21–654 was approved on November 10, 2004.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,477 (U.S. Patent No. 5,656,667), 1,413 (U.S. Patent No. 5,698,594), and 1,728 (U.S. Patent No. 5,502,077) days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by April 3, 2006. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 1, 2006. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 5, 2006.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E6–1365 Filed 2–1–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Emerging Infectious Diseases Laboratories Record of Decision

ACTION: Notice.

SUMMARY: The Department of Health and Human Services, the National Institutes of Health (NIH), has decided, after completion of a Final Environmental Impact Statement (FEIS) and a thorough consideration of the public comments on the Draft EIS and Supplemental EIS, to implement the Proposed Action, which is identified as the Preferred Alternative in the Final EIS. This action is to partially fund the construction of a state-of-the-art National Biocontainment Laboratory (NBL), to be called the National Emerging Infectious Diseases Laboratories (NEIDL), at the Boston University Medical Center (BUMC) Campus in Boston, Massachusetts.

FOR FURTHER INFORMATION CONTACT: Valerie Nottingham, Chief of the Environmental Quality Branch, Division of Environmental Protection, Office of Research Facilities Development and Operations, NIH, Building 13, Room 2W64, 9000 Rockville Pike, Bethesda, MD 20892, Fax 301–480–8056, e-mail *nihnepa@mail.nih.gov.*

SUPPLEMENTARY INFORMATION:

Decision

After careful review of the environmental consequences in the Final Environmental Impact Statement for the National Emerging Infectious Diseases Laboratories (Final NEIDL EIS), and consideration of public comment throughout the NEPA process, the NIH has decided to implement the Proposed Action described below as the Selected Alternative.

Selected Alternative

The NIH plans to partially fund the construction of a state-of the art National Biocontainment Laboratory, which will be known as the National Emerging Infectious Diseases Laboratories (NEIDL), on the Boston University Medical Center Campus in Boston, Massachusetts. The NIH will fund approximately $128 million dollars. The proposed NEIDL will enhance national security through the development and evaluation of improved diagnostics, therapeutics, and vaccines for the protection against naturally emerging and re-emerging diseases, including those that have the potential for bioterrorism. The proposed NEIDL will not conduct research to develop biological weapons.

The proposed NEIDL facility will be a new steel and reinforced concrete seven-story building that will be constructed within the BioSquare Research Park, with a total assignable area of 84,100 square feet, and will house Biosafety Level (BSL)–4, BSL–3, and BSL–2 facilities, BSL–4 and BSL–3 animal facilities, an Arthropod Containment Level (ACL)–3 insectary, offices, conference rooms, and support facilities including an effluent treatment room, secure loading dock, and dedicated mechanical floors to enhance containment features of the building.

The proposed NEIDL facility will be designed to safely support all the superimposed loads applied to the building and will be constructed to the requirements of Seismic Performance Category C, which assures that the building structure stays functional after a seismic event. In addition to standby generators to provide power in the event of a power outage, the NEIDL facility will have a distributed on-line uninterruptible power supply to power the BSL–4 laboratory biosafety cabinets, critical building control panels and alarms. The four biosafety levels have increasingly stringent design, security, and containment requirements. The safety levels are determined based on the biological materials used in research and the ways they affect the human population. BSL–1 facilities have no requirements for safety equipment, while BSL–4 facilities have extensive and multiple requirements for safety equipment and facility design such as isolation, buffer zones, airflow and pressure requirements, and high efficiency particulate air (HEPA) filtration.

The building also will be provided with an environmental monitoring system to assess room pressure differentials (to ensure negative pressure in the biocontainment areas), smoke detection, and the pressure drop condition HEPA filters. Visual indicators (such as pressure gauges) and audible or strobic alarms will alert NEIDL personnel in the event of an emergency or situation that requires corrective action or other response. The NEIDL will have fire protection systems that meet or exceed requirements specified by the National Fire Protection Association and all applicable local, state, Federal, and BUMC requirements.

The design of the proposed NEIDL facility's BSL–4, –3, and –2 laboratories will comply with the recommendations and requirements of the Centers for Disease Control (CDC) and the NIH joint publication addressing biosafety in laboratories, the current edition Biosafety in Microbiological and Biomedical Laboratories, as well as NIH's Design Policies and Guidelines for Biomedical Research Laboratories. The BSL–4, –3, –2 animal laboratories will further comply with the recommendations and requirements of the latest edition of Guide for Care and Use of Laboratory Animals, published by the National Research Council.

The BSL–4 laboratory environment employs the concept of a ''box-within-a-box'' principle, whereby the laboratory is built within a pressure-

controlled buffer. The BSL–4 laboratories will be physically and functionally independent from other laboratory functions. All penetrations in the walls, ceilings, and floor will be sealed. The control system for maintaining the required pressure differentials will be capable of being monitored inside and outside of the laboratory. The BSL–4 laboratories will utilize a series of airlocks for entry and exit, will have dedicated supply and exhaust ventilation, and workers in the BSL–4 laboratories will use positive pressure ventilation suits.

Workers will be required to take a chemical shower to decontaminate the surface of their suits before they can leave the area. Prior to emission through stacks on the building roof, exhaust air from the negatively pressurized BSL–4 laboratories will pass through dual HEPA filters mounted in series in a dedicated sealed exhaust system. The exhaust will also pass through isolation dampers that will close within seconds upon receipt of a containment isolation signal. In addition, each laboratory will be equipped with multiple Class II Biosafety Cabinets with their own HEPA exhaust system. Liquid waste will be sterilized in a biowaste cooker system before discharge. Solid waste will be sterilized in autoclaves prior to leaving containment areas.

The NEIDL BSL–3 laboratories, BSL–3 animal laboratories, and ACL–3 insectary will be separated by restricted traffic flow within the building and access to the laboratory will be restricted by the use of electronic recognition devices. A ventilated airlock will separate the common corridors from the containment facility. The airlock doors will be interlocked to prevent simultaneous opening of doors between the outside corridor and the containment areas. Directional airflow will be provided through the airlock with differential pressure monitoring.

Similar to the BSL–4 requirements, all electrical conduit, plumbing piping, supply and exhaust ducts and miscellaneous penetrations will be sealed at the point of penetration into the BSL–3 laboratory to ensure a tight structure. Tap water entering the BSL–3 laboratories through spigots in the sinks will have backflow preventors to protect the potable water distribution system from contamination. All BSL–3 laboratories will operate under negative air pressure. A dedicated, ducted HVAC system will draw air into the BSL–3 laboratories from the surrounding areas toward and through the BSL–3 laboratories with no recirculation from the laboratories to other areas of the building. This direction of airflow into the laboratories and the biosafety cabinets will be verifiable with appropriate visual and audible alarm systems to notify personnel of HVAC problems or system failure. All air will be discharged outside the building through HEPA filters. Each BSL–3 laboratory will be equipped with Class II biosafety cabinets. Each BSL–3 laboratory will be provided with shower-out facilities for researchers along with autoclaves for solid waste treatment prior to removal. Liquid waste will be chemically decontaminated prior to discharge and solid waste will be sterilized in autoclaves prior to leaving the laboratories.

Work with moderate-risk biological material will be conducted in BSL–2 laboratories. The air supply system will be designed to maintain negative air pressure in relationship to administrative space, offices, and corridors. There will be no HEPA filtration for BSL–2 exhaust. Liquid waste will be chemically decontaminated prior to discharge and solid waste will be sterilized in autoclaves prior to leaving the laboratories.

The design and construction of the NEIDL facility will address security concerns. Security measures are discussed below. Scenarios involving terrorist or intentionally destructive acts at the NEIDL have been analyzed in an independent Threat and Risk Assessment (TRA). The design as well as security plans and procedures of the NEIDL facility will address the TRA analysis and recommendations.

The NEIDL will be surrounded by a protective fencing system that allows for controlled access at staffed checkpoints for both vehicles and pedestrians and to create setbacks of approximately 100 feet from any location that could accommodate unscreened pedestrian traffic. Vehicular access would be strictly limited to BUMC vehicles and selected delivery and service vehicles. The service and loading area will be located on the south side of the facility within the secure perimeter. Pedestrian access to the building will be limited to a single entrance and security officers will be assigned to provide protective services at the site twenty-four hours a day, monitoring both the building and the grounds.

Access to the NEIDL facility will be strictly controlled by various measures. All employees will undergo background and security checks prior to being assigned to a laboratory area. Strict operational protocols, including specific training, would be imposed on laboratory personnel prior to working in the facility. Security officers will be on duty twenty-four hours a day to monitor controlled access. All employees will be required to wear security badges. Furthermore, security cameras will be in use, biometric access systems will be utilized, and all deliveries will be screened.

Access to the BSL–4 laboratory will be restricted to people whose presence is required and authorized. Air pressure resistant, lockable doors will be monitored and controlled by the security system. A log of persons entering and exiting the laboratory with name, time, date, and reason for entering the lab will be maintained and the log would be frequently audited by BUMC's Office of Environmental Health and Safety (OEHS).

Alternatives Considered

The NIH considered the two reasonable alternatives identified and considered in the Final EIS: (1) The Proposed Action Alternative (now the selected alternative) and (2) the No Action Alternative (not constructing the NEIDL). Previously, NIH examined several sites and various facility designs. Sites for the NBL were evaluated if there was a reasonable expectation that a facility could be constructed with the available funding, in a reasonable time, and while meeting federal safety criteria. To meet these constraints, two minimum siting criteria were established. These criteria included: (1) The site must be controlled (owned or currently leased) by Boston University (to remain within funding and timing constraints); and (2) The lot size must be sufficient to accommodate a minimum building size of 190,000 square feet (sf) and at the same time meet federal security setback requirements. Applying the above screening criteria reduced the potential sites for detailed evaluation to four locations and four designs, one of which became the Proposed Action. The three other alternatives considered were a site on the 210 acre BU Corporate Education Center in Tyngsborough, Massachusetts; a site at the BU Charles River Campus; and a site at the BU Sargent Center for Outdoor Education in Petersborough, New Hampshire. These other sites and designs were considered technically inferior, provided no environmental advantage compared to the Proposed Action, or would not meet the purpose and need as efficiently as the Proposed Action. Therefore, they were eliminated from detailed analysis in the EIS.

Factors Involved in the Decision

Several factors were involved in the NIH's decision to proceed with the Proposed Action. Based on analyses in

the Draft EIS, the Supplemental EIS and Final EIS, the Proposed Action best satisfies the stated Purpose and Need, which is to rectify the national shortage of biological containment facilities with laboratories and procedures for handling potentially lethal infectious agents. This national shortage of biological containment facilities represents a substantial impediment to conducting research on infectious diseases and is a national biodefense vulnerability. To be most effective, these facilities must be located where established teams of researchers are already working on related scientific problems. Additionally, the biological containment facilities should be located in an area with existing infrastructure critical to providing timely public health support in the case of a national, state, or local disease outbreak or bioterrorism emergency. Locating a new national biocontainment laboratory at the Boston University Medical Center campus takes advantage of BU's extensive expertise in biological medical research, and its infrastructure as a regional medical center.

Resources Impacts

The Final EIS describes potential environmental effects of the Selected Alternative. These potential effects are documented in Chapter 4 of the Final EIS. Any potential adverse environmental effects will be avoided or mitigated through design elements, procedures, and compliance with regulatory and NIH requirements. Potential impacts on air quality are all within government standards (federal, state, and local). NIH does not expect negative effects on the environment or on the citizens of Boston from construction and operation of the NEIDL.

Summary of Impacts

The following is a summary of potential impacts resulting from the Selected Action that the NIH considered when making its decision. No adverse cumulative effects have been identified during the NEPA process. Likewise, no unavoidable or adverse impacts from implementation of the Selected Action have been identified. The Selected Action will be beneficial to the long-term productivity of the national and world health communities. Biomedical research conducted at the NEIDL facility will have the potential to advance techniques in disease prevention, develop disease immunizations, and prepare defenses against naturally emerging and re-emerging diseases and against bioweapons. Additionally, the local community will benefit from increased employment, income and, government and public finance.

Housing

Temporary impacts during construction are expected to have a minimal effect on the existing residential neighborhoods. The Boston-NBL site is bounded by a regional commercial wholesale florist market on the east, a highway on the south, the Boston University Medical Center on the north, and the BioSquare Phase 1 Research Park on the west. Residential neighborhoods are found north of the site on two side streets off Albany Street and one block north of the site off of Harrison Avenue. Construction traffic will avoid residential areas and rely on Albany Street for access.

With over 250,000 housing units in the City of Boston, the Project would have no adverse impact on housing stock. As required by local ordinance, the Project would participate in the City of Boston's Affordable Housing Program through a contribution to the City's Neighborhood Housing Trust in the amount of approximately $920,000 to be used for the creation of new affordable housing. NIH funds would not be used for this contribution.

Education

The current public school capacity in the South End would be adequate to accommodate the expected minimal growth caused by the Boston-NBL facility.

Transportation

The results of a traffic analysis conducted for the BioSquare Phase II Final Environmental Impact Report/Project Impact Report (EIR/PIR) demonstrates that the transportation infrastructure is adequate to support the Project. The 70 trips entering and leaving the site during each of the a.m. and p.m. peak hours that are specifically attributed to the NBL represents only 15–16 percent of the additional peak hour traffic; they are not sufficient in and of themselves to change operations significantly at any of the study area locations. The potential introduction of new access to and from the regional highway system would remove existing and future vehicle trips from the congested corridors of Massachusetts Avenue and Albany Street. Traffic flow on the Massachusetts Avenue Connector (MAC) is limited by the signalized intersections at Massachusetts Avenue/Southampton Street/Melnea Cass Boulevard/MAC and Massachusetts Avenue/Albany Street, which are presently at capacity. By creating an access point to BioSquare from the highway system, the Project would reduce existing and future site generated traffic from these critical intersections.

Community Safety and Risk

Records from the past 21 years of accidents at NIAID laboratories indicate an outstanding record of safety showing that in more than 3 million hours of exposure, there have been only one clinical infection and four silent infections (no manifestation of disease symptoms). In this 21-year period, there has been no agent released from any of these laboratories to cause infection in the general population. Nationwide, there have been no clinical infections from working with BSL–4 agents during the past 31 years at NIAID supported laboratories and no documented cases of a laboratory worker's family members or the public acquiring a disease from NIAID laboratory operations.

Records of all reported laboratory accidents were reviewed from the past ten years by the BUMC Occupational and Environmental Medicine Department and it has been confirmed by that BUMC did not have any laboratory-acquired infections from research work at BSL–2 and BSL–3 with the exception of an incident in 2004 in which three research laboratory workers were accidentally infected with tularemia bacteria in their BSL–2 lab. Corrective actions already identified and implemented to prevent this type of accident from occurring again include increased safety training and procedures for lab workers; strengthened laboratory safety procedures; unannounced safety inspections of BUMC laboratories; applying additional tests and safeguards to infectious material sent to BUMC for research purposes; and working with the Boston Public Health Commission to improve the notification process.

With approximately 14 million hours of operating time in the laboratories during the ten year period described above there were nine incidents of animal bites; sixteen incidents of percutaneous penetration; and two incidents of eye splashes that occurred within BSL–2 laboratories. None of the exposures listed above, with the exception of the tularemia incident led to illness or evidence of serological exposure.

Operation of the NEIDL is expected to result in beneficial human health impacts. The NEIDL facility will allow the development of diagnostic tests, management strategies, and vaccines for a number of emerging viral diseases and agents that may be used to cause intentional harm. The NEIDL facility will also allow for the training of additional scientists in maximum

biocontainment conditions, and increase the laboratory space available for conducting experiments that require maximum containment in response to emerging and re-emerging infectious diseases.

To ensure that the project does not create any adverse public health impacts, an analysis was prepared to address the potential risk to the public of a ''worst case scenario'' involving loss of containment systems in the BSL–4 laboratory that coincides with a release within the facility. A quantitative risk assessment was performed with regard to a theoretical infectious agent release to the surrounding community from the Boston-NBL. The risk assessment examined a laboratory accident within the BSL–4 laboratory that coincided with potential catastrophic failure of containment equipment. The ''worst case scenario'' also included an analysis of a scenario depicting a laboratory acquired infection; a scenario depicting a release due to failure to decontaminate exhaust air; a scenario depicting the escape of an infected animal; a scenario depicting a biological material shipment; and a scenario depicting an unauthorized removal of biological material from containment area. The results of these studies showed the predicted maximum exposure to any member of the community from the ''worst case scenario'' is 0.29 spores over the entire duration of the event. As the exposure to a partial spore is not feasible, the risk of public harm is so minute that it may be described as negligible.

In order to address the concerns about community safety that were raised in public comments, the NIH prepared an additional risk assessment. An additional exposure modeling strategy was applied to the proposed Boston University site. The ''Maximum Possible Risk'' or MPR model was developed by the NIH in response to comments from the public. Fifteen different scenarios were subjected to analysis using the MPR model. The MPR model analysis included three scenarios depicting spills and work disruptions; one scenario depicting a spill on the floor with no HEPA filter in the HVAC system; one scenario depicting a spill on the floor during a power outage; two scenarios depicting physical removal of biological material; two scenarios depicting fire; and seven scenarios depicting explosions. The conclusions of the MPR model showed that all fifteen scenarios had no probability of public health harm.

In summary, twenty-one different risk scenarios, six in the original risk assessment and fifteen in the supplemental risk assessment, were examined in total. All twenty-one scenarios supported the conclusion that the facility poses negligible risk to the community.

Employment

The Boston-NBL facility will create approximately 1,300 temporary construction jobs and 660 new permanent positions. These new positions include all types and levels including environmental services, lab technicians, scientists, and administrative staff. The majority of positions would require skilled and experienced workers.

During construction, the project will comply with the City of Boston Jobs Policy through the creation of a Boston Residents Construction Plan, establishing goals for the recruitment of local residents for construction employment.

BUMC is committed to working with City agencies to ensure that Boston residents have the opportunity to benefit from the new employment generated by the facility. Toward this end, there would be opportunities for local residents to obtain training for various positions, such as laboratory staff, which would in turn benefit the local economy. The Boston-NBL facility will contribute approximately $185,000 to the City of Boston's Neighborhood Jobs Trust for training purposes.

Income

The Boston-NBL facility, like other BUMC facilities, would bring large infusions of outside money to the area to finance the laboratory's work. The NEIDL will have positive economic impact on the South End and surrounding neighborhoods throughout the construction and operation phases. The total direct wages to be paid per year at the Boston-NBL is projected to be $33,000,000, of which 21.4%, or a total of $7,062,000, is expected to go to Boston residents.

Environmental Justice

During the construction phase of the project, neighborhoods immediately abutting the Project site, including Environmental Justice communities (communities where 25% or more of the population is defined as a minority), may experience temporary impacts from construction because of their location and proximity. There will be no disproportionate effect on Environmental Justice communities. The project will develop a Construction Management Plan to minimize construction related transportation impacts.

The worst case scenario analysis shows that during operations of the laboratory there will be negligible risk to public health for the entire community. Therefore, there will be no disproportionate impact on Environmental Justice communities during operations.

Visual Quality

The project has been designed to complement the existing urban design context of the project area. The site plan and massing of the project would help to mend the irregular urban edge that now exists along Albany Street. The site design and building massing have been reviewed with the Boston Redevelopment Authority (BRA) urban design staff as part of the design review process to assure compliance with BRA guidelines and recommendations.

Noise

Construction of the project will result in a temporary increase in daytime sound levels near the site. The maximum L_{10} (sound level exceeded 10% of the time) during construction is estimated to be 71 dBA, which complies with the City of Boston Noise Control Regulation that permits L_{10} levels from construction operations to exceed 75 dBA. To reduce noise from construction the project would install high-grade mufflers on the diesel powered construction equipment and generators; combine noisy operations to occur for short durations during the same time periods; and perform construction activities only between the hours of 7 a.m. to 5 p.m.

Air Quality

The laboratory exhaust system will be designed to avoid any air quality impacts inside or outside the building under normal operations. The potential air quality effects from the laboratories will be minimized by: (1) Combining the exhaust vents from the internal laboratory hoods into groups before connecting to rooftop exhaust fans, thus providing enhanced dilution of any laboratory chemical emissions before they reach ambient air; (2) designing the rooftop stacks to have exit velocities of at least 3,000 feet per minute as a stack exit velocity of this magnitude would be sufficient to avoid stack tip downwash, a phenomenon in which the emissions from the stack are drawn downward as strong winds blow by the stack; (3) carefully controlling and limiting the storage of all chemicals within the building to minimize chemical emissions, liquid chemicals would not be left exposed to the air and would always be contained and transferred

within closed glassware; and (4) handling liquid chemicals in small quantities to reduce the potential air quality impacts in the event of an accidental spill.

The National Ambient Air Quality Standards (NAAQS) were established to protect public health and welfare, with a margin for safety. An air quality dispersion modeling analysis was performed for the generators, boilers and laboratory vents at the Boston-NBL in accordance with the U.S. EPA and state Department of Environmental Protection (DEP) modeling guidelines. The dispersion modeling results demonstrated that the maximum cumulative concentrations of criteria air pollutants from the boilers and generators, modeled with the existing interactive sources, and with background air pollutant concentrations added, will be safely in compliance with the NAAQS for all of the criteria air pollutants analyzed.

During the construction period, the project will comply with the state DEP Diesel Retrofit Program to reduce emissions from construction-related vehicle exhaust.

Wastewater/Water Supply

The daily sewage flows are estimated at 45,825 gallons per day (gpd) based on existing flows at similar BUMC labs. The project does not require improvements to existing sewage infrastructure. Sanitary sewage for the proposed project would be carried by the New Albany Street Interceptor, which is designed to carry a theoretical flow of 16 million gallons per day (mgd). This project anticipates a total new daily flow of 45,825 gpd, or approximately 0.29% of the theoretical capacity of the interceptor. The estimated peak sewage flow of 137,475 gpd would be approximately 0.86% of the system capacity. At the time the New Albany Street Interceptor was designed, much larger flows were expected from this area. Accordingly, there is more than sufficient capacity in the system to accommodate the additional flows from this project and the project will have no adverse effects on existing wastewater systems

The Boston-NBL will have a segregated plumbing system that will carry laboratory wastewater from every non-BSL–4 area to mixing tanks in the basement where pH adjustment and compliance sampling would occur prior to discharge to the sanitary system. The BSL–4 areas of the Boston-NBL building would feature a sterilization system designed to use heat to kill any biological agents that might exist in the wastewater from these BSL–4 areas. The sterilized effluent from the BSL–4 areas will be cooled and neutralized before discharge. The discharges from the facility will have no adverse effect on the wastewater treatment system.

Existing public water supply systems have been significantly upgraded in the past several years and has more than adequate capacity to service the Boston-NBL. The project will have no adverse effect on water supply.

Historic Resources

The proposed project will be sited in an area of large commercial, industrial and institutional uses near the South End Landmark District and National Register District. The Project is located within the South End Harrison/Albany Protection Area, which covers a transitional area adjacent to the above districts. The proposed Project meets the goals of the Protection Area and thus has no adverse effects on historic resources.

Practicable Means To Avoid or Minimize Potential Environmental Harm From the Selected Alternative

All practicable means to avoid or minimize adverse environmental effects from the Selected Action have been identified and incorporated into the action. The proposed NEIDL facility will be subject to the existing BUMC pollution prevention, waste management, and safety, security, and emergency response procedures as well as existing environmental permits. Best management practices, spill prevention and control, and stormwater management plans will be developed and followed to appropriately address the construction and operation of the NEIDL and comply with applicable regulatory and NIH requirements. No additional mitigation measures have been identified.

Pollution Prevention

Pollution prevention measures are described in Chapter 2 of the FEIS and reflect standard spill prevention procedures. Additional pollution from the NEIDL facility is not anticipated. Air quality permit standards will be met, as will all federal, state, and local requirements to protect the environment and public health. Additional pollution prevention methods will include:

Reducing construction waste by recycling materials wherever possible;

Water efficient landscaping; and

Adhering to current BUMC waste management practices.

Monitoring and Enforcement Program for Mitigation Measures

During the preparation of the FEIS, several potential environmental issues associated with implementation of the Selected Alternative were identified.

The local community is concerned about transportation impacts. Transportation of agents to and from the NEIDL is a concern for some. Strict rules and regulations govern how agents are packaged, labeled, handled, tracked, and transported. The transportation of agents will comply with all rules and regulations. According to the World Health Organization (WHO), worldwide, there have never been any cases of illness attributable to the release of infectious materials during transportation. There have been reports of damage to outer packaging. The risk to the community from the transport of infectious agents or other biologically-derived material is negligible.

Emergency planning was raised as a concern. BUMC has an existing Incident Command System and a detailed Disaster Operations Plan that is regularly reviewed and will be revised to include the operations of the NEIDL. Emergency responders in the area are confident that they will be capable of handling emergency situations.

In addition, possible adverse health and safety impacts on laboratory workers in the NEIDL and on nearby residents during the operational phase of the project were evaluated. The risks were deemed to be negligible and mitigable through adherence to guidelines outlined in the current edition of Biosafety in Microbiological and Biomedical Laboratories, a joint publication of the NIH and CDC, as well as other standards for safe operational practices.

Conclusion

Based upon review and careful consideration, the NIH has decided to implement the Selected Alternative to partially fund the construction of a state-of the-art national biocontainment laboratory, which will be known as the National Emerging Infectious Diseases Laboratories (NEIDL) on the Boston University Medical Campus (BUMC) in Boston, Massachusetts.

The decision was based upon review and careful consideration of the impacts identified in the Final EIS and public comments received throughout the NEPA process. The decision was also based on BUMC's extensive expertise in biological medical research, its experience in operating BSL–2, and –3 laboratories, and its infrastructure as a regional medical center being able to

fulfill the purpose and need to provide national biocontainment facilities. Other relevant factors included in the decision, such as NIAID's mandate to conduct and support research on agents of emerging and re-emerging infectious diseases, were carefully considered.

Dated: January 26, 2006.

Juanita M. Mildenberg,

FAIA Acting Director, Office of Research Facilities Development and Operations, National Institutes of Health.

[FR Doc. E6–1402 Filed 2–1–06; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Meeting: Secretary's Advisory Committee on Genetics, Health, and Society

Pursuant to Public Law 92–463, notice if hereby given of the ninth meeting of the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS), U.S. Public Health Service. The meeting will be held from 9 a.m. to 5 p.m. on March 27, 2006 and 9 a.m. to 5 p.m. on March 28, 2006 at the National Institutes of Health, Building 31, C Wing, Conference Room 6, 31 Center Drive, Bethesda, MD 20892. The meeting will be open to the public with attendance limited to space available. The meeting will be webcast.

The first day of the meeting will include sessions on pharmacogenomics and large population studies of genetic variation, the environment and common disease. The pharmacogenomics session will include a review of Federal efforts in pharmacogenomics and deliberation on draft recommendations in this area. The large population studies session will involve discussion of a draft report that identifies policy issues associated with mounting a large population study in the United States.

The second day will be devoted to sessions on genetic discrimination and patents and licensing issues. The genetic discrimination session will include an update on the status of Federal genetic non-discrimination legislation. The patents and licensing session will involve a presentation on the findings and conclusions of a National Academy of Sciences' report on intellectual property rights in genomic research and innovation, and a discussion on whether there are other issues in this arena that warrant SACGHS's further attention.

Time will be provided each day for public comments. The Committee would welcome hearing from anyone wishing to provide public comment on any issue related to genetics, health and society. Individuals who would like to provide public comment or who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the SACGHS Executive Secretary, Ms. Sarah Carr, by telephone at 301–496–9838 or e-mail at *sc112@nih.gov*. The SACGHS office is located at 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892.

Under authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, the Department of Health and Human Services established SACGHS to serve as a public forum for deliberations on the broad range of human health and societal issues raised by the development and use of genetic technologies and, as warranted, to provide advice on these issues. The draft meeting agenda and other information about SACGHS, including information about access to the webcast will be available at the following Web site: *http://www4.od.nih.gov/oba/sacghs.htm*.

Dated: January 26, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–979 Filed 2–1–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Meeting: Secretary's Advisory Committee on Genetics, Health, and Society

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The second day will be devoted to sessions on genetic discrimination and patents and licensing issues. The genetic discrimination session will include an update on the status of Federal genetic non-discrimination legislation. The patents and licensing session will involve a presentation on the findings and conclusions of a National Academy of Sciences report on intellectual property rights in genomic research and innovation, and a discussion of whether there are other issues in this area that warrant SACGHS's further attention.

Time will be provided each day for public comments. The Committee would welcome hearing from anyone wishing to provide public comment on any issue related to genetics, health and society. Individuals who would like to provide public comment or who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodation, should notify the SACGHS Executive Secretary, Ms. Sarah Carr, by telephone at 301–496–9838 or e-mail at *sc112c@nih.gov*. The SACGHS office is located at 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892.

Under authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, the Department of Health and Human Services established SACGHS to serve as a public forum for deliberations on the broad range of human health and societal issues raised by the development and use of genetic technologies and, as warranted, to provide advice on these issues. The draft meeting agenda and other information about SACGHS, including information about access to the webcast will be available at the following Web site: *http://www4.od.nih.gov/oba/sacghs.htm*.

Dated: January 26, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

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