be reached by telephone at 301–443–1896, e-mail: *Thom.Balbier@hrsa.hhs.gov*, or in writing at the address of the Division of Transplantation provided below. Management and support services for ACOT functions are provided by the Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Parklawn Building, Room 12C–06, Rockville, Maryland 20857; telephone number 301–443–7577.

After the presentations from CMS and ACOT discussions, members of the public will have an opportunity to provide comments. Because of the Committee's full agenda and the timeframe in which to cover the agenda topics, public comment will be limited. All public comments will be included in the record of the ACOT meeting.

Dated: April 5, 2005.

Elizabeth M. Duke,

Administrator.

[FR Doc. 05–7160 Filed 4–8–05; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Galveston National Laboratory 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 (EIS) and a thorough consideration of the public comments on the Draft 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), which will be known as the Galveston National Laboratory (GNL), on the University of Texas Medical Branch (UTMB) Campus in Galveston, Texas.

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, telephone 301–496–7775, 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 Galveston National Laboratory for Biodefense and Emerging Infectious Diseases Research Facility in Galveston, TX (Final GNL 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 Galveston National Laboratory (GNL), on the UTMB Campus in Galveston, Texas. The total cost of the proposed GNL project is estimated at approximately $147 million. NIH will fund approximately $110 million with UTMB providing the remaining approximately $37 million. The proposed GNL will enhance national security through the development and evaluation of improved diagnostics, therapeutics, and vaccines for protection against diseases, including those that have the potential for bioterrorism. The proposed GNL will not conduct research to develop biological weapons.

The proposed GNL facility will be a new reinforced concrete seven-story building that will be constructed within the footprint of a recently demolished building on the UTMB campus. The proposed GNL, with a total net area of approximately 82,411 square feet, will house Biosafety Level (BSL)–4, BSL–3, and BSL–2 facilities, BSL–4 and BSL–3 animal facilities, 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 and minimize the risk of exposure.

The proposed GNL facility will be designed to safely support all of the superimposed loads applied to the building and to resist 140 mile-per-hour hurricane force winds. Also, as required by the National Earthquake Hazards Reduction Program, it will be designed and constructed to the highest building protection classification category of IV. Furthermore, the proposed GNL will be designed with regard to its location within a 100-year flood plain. For example, the BSL–4 laboratories will be located above the extreme 25-foot storm surge that might occur during a category 4 or 5 hurricane. In addition to standby generators to provide power in the event of a power outage, the proposed GNL facility will have a distributed on-line uninterruptible power supply module or a fuel cell power supply to power the BSL–4 biosafety cabinets, BSL–3 enhanced biosafety cabinets, critical building control panels and alarms.

In addition to designing for severe weather conditions, operating procedures will call for a lockdown of all infectious materials and decontamination of high-level biocontainment laboratories in the event of an approaching hurricane. Storm preparedness will be based on approximately 24-hour notice of probable landfall, taking into account the predicted strength of a storm. This allows sufficient time to close down high containment operations, should this be deemed necessary, including the management of animals.

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, automatic watering system pressure and flow, and the condition of high efficiency particulate air (HEPA) filters. Visual indications (such as pressure gauges) and audible or strobic alarms will alert GNL personnel to an emergency or a situation that requires corrective action. The proposed GNL will have fire protection systems that meet or exceed requirements specified by the National Fire Protection Association and all applicable local, State, Federal, and UTMB requirements.

The design of the proposed GNL 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 4th 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 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 HEPA filtration.

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 use positive pressure ventilation suits and will have dedicated supply and exhaust ventilation. A chemical shower will be provided to decontaminate the surface of the suit before a worker could 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 bioseal isolation dampers that will be ''bubble tight'' and will close in less than one second 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 proposed GNL 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 gauges and an audible alarm system 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 removal. Liquid waste from Enhanced BSL–3 laboratories will be sterilized in a biowaste cooker system before discharge.

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

Vehicular traffic to the proposed GNL facility will be controlled by the creation of a security perimeter that will include the existing surrounding buildings and constructed barriers that are outside of the 200-foot radius around the proposed GNL facility. Only two streets currently allow vehicular traffic within 200 feet of the proposed GNL site, and access to these sites will be controlled.

The main entrance to the security perimeter of the proposed facility will be located on The Strand and 11th Streets, in the northwest corner of the perimeter. A security booth will be constructed on The Strand and manned by UTMB Police Department personnel. Only authorized and inspected vehicles will be allowed to enter per acceptable protocol. Traffic control gate arms will be installed on either end of the booth and pop-up vehicle wedge barriers will be installed on the inbound and outbound lanes. A secondary entrance will be locked at all times and only will be used for fire department access in emergencies and for infrequent, large deliveries. Around the security perimeter, where space could allow four-wheeled vehicles to penetrate the 200-foot radius, high security walls or bollards will be constructed or boulders will be placed.

Access into the proposed GNL facility will be controlled by various measures. Employees will have to undergo background checks and their hand-carried items may be screened at anytime. Visitors will have to be cleared and escorted by an UTMB employee at all times. Visitor hand-carried items will be screened.

Exit only doors will be monitored and alarmed. Security hardware will be provided for manholes or hatches. Exterior utility and roof doors will be card access-controlled. Roof doors also will have an intercom station or emergency phone installed outside each door. Closed-circuit television (CCTV) cameras will monitor all exterior doors. Interior doors for building systems rooms and laboratories will be card access-controlled doors, as appropriate. BSL–2 labs will be card access-controlled. CCTV surveillance of entrances and emergency exits will be provided. BSL–3 and –4 labs will be controlled with card readers, pin code readers, plus biometric readers. CCTV surveillance of entrances and exits will be provided. CCTV coverage of internal lab spaces will be monitored by laboratory personnel within the containment laboratory for the monitoring of procedures and safety. Animal receiving areas will be card access controlled, and CCTV surveillance will be provided. Laboratories will be locked and accessible to authorized personnel only. CCTV cameras will monitor areas where biological agents are stored.

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 GNL). Previously, NIH examined nine sites and various facility designs. Applying screening criteria reduced the potential sites for detailed evaluation to three locations and three designs, one of which became the Proposed Action. The two other alternatives considered were a six-level building with a total of

208,300 gross square feet located elsewhere on the UTMB campus and a three-level building with a total of 207,000 gross square feet located off campus near the Primary Care Pavilion. These other sites and designs were considered technically inferior, provided no environmental advantage compared to the Proposed Action, and will 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 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 condition 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 assistance in the case of a national, state, or local disease outbreak or bioterrorism emergency. Locating a new national biocontainment laboratory on the UTMB campus takes advantage of UTMB's extensive expertise in biological medical research, its experience in operating BSL–2, –3 and –4 laboratories (only five other operational BSL–4 laboratories exist in the United States), and its infrastructure as a regional medical center.

UTMB is a complex of educational, medical, and research facilities, with 6 interconnected hospitals with over 809 hospital beds. There are over 2,000 students enrolled in UTMB's four schools: the School of Medicine, the Graduate School of Biomedical Sciences, the School of Nursing, and the School of Allied Health Sciences. UTMB provides nearly 400,000 square feet of space designed for research and houses one of the largest research libraries in the southwest. Instruction and research take place within 15 clinical and 6 basic science departments, in addition to interdisciplinary centers and programs within the School of Medicine.

UTMB researchers and clinicians have considerable specialized expertise in infectious diseases, including tropical and newly emerging viral diseases, as they have been conducting research on biodefense and emerging infectious diseases for more than 20 years. In particular, UTMB possesses distinctive research capabilities in emerging arthropod-borne and rodent-associated viruses. Scientists in other fields such as molecular virology, immunology, and structural biology, who contribute to the biomedical discovery of new drugs and treatments, will complement the expertise in infectious diseases present at UTMB.

In support of infectious disease research, UTMB has safely operated several large suites of BSL–3 and Animal BSL (ABSL) laboratories for several years. UTMB currently operates a suite of eight BSL–3 laboratories comprising a total of over 5,200 square feet and 2,400 square feet of ABSL–3 laboratories. UTMB also operates a 2,100-square foot BSL–4 facility. In addition, UTMB houses one of the most complete reference collections of bacteria, fungi, and viruses.

UTMB was the lead institution in organizing a consortium of over 20 universities, regional primate centers, and national laboratories that filed an application with the National Institute of Allergy and Infectious Diseases (NIAID) in January 2003 for funding as the Region VI Center of Excellence for Biodefense and Emerging Infectious Disease Research (RCE). NIAID awarded UTMB an RCE grant in September 2003. The RCE program's primary role is to foster the physical and intellectual environments in which wide-ranging research on infectious diseases can proceed productively and safely. NIH selected the proposed GNL site based on UTMB's ability to contribute to the overall NIAID biological defense research agenda. The No Action Alternative will result in the GNL not being built, and will impair the NIH's ability to counter the serious strategic national shortage of biological containment facilities.

Resources Impacts

The Final EIS describes potential environmental effects of the selected action. These potential effects are documented in Chapter 3 of the Final EIS. The GNL will result in insignificant impacts to the environment, human health, and the surrounding community. A larger impact will be to the UTMB community and its patrons with regard to restricted vehicular traffic near the proposed GNL. Adverse environmental effects are 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 Galveston from construction and operation of the proposed GNL.

Summary of Impacts

The following is a summary of potential impacts resulting from the Proposed 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 proposed GNL facility will have the potential to advance techniques in disease prevention, develop disease immunizations, and prepare defenses against bioweapons. Additionally, the local community will benefit from having world-class biomedical expertise available at the GNL facility on the UTMB campus.

Land Use

The proposed GNL facility will occupy approximately 1 acre and be constructed within the footprint of the recently demolished building. The total construction area will be 6.9 acres, including the plaza space within the 200-foot security perimeter as it will be reconstructed to include security walls, boulders, and bollards. The operation of the proposed GNL facility will be consistent with the current land use patterns on and within the immediate vicinity of the UTMB campus.

Geology, Soils, and Seismicity

Despite the historical record of low seismicity in the region, the risk for an earthquake exists in association with the Gulf Coast Normal Faults Region. To mitigate any potential damage from an earthquake, and as required by the National Earthquake Hazards Reduction Program, the proposed GNL facility will be designed and constructed to the highest building protection classification category of IV, which is required for all buildings that are classified as having essential facilities and that contain hazardous substances. There are no identified long-term effects to either geology or soils in the region from the proposed GNL facility.

Infrastructure

Construction and operation of the proposed GNL facility will include small increases in water, electricity, and

natural gas consumption, demand on sewage treatment and stormwater management systems, and steam and chilled water usage. These increases will not exceed the capacity of these services.

Transportation

During construction, some local vehicular and pedestrian traffic may be re-routed to avoid construction areas. Post construction, there will be no permanent closing, restriction, or re-routing of municipal streets or municipal traffic patterns. However, on the UTMB campus, The Strand and Ninth Streets within 200 feet of the proposed GNL facility will be closed to regular vehicular traffic. Transportation accidents involving micro-organisms are not expected to increase.

Human Health and Safety

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 has 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 and no documented case of a laboratory worker's family members or the public acquiring a disease from CDC laboratory operations.

UTMB has been conducting research on emerging infectious diseases and biodefense for more than two decades. Safety is a major concern in working with and preventing the spread of highly infectious disease agents. UTMB's safety record for its BSL–3 containment facilities from May 2002 to May 2004 indicate that there have been no non-animal related accidental exposures in any of the BSL–3 laboratories. There have been two animal bites but neither resulted in infection. Additionally, there have been no animal escapes from UTMB's biocontainment laboratories. Key UTMB scientists and support personnel have a combined experience of over 82 years in working with infectious diseases at the BSL4 level.

The proposed GNL could result in beneficial human health impacts. The proposed GNL facility will allow UTMB to become a leader in developing diagnostic tests, management strategies, and vaccines for a number of emerging viral diseases and potential biological weapons. The proposed GNL facility will also allow for the training of additional scientists for high level biocontainment conditions, provide a state-of-the-art telemedicine system, and increase the laboratory space available for conducting experiments.

Community Safety

A quantitative risk assessment using the Maximum Possible Risk model and anthrax as the worst-case scenario agent concluded that there will be no risk to the public from the accidental release of anthrax spores at the proposed GNL facility. Six risk scenarios, assuming the use of a powder-like preparation of purified *B. anthracis* containing $1x10^6$ spores, were run and the maximum number of spores released into the environment was calculated to be 120 spores per cubic meter of air (2,083 spores per cubic meter is needed to establish human infection). In all scenarios, there was no probability of harm to the public from an accidental release of anthrax spores due to the level of safety and redundancy incorporated into the design of the facility (*e.g.*, use of biosafety cabinets, HEPA filters, emergency backup power sources, and pressure monitoring devices and alarms).

Air Quality

Galveston County and the city of Galveston, including UTMB, lie within the Houston/Galveston Ozone Nonattainment Area, as designated by the Texas Commission on Environmental Quality and the Environmental Protection Agency (EPA), for both the 1-hour and 8-hour ozone standards. Concentrations of ozone exceeding the National Ambient Air Quality Standards (NAAQS) are attributed to industrial and vehicular emissions including emissions of volatile organic compounds and nitrogen oxide compounds (NO_X). Galveston County is in attainment of the NAAQS for all other criteria pollutants for which EPA has made attainment designations. During site preparation and construction, the use of heavy equipment, delivery vehicles, and construction workers' personal transportation will generate combustion engine exhaust containing air pollutants associated with fuel (*e.g.*, diesel). The amount of construction equipment and number of construction workers at the GNL site are anticipated to be small and of short duration, approximately 637 workers and a three year construction time. The quantities of air pollutants produced by vehicles and equipment associated with construction will be a minimal contribution to the total emissions from mobile sources already operating in the area. During normal operations of the proposed GNL facility, gaseous and particulate air contaminant emissions (including biological toxins, chemical agents, and hazardous air pollutants) generated will be prevented from escaping to the outdoor air through the use of engineering controls including a double HEPA-filtration system. Discharges from the facility are expected to be small and have minimal impact to NAAQS. Emergency generators will be added to existing generators in the Basic Science Building located immediately west of the proposed GNL facility. Emissions of regulated pollutants may increase and a permit review will need to be conducted and a possible modification to the permit needed.

Noise

During construction of the proposed GNL facility, there will be increased noise levels of 10 to 15 dB from the daytime ambient levels for approximately 80dB. However, this effect will be temporary and intermittent. During operation of the proposed GNL facility, a low level of noise will be generated, but this noise will be consistent with the operation of similar laboratory/academic facilities on the UTMB campus.

Waste Management

The waste and wastewater amounts estimated for the proposed GNL facility are small increments, 0.4%, above the volumes generated by the UTMB campus. The offsite treatment and disposal facilities that receive waste and wastewater from the UTMB campus have available capacity. The proposed GNL facility will be designed to treat the liquid biohazardous waste by chemical decontamination or sterilization. This waste will then be released into the building effluent treatment system where it will be sterilized, cooled, and then discharged into the sanitary sewer system. The solid waste that will be generated in the laboratories and animal areas will also be considered biohazardous. Solid waste from the BSL–2 laboratories will be placed into biohazard red bags for incineration or will be autoclaved and disposed of as solid waste. BSL–3 and -4 wastes will be sterilized in an autoclave then placed in boxes for incineration. UTMB has a protocol for disposal of all biohazardous waste from the existing BSL–4 laboratory. This same protocol will be applied to the biohazardous waste generated by the proposed GNL BSL–4 facilities.

Socioeconomics

The short-term economic benefits from construction of the proposed GNL facility will be temporary and diminish as the project reaches completion at the end of the 3-year construction period (2005–2008). Construction of the proposed GNL facility is estimated to employ more than 637 direct workers during peak construction and will generate additional employment in associated sectors in the Region of Influence (ROI) Galveston County. During construction, personal income will increase by more than $30 million, or about 0.4 percent over the baseline of $7.7 billion. Operation of the proposed GNL facility will commence in the year 2008 and will continue for at least 20 years. The proposed GNL facility workforce will consist of a mix of scientific and administrative staff, including students. Although a total resident population for the proposed GNL facility has not been established, it is estimated that the facility will generate about 270 new direct jobs. The proposed GNL facility will generate a total of 328 permanent jobs (direct, indirect, and induced) in the Region of Influence (ROI) of Galveston County. The majority of the indirect and induced jobs will be in the retail trade and services sectors. Given the small number of secondary jobs created by the Proposed Action relative to the regional economy, the available labor force in the ROI will likely be able to meet the increased demand for workers. Minor short-term benefits will be expected. Tax revenues will exceed $2.2 million. The majority of the tax revenue will derive from payroll taxes and will not remain in the ROI. Total additional business output will be about $14.7 million.

Environmental Justice

The selected action will result in minor positive changes to economic indicators, including personal income and employment. No health and environmental impacts are projected for any population within the ROI, including minority or low-income communities. Therefore, no environmental justice issues will be expected.

Cultural Resources

Construction activities for the proposed GNL facility will not have an impact on adjacent historical buildings. The proposed GNL facility will be one laboratory building located among many others and will have an exterior facade similar to the other UTMB campus buildings around it. Thus, the view of that portion of the campus from any historic properties will remain essentially as it is now. Most of the activities related to operation of the proposed GNL facility will occur within the facility. Those activities conducted outside will be similar to those already conducted in relation to the campus buildings in the vicinity. Thus, there will be no impact to historic properties or Recorded Texas Historical Landmarks from operations of the proposed GNL facility.

Ecological Resources

The proposed GNL facility will be located within the built environment in the heart of the UTMB campus. Vegetation consists of grasses, shrubs, and trees characteristic of a landscaped environment. Wildlife present are common species that have adapted to a landscaped and built environment bustling with human activity. There are no wetlands or natural aquatic environments within the UTMB campus. A review of U.S. Fish and Wildlife Service files indicated that no federally listed threatened or endangered species are likely to occur on the campus and the campus is not located within officially designated critical habitat.

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 GNL facility will be subject to the existing UTMB 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 revised and followed to appropriately address the construction and operation of the proposed GNL and comply with applicable regulatory and NIH requirements. No additional mitigation measures have been identified.

With regard to the restriction of vehicular traffic surrounding the proposed GNL facility, UTMB has taken steps to ensure continued patient access to the University Hospital Clinics (UHC) Building. The patient access and drop-off area (with a new covered walkway) has been relocated to the opposite side of the UHC Building.

Pollution Prevention

Pollution prevention measures are described in Chapter 2 of the FEIS and reflect standard spill prevention procedures. Additional pollution from the GNL 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

Use of heat reflective roofing material.

Monitoring and Enforcement Program for Mitigation Measures

During the preparation of the FEIS, several potential environmental issues associated with implementation of the Proposed Action were identified. The local community is concerned about transportation impacts including patient access to the University Hospital Clinics Building. To mitigate this impact to patients, a new patient access drop-off area with a covered walkway will be accessible on the opposite side of the Hospital. Non-ambulatory patient assistance will continue as usual.

Transportation of agents to and from the GNL is a concern for some. Strict rules and regulations govern how agents are packaged, labeled, handled, tracked, and transported. The risk to the surrounding community from the transport of biological material is as negligible as anywhere else along the transport path.

Emergency planning was raised as a concern. UTMB has an existing Institutional Emergency Operations Plan that is regularly reviewed and that will be updated before the GNL becomes operational. 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 proposed GNL 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 4th Edition 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 Proposed Action to partially fund the construction of a state-of the-art national biocontainment laboratory, which will be known as the Galveston National Laboratory (GNL), on the University of Texas Medical

Branch (UTMB) Campus in Galveston, Texas.

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 UTMB's extensive expertise in biological medical research, its experience in operating BSL–2, –3 and –4 laboratories (only five other operational BSL–4 laboratories exist in the United States), 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: March 29, 2005.

Leonard Taylor, Jr.,

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

[FR Doc. 05–7249 Filed 4–8–05; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Best Practices for the Licensing of Genomic Inventions: Final Notice

AGENCY: National Institutes of Health, Public Health Service, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: On November 19, 2004 the National Institutes of Health (NIH) published for public comment in the **Federal Register** proposed Best Practices for the Licensing of Genomic Inventions [69 FR 67747]. These Best Practices are recommendations to the intramural Public Health Service (PHS) technology transfer community as well as to PHS funding recipients. Comments on the proposed Best Practices were requested with a deadline of January 18, 2005. This Notice presents the NIH's final Best Practices for the Licensing of Genomic Inventions together with NIH's response to the public comments received.

FOR FURTHER INFORMATION CONTACT: Bonny Harbinger, Ph.D., J.D., NIH Office of Technology Transfer, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Fax: (301) 402–3257; E-mail: *harbingb@mail.nih.gov.*

SUPPLEMENTARY INFORMATION:

Background

NIH recognizes the importance of public involvement in the development of best practices and sought comment and participation by the biomedical research and development communities regarding the proposed Best Practices for the Licensing of Genomic Inventions (Best Practices). To this end, NIH sought comments from the public as well as grantees and academic, not-for-profit, and private sector participants in the biomedical research and development communities. In order to solicit comments from as many interested parties as possible, the draft was presented in various venues. In addition to the publication on November 19, 2004 in the **Federal Register**, the proposed Best Practices were made available on the NIH Office of Technology Transfer Web site and were highlighted in a variety of publications.

In response to the November 19, 2004 proposal, NIH received 12 letters, each of which contained one or more comments. Comments were received from an academic institution, scientific foundations, a biotechnology company, industry trade associations, professional societies, individual researchers, and other individual respondents.

Comments and Agency Response

The majority of comments generally supported the Best Practices and some expressly stated support for non-exclusively licensing of genomic inventions. Most requested further clarification about a variety of different issues. A general response to the comments is provided below.

Respondents criticized the singling out of this area of technology for special treatment as poor policy precedent. NIH disagrees with this representation. Genomic inventions have evoked special attention in the legal community as evidenced by various U.S. Patent and Trademark (USPTO) guidelines and court decisions directed to the criteria required to meet the non-obviousness, utility, and written description patentability standards for genomic inventions and discoveries. Similarly, the availability of genomic inventions for diagnostic testing and research purposes has been an area of active debate and controversy. As a major source of funding and research leading to the discovery of genomic inventions, NIH has an obligation to address these special issues to promote and advance the best possible balance between research availability and commercial development of these important technologies. In this regard, NIH considers the fundamental principles and concepts addressed by these Best Practices to be consistent with our grant recipients' responsibilities under the Bayh-Dole Act as well as our prior publications, including our Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources.

Respondents commented on the identification of these recommendations as ''best'' practices as opposed to ''good'' practices. The respondents reasoned that use of the term ''best practices'' would imply these recommendations would be viewed as mandates and auditable prescriptive regulation. One respondent indicated that these Best Practices would lead to an added burden for university technology transfer licensing offices, as grantees would feel compelled to document and justify reasons for any departures from them in individual licensing situations. In response, it is noted that the Best Practices document clearly and specifically articulates that the recommendations are not intended to constitute additional regulations, guidelines, or conditions of award for any contract or grant. These Best Practices create no new auditable regulation. While not imposing regulations or requirements on any licensing situation, it is generally the object of best practices to inform practicing professionals to a set of principles against which they should test their judgments in any particular fact situation. As such, best practices serve as an industry benchmark for the most current, innovative, and advanced practices. In this regard, as in all others, our grantees should expect no less than the best guidance possible from NIH.

A respondent criticized the proposed Best Practices document for not clearly defining genomic inventions. According to this respondent, the Best Practices document does not distinguish compositions of matter and diagnostic technologies from basic research tools. Consequently, this broad definition of basic genomic inventions undermines a company's ability to obtain an exclusive license to a composition of matter or a commercially viable diagnostic test. In response, it is noted that NIH intends the Best Practices to apply broadly to all genetic inventions. Contrary to respondent's conclusion, the proposed Best Practices document contemplates intellectual property and exclusive licensing to be appropriate for certain genomic inventions. The determination of when patent protection and exclusive licensing is necessary derives from the specific fact situation attendant the nature of the invention and its market;