finally, plaintiffs have expressed concerns that placing the BioLab in the Roxbury and South End neighborhoods would disproportionately affect minority and low-income communities. The FSRA recognizes that health disparities might increase these communities' susceptibility of infection, particularly in the unlikely event of a release of transmissible airborne pathogens. Perhaps it would have been wiser to construct the laboratory in a less densely populated area, where public fear and opposition would not be so intense. However, it is not the Court's job to determine where the BioLab should be built. See Geer v. FHA, 975 F. Supp. 47, 61 (D. Mass. 1997)("NEPA does not require that an agency choose the alternative that some of the commentators – or even the court – might believe is best.").

The NIH has explained that the benefits of having the BioLab in Boston include opportunities for efficient medical research collaboration and training with other institutions in Boston, such as Harvard Medical School's NIAD-Sponsored Regional Center of Excellence for Biodefense and Emerging Infectious Diseases. The NIH hopes that the existing research infrastructure in Boston and Cambridge will help the BioLab advance critical research on biodefense and emerging infectious diseases. The BioLab is intended to address this important need.

In sum, the Court is satisfied that the FSRA adequately analyzes the risks associated with building the BioLab, including "worst case" scenarios and suburban and rural alternatives. The NIH provides sufficient scientific support for its ultimate conclusions that the risks to the public are extremely low to not reasonably foreseeable, and the differences between the Boston location and the suburban and rural sites are not significant. In light of the benefits of placing the BioLab in an urban area like Boston, which provides opportunity for expert medical research collaboration, and the low risk of harm to the public, NIH's decision is rational.

V. ORDER

The Court **ALLOWS** defendants' motions for summary judgment (Doc. Nos. 83 & 90) and **DENIES** plaintiffs' motion for summary judgment and permanent injunctive relief (Doc. No. 87).

/s/ PATTI B. SARIS
PATTI B. SARIS
Chief United States District Judge