

Appendix 1

NIAID PUBLICATION
“THE NEED FOR BIOSAFETY
LABORATORY FACILITIES”
FEBRUARY 2004

February 2004

The Need for Biosafety Laboratory Facilities

Introduction

In the past century, medical research has led to improved health and increased life expectancy largely because of success in preventing and treating infectious diseases. This success has come about through the use of antibiotics and vaccines, improved hygiene, and increased public awareness. New threats to health continually emerge naturally, however, as bacteria and viruses evolve, are transported to new environments, or develop resistance to drugs and vaccines. Some familiar examples of these so-called emerging or re-emerging infections include HIV/AIDS, West Nile virus, severe acute respiratory syndrome (SARS), monkeypox, and annual outbreaks of influenza.

To control epidemics and protect the public health, medical researchers must quickly identify naturally occurring microbes and then develop diagnostic tests, treatments, and vaccines for them. Preparing for bioterrorism - the deliberate release of a microbe into a community in which it is not a current health concern - calls for the identical scientific skills and strategies.

For more than 50 years, the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), has led the nation's medical research effort to understand, treat, and prevent the myriad infectious diseases that threaten hundreds of millions of people worldwide. NIAID's portion of the NIH budget-received each year from Congress-not only supports medical research conducted on the NIH campus in Maryland but also at universities and research centers primarily nationwide but also overseas. The benefits of this research reach people of all ages worldwide.

Because NIAID has broad experience, expertise, and success in developing medical tools to fight infectious diseases, it now also plays a leading role in the nation's fight against bioterrorism. The Institute is expanding its research programs to accelerate the development of new and improved diagnostics, treatments, and vaccines to protect civilians from deadly infectious diseases, whether they emerge naturally or are deliberately released in a bioterrorist attack.

NIAID'S BIODEFENSE RESEARCH PLAN

Through a process of extensive expert consultation, NIAID has developed a strategic plan for biodefense and emerging infectious diseases research. Key elements of the plan include the following:

- Support medical research on microbes and the human immune response to them
- Apply such research to the discovery and development of vaccines, drugs, and diagnostic tests designed to protect the general population
- Ensure that the United States has enough research facilities to carry out these activities

NIAID's strategic plan for biodefense, detailed research agendas, and a progress report can be found at <http://biodefense.niaid.nih.gov>.

ENSURING SUFFICIENT RESEARCH FACILITIES

NIAID's ultimate goal is to develop new and improved diagnostics, vaccines, and treatments for diseases caused by infectious agents. Medical tools such as these can only be developed, however, with a solid understanding of the biology of the disease-causing agents, whether they occur naturally or are deliberately released by terrorists. Such research sometimes requires working with the actual microbes or their toxins. This research must be conducted in special biosafety laboratories and in accord with the many laws, regulations, policies, and well-established guidelines that govern research on these microbes and the design, management, and operation of these laboratories. All these provisions aim to protect not only the lab workers but also the surrounding community from accidental exposure to infectious agents.

Certain guidelines (*Biosafety in Microbiological and Biomedical Laboratories*, <http://bmbi.od.nih.gov/index.htm>) specify four levels of safety and security required for laboratory facilities in which such research will take place. The general characteristics of the biosafety levels (often referred to as BSL-2 to BSL-4) are summarized in Table 1.

Many U.S. institutions and companies with infectious disease research programs have BSL-3 laboratory suites required to perform their research. Most such laboratories, however, are small, dedicated to particular uses, or in need of modernization. In addition, some hospitals have small laboratory or clinical areas that can operate at this level, including space for isolating patients suspected or known to have certain highly contagious diseases.

BSL-4 labs have the most stringent safety and security requirements. There are currently only four operational BSL-4 laboratory suites in the United States: at the Centers for Disease Control and Prevention in Atlanta; at the United States Army

Medical Research Institute for Infectious Diseases at Fort Detrick in Frederick, MD; at the Southwest Foundation for Biomedical Research in San Antonio; and at the University of Texas at Galveston. A small BSL-4 facility exists on the NIH campus in Bethesda, MD, but it is currently being operated only at a BSL-3 level for research on important emerging infectious diseases.

The recent bioterrorist events made it very clear that from a strategic national perspective, a serious shortage of BSL-3 and BSL-4 laboratory space exists. This problem has been well documented by the Institute of Medicine, and it has repeatedly been identified in NIAID's strategic planning process. Thus, NIAID's research agenda for biodefense and emerging infectious diseases includes plans to construct and renovate BSL-3 and BSL-4 laboratories around the country. To be most effective, these laboratories must be located where established teams of researchers already work side-by-side on related scientific problems.

PROPOSED BIOSAFETY LAB FACILITIES

1. NIAID has received funding to construct four new national facilities, all of which will include BSL-4 and BSL-3 laboratory suites as well as BSL-2 space

- A new NIAID facility at Fort Detrick, a U.S. Army installation located in Frederick, MD
- A new facility at NIAID's Rocky Mountain Laboratories, located in Hamilton, MT
- Two National Biocontainment Laboratories, located at Boston University and at the University of Texas Medical Branch at Galveston. The sites for these were chosen in a competitive process known as peer review from among applications received from researchers nationwide

Additional individual information on all these projects can be found at these links

http://www.niaid.nih.gov/biodefense/public/detrick_rocky_ga.htm

<http://www.niaid.nih.gov/newsroom/releases/nblscorrect21.htm>

2. NIAID also is funding construction or renovation of facilities that include BSL-3 and BSL-2 laboratory suites

- Building 33, a new integrated research facility, on the NIH campus in Bethesda, MD
- Nine Regional Biocontainment Laboratories, selected in a competitive, peer-review process from applications received from researchers nationwide

Additional individual information on all these projects can be found at

these links

<http://www.niaid.nih.gov/factsheets/qanda.htm>

http://www.nih.gov/news/NIH-Record/10_14_2003/story01.htm

<http://www.niaid.nih.gov/newsroom/releases/nblscorect21.htm>

FEATURES OF RESEARCH PLANNED FOR THESE FACILITIES

NIAID-Funded Research Will Include

- Laboratory research on the biology of the disease-causing agents
- Laboratory and animal model studies testing the usefulness of new drugs, vaccines, and diagnostic tests to detect, treat, and prevent illness among civilians
- Adherence to all relevant security and safety standards required by law

NIAID-Funded Research Will NOT Include

- Research on bioweapons (which is not even permissible under international law)

NIAID Policies Regarding Security, Publication, and Secrecy

- The extent to which publications or access to data from biodefense research should be limited is being widely debated. NIAID supports a policy encouraging publication and dissemination of research findings through proper scientific channels in the belief that this policy will provide many more opportunities for good than for harm. More people will know more about microbes and toxins and be able to use that information for beneficial purposes. The fact that the information is widely available in the scientific community makes it less attractive to use with malicious intent.
- NIAID is not supporting any secret (so-called "classified") research. Furthermore, NIAID has no plans to do so. This matter is also being widely debated among scientists and policy makers, and it is possible that in the future, the criteria for what should and should not be classified might change. Nonetheless, NIAID supports a policy of openness. The justification for classifying certain projects would require a clear case that the potential for harm from misuse of specific information by individuals with nefarious intents significantly exceeds the potential for good. Whether it is classified or not, however, it is important to emphasize that NIAID-funded research will not include research on bioweapons.

Table 1: Biosafety Levels

| Biosafety Level | Agents | Practices | Safety Equipment | Facilities |
|-----------------|--|---|--|---|
| BSL-1 | These agents are not generally associated with disease in healthy people | <ul style="list-style-type: none"> • Good microbiological practice • Hand washing • No eating, drinking or gum chewing in the laboratory | <ul style="list-style-type: none"> • Pipeting devices- mouth pipeting is prohibited | |
| BSL-2 | These agents are associated with human disease | <ul style="list-style-type: none"> • Limited lab access • Most work may be performed on a bench top • Biohazard warning signs • "Sharps" precautions • Biosafety manual defining any needed waste decontamination or medical surveillance policies | <ul style="list-style-type: none"> • Class I or II Biological Safety Cabinets (BSCs) or other physical containment devices • Lab coats, gloves, face protection, as needed | <ul style="list-style-type: none"> • Open bench-top • sink for hand washing is required • Autoclave available |
| BSL-3 | <p>These agents:</p> <ul style="list-style-type: none"> • Are associated with human disease and cause illness by spreading through the air (aerosol) • Cause diseases that may have serious or lethal consequences | <p>BSL-2 practice plus</p> <ul style="list-style-type: none"> • Controlled access • Decontamination of all waste • Decontamination of lab clothing before laundering | <ul style="list-style-type: none"> • Class I or II Biological Safety Cabinets (BSCs) or other physical containment devices • Protective lab clothing, gloves, respiratory protection as needed | <p>BSL-2 plus</p> <ul style="list-style-type: none"> • Physical separation from access corridors • Self-closing, double-door access • Exhaust air is not recirculated • Negative airflow into laboratory • Design includes back-up/redundant systems |
| BSL-4 | These agents: | BSL-3 practices plus | <ul style="list-style-type: none"> • All procedures | BSL-3 plus |

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|--|--|--|--|--|
| | <ul style="list-style-type: none"> • Are associated with human disease and cause illness by spreading through the air (aerosol) or have an unknown cause of transmission ; • Cause diseases that are usually life-threatening; | <ul style="list-style-type: none"> • Clothing change before entering • Shower on exit • All material decontaminated on exit from facility | <p>conducted in Class III BSCs or Class I or II BSCs in combination with full-body, air-supplied, positive-pressure personnel suit</p> | <ul style="list-style-type: none"> • Separate building or isolated zone • Dedicated supply and exhaust, vacuum, and decontamination systems • Design includes back-up/redundant systems • Other requirements outlined in NIH/CDC publication "Biosafety in Microbiological and Biomedical Laboratories"* |
|--|--|--|--|--|

NIAID is a component of the National Institutes of Health (NIH), which is an agency of the Department of Health and Human Services. NIAID supports basic and applied research to prevent, diagnose, and treat infectious and immune-mediated illnesses, including HIV/AIDS and other sexually transmitted diseases, illness from potential agents of bioterrorism, tuberculosis, malaria, autoimmune disorders, asthma and allergies.

News releases, fact sheets and other NIAID-related materials are available on the NIAID Web site at <http://www.niaid.nih.gov>.

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Last Updated April 30, 2004 (alt)