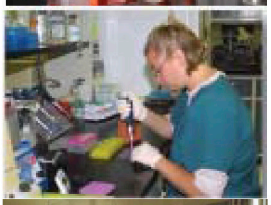
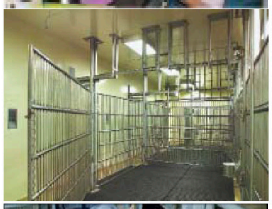
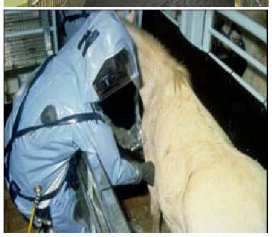
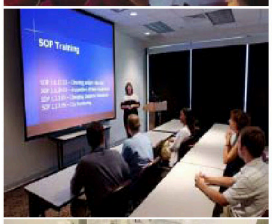
NATIONAL BIO AND AGRO-DEFENSE FACILITY

Science and Technology Directorate/Office of National Laboratories

US DEPARTMENT OF HOMELAND SECURITY NATIONAL BIO AND AGRO-DEFENSE FACILITY

APPENDIX A

FEDERAL REGISTER NOTICES

JUNE 2008

U.S. DEPARTMENT OF HOMELAND SECURITY

Notice of Intent

Dated: July 25, 2007.

Jennifer Spaeth

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–3725 Filed 7–30–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Molecular and Cellular Neuroscience.

Date: August 3, 2007.

Time: 2 p.m. to 3:30 p.m.

Agenda: To Review and Evaluate Grant Applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Jonathan K. Ivins, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4040A, MSC 7806, Bethesda, MD 20892, (301) 594–1245, *ivinsj@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting to the time limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893. National Institutes of Health, HHS).

Dated: July 24, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–3728 Filed 7–30–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HOMELAND SECURITY

Science and Technology Directorate; Notice of Intent To Prepare an Environmental Impact Statement

AGENCY: Science and Technology Directorate (Office of National Laboratories within the Office of Research), DHS.

ACTION: Notice of intent to prepare an Environmental Impact Statement for the National Bio and Agro-Defense Facility (NBAF).

SUMMARY: DHS announces its intent to prepare an Environmental Impact Statement (EIS) to evaluate reasonable siting alternatives for the construction and operation of the proposed NBAF. DHS invites individuals, organizations, and agencies to present oral or written comments concerning the scope of the EIS, including the environmental issues and alternatives that the EIS should address.

DATES: The public scoping period starts with the publication of this Notice in the **Federal Register** and will continue until September 27, 2007. DHS will consider all comments received, postmarked, or emailed by that date in defining the scope of the EIS. DHS also intends to hold public meetings during this comment period to provide the public with added opportunities to present comments, ask questions, and discuss concerns regarding the EIS with DHS officials.

All public meetings are listed in the **SUPPLEMENTARY INFORMATION** section.

DHS will publish additional notices regarding the dates, times, and locations of the public meetings in local newspapers in advance of the scheduled meetings. Any necessary changes will be announced in the local media and on the NBAF Web site (*http://www.dhs.gov/nbaf*).

ADDRESSES: Comments may be submitted by mail, online, fax, or voice mail:

U.S. Mail: Department of Homeland Security; Science and Technology Directorate; James V. Johnson; Mail Stop #2100; 245 Murray Lane SW., Building 410; Washington, DC 20528; Online: *http://www.dhs.gov/nbaf* (click on Public Involvement); Toll-free fax: 1–866–508-NBAF (6223); or Toll-free voice mail: 1–866–501–NBAF (6223).

Updates and other information will be posted to the NBAF EIS Web page at: *http://www.dhs.gov/nbaf.*

In addition to providing comments at the public meetings, all interested parties are invited to record their comments, ask questions concerning the EIS, or request to be placed on the EIS mailing or document distribution list by leaving a message on the EIS Hotline at (toll free) 1–866–501–NBAF (6223). The Hotline will have instructions on how to record comments and requests. Additional information on public participation opportunities is included in the **SUPPLEMENTARY INFORMATION** section.

All interested persons and organizations including minority, low income, disadvantaged, and Native American groups are urged to participate in this environmental impact review process. Assistance will be provided upon request to anyone with special needs to facilitate their participation in the process.

SUPPLEMENTARY INFORMATION: Consultations between DHS and the United States Department of Agriculture (USDA) on a coordinated biodefense strategy called for in Homeland Security Presidential Directives 9 and 10 have revealed a gap that must be filled by an integrated research, development, test and evaluation (RDT&E) infrastructure for combating bio and agro terrorism threats. DHS S&T is responsible for filling this gap in a safe, secure, and environmentally sound manner. The proposed NBAF is envisioned to provide the nation with the first integrated agricultural, zoonotic disease, and public health RDT&E facility with the capability to address threats from human pathogens, high consequence zoonotic disease agents, and foreign animal diseases.

DHS intends to select a single site for the construction of the NBAF. A competitive selection process to identify and evaluate potential candidate sites, other than Plum Island, for the NBAF was recently completed. This process was initiated by issuance of a notice of request for Expressions of Interest (EOI), on January 19, 2006 (71 **Federal Register** 3107–3109). DHS has determined that the following ''Site Alternatives'' are reasonable alternative sites for the construction of the NBAF:

Manhattan Campus Site Manhattan, Kansas: This alternative would locate the NBAF within what is identified as the Kansas City Health Corridor on the Kansas State University Campus.

South Milledge Avenue Site, Athens, Georgia: This alternative would locate the NBAF on the campus of the University of Georgia Whitehall Farm.

Texas Research Park Site, San Antonio, Texas: This alternative would locate the NBAF on the land of the Texas Research Park in San Antonio Texas.

Umstead Research Farm Site, Butner, North Carolina: This alternative would

locate the NBAF on the Umstead Research Farm site in Butner, North Carolina.

Flora Industrial Park Site, Flora, Mississippi: This alternative would locate the NBAF in Flora Industrial Park in Flora, Mississippi.

Although not included in the competitive selection process outlined above, the DHS-owned Plum Island Animal Disease Center (PIADC) will also be considered as a reasonable alternative.

Plum Island Site, Plum Island Animal Disease Center, Plum Island, New York: This alternative would locate the new NBAF on the same federally owned property as the existing PIADC.

Additionally, a No Action alternative will also be evaluated. Under the No Action Alternative, the NBAF would not be built and DHS would continue to use PIADC with necessary investments in facility upgrades, replacements, and repairs so that it could continue to operate at its current capability.

Additional alternatives may be identified during the public scoping process. DHS invites comments and suggestions on alternatives that should be considered. A preferred location for the construction of the NBAF has not been identified at this time.

DATES: The Public Meeting dates are:

1. Wednesday, August 22, 2007, from 7 p.m. to 10 p.m. Old Saybrook, CT Saybrook Point Inn, Two Bridge Street, Old Saybrook, CT 06475.

2. Thursday, August 23, 2007, from 7 p.m. to 10 p.m. Greenport, NY, Southold Town Hall, 53095 Main Road (Route 25), Greenport, NY 11971.

3. Tuesday, August 28, 2007, from 7 p.m. to 10 p.m. Manhattan, KS, Kansas State University, K-State Student Union, Manhattan, KS 66505.

4. Thursday, August 30, 2007, from 7 p.m. to 10 p.m. Flora, MS, First Baptist Church, Christian Life Center, 121 Center Street, Flora, MS 39071.

5. Thursday, September 6, 2007, from 1:30 p.m. to 4:30 p.m. Washington, DC, Grand Hyatt Washington, 1000 H Street NW, Washington, DC 20001.

6. Tuesday, September 11, 2007, from 7 p.m. to 10 p.m. San Antonio, TX, Marriott Plaza San Antonio, 555 South Alamo Street, San Antonio, TX 78205.

7. Tuesday, September 18, 2007, from 7 p.m. to 10 p.m. Creedmoor, NC, South Granville High School, 701 North Crescent Drive, Creedmoor, NC 27522.

8. Thursday, September 20, 2007, from 7 p.m. to 10 p.m. Athens, GA, The University of Georgia, Center for Continuing Education, 1197 South Lumpkin Street, Athens, GA 30602.

Onsite registration and sign-up to present oral comments will be available at 6 p.m. for all meetings (12:30 p.m. for the Washington, DC meeting).

Preliminary Identification of Environmental Issues: The following issues have been tentatively identified for analysis in the EIS. DHS invites suggestions for the addition or deletion of items on this list:

- Land-use plans, policies, and controls;
- Visual resources;
- Air quality;
- Acoustic (noise) environment;
- Geology and soil characteristics;
- Water resources, including surface and groundwater, floodplains and wetlands, and water use and quality;
- Plants and animals, and their habitats, including Federally-listed threatened or endangered species and their critical habitats, wetlands and floodplains;
- Cultural resources, including historic and prehistoric resources and traditional cultural properties encompassing Native American or culturally important sites;
- Human health and safety (involving both members of the public and laboratory workers);
- Socioeconomic effects that may be related to the new construction and facility operations;
- Public infrastructure, including utilities and local transportation;
- Waste management practices and activities including the handling, collection, treatment, and disposal of research wastes; and
- Compliance with all applicable federal, tribal, state, and local statutes and regulations and with international agreements, and required environmental permits, consultations and notifications.

The list of issues discussed above for consideration in the NBAF EIS is preliminary and is intended to facilitate public comment. It is not intended to be all-inclusive, nor does it imply any predetermination or relative importance of potential impacts. During the process of preparing the EIS, DHS will evaluate the potential environmental and human health impacts of the alternatives, together with engineering and socioeconomic considerations. The NBAF EIS will present the results of this environmental impact evaluation process.

DHS anticipates that certain classified or otherwise protected information will be consulted in the preparation of this EIS and used by decision-makers to decide where and how to relocate the NBAF. To the extent allowable, the EIS will summarize and present this information in a publicly releasable form.

EIS Preparation and Public Participation Process: The process for preparing the NBAF EIS begins with the publication of this Notice of Intent in the **Federal Register**. After the close of the public scoping period, DHS will begin the environmental impact evaluation process. DHS expects to issue a draft NBAF EIS for public review in the spring of 2008. Public comments on the draft will be accepted during a comment period of at least 60 days following its publication. DHS will consider the public comments received on the draft EIS, perform further environmental impact evaluation if needed, and expects to publish a final NBAF EIS during fall 2008. No sooner than 30 days after publication of the Notice of Availability of the final NBAF EIS in the **Federal Register**, DHS will issue its Record of Decision and publish it in the **Federal Register**. In addition to the **Federal Register**, the Notices of Availability for the draft EIS, final EIS, and EIS Record of Decision will be provided through direct mail and other media.

Authority: 42 U.S.C. 4321–4347 (National Environmental Policy Act).

Dated: July 30, 2007.

Jay M. Cohen,

Under Secretary, Science & Technology.

[FR Doc. E7–14692 Filed 7–30–07; 8:45 am]

BILLING CODE 4410–10–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2007–27923]

Collection of Information Under Review by Office of Management and Budget: OMB Control Numbers: 1625–0019, 1625–0062, 1625–0082, and 1625–0092

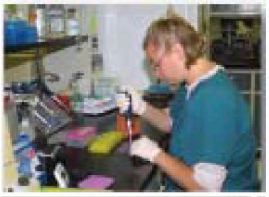
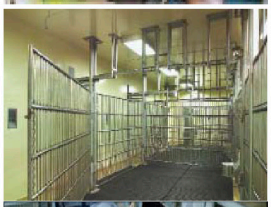
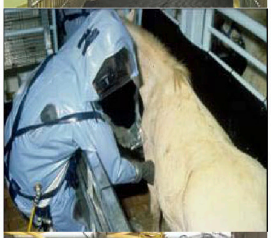
AGENCY: Coast Guard, DHS.

ACTION: Request for Comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, this request for comments announces that the Coast Guard is forwarding four Information Collection Requests (ICRs), abstracted below, to the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB) requesting an extension of their approval for the following collections of information: (1) 1625–0019, Alternative Compliance for International and Inland Navigation Rules—33 CFR Parts 81 and 89; (2) 1625–0062, Approval of Alterations to Marine Portable Tanks; Approval of Non-Specification Portable Tanks; (3) 1625–0082, Navigation Safety

NATIONAL BIO AND AGRO-DEFENSE FACILITY

Science and Technology Directorate/Office of National Laboratories


US DEPARTMENT OF HOMELAND SECURITY NATIONAL BIO AND AGRO-DEFENSE FACILITY

APPENDIX B

BIOCONTAINMENT LAPSES AND LABORATORY ACQUIRED INFECTIONS

JUNE 2008

U.S. DEPARTMENT OF HOMELAND SECURITY

Note: *This appendix is provided as a general indicator of the safety experiences at biocontainment level 3 and 4 laboratories. It reflects experience in research and clinical laboratories throughout the world with a broad range of microbes. Very few of the microbes discussed will be studied at the National Bio and Agro-Defense Facility (NBAF). United States (U.S.) Department of Homeland Security and U.S. Department of Agriculture have identified several disease agents that potentially would be studied at the NBAF. These agents are foot and mouth disease viruses, Rift Valley fever virus, Nipah virus, Hendrah virus, classical swine fever virus, African swine fever virus, Japanese encephalitis virus, and Mycoplasma mycoides. The NBAF will be designed specifically to mitigate risks involved in working with these pathogens as described in Chapter 2 and Chapter 3 of the NBAF Environmental Impact Statement. The NBAF research mission would be based on current pathogen and disease risk assessments, subject to change as threat and risk assessments change.*

A REVIEW OF BIOCONTAINMENT LAPSES AND LABORATORY-ACQUIRED INFECTIONS

B.1 GENERAL HISTORY OF LABORATORY-ACQUIRED INFECTIONS

Accounts of laboratory-acquired infections (LAI) appear in the literature as distantly as the late 19th century (Harding and Byers 2000). State policies have varied widely with regard to the requirements for reporting LAI, and until the advent of the Select Agent Program in 2002, there was no federal requirement. As a result, the collected data have necessarily been incomplete (Schell 2006; CDC and NIH 1999). Also, it has been suggested that these reports might under-represent the true number of LAI because they do not account for subclinical (asymptomatic) infections. Collection of accurate data regarding LAI continues to be "hampered by an indifference to and, frequently, an unwillingness to report these incidents" in part "due to fear of reprisal and the stigma associated with such events" (Harding and Byers 2000; Harding and Byers 2006). Recent Congressional testimony has suggested that a no-fault reporting system for biocontainment failures, similar to that used by the Federal Aviation Administration, could be beneficial (U.S. House of Representatives 2007). The potential advantage of such an approach is two-fold. First, incidents could be reported without fear of penalty or stigma. Second, root cause analysis of failures often will demonstrate common factors that, when identified and shared, can be used to reduce the likelihood of similar events in the future.

It is significant that LAI have not been shown to be a threat to the community at large. Experience with 109 LAI at the Centers for Disease Control and Prevention (CDC), United States (U.S.) Department of Health and Human Services (USDHHS), between 1947 and 1973 showed that no secondary infections occurred among family or community members (CDC and NIH 1999). The National Animal Disease Center (NADC), Agriculture Research Service (ARS), U.S. Department of Agriculture (USDA) (Ames, Iowa), similarly found no secondary infections associated with 18 LAI at their institution between 1960 and 1975. Two secondary infections were reported between 1975 and 1999, and these involved agents (smallpox virus and monkey B virus) that required biosafety and biocontainment precautions in excess of biosafety level-3 (BSL-3) (CDC and NIH 1999).

Comparison of the recent literature with previous reports suggests that the number of LAI is generally decreasing (CDC and NIH 2007; Harding and Byers 2000; Harding and Byers 2006). However, there has been an increase in LAI with *Neisseria meningitidis* (often fatal), and there is some evidence to suggest that the number of viral and parasitic LAI is not decreasing (Harding and Byers 2006). Although it is not possible to conclude with certainty that the apparent overall decrease in LAI has been real, it has been suggested that, from this point forward, an overall decrease in LAI can be expected (CDC and NIH 2007; Harding and Byers 2000; Harding and Byers 2006). This expectation, even during an era of accelerated construction of biocontainment facilities, is based on progress that has been made in the design of safety equipment and laboratory facilities, safer work practices, and refinement and implementation of biosafety programs. An

additional safeguard was published in 1976 and reiterated in 1994 when the National Institutes of Health (NIH) initiated a requirement that an Institutional Biosafety Committee (IBC) be established for any NIH-funded entity that conducts research with genetically recombinant material.

B.2 NIH/CDC'S NATIONAL GUIDELINES

Primary and secondary biocontainment barriers were established by the NIH and the CDC, who first promulgated national guidelines for safe work with a broad range of infectious microorganisms in 1980. Four levels of increasing physical biocontainment and work practices were designated for pathogens with differing virulence for humans, different relative risks of infection from aerosols induced by laboratory manipulation, and different availabilities of vaccines or therapies. BSL-4 is assigned to microorganisms posing a high individual risk of life-threatening disease by infectious aerosols and for which no treatment is available. Examples include Nipah and Hendra viruses. BSL-3 is assigned to microorganisms having a potential for respiratory transmission and which can cause a serious and potentially lethal infection. Examples include *Mycobacterium tuberculosis* and West Nile virus (WNV). For such agents, all procedures must be carried out in biosafety cabinets (BSCs) fitted with high-efficiency particulate air (HEPA) filters. Centrifuges require sealed rotors or cups that ensure that if a tube breaks during operation, the contents will be contained until the rotor or cups are opened inside the BSC.

In addition to pathogens known to be aerosol-transmitted, microbiological science continues to confront newly discovered viruses and bacteria for which aerosol infectivity is uncertain. The National Institute of Allergy and Infectious Diseases (NIAID) has adopted a policy for such microorganisms that stipulates BSL-3 equipment and practices in BSL-2 laboratories with negative pressure.

B.3 REVIEW OF BIOSAFETY AT THE NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES: 1982–2003

A review was undertaken in 2003 in which researchers were interviewed regarding laboratory conditions and practices. This review was limited to work done during the past two decades by scientists at intramural laboratories of NIAID located on the Bethesda campus, at a neighboring facility in Rockville, Maryland, and at the Institute's Rocky Mountain Laboratories (RML) in Hamilton, Montana.

Senior scientists were interviewed to ascertain pathogens studied, the variety of research programs that evolved over two decades, animals employed – if any, laboratory space, daily number of workers in the laboratories, and specific histories of laboratory accidents and consequences. Problems with function of facilities also were solicited and recorded.

Independent records of reported laboratory accidents that might expose workers to infection were reviewed. During those 21 years, all such accidents were to be reported quickly to the NIH Occupational Medical Service (OMS) for epidemiological and medical evaluation, as well as immediate prophylactic treatment if indicated. Invasive wounds received in course of laboratory work and clinical care of persons with chronic human immunodeficiency virus (HIV) infection are of continuing concern. The OMS is now able to provide antiviral therapy within 2 hours of an accident on a 7 day/24 hour basis when circumstances indicate the need for therapy.

Intake records of all accidents on the NIH campus were initially paper documents. Copies were forwarded to the Occupational Safety and Health Branch (OSHB) in the Director's office to follow up circumstances of an accident and for remedial action, when indicated. In addition to such immediate reaction to accidents and facility emergencies, the OSHB has developed standardized protocols for periodic review of all laboratories for compliance with NIH safety practices. Laboratories at BSL-3 level are reviewed at 6-month intervals; all others are done annually. For the past decade, all records are computerized and electronic copies go from OMS to OSHB instantly. Records for this 21-year interval were cross-checked for details by staff of both

offices, together with specific scientist memory, in constructing the biosafety record for NIAID since 1982. Records for the RML were reviewed with biosafety and scientific staff at that facility.

The detailed report is organized by laboratory within the NIAID Division of Intramural Research. Pathogens, research agendas, biocontainment levels, animal use, location, and space for laboratories are presented in tabular form, together with histories of laboratory accidents and of facility problems that have affected work in those laboratories. By any measure, the safety record at intramural NIAID laboratories, where work is done with the Institute's most pathogenic agents, is outstanding. No pathogen has escaped from any laboratory to cause infection in adjacent civilian communities. Indeed, this record stretches to almost 70 years at RML where several agents now on the national Select Agent List have been studied for decades.

If one takes the number of 8-hour person-days estimated by senior research staff during direct conversations and translates these into 2,000 person-hours per year in exposure to microbial organisms, impressive numbers of safe operation emerge as shown in Table B.3-1. Similar reviews were undertaken for experience with BSL-4 level pathogens from 1972 to 2003 at three agencies: U.S. Army Medical Research Institute for Infectious Diseases (USAMRIID), CDC Special Pathogens Branch, and National Institute for Communicable Diseases, which is a branch of the South Africa National Health Laboratory Service (NICD). Results are shown in Table B.3-2.

During the 1970s and 1980s, biocontainment procedures were developed to assure the safety of personnel and the environment from the biological materials being handled. The development of standardized laboratory practices, equipment, and facility design was established in 1984 with the publication of the *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) by CDC and NIH. It is an evolving guidance document that has become a mandatory compliance requirement for biomedical and clinical laboratories. The BMBL specifies laboratory practices, biosafety equipment, and facility design requirements for each biosafety level that is necessary to maintain biocontainment of biological materials, for the safety of the workers, the public, and the environment. Table B.3-1 summarizes LAIs under past practices and work conditions. The data reference partial BSL-2 and BSL-3 facilities, which refers to the application of biosafety practices, microbiological techniques, and/or equipment to augment biocontainment; nevertheless, the addition of such measures does not meet the requirements for achieving the next level of biocontainment. The partial (P) designation precedes the BMBL and is no longer recognized as an authorized work environment for work with biological materials. The term "partial" refers to the absence of single-pass directional air flow through a HEPA filter within the laboratory. In partial laboratories, all bench work was conducted within a BSC, which incorporated HEPA filtration within the BSC before air was exhausted from the BSC to the facility heating, ventilation, and air conditioning system. BSL-2 and BSL-3 ventilation requirements have become more stringent since 2003.

Table B.3-1 — Personnel Hours Worked and Outcomes of Accidental Exposures to Infectious Agents: Intramural NIAID 1982–2003

Hours at Risk			
	Bench	Animal	Total
BSL-3	553,000	81,500	634,500
BSL-2/3 P[a]	2,235,500	360,200	2,555,200
Total	2,788,500	441,700	3,189,700

Outcomes of Accidental Exposures			
	Clinical Infections	Silent Infections	Other Exposures, No Infections
BSL-3	1	2	9
BSL-2/3 P[a]	0	2	15
Total	1	4	24

[a]P refers to partial, which was used in past practices preceding BMBL requirements. Partial laboratory status refers to the absence of single-pass directional air flow through a HEPA filter within the laboratory; however, all bench work was conducted within a BSC, which incorporated HEPA filtration within the BSC before air was exhausted from the BSC to the facility heating, ventilation, and air conditioning system.

One clinical infection without secondary consequences and four silent infections in more than 3 million hours of exposure is a remarkable record, especially when continuous exposure of personnel to fluids containing HIV virus over many years is a significant part of that record. Indeed, only a single instance was considered worthy of immediate prophylaxis for that agent, and no infection occurred.

Table B.3-2 — Personnel Hours Worked and Outcomes of Accidental Exposures to BSL-4 Agents: 1972–2003

	Hours at Risk	Incidents	Infections
USAMRIID	343,980	2	0
CDC Special Pathogens	120,560	2	0
NICD	40,000	2	0
Total	504,540	6	0

B.4 RECENT LABORATORY-ACQUIRED INFECTIONS AND OTHER NOTABLE BIOCONTAINMENT PROTOCOL LAPSES

Tables B.4-1, B.4-2, and B.4-3 present recent reviews of international and domestic incidents regarding human health that are pertinent to the biosafety experience of laboratories of various biocontainment levels. Particular attention is given to LAI. Biocontainment failures and other protocol lapses that did not result in a LAI are included for certain cases that may have posed potential risk to workers and/or the community. It is important to note that federal requirements for reporting such incidents are limited to agents specified by the Select Agent Program. Therefore, incidents involving other serious agents of disease may be incompletely represented in the tables.

Table B.4-4 reviews laboratory-related outbreaks from livestock pathogens that require high biocontainment precautions during experimental research. A special category of biocontainment precautions has been delineated for research involving experimentally infected animals that are too large to be kept in individual biocontainment enclosures. Such animals include cattle, pigs, and horses. In such cases, primary biocontainment of the pathogen is provided by the room itself through an elaborate set of biocontainment design features. This level of biocontainment is classified as BSL-3Ag. The BSL-3Ag facility can be a separate building, but more often it is an isolated zone contained within a facility operating at a lower biosafety level, usually BSL-3.

The following tables are designed to show that working with certain biohazards, especially those that can infect via the respiratory route, carries significant risks and that all safety equipment and facility protocols

should be taken seriously and followed at all times to minimize the chances of contracting and spreading infections. In October 2007, the CDC released to Congress a compilation of 111 incidents involving materials covered by the Select Agent Program (U.S. House of Representatives 2007). Not all of those incidents are included in the tables.

Table B.4-1 — Recent Incidents of International BSL-3 and BSL-4 Laboratory-Acquired Infections

Location	Date	Research Agent(s)	Description	Result	Actions
The National Institute of Virology in Beijing, China	February and April 2004	Severe acute respiratory syndrome corona virus (SARS-CoV)	Two researchers working with SARS were sickened and diagnosed with the disease 2 weeks apart in April. The identity of these infections was not recognized until the mother of one of the workers sickened as well.	The mother died, and six other persons in contact with the two individuals became infected.	An intense lab investigation revealed that two other workers had experienced SARS-compatible illnesses in Feb. 2004 and were found to have the antibodies of the etiologic SARS-CoV.
Vector Laboratory, in Novosibirsk, Russia	May 19, 2004	Ebola virus (BSL-4)	A researcher several days earlier had suffered an accidental finger stick with a hypodermic needle that contained the Zaire strain of Ebola virus. She was working with a guinea pig model of the infection at the time.	The researcher died from Ebola infection on May 19.	No information available.
The National Defense University in Taipei, Taiwan	December 10, 2003	SARS-CoV	On Dec. 6, 2003, a senior research scientist working with SARS in a Class III BSC cleaned up waste fluid that leaked from a tightly docked transfer chamber connected to the main cabinet. From the main cabinet, he sprayed alcohol into the chamber, waited 10 min, opened the chamber to spray more, and finally physically cleaned it up. The next day he attended a SARS meeting in Singapore.	On Dec. 10, 2003, he noted fever and fatigue, which progressed into a dry cough and severe myalgia. He was hospitalized Dec. 16 and experienced moderately severe clinical illness.	Contacts, especially plane passengers, were monitored or quarantined; no secondary infections occurred. An investigation of the lab revealed that SARS-CoV nucleic acid was on the handle of an alcohol bottle in the transfer chamber and on the light switch in the Class II cabinet
A BSL-3 lab at an Institute in Singapore	August 26, 2003	West Nile virus (WNV) SARS-CoV	A graduate student working on a virulent recent New York strain of WNV became sick with fever and myalgia after making several passages of the new virus in Vero E6 cells also used to grow SARS-CoV. The student had minimal training and help from an institute technician.	On Sept. 3, he was admitted to the hospital with a dry cough and signs of pulmonary inflammation. He was transferred to isolation and developed a moderately severe evolution of the disease. The technician was not infected.	Surveillance and quarantine was maintained on several dozen contacts, but no secondary infections occurred. An investigation of the lab proved that the WNV was contaminated with the SARS-CoV.
Vector Laboratory, in Novosibirsk, Russia	1988	Marburg virus (BSL-4)	Two workers were infected in 1988 with no further details available. It is not clear whether the two infections occurred at the same time.	One of the infections was fatal.	No information available.

Source: Lim et al. 2004; Lingappa et al. 2004; Normile 2004; ProMed 2004a.

Table B.4-2 — United States: Recent Incidents of BSL-4 Incidents

Location	Date	Research Agent	Description	Results	Action
University of Wisconsin-Madison	July 28, 2006	Ebola virus	The Madison Institutional Biosafety Committee sought NIH guidance on whether work they had been conducting during the past year on full-length cDNA made from the Ebola virus RNA genome could be continued under BSL-2 rather than BSL-3 biocontainment.	NIH advised that all work during the 2005-2006 period should have been conducted under BSL-4 biocontainment as specified under Section III-D-2 of NIH guidelines for Research Involving Recombinant DNA Molecules.	The research was halted at Madison and moved to the National Microbiology Laboratory, Winnipeg, Canada, which is a BSL-4 biocontainment facility.
Ft. Detrick, MD	February 10, 2004	Ebola virus	U.S. Army officials reported that a civilian scientist accidentally grazed her hand with a hypodermic needle while injecting mice that had been infected 2 days earlier with an attenuated strain of Ebola virus. The report does not specify the contents of the syringe and needle, but a February 19 report by CNN specified that the needle contained the virus.	The scientist was sequestered in the biocontainment care suite until it could be concluded that no infection ensued.	No further information.

Source: Associated Press 2006; ProMed 2004a; ProMed 2004b; CNN 2004; NIH Correspondence 2006.

Table B.4-3 — United States: Recent Incidents of BSL-3 Laboratory-Acquired Infections, Accidents, or Notable Protocol Lapses

Location	Date	Research Agent	Description	Results	Action
University of Mississippi Medical Center, Jackson, MS	August 11, 2007	*Bacillus anthracis* (anthrax)	A graduate student accidentally broke a flask containing *Bacillus anthracis* cells.	The student was exposed to *Bacillus anthracis*.	Procedures for spill containment and decontamination were followed. The student received prophylactic antibacterial therapy.
University of Texas Houston Health Science Center, Houston, TX	May 7, 2007	*Bacillus anthracis* (anthrax)	Tube leakage occurred inside a centrifuge used for concentration of *Bacillus anthracis* cells.	Four people apparently were exposed to *Bacillus anthracis*.	Prophylaxis was refused. No infections resulted. Procedures were modified to require that centrifuge buckets be opened only within a BSC and inspected and decontaminated after each use.
Texas A & M University (TAMU), College Station, TX	December 21, 2006	*Coxiella burnetii* (Q Fever)	A mouse infected with *Coxiella burnetii* was found to be unaccounted for and was believed to be missing.	A report to CDC was filed on Dec. 22.	The discrepancy never was resolved.
University of Texas at Austin, TX	April 2006	Recombinant Influenza A H3N2 virus, containing genes from strain H5N1 (bird flu)	A centrifuge secondary container lid broke during centrifugation of virus, causing the rotor to become unbalanced. The researcher noted loss of volume in one viral tube and, suspecting viral leakage, undertook decontamination of centrifuge, centrifuge tube, work area, adjacent equipment, and himself.	A decision was made to treat the researcher empirically using Tamiflu. Secondary decontamination of lab room was undertaken the following day.	Responsible officials maintain that it is unclear whether a leakage of virus occurred. However, their records show that proper decontamination protocol was not followed for the suspected leak.

Table B.4-3 — United States: Recent Incidents of BSL-3 Laboratory-Acquired Infections, Accidents, or Notable Protocol Lapses (Continued)

Location	Date	Research Agent	Description	Results	Action
TAMU, College Station, TX	April 2006	*Coxiella burnetii* (Q Fever)	Previously undiagnosed exposures to *C. burnetii* are diagnosed in three lab workers by serologic testing.	Responsible officials did not report these infections to federal authorities as required by federal law.	CDC issued a cease and desist order to TAMU on April 20, 2007, which was expanded on June 30 to include work with all Select Agents. Other serious violations were found during a site visit inspection in July 2007.
TAMU, College Station, TX	February 2006	*Brucella* species	A researcher contracted undiagnosed *brucellosis* during improper disinfection of aerosolization chamber. She later required prolonged administration of intravenous and oral antibiotics.	Responsible officials did not report this infection to federal authorities as required by federal law.	CDC issued a cease and desist order to TAMU on April 20, 2007, which was expanded on June 30 to include work with all Select Agents. Other serious violations were found during a site visit inspection in July 2007.
Yeshiva University, New York, NY	December 2005	*Mycobacterium tuberculosis*	Two lab workers converted to skin test–positive status, indicating an infection with *M. tuberculosis*. One of these worked in both the BSL-2 and BSL-3 labs, whereas the second worked only in the BSL-2 lab.	Infections were sub-clinical. Prophylactic antibiotic treatment was administered.	All other workers were given tuberculosis (TB) skin tests. Neither of the two positive employees worked with the TB aerosolization animal chamber. No accidents had occurred in the labs.
Lawrence Livermore National Laboratory (LLNL), Livermore, CA	September 2005	*Bacillus anthracis* (Anthrax)	A total of 1,025 vials were shipped to a Palm Beach, FL, laboratory. Two of the vials were missing caps, and a third vial had a loosened cap. A subsequent shipment to a second laboratory contained an incorrect number of vials.	Two workers possibly were exposed to *Bacillus anthracis*.	The workers were prophylactically treated with antibiotics. LLNL was fined $450,000 for the violations.

Table B.4-3 — United States: Recent Incidents of BSL-3 Laboratory-Acquired Infections, Accidents, or Notable Protocol Lapses (Continued)

Location	Date	Research Agent	Description	Results	Action
University of Medicine and Dentistry, NJ	September 2005	*Yersinia pestis* (bubonic plague)	Three mice experimentally infected with *Yersinia pestis* went missing from a containment lab.	No one was infected by the mice. If they had escaped, there would have been no public threat according to spokesmen.	An investigation by the CDC and FBI ruled out theft and concluded that lab error, mouse cannibalism, and unauthorized removal all are possibilities.
Medical University of Ohio, OH	2005	*Coccidioides immitis* (Valley Fever)	A potential aerosol exposure of a student was reported.	Medical evaluation was provided.	The BSL-3 facility director, who was in charge of the *C. immitis* research, resigned as Director and was replaced both as Animal and Biosafety Protocol Principal Investigator and as advisor to the students (see 2004 *C. immitis* incident elsewhere in this table).
University of Chicago, Chicago, IL	July/August 2005	Select agent, not further specified	Percutaneous trauma from an instrument (presumably a hypodermic syringe) that had been used on an infected animal.	Possible infection with select agent.	Medical personnel administered antibiotic prophylaxis. Laboratory procedures were reviewed and revised as needed.
The University of North Carolina at Chapel Hill, Chapel Hill, NC	March 19, 2005	*Mycobacterium tuberculosis* (tuberculosis) (recombinant)	An exhaust fan servicing two BSCs and the general laboratory space failed. Audible alarms on the cabinets and air pressure monitors had been turned off.	Loss of primary and secondary biocontainment occurred.	A review of all BSL-3 laboratories was scheduled to identify renovation needs in order to ensure compliance with current design standards.

Table B.4-3 — United States: Recent Incidents of BSL-3 Laboratory-Acquired Infections, Accidents, or Notable Protocol Lapses (Continued)

Location	Date	Research Agent	Description	Results	Action
Cincinnati, OH	October 2004	Non-Contemporary Human Influenza (H2N2)	H2N2 from the 1957-1958 flu pandemic was accidentally distributed to 2,750 labs in the U.S., along with 3,747 labs in 18 different countries, by the College of American Pathologists (CAP). The error was discovered in March by a participating lab in Canada. This virus requires Enhanced BSL-3 biocontainment precautions.	CAP was requested by the U.S. government to notify all participating labs to destroy the virus, to investigate, and to report to national health authorities any respiratory infection in lab workers.	CAP sent out notifications on April 8 and 12, 2004. No infections were reported as of April 12, 2005.
University of Illinois at Chicago, Chicago, IL	September 2004	Not specified (redacted by IBC)	Both doors of the double-door biocontainment entryway were propped open by laboratory staff while experiments were in progress.	Infectious materials were not being handled at the time.	Principal Investigator was counseled and warned. Staff was retrained and tested.
NIH, Bethesda, MD	July/August 2004	Various	A waste treatment tank steam valve failed, resulting in severe damage to the maximum biocontainment laboratory. The NIH OSHB had been previously informed about problems with the valve but elected to defer repairs.	No exposures resulted.	The building was closed for repairs and renovation.
Oakland, CA	June 11, 2004	*Bacillus anthracis* (anthrax)	Children's Hospital and Research Center Southern Research Institute sent live, rather than dead, anthrax samples to researchers in Oakland. The problem was detected after 49 of the 50 research mice quickly died after inoculation with the samples.	Seven scientists were exposed but not infected.	No human infections were reported.

Table B.4-3 — United States: Recent Incidents of BSL-3 Laboratory-Acquired Infections, Accidents, or Notable Protocol Lapses (Continued)

Location	Date	Research Agent	Description	Results	Action
Boston University Boston, MA	May and September, 2004	*Francisella tularensis* (Rabbit Fever)	Researchers were performing an experiment that called for a non-infectious form of the bacterium.	Two researchers became infected with *Francisella tularensis* in May and were not correctly diagnosed until a third scientist became infected with the bacterium in September.	An investigation revealed that researchers unknowingly used a mixed culture that contained both a non-virulent and a virulent strain. It also found that the researchers failed to follow proper biocontainment protocol.
Medical University of Ohio, OH	2004	*Coccidioides immitis* (Valley Fever)	An infection, possibly laboratory acquired, was diagnosed. However, the employee previously resided in an endemic area and previously had worked with *C. immitis* in another laboratory. Therefore, it could not be proven when and how the infection began.	The infected employee was provided with medical treatment and re-assigned to other duties.	Safety policies were revised, video surveillance was installed, serologic monitoring of staff was reviewed (see 2005 *C. immitis* incident elsewhere in this table).
Infectious Disease Research, Inc., Seattle, WA	Late 2003 – March 2004	*Mycobacterium tuberculosis* (Tuberculosis)	Three researchers became skin test–positive for tuberculosis after using a newly acquired aerosolization chamber for experimental infection of animals.	Infections were sub-clinical. Prophylactic treatment typically is employed in such cases.	Investigation revealed multiple faulty seals in the device and that researchers were not fully familiar with proper operation of the device.
Columbus, OH	March 1, 2003	WNV, genus *Flavivirus*	An improperly packaged shipment containing dry ice burst. The package was carrying frozen infected bird tissue.	Workers at a Federal Express shipping building were potentially exposed.	Authorities characterized the risk of infection as low.
University of New Mexico, Albuquerque, NM	2003	Redacted by IBC; likely was *Bacillus anthracis* (Anthrax)	Puncture of thumb with hypodermic needle harboring spores to be used in mouse infections.	Worker received prophylactic treatment; no infection resulted.	It was proposed that alternative methods for mouse inoculation be considered.

Table B.4-3 — United States: Recent Incidents of BSL-3 Laboratory-Acquired Infections, Accidents, or Notable Protocol Lapses (Continued)

Location	Date	Research Agent	Description	Results	Action
U.S.	October 2002	WNV, genus *Flavivirus*	A microbiologist working under BSL-3 conditions suffered a finger puncture from a hypodermic needle harboring WNV that was being harvested from infected mouse brain.	The wound was cleansed and bandaged. Serologic testing showed evidence of acute WNV infection. Mild symptoms developed and resolved.	CDC determined that applicable handling and biocontainment protocols were followed.
Fort Detrick, MD	April 20, 2002 April 1, 2002	*Bacillus anthracis* (Anthrax)	A researcher tested positive for exposure to anthrax spores, which were also released into a locker room and adjacent hallway. U.S. Army officials reported evidence of a second accidental release of anthrax spores.	No one was infected in either incident.	The first incident involved a virulent strain. Test samples connected with the second incident tested positive for the attenuated (vaccine) strain.
Texas	March 2002	*Bacillus anthracis* (Anthrax)	A lab worker used an incorrect disinfectant, failed to wear disposable gloves, and failed to cover a preexisting skin defect (facial cut from shaving).	Cutaneous anthrax resulted following skin exposure to a contaminated surface.	Patient was successfully treated using antibiotics. CDC reviewed proper biosafety measures with laboratory personnel.

Source: CIDRAP 2005; Hammond 2007; Medical Univ. of Ohio, IBC 2004, 2005; Nature.com 2005; New Scientist 2005; NIH and CDC 2007; Normile 2004; NY Times 2003; ProMed 2005a; ProMed 2005b; ProMed 2005c; San Francisco Chronicle 2007; Texas A&M Univ. 2006; Texas A&M Univ. 2007; Weiss and Snyder 2002; WHO 2005; Univ. of Chicago IBC 2005; Univ. Illinois at Chicago IBC 2004; Univ. New Mexico IBC 2003; Univ. North Carolina at Chapel Hill IBC 2005; Univ. Texas at Austin 2006; CDC 2007a; CDC 2007b; Yeshiva University IBC 2006; University of Texas, Houston 2007; Clarion-Ledger 2007; NIH IBC 2004.

Table B.4-4 — Recent Incidents of United States and International Laboratories Involving BSL-3Ag (Current Status) Microbes

Location	Date	Research Agent(s)	Description	Result	Actions
Pirbright, United Kingdom (U.K.)	August 3, 2007	Foot and mouth disease virus (FMDV)	An outbreak of foot and mouth disease was confirmed at a farm in Surrey, U.K.	It was concluded that the FMDV likely originated from the nearby Pirbright Research and manufacturing site in Surrey because of construction activities surrounding a leaking drainage pipe. A subsequent outbreak on September 12, 2007 was shown by genetic analysis to be unrelated to the Pirbright facilities.	The outbreak of FMDV was contained by setting up a quarantine zone and culling all susceptible species within the zone. A government investigation subsequently made seven key recommendations.
Plum Island Animal Disease Center (PIADC), Plum Island, NY	July 19, 2004	FMDV	Four pigs not involved in live virus research were observed with clinical foot and mouth disease.	The FMDV was type O. No specific explanation for the unintended infections was found.	Following this and the June 24 incidents, “new animal care protocols were instituted to restrict access to all animal rooms.” Restrictions included clothing exchange, mandatory exit showers, and “decontamination of all laboratory samples leaving/removed from the animal rooms.”

Table B.4-4 — Recent Incidents of United States and International Laboratories Involving BSL-3Ag (Current Status) Microbes (Continued)

Location	Date	Research Agent(s)	Description	Result	Actions
Plum Island Animal Disease Center, Plum Island, NY	June 24, 2004	FMDV	Two cattle not involved in live virus research were observed with clinical signs of foot and mouth disease.	FMDV was type O but a different type O strain than the one involved in the July 19 incident. No specific explanation for the unintended infections was found.	Following this and the July 19 incidents, "new animal care protocols were instituted to restrict access to all animal rooms." Restrictions included clothing exchange, mandatory exit showers, and "decontamination of all laboratory samples leaving/removed from the animal rooms."
PIADC, Plum Island, NY	September 2003	FMDV; others	An investigation to assess security at PIADC in the aftermath of the 2001 terrorist attacks is concluded.	The report enumerated fundamental concerns that pathogens were not adequately secured from unauthorized access.	Security recommendations were incorporated into the operations of the facility.
PIADC, Plum Island, NY	August 18, 1991	FMDV; others	Main electrical power lines to one lab were knocked out due to hurricane-force winds. Back-up power was unavailable due to deferred repairs on an inoperable emergency transmission line.	Disposal systems for virus-laden waste were inoperable for 32 hours, causing a back up of infectious sewage. No infections in animals were reported.	No further information available.
PIADC, Plum Island, NY	May 26, 1987	FMDV	One heifer without previous inoculation or known exposure to FMDV was found to be infected with type O virus.	Type O had been used in nearby rooms, and these animals from these rooms had been euthanized and then transported through the corridor.	Actions were taken to replace equipment used in transport and to decontaminate corridors more thoroughly.

Table B.4-4 — Recent Incidents of United States and International Laboratories Involving BSL-3Ag (Current Status) Microbes (Continued)

Location	Date	Research Agent(s)	Description	Result	Actions
PIADC, Plum Island, NY	February 24, 1981	FMDV	Four steer vaccinated with FMDV type O were found to be infected with type A.	The cause was not identified, but it was surmised that cross-contamination from another lab area was most likely.	None specified.
PIADC, Plum Island, NY	August 21, 1980	FMDV	Approximately nine steers were found to have antibodies to type O FMDV, with no known reason for this unintentional exposure to FMDV.	It was surmised that a laboratory worker could have accidentally transmitted the virus to the animals.	None specified.
PIADC, Plum Island, NY	September 15, 1978	FMDV	FMDV escaped from the biocontainment facility. The suspected cause was construction work in progress.	Cattle outside of the laboratory facility were found to be infected with FMDV.	All animals on the island were euthanized and incinerated. The virus outbreak was limited to the island.
PIADC, Plum Island, NY	April 12, 1974	FMDV	Two steers that had never been inoculated with FMDV were found to be infected.	It was determined that FMDV probably came into the room through leaks in the walls, possibly in conjunction with a power failure that may have caused a difference in air pressure between the two rooms.	Preventive maintenance of the rooms was conducted to prevent recurrence.

Source: GAO 2003; Caroll 2004; Health and Safety Executive 2007; DHS response to GAO 2008.

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ABBREVIATIONS AND ACRONYMS:

BMBL	Biosafety in Microbiological and Biomedical Laboratories
BSC	Biosafety Cabinet
BSL	Biosafety Level
CAP	College of American Pathologists
CDC	Centers for Disease Control and Prevention
cDNA	Complementary Dexyribonucleic Acid
DNA	Deoxyribonucleic Acid
FBI	Federal Bureau of Investigations

FMDV	Foot and Mouth Disease Virus
H2N2	Non-Contemporary Human Influenza
H3N2	Recombinant Influenza A
H5N1	Avian Influenza (Bird Flu)
HEPA	High-Efficiency Particulate Air
HIV	Human Immunodeficiency Virus
IBC	Institutional Biosafety Committee
LAI	Laboratory-Acquired Infection
LLNL	Lawrence Livermore National Laboratory
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
OMS	Occupational Medical Service
OSHB	Occupational Safety Health Branch
P	Partial
PIADC	Plum Island Animal Disease Center
RML	Rocky Mountain Laboratories
RNA	Ribonucleic Acid
SARS	Severe Acute Respiratory Syndrome
SARS-CoV	SARS Corona Virus
TAMU	Texas A&M University
U.S.	United States
WNV	West Nile Virus

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