THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

MAY 16 2006

Scott J. Bloch
Special Counsel
U.S. Office of Special Counsel
1730 M. Street, NW, Suite 300
Washington, D.C. 20036-4505

Dear Mr. Bloch:

The purpose of this letter is to formally respond to your March 24, 2006, referral of a whistleblower disclosure that Rocky Mountain Laboratory has been compromised and rendered unsafe (OSC File No. DI-06-1221).

In response to your referral, the Office of Inspector General conducted a formal investigation. Enclosed with this letter is the Office of Inspector General's Report of Investigation. This report details the efforts made by the Office of Inspector General during the investigation and fulfills the report requirements under 5 U.S.C. section 1213(d) that were outlined in your referral letter to me.

In summary, at the conclusion of this investigation no evidence of any violation was uncovered. Furthermore, no evidence of a public health hazard was found.

Thank you for referring this matter of mutual interest. If you have any questions, please contact Daniel R. Levinson, Inspector General, at (202) 619-3148.

Sincerely,

Michael O. Leavitt

Enclosure

OFFICE OF INSPECTOR GENERAL
OFFICE OF INVESTIGATIONS
REPORT OF INVESTIGATION

Case Title	**Date of Report** May 8, 2006
HHS/OIG File #7-06-00186-4 Case Title: National Institutes of Health, National Institutes of Allergy and Infectious Diseases-Rocky Mountain Laboratories Hamilton, Montana	**Type of Report** Report of Investigation
	Report of SA Van Prewitt
	Signature
	Cross Reference Number OSC Disclosure #DI-06-1221

Notice

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Approved: Special Agent in Charge Gary M. Holst	File Number: 7-06-00186-4
Copies:	

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United States
Department of Health
And Human Services

OFFICE OF INSPECTOR GENERAL
OFFICE OF INVESTIGATIONS
REPORT OF INVESTIGATION CONCERNING

National Institutes of Health
National Institutes of Allergy and Infectious Diseases
Rocky Mountain Laboratories
Hamilton, Montana

OI File # 7-06-00186-4

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*Section not applicable in this report.

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U.S. OFFICE OF SPECIAL COUNSEL
1730 M Street, N.W., Suite 218
Washington, D.C. 20036-4505
202-254-3600

REPORT OF DISCLOSURES REFERRED FOR INVESTIGATION
OSC FILE NO. DI-06-1221

I. SUMMARY

Albert Hurley, licensed master electrician, disclosed to OSC an ongoing health hazard at the U.S. Department of Health and Human Services, National Institutes of Health (NIH), National Institute of Neurological Disorders and Stroke, Rocky Mountain Laboratory, Hamilton, Montana. Specifically, he alleges that the doors to a high containment laboratory cannot close properly due to a chronic airflow problem, leaving employees in the building at risk of exposure to dangerous microorganisms.

II. THE INFORMATION DISCLOSED

Mr. Hurley, who has consented to the release of his name, has worked as an electrician for 20 years. He has worked for the NIH Rocky Mountain Laboratory for 11 years.

Mr. Hurley alleges that an airflow problem at the Biohazard Level 3* laboratory in Building 25 poses a danger to public health. He advises that scientists in this lab are conducting research on several contagious, dangerous diseases, including tuberculosis and mad cow disease. According to Mr. Hurley, the doors to this lab do not close properly, thereby posing a risk that employees working elsewhere in the building could become infected. Mr. Hurley asserts that the lab doors do not close properly because of an airflow problem in the lab. He advises that he has checked the lab's airflow log book, and the entries show that the airflow measurements deviate significantly from standard requirements. Mr. Hurley also states that the scientists working in the lab have repeatedly expressed concern to him that the doors do not close properly.

According to Mr. Hurley, management officials are aware of the problem, but they have not taken adequate steps to correct it. He states that the individuals responsible for adjusting airflow in the lab, Clyde Truex and Kevin Mora, have attempted to remedy the situation, but thus far have been unsuccessful. Mr. Hurley notes that Mr. Truex and Mr. Mora are not licensed HVAC technicians. He strongly suggests that the agency procure the services of a licensed HVAC technician to assess the situation and resolve problem.

* The U.S. Centers for Disease Control and Prevention categorize various diseases into Biohazard Levels (BLs) 1 through 4, with "BL 1" signifying minimal risk, and "BL 4" signifying extreme risk.

III. THE SPECIAL COUNSEL'S FINDINGS

Given Mr. Hurley's apparent expertise regarding the matters he has disclosed, the detail he has provided, and his first-hand knowledge of many of the incidents he has described, I have concluded that there is a substantial likelihood that the information Mr. Hurley provided to OSC discloses a substantial and specific danger to public health.

Requirements of 5 U.S.C. § 1213 (d)

Any report required under subsection (c) shall be reviewed and signed by the head of the agency and shall include—

(1) a summary of the information with respect to which the investigation was initiated;

(2) a description of the conduct of the investigation;

(3) a summary of any evidence obtained from the investigation;

(4) a listing of any violation or apparent violation of any law, rule, or regulation; and

(5) a description of any action taken or planned as a result of the investigation, such as—

(A) changes in agency rules, regulations, or practices;

(B) the restoration of any aggrieved employee;

(C) disciplinary action against any employee; and

(D) referral to the Attorney General of any evidence of a criminal violation.

OFFICE OF INVESTIGATIONS
OFFICE OF INSPECTOR GENERAL
DEPARTMENT OF HEALTH AND HUMAN SERVICES

File No: 7-06-00186-4 **Date:** May 8, 2006

Report of: Special Agent Van Prewitt **Office:** Billings, Montana

Section A – Narrative

CASE INITIATION

On April 18, 2006, the U.S. Department of Health and Human Services, Office of Inspector General, Office of Investigations (USDHHS) received an official whistleblower disclosure from the Office of Special Counsel (OSC) regarding the U. S. Department of Health and Human Services, National Institutes of Health, National Institutes of Allergy and Infectious Diseases, Rocky Mountain Laboratories (NIAID) in Hamilton, Montana.

Specifically, the OCS disclosure alleges the door to a Biohazard Level Three (BL3) high containment laboratory is not functioning properly due to a chronic airflow problem, leaving employees in the building at risk of exposure to dangerous microorganisms.

The OSC concluded there is a substantial likelihood that the information provided discloses a substantial and specific danger to public health. The OSC referred this disclosure to the USDHHS for further investigation. The OSC disclosure file number is DI-06-1221.

CASE INVESTIGATION

The investigation of this matter consisted of interviewing the complainant, other NIAID employees, employees of the Office of Research Facility (ORF) and representatives from the Centers for Disease Control and Prevention – Select Agent Program (CDC).

Interview of Albert Richard Hurley, Complainant and Electrician, ORF

On April 19, 2006, Agents interviewed Albert Richard Hurley, Electrician for the ORF, at a restaurant in Hamilton, Montana. Mr. Hurley is the complainant that filed the OSC whistleblower disclosure.

BL3: Building 25 Door Issues

According to Mr. Hurley, the problems with the door in Building 25, Suite D, a BL3 high containment facility, began to surface several months after the building was commissioned. He wasn't sure, but believed the building was commissioned approximately three to four-years ago.

Mr. Hurley became involved with the door issue after being asked to trouble-shoot why the door was not shutting properly. After trouble-shooting the door on several occasions, Mr. Hurley concluded that airflow problems with the Heating, Ventilation and Air Conditioning (HVAC) system in the laboratory suite was not allowing the door to completely close.

Most Recent Issue With Building 25

On February 15, 2006, Mr. Hurley responded to Building 25, Suite D to examine and trouble-shoot why the door to this particular laboratory suite was not closing properly. Upon completing his trouble-shooting of the door, Mr. Hurley determined that incorrect airflow was the cause of the malfunctioning door.

Mr. Hurley met with his supervisor, Randy Williamson, concerning the door issue and requested a meeting with Mr. Williamson and the HVAC mechanics to discuss the airflow issues. Mr. Williamson sent an email to Mr. Hurley, John Bailey, Kevin Mora and Mike Parnell regarding Mr. Hurley's request for a meeting to discuss the door and airflow issues.

On February 17, 2006, Kevin Mora, the Facility Containment Specialist and former HVAC mechanic for the ORF, sent an email to Mr. Williamson advising he had examined the TSI controller (TSI 118), which controls the airflow for the affected door. Mr. Mora indicated the TSI controller wasn't functioning properly and that he had reset the TSI controller. Furthermore, Mr. Mora stated the TSI controller was functioning correctly and the door was shutting as required.

Approximately one-hour after Mr. Mora claimed to have corrected the problem, Mr. Hurley ran into Nancy Hoe, Biosafety Officer, and Greg Raymond, Senior Research Assistant, at Building 25. Mr. Raymond stated to Mr. Hurley, "What in God's name is going on, it sound like a jet airplane is going off in my lab."

Mr. Hurley advised, as of February 23, 2006, the problem had still not been corrected.

Interview of Nancy Hoe, Ph.D, Biosafety Officer, NIAID

On April 19, 2006, Agents interviewed Dr. Nancy Palme Hoe, Biosafety Officer for the NIAID, at her place of employment in Hamilton, Montana. As the Biosafety Officer, Dr. Hoe is responsible for overseeing the safe conduct of research as relates to the select agents at the NIAID.

BL3: Building 25 Door Issues

Dr. Hoe stated the airflow issues associated with Building 25, Suite D, could have existed as long as a year before the problem was finally fixed.

According to Dr. Hoe, the Maintenance Unit initially believed the magnet on the exterior door of Suite D wasn't strong enough to completely close the door. Randy Williamson, the Maintenance Unit Supervisor, unsuccessfully attempted to repair the door. Subsequently, it was determined that the door mechanism wasn't the issue, but rather the door couldn't close because there was too much negative airflow entering the laboratory suite. Dr. Hoe said that the negative airflow changed from "negative .025 inches of water, to negative .03 inches of water and then to negative .1 inches of water." The negative airflow was causing air to rush into Suite D, which prevented the exterior door from closing properly without the manual efforts of laboratory employees.

Dr. Hoe stated that Greg Raymond, Senior Research Assistant for the NIAID had numerous conversations with the Maintenance Unit concerning the door issue before the problem was finally corrected.

Dr. Hoe stated that the select agent Bovine Spongiform Encephalopathy (BSE), also known as Mad Cow Disease, is stored in Building 25, Suite D. She further advised that the malfunctioning door did not lead to a risk of exposure, because the negative airflow from the laboratory suite would have prevented the escape of any airborne contaminants.

Centers For Disease Control and Prevention (CDC) Inspection

On January 11, 2006, Brian Satterfield, of the CDC, conducted an inspection at the NIAID. During this inspection, Mr. Satterfield toured Building 25 and discovered that the exterior door leading into Suite D was not self-closing. In a report provided by Dr. Hoe, Mr. Satterfield cited the NIAID as being deficient and in violation of Biosafety in Microbiological and Biomedical Laboratories (BMBL), page 33, section (D) subsection (1). The inspection report states the requirement for a BL3 laboratory as,

> "The laboratory is separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory is restricted. Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors. Doors are lockable. A clothes change room may be included in the passageway. [BMBL, p.33, D (1)]"

Mr. Satterfield's observations stated,

> "Both the outer door of the anteroom and the anteroom door leading into Suite D in building 25 were self-closing. However, the self-closing mechanism was not working properly and did not close the door shut. Please provide documentation, which shows how this deficiency has been met."

Mr. Satterfield's inspection notice provided the NIAID with 14 calendar days to correct the noted deficiencies and respond back to the CDC.

Dr. Hoe provided the Investigating Agents a copy of her response letter to the CDC regarding the inspection deficiencies. This letter stated,

> "A work order was placed with the NIH Office of Research Facilities to fix the self-closing door mechanism on the inner and outer doors of the anteroom leading into Suite D. This task has been completed. A copy of the completed work order is enclosed."

Dr. Hoe also provided a copy of the work order referenced in her response to the CDC. The work order shows that Dr. Hoe submitted a request on January 20, 2006 to have the Suite D door adjusted. Furthermore, the work order listed the status of this repair as completed.

Interview of Gregory Raymond, Senior Research Assistant, NIAID

On April 20, 2006, Agents interviewed Gregory Raymond, Senior Research Assistant for the NIAID, at his place of employment in Hamilton, Montana. As a Senior Research Assistant, Mr. Raymond is responsible for overseeing Building 25, Suite D at the NIAID.

BL3: Building 25 Door Issues

Mr. Raymond is responsible for managing Building 25, Suite D. This suite contains Transmissible Spongiform Encephalopathy (TSE) agents. Mr. Raymond described TSE, in layman terms, as diseases capable of causing human diseases. He confirmed that the select agent contained in Suite D is BSE or Mad Cow Disease.

Mr. Raymond doesn't believe the failure of the Building 25, Suite D self-closing door created a risk of exposure to the NIAID employees or the public. He explained that BSE has a very low risk of exposure because of how the agent would have to be transferred to humans. In order for an individual to be infected with BSE, they would have to digest material that contains the BSE. BSE is not an airborne virus or disease.

Furthermore, scientists at the NIAID have not worked with the BSE since Building 25 became operational.

Mr. Raymond's concern regarding the risk created by the malfunctioning door was that Suite D might be shut down for failing to meet regulatory guidelines requiring self-closing doors on BL3 facilities. He felt this would be detrimental to the cultures and lab research currently being conducted in Suite D.

Mr. Raymond reiterated that there wasn't a risk of contamination or exposure, but he did have a concern regarding security. Mr. Raymond stated, "The Building 25, Suite D door hasn't worked properly since the building was opened." He made numerous requests to maintenance, but had been unsuccessful at getting the door problem corrected. He created a new standard operating procedure (SOP), which "instituted a human aspect" and trained all his people to manually ensure the door is securely shut.

The CDC inspected the NIAID in January 2006, and the NIAID was cited for a deficiency for having an inoperable self–closing door in Building 25, Suite D. Since the inspection, the door has been repaired and is "working beautifully."

Interview of Kevin Gene Mora, Facility Containment Specialist, ORF

On April 20, 2006, Agents interviewed Kevin Gene Mora, Facility Containment Specialist and former HVAC mechanic at the ORF, at his place of employment in Hamilton, Montana. As the Facility Containment Specialist, Mr. Mora is responsible for insuring the maintenance related work at the Integrated Research Facility (IRF), a BL3 and BL4 facility (which is currently under construction), is correctly completed.

Maintenance Unit's Ability to Handle Building 25 Maintenance Issues

Mr. Mora indicated that the air handling system utilized in Building 25, Suite D is very complicated. This particular system is a constant exhaust/negative pressure system, which has been problematic since the building was opened.

When Mr. Mora took the promotion to Facility Containment Specialist, Clyde Truex became the primary HVAC mechanic for the ORF. In addition, there was a hiring freeze, which prevented the maintenance unit from hiring a replacement for the vacancy created by Mr. Mora's promotion. This left the ORF short one HVAC mechanic.

Initially, according to Mr. Mora, Mr. Truex wasn't up to speed on the Building 25 systems. Mr. Mora arranged for a facility shutdown in October 2005 and had Trane (the company that installed the Building 25 system) conduct a four-hour training session on the buildings air handling system.

Interview of Paul Carlson, Occupational Safety and Health Manager, NIAID

On April 24, 2006, an Agent telephonically interviewed Paul Carlson, Occupational Safety and Health Manager for the NIAID. As the Occupational Safety and Health Manager for the NIAID, Mr. Carlson is responsible for new employee orientations, coordinating refresher training, insuring that policies and procedures are being followed, issuing new policies when necessary and most any issue dealing with the safety and health of the NIAID employees.

BL3: Building 25 Door Issues

According to Mr. Carlson, there was a period of time when one of the Building 25, Suite D doors did not self-close. However, in his opinion, this did not create a hazardous condition because the employees were instructed to manually secure the door.

There was no risk of exposure to the employees or the public. The particular pathogen in Building 25, Suite D is a Mad Cow Disease or pathogen. When scientists are "actively manipulating" the pathogen(s) in these suites, the pathogen(s) are contained within a biological safety cabinet.

The problem created by the malfunctioning door had to do with the alarm system. The door is designed so that one door won't open until the other is completely closed. Therefore, if a technician was inside the suite and the outermost door wasn't securely closed, then the technician wouldn't be able to exit the suite. The only way for the technician to exit the suite was if they pressed a manual override button to release the door. An audible alarm sounds whenever the manual override button is utilized.

Laboratory Security Measures

According to Mr. Carlson, all of the suites are under constant video surveillance, and two security officers are always surveying the security camera feeds. In addition, Building 25 requires a proximity card to enter the main building, and a proximity card and thumbprint to enter an actual laboratory suite. The proximity card and thumbprint must coincide with each other.

The pathogens are maintained in locked freezers or refrigerators when they are not actively being manipulated.

Emergency Situations

According to Mr. Carlson, there is an actual Hazardous Materials (HAZMAT) Team stationed at NIAID to deal with any emergency situations that might occur. This team is part of the Missoula Regional HAZMAT Team and they are fully trained and equipped to handle situations involving chemical, biological and radiological materials.

Interview of Randy Williamson, Maintenance Unit Supervisor, ORF

On April 24, 2006, an Agent telephonically interviewed Randy Williamson, Maintenance Unit Supervisor at the ORF. As the Maintenance Supervisor, Mr. Williamson is responsible for assigning work orders and overseeing the maintenance staff.

BL3: Building 25 Door Issues

Mr. Williamson acknowledged that Suite D has been particularly problematic. Recently, Mr. Williamson assigned Clyde Truex, Air Conditioning Mechanic, to trouble-shoot and determine why the door wouldn't close. Mr. Williamson also had Kevin Mora, former Air Conditioning Mechanic and now Facility Containment Specialist, to examine the door to determine why it wasn't closing properly.

Mr. Truex and Mr. Mora determined that the TSI controller, a sensor that controls airflow, was the primary problem. The TSI controller is supposed to control the differential air pressure in the laboratory suite. This particular TSI controller was installed when the building was initially constructed five or six years ago.

Mr. Truex ordered several new TSI controllers - one to replace the malfunctioning TSI controller and several more to keep on hand for future repairs. This corrected the door closure problem in Building 25, Suite D, and Mr. Williamson hasn't received any new complaints since the TSI controller was replaced.

According to Mr. Williams, Will Daellenbach, the Western Regional Director for the ORF, has instructed Mr. Williamson to insure that any maintenance related issues at Building 25 (BL3 facility) and Building 28 (BL4 facility) are given top priority.

Interview of Richard Henkel, Ph.D. and Roger Farmer, CDC

On April 28, 2006, an Agent telephonically interviewed Richard Henkel, PhD and Roger Farmer of the CDC. Dr. Henkel is the Occupational Health and Safety Manager and Mr. Farmer is the Program Manager for the CDC (Select Agent Program). They provided the following information regarding the CDC inspection of the NIAID:

Review of CDC Inspection Report

Dr. Henkel and Mr. Farmer conducted a review of the inspection report completed by Brian Satterfield of the CDC. Upon completing their review they provided the following information:

- The tension on the exterior door of Building 25, Suite D was not strong enough to completely self-close.
- The staff at the NIAID had been instructed to manually check the door to insure that it was completely secured.
- The inspection team cited the NIAID with a deficiency for failing to have a self-closing door that operated correctly. The NIAID was given a grace period in which to have the door repaired so that it would self-close.
- The NIAID submitted a work order to have the door repaired.
- The NIAID provided the CDC with documentation showing that the door had been repaired.
- The inspection deficiency was satisfied and the CDC inspection was "closed out."

BL3 Doors: General Information

Dr. Henkel stated the main reason the NIAID was cited for the door was due to the potential security vulnerability during the time-period that the door wasn't self-closing.

When the CDC inspects a BL3 facility, they are verifying that the facility has two self-closing doors between the common areas and the laboratory suites. The inner door leads

into the laboratory suite, and the outer door provides access from the pedestrian corridor. The outer door needs to be self-closing to prevent an unauthorized person from entering the suite from the pedestrian corridor.

There was no evidence during the inspection to indicate that a security breach had occurred.

Explanation of BL3 Exposure Risk

In general, according to Dr. Henkel, the public can only become infected with BSE or Mad Cow Disease by digesting an infected food source. However, in a laboratory setting, you can overcome this transmissible limitation. For instance, a scientist could be stuck with a needle during a laboratory manipulation of the pathogen, which could lead to an exposure incident.

BL3 laboratories are required to have inward directional airflow, which is exhausted to some type of High Efficiency Particulate Airflow (HEPA) filtration system. The reason the door needs to remain closed is because the airflow system in the laboratory suite acts similar to a "giant vacuum." This design is to prevent the release of any airborne contaminants.

If a door is left open, the ability to regulate the airflow is lost and the room could go positive (airflow could escape the suite). In this particular case, the door was shutting, but the tension on the door wasn't strong enough to completely latch the door. This situation would not have sufficiently disrupted the negative airflow system to allow the room to go positive. Therefore, there was no risk of airborne contaminants escaping the laboratory suite.

Professional Opinion

In Dr. Henkel and Mr. Farmer's opinions, there really was no safety hazard created by the malfunctioning door. There was the potential security risk of a Non-Security Risk Assessment (SRA) individual being able to enter the secured laboratory suite. A Non-SRA individual is a person that has not been cleared to enter a secured area via a background check through the Federal Bureau of Investigation.

In Dr. Henkel's estimation, there was a zero possibility of exposure to the employees of the NIAID. He further noted that the researchers actually working with the agents in the laboratory suites aren't vaccinated against these pathogens. If these individuals weren't getting sick then it is highly unlikely that anyone outside the suite would have been exposed.

CONCLUSION AND INVESTIGATIVE FINDINGS

Substantial Risk to Public Health Not Substantiated

Interviews conducted with NIAID employees, ORF maintenance staff and CDC personnel, uncovered no evidence to substantiate the allegation that the failure of the Building 25, Suite D door created a substantial risk to public health.

No Safety Risk Identified

The self-closing doors of BL3 facilities are not designed to be airtight. Therefore, these doors are not intended to serve as the first line of defense against the release of airborne contaminants. The scientists performing research and manipulating select agents in these facilities utilize biosafety cabinets, which prevent the pathogen from contaminating the laboratory suite. In addition, the release of airborne contaminants is prevented by the positive to negative airflow differential systems utilized in these facilities. CDC inspection personnel advised that the door issue cited in their inspection report would not have caused or created a risk of airborne contaminants escaping the laboratory suite.

Temporary Security Risk, but No Evidence of Security Breach

CDC personnel advised that the failure of the self-locking door entering into Suite D did create a security vulnerability. They noted that if the door does not completely close, then there is the possibility that a non-authorized individual could enter the laboratory suite. However, they also stated they didn't uncover any evidence indicating that a security breach of Suite D had occurred.

Information provided by the Biosafety Officer for NIAID and CDC Personnel indicated the door in Building 25, Suite D has been repaired and is functioning properly. During this investigation, the Investigating Agents toured this particular laboratory suite and observed the door open and self-close several times.

Changes Currently Being Pursued at the NIAID/ORF

- The NIAID and ORF are currently working together to develop standard operating procedures to ensure that the NIAID and the Maintenance Unit communicate effectively on matters involving maintenance issues.

- Randy Williams, the Maintenance Supervisor has a heightened awareness of the importance of quickly resolving maintenance issues regarding BL3 and BL4 high containment facilities. He has been instructed by the Western Regional Director of ORF to ensure that these facilities receive top-priority regarding maintenance issues.

Observations

- Interviews with NIAID and ORF employees disclosed that there is a high level of confusion and frustration over the command and control structure and the lack of effective lines of communication. One individual simply stated, "The system is broken." The need to establish a clear and concise protocol for requesting maintenance support, along with an accountability measure to ensure that maintenance requests are performed in an efficient and timely manner was expressed as a means to resolve the confusion and frustration problems disclosed by the employees of the NIAID and the ORF.

- This investigation unveiled serious personnel conflicts within the ORF Maintenance Unit. This problem involves name-calling, internal strife, and accusations of unfair labor practices among members of the Maintenance Unit. It was expressed that this internal conflict is being fueled by paranoia, fear and frustration over the Maintenance Units being placed in the ORF under the MEO program.

  This issue is discussed in greater detail in Section (F) "Unproductive Investigation" portion of this report.

Section B - Entities and Individuals

NATIONAL INSTITUTES OF HEALTH
NATIONAL INSTITUTES OF ALLERGY AND INFECTIOUS DISEASES
ROCKY MOUNTAIN LABORATORY
903 S. 4th Street
Hamilton, Montana 59840
(406) 363-3211

Section C – Government Program Involved

National Institute of Health
National Institutes of Allergy and Infectious Diseases

The following information was obtained from the NIH Internet website, and provides a description of the research efforts and activities being conducted at the NIAID.

The NIAID conducts and supports basic and applied research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases. For more than 50 years, NIAID research has led to new therapies, vaccines, diagnostic tests, and other technologies that have improved the health of millions of people in the United States and around the world.

Expanded NIAID Research Portfolio

The scope of the NIAID research portfolio has expanded considerably in recent years in response to new challenges such as:

- bioterrorism
- emerging and re-emerging infectious diseases including:
  - Acquired Immunodeficiency Syndrome (AIDS)
  - Severe Acute Respiratory Syndrome (SARS)
  - West Nile Virus
  - Malaria
  - Tuberculosis
- The increase in asthma prevalence among children in this country

The growth of NIAID programs also has been driven by unprecedented scientific opportunities in the core NIAID scientific disciplines of:

- microbiology
- immunology
- infectious diseases

Advances in these key fields have led to a better understanding of the human immune system and the mechanisms of infectious and immune-mediated diseases.

Biodefense

The threat of bioterrorism has created new challenges for medicine and public health. Our nation's ability to detect and respond to acts of bioterror requires new and improved countermeasures, including diagnostics, vaccines, and therapies. The development of countermeasures is driven by biomedical research on disease-causing microbes and on the immune system response to these pathogens. NIH and NIAID support much of this research.

As the lead agency at NIH for infectious diseases and immunology research, NIAID has developed:

- **The NIAID Strategic Plan for Biodefense Research**
- **The detailed NIAID Biodefense Research Agenda for CDC Category A Agents, with short, intermediate, and long-term goals**
- **The NIAID Biodenfense Research Agenda for Category B and C Priority Pathogens**

The Strategic Plan and Research Agendas stress two overarching and complementary components:

1. Basic research into agents with bioterrorism potential and the specific and nonspecific host defense mechanisms against those agents.
2. Applied research with predetermined milestones for the development of countermeasures.

Advances in biodefense research have been rapid and significant, as delineated in the **NIAID Biodefense Research Agenda for CDC Category A Agents Progress Report** and the **NIAID Biodefense Research Agenda for Category B and C priority Pathogens, Progress Report**. We anticipate that the large investment in research on biodefense will have many positive spin-offs for other diseases. NIAID research on microbial biology and on the pathogenesis of organisms with bioterror potential will certainly lead to a better understanding of other more common and naturally occurring infectious diseases that afflict people here and abroad. Furthermore, and importantly, the NIAID biodefense research agenda promises to enhance our understanding of the molecular and cellular mechanisms of the innate immune system and its relationship to the adaptive immune system. Such knowledge will help in the search for new ways to treat and prevent a variety of immune-mediated diseases.

Vaccine Research

Vaccine research has long been a cornerstone of NIAID research. Effective vaccines have contributed enormously to improvements in public health worldwide, and research supported by NIAID has led to new or improved vaccines for a variety of serious diseases, including:

- rabies
- meningitis
- whooping cough
- hepatitis A and B
- chickenpox
- pneumococcal pneumonia

NIAID is committed to improving global health through the rigorous pursuit of effective vaccines for human diseases.

Vaccine Research Goals

NIAID has three broad goals in vaccine research:

- identifying new vaccine candidates to prevent diseases for which no vaccines currently exist
- improving the safety and efficacy of existing vaccines
- and designing novel vaccine approaches such as new vectors and adjuvants

Vaccine Development Challenges

One of the important challenges for the 21st century is the development of safe and effective vaccines for the three greatest microbial killers worldwide:

- HIV/AIDS
- malaria
- tuberculosis

These three diseases account for one-third to one-half of healthy years lost in less-developed countries. NIAID has a robust portfolio of vaccine research and development for these and other diseases of global importance, including agents of bioterrorism.

HIV/AIDS

Despite recent progress in treatment and prevention, human immunodeficiency virus (HIV) disease and AIDS continue to exact an enormous toll throughout the world. Estimates on the scope of the HIV/AIDS pandemic are profoundly sobering. As of the end of 2003, an estimated 40 million people worldwide are living with HIV/AIDS, 5 million people worldwide were newly infected with HIV, and 3 million people with HIV/AIDS died. More than 95 percent of these infections and deaths have occurred in developing countries, most of which also are burdened by other significant health challenges.

HIV/AIDS Research Collaborations

To help turn the tide of the global HIV/AIDS pandemic, NIAID has established research collaborations with international colleagues in more than 50 countries to develop comprehensive approaches to the HIV pandemic, encompassing vaccine development and other prevention activities, therapeutics and care of the HIV-infected person. These collaborations already have yielded important results, notably in developing methods to reduce mother-to-child transmission of HIV.

NIAID-sponsored Research Efforts

NIAID-sponsored researchers have made critical discoveries about the basic biology of HIV and the immune response to HIV infection, which in turn have led to the development of therapies that suppress the growth of the virus in the body. Although much has been learned in recent

years, questions remain about the molecular interactions involved in the regulation of HIV expression and replication, why the host immune response fails to control the infection, and how reservoirs of virus persist in the body despite highly active antiretroviral treatment (HAART). NIAID continues to search for more scientific information about how the virus attacks the body and how the body defends itself, which is critical for identifying additional targets for therapeutic interventions and vaccines.

Immune System Research

An important NIAID research focus is the immune system, the complex network of cells, tissues, and organs that work together to defend the body against attacks by foreign invaders such as bacteria, viruses, parasites and fungi. Because the human body provides an ideal environment for many microbes, they try to break in. It is the immune system's job to keep them out or, failing that, to seek out and destroy them. When the immune system hits the wrong target or is crippled, however, it can unleash a torrent of diseases, including asthma and allergy diseases, arthritis, or AIDS.

NIAID-funded Research in Basic and Clinical Immunology

NIAID-funded research in basic and clinical immunology has led to many promising approaches for treating individuals with immunologic conditions such as multiple sclerosis, type 1 diabetes, and asthma. For example, researchers are developing novel ways of selectively blocking inappropriate or destructive immune responses while leaving protective immune responses intact, an area of research known as tolerance induction.

The NIAID-supported Immune Tolerance Network (ITN) is an international consortium consisting of approximately 80 basic and clinical scientists and physicians at more than 40 institutions in the United States, Canada, Europe, and Australia. The ITN has 18 approved clinical protocols that are enrolling patients, or will do so soon, in areas such as islet transplantation for type 1 diabetes, kidney transplantation, autoimmune diseases, and asthma and allergic diseases.

Asthma

For the past decade, NIAID also has focused on reducing the significant and growing burden of asthma among inner-city minority children.

NIAID's Inner-City Asthma Study

NIAID's Inner-City Asthma Study has investigated novel interventions to improve the health of inner-city children with asthma.

Physician feedback intervention

One approach, called a physician feedback intervention, involves periodic reports to the child's doctor about the status of the child's asthma. These reports, generated from bimonthly phone

interviews with parents, recommend changes in the child's treatment regimen according to National Heart, Lung, and Blood Institute (NHLBI) guidelines, if warranted.

Environmental intervention

Another method involves an environmental intervention to identify and remove asthma triggers, such as cigarette smoke or cockroaches, from the child's home. Both interventions are reducing health care utilization, and the children receiving the environmental intervention gained an additional 3 weeks of symptom-free days during the intervention year. We are working to make such interventions available nationwide.

Section D - Prosecutive Status

No Criminal or Civil Violations Uncovered

This investigation was initiated based on allegations presented to the OSC in a whistleblower disclosure. The disclosure alleged that a BL3 high containment laboratory at the NIAID in Hamilton, Montana, had been compromised and rendered unsafe.

The OSC concluded that there is a substantial likelihood that the information the whistleblower provided disclosed a ***substantial and specific danger to public health***.

The allegations contained in the OCS whistleblower disclosure and the facts uncovered during this investigation were shared with the Criminal and Civil Chiefs of the United States Attorney's Office for the District of Montana. After reviewing this information, it was determined that there were no grounds for criminal or civil actions related to this investigation.

Failure to Maintain Regulatory Compliance

It was discovered that the self-closing doors of the BL3 facility (Building 25, Suite D) have consistently malfunctioned on and off since the building became operational three-years ago.

On January 11, 2006, CDC personnel conducted an inspection of the NIAID and discovered that the self-closing doors of Building 25, Suite D were malfunctioning.

The CDC inspectors noted that the facility was ***not in regulatory compliance***, because a BL3 laboratory is required to have two self-locking doors.

The malfunctioning doors were repaired and have been functioning properly since January 24, 2006.

Section E - Witnesses and Evidence

1. Albert Richard Hurley, Electrician
Office of Research Facility
Rocky Mountain Laboratory
903 S. 4th Street
Hamilton, Montana 59840
(406) 363-9383

Mr. Hurley has approximately 20 years of service as a federal government employee. He served four years as an Electricians Mate with the United States Navy and four years as an electrician with the Veteran's Administration Medical Center in Houston, Texas before transferring to the NIAID. As of January 2006, Hurley has been employed as an electrician with the NIAID for 12 years.

Mr. Hurley filed a complaint with the OSC alleging that the self-locking doors in Building 25, Suite D were malfunctioning because of airflow problems, and that this was creating a safety and security issue at the laboratory.

2. Nancy Palme Hoe, Ph.D., Biosafety Officer
National Institutes of Allergy and Infectious Diseases
Rocky Mountain Laboratory
903 S. 4th Street
Hamilton, Montana 59840
(406) 531-5259

Dr. Hoe has been employed with the NIAID since December 1999. She began her career with NIAID as a Staff Scientist, and assumed the position of Biosafety Officer in November 2004. She has a Bachelors of Arts in Liberal Arts Studies from Sweetbriar College in Amherst, Virginia and a Doctorate in Biomedical Science from the University of Massachusetts.

Dr. Hoe acknowledged that the self-closing doors in Building 25, Suite D have been a consistent problem since the building was opened. She participated in an inspection conducted by the CDC when it was noted as a deficiency that the self-locking doors were malfunctioning. She took proactive steps to have the door repaired, and the door is now operating correctly.

3. Greg Raymond, Senior Research Assistant
National Institutes of Allergy and Infectious Diseases
Rocky Mountain Laboratory
903 S. 4th Street
Hamilton, Montana 59840
(406) 363-9291

Mr. Raymond has been employed with the NIAID from November 1990 to present. He is a Microbiologist and began his employment at the NIAID as a Research Assistant. In 2001, he was promoted to the position of Senior Research Assistant.

According to Mr. Raymond, there was no danger caused by failure of the Suite D laboratory doors to self-close. He explained that BSE has a very low risk of exposure, because of how the agent would have to be transferred. In order for an individual to be infected with BSE they would have to digest material that contains the BSE agent. BSE is not an airborne virus or disease. Furthermore, scientists at NIAID have not worked with the BSE since Building 25 has been operational.

4. Kevin Gene Mora, Facility Containment Specialist
Office of Research Facility
Rocky Mountain Laboratory
903 S. 4th Street
Hamilton, Montana 59840
(406) 363-9447

Mr. Mora began his employment with NIAID in 1995 as an Utility System Repair Operator. In September 2005, he was promoted to the position of Facility Containment Specialist. As the Facility Containment Specialist, Mr. Mora is responsible for ensuring maintenance at the IRF, a BL4 facility, is correctly performed.

Mr. Mora indicated that the air handling system utilized in Building 25, Suite D is very complicated. This particular system is a constant exhaust/negative pressure system, which has been problematic since the building was opened.

5. Paul Carlson, Occupational Safety and Health
National Institute of Allergy and Infectious Diseases
903 S. 4th Street
Hamilton, MT 59840
(W) 406-363-3211
(M) 406-531-9997

Mr. Carlson is the Occupational Safety and Health Manager for the NIAID. He is responsible for new employee orientations, coordinating refresher training, insuring that policies and procedures are being followed, issuing new policies when necessary and most any issue dealing with the safety and health of the NIAID employees.

According to Mr. Carlson, there was no risk of exposure to the employees or the public. The particular pathogen in Building 25, Suite D is a Mad Cow Disease or pathogen. When scientists are "actively manipulating" the pathogen(s) in these suites, the pathogen(s) are contained within a biological safety cabinet.

6. Randy Williamson, Maintenance Supervisor
903 S. 4th Street
Hamilton, MT 59840
(W) 406-363-9225

Mr. Williamson acknowledged that Suite D has been particularly problematic. Recently, Mr. Williamson assigned Clyde Truex, Air Conditioning Mechanic, to trouble-shoot the door to determine why it wouldn't close. Mr. Williamson also had Kevin Mora, former Air Conditioning Mechanic and now Facility Containment Specialist, examine the door to determine why it wasn't closing properly.

Will Daellenbach, the Western Regional Director for the ORF, has instructed Mr. Williamson to insure that any maintenance related issues at Building 25 (BL3 facility) and Building 28 (BL4 facility) are given top priority.

7. Dr. Richard Henkel and Roger Farmer, CDC
Richard Henkel, PhD, Occupational Health and Safety Manager
Roger Farmer, Program Manager
Division of Select Agents and Toxins
Centers for Disease Control and Prevention
1600 Clifton Rd NE Mailstop E79
Atlanta, GA 30333
(W) 404-498-2294

Dr. Richard Henkel and Roger Farmer are associated with the CDC in Atlanta, Georgia.

In their opinion, there was no safety hazard created by the malfunctioning door. There was the potential security risk of a Non-SRA individual being able to enter the secured suite area

In Dr. Henkel's estimation, there was a zero possibility of exposure to the employees of the NIAID. He further noted that the people actually working with the agents in the laboratory suites aren't vaccinated against these pathogens. If these individuals weren't getting sick then it is highly unlikely that anyone outside the laboratory suite would have been exposed.

Section F - Unproductive Investigation

Personnel Conflicts within the Maintenance Unit

During the course of this investigation, it became apparent that the Maintenance Unit is currently experiencing poor morale, personnel conflicts and internal strife. The following information was gleaned from interviews conducted during this investigation:

Albert Hurley: Accusations of Cronyism and Nepotism

Mr. Hurley referred to the other members of the Maintenance Unit as "criminals and morons" and repeatedly accused them of engaging in "cronyism and nepotism." He ended the interview stating, "you guys arrest them and I'll take over the maintenance shop."

The Investigating Agents noticed that Mr. Hurley appeared aggravated when the agents informed him that they were strictly investigating the malfunctioning door of Building 25, and any safety and security risks created by the failure of the door to operate correctly. Several times throughout the interview, Mr. Hurley digressed into issues surrounding "cronyism and nepotism" and the "criminals and incompetent workers of the maintenance unit." The Investigating Agents observed that Mr. Hurley was very emotionally charged and visibly angered when discussing the topic of "cronyism and nepotism." Mr. Hurley provided the Investigating Agents with a packet of information detailing a history of internal personnel issues he has had with other members of the Maintenance Unit.

Kevin Mora: Morale Problems created by Most Efficient Organization (MEO) Program

The Maintenance Unit was formerly part of the NIAID. Approximately three years ago, the NIH conducted an A-76 study and moved all the maintenance and support personnel under the ORF. "This was part of the Most Efficient Organization Program."

Under this program, according to Mr. Mora, the ORF (formerly the Maintenance Unit) had to submit a competitive bid to retain their jobs. Recently, the ORF had to compete with a bid from Johnston Controls. The ORF originally won the bid, but Johnston Controls filed an appeal arguing that the ORF wasn't performing the duties contained in the bid proposal. Mr. Mora believes that the General Accounting Office is currently reviewing the bid proposals.

Mr. Mora feels the Maintenance Unit's transition from NIAID to the ORF has had a terrible effect on the efficiency of the maintenance mechanics. In addition, it has created a communications problem. Individuals at the NIAID want things to operate like they use to, but now that the Maintenance Unit is under the ORF, they are required to maintain work orders, track man hours and be prepared to justify their contract. The Maintenance Unit can't operate simply by taking phone calls from the NIAID employees.

Mr. Mora advised, "The maintenance employees are under constant pressure of wondering if they have a job or not. This has led to morale problems within the Maintenance Unit."

Kevin Mora: Personnel Conflict

Approximately two weeks prior to this investigation, Mr. Hurley accused Mr. Mora of not being qualified for the position of Facility Containment Specialist. This incident occurred in the presence of Will Daellenbach, the Western Regional Director of ORF. Even though, Mr. Hurley didn't apply for the Facility Containment Specialist position, he thinks that Mr. Mora should be fired and he should be appointed as the Facility Containment Specialist. Mr. Mora showed the Investigating Agents an email documenting this incident that he sent to Johnny Walker, of the ORF in Bethesda, Maryland.

Randy Williamson: Poor Morale & Communication

MEO: Effect on Morale

According to Mr. Williamson, the Maintenance Unit was moved under the MEO program and became part of the ORF. Under this new organizational structure, the Maintenance Unit had to competitively bid against private sector contractors to maintain their work and jobs. Mr. Williamson bid for his job through an A-76 contracting process.

The entire Maintenance Unit is going through this process and the issue has still not been settled. Mr. Williamson is the only employee of the Maintenance Unit that has bid for and secured his job. The remainder of the Maintenance Unit will have to apply for their jobs through a hiring process once the MEO issue is settled.

Mr. Williamson believes the MEO process has damaged the morale of the Maintenance Unit. His job was downgraded from a Wage Supervisor (WS-10) position to a Wage Supervisor (WS-9) position. The ORF anticipates that there will be more downgrades for the mechanics and electricians.

MEO: Effect on Communication

Mr. Williamson advised that the NIAID is not supposed to contact the Maintenance Unit directly. They are supposed to complete a work order that is routed through the ORF offices in Bethesda, Maryland, and then back to the Maintenance Unit. This is how the Maintenance Unit is informed of work that needs to be completed at the NIAID. The NIAID and the Maintenance Unit used to be a tight knit group, so this new process has created a strain.

Mr. Williamson doesn't believe this new system of reporting maintenance requests has hampered the Maintenance Unit ability to respond to maintenance problems in a timely manner because he has asked the NIAID to call him directly if they have an emergency situation.

Randy Williamson: Internal Personnel Problems at the ORF

Tension Between Electricians

Mr. Williamson stated, "The tension between the two electricians is "horrific." The two electricians don't seem to get along, and Mr. Williamson believes it is a result of the MEO problems because the electricians were told up front that one of them would be downgraded.

Mr. Hurley is currently a Wage Grade (WG 11-5) Utility Electrician, and Jim Vargovich is a Wage Grade (WG 11-5) Power Generator Technician. Both Mr. Hurley and Mr. Vargovich perform electrical work at the NIAID.

Mr. Williamson hasn't received final word, but it was initially indicated that one of the electricians would be downgraded to a Wage Grade (WS-10).

Mr. Williamson didn't feel it was necessary for the electricians to know this up front, but it somehow became common knowledge.

Proposed Suspension of Rick Hurley, Electrician

According to Mr. Williamson, Mr. Hurley feels he is the only individual in the Maintenance Unit qualified to do their respective job. In addition, he told Mr. Williamson that he is the only one in the Maintenance Shop qualified to be the Maintenance Supervisor.

On April 22, 2006, Mr. Williamson provided Mr. Hurley with a letter of proposed suspension in relation to an incident that occurred at a meeting on March 9, 2006. In this meeting, Mr. Hurley began "blasting Kevin Mora and Clyde Truex" in front of Mr. Williamson and Will Daellenbach. Mr. Hurley accused Mr. Mora and Mr. Truex of being incompetent to perform their respective jobs. Mr. Williamson asked Mr. Hurley to stop what he was saying, but he refused to quit.

Mr. Williamson has never feared Mr. Hurley, but he is concerned about Mr. Hurley's attitude. After Mr. Williamson provided Mr. Hurley with the proposed letter of suspension, Mr. Hurley responded,

> "I don't have a problem with you Randy [Williamson]. I've got the hornet's nest stirred up now and I'm going after the big boys. I'm not worried about my job, I can go back to Texas and live on my families ranch."

Mr. Williamson is bothered by Mr. Hurley's attitude of not being concerned about his job after completing over 18 years of service in the federal government.

NIAID Lacks Confidence in the Maintenance Unit's Capabilities

During this investigation, members of the NIAID expressed their concerns and a lack of confidence in the capabilities and effectiveness of the Maintenance Unit.

Nancy Hoe: Concerns Regarding the Maintenance Unit

Dr. Hoe said the biggest safety issue at NIAID is the ORF and their incompetence. Specifically, she expressed a concern that the maintenance personnel might inadvertently shut off or turn the wrong valve should an emergency situation arise.

She added that her safety concerns would be eased, if the ORF would incorporate proper training, standard operating procedures, effective lines of communication, and employee accountability in their organization.

Gregory Raymond: Lack of Confidence in the Maintenance Unit's Capabilities

Mr. Raymond indicated that there is a real lack of confidence in the capabilities of the maintenance unit. Some of the instances fueling Mr. Raymond's concerns include:

- Mr. Raymond feels that some of the maintenance mechanics are covering up their lack of knowledge of the mechanical systems utilized in Building 25.

- Mr. Raymond had to draw a chart for one of the HVAC mechanics explaining the difference between positive and negative numbers. Specifically, the mechanic didn't seem to understand that -.0025 indicated a more positive airflow pressure than a reading of -.025. In addition, the HVAC mechanic appears to have a problem understanding decimal points.

- One of the engineers from the architectural team that designed Building 25 told Mr. Raymond that the air handling system should equilibrate in approximately 2-5 seconds from having an airflow adjustment. In contradiction, the HVAC mechanics told Mr. Raymond that it would take a couple of days for the system to equilibrate.

According to Mr. Raymond, "the system is broken." There is a disconnection between the NIAID and the ORF. The Maintenance Unit used to be a part of the NIAID, but was separated into the ORF approximately three-years ago. Mr. Raymond attributes some of the maintenance problems to a breakdown in communication caused by this change. This all leads to an increase in Mr. Raymond's concerns, since the NIAID is scheduled to open a BL4 facility in the early part of 2007.

Comments on agency report, OSC File No. DI-06-1221

The following our my comments on the report from Michael Leavitt, Secretary, Department of Health and Human Services, in response to my allegations of substantial and specific danger to public health arising out of actions by employees at the US Department of Health and Human Services, National Institute of Health (NIH), National Institute of Neurological Disorders and Stroke, Rocky Mountain Laboratory, Hamilton Montana.

I am a WG11-5 licensed Master electrician, and until approximately 3 weeks ago, the only qualified license electrician on staff for 11 years 7 months. I would like to begin by stating that portions of this report are misleading do to my statements or statements attributed to me, taken out of context and or a misinterpretation of what I was attempting to convey.

I.e. I have never made a statement that all shop personnel are incompetent. It has also been brought to my attention that scientific personnel interviewed did not make the statement that the shop as a whole is incompetent, and when specifically asked about my competence, I was given a high mark on competency, and on the contrary Kevin Mora and Clyde Trueax were given very low marks.

These are but two examples of what I see as a mischaracterization of my and others comments to give political cover to cronies and to justify their promotions to critical positions in the soon to open Bio-Level 4 facility.

I am very disappointed in what I see as shameless behavior by mangers, such as Pat Stewart , John Walker, Jeff Fellows, and most recently Will Daellenbach. I have been relentlessly attacked, and my life has been threatened by one of their cronies.

I have been an electrician with the federal government for over 19 years 6 months. My record has been exemplarily, until Pat Stewart took over as director at RML, Her crony relations with Mark Mora and his brother, Kevin Mora, along with the fact that they have no concept as to the National Electrical Code has caused great strife. I have done everything possible to keep this facility from burning down. I have been rewarded along the way with unwarranted reprimands generated by Pat Stewart and her cronies.

I am in possession of many documents supporting my statements. I would be more than willing to discuss these matters with the agency head, the President,

and the appropriate congressional oversight committees.

Albert Richard Hurley
Licensed Master Electrician
Dedicated Federal Employee
19 plus years of service

Albert R Hurley
8/30/06