FINAL
ENVIRONMENTAL IMPACT STATEMENT

RML INTEGRATED RESEARCH FACILITY

National Institutes of Health

Ravalli County

Hamilton, Montana

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Abstract

The National Institutes of Health (NIH) is considering constructing and operating an Integrated Research Facility at Rocky Mountain Laboratories (RML) in Hamilton, Montana. The Integrated Research Facility would include Biosafety Level - 4 (BSL-4) laboratories, in addition to BSL-3 and BSL-2 laboratories, animal rooms, offices, conference rooms, and break areas. The facility is needed to improve the nation's ability to study and combat emerging and re-emerging infectious disease and to protect public health in keeping with NIH's mission.

Two alternatives were considered in detail in the Final Environmental Impact Statement: the Proposed Action (build and operate the Integrated Research Facility), and No Action (continue current RML operations). Four additional alternatives were considered, but were eliminated from detailed study.

The agency's preferred alternative is the Proposed Action. The public comment period on the Final Environmental Impact Statement will close 30 days after the Notice of Availability appears in the Federal Register. Comments should be sent to Valerie Nottingham at the above address.

SUMMARY

INTRODUCTION

Rocky Mountain Laboratories' (RML) mission is to play a leading role in the nation's effort to develop diagnostics, vaccines, and therapeutics to combat emerging and re-emerging infectious diseases. Following events of September 11, 2001, and the anthrax attacks soon after, the public is aware of the potential for exposure of the civilian population to bioterrorism. President Bush and Congress directed the National Institute of Allergy and Infectious Diseases (NIAID) to increase its research into development of safe and effective measures to protect the public. These goals are commensurate with past and current research by NIAID. Research is needed to develop safe vaccines and drugs to prevent or cure infectious diseases. In response to this need for research directed at protecting public health, Congress authorized $66.5 million to NIAID for construction of a biosafety laboratory and related infrastructure (Public Law 107-117, January 10, 2002). NIAID has also developed a Strategic Plan for Biodefense Research and a research agenda for priority (Category A) biological agents, which is included as **Appendix A** (USDHHS 2000a, b).

A lack of available and adequate facilities is a major impediment to the study of organisms. As a result, many important pathogens have received little attention recently and many have not been examined using the tools of modern science. This research deficit becomes most apparent now when there has never been a greater demand for information on the pathogens and host responses to them. Information from basic research studies is critical for development of effective vaccines and therapies to combat infectious diseases. Such products can be developed only through understanding the basic biology of disease-causing agents. Cutting-edge discoveries in infectious disease research have resulted from NIAID programs and it is proposed to enhance the capability of the Institute to carry out basic research on important pathogens in this proposed facility. These enhanced capabilities, once in place, would have an additional benefit to the American public in that they would strengthen the Nation's ability to respond to outbreaks of naturally occurring diseases. Recent outbreaks of SARS and West Nile Fever underscore the need to have an extensive and flexible infrastructure to support infectious disease research to meet the challenge of emerging diseases.

NIAID has a history of research that has had global impacts on public health improvement. This research capability allows NIAID to address unknown, future health threats associated with emerging and re-emerging infectious disease. NIAID is comprised of both intramural and extramural research areas. The Division of Intramural Research (DIR) and the Vaccine Research Center (VRC) conduct intramural research. The DIR is located in laboratories on the main NIH campus in Bethesda, Maryland, the Twinbrook facilities in Rockville, Maryland, and at the Rocky Mountain Laboratories in Hamilton, Montana. DIR conducts research in virology, biochemistry, parasitology, epidemiology, mycology, molecular biology, immunology, immunopathology, and immunogenetics, and supports clinical, patient-centered research in allergy, immunology, and infectious diseases at NIH's Clinical Center (NIAID 2002a). NIAID supports extramural research, done by non-federal scientists in universities, medical schools, hospitals, and research institutions.

NIAID is one of 27 Institutes or Centers of NIH. NIH is one of 12 agencies of the U.S. Department of Health and Human Services.

As part of the expanded research program, NIH is proposing to construct an Integrated Research Facility and complete infrastructure upgrades to existing facilities at the RML campus in Hamilton. In the U.S., facilities to conduct research with pathogenic material at the highest level of containment are limited to Atlanta, Georgia; Frederick and Bethesda, Maryland; and San Antonio and Galveston, Texas.

PURPOSE OF AND NEED FOR ACTION

The purpose for the Proposed Action is to provide a highly contained and secure intramural laboratory at RML dedicated to studying the basic biology of agents of emerging and re-emerging diseases, some of which have potential as bioterrorism agents. Because of its traditional strengths in the area of infectious disease research and the federal funding parameters associated with NIAID's intramural laboratory program, the Integrated Research Facility is proposed to be located at RML in Hamilton, Montana.

In order to conduct necessary research to gain an understanding of pathogen and host response, specialized high-containment laboratories are required. The need for the Project (construction of the proposed Integrated Research Facility at RML) is based on the following aspects of the current facility at RML:

- RML is renowned for expertise in research on infectious microbes;
- Researchers at RML provide a core of unparalleled scientific knowledge uniquely qualified to develop strategies and products to counter emerging and re-emerging diseases;
- RML currently has BSL-2 and BSL-3 laboratories;
- Existing infrastructure at RML can efficiently and effectively provide a realistic, orderly, and comprehensive effort to safeguard the health of the American people through basic research as well as detection, investigation, control, and prevention of diseases.

Emergence of new diseases (e.g., HIV/AIDS, hantavirus pulmonary syndrome, West Nile fever, severe acute respiratory syndrome (SARS)) and re-emergence of drug-resistant pathogens (e.g., tuberculosis, malaria, *Staphylococci aureus*) are reminders that infectious diseases remain dominant features of national and international public health (USDHHS 1998; Fauci 2001). Societal, technological, and environmental factors (e.g., population growth, poverty, ease of travel, alteration of habitats) facilitate occurrence and spread of disease. A critical need exists for continued research, not only on new diseases, but also on old and familiar ones.

SUMMARY OF PROPOSED ACTION

NIH proposes to construct an Integrated Research Facility to house Biosafety Level (BSL)-2, BSL-3, and BSL-4 laboratories, animal research facilities, administrative support offices, conference rooms, and break areas at the RML Facility in Hamilton, Montana. The Proposed Action would encompass approximately 105,000 square feet of building constructed within the existing 33-acre RML campus in the southwest portion of Hamilton.

The Integrated Research Facility and research programs would require additions and upgrades to the existing RML campus. Upgrades would include:

- A new chilled water plant and emergency power backup system;
- A new addition to Boiler Building 26 to house a new natural gas-fired boiler; and
- Construction of below grade systems and utility distribution tunnels to service the Integrated Research Facility.

Research at the RML site would include pathogenesis, immune response, vaccine, diagnostics and therapeutics work and will focus on RML's strength in vector-borne pathogen research. RML does not and will not conduct research to develop offensive biological weapons.

Biosafety Level 4 (BSL-4)

A BSL-4 laboratory would be constructed within the Integrated Research Facility to provide the highest possible level of protection for scientists and the public and to expand the research capability of RML. The use of a BSL-4 laboratory would be required for research of certain agents and experiments, such as testing of vaccines for emerging and re-emerging infectious microbial agents that are normally ranked at BSL-3 level. Stringent safeguards, including engineering and design features (see Appendix E) are required for BSL-3 and BSL-4 laboratory facilities to prevent pathogens from escaping into the environment. In addition, the BSL-4 laboratory would be designed

to prevent contact between pathogens and people inside the workspace and provide secure storage for infectious agents.

The BSL-4 laboratory would be located within the central core of the building, surrounded by a buffer corridor between the laboratory and the exterior. A specific facility operations manual would be prepared and adopted prior to operation of the laboratory.

PROJECT ALTERNATIVES

Alternatives were identified during the public scoping process or by RML during review and analysis of the Proposed Action. The following alternatives were considered technically infeasible, provided no environmental advantage over the Proposed Action or No Action, or did not meet the purpose and need:

- Build the Integrated Research Facility in Bethesda, Maryland
- Relocate Rocky Mountain Laboratories to a Less Populated Area
- Construct the Integrated Research Facility at Alternate Location
- Construct and administer the Integrated Research Facility by another agency, or at another NIH Location

The only alternative to the Proposed Action discussed in detail in this EIS is the No Action Alternative. Under the No Action Alternative, the Proposed Action would not be implemented at RML. Existing operations at RML would be maintained and operated at current levels.

SUMMARY OF IMPACTS

Analysis of potential impacts and mitigation measures associated with the Proposed Action and Alternatives is presented in Chapter 4 – *Environmental Consequences.* The following is a summary of potential impacts resulting from the Proposed Action and No Action Alternative.

SOCIAL RESOURCES

Proposed Action

Additional employment associated with the proposed Integrated Research Facility includes up to 200 workers at the peak of construction and about 100 employees in late 2005/early 2006 when the facility would be opened. Based on the Ravalli County rate of 2.45 persons per household, this would add a total of 245 new residents to the county. This represents between 1.4 percent and 3 percent of all new residents projected for the County, based on estimates in the Ravalli County Economic Needs Assessment (Swanson, 2002). Addition of new homes would result in increased business for homebuilders and real estate developers. School capacity is adequate for new growth, but operating and maintenance costs would increase to accommodate the new students. No impact is expected on the ethnic or gender make-up of the population.

Traffic around the RML associated with construction, delivery of equipment and materials would increase over the 2-year construction period. Following construction, traffic levels would likely remain elevated due to the 100 new permanent employees at RML (approximately 20 percent during peak hours), although large truck traffic to support RML would return to current levels.

No Action Alternative

Under the No Action Alternative, population growth and housing starts would likely continue at the current pace. Current levels of community services, programs, and infrastructure would not change. Current levels of traffic would continue in the neighborhood adjoining RML. Research on agents at the BSL-2 and BSL-3 level would continue.

COMMUNITY RISK

Proposed Action

Redundancy of safety equipment and procedures, operational safeguards, and monitoring systems inherent to biosafety laboratories reduce the risk

of an accidental release. Theoretically, human error or multiple, simultaneous mechanical failures could lead to accidental release of biological materials from a biosafety laboratory. The overall safety record of biomedical and microbiological laboratories also indicates that there is not a risk of accidental release. Nevertheless, in order to address community safety concerns, the NIH applied both qualitative and quantitative risk assessment strategies to investigate potential community impacts of the proposed Integrated Research Facility at the RML. The qualitative assessment included a literature review regarding laboratory acquired infections; a review of all infectious disease research protocols performed by the NIAID requiring BSL-2 with BSL-3 practices, BSL-3, or BSL-4 facilities for the past two decades; review of all NIAID accidents associated with these laboratories; injuries and illnesses during the same period of time; review of RML medical waste incinerator operations, infectious waste handling procedures, animal containment, and procedures for biological material shipment. Additionally, a survey was conducted to determine the safety records of BSL-4 laboratories worldwide with 20 or more years of operating experience. Additionally, the NIH performed a quantitative assessment of risk with regard to infectious agent release to the surrounding Hamilton community from the proposed BSL-4 Integrated Research Facility at RML. The quantitative risk assessment was driven by reasonably foreseeable, credible threat scenarios and addressed spills and work disruption; safety system operation and potential failures; and fire and explosion. The modeling tool used to perform these analyses is the Maximum Possible Risk (MPR) model developed by the NIH. Anthrax, in spore form, was chosen as the worst-case scenario agent based on public health impact and dissemination potential (Rotz *et. al.* 2002).

Qualitative and quantitative risk analysis revealed that the potential risk to the community surrounding the Rocky Mountain Laboratories and specifically the IRF from potential release of infectious agents is negligible.

No Action Alternative

Under the no action alternative, human error or multiple, simultaneous mechanical failures could lead to accidental release of biological materials from the existing RML facilities. However, safety equipment and procedures, operational safeguards, and monitoring systems inherent to biosafety labs significantly reduce the risk of accidental release. The overall safety record of biomedical and microbiological laboratories indicates that there is not a significant risk of accidental release. Therefore, the potential risk to the community surrounding the Rocky Mountain Laboratories from the existing laboratories in which infectious disease research is currently conducted is negligible.

ECONOMIC RESOURCES

Proposed Action

The Proposed Action would have direct economic impacts on both the City of Hamilton and Ravalli County throughout construction and operation. Payroll associated with construction of the Integrated Research Facility is estimated at $4.7 million. Using the current economic multiplier in the 2002 Ravalli County Needs Assessment, approximately $18.9 million in economic activity would be gained in the 2-year construction period.

Annual payroll for 100 new employees is estimated at $6.6 million. Added to the current $10.4 million annual payroll, RML would contribute $17 million annually to the local economy. The RML and the proposed Integrated Research Facility meet community goals listed in the 2002 Ravalli County Economic Needs Assessment, Ravalli County Growth Policy, and the City of Hamilton Comprehensive Master Plan.

Public finance revenues would increase from income tax on the Integrated Research Facility-related construction and operations payrolls, as well as income of spouses and older children of the additional RML employees, increased number of licensed vehicles, and property tax revenues based on additional new homes and property assessments.

No Action

Selection of the No Action alternative would not have direct economic impacts. An opportunity to

stabilize the local economy with government jobs and increased tax revenue would be lost, slowing the realization of economic development goals of the city and county.

NOISE

Proposed Action

Additional noise producing equipment would be associated with construction of the Integrated Research Facility. With specified noise reduction measures, the Integrated Research Facility would meet RML's 2003 noise guidelines. Reasonably foreseeable action and recently implemented noise reduction features have and would reduce noise further.

No Action

There would be no change in the noise level from not implementing the Proposed Action. Periodic noise measurements will be taken by an independent professional acoustic contractor to evaluate compliance with the voluntary guidelines. In the event that noise levels exceed the guidelines, funding will be sought to institute remedial measures. Reasonably foreseeable action and recently implemented noise reduction features have and would reduce noise further.

VISUAL QUALITY

Proposed Action

The primary visual impact of the Proposed Action would be the addition of a large building into an area of existing buildings. Existing and proposed stacks associated with the Boiler Plant would create vertical linear contrast to surrounding structures. Ventilation stacks on the Integrated Research Facility would not be visible from off the campus. Proposed landscaping around the Integrated Research Facility would have a positive impact on visual quality in the neighborhood.

No Action

There would be no change in existing visual condition under the No Action Alternative. The site is vegetated with scrub grasses and weeds. There are also dirt/gravel roadways and areas of deteriorating asphalt. A variety of outside clutter and covered storage is visible but could be removed to improve facility aesthetics.

HISTORICAL RESOURCES

Proposed Action

The Proposed Action would be partially visible from the RML Historic District. The Integrated Research Facility could affect the view from the historic district, but there would be no adverse effect on the qualities inherent in the Historic District.

No Action

Selection of the No Action Alternative would have no effect on the existing historic district.

AIR QUALITY

Proposed Action

Gaseous and particulate air contaminant emissions would be generated during normal laboratory operations. Source emissions would comply with all air quality standards. Use of the incinerator to dispose of refuse generated at the facility, including those from the Integrated Research Facility, would increase from 2-3 days/week to 3-4 days/week. Permit limits (Montana Air Quality Permit 2991-04) on the incinerator would not be exceeded.

No Action

Emissions from RML would remain at current levels under the No Action Alternative.

WATER SUPPLY AND WASTEWATER

Proposed Action

The estimated increase in water use of 17,000 gallons per day represents about a 1 percent increase in the amount of water pumped by the City of Hamilton Department of Public Works (CHDPW) on a daily basis. With respect to available capacity, the Integrated Research Facility

would use about 5.3 percent (12 gpm of 226 gpm) of system capacity. Increased demand for water created by operation of the Integrated Research Facility would have a minor impact on the CHDPW municipal water supply system, and the system would be able to handle the increased demand.

Approximately 1,000 to 1,200 pounds of solids per day are currently handled at the CHDPW. (Lowry 2003). The Integrated Research Facility would generate an estimated 28 pounds of additional solids, representing a 2.3 to 2.8 percent increase in solids load to the CHDPW wastewater facility.

The Proposed Action would not have an impact on the solids handling capacity at the CHDPW because the planned upgrade of the solids handling capacity at the facility would accommodate current and future needs of Hamilton as well as additional solids produced by the Integrated Research Facility.

No Action

Selection of the No Action Alternative would have no adverse affects on the Hamilton water supply and wastewater treatment systems.

CUMULATIVE EFFECTS

Cumulative effects on the environment resulting from past, present and reasonably foreseeable actions (NIH, other organizations, growth), along with construction of the Integrated Research Facility would include an increase in area traffic, increased demand on community services and programs, increased water use and demand on CHDPW water and sewage treatment systems, and population growth in the Bitterroot Valley. Increased payroll would benefit the local economy and tax revenue from income and property assessments would benefit local and state government. These effects may be compounded by the expansion of Corixa, Inc. and growth projected in Hamilton.

PREFERRED ALTERNATIVE

The NIH has identified the Proposed Action as the preferred alternative.

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CHAPTER 1
PURPOSE AND NEED

1.1 BACKGROUND

Rocky Mountain Laboratories' (RML) mission is to play a leading role in the nation's effort to develop diagnostics, vaccines, and therapeutics to combat emerging and re-emerging infectious diseases. Following events of September 11, 2001, and the anthrax attacks soon after, the public is aware of the potential for exposure of the civilian population to bioterrorism. President Bush and Congress directed the National Institute of Allergy and Infectious Diseases (NIAID) to increase its research into development of safe and effective measures to protect the public. These goals are commensurate with past and current research by NIAID. Research is needed to develop safe vaccines and drugs to prevent or cure infectious diseases. In response to this need for research directed at protecting public health, Congress authorized $66.5 million to NIAID for construction of a biosafety laboratory and related infrastructure (Public Law 107-117, January 10, 2002). NIAID has also developed a *Strategic Plan for Biodefense Research* and a research agenda for priority (Category A) biological agents, which is included as **Appendix A** (USDHHS 2000a, b).

A lack of available and adequate facilities is a major impediment to the study of organisms. As a result, many important pathogens have received little attention recently, and many have not been examined using the tools of modern science. This research deficit becomes most apparent now when there has never been a greater demand for information on the pathogens and host responses to them. Information from basic research studies is critical for development of effective vaccines and therapies to combat infectious diseases. Such products can be developed only through understanding the basic biology of disease-causing agents. Cutting-edge discoveries in infectious disease research have resulted from NIAID programs. It is proposed to enhance the capability of the Institute to carry out basic research on important pathogens in this proposed facility. These enhanced capabilities, once in place, would have an additional benefit to the American public in that they would strengthen the nation's ability to respond to outbreaks of naturally occurring diseases. Recent outbreaks of SARS and West Nile Fever underscore the need to have an extensive and flexible infrastructure to support infectious disease research to meet the challenge of emerging diseases.

NIAID has a history of research that has had global impacts on public health improvement. This research capability allows NIAID to address unknown, future health threats associated with emerging and re-emerging infectious disease. NIAID is comprised of both intramural and extramural research areas. The Division of Intramural Research (DIR) and the Vaccine Research Center conduct intramural research. The DIR is located in laboratories on the main NIH campus in Bethesda, Maryland; the Twinbrook facilities in Rockville, Maryland; and the Rocky Mountain Laboratories in Hamilton, Montana. DIR conducts research in virology, biochemistry, parasitology, epidemiology, mycology, molecular biology, immunology, immunopathology, and immunogenetics, and supports clinical, patient-centered research in allergy, immunology, and infectious diseases at National Institutes of Health's (NIH) Clinical Center (NIAID 2002a). NIAID supports extramural research, done by non-federal scientists in universities, medical schools, hospitals and research institutions.

NIAID is one of 27 institutes or centers of NIH. NIH is one of 12 agencies of the U.S. Department of Health and Human Services.

RML does not and will not work on or develop biological weapons, as this is forbidden by a national security directive and international law. President Nixon, in 1969, agreed to a National Security Decision Memorandum (35), which renounced use of lethal methods of bacteriological/biological warfare and ordered destruction of all stockpiled agents. The U.S. signed the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, which became effective March 26, 1975 (signed by President Ford and ratified by Congress), which remains in effect

today. The U.S. government maintains the position that there is no justification, including retaliation, for offensive biological weapons research or use.

As part of the expanded research program, NIH is proposing to construct an Integrated Research Facility and complete infrastructure upgrades to existing facilities at the RML campus in Hamilton (**Figure 1-1**). In the U.S., facilities to conduct research with pathogenic material at the highest level of containment are limited to Atlanta, Georgia; Frederick and Bethesda, Maryland; and San Antonio and Galveston, Texas.

Public participants have expressed concern over installation of the proposed Integrated Research Facility and potential risks of biological and infectious agents to be studied. This Final Environmental Impact Statement (FEIS) analyzes potential impacts associated with the proposed Integrated Research Facility as required by the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. § 4321 *et seq.*), and U.S. Department of Health and Human Services General Administration Manual Part 30: Environmental Protection. This document follows the Council on Environmental Quality's regulations for implementing procedural provisions of NEPA (40 CFR Parts 1500-1508).

1.1.1 Organization of the Document

Chapter 1 – Purpose and Need. This chapter explains the purpose and need for the Proposed Action. It also includes a summary of public comment and how issues raised during public scoping were used.

Chapter 2 – Proposed Action and Alternatives. This chapter discusses in more detail alternatives considered in the EIS and compares them.

Chapter 3 – Affected Environment. This chapter explains the current condition of resources that may be affected by the Proposed Action. Resources that would not be affected are identified and rationale provided as to why they will not be discussed further.

Chapter 4 - Environmental Consequences. This chapter discloses potential effects of alternatives, including direct, indirect, and cumulative effects.

Chapter 5 - Response to Comments. This chapter contains a copy of all comments received on the SDEIS along with NIH's response to substantive comments.

Appendix A - Strategic Plan for Biodefense Research.

Appendix B - Characteristics of Diseases Studied at RML.

Appendix C - Transportation of Agents.

Appendix D - Review of Biocontainment Laboratory Safety Record.

Appendix E - Standard Operating Procedures for a BSL-4 Facility.

1.1.2 Required Disclosures

In accordance with section 40 CFR 1502.16 (Regulations Implementing the Procedural Provisions of NEPA), the following list details the required disclosures and where they can be found:

- Direct and indirect effects and their significance (Chapter 4);
- Potential conflicts between the Proposed Action and objectives of federal, state, and local land use plans, policies, and controls (Chapter 1);
- Potential environmental effects of alternatives (Chapter 4);
- Energy requirements and conservation potential and mitigation measures (Chapter 2 – Proposed Action);
- Natural and depletable resource requirements, conservation potential, and mitigation measures (Chapter 2 – Proposed Action);
- Urban quality, historic and cultural resources, and design of the built environment (Chapter 3 and Chapter 4 – Historic Resources); and
- Means to mitigate adverse environmental impacts (Chapter 4).

1.2 HISTORY OF ROCKY MOUNTAIN LABORATORIES

RML is located in Hamilton, Montana, approximately 50 miles south of Missoula, in Ravalli County. Hamilton has a population of approximately 3,700 and is located in the center of western Montana's Bitterroot Valley. RML is located east of the Bitterroot River in the southwest portion of Hamilton (**Figure 1-1**).

Infectious diseases are the second leading cause of death worldwide (WHO 2000) and rank third in the United States (Armstrong *et al.* 1999). NIAID, through work at the RML facility, "conducts and supports research that strives to understand, treat, and ultimately prevent the myriad of infectious, immunologic, and allergic diseases that threaten millions of human lives" (USDHHS 2000a). NIAID has a history of research that has had global impacts on public health improvement, which allows it to address unknown, future health threats associated with emerging and re-emerging infectious disease.

RML began in 1902 as a camp that served as a research laboratory. The researchers found that ticks transmitted Rocky Mountain spotted fever. During the 1920s, ticks were ground up to make a vaccine for this disease at RML.

After successful work with spotted fever, RML expanded its facilities and programs in the 1930s and 1940s to work on other insect-borne diseases, including yellow fever and spirochetal relapsing fevers. In the 1940s, scientists made vaccines (in buildings that are part of RML's current complex) that protected troops against typhus and yellow fever during World War II.

In 1948, RML and the Biologics Control Laboratory joined the Division of Infectious Diseases of the NIH to form the National Microbiological Institute. Six years later, Congress gave the institute its present name, NIAID, to reflect inclusion of allergy and immunology research.

In 1979, the laboratory was renamed Rocky Mountain Laboratories because it consisted of multiple laboratories and branches. The current organizational structure consists of the Laboratory of Persistent Viral Diseases, Laboratory of Human Bacterial Pathogenesis, Laboratory of Intracellular Parasites, Rocky Mountain Veterinary Branch, and the Administrative and Facilities Management Section (USDHHS 2002a).

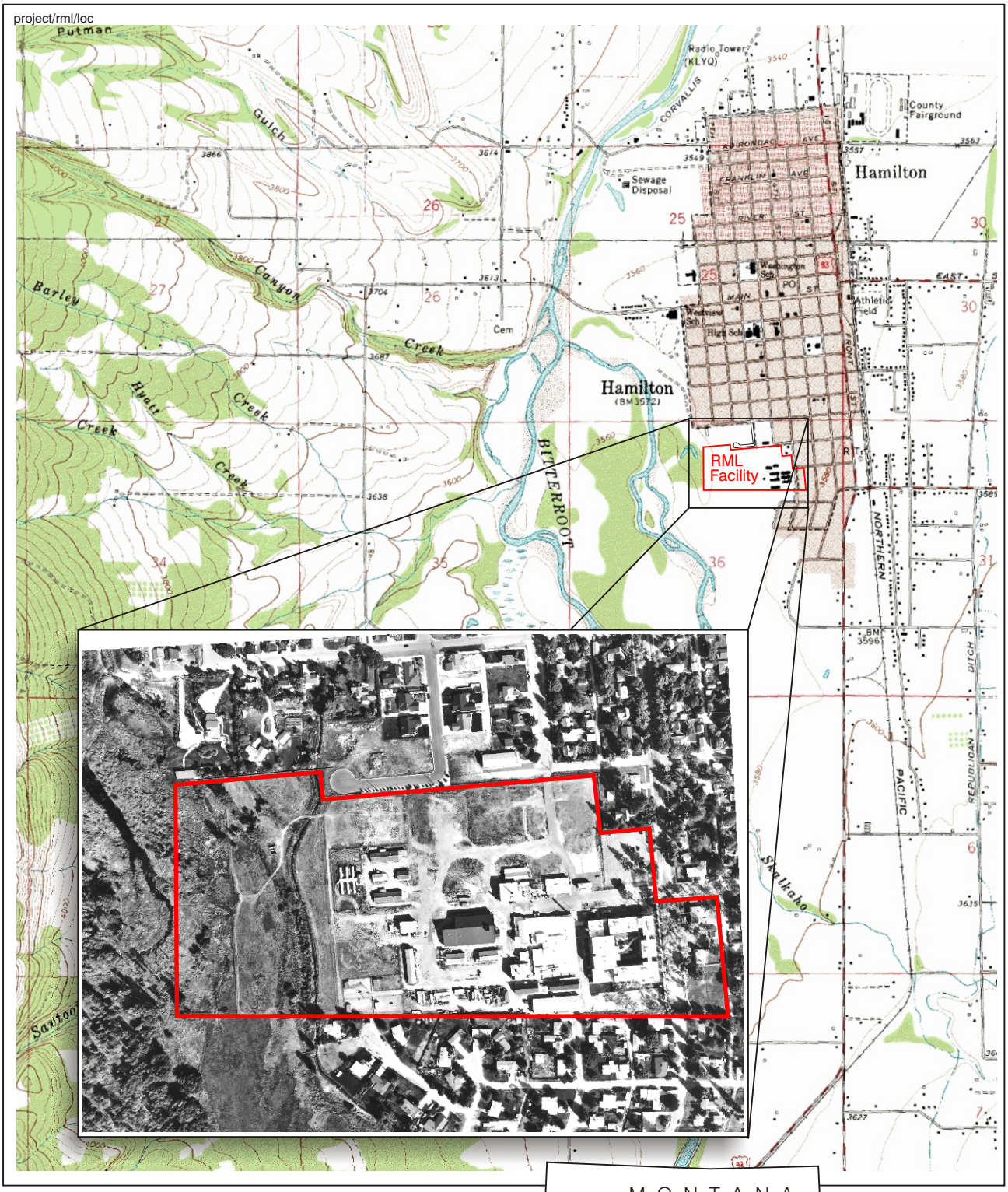
In 1982, the agent that causes Lyme disease, also transmitted by ticks, was identified at RML. Today, scientists at RML are investigating infectious diseases including Rocky Mountain spotted fever, chlamydia, HIV/AIDS, Q fever, tuberculosis, plague, Lyme disease, salmonella (typhoid fever), and transmissible spongiform encephalopathies (e.g., sheep scrapie and mad-cow disease).

1.3 ELEMENTS OF BIOSAFETY CONTAINMENT

The three elements of containment in biosafety laboratories are laboratory practice and technique, safety equipment, and facility design. The pathogen, health hazard, and research purpose (e.g., tissue culture, vaccine production) determine the elements of containment necessary (USDHHS 1999). Biosafety levels are combinations of these elements (**Table 1-1**).

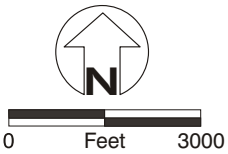
While certain biological agents may require a given biosafety level (e.g., syphilis is BSL-2 for all procedures), the recommended biosafety level may vary by agent and type of research. An example using hantavirus helps to illustrate this point.

Hantaviruses are Category C biological agents according to U.S. Department of Health and Human Services (USDHHS 1998). Category C agents are emerging pathogens that could be engineered for mass dissemination in the future because they are available, easy to produce and disseminate, and have potential for high mortality rates and major health impacts. Hantavirus pulmonary syndrome is an emerging disease. According to biosafety standards (USDHHS 1999), BSL-2 practices and procedures are recommended for laboratory handling of sera with potential infections of hantavirus pulmonary syndrome. Use of a certified biological safety cabinet (BSC) is recommended for handling human body fluids when potential exists for spillage or aerosol. Potentially infected tissue samples are handled in BSL-2 facilities following BSL-3 practices and procedures. Cell-culture virus propagation is carried out in a BSL-3 facility following BSL-3 practices and procedures. Preparation and handling of viral concentrates is performed in BSL-4 containment facilities. Therefore, appropriate biosafety levels and the agent and type of research determine which procedures are to be used. Additional operational procedures may be implemented based on experience.



Basemap from USGS 7.5' Hamilton North and South Quads,1964
Photobase from MAP, Inc., 2002 (edited 2003)

Location Map
RML Integrated Research Facility FEIS
Hamilton, Montana
FIGURE 1-1



1.4 PURPOSE AND NEED FOR ACTION

The purpose for the Proposed Action (described in detail beginning on page **Error! Bookmark not defined.**) is to provide a highly contained and secure intramural laboratory at RML dedicated to studying the basic biology of agents of emerging and re-emerging diseases, some of which have potential as bioterrorism agents. Because of its traditional strengths in the area of infectious disease research and the federal funding parameters associated with NIAID's intramural laboratory program, the Integrated Research Facility is proposed to be located at RML in Hamilton, Montana.

To protect citizens of the U.S., the public health system and primary healthcare providers must be

Table 1-1.
Summary of Recommended Biosafety Levels for Infectious Agents

BSL	Agents	Practices	Safety Equipment (Primary Barriers)	Facilities (Secondary Barriers)
1	Not known to consistently cause disease in healthy adults	Standard microbiological practices	None required	Open bench-top sink required
2	Associated with human disease, hazards are percutaneous injury, ingestion, mucous membrane exposure	BSL-1 practice plus: • Limited access • Biohazard warning signs • "Sharps" precautions • Biosafety manual defining any needed waste decontamination or medical surveillance policies	Primary barriers are Class I or II BSCs or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials; PPE are laboratory coats, gloves, and face protection as needed	BSL-1 plus: Autoclave available Directional airflow into laboratory
3	Indigenous or exotic agents with potential for aerosol transmission; disease may have serious or lethal consequences	BSL-2 practice plus: • Controlled access • Decontamination of all waste • Decontamination of lab clothing before laundering • Baseline serum	Primary barriers are Class I or II BSCs or other physical containment devices used for all open manipulations of agents; PPE are protective lab clothing, gloves, respiratory protection as needed, and solid front gowns	BSL-2 plus: • Physical separation from access corridors • Self-closing, double-door access • Exhausted air not recirculated • Negative airflow into laboratory
4	Dangerous/exotic agents which pose high risk of life-threatening disease, aerosol-transmitted lab infections; or related agents with unknown risk of transmission	BSL-3 practices plus: • Clothing change before entering • Shower on exit • All material decontaminated on exit from facility	Cabinet Laboratory All procedures conducted in Class III BSC; workers not in full-body, air-supplied, positive pressure suit Suit Laboratory Procedures conducted in suit lab area in combination with Class I or Class II BSCs; Workers in full-body, air-supplied, positive pressure suit	BSL-3 plus: • Separate building or isolated zone • Dedicated supply and exhaust, vacuum, and decontamination systems • Other requirements outlined in the text

BSL = Biosafety Level
BSC = Biological Safety Cabinet
PPE = Personal Protective Equipment.
Source: USDHHS 1999.

agents, including rarely seen pathogens. Research plays a major role in developing techniques for identifying and characterizing biological agents. Also, several of the "critical biological agents" identified in the Centers for Disease Control and Prevention's (CDC) strategic plan are listed as priority emerging or re-emerging diseases in CDC's strategy for preventing emerging infectious diseases (USDHHS 1998).

The goal of successful preparation for the threat of diseases depends in large measure on availability of effective diagnostic tests, vaccines, and therapeutic drugs. Information from basic research studies is critical for development of effective vaccines and therapies to strengthen the response to outbreaks. Effective vaccines and therapies can be developed only through understanding the basic biology of disease-causing agents.

The President's budget for 2003 devotes funds to NIAID for basic and applied research, including funds designated specifically for construction of intramural facilities.

NIAID has developed a research agenda for Category A agents (USDHHS 2002b). Category A agents are easily transmitted from person to person, have high mortality rates, may have major public health impacts, might cause public panic and social disruption, and require special action for public health preparedness. The research agenda emphasizes the following five interrelated areas:

- Basic biology and disease-causing mechanisms;
- Host immune response;
- New and improved vaccines;
- New and improved treatments against new and drug-resistant agents; and
- New techniques for rapidly and accurately identifying the disease agent.

In order to conduct necessary research to gain an understanding of pathogen and host response, specialized high-containment laboratories are required. Building upon available expertise is required for a response in a timely fashion. The need for the Project (construction of the proposed Integrated Research Facility at RML) is based on the following aspects of the current facility at RML:

- RML is renowned for expertise in research on infectious microbes;
- Researchers at RML provide a core of unparalleled scientific knowledge uniquely qualified to develop strategies and products to counter emerging and re-emerging diseases;
- RML currently has BSL-2 and BSL-3 laboratories;
- Existing infrastructure at RML can efficiently and effectively provide a realistic, orderly, and comprehensive effort to safeguard the health of the American people through basic research as well as detection, investigation, control, and prevention of diseases.

Emergence of new diseases (e.g., HIV/AIDS, hantavirus pulmonary syndrome, severe acute respiratory syndrome (SARS), West Nile fever) and re-emergence of drug-resistant pathogens (e.g., tuberculosis, malaria, *Staphylococci aureus*) are reminders that infectious diseases remain dominant features of national and international public health (USDHHS 1998; Fauci 2001). Societal, technological, and environmental factors (e.g., population growth, poverty, ease of travel, alteration of habitats) facilitate occurrence and spread of disease. A critical need exists for continued research, not only on new diseases, but also on old and familiar ones.

A lack of available and adequate facilities is a major reason that study of these organisms has received little attention in the recent past. There has never been a greater demand for basic information on pathogens and host responses for development of effective vaccines and therapies. Such information can be developed only through understanding of the basic biology of disease-causing agents in laboratories designed with the highest safety precautions (BSL-4).

1.5 SCOPE

The scope of the Project is established by the purpose and need and by U.S. Department of Health and Human Services (USDHHS) procedures and authority. The scope (40 CFR 1508.25) consists of the range of actions, alternatives, environmental issues, and impacts to be considered and discussed in the EIS.

1.5.1 Impacts

Regulations contained in 40 CFR 1508.25[c] require analysis of direct, indirect, and cumulative impacts. Direct impacts are caused by the action and occur at the same time and place. Indirect impacts are caused by the action and occur later in time or farther removed in distance, but they are still reasonably foreseeable. Cumulative impacts result from incremental impact of the action when added to other past, present, and reasonably foreseeable future actions.

1.5.2 Alternatives

In determining the scope of analysis, NIH must consider three types of alternatives (40 CFR 1508.25[b]): no action, other reasonable courses of action, and mitigation measures. Other reasonable courses of action include alternatives that meet the stated purpose and need and, in this case, are within the available budget. Alternatives are discussed in Chapter 2. Impacts of the No Action Alternative, which would maintain the current operations, are also considered.

1.5.3 Connected, Cumulative, and Similar Actions

The Code of Federal Regulations (40 CFR 1508.25) addresses the scope of analysis and elements to be considered in a Proposed Action. The regulations recognize that separate activities can combine and interact to create impacts that *may be significantly beyond* the effects of individual actions. These actions are considered *cumulative*, and their additive effects must be addressed in the analysis.

Federal regulations also require a combined analysis of *connected* actions. Connected actions are closely related and 1) automatically trigger other actions, 2) could not or would not proceed unless other actions are taken previously or simultaneously, and 3) are interdependent parts of a larger action and depend on the larger action for their justification. The effects of connected actions should be analyzed together. *Similar* actions are those that share a common timing or geography and are evaluated together.

1.5.4 Decision To Be Made

Based on the environmental analysis and consideration of public comments on the Proposed Action, NIH will decide:

- Whether to construct an Integrated Research Facility including a Biosafety Level 4 laboratory at RML;
- Whether upgrades to existing infrastructure included in the Proposed Action would be accomplished; and
- What mitigation and monitoring measures (if any) would be required.

The scope of the Project is confined to issues and potential environmental consequences relevant to the decision. The decision is subject to direction from higher levels. Other agencies with regulatory authority are shown in **Table 1-2**.

The Council on Environmental Quality regulations implementing NEPA require consideration of environmental effects and prescribe mitigation where practical to limit those effects. Reconsideration of other existing NIH/RML decisions or programmatically prescribing mitigation or standards for future NIH/RML activities is beyond the scope of this document.

1.6 PUBLIC SCOPING

A Notice of Intent to prepare an EIS was published in the Federal Register on October 4, 2002. Publication of this notice initiated a 30-day public scoping period that provided for acceptance of comments through November 4, 2002. NIH allowed an additional two weeks for comments, through November 18, 2002. A public scoping meeting was held in Hamilton on October 21, 2002. About 100 people attended that meeting.

NIH published and distributed the draft EIS (DEIS) for the proposed Integrated Research Facility in May 2003. A Notice of Availability was published in the Federal Register on May 23, 2003, which initiated a 60-day public comment period on the DEIS ending on July 21, 2003. A public meeting was held on June 26, 2003, to solicit comments from the public on the DEIS. Approximately 200 people attended the public meeting, at which 31 people provided verbal comments.

Table 1-2.
Regulatory Responsibilities

Authorizing Action	Regulatory Agency
Air Quality Permit	Montana Department of Environmental Quality (MDEQ)
Emergency Response	MDEQ, the Department of Military Affairs, Disaster and Emergency Services Division, and Occupational Safety and Health Administration (OSHA)
National Environmental Policy Act	U.S. Environmental Protection Agency (USEPA), U.S. Department of Health and Human Services (USDHHS), and Council on Environmental Quality
National Historic Preservation Act	State Historic Preservation Office (SHPO)
Infectious and Hazardous Material/Waste Management	MDEQ and OSHA
Transport of Hazardous Material (Wastes)	U.S. Department of Transportation, Federal Aviation Administration, International Air Transportation Association (IATA), MDEQ
Construction Safety	OSHA
Emergency Planning and Community Right-to-Know Act (EPCRA)	USEPA (Region 8)
Safe Drinking Water Act	MDEQ and the City of Hamilton
Radioactive Materials	Nuclear Regulatory Commission

One hundred twenty-two letters, emails, faxes, and comment forms were submitted from 114 separate groups, individuals, and government agencies during the comment period. In response to the comments received by NIH on the DEIS, NIH determined that a supplemental DEIS (SDEIS) would be prepared and submitted to the public for review.

1.6.1 Community Liaison Group Meetings

Regular Community Liaison Group meetings are held at the RML campus to provide a forum for discussion of public issues and concerns about RML. The Community Liaison Group consists of 25 key community stakeholders, including, but not limited to, representatives from local government (mayor of Hamilton and Ravalli County commissioners), advocacy groups, realtors, natural resource agencies, local residents, and emergency response agencies. Members of the Community Liaison Group are encouraged to bring questions and concerns to the meetings for open discussion.

1.6.2 Open House Public Meetings

NIH has held two open house public meetings where citizens expressed their concerns and questions to specialists in biosafety, biosecurity, and disease. One meeting was held before release of the DEIS. One was held after release of the DEIS to take comment on the DEIS. Another public meeting was held January 22, 2004, to take comment on the supplement draft environmental impact statement.

1.6.3 Needs Assessment

As additional public outreach, NIH held informal meetings with people who commented during scoping and with other key community stakeholders in February 2003. The objectives of the "needs assessment" were to provide an opportunity for these people to voice their concerns. Information gathered in the needs assessment was used to develop the Proposed Action, describe the affected environment, determine effects, and help identify reasonably foreseeable actions.

1.6.4 DEIS Comment Period

The comment period on the DEIS began on May 23, 2003, with the Notice of Availability that appeared in the Federal Register. Agencies and people who had submitted written comments at scoping, as well as those who requested it, were provided a copy of the DEIS. The DEIS was posted on the Internet and distributed to local libraries. The comment period ended July 21, 2003. Comments on the DEIS were considered as scoping comments for compilation of the SDEIS.

Comments on the DEIS are summarized and used as described in Section 1.7 below.

1.6.5 SDEIS Comment Period

A public comment period followed the SDEIS. The comment period opened on December 29, 2003, with the notice of availability in the Federal Register. The comment period was 45 days and closed on February 11, 2004. Comments on the SDEIS are included in their entirety in Chapter 5, along with responses.

1.7 IDENTIFICATION OF ISSUES

Five hundred eighty-eight (588) public comments were received during scoping in 103 separate documents (letters, e-mails, phone calls, comment forms). Approximately 10 percent of the comments focused on a need for additional alternatives, six percent identified potential mitigation measures, 60 percent related to issues that could be addressed through effects analyses, and 20 percent were considered to be outside the scope of the EIS. Statements in favor or not in favor of the Project were in 12 comments. Sixteen comments could not be categorized.

Issues identified in the comments were assigned to the following four categories:

- Issue or concern that could develop an alternative;
- Issue or concern that could result in a mitigation measure;
- Issue or concern that could be addressed by effects analysis; and
- Issue or concern outside the scope of the EIS.

A list of issues raised by the public with respect to alternatives, mitigation measures, and the analyses to be completed in the EIS is provided below. There were no unresolved conflicts identified with the Proposed Action that were not addressed by the No Action Alternative.

1.7.1 Alternative Development Comments

Key public scoping comments made concerning alternative development included:

- Requests to construct the Integrated Research Facility in a less populated area, at a more secure facility such as a military installation, or at the NIH campus in Bethesda, MD. These comments are addressed through Alternatives Considered but Eliminated from Detailed Study (Section 2.2.2) on page 2-17.
- Request for more information as to how and why RML was selected overall and given the potential risk to the community through disease outbreaks or increased terrorism. This is addressed in Purpose and Need (Section 1.4), in the Community Safety and Risk section on page 4-5 and in **Appendix B**.
- Comments that a BSL-4 laboratory should not be built, regardless of location. Some people voicing this concern believed that more BSL-4 laboratories would increase the probability of unintentional outbreak through releases, sabotage, or terrorism. This is addressed in the No Action Alternative.

Additional comments on the DEIS related to alternatives considered include:

- Request for additional information about the project, including laboratory equipment used, testing procedures, energy consumption of the Integrated Research Facility, and more details regarding budget and finances. This information is found in the EIS within Sections 2.2 (Proposed Action) and 2.2.1 (No Action Alternative) and **Appendix E** (Standard Operating Procedures of a BSL-4 Laboratory).
- No alternatives besides the No Action Alternative were considered. The rationale for the alternatives considered is presented in Section 2.2.2 of the EIS. Additional information has been included in the Purpose and Need (Section 1.4).
- Information on training opportunities for local emergency providers and requirements for training of laboratory workers has been included in **Appendix E** (Standard Operating Procedures for a BSL-4 Laboratory).
- Animals used for experiments. More information on the care and use of animals has been included in Section 2.1.4.1 beginning on page 2-10.

Additional comments on the SDEIS related to alternatives include:

- Disposal of prions. More information on the disposal of prion-contaminated materials is included in the FEIS.

1.7.2 Mitigation Measures

Potential mitigation measures raised by those individuals providing comments during scoping include:

- Adoption of pollution prevention strategies to avoid or reduce the amount of pollution generated at the facility. Efforts are described in the Disposal of Non-Contaminated Material section on page 2-11 (Section 2.1.5).
- Improving parking for workers and visitors during and after construction of the Integrated Research Facility. This is part of the Reasonably Foreseeable Actions as described on page 4-1.
- Implementation of a car-pooling program for workers commuting to the RML campus. This measure will not be included in the Proposed Action. Parking and traffic are addressed under social issues in Chapter 4. Impacts from added traffic do not require mitigation. Additional analysis of the alternatives on traffic has been included in Section 4.2.1.
- Adopting a policy of studying only those agents associated with emerging diseases at the Integrated Research Facility, and not agents associated with bioterrorism or biodefense. This measure is not included in the Proposed Action because it is in direct conflict with the Purpose and Need (see Section 1.4).
- Creation of a citizen oversight committee to monitor activities at the Integrated Research Facility. This measure will not be included in the Proposed Action because monitoring is done by RML for a number of state and federal agencies and the results are made public. The Community Liaison Group, composed of community members, serves to monitor activities at RML. The RML Institutional Biosafety Committee and the RML Animal Care and Use Committee also have community representatives.
- Improving aesthetics of the campus. This measure is included in the Proposed Action, as well as in Reasonably Foreseeable Actions as described on page 4-1. Aesthetics were considered in the design of the building and landscaping, as well as in the effects analysis.
- Implementation of regular effluent monitoring of air emissions and wastewater discharges are included in Air Quality and Wastewater sections in Chapter 3. The City of Hamilton Department of Public Works conducts wastewater testing (which RML pays for), and RML conducts monitoring of incinerator operating parameters every 60 seconds when the incinerator is operating, as required by their MDEQ Air Quality Permit.
- Use of local contractors for design and construction of the Integrated Research Facility to the greatest extent possible. NIH has hired a national design and engineering firm that specializes in designing and building BSL-4 laboratories. Federal Acquisition Regulations (FAR) require one quarter of participating companies to be small businesses from the region. Local contractors would have the same opportunities as others to work on the project.
- A commitment for direct improvements to the hospital, streets, and emergency response agencies by NIH. This is included in the Reasonably Foreseeable Actions as described on page 4-1.
- Noise and light reduction through more landscaping and buffering. This measure is included in the Proposed Action, as well as Reasonably Foreseeable Actions as described on page 4-1, and was considered in the design of the building as well as in the effects analysis. Information on recently completed noise reduction efforts has been included in Section 3.4.
- Establishment of a process where neighbors could bring concerns to RML during and after construction of the Integrated Research Facility. This measure was included in the Proposed Action. Meetings with neighborhood representatives would be held regularly before, during, and after construction. In addition, the Community Liaison Group, including local residents, will address issues brought to it.
- Purchase of homes at fair market value for anyone that requested it within a few blocks of the Integrated Research Facility because of a

perceived fear of lost value once the Integrated Research Facility is completed. This measure is not included in the Proposed Action because there is no indication that the Proposed Action will have a negative effect on property values (see Chapter 4).

- Publish an emergency plan to be implemented should a laboratory worker be exposed to an agent or in the unlikely release of an agent to the neighborhood. This is already planned, regardless of which alternative is selected, and is included in the description of No Action. RML staff meets periodically with representatives from the FBI, U.S. Attorney's Office, and other local law enforcement to share information and strengthen communication among these groups. RML is a member of the Montana Anti-Terrorism Task Force, the Ravalli County Local Emergency Planning Committee, and Ravalli County Terrorism Preparedness Task Force and will participate in the Ravalli County Pre-Mitigation Plan authorized under the Disaster Mitigation Act of 2000. Emergency BSL-4 procedures are outlined in **Appendix E**, Part 4 of the Standard Operating Procedures (pp E-23 to E-27).

Additional mitigation measures were suggested in comments on the DEIS. They are:

- Include in the federal budget all necessary funds to replace or repair inadequate water mains, pipes/sewer lines, and roads in the city of Hamilton. This measure will not be included in the EIS because these are the responsibility of the city. RML pays for these services as well as their share of upgrades through utility bills.
- Commit to posting a bond in an amount that would cover the expenses of a worst-case scenario where an infectious agent is released to the community. NIH is prohibited by statute from agreeing to post such a bond, but any claims for personal injuries and property damage arising from the negligent acts or omissions of a federal employee may be filed with the United States in accordance with the Federal Tort Claims Act, 28 U.S.C 2671-2680.
- Direct filtered airflow discharges from BSL-4 lab to incineration or autoclave system and monitor temperatures and pH levels of biowaste cookers and digesters. This measure was not included because HEPA filtration of air and sterilization of waste leaving the containment zones undergo several stages of purification before discharge. At the time of release, by-products have already undergone destruction under extreme heat; therefore no additional assurances through incineration or autoclaving are needed. Additional information on the HEPA filters and their maintenance are included under Air Treatment in Section 2.1.3.

There were no additional mitigation measures identified in the comments on the SDEIS.

1.7.3 Effects Analysis Comments

The bulk of the public comments are addressed in the DEIS through a detailed description of the Proposed Action and evaluation of direct, indirect, and cumulative impacts and operations. Issues addressed in the EIS include:

- Short- and long-term impacts associated with parking, noise, lighting, visual aesthetics, and increased traffic in the neighborhood surrounding the RML. This information is included in Chapters 2 and 4 of the EIS. For the SDEIS, additional information on the construction noise and the cumulative effects analysis was clarified. New information was obtained on the current site conditions, which is also included in Chapter 3.
- Impacts on the underlying aquifer from increased water usage. This topic was included in the DEIS in Section 4.8. Additional information was included in Water Supply (Section 4.8) of the SDEIS. This information has been clarified for the FEIS.
- Impacts on the City of Hamilton water and wastewater systems. This topic was included in the DEIS in Section 4.8. Additional information has been included in the Water Supply (Section 4.8).
- Impacts on community infrastructure such as schools, roads, and emergency response agencies. Information was included in Section 4.2 of the DEIS. Additional information on the effects on emergency providers has been included in subsequent EIS documents.
- Increased use and disposal of hazardous chemicals by the Integrated Research Facility.

Information on the use and disposal of hazardous waste was included in the DEIS in Section 2.1.3. Additional information on past use and existing permitted levels has been included in Section 2.1.5 and 2.2.1.2.

- Potential increased threat of outbreak of agents through transport, internal sabotage, inadvertent releases, and outside terrorism. Community safety was addressed in the DEIS. Additional information on the past safety record of biocontainment facilities worldwide is included in the EIS in **Appendix D** – Review of Biocontainment Laboratory Safety Record.
- Cultural and historical impacts. This assessment was included in the DEIS in Section 4.6. Since the DEIS was completed, the Montana State Historic Preservation Office has determined that the project would have no adverse effect on the RML historic district. This information has been included in the SDEIS and FEIS.
- Full description of agents to be studied at the lab. This information was included in **Appendix B**.
- Discussion of the security of the facility, including worker clearances. This information is discussed in Section 2.1 and **Appendix C**. In addition, **Appendix E** – Standard Operating Procedures for a BSL-4, is included in the SDEIS (and FEIS) with additional information on security measures.
- Impacts on air quality associated with increased use of the incinerator. Information was included in Section 4.7.1 of the DEIS. Additional information on air quality has been included in Sections 3.7 and 4.7.
- Social and economic impacts of the Integrated Research Facility such as population growth, potential decrease in property values, employment, and school enrollment. This information was included in Section 4.2 of the DEIS. Additional information on the effects of BSL-4 laboratories on housing prices has been included in Section 4.2.
- Potential damage to the Integrated Research Facility from an earthquake or flood. Construction methods to prevent damage from earthquakes were included in Section 2.1 of the EIS. Flood damage would be avoided by not constructing the facility in the 100-year floodplain, which is addressed in Chapter 3 (Section 3.9.3).
- Description of previous releases of biological agents at RML. This information is included in the new **Appendix D**.
- Discussion of any new or expanded permits that would be required for the Integrated Research Facility. This information was included in Chapter 3 of the DEIS and subsequent EIS documents.

Additional comments made on the DEIS on effects analysis include:

- Impacts on wetlands, wildlife, and threatened and endangered species. These resources were addressed in the DEIS as Resources Not Affected (Section 3.9). Rationale for why these resources would not be affected is included in that section.

There were no new analysis issues identified in comments on the SDEIS.

1.7.4 Issue or Concern Outside the Scope of the EIS

The following comments made during the initial scoping period were determined to be outside the scope of the analysis because the information was not relevant to the decision, not affected by the proposed action, not within the analysis area, or already decided by law or policy:

- Statements of support or in opposition to the project. These comments are outside of the scope of the analysis in the EIS, but they will be considered during decision-making and addressed in the Record of Decision.
- Delays caused by the NEPA process.
- Decision-making authority.
- Research of cancer incidents in the neighborhood and results of toxic dumping.
- A programmatic EIS should be done for the proposed upgrade at RML as well as those upgrades or new facilities proposed across the country. Locations and plans for current and future BSL-4 laboratories nationwide should be disclosed.

- How long would it take for smallpox to spread through a town such as Hamilton?
- Redirect the money for this project to AIDS research or universal health care.
- NEPA coverage for previous projects at RML was inadequate.
- Provide detailed project budget in the EIS.
- Please list all violations in RML's history. What were they? When did they occur? How and when were they cleaned up or resolved?
- Provide a detailed budget for the project disclosed in the EIS.
- Will public have opportunity to oversee the building/engineering process? Commentors would like for public to be involved in the certification process, specifically the testing to meet BSL-4 standards and codes, and for these documents to be made public.

An additional comment was made on the DEIS that was considered outside the scope of the EIS:

- Effects downwind on our Canadian neighbors.

There were no additional comments on the SDEIS that were considered outside the scope.

1.7.5 Other Comments on the EIS

A few comments on the EIS were received that did not fit into the categories for scoping comments, but information has been included to address them. They are:

- No one who prepared the DEIS appear to have the experience in safety or microbiology to assure the public that the DEIS has the scientific integrity required by NEPA. In response to this comment, the List of Preparers has been expanded to include NIH personnel who were integral in the preparation of the DEIS and SDEIS and their qualifications.
- Construction began for proposed alternative, which has irrevocably committed resources. To clarify, no construction on the Integrated Research Facility has occurred. Some money has been spent by NIH to design the facility, which is needed to complete the NEPA analysis.

CHAPTER 2
PROPOSED ACTION AND ALTERNATIVES

This chapter describes NIH's proposal to construct an Integrated Research Facility and upgrade existing facilities at the RML campus in Hamilton, Montana. The proposed new structure and infrastructure upgrades are collectively referred to as the Proposed Action. Alternatives to the Proposed Action are also included in this chapter.

Detailed discussions of the following topics are presented in this chapter:

- The Proposed Action; and
- Alternatives to the Proposed Action, including the No Action Alternative and Alternatives Considered but Eliminated from Detailed Study.

2.1 PROPOSED ACTION

NIH proposes to construct an Integrated Research Facility to house Biosafety Level (BSL)-2, BSL-3, and BSL-4 laboratories, animal research facilities, administrative support offices, conference rooms, and break areas at the RML facility in Hamilton, Montana. The Proposed Action would encompass approximately 105,000 square feet of building constructed within the existing 33-acre RML campus in the southwest portion of Hamilton (**Figure 2-1**).

The Integrated Research Facility and research programs would require additions and upgrades to the existing RML campus. Upgrades would include:

- A new chilled water plant and emergency power backup system;
- A new addition to Boiler Building 26 to house a new natural gas-fired boiler; and
- Construction of below-grade systems and utility distribution tunnels to service the Integrated Research Facility.

Research at RML would include pathogenesis, immune response, vaccine, diagnostics, and therapeutics work and would focus on RML's strength in vector-borne pathogen research.

2.1.1 Biosafety Level 4 (BSL-4)

A BSL-4 laboratory would be constructed within the Integrated Research Facility to provide the highest possible level of protection for scientists and the public and to expand the research capability of RML. The use on a BSL-4 laboratory would be required for research of certain agents and for certain experiments, such as testing of vaccines for emerging and re-emerging infectious microbial agents that are normally ranked at BSL-3 level. Stringent safeguards, including engineering and design features (see **Appendix E**), are required for BSL-3 and BSL-4 laboratory facilities to prevent pathogens from escaping into the environment. In addition, the BSL-4 laboratory would be designed to prevent contact between pathogens and people inside the workspace and provide secure storage for infectious agents.

A BSL-4 laboratory is required for work with agents that pose a high individual risk of aerosol-transmitted infections and life-threatening disease. Agents with a close or identical antigenic relationship to BSL-4 agents would be handled at this level until sufficient data are obtained to confirm continued work at this level, or at a lower level. All laboratory staff would have thorough training in handling hazardous, infectious agents; understanding primary and secondary containment functions of standard and special practices; and understanding containment equipment and laboratory characteristics. All laboratory staff would be supervised by trained and experienced scientists (see **Appendix E**).

Prior to gaining access to the BSL-4 laboratory for the first time, a scientist would submit a copy of an experimental protocol to be reviewed by the Laboratory and Branch Chief. Upon approval, the protocol would then be reviewed by the Institutional Biosafety Committee. Next, the Scientific Director and the Program Review Committee must approve the plan. After all these approvals have been received, individuals seeking access to the BSL-4 laboratory would undergo a security authorization.

A specific facility operations manual would be prepared and adopted. The BSL-4 laboratory would have special engineering and design features to prevent microorganisms from escaping into the environment (**Figure 2-2**).

The primary containment barrier in the laboratory is the biological safety cabinet, designed to provide a clean workspace and filter exhaust air. The second containment barrier is the BSL-4 laboratory itself. The BSL-4 laboratory would be located within the central core of the building, surrounded by a buffer corridor between the laboratory and the exterior. The buffer creates a stable pressure zone to eliminate impacts such as wind and temperature on the exterior of the building, which can affect pressure differentials. The BSL-4 laboratory would be designed and tested to ensure it is airtight.

2.1.2 Integrated Research Facility

The Integrated Research Facility would be a three-storied building, linked to the existing BSL-3 laboratory by two on-grade corridors. The Proposed Action consists of BSL-2, -3, and -4 laboratories and a boiler plant addition. The area of each component is shown below. The total area is approximately 105,000 functional gross square feet (**Table 2-1**).

Table 2-1. Proposed Action Areas

Area	Size (feet^2)
BSL-4	6,750
BSL-3	2,950
BSL-2	14,650
Common Areas/Office	25,650
Boiler Addition	1,810
Connection to Bldg. 25	2,034
Chiller	2,679
Mechanical	48,609
Total	**105,132**

2.1.3 General Building Design Components

Water System

The proposed Integrated Research Facility would be connected to the existing water main south of the proposed building. Hook-up would include a backflow prevention device. Water would be supplied by the City of Hamilton.

Sanitary Sewer

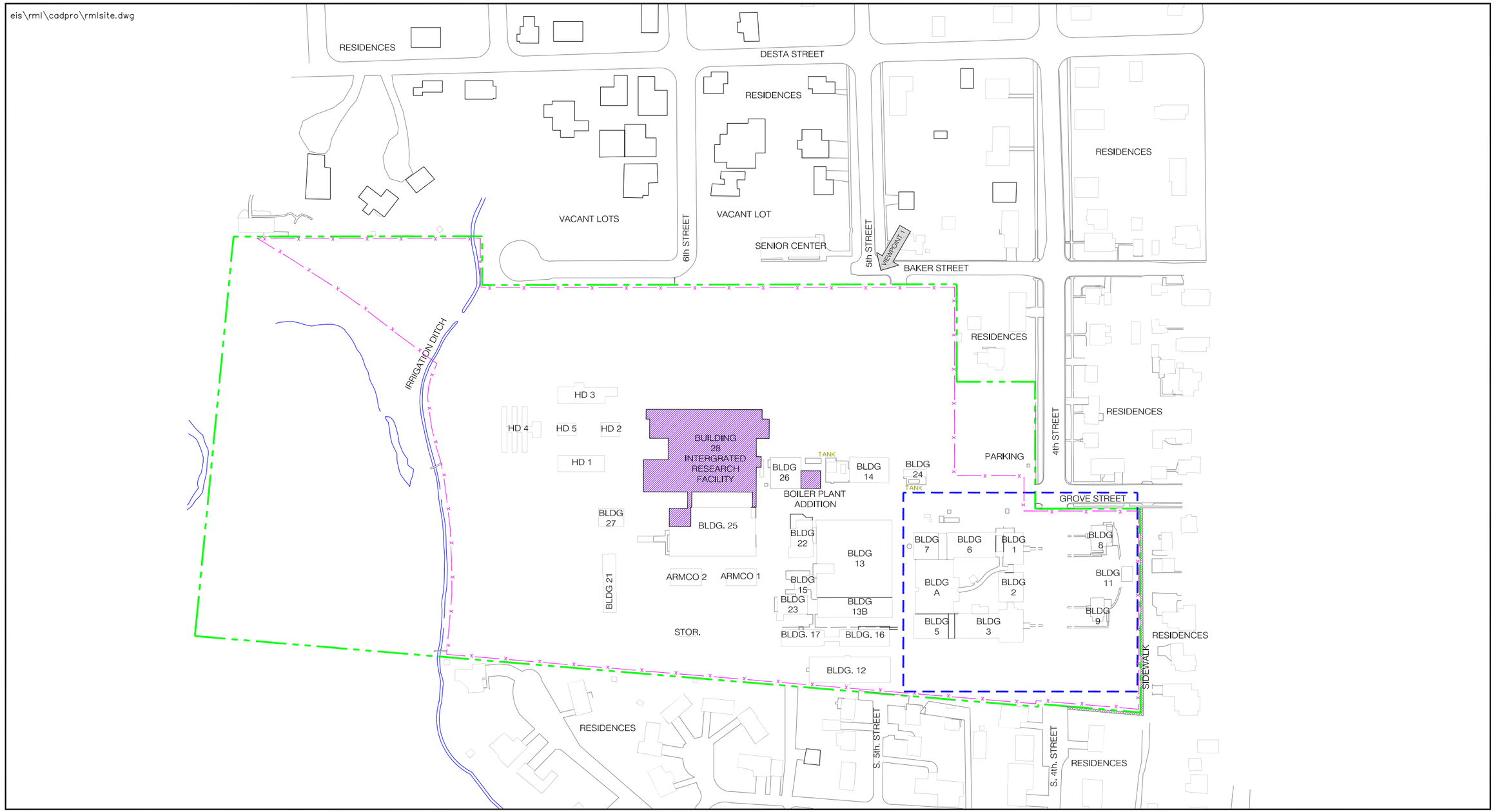
The Integrated Research Facility would connect to the existing City of Hamilton sewer system. All liquid waste from the high containment area would receive additional special treatment and monitoring before entering the sewer system (see Waste Decontamination on page 2-6).

Air Treatment

All air supplied to and exhausted from the BSL-4 laboratory would be High Efficiency Particulate Air (HEPA) filtered. Laboratory air passes through a minimum of two HEPA filters, in series, prior to release to the outdoors. All ventilating systems would be redundant, monitored, and maintained to assure appropriate containment (CDC/NIH 1999).

HEPA filters use a combination of methods to remove particles. As air moves across the filter, particles are caught by interception, inertial forces, and diffusion. The 0.3-micron particle size represents the most difficult size to capture for the HEPA filters; particles that are larger and smaller than 0.3 microns are actually captured more efficiently. Most bacterial and fungal particles are larger than 0.3 microns; most viruses are smaller. Therefore, these particles are filtered at a higher efficiency than 99.97 percent. Research has shown that undamaged filters remove 99.97 percent of 0.3 micron particles after more than a decade of continuous use (Edwards 2002).

Exhaust air from the BSL-4 laboratory suit area, decontamination shower, and decontamination airlock would be treated by passage through two HEPA filters in series rated for microbial aerosols before discharge to the outside. The air would be discharged away from occupied spaces and air intakes. HEPA filters would be located as near as practicable to the source in order to minimize the length of potentially contaminated ductwork. Laboratory biological safety cabinets (including air filters) would be certified once a year to ensure proper function. Safety cabinets would be re-certified when moved or relocated to a new area, as this could alter airflow and the functioning of the cabinet. Re-certification includes testing the HEPA filter, gaskets, and other air-handling systems in the cabinet.



Source: Architects Design Group (2002)

N

0 Feet 200

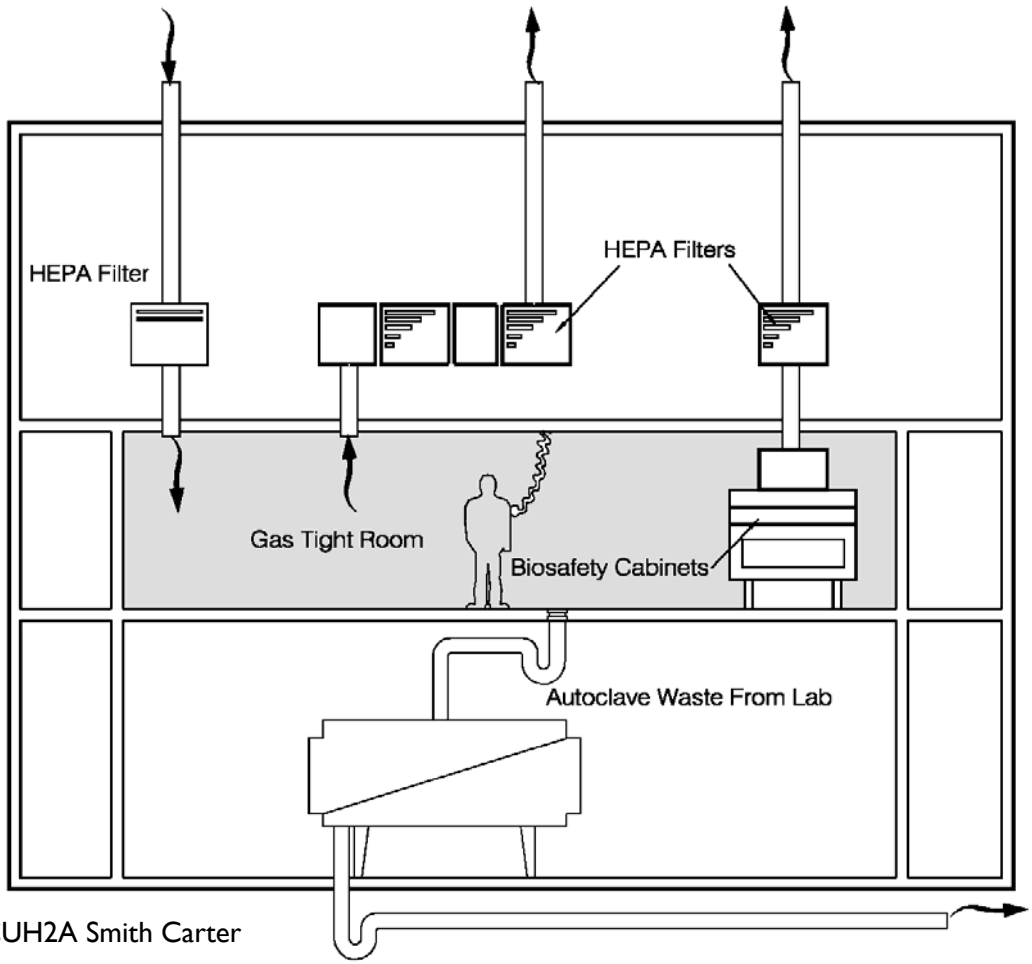
Property Line

Fence

Historic District

Proposed Action

Site Map
RML Integrated Research Facility
Hamilton, Montana
FIGURE 2-1



Source: CUH2A Smith Carter

Figure 2-2. Containment Design

HEPA filters would be disposed of through decontamination and incineration. HEPA filter housings would be designed to allow for decontamination of the filter before removal for incineration. Alternatively, the filter can be removed in a sealed, gas-tight primary container for decontamination and/or incineration.

Storm Water

Storm water runoff from the RML campus would flow into drywells, which would discharge to groundwater below the site. One drywell would be constructed for each 300 square feet of drainage area. The drywells would be six feet in diameter and eight feet deep. Roof drains would be connected to a drywell.

Fire Protection

Fire protection systems would be installed in the Integrated Research Facility to meet or exceed requirements of all applicable codes, standards, and guidelines. The fire protection system would be simple to understand and maintain, and able to respond to changes in function or load with only minor modifications. It would perform under varying operating conditions.

Emergency Electrical Power Systems

A 2,000 KW/1563 KVA emergency generator with a 2000-ampere emergency/standby switchboard would be installed on the lowest floor of the Integrated Research Facility. Sufficient fuel storage would be provided to run the emergency generator for 72 hours. Additionally, a second 600 KW standby generator would be installed to support the new chiller plant.

Seismic Requirements

The Integrated Research Facility would be designed in accordance with Essential Facility requirements

of the International Building Code developed by the International Code Council with the intention that the facility would remain fully operational after a seismic event of a magnitude prescribed by the code. The facility would be classified as a Seismic Use Group III building in accordance with the International Building Code. The facility would be designed under Seismic Design Category C, which requires structure functionality to survive the event.

Showers

The BSL-4 laboratory would be designed to ensure passage through changing and decontamination areas prior to entering rooms where work would be preformed with BSL-4 agents (suit area). Personnel entering a decontamination area would wear a one-piece positive pressure suit ventilated by a life-support system protected by HEPA filtration. The life support system includes redundant breathing air compressors, alarms, and emergency backup air tanks. Entry to this area would be through an airlock fitted with airtight doors. A chemical shower would be provided to decontaminate the surface of the suit and other personal protective equipment before the worker leaves the area. BSL-4 laboratory workers leaving the laboratory would also take a shower. An automatic emergency power source would be provided at a minimum for the exhaust system, life support systems, alarms, lighting, and entry and exit controls. Air pressure within the suit would be higher than that of any adjacent area. All penetrations into the suit area, chemical showers, and airlocks would be sealed and tested to be gas tight.

Waste Decontamination

Contaminated solid waste which has been exposed to a biohazardous agent or generated in a laboratory, such as animal bedding, would be treated before disposal. All waste from the BSL-4 laboratory would be considered contaminated. Treatment would consist of autoclaving and disposing as general waste; incinerating and disposing as general waste; incinerating and disposing of ash or alkaline hydrolysis; and disposing through sewage systems.

Laboratory liquid waste from the BSL-4 laboratory would be piped to three biowaste cookers (one cooker would be operating, one filling, and one for redundancy). The liquid waste would be heated under pressure to a temperature above 121°C for a minimum of 60 minutes to ensure sterilization. Biosensors, electronic monitoring, and charting would be used to verify proper operation of waste decontamination systems.

An alkaline hydrolysis process tissue digester would be installed for solid (animal) infectious waste disposal. This system would use alkaline hydrolysis at an elevated temperature to convert proteins, nucleic acids, and lipids of all cells and tissues, as well as infectious microorganisms (including prions), to a sterile aqueous solution of small peptides, amino acids, sugar, and soap suitable for disposal to a sanitary sewer. The tissue digester would consist of an insulated, steam-jacketed, stainless steel vessel. Liquid waste from the tissue digester would be discharged to a stainless steel holding tank. The holding tank would slowly discharge the waste into the sanitary sewer storage tank over a 48-hour period to dilute the waste to acceptable limits for the Hamilton City Sewer Treatment plant (CHDPW 2002).

Effluent from biowaste cookers would be discharged to a 12,000-liter (3,170-gallon) atmospheric tank for blending with other liquid waste from the building. The blending tank acts as a cool-down for biowaste material discharged from the cookers and dilutes the waste from the building to ensure compatibility with the city sewer treatment facility. Duplex grinder submersible pumps would evacuate the tank. A cold-water injection system would be installed for backup in the event that discharge from the blending tank exceeds the maximum 60°C temperature requirement. A test port would be provided downstream to allow users and city representatives to insert a test probe to analyze sewer discharge on a regular basis.

All vent piping from the biowaste system would pass through a double HEPA filter (or other microbial filters) before venting to the atmosphere. HEPA filters would be changed every five years and disposed of after decontamination with chemical disinfectant and incineration.

Biological materials removed from the BSL-4 laboratory in a viable or intact state would be contained in a sealed, primary container. The

primary container would be placed inside a non-breakable, sealed secondary container and removed from the facility through a disinfectant dunk tank, fumigation chamber, autoclave, or an airlock designed for this purpose. No materials, except biological materials that are to remain in a viable or intact state, would be removed from the BSL-4 laboratory unless they have been autoclaved or otherwise decontaminated before leaving the laboratory. Equipment or material that could be damaged by high temperatures or steam may be decontaminated by gaseous or vapor methods in an airlock or chamber designed for this purpose.

The digester system would be physically and biologically tested to verify that design and operation parameters have been met before operation, and annually thereafter. Testing of the system would include introduction of a carcass which has been injected (in multiple locations) with a suspension of benign indicator spores. A minimum six-log reduction (1/1,000,000) of the culture population would constitute acceptable performance of the liquid decontamination system. The control system for the tissue digester generates a batch report to confirm a successful digester run, including the date, time, temperature, pressure, load weight, level, and process time for each cycle. Using this information, the operator can modify the temperature, pressure, and length of cooking time to achieve acceptable decontamination before the system is operational.

Each batch of digestate (remaining solids) is transferred to the digestate holding tank, which is equipped with a discharge pipe that releases the batch into the blending tank. The amount blended into the tank is controlled by allowable limits for discharge to the sanitary sewer. The high biological oxygen demand wastewater generated by the alkaline hydrolysis process requires that no more than three times the volume of the discharge pipe (800 liters) be added to the 12,000-liter blending tank.

Safety

The RML Biosafety Committee, NIH Associate Director for RML, and relevant RML safety and biosafety staff would oversee efforts related to planning and design of the facility including review and approval of proposed protocols and standard operating procedures for the laboratory prior to use. RML would use the standards and procedures (USDHHS 1999) recommended for all institutions engaged in biological research. A description of standard and special safety practices for working with biological materials is contained in **Appendix E**.

One-piece positive pressure personnel suits ventilated by a life support system would be used for all activities in the suit laboratory (BSL-4). Standard safety practices for access, personnel protection, and disposal of contaminated material are described elsewhere in this chapter. A complete description of standard and special safety practices for a BSL-4 laboratory is contained in **Appendix E**.

Energy Consumption

RML currently spends approximately $1.4 million annually for electricity and natural gas used at the facility. The electrical power source is Kerr Dam near Polson, Montana. Natural gas is provided by NorthWestern Energy from sources within and out-of-state. Power consumption at the Integrated Research Facility is estimated to increase to an annual cost of $2.1 million. The additional electrical power and natural gas would be supplied by current sources.

Several energy-saving devices would be incorporated into the proposed facility including, but not limited to, power-saving equipment and lighting and enhanced insulation.

Noise Reduction

The Integrated Research Facility would be designed to not exceed RML's draft noise guideline of 55 dBA at the property boundary during the day and 50 dBA at night (7:00 pm to 7:00 am). Design elements to reduce noise include:

- Selecting fans for exhaust and air handling units that can work adequately at their lowest possible speed to reduce fan noise;
- Installing a silencer or bank of silencers in the air-handling unit, in the exhaust ductwork or stacks, and in the emergency generator;
- Smooth transitions and elbows to limit turbulent airflow;
- Selecting quiet equipment;

- Conducting tests of the emergency generator during normal weekday working hours and not during quiet periods;
- Installing a muffler as part of the generator exhaust system;
- Covering as much of the ceiling and wall surfaces inside the generator room as feasible with absorptive material;
- Limiting the discharge air opening for the emergency generator to as small as feasible;
- Construction of an eight-foot high acoustical concrete masonry screen wall west of the relocated chiller; and
- Using manufacturer-supplied inlet and discharge attenuators on the cooling towers.

To reduce noise from construction, the following measures would be used to mitigate for temporary construction noise:

- Construct temporary barrier walls prior to construction;
- Install high-grade mufflers on the diesel-powered construction equipment and generators;
- Combine noisy operations to occur for short durations during the same time periods; and
- Construction activities would only occur from 7:00 am to 5:00 pm.

Noise monitoring and mitigation would occur as described in the No Action Alternative.

2.1.4 Operations

2.1.4.1 Commissioning Plan[1]

Commissioning the BSL-4 laboratory would consist of systematically subjecting the facility to various operating and failure modes to ensure the laboratory systems function properly. The process would document that specified structural components, systems and/or system components have been installed, inspected, functionally tested, and verified to meet specific requirements. The respective system's design criteria and design function establish these requirements.

Commissioning

Commissioning is a systematic process of ensuring that all building systems perform interactively according to the design intent and operational needs. The commissioning process shall encompass and coordinate the traditionally separate functions of system documentation, equipment start-up, control system calibration, testing and balancing, performance testing, and training.

Commissioning during the construction phase is intended to achieve the following:

- Verify applicable equipment and systems are installed according to the manufacturer's recommendations and industry standards, and they receive adequate operational checkout;
- Verify and document proper performance as well as failure modes of critical equipment and systems;
- Verify that operation and maintenance documentation is complete; and
- Verify that RML's operating personnel are adequately trained.

System Testing

System tests are to ensure that equipment and systems have been properly installed and meet applicable operational design specification. In general, each system would be operated through all modes of operation (seasonal, occupied, unoccupied, warm-up, cool-down, part- and full-load and redundant, fail safe) where there is a specified system response. Verifying each sequence of operation is required. Proper responses to modes and conditions such as power failure, fire alarm conditions, biohazard, and specific system failures. System tests include:

- Pressure test of special rooms;
- Breathing air system (including suits);
- Liquid decontamination system;
- Chemical shower system;
- Chilled water system;

[1] Information from the 95% complete CUH2A Smith Carter Pre-Final Review Project Manual dated August 7, 2003.

- Emergency generator system; and
- Security system (proximity card, operational software, door zones' access, interlock groups, closed-circuit TV cameras, and recording).

Integrated System Testing

Integrated system tests are used to demonstrate that each system is operating in concert with other systems according to the specified design. Proper responses to modes and conditions such as power failure, fire alarm conditions, biohazard, and specific system failures would also be tested. Goals of the integrated system tests are:

- Verifying that the facility has met construction design criteria;
- Providing the operation and maintenance staff with meaningful, hands-on demonstration of the facility's operation;
- Documenting the failure condition and response of the facility; and
- Identifying any trends in baseline data.

Functional Operation System Test

The functional operation system test provides a 30-day period for the facility to adjust to normal operational patterns. The test monitors the facility and lab functions, the life safety elements of the system operations (specifically as they relate to the interlocks of the various systems), fire alarms, and security and air systems. Training RML and local emergency personnel for high containment systems would be held during this period.

The functional operation system test would begin after the BSL-3 and BSL-4 laboratories and systems are complete with no deficiencies. Some minor adjustments may be made to optimize some system operations.

The testing would ensure fail-safe operation of the building to demonstrate that the building, occupants, and general public remain safe and biological hazards remain contained. Additional testing would be conducted to verify or recommission areas of specific concern or failure during the test. This would be the final acceptance test for the facility. Goals of the functional operating system test are:

- Demonstrate that each system is operating in concert with other systems;
- Verify the facility has met construction design;
- Provide operations and maintenance staff and local emergency personnel with in-depth training on various systems;
- Bring the entire facility from a state of substantial completion to full dynamic operation;
- Document failure conditions and response of the facility;
- Adjust systems for optimal performance as systems settle into a routine operating pattern; and
- Document variables to obtain facility operational and utility baseline data.

Animal Care and Use

Some of the biodefense and human disease research conducted in the proposed Integrated Research Facility would use animal models. The NIAID DIR would oversee all research activities involving the use of laboratory animals. These research activities would conform to the:

- Counter-Bioterrorism Research Agenda of NIAID for CDC Category A Agents;
- NIAID Biodefense Research Agenda for Category B and C Priority Pathogens; and
- NIAID Strategic Plan for Biodefense Research.

The Comparative Medicine Branch would administer the NIAID, DIR Animal Care and Use Program of the Integrated Research Facility. The number of laboratory animals required would depend on research requirements.

The Integrated Research Facility would use existing NIH and RML committee structures to oversee the animal facilities and programs at the Integrated Research Facility including research involving animals, research protocol reviews, documentation of training reviews, and semi-annual facility inspections. All research involving animals at RML will be conducted in full compliance with applicable regulations, including the Animal Welfare Act 7USC 2131 *et seq.*, The United States Department of Agriculture regulations implementing the Animal Welfare Act, 9 CFR Part 1, 2, and 3, the Public

Health Service Policy on Humane Care and Use of Laboratory Animals, and NIH Policy Manual Chapter 3040-2, Animal Care and Use in the Intramural Program (2002). Research protocols involving animals will be reviewed by the RML Animal Care and Use Committee.

RML has been inspected and fully accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International) since the 1970s. These inspections are done every three years by experts in animal care and use. Animal facilities are designed to provide suitable, secure, and consistent environmental conditions for research animals.

The Chief, RMVB, would provide support, research, and consultation in laboratory animal medicine; attending veterinary care; comprehensive animal husbandry; training in laboratory animal medicine, science, and animal care and use procedures; and review of research protocols for proper and lawful animal use. The Chief, RMVB, would conduct safety reviews, risk assessments, and semi-annual inspections of animal facilities. NIAID DIR would develop standard operating procedures that specify administrative guidelines; feed, bedding, and water; animal procurement and care; facility and equipment operations; waste disposal, sanitation, and sterilization procedures in accordance with NIH policies.

The Chief, RMVB, would report to the Director of the Division of Intramural Research (DDIR), NIAID. The DDIR would be responsible for implementing and administering animal use policies and would serve as a liaison between the Chief, RMVB, scientists, and NIH officials (e.g., Deputy Director for Intramural Research, Director of the Office of Animal Care and Use). The DDIR is also responsible for ensuring participation in the Animal Exposure Surveillance Program (AESP) by researchers that would work with animals. The AESP is a mandatory surveillance program managed by the Occupational Medical Service of NIH, and individuals that elect out of the program would be denied permission to participate in animal studies (NIH Policy Manual 3040-2, 28 March 2002).

Research involving rodents and lagomorphs would be performed in the biocontainment suites of the Integrated Research Facility. The procedure for removal of rodents and lagomorphs (e.g., rabbits) from the biocontainment suites would involve euthanizing animals and then autoclaving the carcasses. Animals would be held in species-specific animal housing within biocontainment animal rooms. All studies involving etiologic agents would be conducted at levels appropriate to the study (BSL-2, -3, or -4).

Non-human primates (NHPs) would also be used as animal models in the Integrated Research Facility. NHPs would be housed in the Integrated Research Facility in accordance with federal, state, and local guidelines and regulations. Personal protective equipment used in NHP housing areas would follow guidelines outlined in the NIH Policy Manual 3044-2, Protection of NIH Personnel Who Work with Non-human Primates (9 February 1993), and the Biosafety in Microbiological and Biomedical Laboratories (4th edition 1999).

NHPs within Animal Biosafety Level - 2 (ABSL-2) suites containing only non-transmissible, non-latent infectious agents may be removed from the suite provided they are healthy and demonstrably immune to all agents in use. NHPs previously infected with transmissible or possibly latent agents would only be removed to other biocontainment suites with an equal or higher level of biocontainment. Removal to other biocontainment suites would be coordinated with the Chief, RMVB, and only done if the principal investigator and DDIR are informed and concur with the movement. NHPs would be transported between suites in sealed, leak-proof containers that have been disinfected. The containers would be sterilized after use. NHPs in suites where transmissible possible latent agents are used would be treated as potentially infected with these agents (Elkins 2003).

Neighborhood Meetings

Meetings with community representatives would be held regularly before, during, and after construction to maintain dialogue about RML's operations. Additional means of communication (mailing lists, e-mail lists) would be established with neighbors and people in the Community Liaison Group.

BSL-4 Laboratory Access

Only people completing the security clearance and approval process would be allowed to enter the

BSL-4 area. Safety precautions at the access point for the BSL-4 laboratory would include:

- Only persons whose presence in the respective laboratory is required for program or support purposes would be authorized to enter;
- Access would be limited by secure, self-closing, lockable doors managed by the facility manager or biosafety control officer;
- Biometric devices and touch pads would be used to screen anyone entering the laboratory;
- Upon entry, everyone would be advised of the potential biohazards and given instructions on safeguards;
- Date and time of entry and exit would be logged for everyone accessing the BSL-4;
- Complete laboratory clothing (undergarments, pants, shirt, shoes, gloves, etc.) would be used by all personnel entering the laboratory;
- A complete clothing change and decontamination shower would be required of personnel leaving the laboratory; and
- Supplies and materials used in the laboratory would be brought through a double-door autoclave, fumigation chamber, or airlock, which would be decontaminated between uses.

Personnel Protection

Personnel protection measures used by laboratory workers would include:

- Laboratory personnel would receive available immunizations for agents handled or potentially present in the laboratory;
- The current serologic surveillance program would be continued whereby baseline serum samples for all laboratory and other at-risk personnel would be collected and stored;
- Laboratory and support personnel would receive appropriate training concerning potential hazards associated with the work;
- Laboratory equipment would be decontaminated daily and after each procedure;
- Equipment would be decontaminated before repair or maintenance is performed; and
- Daily inspections of all containment parameters (e.g., directional airflow) and life support systems would be completed before laboratory work is initiated.

Disposal of Contaminated Material

Except where noted above, disposal of contaminated materials generated by the Integrated Research Facility would be the same as described under the No Action Alternative.

Disposal of Non-Contaminated Material

Except where noted above, disposal of non-contaminated materials generated by the proposed Integrated Research Facility would be the same as described under the No Action Alternative.

Security

Planning and implementation of the NIH police force would continue as described under the No Action Alternative. Under the proposed action, police would be located throughout the RML campus and within the Integrated Research Facility. Additional police officers may be hired depending on current security policies and procedures. All construction contractors would be subject to background checks prior to commencing work.

Security described under the No Action Alternative would apply to the Proposed Action.

Emergency Plan

The current Emergency Plan would be updated and address issues associated with the building prior to its operation. See Section 2.2.1 under the No Action Alternative for a description of the current plan.

2.1.5 Pollution Prevention

Spill Prevention

Spill prevention associated with the Integrated Research Facility would be the same as described under the No Action Alternative. In addition, fuel storage and dispensing during construction would occur in a designated staging area at the construction site. The construction contractor would limit equipment and materials storage to the staging area and be responsible for securing access and hazardous material containment and cleanup.

The contractor would also be responsible for all other materials and chemicals used in the maintenance of equipment and machinery during construction. All spills, except as noted below, will be reported immediately to the state's Disaster and Emergency Services Division (DES) 24-hour phone number (406) 841-3911. If no one can be reached at that number, the spill may be reported to the Montana Department of Environmental Quality (MDEQ) duty officer at (406) 431-0014.

The following types of spills are not required to be reported, provided, the spilled material does not enter or threaten to enter state water, and that it is immediately contained, removed, and properly treated or disposed of in accordance with state regulations:

- 10 barrels (420 gallons) or less of crude oil, produced water, injection water, or combination thereof; or
- 25 gallons or less of refined crude oil products, including but not limited to gasoline, diesel fuel, aviation fuel, asphalt, road oil, kerosene, fuel oil, and derivatives of mineral, animal, or vegetable oils.

Through use of a designated staging area for construction equipment and materials, accidental spills would be limited to a specific area. Storm water and runon/runoff management controls would be implemented and include mitigations such as a silt fence on the west side of the site. Site personnel would be able to respond rapidly and appropriately to spills and minimize their extent and magnitude.

Hazardous Materials

Hazardous waste generated at the Integrated Research Facility would be managed as described in the No Action Alternative. Hazardous waste generated during and after construction of the Integrated Research Facility would be less than 220 pounds of hazardous waste generated within any calendar month. No more than 2,200 pounds of hazardous waste would be accumulated at any one time, and no more than 2.2 pounds of acute hazardous waste or 220 pounds of soil contaminated from an acute hazardous waste spill would be generated or accumulated at any one time, on the entire RML campus. Use of hazardous materials and generation of hazardous waste may be expected to increase slightly with the addition of the Integrated Research Facility, but not commensurate with the 30 percent increase in the number of employees at RML.

Radioactive Materials

Radioactive materials used at the Integrated Research Facility would continue to be managed and disposed of as described in the No Action Alternative.

Generation of low-level radioactive waste is anticipated to increase about 30 percent with construction of the Integrated Research Facility. However, alternative technologies that do not require use of radioisotopes have become available for labeling of proteins such as chemical luminescence and immunofluorescence. These technologies may be expected to reduce any potential increase in radioisotope usage at RML. Use of sulfur-35 is likely to increase because, according to RML personnel, it is the best way to label proteins within cells. RML has sufficient capacity in its decay-in-storage program to manage projected increases.

2.2 PROJECT ALTERNATIVE

The only alternative to the Proposed Action discussed in detail is the No Action Alternative.

2.2.1 No Action Alternative

Under the No Action Alternative, the Proposed Action would not be implemented. Existing operations at RML, including pollution prevention discussed under the Proposed Action, would be maintained and operated at current levels, and construction of a new Integrated Research Facility would not occur. The NIAID mission and its resources have been expanded to include development of diagnostics, therapeutic, and vaccines, which RML's current facilities cannot fully accommodate. It is likely that in the long term, current staffing levels and the operating budget at RML would be redirected to support this new mission.

Because of the need for the BSL-4 laboratory to be constructed at an intramural facility and within the limits of the budget, the No Action Alternative addresses all alternatives suggesting construction of the facility at another location. Selection of the No

Action Alternative would not preclude construction of the facility at another location. Consideration of constructing the BSL-4 laboratory at another location would require congressional action (authorization of additional funding) and another NEPA analysis on a site specific proposal, including scoping and other public comment opportunities. See Section 2.2.2 - Alternatives Considered But Eliminated from Detailed Study.

2.2.1.1 Operations

Noise Reduction

Periodic noise measurements will be taken by an independent professional acoustic contractor to evaluate compliance with voluntary guidelines. In the event that noise levels exceed the guidelines, NIAID would review possible alternatives to resolve the issues.

Disposal of Contaminated Material

Clothing used in the laboratory is autoclaved before laundering. Containers of used needles, sharp instruments, and broken glass are decontaminated before disposal in accordance with federal, state, and local regulations.

All prion contaminated animals and animal bedding/waste are disposed of via the approved method of on-site incineration. Ash from the incinerator is transported to a landfill. RML has been conducting TSE research for over 40 years employing these disposal methods.

Disposal of Non-Contaminated Material

Waste that has not come in contact with a biohazardous, radioactive, or chemical material is considered noncontaminated and is disposed of as general waste.

Security

Traditional laboratory biosafety guidelines emphasize good work practices, appropriate containment equipment, well-designed facilities, and administrative controls to minimize risks of accidental infection or injury for workers and to prevent contamination of the environment outside the laboratory.

Security at RML is governed by GSA Security guidelines and by statutes and regulations governing possession, use, and transfer of certain biological toxins and agents (select agents). Governing rules and guidelines include Section 817 of the USA PATRIOT Act; Section 351A of the Public Health Service Act (as amended by Section 201 of the Public Health Security and Bioterrorism Preparedness and Response Act and amended by Section 302(9) of the Homeland Security Act); and USDHHS regulations at 42 CFR Parts 72 and 73. Management periodically reviews safety policies and procedures for consistency with these regulations, other facilitywide policies, and adequacy to meet current conditions. Supervisors ensure that all workers and visitors understand security requirements and are trained and equipped to follow procedures. Safety policies and procedures are reviewed on an ongoing basis and whenever an incident occurs or a new threat is identified. Guidelines implemented for security include preventing unauthorized entry to laboratory areas and removal of dangerous biological agents from the laboratory.

An NIH police force has been established at RML. A full-time captain has been hired and is currently on site, and a sergeant was hired in January 2004. RML will eventually have six full-time federal police officers. The NIH police force will assist the current security guards in screening workers and visitors, conducting background checks, preparing and monitoring identification cards, security planning, and security implementation.

Access Control

Access into RML is controlled through the following measures:

- Background and security checks are conducted on new employees by the Office of Personnel Management for any security or laboratory assignment;
- Workers and visitors would display visible identification badges with a photograph and expiration date;
- A proximity reader system is used for clearance into restricted areas;
- Laboratories and animal care areas are separated from public areas;
- Laboratory and animal care areas are locked at all times;

- Entry and exit from laboratory and animal care areas is recorded;
- Only authorized personnel are allowed in laboratories and animal care areas;
- Freezers, refrigerators, cabinets, and other containers are locked where biological agents, hazardous chemicals, or radioactive materials are stored in unattended storage areas;
- Security cameras are located throughout the facility, on the perimeter, and in select buildings, including areas where biological agents are stored; and
- Visitors are cleared at the main entrance and escorted into the RML campus accompanied by an RML employee at all times. RML facilities are designed for high security maintained around-the-clock. Security guards and NIH police officers will be on campus at all times. Security of the interior is based on layers, where separate security zones in combination with access control devices, biometrics, and touch pads are required for access.

As a condition of their contract with RML, all contract security guards must successfully complete training which includes:

- Approximately 32 hours of basic curriculum training. This is the core security training where guards are instructed in handling emergencies, security patrol methods, firearms safety/handling, vehicle inspection techniques, security patrol methods, and search and seizure;
- Orientation training. The training focuses on post familiarization, the facility emergency plan, personnel identification, entry/exit control procedures, explosive detection machine operation, and the guard duty book logging; and
- Supervisory training. This training covers topics such as issuing verbal and written orders, record keeping, and managerial public relations.

Security personnel must complete refresher course training quarterly on the aforementioned topics. In addition, all security personnel must maintain a current certification related to first aid, cardiopulmonary resuscitation, and OSHA Standard 29 CFR 1910.1030, Occupational Exposure to Blood-borne Pathogens.

NIH police officers will be present at RML along with contracted security guards. All officers will be graduates of the Federal Law Enforcement Training Center's Mixed Basic Police Officer Training Program or of a Police Academy which meets the federal program criteria. NIH police officers at RML must also complete 40 hours of annual in-service training, a semi-annual training related to firearms, security, and supervision.

Laboratory Deliveries

All packages will be screened at the perimeter (using K-9 units, chemical sniffers, or X-ray) before entering the RML campus, and packages containing specimens, bacterial or virus isolates, or toxins will be opened only in a safety cabinet or other appropriate containment device.

Material Removal from Laboratory Areas

Biological materials/toxins for shipment will be packaged and labeled in accordance with all applicable federal, state, and local regulations (see **Appendix C**, (Transportation and Transfer of Agents). Traditional laboratory biosafety guidelines emphasize good work practices; appropriate containment equipment; well-designed facilities; administrative controls to minimize risks of accidental infection or injury for workers; and administrative controls to prevent contamination of the environment outside the laboratory.

2.2.1.2 Pollution Prevention

Spill Prevention

RML has a Spill Prevention Control and Countermeasure (SPCC) plan that complies with Clean Water Act rules. The SPCC plan covers petroleum fuel stored in eight aboveground storage tanks at RML. EPA currently requires the plan to be reviewed every five years. The plan contains standard operating procedures for responding to spills of oil and hazardous substances and describes actions required for spill reporting, containment, and cleanup. The plan is reviewed and modified as necessary. RML has standard operating procedures in place and trained personnel to respond to spills. Eleven RML employees are trained as hazardous materials specialists and are part of RML's HAZMAT team. Members of the HAZMAT team are trained in

toxicology, decontamination, spill containment, chemical characteristics, communication, and first aid. Specialists are accessible 24 hours per day, seven days per week for any spill incident that may occur at RML. Security staff is also trained to monitor the site for potential areas of concern, including accidental spills.

Response actions for fuel spills focus on protecting public health, safety, and the environment. Trained site personnel contain spills through use of berms and absorbent materials. The nature, extent, and magnitude of the spill is defined under the direction of the Montana Department of Environmental Quality (MDEQ).

RML has designated several storage areas with secondary containment to prevent releases to soil and water. Should a spill occur, HAZMAT personnel mobilize equipment to control the hazard and implement cleanup. Spill response supplies available at RML include absorbers, neutralizers, and sewer drain caps.

Hazardous Materials

RML is licensed by the U.S. Environmental Protection Agency as a small-quantity generator of hazardous chemicals and materials. Hazardous chemical wastes are accumulated on site in accordance with RCRA Subtitle C. The RML facility is registered with MDEQ under USEPA Hazardous Waste Management Identification Number # MT3750802875. Transportation and final disposition of stored hazardous waste is conducted by a licensed hazardous waste management contractor approximately once a year. The hazardous chemical storage area is located west of the main campus laboratory complex in a specially designed structure with secondary containment, spill alarms, and automatic fire suppression systems. The chemical waste storage structure is equipped with fire suppression systems, ventilation, and Class I Division 2 explosion-rated wiring.

RML is currently stressing waste minimization practices. Hazardous waste manifests show a declining trend in the disposal of hazardous waste from RML over the last few years. Waste minimization practices include ordering necessary laboratory chemicals in smaller quantities. Currently RML produces less than the 220 pounds of hazardous waste per month allowed for conditionally exempt, small-quantity hazardous waste generators.

Most hazardous materials used at RML are used in laboratory experiments. Most of the hazardous waste generated at RML can be grouped into categories based on their physical and chemical properties: toxic, flammable, or corrosive. Flammable compounds used in the greatest quantities at RML include acetone, acetonitrile, formamide, toluene, triethyl amine, and xylene. Corrosive compounds used in the greatest quantities by RML include acetic acid, formic acid, hydrochloric acid, potassium hydroxide, and sulfuric acid. Toxic compounds used in the greatest quantities at RML include formaldehyde, chloroform, phenols, and propylene glycol ether mixed with parafinic solvents.

RML periodically contracts with licensed hazardous waste transporters such as Safety-Kleen, Inc. or Burlington Environmental to haul wastes to licensed hazardous waste disposal facilities such as Safety-Kleen's facility in Argonite, Utah, or N.S.S.I. Recovery Services' facility in Houston, Texas.

A solid and hazardous waste specialist from the MDEQ inspected RML for its compliance with hazardous waste rules and regulations. A February 20, 2003, letter from MDEQ to Ms. Dianne Huhtanen at RML noted that no violations of applicable hazardous waste regulations were observed during the inspection.

Radioactive Materials

RML operates under a U.S. Nuclear Regulatory Commission (NRC) Materials License number 25-01203-01 which authorizes receipt, possession, location, and conditions for using radioactive materials. The RML Radiation Safety Committee and the radiation safety officer are responsible for supervision and regulatory compliance.

The CFR Part 20 specifies licensee requirements for radiation protection programs, including dose limits, storage, and control of licensed material, waste disposal, and record keeping. NRC conducted a safety and compliance inspection on May 8, 2002. The report stated that, based on inspection findings, no violations were identified.

RML's NRC license specifies amounts of various radioactive isotopes that may be in possession at any one time. Researchers must submit protocols for use of radioactive materials to the Radiation Safety Committee for approval. The protocol must specify names of users, isotopes, activity to be ordered, safety precautions, types of waste generated, procedures for handling waste, and actual scientific procedures performed. All scientific staff using isotopes are trained on topics including properties of ionizing radiation, safety procedures, proper handling techniques, NRC regulations, RML requirements, appropriate survey procedures, security, and record keeping.

The RML radiation safety officer tracks every isotope from the time of ordering until final disposition. Inventories of isotopes on hand are updated every month. In addition, RML has instituted a decay-in-storage program for radioactive waste of isotopes having less than a 120-day half-life. Each radioactive storage bag for solid waste or container for liquid waste must identify the specific isotope, date of storage, generator name, and activity. Waste disposal inventories that account for radioactive decay are updated monthly to show actual activity on hand for each waste unit.

The RML radiation safety policy emphasizes waste minimization. Final disposition of waste is conducted by the radiation safety officer or a designee. Extremely low levels of radioactive solid waste are incinerated. The EPA compliance code applied to RML incineration of radioactive waste has resulted in an exempt designation. Ash from the radioactive waste incinerator has been collected for storage, and disposal will occur according to NRC regulations. On one occasion a licensed broker has transported uranium and thorium waste compounds to the US Ecology Site for low-level radioactive waste in Washington. RML maintains a current site use permit at the Richland, Washington site to provide options for disposal of long half-life radioactive waste.

The NRC license for RML includes possession and use of a JL Shepherd Mark I, Model 30 irradiator containing a sealed source of cesium. This equipment is used to irradiate tissue culture cells or other biological specimens. Safety precautions include training, room monitor, monthly safety and interlock checks, and semi-annual leak tests.

Emergency Plan

Emergency plans for RML are periodically updated. Principal elements of the current plan include:

- evacuation;
- room clear;
- shelter in place;
- lockdown;
- dangerous person on site;
- suicide threat or attempt;
- death, serious injury or medical condition on site;
- fire or explosion;
- hazardous material spill;
- bomb or suspicious device;
- bomb threat; earthquake;
- civil disturbance;
- severe weather conditions;
- electrical outage;
- blood borne pathogen exposure;
- medical assessment procedure;
- emergency communications for use in extreme emergencies;
- radiation spill on body;
- chemical spill on body;
- biological spill;
- suspicious packages or mail;
- emergency evacuation of animal facility; and
- elevator failure.

Emergency plan revisions will involve the facility administration; Laboratory and Branch Chief; principal investigators; laboratory workers, and facility and NIH safety and security personnel. Local police, fire, and other emergency responders will be informed of the types of biological materials used in the laboratory and consulted in developing the revised emergency response plan.

NIH works closely with other government agencies to monitor intelligence regarding terrorist activities. The NIH also maintains an alert system that is based on the perceived threat to NIH's facilities. All NIH facilities, regardless of location, employ these security standards.

NIH has developed a comprehensive security plan that includes biological security. While exact details of the security plan are security-sensitive, NIH will use the most stringent security standards relating to physical security, background checks, intelligence gathering, and coordination with local, state and federal law enforcement agencies. Standard operating procedures will be developed in partnership with the RML, infectious disease specialist Dr. George Risi, the Ravalli County health officer, and local emergency response coordinator (as required by the Ravalli County Disaster and Emergency Operations Guideline).

The plan will be expanded to address facility-specific protocols for transporting injured or potentially infected personnel to emergency care facilities outside of the RML. Dr. Risi and NIH staff will review current agreements with emergency providers from other government and civilian laboratory facilities. A memorandum of understanding is planned with local emergency services and hospitals. The memorandum will outline RML's expectations in regard to the transportation, acceptance, admittance, and short- and long-term care of patients under various injury scenarios, including patients believed to be exposed to agents.

Incident Reporting and Protocols

The revised Emergency Response Plan will include provisions for notifying the Laboratory and Branch Chief, workers, safety personnel and other appropriate personnel, and the public in the event of an incident having the potential to impact the public. Policies and procedures will be in place for reporting and investigating incidents or potential incidents (e.g., undocumented visitors, infectious diseases, missing chemicals, unusual or threatening phone calls).

In the event of an incident, public communication will be facilitated by the Ravalli County public information officer in conjunction with the RML public affairs office, and in accordance with the Ravalli County Disaster and Emergency Operations Guide. The Health Department maintains a public health emergency communication system called the Ravalli County Health Alert Network (RCHAN) to inform the public of infectious diseases or environmental hazards. Targeted community contacts are informed by telephone, fax, and email. The public information officer at the county will communicate information and instructions through news releases to the media as needed.

2.2.2 Alternatives Considered But Eliminated From Detailed Study

This section describes alternatives to the Proposed Action that were eliminated from further review. These alternatives were identified during the public scoping process or by RML during review and analysis of the Proposed Action. These alternatives were considered technically infeasible, provided no environmental advantage over the Proposed Action or No Action, or would not meet the purpose and need.

2.2.2.1 Build the Integrated Research Facility in Bethesda, Maryland

Some comments suggested that the Integrated Research Facility should be built at the NIH campus in Bethesda, Maryland.

Rationale for Dismissing

Construction of the Integrated Research Facility at the Bethesda, Maryland campus would not meet the purpose "to provide a highly contained and secure intramural laboratory at RML dedicated to studying the basic biology of agents of emerging and re-emerging diseases, some of which have potential as bioterrorism agents.… in conjunction with "federal funding parameters associated with NIAID's intramural laboratory program." Bethesda, Maryland and Rockville, Maryland, are the only other intramural research facilities NIAID operates. A BSL-4 laboratory for NIH use has been constructed at the Bethesda site.

Locating the proposed Integrated Research Facility at either the NIH Bethesda or Rockville campuses is not prudent or practicable.

Based on the NIH Bethesda Master Plan, there are currently no available spaces on either campus capable of accommodating the Proposed Action.

All unoccupied sites have been developed or are otherwise allocated. Other areas of the campus approved for laboratory activities presently contain laboratory or service and support uses, which provide critical support space for other aspects of the NIH mission. These facilities cannot be relocated until suitable replacement space can be provided, a process estimated to require more than a decade to complete. Developing the Proposed Action within the footprints of these structures is not realistic.

Issues addressed through this alternative are also addressed through the No Action Alternative.

2.2.2.2 Relocate Rocky Mountain Laboratories to a Less Populated Area

Several commenters suggested that NIH/NIAID relocate RML to another, less populated site. The commenters noted that relocation of RML would avoid potential impacts posed by biological and infectious agents studied at RML.

This alternative would eliminate some of the consequences of the Proposed Action (such as additional traffic, construction noise, and increased water consumption associated with the Integrated Research Facility), and the effects would be the same as the No Action Alternative described in Chapter 4.

Rationale for Dismissing

To relocate RML to a less populated area would require NIH to obtain land; plan, design, construct, and commission new facilities that meet programmatic needs, requisite codes, and requirements; and obtain needed local, state, and federal permits. A new facility would require adequate and reliable utility and infrastructure services (water, sewer, power, roads) and access to reliable transportation and shipping services. Relocation of existing government staff and family members, secure adequately trained contract and repair services, recruitment of new staff to a more remote area, and provisions for schools for family members would be required. Relocation would necessitate decommissioning and closure of the present RML facility. Relocation would take approximately 15 years and cost nearly $1 billion.

The cost of building the proposed facility at a different location was determined by considering the total costs for not only the facility, but also for the structure needed to support the facility that currently exists at the RML. These costs included the following:

- Site location and site purchase ($9.84M);
- Site development/ utility infrastructure ($297.13M);
- Research facilities including the proposed BL-4 facility and the adjacent existing BL3 that will support the BL-4 ($167.7M);
- Research support facilities that currently exist at the RML and will be used to support the BL-4 ($47.86M);
- Emergency response service ($20.75M); and
- Additional staffing that will be available at the RML available to support the BL-4 ($2.5M) and other additional costs including transportation and contracted services ($11.35M).

The total cost of these services is approximated at a total of $920.18M. The length of time to provide a facility at the alternate location would be 15 years. Cost and time ultimately make the alternative unreasonable.

The highly trained and specialized staff at RML would not likely transfer en-masse, increasing the time needed to attain current levels of research performed at RML.

This alternative does not meet the purpose and need "to provide a highly contained and secure intramural laboratory at RML dedicated to studying the basic biology of agents of emerging and re-emerging diseases, some of which have potential as bioterrorism agents…." in conjunction with "federal funding parameters associated with NIAID's intramural laboratory program." Congress has authorized expenditure of $66.5 million for construction of an Integrated Research Facility through NIH's Intramural Laboratory Program. Construction of the facility at an alternate site would require new funding to provide infrastructure and research laboratory support currently in place at RML.

This alternative is also outside the scope of the Project (see Decision to Be Made on page 1-7).

This alternative is represented by the No Action Alternative (which includes not building the

Integrated Research Facility at RML). An alternative such as this could be considered in a future NEPA analysis, regardless of which alternative is selected under this project.

2.2.2.3 *Construct Integrated Research Facility at Alternate Location*

Other commenters suggested that the proposed Integrated Research Facility containing the BSL-4 laboratory be constructed at a more remote site away from Hamilton, at a military base, or somewhere with an existing infrastructure. These commenters suggested the relocation of the BSL-4 laboratory would avoid potential impacts posed by biological and infectious agents studied at RML, or that these other areas might be more easily protected from terrorist attack. This suggestion was also made in several comments on the DEIS and SDEIS.

This alternative would also eliminate some of the consequences of the Proposed Action, and the effects in Hamilton and Ravalli County would be the same as the No Action Alternative described in Chapter 4.

Rationale for Dismissing

A key component of the studies in the proposed Integrated Research Facility involves integration of current RML scientists with those working in the new facility. Locating the BSL-4 laboratory at a separate location from the existing RML campus would eliminate the connected research on projects that use BSL-2 and BSL-3 facilities, making research inefficient and impractical.

This alternative also fails to meet the purpose "to provide a highly contained and secure intramural laboratory at RML dedicated to studying the basic biology of agents of emerging and re-emerging diseases, some of which have potential as bioterrorism agents. … "in conjunction with "federal funding parameters associated with NIAID's intramural laboratory program." A site other than at NIH would have to either be purchased or go through the lengthy federal and state permitting processes. Utilities, roads, and other infrastructure or services would be necessary to support the facility.

Issues addressed through this alternative are also addressed through the No Action Alternative. An alternative to locate an Integrated Research Facility at an alternative location could be considered in a future NEPA analysis, regardless of which alternative is selected under this project.

2.2.2.4 *Construction and Administration of Integrated Research Facility Be Conducted By Another Agency, or at Another NIH Location*

Commenters suggested that the Integrated Research Facility should be authorized and operated by another agency, not NIH, or that it should be constructed as part of a different facility operated by NIH. Some of the alternative locations mentioned were NIH at Bethesda, Maryland, or Ft. Detrick, Maryland.

Rationale for Dismissing

NIH has no authority to direct other agencies to construct an Integrated Research Facility. Legislation approved by Congress and the President is needed to construct a research laboratory building. Actions by other agencies related to BSL-4 laboratory construction are outside the scope of this EIS.

Construction and administration of the proposed Integrated Research Facility at RML in Hamilton by another agency, private group(s), or at different NIH facility would not meet the purpose "to provide a highly contained and secure intramural laboratory at RML dedicated to studying the basic biology of agents of emerging and re-emerging diseases, some of which have potential as bioterrorism agents.…" in conjunction with "federal funding parameters associated with NIAID's intramural laboratory program." Bethesda, Maryland, already has a BSL-4 laboratory. Fort Detrick, Maryland, is operated by the U.S. Army. NIH has just completed an EIS on a BSL-4 facility at Fort Detrick planned for NIAID.

Issues addressed through this alternative are also addressed through the No Action Alternative.

2.3 AGENCY'S PREFERRED ALTERNATIVE

After reviewing the potential effects of the alternatives (**Table 2-2**) along with the purpose and need for the Project, NIH has identified the Proposed Action as the preferred alternative.

2.4 SUMMARY COMPARISON OF ALTERNATIVES

Table 2-2.
Comparison of Alternatives

Purpose and Need	Proposed Action	No Action
Provide a highly contained and secure intramural laboratory at RML dedicated to studying the basic biology of agents of emerging and re-emerging diseases, some of which have potential as bioterrorism agents.	The Proposed Action meets the purpose of the Project.	No action does not fulfill the purpose of the Project.
Issue	**Proposed Action**	**No Action**
Housing	The adjacent neighborhood could encounter direct negative impacts during construction of the Integrated Research Facility from noise and dust for two years. New housing units would be needed within commuting distance.	Additional annoyances of the construction phase would be eliminated. Housing starts would continue at about the same pace, although houses may remain on the market longer with fewer qualified buyers.
Education	School capacity is adequate for new growth, especially since school-aged populations are decreasing, but operating and maintenance costs would continue to increase.	No change in school enrollment.
Community Safety	No increased risk to the community.	Negligible risk to the community.
Transportation	RML traffic expected to increase total traffic by 16% during peak hours by 2006; residential traffic would make the increase a total of approximately 20%.	Residential traffic is expected to increase approximately 4% by 2006.
Economic Resources Income	100 new employees with total annual payroll estimated at $6.6 million. RML would contribute a total of $17 million in payroll annually.	No new employees, total annual payroll would remain at $10.4 million.
Government and Public Finance	Public finance revenues would increase as a result of increased income tax on the Integrated Research Facility-related construction and operations payrolls, as well as the incomes of spouses and older children of RML employees, increased vehicles being licensed, and property tax revenues based on the additional new homes and increased property assessments.	No increase in tax revenues from the Integrated Research Facility.

Table 2-2.
Comparison of Alternatives

Issue	Proposed Action	No Action
Noise	Noise from the Integrated Research Facility would be in the 35-50 dBA range at the property lines when all equipment is operating. Construction activities associated with the Proposed Action would generate intermittent short-term noise impacts. Overall noise level would remain at the current 44-58 dBA until reasonably foreseeable improvements are made to reduce them to 55 dBA at the property lines, which is the draft noise guideline for RML.	Existing noise would range from the current 44 to 58 dBA with the steam vents and incinerator operating and 43 to 61 dBA with the emergency generator operating, until reasonably foreseeable improvements are made to reduce them to 55 dBA at the property lines, which is the draft noise guideline for RML.
Visual Quality	A general improvement of the appearance of the site, due to the Proposed Action and cumulative effects.	No effect due to no action. Cumulative effects are a general improvement of the appearance of the site.
Historical Resources	No adverse effect.	No adverse effect.
Air Quality	Construction activities associated with the Proposed Action would generate short-term air impacts. Operation of the Integrated Research Facility increases the activity level at the laboratories and related emissions from the facility. Applicable air quality standards would be met.	Emissions from RML would remain at current levels. Applicable air quality standards would be met.
Water	Water consumption at RML would increase by up to 35 percent. Wastewater discharge at RML would increase by about 30 percent. Both water supply and wastewater treatment in Hamilton can adequately handle this increase.	No increase in water or wastewater.

CHAPTER 3
AFFECTED ENVIRONMENT

3.1 INTRODUCTION

Existing environmental resources in the Project area are described in this chapter with a summary of environmental baseline information. In the following sections, "Project area" refers to the Proposed Action, and "study area" refers to land surrounding RML. The "area of potential effect" as used in the Historical Resources section refers to the Project area.

The USDHHS manual (30-50-00 NEPA Review) requires the EIS to incorporate the material required by the applicable statute or Executive Order. Those assets that may be affected are addressed in this chapter.

The following resources are potentially affected by the Proposed Action and are addressed in detail:

- Social Resources;
- Economic Resources;
- Noise;
- Visual Quality;
- Historic Resources;
- Air Quality; and
- Water Supply and Wastewater.

The following resources have been analyzed and are either not present in the Project area or would not be affected by the Proposed Action:

- Soil;
- Geology;
- Floodplains;
- Wetlands and Riparian areas;
- Vegetation;
- Fish;
- Wildlife;
- Threatened and Endangered Species;
- Environmental Justice; and
- Surface Water.

Rationale for providing no further discussion of the resources is also included in this chapter.

3.2 SOCIAL RESOURCES

3.2.1 Analysis Methods

The socioeconomic study area includes Ravalli County and the City of Hamilton. Data for the State of Montana and the United States are used where appropriate for comparison purposes.

Baseline data for Hamilton and Ravalli County include population and demographic data, land, community infrastructure information, and current economic and business statistics. Data were collected to comprehensively describe existing conditions for both the county and the city. Data contain current population statistics from the U.S. 2000 Census, including age categories and education levels. Existing land use is described using the Ravalli County Growth Policy (2002), City of Hamilton Comprehensive Master Plan (1998), and the draft City of Hamilton Growth Policy (2002). Housing information includes number of units, vacancy rates, costs, and cost-burden derived from U.S. 2000 Census reports, Ravalli County Growth Policy, and City of Hamilton's Comprehensive Master Plan. Economic information includes employment by industry, labor force, income, and public finance. Data were collected primarily from the U.S. 2000 Census, the Montana Department of Labor and Industry, and the Ravalli County Economic Needs Assessment (Swanson 2002).

3.2.2 Affected Environment

Ravalli County was established in 1893 and named for Jesuit Missionary Father Anthony Ravalli, who settled in the region in 1845. County residents value the rural character of living close to nature and have a strong concern about the fate of the area's land, natural resources, local businesses, and quality of life.

The City of Hamilton, the largest community in Ravalli County, was incorporated in 1894 and named after James Hamilton, a Marcus Daly employee who platted the town along the route of

the Northern Pacific Railway in 1890. Hamilton was a company town revolving around the activities of Daly's large lumber mill, owned by the Anaconda Copper Mining Company, and Bitterroot Stock Farm. Most of the residents worked for the Daly interests, living in company homes and shopping in company stores. By the time Daly died in 1900, Hamilton was the commercial center of the Bitterroot Valley and the seat of Ravalli County.

Population Trends and Demographic Characteristics

Ravalli County is one of Montana's fastest growing counties. It was one of the fastest growing counties in the U.S. during the 1990s. In the last decade, net in-migration resulted in more than 10,500 new residents to the valley, an increase of 44.2 percent in 10 years. Hamilton is one of the fastest growing communities in Montana as well. The population increased from 2,737 in 1990 to 3,705 in 2000, a net increase of 35 percent during the 10-year period. In comparison, Missoula County, the region's main population center, grew 21.75 percent, and the state's population growth was 12.9 percent from 1990 to 2000 (**Table 3-1**). Ravalli County is growing faster than Hamilton. In the 1960s, Hamilton's population was 20 percent of the county; in 2000, it was only 10 percent of the county.

According to the Ravalli County Economic Needs Assessment (Swanson 2002), "about 95 percent of this recent population growth is the result of much higher rates of net in-migration to the county (which considers only new residents who have declared Ravalli County as their permanent residence)."

Many of the newcomers visited and decided to relocate to the area. Others are previous residents returning to the area, retirees, and in-migrants from nearby Missoula, which continues to grow as the regional employment and retail center. High rates of net in-migration have developed in many areas of the interior west, as people move to take advantage of the area's quality of life and proximity to National Forests and outdoor recreational opportunities. The valley has good access to airline service and to cultural and social activities in Missoula. A low crime rate and moderate climate enhance the area's desirability.

The Ravalli County population (**Table 3-2**) aged between 1990 and 2000, with large increases in the 45-64 year-old age group. The 65 and older group decreased as a percentage of the total population. Median age of county residents was 41.1 years in 2000, up from 37.8 years in 1990. The median age for the state's population in 2000 was 37.5 years. Aging of the population is expected to increase and continue to be a demographic factor, producing a lower birth rate. In 1980, the birth rate was 15.8 per 1,000, falling to 9.8 by 2000. This compares to a statewide average of 13.8 (US Census 2001).

The school population is growing more slowly than the general population. The Ravalli County Economic Needs Assessment (Swanson 2002) points out that new in-migrants to Ravalli County are people in their 40s, 50s, and 60s who are not adding to their families. If they have children still at home, they are likely high-school age and older. Education levels attained in the county match those of the state and the City of Hamilton in the percent of high school graduates, but both the county and the city have lower rates of college and graduate or professional degree holders than does the state.

Table 3-1. Population Estimates

Area	2001 Census Estimates	2000 Census	1990 Census	% Increase 1990 -2000	% Increase 2000 - 2001
Montana	904,433	902,195	799,065	13%	2%
Ravalli County	37,304	36,070	25,010	44%	3%
Hamilton	NA	3,705	2,737	35%	NA

Source: Montana Department of Labor and Industry 2002.

Table 3-2.
Demographic Characteristics, 2000

Demographic Characteristic	Montana	Ravalli County	City of Hamilton
Total population	902,195	36,070	3,705
Gender			
Male	449,480	17,910	1,672
Female	452,715	18,160	2,033
Age Group			
0-4	54,869	2,073	220
5-9	61,963	2,477	184
10-14	69,298	2,863	215
15-19	71,310	2,662	201
20-24	58,379	1,379	181
25-34	103,279	3,570	412
35-44	141,941	5,340	479
45-54	135,088	5,854	445
55-59	47,174	2,313	152
60-64	37,945	1,950	167
65-74	62,519	2,981	348
75-84	43,093	1,949	425
85 and over	15,337	659	276
Median Age	37.5	41.1	44.3
Education (population 25 and over)			
< High School graduate	75,358	3,095	482
High School (or GED)	183,415	7,738	860
Some college, no degree	150,467	6,916	708
Associate degree	34,420	1,284	82
Bachelor's degree	100,758	3,897	423
Post Graduate	42,203	1,631	175

Source: US Census 2001.

3.2.3 Housing

Ravalli County

According to the 2000 U.S. Census, there were 15,946 housing units in Ravalli County, almost eight percent of which were multiple family units. Over 75 percent of the housing is owner-occupied, with an average of 2.48 people residing in each household. The Ravalli County Growth Policy, adopted in December 2002, notes that providing quality affordable housing is a primary community goal. According to the policy, a household is described as experiencing "cost-burden" when their housing costs exceed 30 percent of income. In 1990, the U.S. Census indicated that 16 percent of homeowners and more than 34 percent of renters were experiencing cost-burden. In 2000, these figures had increased to almost 29 percent of homeowners and 38 percent of renters. The rate of growth in household income has not kept pace with the cost of homes in Ravalli County. Between 1990 and 2000, median household income increased from $28,376 (adjusted for inflation to 2000 values) to $31,992, or 12.7 percent. In contrast, the median home value was $82,923 in 1990 (adjusted for inflation to 2000 values) and increased to $133,400 in 2000, an increase of 60.9 percent and about 134 percent of the Montana median home value of $99,500.

Hamilton

Within the city limits, 80 percent of the area is built out, with less than 15 percent vacant land remaining. The 2000 U.S. Census reports there were 1,915 housing units in the city. Of the 1,772 occupied housing units, 51 percent were owner-occupied, with 49 percent renter-occupied. On average, 1.95 persons live in each household, indicating smaller households than in the county, consistent with the higher median age of city residents. The vacancy rate is approximately four percent for homeowners and six percent for rentals. The 1998 City of Hamilton Comprehensive Master Plan states that Hamilton has a jobs-to-housing balance of 300 jobs for every 100 units of housing. The vacancy rates suggest that a substantial percentage of those employed in Hamilton do not live in the city. It is not clear whether that is by choice or necessity; some employees may live out of town for more affordable housing. Local realtors report that home prices in Hamilton currently range from $95,000 to $185,000 and that homes near RML are worth between $20,000 and $30,000 more than away from RML.

RML is located in a residential area of Hamilton. Some current residents report that the facility is

not a good neighbor because of high noise volumes, steady traffic, and parking conflicts. They also note that the facility has not been maintained, with no landscaping or yard maintenance (see the Visual Quality and Noise sections in Chapter 4).

The City of Hamilton has zoned the area around RML as a Public and Institutional (PI), which is intended to "accommodate those public and institutional uses which are related to the health, safety, educational, cultural, and welfare needs of the city." The zone recognizes "government owned and operated facilities" and "other similar uses which the city finds to fall within the intent and purpose of this zone, that will not be more obnoxious or materially detrimental to the public welfare or to the property in the vicinity of the uses, and which the city finds to be of a comparable nature and of the same class as the uses enumerated" (Section 17.92.010, City of Hamilton Zoning Code). As a federal facility, RML is not obligated to follow local zoning regulations. The draft Hamilton Growth Policy (2002) confirms uses in the district.

3.2.4 Education

There are 16 public schools in Ravalli County with a total enrollment of approximately 6,280 pupils. Of the 16, there are six high schools, one middle school, seven elementary schools, one primary school, and one unclassified.

Enrollment in the PK-12 schools in the Hamilton District is approximately 1,612 (US Census 2002a). Higher education in the region includes the University of Montana and its College of Technology, both in Missoula. The Hamilton school superintendent reports that the middle school and high school have sufficient capacity to handle up to 100 new students. The elementary schools are at capacity; however, another facility is available, if necessary (Lyons 2003).

3.2.5 Community Safety

Law Enforcement

Law enforcement in Ravalli County is provided by the Montana Highway Patrol dispatched out of Missoula; the Ravalli County Sheriff's Department; and local police departments in Hamilton, Stevensville, Darby, and Pinesdale.

The Ravalli County Sheriff's Department has 31 full-time sworn officers, approximately 31 reserve deputies, 19 full-time sworn detention officers, 11 administrative and jail staff, 11 dispatchers for 911, and a disaster and emergency services coordinator. The Sheriff's Department uses a reserve deputy sheriff force and a trained group of volunteers for search and rescue activities.

The City of Hamilton Police Department has 13 sworn officers, one non-sworn full-time employee, and one part-time, non-sworn employee. The sworn officers include the chief, a sergeant, two detectives, eight patrol officers, and an animal control/parking enforcement officer.

RML currently has contracted security guards on site at all times. An NIH police force has been established at RML. A full-time captain has been hired and is currently on site, and a Sergeant was hired in January 2004.

Fire Protection

Fire protection services are supplied by 12 volunteer fire departments, with approximately 155 volunteer firefighters located throughout the Bitterroot Valley. The Hamilton Fire Department has 28 volunteer firefighters and five fire engines, one aerial truck capable of handling fires above the second floor of a building, and three water tenders. Three certified HAZMAT responders on the Fire Department work at RML and are also members of the Missoula Regional HAZMAT Team, a 40-person team available to RML to provide emergency services (Wilson 2003). In addition, RML has its own 11-member HAZMAT team.

During major fire and emergency situations that exceed the capacity of local departments and response units, the Ravalli County disaster and emergency services coordinator offers assistance to develop combined plans and actions.

Health Care

The Marcus Daly Memorial Hospital in Hamilton is the only hospital in Ravalli County. Marcus Daly cannot handle more than 10 emergency patients at a time (Bartos 2003). The 48-bed acute care facility offers 24-hour emergency care. Ambulance services are provided by Bitterroot Valley EMS (Emergency Medical Services), which currently has eight ambulances and 102 people on staff. A full

range of specialty medical services are available in Missoula.

3.2.6 Transportation

Other than general city ordinances and laws, no special restrictions on traffic or parking exist for the RML campus.

Regulations concerning transportation of biological agents are aimed at ensuring that the public and workers in the transportation chain are protected from exposure to any agent in the package. Transportation of biological agents is regulated by the Public Health Service, Department of Transportation, United States Postal Service, the International Air Transport Association, and the Occupational Health and Safety Administration. Transportation of the various agents currently studied at RML or potentially studied in the Integrated Research Facility is described in detail in **Appendix C**. RML is currently meeting requirements for transporting biological agents.

Information for the transportation analysis was gathered from the Hamilton Transportation Plan 2002 (Morrison Maierle, Inc. 2002). Existing traffic counts were used and base traffic projections were developed through historical roadway growth rates. Existing land use characteristics were used, and forecast land use projections were developed through interviews with city staff and historical population data from the U.S. Census Bureau.

Investigation of accident records for the past three years indicates that, in general, accident rates for Hamilton City collector streets have been average. Nearly 69 percent of the recorded collisions occurred on U.S. Highway 93; 16 percent occurred on a four-block section of Main Street (Morrison Maierle, Inc. 2002).

The four traffic signals in Hamilton (three on U.S. Highway 93 and one on Main Street) are functioning adequately or have been scheduled for upgrades in the near future. Currently, new signals may be warranted at two locations on U.S. Highway 93, one at Pine Street and another at Ravalli Street (seven blocks and three blocks north of RML, respectively).

Near RML, 7th and 4th streets are local collector streets, while the remaining streets in the area are considered residential. Both types of streets function primarily as access to abutting properties, with typically low traffic volumes. They carry less than 1,000 vehicle trips per day (Morrison Maierle, Inc. 2002).

Traffic into RML currently enters through the main gate at the corner of 4th and Grove streets (see Figure 2-1). During periods of heightened security, when vehicles entering the campus must be searched, traffic congestion is a problem as employees arrive for work. Many choose to park their vehicles along city streets instead of on campus, which causes parking problems near the site. Adequate visitor and employee parking is currently available without using adjacent streets.

The Hamilton Transportation Plan recommended that 7th Street from Adirondac Avenue to Desta Street (near RML, see Figure 2-1) have pavement replaced and curbs, gutters, and sidewalks upgraded to provide added capacity, improve surface drainage, and provide dedicated residential parking areas and dedicated pedestrian/bicycle facilities.

3.3 ECONOMIC RESOURCES

Ravalli County has experienced several boom/bust economic cycles based first on fulfilling the timber needs of the mines in Butte and Anaconda and then on orchard agriculture that relied on extensive irrigation systems. By 1915, easily accessible timber had been cut and the sawmill closed. In 1917, financial problems of the "Big Ditch" had peaked, and the orchard business went bust. The local economy was depressed and uncertain until RML was established in 1927 to research the cause of Rocky Mountain spotted fever. Hamilton actually grew during the 1930s when the rest of the country was experiencing a depression. Ravalli County and Hamilton are currently experiencing another economic boom because of the rapid population growth, apparently spurred by urban professionals wanting a rural, outdoor quality of life.

According to the Ravalli County Economic Needs Assessment (Swanson 2002), the economy is increasingly "growth driven" and "growth dependent," with most employment and income growth associated with people moving to the area and the resulting real estate development and construction activity. Concerns exist that high

levels of population growth cannot be maintained indefinitely because the growth is based on the attractiveness and desirability of the area, highlighting the volatility of the current economic situation. The Ravalli County Growth Policy (2002) lists major goals of encouraging economic growth in order to provide both good pay and good profit, and supporting the Ravalli County Economic Development Authority. The City of Hamilton Draft Growth Policy (2002) lists protecting the rural way of life without neglecting economic growth as a major community goal. The Ravalli County Economic Needs Assessment (Swanson 2002) lists developing quality businesses and job growth as one of three points of an economic development strategy by:

- Increasing the number of good paying jobs for skilled and educated workers with jobs paying above the area average; and
- Increasing the number of jobs that can serve as "ladders" for elevating area workers from low paying, low-skill jobs.

The report specifically identifies the bioresearch and biotechnology fields.

3.3.1 Employment

Along with the influx of population during the 1990s came a construction boom that has kept many contractors in the Bitterroot Valley actively engaged in building homes and commercial developments. In addition to construction activities, much of the boost in the valley's economy has been in services (2,242 employees) and retail trade (2,086 employees) (**Table 3-3**). According to the Ravalli County Economic Needs Assessment (Swanson 2002), growth in the service sector outpaces employee and income growth in any other sector. Not only are the jobs increasing, but the pay is also getting better, probably due to the increase in health services jobs. Retail trade is also growing because of the "growth driven" economy.

Despite losses in agricultural land over the last 10 years, agricultural production in Ravalli County remains strong. According to 2000 USDA County Profile, Ravalli County ranks second (out of 56 Montana counties) in dairy production, seventh in hay production, eleventh in oat production, thirteenth in alfalfa production, and above average in production of beef cows and heifers, cattle, sheep and lambs, and pigs.

The top 10 private employers in Ravalli County are Albertson's, Corixa, Discovery Care Center, Farmers State Bank, Fox Lumber Sales, Marcus Daly Memorial Hospital, Rocky Mountain Log Homes, Selway Corporation, Stock Farm Club, and Valley View Estates Health Care Center (Montana Department of Labor and Industry 2001).

Government employment is especially important to Ravalli County because it is a steady source of outside dollars coming into the county, thereby contributing to the economic base. Each economic base dollar generates about two dollars (Swanson 2002), whereas dollars earned from inside the community generate only one dollar. Employment at public schools, RML, and the U.S. Forest Service make up the majority of government jobs.

Table 3-3.
Ravalli County Employment by Industry

Industry	Average Annual Employed	Annual Wages Paid
Agriculture, Forestry, Fish	311	$ 5,213,462
Mining	4	$ 142,609
Construction	659	$ 15,587,371
Manufacturing	1,129	$ 33,360,408
Transportation, Communications, and Utilities	345	$ 8,413,587
Wholesale Trade	313	$ 9,595,714
Retail Trade	2,086	$ 28,058,822
Finance, Insurance, and Real Estate	445	$ 11,402,785
Services	2,242	$ 45,496,603
Nonclassifiable	12	$ 456,537
Private Business	**7,552**	**$157,498,717**
Government	1,782	$ 50,897,183
Total All Industries	**9,334**	**$208,395,900**

Note: Totals may not agree due to nondisclosure of confidential industry data or to rounding.

Source: Montana Department of Labor and Industry 2002.

In 1990, the last period for which data was published, an estimated 15 to 20 percent of employed Ravalli County residents commuted to work in Missoula County. Over three percent of all employees in Ravalli County commuted from Missoula County (Montana Department of Labor and Industry 2002).

The unemployment rate of Ravalli County has been higher than the state rate since 1990, ranging from 10.8 percent in 1991 to a low of 4.6 percent in 2001. The state unemployment rate in 2001 was also 4.6 percent (**Table 3-4**).

3.3.2 Income

Personal income is defined as all income received by individuals from all sources – income from work (labor income or earnings), income from savings and investments (investment income), and income from outside sources such as Social Security or Medicare (transfer payment income). The Ravalli County economy has undergone an important shift in its income base as a result of the population and demographic dynamics of the 1990s. According to the Ravalli County Economic Needs Assessment (Swanson 2002), investment income and transfer payment income grew during this period while labor earnings saw gain. Labor earnings accounted for less than 54 percent of all personal income in the county in 2002; non-labor income is expected to increase to over half of the total income by 2010. Labor earnings account for about 60 percent of personal income in Montana and for about 65 percent of all income in the nation. The Ravalli County Economic Needs Assessment (Swanson 2002) notes that the greatest deficiency in the area's economy is the relatively low level of per worker earnings, both for wage and salaried employees and for proprietors (**Table 3-5**).

Table 3-4.
Ravalli County Annual Average Labor Force

Year	Labor Force	Unemployed	Unemployment Rate
2001	18,163	840	4.6%
2000	18,272	950	5.2%
1999	17,730	1,072	6.0%
1995	15,973	966	6.0%
1991	12,251	1,328	10.8%

Source: Montana Department of Labor and Industry 2002.

Labor income is income from work or earnings. Average annual wages for all Ravalli County industries ($22,326) in 2000 lagged behind the state ($24,275) by approximately nine percent. The mining sector in Ravalli County, although employing an average of only four employees in 2000, paid the highest wage in the county at $36,652, while the retail trade section paid the lowest average annual wage of $13,451 (Montana Department of Labor and Industry 2001). Government workers (federal, state, and local, including public education) constituted 19 percent of the total workforce, earning an average annual wage of $28,562.

RML has approximately 250 federal employees, fellows, and facility contractors (not including construction workers) and an annual payroll of $10.4 million for fiscal year 2003.

Per capita income (**Table 3-5**) is calculated by dividing all personal income received by all permanent county residents by the total county population. Per capita income was listed as $16,560 in 1997, an 11 percent gain over the 1987

Table 3-5.
Comparison of Per Capita Personal Income, 1970-2000

Year	U.S.	Montana	Montana % of U.S.	Ravalli County	Ravalli County % of U.S.	Ravalli County % of Montana
2000	$29,469	$22,518	76%	$18,959	64%	84%
1995	$23,255	$18,592	80%	$16,036	69%	86%
1990	$19,572	$15,516	79%	$13,660	70%	88%
1980	$10,183	$ 9,143	90%	$ 7,507	74%	82%
1970	$ 4,095	$ 3,625	89%	$ 3,029	74%	85%

Source: Montana Department of Labor and Industry 2002.

level. The latest estimate is $17,235 for 2000, a four percent gain over the 1997 level. Montana is ranked 47th in personal per capita income in the nation, and Ravalli County is 35th of the 56 counties in the state (US Census 2002a).

Poverty levels indicate the percentage of the population with incomes below that necessary for basic necessities – adequate housing, food, transportation, energy, and health care. The 2000 U.S. Census reports that 13.8 percent of Ravalli County residents were classified as living in poverty, based on the national poverty threshold. At the same time, poverty levels were estimated at 14.6 percent of the state's population and at 11.8 percent of the nation's population.

3.3.3 Government and Public Finance

According to the Ravalli County Economic Needs Assessment (Swanson 2002), the high rate of population growth is causing economic restructuring in the county. The report presents evidence that in the midst of this fast growth, local government officials are hard pressed to meet the growing demand for services that rapid population and other growth brings with the constrained revenues available. In Ravalli County, both taxing and spending for local governments and special districts are low.

The two primary sources of local government revenues are intergovernmental transfers (funds passed through from federal and state governments, such as grants-in-aid and payments in lieu of taxes for federally owned land) and local taxes and assessments. The Ravalli County Economic Needs Assessment (Swanson 2002) notes that, in 1997, total revenue for local governments in Ravalli County was $45 million (1997 is the last year for which data has been reported). Of that total:

- Intergovernmental transfers accounted for $22.4 million, or 50 percent of the total;
- Taxes accounted for $16.3 million, or 36 percent; and
- Sales, fees, and earnings accounted for $6.3 million, or 14 percent.

Of the $16.3 million collected in taxes, $15.7 million was collected as property tax. While property taxes (**Table 3-6**) are low in Montana compared with other mountain west states, they are not low for individual owners and commercial establishments, and they are rising faster than per capita incomes.

Table 3-6.
Taxable Values, Ravalli County

	1987	1994	2000
Residential	57.8%	63.9%	69.5%
Commercial	9.5%	11.1%	13.4%
Subtotal	67.3%	75%	82.9%
Taxable Values	$28,400,000	$40,700,000	$49,000,000

Source: Nicholson 2002.

The Montana Legislature lowered rates on utilities and business equipment, placing almost 83 percent of the tax burden in Ravalli County on residential and commercial property owners. Assessed property values almost doubled, and property tax bills more than doubled, as special districts such as fire departments and schools raised their mill levy requests in an attempt to maintain cuts from the state share of taxes. Local wages, which pay these taxes, have not increased at the same pace.

3.4 NOISE

There are no local, state, or federal noise ordinances in effect for the area. However, RML has drafted guidelines to limit noise levels due to its operations (**Table 3-7**).

A noise level study of the current operation was conducted in May 2003 (Big Sky Acoustics 2003). Measurements were conducted at 13 locations (**Figure 3-1**). Measurements were taken with equipment operating, including the emergency generator, boiler steam vent, and/or the incinerator. Information concerning testing methods is available in the Final Noise Analysis Report in the administrative record.

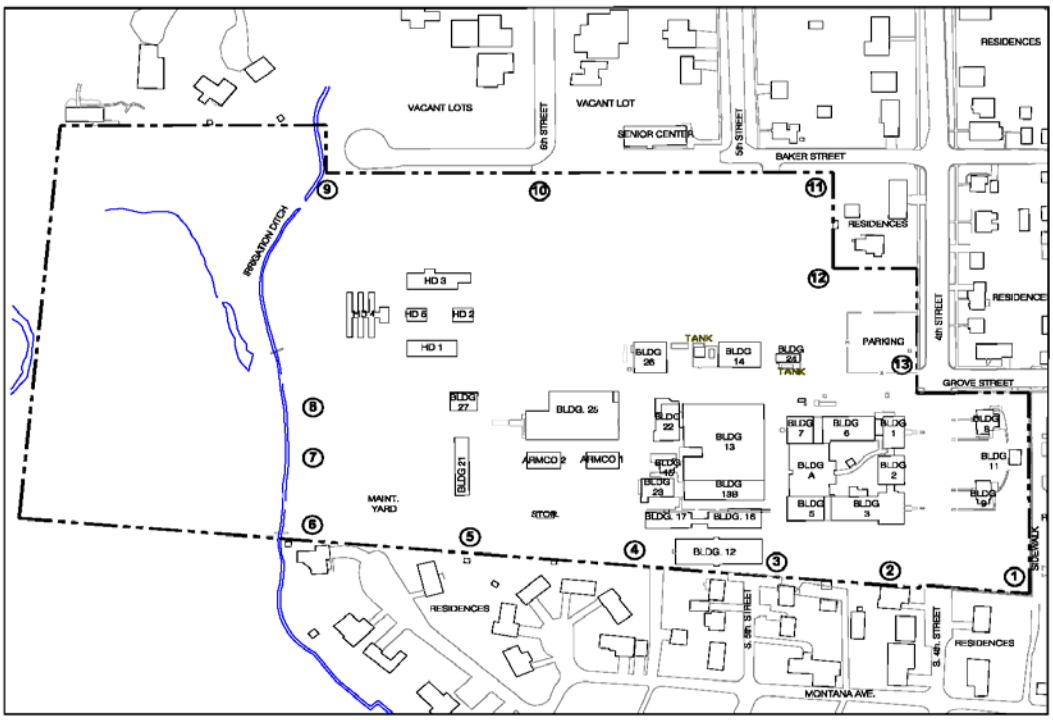


Figure 3-1. Ambient Noise Levels for Table 3-8.

Table 3-7.
RML Campus Noise Guidelines

Noise	Daytime[1]	Nighttime[1]
Cumulative	55 dBA	50 dBA
Tonal[2]	50 dBA	45 dBA
Emergency Generator[3]	60 dBA	NA

1. Daytime 7:00 am to 7:00 pm, nighttime 7:00 pm to 7:00 am
2. Audible discreet tones shall be identified when the noise level in one-third octave-band frequency exceeds the arithmetic average of the levels in the two adjacent one-third octave band frequencies by 15 dB or more at frequencies below 125 Hertz, by 8 dB or more between 160 and 400 Hertz, and by 5 dB or more at frequencies equal to or greater than 500 Hertz.
3. During weekly testing of emergency generators, noise shall not exceed 55 dBA, and the combination of the generator and other campus equipment noise shall not exceed 60 dBA. Emergency generators will only be tested during daytime hours.

Table 3-8.
Existing Ambient Noise

Location[1]	Daytime	Nighttime
1	48	45*
2	52	50*
3	52	51
4	51	50*
5	50	45*
6	44	40*
7	41	40*
8	44	40*
9	43	39
10	50	44
11	46	45
12	47	45*
13	49	45*

1 See Figure 3-1 for locations.

* Nighttime ambient levels that were estimated.

The study results indicated that existing ambient noise levels at the property line ranged between 41 and 52 dBA during the daytime and between 39 and 51 dBA at night (**Table 3-8**), which is considered faint to moderately loud (**Table 3-9**). Since the study was completed, noise reduction features have been installed, including putting a silencer on the incinerator stack, enclosing the incinerator cooling tower, muffling the steam plant,

and muffling the generator buildings. These actions have reduced the noise emitted from the RML campus.

Table 3-9. Perception of Noise

Noise Level (dBA)	Noise Source	Subjective Evaluation
70	Vacuum cleaner 10 feet away or outdoors in a commercial area	Loud
60	Normal speech 3 feet away	Moderate
50	Typical office activities or background noise in a conference room	Moderate
40	Library background noise, quiet suburban environment at night, or typical background noise in a residence	Faint
30	Whisper 3 feet away or quiet rural environment at night	Faint
21	Concert hall background noise	Very faint
10	Human breathing	Very faint
0	Threshold of hearing or audibility	

Sources: Big Sky Acoustics 2002.

3.5 VISUAL QUALITY

The objectives of the visual resources investigation are to identify and describe visual resources that could be affected by the proposed expansion and related facilities. A viewpoint was selected for evaluating the visual characteristics presented in Chapter 4, Visual Quality. Factors considered in selecting the viewpoint included angle of observation, number of viewers, duration of view, relative apparent size of project, and lighting conditions. Viewpoint 1 was selected to represent a location from which a person may be expected to view the proposed Project features in the most direct manner. One viewpoint was established for the Proposed Action.

Viewpoint 1 is located at the intersection of Fifth and Baker streets and faces in a southwesterly direction (**Figure 2-1**). Viewpoint 1 is at the same elevation as the proposed Integrated Research Facility building. From this aspect, the existing landscape presents a flat valley floor with mountains rising in the background (**Figure 3-2**). The site as seen through the existing chain link fence is vegetated with scrub grasses and weeds. Dirt and gravel roadways and areas of deteriorating asphalt are also evident. Many buildings in this view are for storage and maintenance purposes. A variety of outside clutter and covered storage is visible. The buildings offer combination colors of reddish brick and gray metal. The upper portion of Building 25 blends with the dark tree-covered mountains in the background. Vertical stacks contrast sharply with the rectangular shapes of the structures.

3.6 HISTORICAL RESOURCES

The Rocky Mountain Laboratories Historic District, 24RA373 (**Figure 2-1**) was listed on the National Register of Historic Places (NRHP) in 1987. The district is eligible for the National Register for its significant architecture and historic role in scientific research (NRHP 1987). The Historic District consists of 10 structures.

Buildings 1 and 2 (**Figure 3-3)** were constructed in 1932-34 and are three-story Collegiate Gothic structures designed in a tripartite scheme, with a brick base below the first floor window sills. The buildings are of common bond, multi-colored, striated brick construction, which starts at the sill level of the first floor windows and terminates at the head of the third floor windows. Above the concrete belt course is a crenelated brick parapet with a cast concrete cap. The second and third story windows have cast concrete sills. The main entry vestibules are brick with corner quoining, terminated on the top and at each corner by a square block and ball motif cast in concrete.

Building 3 (**Figure 3-4**), constructed in 1938, is a three-story Collegiate Gothic structure. The details of Building 3 are the same as Buildings 1 and 2.

Building 4, constructed in 1936-37, was removed and replaced with Building A (**Figure 3-5**) in 1998. Building A has many of the same details as Buildings 1, 2, and 3.

Source: Maxim (May 2003)

Visual Quality Existing Conditions
RML Integrated Research Facility FEIS
Hamilton, Montana
FIGURE 3-2

Figure 3-3. Overview, Building 1, facing southwest

Figure 3-4. Building 3, facing west

Figure 3-5. Building A, facing south

Figure 3-6. Buildings 5, A, and 7, facing north

Figure 3-7. Building 9, facing southeast

Buildings 5 (**Figure 3-6**) and 6, constructed in 1938 and placed into service in 1940, are both two-story Moderne style structures. These simple, rectangular masonry buildings have regularly spaced windows set singly or in pairs.

Building 7, the former heating plant, was constructed in 1938-40 and is a Moderne style structure. This three-story structure has similar details as Buildings 5 and 6 and has a tall, round masonry smoke stack on the west side.

Buildings 8 and 9 (**Figure 3-7**) are two Late Colonial Revival style residences located across 4th Street from the laboratories.

Building 8, constructed in 1936-37, is a two-story, rectangular, wood-frame structure resting on a concrete foundation with shed dormers on the second floor. The gable roof, which runs parallel to 4th Street, has a 10/12 pitch and slight eave

returns. Beneath the eaves is a molded fascia that provides a lateral six-inch overhang. The lap siding has seven-inch reveal, the first floor windows are 8-over-12 wooden double hung units. The dormer windows are 8-over-8 double hung windows. The doorway is approached by four risers and is covered with an enclosed, bow-roofed portico.

Building 9, constructed in 1937, is a two-story wood frame residence set on a concrete foundation with a shed dormer on the second floor. The building is symmetrically organized with a central entry flanked by two small projecting bay windows set beneath the flared overhang of the gambrel roof. The bay windows are 8/12 on the first floor and 4/6 on each angle. The entry is marked by a gable-roofed, arched overdoor that is cut into the eave overhang and accessed by a three-riser concrete stair. Building 11 is located behind and between Buildings 8 and 9, was constructed in 1937.

The primary laboratory buildings, the power plant, and the two residences possess architectural significance in the context of the type and quality of construction. The cohesive facades, massing, and detailing of the understated Collegiate Gothic buildings creates a strong visual impression. The pair of Colonial Revival style residences located across the street from the laboratories exhibit higher than average design sophistication, craftsmanship, and use of materials. Attention to landscaping and setbacks affords a sense of continuity with the residential character of the surrounding neighborhood.

Section 106 of the National Historic Preservation Act of 1966 (as amended) requires federal agencies to consider the effects of their actions on historic properties. The procedure for meeting Section 106 requirements is defined in regulations of the Advisory Council on Historic Preservation, Protection of Historic Properties (the Code of Federal Regulations, hereafter cited as 36CFR Part 800 with subparts). The Montana State Historic Preservation Office (SHPO) provided comments on the proposed research facility. The concerns noted by SHPO centered on the potential for "an adverse effect visually, at the least" on the historic district. The SHPO comments also noted that the proposed building should be compatible with the original structures in materials, that the proposed building should be set back so as to not block a major elevation of the original structure, and that it should also be in keeping with the scale of the historic district (Dawson 2002).

3.7 AIR QUALITY

The study area for air resources consists of the area within 30 miles of the RML site. The site experiences a cool climate typical of intermountain valleys of the Rocky Mountain area.

Meteorology

Climate in the study area is influenced by major topographic features, including the Bitterroot Mountain Range to the west and the Sapphire Mountains to the east. Mountain ranges in the Bitterroot Valley trend generally north and south and affect local wind, precipitation, and temperature patterns.

Typical precipitation levels are one inch or less of precipitation per month, and temperatures range from warm to hot during the summer months. Winters are cool to cold. The average daily temperature ranges from 36° F in January to 83° F in July in Hamilton.

Wind speed and direction data for the Project area obtained from the National Oceanic and Atmospheric Administration (NOAA) show varying speeds and direction. Based on data at Corvallis and Hamilton, typical maximum wind is primarily to the southeast/south-southwest.

Due to the City of Hamilton's physical location (e.g., proximity to mountains), meteorological conditions are conducive to atmospheric inversions. These inversions can occur throughout the year; however, they are most prevalent from October through March. When wind speed and mixing heights are low, inversions can occur, restricting emission mixing and dispersion.

The fall and winter climates in the area are cool to cold with few extended cold spells. Most precipitation during this period is in the form of snow, which accumulates in the valleys and on surrounding ridges. Precipitation during the spring usually occurs during May and June. The western portion of the valley receives more precipitation than the eastern portion, which is a function of the proximity to the Bitterroot Mountains. Summer precipitation is often associated with

thunderstorms. Precipitation in the Valley area ranges from 12 to 16 inches annually along the Highway 93 corridor from Corvallis to Sula. Mean annual precipitation is about 14 inches in Hamilton, with 16 inches to 48 inches on the surrounding upland areas.

Air Quality

The State of Montana and the federal government have established ambient air quality standards for criteria air pollutants. The criteria pollutants are carbon monoxide (CO), lead (Pb), sulfur dioxide (SO_2), particulate matter smaller than 10 microns (PM_{10}), ozone, and nitrogen dioxide (NO_2). In 1997, the U.S. EPA revised the federal primary and secondary particulate matter standards by establishing annual and 24-hour standards for particles smaller than 2.5 microns diameter ($PM_{2.5}$). **Table 3-10** lists federal and state standards.

Ambient air quality standards must not be exceeded in areas where the general public has access. National primary standards are levels of air quality necessary to protect public health. National secondary standards are levels necessary to protect public welfare from known or anticipated adverse effects of a regulated air pollutant.

The attainment status for pollutants within the Project area is determined by monitoring levels of criteria pollutants for which National Ambient Air Quality Standards (NAAQS) and Montana Ambient Air Quality Standards exist. Air quality in the Hamilton and Ravalli County area is designated as attainment or unclassified for all criteria pollutants. This designation means that based on monitored and assumed air pollutant levels, there are no exceedances of air quality standards in the area.

Air emission modeling conducted at RML, which is discussed in more detail later, was performed using meteorological data from a number of sites, including data from Missoula, an area also subject

Table 3-10.
State of Montana and National Ambient Air Quality Standards

Pollutant	Averaging Time	Air Quality Standard Concentration [(a)]	
		Montana	National
Ozone	1 hour	195 μg/m³ (0.12 ppm)	235 μg/m³ (0.12 ppm)
	8 hours	None	157 μg/m³ (0.08 ppm)
Carbon Monoxide	1 hour	25,560 μg/m³ (23 ppm)	40,000 μg/m³ (35 ppm)
	8 hour	10,000 μg/m³ (9.0 ppm)	10,000 μg/m³ (9.0 ppm)
Nitrogen Oxides	Annual Arithmetic Mean	100 μg/m³ (0.05 ppm)	100 μg/m³ (0.05 ppm)
Sulfur Dioxide	Annual Arithmetic Mean	52 μg/m³ (0.02 ppm)	80 μg/m³ (0.03 ppm)
	24 hours	261 μg/m³ (0.10 ppm)	365 μg/m³ (0.14 ppm)
	3 hours	NA	1,300 μg/m³ (0.50 ppm) (b)
	1 hour	1,300 μg/m³ (0.50 ppm)	NA
Particulate Matter as PM_{10}	Annual Arithmetic Mean	50 μg/m³	50 μg/m³
	24 hours	150 μg/m³	150 μg/m³
Particulate Matter as $PM_{2.5}$	Annual Arithmetic Mean	15 μg/m³	15 μg/m³
	24 hours	65 μg/m³	65 μg/m³
Lead (Pb)	Quarterly Arithmetic Mean	1.5 μg/m³	1.5 μg/m³

Note: μg/m³ = micrograms per cubic meter; ppm = parts per million; PM_{10} = particulate matter smaller than 10 microns; $PM_{2.5}$ = particulate matter smaller than 2.5 microns.

Sources: Administrative Rules of Montana (ARM) 17.8 and Code of Federal Regulations, 40 CFR Part 50, National Primary and Secondary Ambient Air Quality Standards.

(a) Primary standard unless otherwise noted.

(b) Secondary standard.

to atmospheric inversions.

Modeling was completed in response to an air quality permit modification by RML to incorporate the addition of two new boilers in 1999. Results of air modeling, which included operation of the existing incinerator, predicted that emission rates from RML resulted in an ambient air quality impact of seven to 22 percent (Doucet and Mainka 1999) of the federal and Montana primary standards, designed to protect human health.

Particulate Emissions

Sources of air contaminant particulate emissions at the RML campus include incinerators, steam-generating boilers, emergency power generators, and laboratory vent hoods. Medical waste and general refuse is disposed of in the natural gas-fired incinerators. Off-gas emissions are processed through a wet scrubber to remove particulate and hydrogen chloride from combustion gases before discharge through a vertical stack to the atmosphere. The incinerators have automation systems that monitor the waste material feed rate and essential operating parameters. The boilers are fired by natural gas with diesel as a secondary fuel supply. Boiler combustion gases exit through vertical discharge stacks. Diesel-fired emergency power generator emissions primarily result from testing the units weekly. Units run for short periods to test system function. Air from the current BSL-3 laboratories is discharged through HEPA filters.

Gaseous Emissions

Gaseous emissions from RML include sulfur dioxide (SO_2), nitrogen oxides (NOx), carbon monoxide (CO), volatile organic compounds (VOCs), and particulate matter (PM) from incinerators, steam-generating boilers, emergency power generators, and laboratory vent hoods. Gaseous emissions result from waste and fuel combustion, filling and dispensing fuel from above-ground fuel tanks, and from vent hoods (operations within the laboratories).

Air Quality Monitoring Data

Ambient air quality data have been collected at monitoring stations in Hamilton and at U.S. Forest Service ranger stations at Stevensville and West Fork (**Table 3-11**). All three stations are within Ravalli County. PM_{10} data have been collected at all three sites and $PM_{2.5}$ data at one of the sites. None of the three stations reported any violations of ambient standards during the period of record.

Table 3-11. Monitoring Data – PM_{10} and $PM_{2.5}$

Site	Year	Annual Geometric Mean (µg/m³)	24-Hour High (µg/m³)	24-Hour 2nd High (µg/m³)
#0001 Ravalli County Courthouse Hamilton	1994	22.8	88	73
	1995	19.1	67	63
	1996	17.7	59	55
	1997	20.1	35	55
	1998	---	---	---
	1999	13.9	38	37
	2000	17.8	66	60
#0002 111 S. Hwy 93 Hamilton	1994	31.9	92	81
	1995	26.1	78	74
	1996	26.2	96	69
	1997	25.6	61	53
	1998	23.1	98	57
	1999	21.6	77	67
#0003 Stevensville Ranger Station	1994	23.3	60	52
	1995	20.7	61	47
	1996	21.0	56	54
	1997	23.6	54	47
	1998	22.3	96	75
	1999	18.6	47	44
	2000	16.0	33	31
#0004 W. Fork Ranger Station	1994	8.6	54	50
	1995	6.4	58	50
	1996	9.3	48	47
	1997	7.9	93	67
	1998	9.3	---	---
	1999	6.3	48	41
	2000	6.7	93	51
$PM_{2.5}$ Data				
#0001 Ravalli County Courthouse Hamilton	2000	8.01	62.7	55.7

Note: PM_{10} = particulate matter < 10 microns; $PM_{2.5}$ = particulate matter < 2.5 microns; µg/m³ = micrograms per cubic meter.

Source: USEPA 2001.

Existing Sources

Twelve known permitted or pending air emission sources occur in Ravalli County. Of them, four are fixed location sources, while the remainders are portable. The fixed location sources in Hamilton are RML, a crematorium, a biomedical manufacturing facility, and a surgical device manufacturing facility in Victor. The portable sources are gravel crushers, associated processing equipment, and asphalt plants.

Existing, permitted, industrial emission sources located within Ravalli County include: Rocky Mountain Laboratories, Bitterroot Pet Crematorium, SSP Inc., Corixa Corp., Ravalli County Road Department, Bitterroot Rock Production, Donaldson Brothers, Stewart Excavating, Gasvoda Construction, John Schlect Excavation, RBC Enterprises, and Blahnik Construction. The facilities can emit combustion products including CO, NOx, SO_2, and hydrocarbons from boilers, pathological furnaces, engines, kilns, and other processes. Other potential fugitive dust and smoke sources include farming, field and forest burning, and dust from gravel roads.

Air Quality Permit

Industrial air quality permitting is part of the Montana State Implementation Plan process. The Montana Department of Environmental Quality uses air quality permit conditions to help ensure compliance with applicable Montana and National Ambient Air Quality Standards and Prevention of Significant Deterioration increments.

Primary emitting sources at RML include the boilers for process and facility steam and the incinerators for refuse disposal. The boilers are subject to 40 CFR Part 60, Subpart Dc, Standards of Performance for Small Industrial-Commercial Steam Generating Units. The incinerators are subject to 40 CFR Part 60, Subpart Ce, Standards of Performance for Hospital/Medical/Infectious Waste Incinerators. The New Source Performance Standards for particulate matter, including visual emissions (opacity), are included in regulations for both the boiler plant and incinerators.

Potential emissions from RML were analyzed in 1999 using the EPA's Industrial Source Complex Short Term (ISCST3) air model. In the analysis (Doucet and Mainka 1999), emissions from RML were used to predict their effect on ambient air quality. Meteorological data used in the emission modeling for RML included 10 years of data from Missoula and Kalispell, Montana (Douchet and Mainka). The ISCST3 model uses source data (emissions), terrain information, and meteorological information to predict emission concentrations at distance. Results of the modeling, using meteorological data from several locations, including Missoula, Montana, a site that experiences atmospheric inversions, predicted that RML source emissions would not result in a total facility impact above Montana and federal air quality standards.

RML is currently operating under Montana Air Quality Permit to Construct No. 2991-04. Through the permit, MDEQ has set conditions that ensure provisions of ARM Title 17.8 are met (Administrative Rules for Montana, Control of Air Pollution in Montana). The current permit reflects the planned additions of another boiler, emergency power generating equipment, an above-ground fuel storage tank for the emergency generators, and laboratory fume hoods for the proposed laboratory.

Incinerator emission testing is completed annually in accordance with the Montana Source Test Protocol and Procedures Manual. Source testing for priority pollutants, (NOx, SO_2, CO_2, and PM_{10}) and other constituents (e.g., dioxins and furans), show that emissions are within MDEQ air permit limits. In addition, six operating parameters are monitored to maintain compliance with emission limits established by the air quality permit.

Source test results at RML for dioxin and furans (potential by-products resulting from incomplete combustion of plastics) show concentrations up to 0.0000000000024 grams per cubic meter of air. Based on 2003 source test results, facility dioxin/furan emissions are approximately 1/1000th of the MDEQ air permit limit of 0.0000000023 grams per cubic meter.

PSD Classification

The area surrounding the RML site is designated a Class II area, as defined by the Federal Prevention of Significant Deterioration (PSD) Air Quality

program. The PSD Class II designation allows for moderate growth or degradation of air quality within certain limits above baseline air quality. Industrial emission sources proposing construction or modifications must demonstrate that proposed emissions would not exceed ambient air quality standards. Emission modeling and subsequent regulatory analysis (MDEQ 2003) demonstrate that emissions from the RML facility comply with air quality standards.

The nearest Class I area is the Selway Bitterroot Wilderness, approximately six miles west of RML.

3.8 WATER SUPPLY AND WASTEWATER

Hamilton Water Supply

The City of Hamilton's public drinking water supply is currently supplied by four municipal wells in the Hamilton area. The City of Hamilton Department of Public Works (CHDPW) owns a fifth well that is currently not operating.

The four wells currently in use have a combined maximum capacity of 2,350 gpm (CHDPW 2002). The system produced a total of 618 million gallons in 2002(CHPWD data). Of this total, the CHDPW sold 260 million gallons. The difference between the volume produced and the volume sold (60%) is attributed primarily to water lost to leaks in the system. **Figure 3-8** is a graph showing the estimated quantity of water produced in 2002 compared to the quantity lost from the system on a monthly basis.

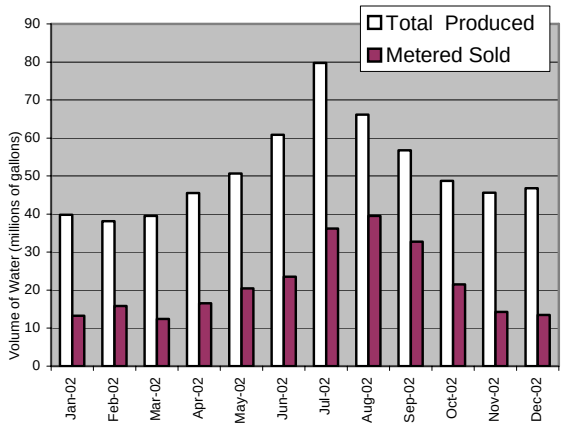


Figure 3-8.
Comparison of Volume of Water Produced to Metered Water Sold by CHDPW in 2002

CHDPW has an on-going program to identify and repair leaks. Between September 2001 and September 2002, a total of 16 leaks in the system were identified and repaired: three water main leaks, two water main gate valve leaks, three fire hydrant leaks, and five curb-stop valve leaks. Four additional leaks were identified on private service lines scheduled for repair in 2003.

The CHDPW municipal water supply system currently includes a 500,000-gallon steel storage tank and a pump station comprised of a pressure pump station using five pumps. This station provides supplemental pressure for subdivisions located on the bench southeast of Hamilton. An upcoming water improvement project includes installation of a new 1,500,000-gallon storage tank, a baffled contact basin, and an additional pressure pump station (Lowry 2003b). Long range plans include development of an additional well field to supplement water supplies and serve as a backup for the wells being installed in 2003 (Lowry 2003a).

The water system currently has an emergency backup generator capable of supplying 650 gallons per minute (gpm) that can be connected to a single well in the event of a power outage. A fixed power plant is planned by June 2004 at the new pump station. The power plant will supply three new wells capable of producing 2,500 gpm during power outages. The existing portable backup generator will still be available to produce an additional 650 gpm if needed (Lowry 2003b).

City of Hamilton policy currently allows for restricting irrigation to alternating odd and even day schedules in the event of extreme water demand.

Water used at RML is supplied by the CHDPW through a metered 10-inch water main. The average monthly water consumption at RML during 1995 and 1996 was approximately 2.277 million gallons per month (Stewart 2003). Hemisphere (2003) estimates the current average monthly water consumption at 1.7 million gallons. Five irrigation wells are located on the RML campus; water from these wells is not used for drinking or industrial purposes.

Under Hamilton Municipal Code 161, revision to Title 13 of the city water regulations, installation of new private potable water supply wells is prohibited if a residence is within 200 feet of a

public water supply main. Additionally, installation of any private potable water supply well within city limits requires approval from the city council and city water department.

Groundwater

The regional direction of groundwater flow in the Bitterroot Valley is from the mountains along the basin margins toward the center of the basin and diagonally down valley (Briar and Dutton 2000). Groundwater in the Bitterroot Valley generally flows toward the Bitterroot River from the valley margins and parallel to the river in the flood plain. A groundwater investigation completed at the site in 2002 (Maxim 2003) identified that groundwater flow beneath the site is to the northwest. This is generally consistent with other studies of groundwater flow in the Bitterroot Valley (McMurtrey *et al.* 1972, Briar and Dutton 2000, Uthman 1988).

Western Groundwater Services (2000) completed a Source Water Protection Plan for the City of Hamilton in 2000. The Source Water Protection Plan for the City of Hamilton indicates that the water table in the portion of the aquifer supplying municipal wells slopes to the northwest, with a direction of flow approximately 20 to 30 degrees west of true north. The hydraulic gradient was approximated at one percent. The plan delineated the recharge zone for the municipal wells that are currently used for water supply (**Figure 3-9**). According to this analysis, the width of the aquifer contributing to the municipal wells in Hamilton is approximately 8,000 feet.

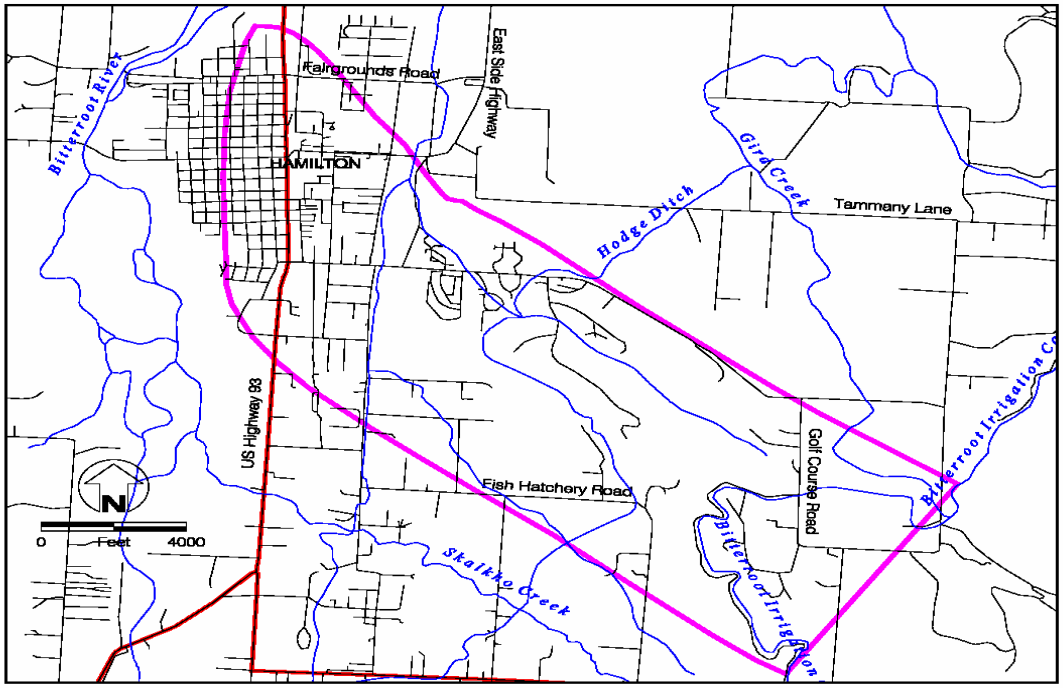
To determine the availability of groundwater, a conservative approach was used to estimate the daily flux (flow rate) of water in the shallow alluvial aquifer that is the current source of water, using Darcy's Law:

$$Q = K \times i \times ST \times W$$

Where:

Q = Flow rate
K = Hydraulic conductivity
i = Hydraulic gradient
ST = Aquifer saturated thickness
W = Aquifer Width

Figure 3-9. Hamilton Recharge Area



Source: Western Groundwater Services, 2000

Recharge Area for Existing Hamilton Wells

The following conservative input values were used for this calculation:

K = 214 feet/day

i = 0.01 (dimensionless)

ST = 49.4 feet

W = 8,000 feet

The flux or daily flow in the portion of shallow aquifer currently supplying water to municipal wells is estimated at 845,728 feet^3 per day. As a comparison, in 2002, CHDPW sold an average of 91,869 feet^3 per day, consuming about 10.9 percent of the available groundwater in 2002.

Wastewater Treatment

Currently, wastewater generated at RML is discharged to the sanitary sewer system operated by the CHDPW. Current sources of wastewater at RML include sanitary waste, liquid waste from animal facilities, boiler water, and cooling water. Wastewater discharges from RML to the CHDPW sanitary sewer via three sewer mains.

Wastewater from the following sources is treated before discharge to the sanitary sewer:

- Wastewater from cage-wash facilities in Building 13. Temperature and pH of this wastewater are measured in the holding tank before discharge to the sanitary sewer.
- Blowdown water from Building 23 incinerator scrubber. The pH and temperature of this wastewater are monitored in a settling tank before it is discharged to the sanitary sewer.
- Building 26 boiler blowdown. Temperature of this wastewater is monitored before discharge.
- Water from the cooling tower and incinerator scrubber cooling tower. Hardness and pH of this wastewater are monitored before discharge.
- Excess water from dust suppression during removal of incinerator ash. This wastewater is discharged to a settling tank before discharge to the sewer.

The CHDPW is required to conduct static replacement toxicity tests on effluent from its water treatment facility. CHDPW collects the samples and an independent laboratory conducts the tests. Marine organisms (*Ceriodaphnia sp.* or *Pimephales promelas*) are placed in samples of the treatment plant effluent and mortality is recorded over two to four days. Acute toxicity occurs when 50 percent or more mortality is observed for either species at any effluent concentration. Effluent samples from RML have not failed a test since testing began in 1996. Hemisphere (2003) estimates that RML's current wastewater effluent rate is 15,000 gallons per day.

The CHDPW wastewater treatment plant is an oxidation ditch-activated sludge facility. CHDPW upgraded the facility in 1997, adding a third clarifier and an automated sludge return and waste system resulting in the following designed operating capacities at the plant (CHDPW 2002):

- Average daily summer flow – 1.98 million gallons per day (MGD)
- Peak daily summer flow – 2.8 MGD
- Average daily winter flow – 0.5 MGD
- Peak winter flow – 1.1 MGD

As of April 2003, the wastewater treatment plant was operating within its design capacity (Lowry 2003a). Between July 2001 and July 2002, 220.81 million gallons of wastewater were treated at the plant at an average rate of 0.605 MGD (CHDPW 2002). The peak flow of 1.59 MGD occurred on July 1, 2001. From July 2001 to July 2002, the plant operated within its MDEQ discharge permit, and sampling and analysis required by the permit showed no exceedances of standards.

Solids removed from the effluent stream are collected as sludge and stored. The sludge is then composted during warm-weather months. The compost is made available for land application but is not allowed for use on vegetable gardens.

According to Dan Harmon of HDR Engineering, CHDPW's wastewater engineer (Personal communication October 7, 2003), the CHDPW produced an average of 1,000 to 1,200 lbs per day of waste solids.

The current seasonal nature of the composting operation requires that solids be stockpiled through the winter for composting in the spring. Available storage space and seasonal composting capacity are currently limiting the ability of the

plant to handle more than minimal increases in annual solid load.

To accommodate increasing solids storage and handling requirements, the CHDPW is planning to construct a temporary solids storage basin to meet current requirements in the interim until a facility expansion plan is prepared (personal communication, Dan Harmon of HDR Engineering, October 3, 2003). The CHDPW plan may include implementing a year-round composting operation to upgrade solid handling capabilities (Lowry 2002).

3.9 RESOURCES NOT AFFECTED

3.9.1 Soil

3.9.1.1 Existing Condition

Native soil is mixed with fill material within the RML facility. Most soil within the RML campus is mapped as the Dominic cobbly sandy loam, which is a deep, well drained soil formed in alluvium (Bourne 1959). On-site native soil consists of 16 to 30 inches of pale brown (dry) to brown (moist) loose sand, gravel, and cobbles that is non-calcareous except for a thin carbonate coating on some cobbles. Soil in the south and east portion of the RML campus is mapped as Grantsdale loam. The Grantsdale series is a deep, well drained, moderately thick, grayish-brown surface soil underlain by moderately thick friable loam subsoil and brownish-gray, highly calcareous loam substrata. On-site fill material consists of poorly graded gravel and sand with scattered debris and pipe fragments (Huntingdon 1995).

A geotechnical investigation was completed (GMT 2002) to determine suitability of the soil at RML for construction and design standards for building footings. The Integrated Research Facility and other buildings included in the Project would be designed to meet these standards.

Several closed waste management units exist on the campus, including former seepage pits, septic tanks, and drainfields.

3.9.1.2 Rationale for No Further Discussion

Soil resources would not be affected by operations of the RML Integrated Research Facility. Construction activities would displace some soil in areas under and immediately adjacent to the proposed buildings. Weeds and grass grow in these areas. Former seepage pits, septic tanks, and filter trenches would not be impacted by construction of the Integrated Research Facility and other facility upgrades. Following construction, these areas would be reseeded and landscaped. No material generated by operation of the Integrated Research Facility would be released to soil. Therefore, soil resources would not be affected. No special measures were identified that would be required to prevent erosion during construction or operation of the facility.

3.9.2 Geology

3.9.2.1 Existing Condition

Geology

The Bitterroot Valley is a north-south trending intermontane basin about seven miles wide and 64 miles long, encompassing about 430 square miles. The Bitterroot Valley ranges from approximately 5,500 feet above sea level on its highest terraces to 3,250 feet at its termination at the Missoula Valley. It is bounded by the Bitterroot Mountains on the south and west, the Sapphire Mountains on the east, the Anaconda-Pintler Mountain range on the southeast, and the Missoula/Clark Fork Valley on the north (**Figure 1-1**). The Bitterroot Valley is characterized by two topographic features: a broad one- to two-mile wide floodplain in the center of the basin; and high, broad alluvial/colluvial terraces on the east and west flanks that are on average two to three miles wide. The terraces slope from 4° to 5° on the basin edges to less than 1° near the Bitterroot floodplain. West side terraces slope gently and merge with the floodplain and are bisected by small drainages. East side terraces have generally smooth topography, are flat topped, and relatively steep escarpments ranging 50 to 150 feet above the floodplain (Kendy and Tresch 1996).

Geologic Structure and Seismicity

The Bitterroot Valley is a structural basin formed during the emplacement of the Idaho Batholith in the late Cretaceous or early Tertiary Period resulting from basin floor dropping along pre-existing faults (McMurtrey *et al.* 1972) or as a result of eastward block displacement of crustal material along low-angle thrust faults (Hyndman *et al.* 1975). Geophysical data indicate that the western valley margin is relatively straight, but the

eastern side has an irregular margin (Noble *et al.* 1982). The structural depth of the basin is one mile (Lankston 1975). Lower Tertiary age sediments within the basin have been deformed into a faulted syncline, whereas Pliocene sediments are relatively undisturbed (McMurtrey *et al.* 1972), indicating that the major tectonic events that formed the Bitterroot basin have slowed considerably since the end of the Tertiary period.

The basin is on the western edge of a broad region of basin and range tectonism. Extensional tectonism in the Bitterroot Valley, relatively dormant at present, occurs along existing fractures which are part of a regional northeast, northwest, and north-south trending fault system that exhibit long histories of recurrent activity (Barkman 1984).

At least six Class A faults or fault systems have been identified within 100 miles of the Hamilton area in western Montana (Haller *et al.* 2000). The closest Class A fault to Hamilton is the Bitterroot Fault, which runs along the east flank of the Bitterroot Mountains for a distance of approximately 60 miles and dips 45° to 90° east (Lindgren 1904, McMurtrey *et al.* 1972). The age of the faults extends from Cenozoic into late Quaternary time, with the most recent deformation occurring in pre-Bull Lake and Bull Lake glacial deposits, 300,000 to 130,000 years ago (Barkman 1984). The surface traces of the Bitterroot Fault system are shown by McMurtrey *et al.* (1972) as four traces that run along and into the Bitterroot Range from near Florence to south of Victor. Barkman (1984) identified several distinct fault scarps in the Bitterroot Valley that have been active in Quaternary time: the Bear Creek Scarp and the Curlew Fault located west of Victor, and the Tin Cup and Como scarps located north of Tin Cup Creek.

The most recent faulting appears to have occurred around 7,700 years ago on the Mission Valley section of the Mission Fault. Class A faults have evidence that at least one large-magnitude earthquake has occurred on that fault during the last two million years.

Within the last 40 years, two recordable earthquakes greater than 2.5 magnitude have occurred within 50 miles of Hamilton, Montana. In 1982, a 2.5 Richter magnitude tremor occurred approximately 20 miles southeast of Hamilton (Stickney *et al.* 2000), and on June 28, 2000, a 4.5 magnitude earthquake occurred approximately 40 miles northeast of Hamilton.

3.9.2.2 Rationale for No Further Discussion

The Bitterroot Valley has one of the lowest seismic activity ratings in western Montana (Stickney *et al.* 2000). The International Conference of Building Officials rates Hamilton as a low seismic risk area (Zone 0). By comparison, Salt Lake City is in Zone 2, and part of San Francisco is in Zone 4.

3.9.3 Floodplains

3.9.3.1 Existing Condition

The Bitterroot River watershed encompasses 2,842 square miles above its confluence with the Clark Fork River, of which 1,685 square miles are above Hamilton (Nolan 1973). The floodplain in the Hamilton area is relatively narrow and confined by older paleo-river terraces to the east and west. The proposed Integrated Research Facility and other facility upgrades would be located about 1,400 feet east of the Bitterroot River on low alluvial terrace deposits above the 100-year floodplain (**Figure 3-10**).

Executive Order 11988 requires that the Project be assessed to determine if activities would occur within a floodplain. The Project location is about 725 feet east of the 100-year floodplain at its closest approach. The elevation at the proposed Project location is about 18 feet above the 100-year floodplain base elevation (FEMA 1998).

3.9.3.2 Rationale for No Further Discussion

The proposed BSL-4 laboratory would not be located within the 100-year floodplain, and therefore requirements of EO 11988 do not apply. No additional analysis of impacts is required.

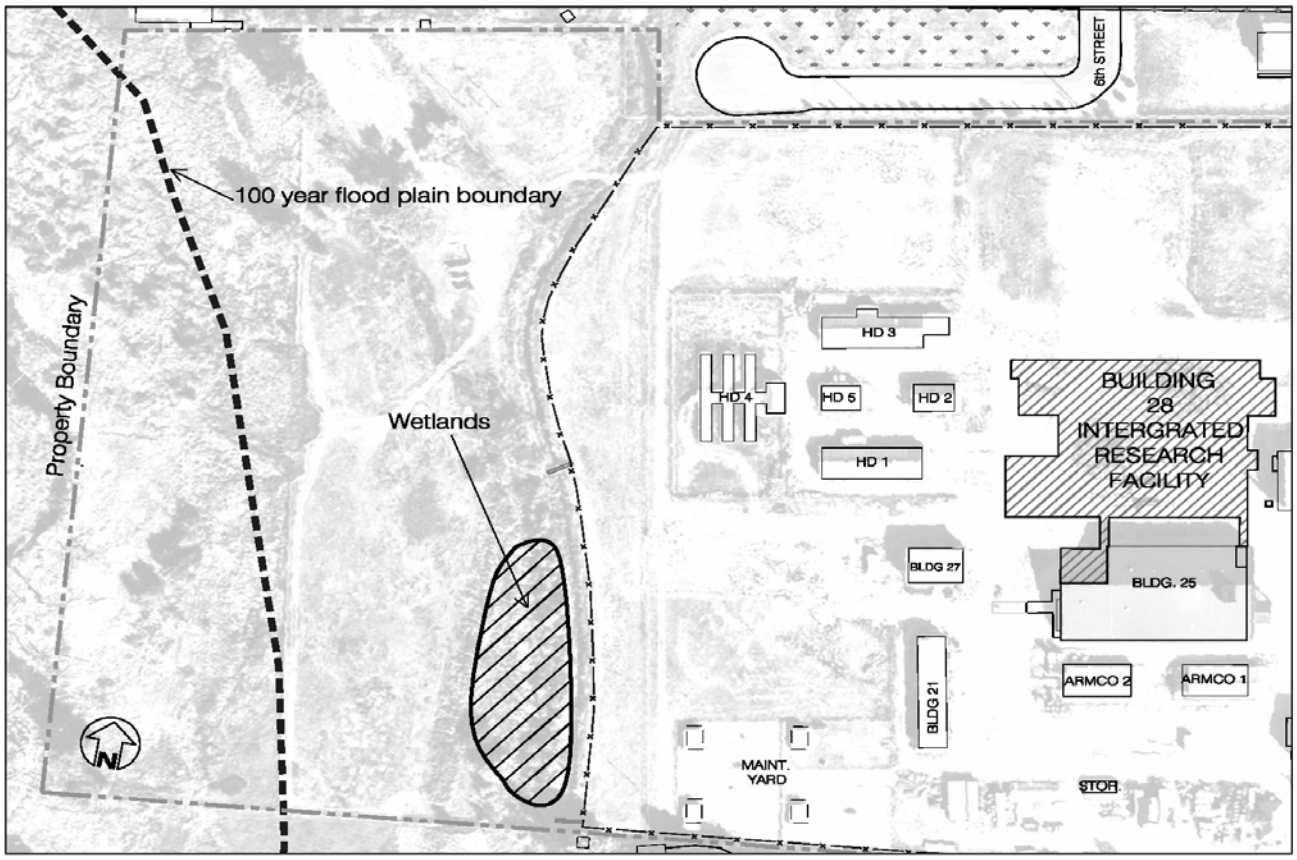


Figure 3-10. Mapped Wetlands and 100-Year Floodplain

3.9.4 Wetlands and Riparian Areas

USDHHS manual 30-40-00 (Natural Asset Review) defines wetlands as those areas inundated or saturated by surface water or groundwater at a frequency and duration sufficient to support, and that under normal circumstances do support, a prevalence of vegetation or aquatic life that require saturated or seasonally saturated soil conditions for growth and reproduction. Wetlands generally include swamps, marshes, bogs, and similar areas.

Executive Order 11990, Protection of Wetlands, 42 FR 2691 (1977) as amended by Executive Order 12608, 52 F 34617 (1987), 42 U.S. Code 4321, directs each federal agency to minimize destruction, loss, or degradation of wetlands and to preserve and enhance such wetlands in carrying out their program responsibilities. Consideration must include a variety of factors such as water supply, erosion and flood prevention, maintenance of natural systems, and potential scientific benefits.

3.9.4.1 Existing Condition

The RML facility is located on a terrace above and east of the Bitterroot River floodplain. The National Wetlands Inventory map and air photos were consulted to identify riparian areas and wetlands near the RML campus. The area within the 100-year floodplain west of the RML campus is a riparian area containing wetlands. Mapped wetlands are shown in **Figure 3-10.** The closest wetland is approximately 430 feet west of the proposed Integrated Research Facility location.

3.9.4.2 Rationale for No Further Discussion

Riparian areas and wetlands would not be affected by the Proposed Action because no construction would occur in or near riparian areas or wetlands. No liquids or wastes would be discharged to wetlands during construction or operation of the Integrated Research Facility.

3.9.5 Vegetation

3.9.5.1 Existing Condition

Vegetation within the RML campus consists of lawn grasses and weeds.

3.9.5.2 Rationale for No Further Discussion

Vegetation would not be disturbed or affected outside the Integrated Research Facility construction area or by other Proposed Action activities.

3.9.6 Fish

3.9.6.1 Existing Condition

In the vicinity of Hamilton, the Bitterroot River provides habitat for approximately 12 species of coldwater fish (Holton 1990; MFWP 2002). Six salmonid species are classified as game fish in the Bitterroot River: bull trout, brook trout, brown trout, rainbow trout, westslope cutthroat trout, and mountain whitefish. Brook, brown, and rainbow trout are not native to the Bitterroot River. One fish species of concern (MNHP 2003a), the westslope cutthroat trout, is listed as common in the Bitterroot River in the vicinity of Hamilton (MFWP 2002). Bull trout, which are listed under the Endangered Species Act, are an incidental and rare resident fish species in the Bitterroot River (MFWP 2002) (see Section 3.9.8, Threatened and Endangered Species).

3.9.6.2 Rationale for No Further Discussion

Since the RML campus is located at least a quarter-mile from the Bitterroot River, and erosion control measures would be implemented at the RML campus during construction, there would be no impacts on fish species in the Bitterroot River or their habitat. Wastewater from the RML facility would enter the City of Hamilton's wastewater treatment facility. Discharges to the treatment facility from the Integrated Research Facility would not cause exceedances of permitted discharge limits for the wastewater treatment facility (see the Water Supply and Wastewater section on page 3-17). Therefore, no change in water quality of the Bitterroot River would result from operation of the Integrated Research Facility. Consequently, there would be no adverse impacts on fish species in the Bitterroot River as a result of facility construction or operation.

3.9.7 Wildlife

3.9.7.1 Existing Condition

The fauna of the valley near Hamilton is characteristic of the northern Rocky Mountains. Approximately 45 species of mammals, five species of amphibians, and nine species of reptiles may occur in the vicinity of Hamilton and RML (Foresman 2001; Maxell *et al.* 2003). Also, approximately 100 species of birds may breed in the valley near Hamilton (MTNHP 2003b). Wildlife habitat has generally been altered by agriculture and other human developments. Highly altered urban environments meet the habitat needs of fewer species, most of which tend to be generalists, and several of which are non-native (e.g., European starling, house mouse, eastern fox squirrel). Species inhabiting urban environments tend to be tolerant of disturbance.

Common species of mammals that may occur in or adjacent to Hamilton include white-tailed deer, mule deer, coyote, red fox, striped skunk, raccoon, badger, long-tailed weasel, deer mouse, house mouse, meadow vole, Columbian ground squirrel, yellow-bellied marmot, eastern fox squirrel, several species of bats (e.g., big brown bat), and shrews (e.g., masked shrew). Terrestrial garter snakes, common garter snakes, and gopher snakes may live in Hamilton. Common bird species likely to breed in the urban habitats of Hamilton include rock dove, mourning dove, great horned owl, downy woodpecker, hairy woodpecker, northern flicker, western wood-pewee, eastern kingbird, tree swallow, barn swallow, black-billed magpie, black-capped chickadee, house wren, American robin, European starling, warbling vireo, yellow warbler, western tanager, American tree sparrow, chipping sparrow, dark-eyed junco, brown-headed cowbird, house finch, American goldfinch, and house sparrow.

3.9.7.2 Rationale for No Further Discussion

The Proposed Action area provides little wildlife habitat, as vegetation consists of native and non-native grasses and weeds. Consequently, few species would find adequate breeding or foraging habitat at RML's campus. Birds nesting on buildings

near the construction area may be temporarily displaced. Less mobile species of small mammals and reptiles could potentially be impacted directly. Any impacts would affect few individuals and not populations.

The Proposed Action would not affect wildlife because of the small area of disturbance and no loss of habitat.

3.9.8 Threatened and Endangered Species

3.9.8.1 Existing Condition

The U.S. Fish and Wildlife Service provided a current list (March 11, 2003) of endangered and threatened species potentially living in Ravalli County. No threatened or endangered plant species appeared on the list. The following threatened or endangered fish or animal species were listed:

- Bull Trout - Threatened
- Bald Eagle - Threatened
- Wolves - Endangered
- Lynx - Threatened
- Yellow-billed Cuckoo (western population) - Candidate

Bull Trout (Threatened)

The major population of bull trout in the Bitterroot drainage today are residential fish that tend to live in higher elevation streams. Migratory forms that live in the Bitterroot River are rare. The main stem of the Bitterroot River contains critical overwintering areas and migratory corridors. Historically, bull trout likely used the Bitterroot River and its tributaries. Currently, however, bull trout are rare in the main stem Bitterroot River from Blodgett Creek to the East Fork (Montana Bull Trout Scientific Group 1998).

Bald Eagle (Threatened)

Bald eagle nesting and roosting habitats include mature and over-mature mixed conifer, ponderosa pine, and cottonwood stands near large rivers or lakes. Bald eagles are common winter residents in the Bitterroot Valley and also pass through the area during migration. The nearest known bald eagle nest to Hamilton is located on the Teller Wildlife Refuge near Corvallis, approximately five miles from RML (Mullen 2002).

Gray Wolf (Endangered, 10(j) Population)

The Project Area is within the Central Idaho Non-essential, Experimental Population designated by U.S. Fish and Wildlife Service (1994). Wolves within this area are managed as a population proposed for listing rather than as a species listed under Section 10(j) of the Endangered Species Act (ESA). No packs are known near the area to be affected directly or indirectly by the action.

Lynx (Threatened)

Lynx often inhabit forested benches, plateaus, valleys, and gently rolling ridgetops in rugged mountain ranges (Koeler and Aubry 1994). Primary lynx habitat in the Rocky Mountains includes lodgepole pine, subalpine fir, and Englemann spruce. Lynx prefer to forage in areas that support their primary prey, the snowshoe hare. In the Bitterroot Mountains, lynx habitat has been identified at elevations of 6,200 feet and higher. Dry Douglas fir and ponderosa pine forest that occurs at lower elevation (such as around RML) is not considered lynx habitat.

Yellow-billed Cuckoo (Candidate)

The yellow-billed cuckoo is a rare transient in western Montana. It prefers areas of low, dense, shrubby vegetation in cottonwood and willow riparian corridors, open woodlands, brushy pastures, and along brushy roadsides (DeGraaf *et al.* 1991; Dobkin 1992). It selects well-concealed nest sites in shrubs or low trees, generally four to six feet above ground. Yellow-billed cuckoo have occasionally been reported (twice in 1988, once in 1997) in the Stevensville area (Montana Natural Heritage Program) but they are not known to occur near the Project area.

3.9.8.2 Rationale for No Further Discussion of Listed Species

There is no designated or proposed critical habitat present in the action area. The proposed laboratory expansion would not disturb areas beyond the existing campus area. Noise and dust created during construction on campus is not going to be loud, long-lasting or intense enough to affect individual animals. For these reasons, no effect on

threatened or endangered species or their critical habitat would result from the Proposed Action. Water and air quality would be maintained, and areas outside of the construction area would not be disturbed.

3.9.9 Environmental Justice

U.S. Executive Order 12898 (Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations) directs federal agencies to assess whether the Proposed Action or alternatives would have disproportionately high and adverse human health or environmental impacts on minority and low-income populations. Identification of environmental issues can be accomplished through public involvement and the scoping process.

3.9.9.1 Existing Condition

The areas of potential effect for environmental justice are neighborhoods and populations adjacent to the Project area.

Five steps are used to determine environmental justice issues: (1) identify minority and low-income populations in the area affected by the Project; (2) consider relevant public health data and industry data regarding multiple and cumulative exposure of minority and low-income populations to human health or environmental hazards; (3) recognize interrelated cultural, social, occupational, historical, and economic factors that could amplify environmental effects of the Project; (4) develop effective public participation strategies that overcome linguistic, cultural, institutional, geographic, and other barriers; and (5) assure meaningful community representation.

Minority Population: For purposes of this assessment, "minority" refers to people who classified themselves in the 2000 U.S. Census as African Americans, Asian or Pacific Islanders, American Indians, Hispanics of any race or origin, or other non-White races. A "minority population" refers to an area where minority individuals comprise 25 percent or more of the population. In Ravalli County, persons of Hispanic or Latino origin account for 1.9 percent of the population, American Indian/Alaska Natives account for 1.8 percent of the population, native Hawaiian or pacific islanders account for 0.2 percent, Asians account for 0.3 percent, and Blacks account for 0.1 percent. White persons, not of Hispanic or Latino origin accounted for 96 percent of the County population in 2000 (U.S. Census Bureau 2002a).

Low-Income Populations: Low-income population refers to a community in which 25 percent or more of the population is characterized as living in poverty, as determined by statistical poverty thresholds used by the federal government. In 2000, the poverty weighted average threshold for a family of four was $17,603 and $8,794 for an unrelated individual (US Census Bureau 2001). In Ravalli County, 13.8 percent of the population is below the poverty threshold (US Census Bureau 2002b).

3.9.9.2 Rationale for No Further Discussion

The area of potential effect does not have minority or low-income populations that fulfill the first step, rendering the remaining steps irrelevant with respect to Environmental Justice.

3.9.10 Surface Water

3.9.10.1 Existing Condition

The Bitterroot River drains a basin of approximately 2,800 square miles (McMurtrey *et al.* 1972). Major tributaries entering the Bitterroot River near Hamilton include Sawtooth, Canyon, Skalkaho, and Gird creeks. The pattern of surface water flow is typical of mountain areas where spring runoff from snowmelt is often augmented by late spring or early summer rain. About 55 percent of runoff in the Bitterroot River occurs during May and June (McMurtrey *et al.* 1972). Permeable soil and extensive farming generally prevent surface runoff, except during storms of high intensity or during snowmelt while the ground is frozen. Portions of both tributaries flowing from the east to the Bitterroot River and the Bitterroot River itself in the vicinity of RML are diverted to canals and ditches during irrigation months of May through September (Western Groundwater Services 2000).

The only surface water body within ½-mile of the site is the Bitterroot River. The Bitterroot River is classified as a B-1 stream, suitable for drinking, culinary and food processing purposes after treatment, as well as swimming, bathing,

recreation, and the growth and propagation of salmonids (MDEQ 2000). The MDEQ reported in the total maximum daily loads (TMDL) screening for the Bitterroot River and associated tributaries that the most probable sources of impairment for the river are pasture and range grazing in riparian areas, bank destabilization, agricultural and urban runoff, storm sewers, and general habitat modifications. The Bitterroot River from Skalkaho Creek to Eightmile Creek fully supports agricultural and industrial uses and it partially supports swimming and recreational activities, fisheries, and aquatic organisms (MDEQ 2000). The Bitterroot River is on the 303(d) list of impaired streams and has been given a high priority for development of TMDLs. Non-point source TMDLs have not been approved by MDEQ on the Bitterroot River, but an anti-degradation point source TMDL has been approved for lead, copper, and zinc.

3.9.10.2 Rationale for No Further Discussion

Construction of the Integrated Research Facility would not affect surface water resources. Surface water would not be used at the Integrated Research Facility, and wastewater discharged to the Hamilton wastewater treatment plant would not result in exceedances of permitted discharge from the plant. Because wastewater treatment standards would be met, there would be no impact on surface water.

3.9.11 Groundwater Quality

3.9.11.1 Existing Condition

Briar and Dutton (2002) sampled 239 wells in the Hamilton aquifer for nitrate and 43 wells for common ions, trace elements, and radon. The median nitrate concentration for samples from wells on the west side of the Bitterroot River was 0.17 milligrams per liter (mg/L), while the median for samples from wells on the east side was 1.05 mg/L (Briar and Dutton 2000). All samples had nitrate concentrations below the MDEQ WQB-7 human health standard of 10 mg/L. Most groundwater in the Hamilton area is a calcium bicarbonate type (Briar and Dutton 2000). One sample contained a cadmium concentration of 5 micrograms per liter (µg/L), equal to the MDEQ circular WQB-7 human health standard. No other concentrations exceeded human health-based groundwater quality standards. Concentrations of fluoride, iron, and manganese measured in groundwater samples from some wells exceeded circular WQB-7 drinking water standards for taste, odor, and color. Radon measured in 43 samples ranged from 150 to 3,700 picocuries per liter (pCi/L), with a median concentration of 765 pCi/L for 18 of the 43 samples collected in the Hamilton area. The five Hamilton municipal wells were sampled in 2001 and exhibited an average radon gas concentration of 1,350 pCi/L (Maxim 2003). There is currently no drinking water standard for radon. The EPA has proposed a maximum contaminant level (MCL) of 300 pCi/L and an alternative MCL of 1,200 pCi/L. The alternative MCL can only be used if an approved mixed-media mitigation program is adopted to educate water users with respect to radon exposure. The proposed standards are anticipated to become final in 2006-2007.

Between 1992 and 2003, several groundwater investigations were completed using site monitoring wells. The investigations included groundwater sampling and analysis (Envirocon 1993; Maxim 1998, 2001a, 2001b, 2003). Samples collected from RML monitoring wells have not exhibited concentrations of any parameters (volatile organic compounds, semivolatile organic compounds, dissolved metals, and radioactivity) exceeding Montana or federal water quality standards (e.g., USEPA MCLs or MDEQ Circular WQB-7 standards), with two exceptions: gross alpha radiation and dissolved lead.

Samples from facility monitoring wells have exceeded the U.S. EPA MCL and/or MDEQ Circular WQB-7 standards for gross alpha emissions on at least one occasion. There is no evidence from any groundwater investigation at RML that suggests radon, gross alpha, or gross beta are originating at RML. Alpha-emitting radionuclides have never been used during biological research at RML or stored at the facility. Alpha particles are produced during the radioactive decay of radium-226 into radon gas. In 2003, upgradient and downgradient monitoring wells at RML were sampled using low-flow techniques and analyzed for gross beta, radon gas, and gross alpha concentrations. Gross beta concentrations were similar in all wells and below the California

Department of Health Services standard of 50 pCi/L. Radon levels were compared to California's standards because Montana and USEPA do not have concentration-based standards for gross beta. Radon gas was present at levels above USEPA's proposed standard of 300 pCi/L (Maxim 2003). Gross alpha levels in all four wells were near or above MDEQ's 1.5 pCi/L standard, but all samples exhibited gross alpha levels below USEPA's MCL (15 pCi/L). Based on these data, data from Briar and Dutton (2000), and 2001 Hamilton municipal well data, the presence of radon, gross alpha radiation, and gross beta radiation in groundwater is associated with the naturally occurring decay of radioactive elements (e.g., uranium and daughter products) in the aquifer matrix.

The second water quality standard exceedance was from a June 1997 sample obtained from monitoring well 92-1 that exhibited total lead above the MDEQ circular WQB-7 standard. To confirm this finding, a sampling and analysis plan to re-sample site wells for total and dissolved lead during low and high groundwater elevations in 2001 was implemented. Results of 2001 groundwater monitoring confirmed that lead was not present above WQB-7 standards and indicated that the lead exceedance in the 1997 sample was most likely associated with naturally occurring suspended sediments entrained in the water sample (Maxim 2003).

3.9.11.2 Rationale for No Further Discussion

Implementing the Proposed Action would not result in release of potential contaminants to groundwater. Hazardous, radioactive, and solid waste would be handled in accordance with applicable laws and regulations. The only additional release of water to the subsurface would be in the five dry wells installed to allow storm water to infiltrate to the subsurface. Typically, minor concentrations of impurities (e.g., grease and oil, road salts) may be entrained by storm water from parking lots. These impurities would be filtered in the drywells. The Integrated Research Facility is not anticipated to have an impact on the quality of groundwater.

CHAPTER 4
ENVIRONMENTAL CONSEQUENCES

4.1 INTRODUCTION

This chapter describes the potential direct, indirect, and cumulative effects of the Proposed Action (Chapter 2) and No Action alternatives. Potential direct and indirect impacts could result from the Project. Cumulative effects are those impacts that could result from combining the impacts of the Proposed Action with past, present, and reasonably foreseeable future actions.

This chapter also describes unavoidable adverse effects (those effects that remain after implementation of mitigation measures) and the relationship between short-term uses of resources and long-term productivity.

Irreversible or irretrievable commitments of resources that could result are also described. Irreversible commitments are those that cannot be reversed except over a very long period of time. Irretrievable commitments are those that are lost for a shorter period.

Reasonably Foreseeable Actions

Several actions are currently under way or will be conducted at the RML campus over the next few years. These activities are independent of the Proposed Action; however, implementation of these actions will affect the Project site. These actions, shown in **Figure 4-1**, are as follows:

- With the exception of the outer six-foot chain link fence on the south side of the RML property, all other existing fence will be replaced with black steel fence surrounding the entire site. This is in compliance with new NIH security guidelines;
- The entrance at 4th and Grove will be moved north to be offset from Grove Street. Staff will enter here and pass through an entrance manned with security guards or NIH police officers 24 hours a day, 7 days a week. A landscaped security barrier (natural materials such as boulders, earth, and vegetation) will be incorporated at 4th and Grove;
- A planned central shipping and receiving building (undetermined size) at the northeast corner of the campus near the north gate will be built for receiving and shipping goods. It will be equipped with an X-ray machine and other security screening devices. Once construction is complete, material delivery will be through the north gate. All commercial delivery vehicles will undergo a vehicle inspection before entering the RML facility. A loading dock will be present at this site, and deliveries will be off-loaded here and transported around campus by RML staff. Commercial delivery trucks would not be allowed to drive around on campus with the possible exception of animal deliveries;
- The fence on the north side of campus will be replaced with the black steel fencing under Phase 2 of the Fence Upgrade Project;
- A visitor's center will be constructed north of the existing guard station and gate to provide information, security screening of visitors, and a meeting area for visitors and RML staff. All visitors conducting business on the RML campus will have their person and personal belongings screened at the visitor center before accessing the RML campus. A special parking area will be provided for visitors where vehicles will be screened;
- A new employee parking lot will be constructed on the north side of the site;
- A new storage building may be constructed in the southwest corner of the campus;
- A silencer has been installed on the incinerator to reduce noise. A project to further reduce the noise on the incinerator cooling tower and the Building 27 load bank is currently under design;
- Roads (shown on Figure 4-1) will be paved; and
- Trees, grass, and other vegetation will be planted inside the paved road on the perimeter of the campus.

4.2 SOCIAL RESOURCES

4.2.1 Direct and Indirect Effects

4.2.1.1 Proposed Action

Population and Demographic Trends

Additional employment from the proposed Integrated Research Facility includes up to 200 workers at the peak of the construction phase, and up to 100 employees phased in over several years following the opening of the facility. If the Proposed Action were to be selected, the number of new residents who would move to Ravalli County and the City of Hamilton would represent a small portion of the anticipated population increase that is expected to occur regardless of the inducement of the Proposed Action. If all new employees were new residents of the county, chose to live in Ravalli County, and had household sizes that matched the Ravalli County rate of 2.48 persons per household, the Proposed Action would add about 248 new residents. These residents would be added to both the low and high projection of 8,000 and 18,000 new people expected as the result of net in-migration by 2010. The population increase from construction of the Integrated Research Facility (248 people) represents 1.4 to 3 percent of the total projected increase in county residents.

The age structure of the county's population has changed during the period of rapid growth (1990-2000), and Integrated Research Facility-related newcomers are expected to more closely match the new population than the historic population. No impact is expected on the ethnic or gender make-up of the population. Most jobs created by the Proposed Action would require skilled and experienced, mature workers. Average education levels in Ravalli County and Hamilton may increase slightly as a result of the additional staff at RML.

Housing

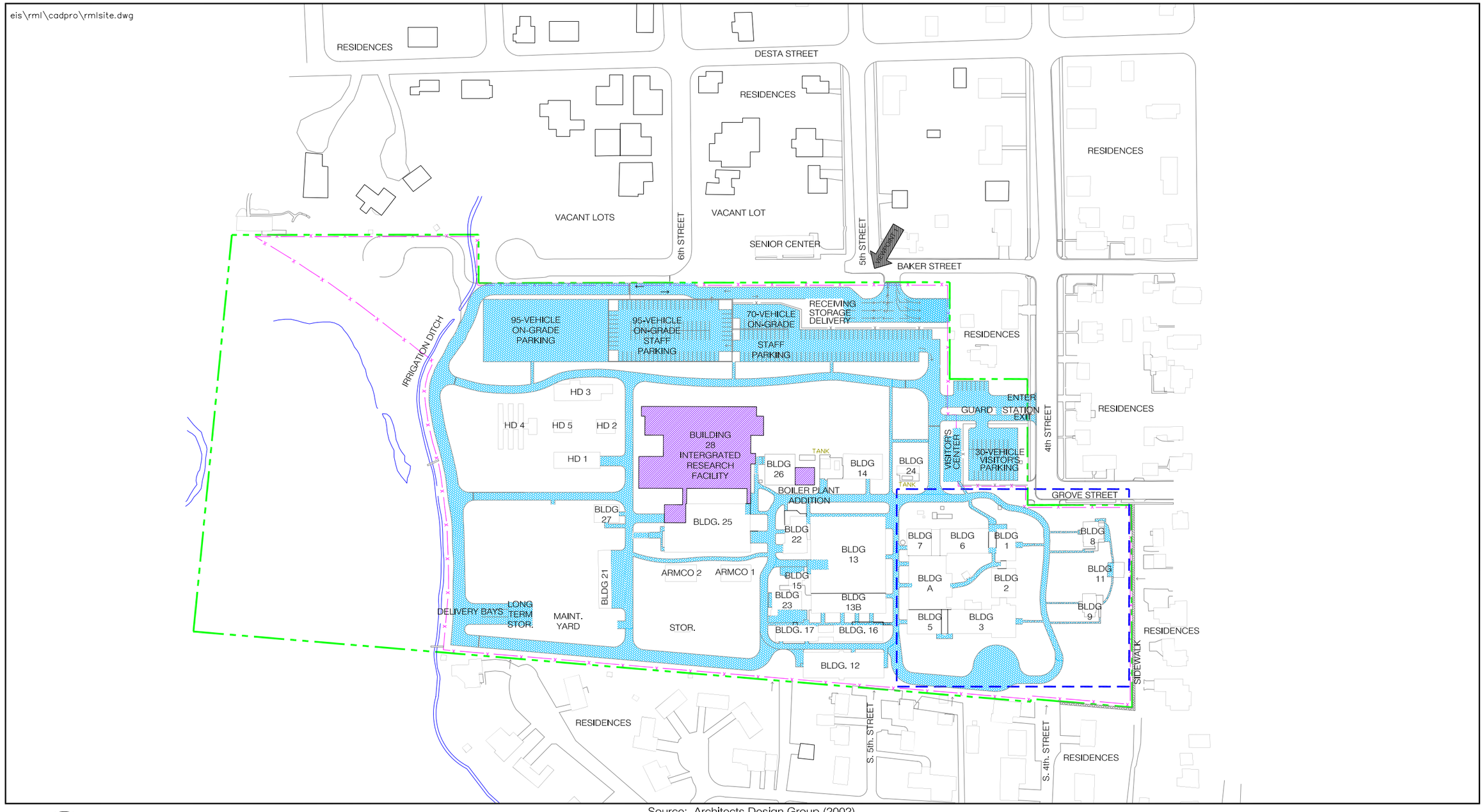
The neighborhood adjacent to RML may encounter direct negative impacts during construction of the Integrated Research Facility if the Proposed Action were selected. Construction is estimated to take two years, during which time trucks would access the property and equipment would be operating.

To evaluate potential impacts to property values, an evaluation of value trends for residential property adjacent to BSL-4 laboratories in other locations was completed. The information suggests that construction and operation of BSL-4 laboratories in residential areas does not result in lowering of property value. The value of residential property adjacent to the Centers for Disease Control (CDC) BSL-4 laboratory in Atlanta, Georgia, has increased over its operational history (Rollins 2003). The surrounding up-scale residential area has townhouses valued between $300,000 and $500,000, and homes selling for over $700,000. Bowers (2003) also reported that property values in the area surrounding a BSL-4 facility in Galveston, Texas have not declined. In Winnipeg, Manitoba, property values have remained consistent with the surrounding mixed-use area despite the development of a BSL-4 laboratory (Halladay 2003).

Property values in the proposed Integrated Research Facility area and prices of property adjacent to RML in Hamilton are stable. Houses do not remain on the market longer than normal since the Proposed Action was discussed at the June DEIS public meeting (Dowling 2003, Polumsky 2003, Rose 2003). Housing prices in the neighborhood are $20,000 to $30,000 higher than in other sections of Hamilton (Dowling 2003).

Based on population projections and numbers of people per household unique to Hamilton, between 335 and 900 new housing units would be needed by 2010 to accommodate projected new growth in the community. While it is unknown whether all new RML employees would move to Hamilton, the number of projected new homes is sufficient to house them.

Housing construction is a thriving industry in Ravalli County. The number of new homes required by Integrated Research Facility-related growth would support that industry. Housing prices in the county continue to increase faster than wages. Addition of new homes would result in an increase in business for homebuilders and real estate developers. The increase in population as a result of the Proposed Action would not require special mitigation actions beyond those listed in the Ravalli County Growth Policy (2002) and the City of Hamilton Comprehensive Master Plan (1998).



Source: Architects Design Group (2002)

N

0 Feet 200

Locations of reasonably foreseeable actions subject to change.

Property Line
Fence
Historic District

Proposed Action
Reasonably Foreseeable Actions

Proposed Action and Reasonably Foreseeable Actions
RML Integrated Research Facility
Hamilton, Montana
FIGURE 4-1

Education

School capacity is adequate for growth, including projections for the Integrated Research Facility, especially since school-aged population levels are decreasing.

Community Safety and Risk

The increased physical and procedural safety measures inherent in the BSL-4 laboratories and the Integrated Research Facility increase security. Increased security would actually reduce threats from terrorism and possible release of a studied agent into the community. The BSL-4 laboratory is designed to be self-contained, and there is complete redundancy in the electrical and mechanical systems. In more than 30 years of working with BSL-4 agents in the U.S., there has never been a confirmed release to a community from a laboratory (see **Appendix D**). Few incidences of infections of laboratory workers have occurred. However, backup mechanical and procedural safety systems for these laboratories identified the incidents, and actions were taken to protect the worker and the public from infection.

The mission of NIH the nature of how agents would be studied at RML, and the inability of many agents to directly transmit from human to human without an intermediate host or deliberate act (e.g. bite, intimate contact), also reduces the risk to the community. NIH, and its associated laboratories, including RML, do not and would not work with weapons-grade material. NIH is the steward of medical and behavioral research for the nation, whose mission is "science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability" (USDHHS 2001). In realizing this mission, NIH provides leadership and direction to programs designed to improve the health of people by conducting and supporting research in the causes, diagnosis, prevention, and cure of human diseases. This research requires a small quantity of nonweapons-grade materials, while reducing the threat of spread to the community and the chance of becoming a target for terrorism.

It is not known specifically what agents would be studied at the Integrated Research Facility. It is known that smallpox would not be studied. In the U.S., CDC in Atlanta is the only place where smallpox research is allowed. Because NIH's mission is to reduce illness from emerging and re-emerging diseases, NIH and RML operate in a reactionary mode, shifting research emphasis to those diseases.

All NIH laboratory facilities are designed and constructed to a BSL-2. The exact containment requirements of agents vary by protocol and are determined through risk assessment by the Institutional Biosafety Committee (IBC), the biological safety officer (BSO), and other relevant entities. New, emerging, or re-emerging pathogens would be handled conservatively, because often the scientific information necessary to conduct a reliable risk assessment has not yet been developed or discovered. Hantavirus with pulmonary syndrome (new world hantaan virus), HIV, and SARS are examples of organisms that have been safely handled by NIAID personnel in laboratories using conservative containment approaches until pertinent scientific data could be collected. Further, NIH maintains Certified Biological Safety professionals on staff to ensure that appropriate practices, procedures, equipment, and containment facilities would be used.

All diseases that would be studied at the Integrated Research Facility are naturally occurring. Spread of diseases may occur as they overcome natural mechanisms that keep them in check or through manipulation by man to make them more virulent. For many diseases, transmission from person to person is not possible without an intermediate host or a deliberate act. For example, person-to-person transmission of Ebola hemorrhagic fever and Marburg fever from person-to-person occurs through direct contact with infected blood, secretions, organs, and semen (see **Appendix B**). Hemorrhagic fevers commonly require the bite of an infected host (e.g., tick) for transmission to occur. Therefore, the nature of transmission of many diseases that would be studied at RML provides a natural mechanism restricting their spread in the community.

Numerous methods would be employed to control access to agents and for the facility to reduce the potential for release of an agent to the environment or community. These include:

- Specialized laboratory construction;
- Employee screening and training;

- Site security;
- Air and wastewater treatment;
- Backup systems; and
- Emergency response.

As described in Chapter 2 and **Appendix E**, BSL-4 laboratories are constructed and operated to reduce or eliminate potential for worker exposure and release of an agent. The laboratory design and decontamination protocols for workers and materials brought in and out of the laboratories (See **Appendices D and E**) provides advanced laboratory safety. All scientists working in the Integrated Research Facility must demonstrate superior training and working knowledge of laboratory procedures aimed at preventing infection and release of agents. Regular training would be completed to ensure that workers remain true to the policies and protocols.

Details on how waste streams (air and water) would be handled to prevent release of an agent can be found in General Building Design Components in Chapter 2. These state-of-the-art systems, proven through use at existing BSL-4 laboratories, would prevent possible release of agents from the Integrated Research Facility. System maintenance and monitoring would be completed to ensure proper operation. Biological safety procedures would be based on the concept of containment and would follow the maximum standards of facility design available (CDC 1999). The facility design for maximum-containment BSL-4laboratories has been established and tested at the CDC facilities in Atlanta, Georgia, and the United States Army Medical Research Institute of Infectious Diseases at Ft. Detrick, Maryland (CDC 1999, Wedum 1996, Crane *et al.* 1999).

Use of primary and secondary laboratory barriers (e.g., personal protective equipment, biological safety cabinets, airlocks, etc.) would be carefully designed and implemented in the NIH exposure control plan. This plan would be followed at the proposed facility. The plan describes integration of biological risk assessment, safety equipment, training, and occupational health services into coordinated standard operating procedures (see **Appendix E**) for prevention, detection, and mitigation of potential laboratory acquired infections.

Engineering controls designed into the BSL-4 facility, particularly the air-handling systems and HEPA filtration placement, would prevent escape of potentially infectious materials from the laboratory. Several backup systems aimed at preventing a release would be put into place, including automatic lock-down when power is lost, backup power generation on campus, and backup wastewater and air systems should one be offline for maintenance and disinfection. These systems would be incorporated into the design to ensure releases would not occur. Backup power on the community water system is also planned by the City of Hamilton (see Water Supply in Chapter 3).

Security measures aimed at protecting workers and the community are provided in Chapter 2. Access to the Integrated Research Facility requires the highest clearance from the Laboratory/Branch Chief in accordance with NIH and RML security protocols for access to the BSL-4 laboratory. No one would be allowed to enter the BSL-4 laboratory alone. No opportunity would exist for unauthorized or undocumented access to the BSL-4 facility.

The combination of pre-planning, engineering controls, and limitation of access to the Integrated Research Facility would reduce the risk of laboratory-acquired infections.

Agent Communicability and Treatment

Understanding communicability of infectious diseases has evolved over the last 10 years. In the past, a person exposed to BSL-4 type agents was immediately placed in isolation for 21 days (Risi 2003). Infectious disease specialists now know that it takes at least 48 hours for an exposed person to become contagious, regardless of microbe type. This provides adequate time to transport and initiate treatment to benefit the individual and isolate a potentially exposed person from the greater population.

Protocols exist for treatment of personnel injured or potentially exposed at RML. Through collaboration with local emergency response agencies, the steps to follow in the event of a potential exposure at RML would include:

- Remove the patient to a safe area outside the laboratory and prepare for transport and complete initial triage;

- Transport the patient to a local hospital if there is a life-threatening injury (in addition to potential exposure) or stabilize for transport to a regional hospital;
- Assess the patient's condition and risk to the community;
- Place the patient in isolation, if warranted; and
- Initiate treatment.

Emergency Response

Local emergency response agencies indicate they have the ability to respond quickly and adequately to any emergency that may arise at RML. The Hamilton Volunteer Fire Department is confident in their ability to respond to an emergency at RML (Wilson 2003a). The Fire Department is working with RML to ensure that it has the equipment needed to respond to any fire incident at the RML campus. Neither the Hamilton Police Department nor the Ravalli County Sheriff's Department expects the proposed construction and operation of the Integrated Research Facility to create the need for more officers and equipment (Auch 2003; Hoffman 2003). The Bitterroot Valley EMS, the local ambulance service, does not anticipate that the proposed Integrated Research Facility would present any specific problems to the EMTs, nor does the organization foresee the need for additional employees or equipment (Neff 2003). The proposed Integrated Research Facility would not create a need for additional staff at Marcus Daly Hospital, but capital improvements may be needed should a potentially infected person with a life-threatening injury be transported to Marcus Daly for stabilization prior to transport to a regional hospital such as St. Patrick Hospital in Missoula (Bartos 2003). St. Patrick Hospital meets all required standards for handling infectious disease cases (Risi 2003).

Most emergency response agencies indicated that additional training on the communicability of agents and anticipated emergency response protocols would be useful. NIH and RML, in collaboration with local emergency response agencies, have committed to provide this training.

Reasonably foreseeable actions are provided in Cumulative Effects, Section 4.2.2.

Risk Assessments

Theoretically, human error or multiple, simultaneous mechanical failures could lead to accidental release of biological materials. However, redundancy of safety equipment and procedures, operational safeguards, monitoring systems, and the overall safety record of biomedical and microbiological laboratories indicate that this is not a significant risk. Nevertheless, in order to address community safety concerns, the NIH applied both qualitative and quantitative risk assessment strategies to investigate potential community impacts of the proposed Integrated Research Facility at the RML. The qualitative assessment included a literature review regarding laboratory acquired infections; a review of all infectious disease research protocols performed by the NIAID requiring BSL-2 with BSL-3 practices; BSL-3; or BSL-4 facilities for the past two decades; review of all NIAID accidents associated with these laboratories; injuries and illnesses during the same period of time (see **Appendix D**); and review of RML medical waste incinerator operations, infectious waste handling procedures, animal containment, and procedures for biological material shipment. Additionally, a survey was conducted to determine the safety records of BSL-4 laboratories worldwide with 20 or more years of operating experience.

Laboratory-Acquired Infections. Literature review reveals that laboratory-acquired infections have occurred since bacteria were first isolated. Within four years of the isolation of diphtheria, Riesman reported the first documented laboratory-acquired infection in 1898. Since that time, laboratory-acquired infections have been tracked in the scientific literature. The most recently published review indicates approximately 5,346 occupationally acquired infections have occurred in individuals working with microorganisms since 1898 (Harding and Byers 1999). Since the publication by Harding *et al.*, six more infections acquired occupationally have been reported by the Centers for Disease Control and Prevention in the Morbidity and Mortality Weekly Report (MMWR) involving *Neisseria meningitis* (bacterial meningitis) in two laboratory workers in clinical settings; a microbiologist in a research laboratory who contracted *Burkholderia mallei* (glanders); two cases of West Nile virus contracted through either

a puncture or laceration in public health laboratory situations; and one case of cutaneous anthrax in an worker in an environmental microbiology laboratory. This is a remarkably small number of occupationally acquired infections reported world-wide over a 100-year period given the vast amount of microbiological activity that has occurred in both clinical and research settings during that time. Further, no reports have been found of laboratory-attributable infection in persons who were never in a laboratory building or who were not in some way associated with the laboratory (Wedum 1996).

The NIAID has recently conducted a retrospective study of all reported injuries and illnesses in the last 20 years (1982-2003) within the Institute occurring in BSL-3 laboratories or BSL-2 laboratories utilizing BSL-3 practices and procedures (Johnson 2003, see **Appendix D**). Employees at risk of exposure worked approximately 3,189, 700 hours with a variety of microbial organisms resulting in one clinical infection and four so-called "silent infections" (meaning without symptoms) documented through antibody production or skin test conversion. There is no evidence that any microorganism was released from these laboratories; nor were there any infections in adjacent civilian communities. This record stretches to 70 years at the Rocky Mountain Laboratories (Johnson 2003, see **Appendix D**).

With regard to other BSL-4 (formerly designated P4) laboratories worldwide, the safety record is remarkable. In a 10-year period from 1959-1969, only one laboratory-acquired infection occurred in a worker in each of the two existing P4 facilities at Ft. Detrick, Maryland (Wedum 1996). Both infections were cutaneous in nature, did not require hospitalization, and posed no risk to the community. NIAID has performed a survey of BSL-4 laboratories worldwide with over 20 years of operating history to determine the number and severity of laboratory-acquired infections occurring within these facilities (Johnson 2003, see **Appendix D**). In the past 31.5 years (approximately 344,000 man-hours of work), in newer BSL-4 suit facilities at the U.S. Army Research Institute for Infectious Diseases (USAMRIID) at Ft. Detrick, Maryland, there have been no clinical or sub-clinical infections from any BSL-4 agent. There have been no environmental releases of infectious agents from these laboratories. The Centers for Disease Control and Prevention has operated P4/BSL-4 facilities for over 30 years (120,560 man-hours of work in BSL-4 laboratories). There have been no clinical or sub-clinical infections and no releases of infectious agents to the environment. The National Institute for Communicable Diseases in Johannesburg, South Africa, has operated BSL-4 laboratories for over 22 years (approximately 40,000 man-hours), where much of the work was devoted to searching for wild reservoirs of Marburg and Ebola viruses. No infections or environmental releases of infectious agents have been recorded. In summary, over 604,000 man-hours of work with exotic agents in BSL-4 laboratories have taken place without any evidence of laboratory-acquired infection or environmental release.

Based on the NIAID safety record over the past two decades; the safety record in general of P4/BSL-4 laboratories; the lack of occupationally acquired infections in employees working in these facilities during the past 30 years; and the fact that there have been no environmental releases of infectious agents from these facilities, the conclusion can be made that the risk to communities surrounding BSL-4 laboratories is negligible.

Inactivation of materials infected with agents of transmissible spongiform encephalopathies (prion diseases). High temperature incineration continues to be the disposal method of choice for medical and veterinary wastes as it has been demonstrated to be effective at inactivating all types of pathogens. Currently the only approved method for disposing of prion-contaminated animals and animal waste/bedding is incineration (WHO 1999). Due to the amount of prion research conducted at RML, an on-site incinerator is required. Modern incinerators with efficient effluent scrubbing systems, such as the RML incinerator, provide an environmentally and economically superior method for disposal of medical/pathological waste compared to transporting via diesel-powered vehicles to a landfill. Additionally, the on-site incinerator provides a critical redundant method for disinfection and disposal of medical/pathological waste generated by research conducted at RML.

Safe disposal of potentially infectious wastes is an issue of concern to all biomedical laboratories. Of particular concern are wastes potentially contaminated with the agents that cause a group of diseases referred to as transmissible spongiform encephalopathies (TSE), commonly referred to as prion diseases. These agents are resistant to most conventional methods of inactivation, including heat processing (Taylor 1998).

The incinerator at RML is a Consumat 325 Incinerator. Both state and federal authorities license it as a hospital medical infectious waste incinerator. To be certified as such, the two-stage incineration process must allow for a minimum of four hours of burn time at approximately 1800°F (983°C). This burn time is much longer than allowed in the following referenced experiments. The operational plans for this incinerator also include a variety of standard maintenance and operational testing to ensure that each run maintains that minimum temperature. (There is another incinerator at RML (Consumat 225), but this unit will not be used to incinerate infectious materials.)

Experiments conducted by the NIH indicate that high-temperature incineration can completely destroy agents of TSE. When experimental inactivation of tissues containing high concentrations of a particularly heat resistant strain of TSE (hamster adapted scrapie strain 263K) was performed under incineration-like conditions at approximately 1000°C for 15 minutes, no detectable infectivity remained in the ash (Brown *et al.* 2000, Brown *et al.* 2003). Similar experiments performed at 600°C for 15 minutes demonstrated a very low level of residual infectivity in the ash.

No information or data has been published to suggest that TSE agent infectivity may form as recombination products from cooling of non-infectious emissions. The presence of an inorganic template of agent replication from infectious material has been hypothesized to explain the extreme resistance of TSE agents in ash to thermal inactivation. This hypothesis assumed potential formation directly from infectious material, not that it formed from non-infectious incineration products (Brown 2000).

In order to evaluate this hypothesis, a series of experiments simulating combustion conditions in medical waste incinerators, including a starved-air, two-stage design similar to the Consumat 325, have recently been completed (Brown *et al.* 2003). Bioassays of cooled air emissions from combustion of tissues infected with high concentrations of scrapie strain 263K at 600°C and 1000°C revealed no evidence of infectivity, confirming that emissions to the stack do not contain detectable infectious agents released from the combustion chamber or formed as recombinants on cooling.

Decontamination of exhaust air. Air exhausted from biological safety cabinets (a piece of laboratory containment equipment in which infectious materials must be manipulated at BSL-3 and above) is passed through a high-efficiency particulate air (HEPA) filter prior to recirculation to a laboratory room or discharge through the building exhaust system. These are disposable, extended/pleated medium, dry-type filters with (1) rigid casing enclosing the full depth of the pleats; (2) minimum particulate removal of 99.97% for thermally generated monodisperse dioctylphthalate (DOP) smoke particles or equivalent with a diameter of 0.3 µm; (3) maximum pressure drop of 250 Pa (1.0 in wg) when clean and operated at rated airflow capacity; and (4) no area showing a penetration exceeding 0.01% when scan-tested with polydisperse aerosol having a light scattering median size of 0.7 µm and a geometric standard deviation of 2.4 (National Sanitation Foundation (NSF) 2002). These filters are also used to treat exhaust air prior to discharge to the outdoors. In a BSL-4 laboratory, two HEPA filters are used in series to assure the exhaust air is sufficiently treated before discharge to the outdoors. In effect, all discharge air is filtered at least twice, and in many cases three times, prior to discharge. HEPA filter installations, whether in containment equipment such as biological safety cabinets or in building mechanical systems, are tested in place at least once per year using NSF Standard 49 procedures (NSF 2002) that provide quantitative assurance that the installations do not contain defects that reduce microbiological safety. HEPA filters are known to have long functional lives; however, age does play a factor in decreasing tensile strength of the filter media (First 1996; Edwards 2002). For this reason, the RML Integrated Research Facility would use a conservative terminal date of five years of service

for HEPA filters in biological safety cabinets and other applications (First MW, 1996). The likelihood of infectious microorganisms being exhausted from the Integrated Research Facility in numbers sufficient to cause harm to the public or the environment is negligible.

Escape of an Infected Animal. The likelihood of escape of an infected animal from a containment animal facility is extremely remote. Due to the specialized design and construction of BSL-3 and BSL-4 laboratories, modes of escape are minimized to the maximum extent. Containment husbandry practices further reduce the already miniscule risk. Simultaneous breakdown of multiple levels of physical and procedural controls would need to occur for a live animal to escape from the containment laboratories. Daily observations of animals are performed to further reduce the possibility that a missing animal would go unnoticed.

A BSL-4 animal room is an airtight room with positive pressure gasket doors providing an absolute seal when the doors are closed. Access to these areas is through airlocks with interlocking positive pressure doors and a chemical shower, thus adding even more physical barriers. In the event that a small animal escapes from a cage or is dropped during a manipulation, there is no avenue of escape available from the room. In these rodent rooms, baited live traps are used as standard practice as an extra precaution so that, in the event an animal escapes into the room, the valuable research animal can be recovered alive. All cages and bedding are decontaminated in an autoclave prior to removal from the containment facility. Should an animal burrow in bedding and not be transferred to a fresh cage prior to removal from the animal room, it would not survive the decontamination process.

The BSL-3 animal rooms are also accessed via air lock through interlocking doors. These doors are fitted with "sweeps" and open inward to preclude animal escapes. Small rodents housed in BSL-3 animal rooms are maintained in micro-isolator cages in ventilated cage racks that serve as a primary barrier preventing escape of the animal. As in the BSL-4 animal room, baited live traps are employed as a secondary measure to prevent escapes and to preserve valuable laboratory animals. Daily animal observation is a matter of good husbandry practice and is required for accreditation of the RML animal care and use program. BSL-3 laboratories are, by design, removed from general access corridors, thus even further reducing the likelihood of an animal reaching an exterior door. Animal bedding and cages must also be decontaminated prior to removal from the containment facility. An animal hidden in bedding would not survive the decontamination process.

The potential risk to the public from an infected animal is so minimal that it can be described as zero.

Biological Material Shipment. The packaging, labeling, and transport of etiologic agents (see **Appendix C**) are regulated 42 CFR 72 (Interstate Shipment of Etiologic Agents); 49 (CFR 172 and 173 U.S. Dept. of Transportation regulations concerning shipment of hazardous materials); 9 CFR 122 (U.S. Dept. of Agriculture [USDA]-Restricted Animal Pathogens, and International Air Transport Association (IATA) rules. In addition, special rules apply for the transport of materials regulated by the U.S. Food and Drug Administration (21 CFR 312.120, Drugs for Investigational Use in Laboratory Research Animals or in Vitro Tests). Recent legislation (the USA PATRIOT Act, and the Public Health Preparedness and Bioterrorism Response Act of 2001) have further strengthened the regulations controlling transport of certain etiologic agents, referred to as select agents, to include controls over possession and use. The RML is registered with the Centers for Disease Control and Prevention and the U.S. Department of Agriculture for possession, use, and transport of these agents. A responsible official is designated at RML and approved by the regulating agencies to oversee the shipping, receipt, and usage. Packaging requirements are strictly implemented in accordance with IATA regulations.

Worldwide, there have been no cases of illness attributable to the release of infectious materials during transport, although incidents of damage to outer packaging of properly packaged materials have been reported (World Health Organization, 2002; U.S. Department of Transportation, 2001).

The risk to the community surrounding RML and specifically the Integrated Research Facility from

transport of infectious agents or other biologically derived material is negligible.

Risk Assessment Scenarios. The NIH has performed a quantitative risk assessment of release of an infectious agent to the surrounding Hamilton community from the proposed BSL-4 Integrated Research Facility at RML. The quantitative risk assessment was driven by reasonably foreseeable, credible threat scenarios. It addresses spills and work disruption; safety system operation and potential failures; and fire. The modeling tool used to perform these analyses was the Maximum Possible Risk (MPR) model developed by the NIH. Anthrax, in spore form, was chosen as the worst-case scenario agent based on public health impact and dissemination potential (Rotz *et. al.* 2002). Anthrax itself is not a BSL-4 agent, but it does pose a higher potential hazard to workers in the immediate vicinity and the surrounding community upon accidental release than the BSL-4 viral agents. This is due to its innate resistance to environmental factors (e.g. sunlight, lack of humidity, etc.) that normally tend to inactivate viruses and ease of airborne dissemination. Preliminary range finding studies were performed simulating accidental laboratory releases of 10 billion anthrax spores to determine the number of respirable particles generated that become airborne. Approximately 400,000 respirable particles were produced in the range finding studies of simulated laboratory accidents and were available to become and remain airborne. These data were introduced into the MPR model to generate a very cautious, quantitative estimate of the risk for each of the scenarios. The estimate of risk is based on potential dispersion of accidentally released spores approximately 100 meters from the BSL-4 ventilation exhaust stack, which represents the nearest residence in the surrounding Hamilton community. Risk scenarios evaluated included those with countermeasures in place and functioning properly, as well as system failure scenarios. Assumptions made for input into the MPR model are as follows:

1. A release point is assumed. For laboratory spills, it is the top of the building exhaust stack. The exhaust velocity is not used in calculation of the dispersion pattern in the MPR, therefore decreasing potential area in which the spores can disperse within the model. A dispersion pattern is also assumed. It is a horizontal cone starting at the release point and extending 100 meters.
2. All the spores are assumed to go in one direction, as if the worst possible wind pattern is at play. In any actual incident, turbulence would, in fact, disperse the spores more broadly so that the concentration would fall to harmless levels well before any spores left the RML grounds.
3. Independent of the dispersion pattern, a pathogenic total cumulative level of spores, e.g. 500, is assumed and is an input to the model. Documented evidence suggests that the pathogenic level is greater than 500 spores over an eight-hour period (Brachman 1966). In addition, a respiration rate of 12 liters per minute and total exposure time of 20 minutes is assumed. From these inputs, a pathogenic concentration, in spores per liter, can be computed. For example, a concentration of 2.08 spores per liter, breathed for 20 minutes at the rate of 12 liters per minute would accumulate to 500 spores. This corresponds to an airborne concentration of 2083 spores per cubic meter of air.
4. The pathogenic concentration is then compared to the concentration produced by the dispersion model at and outside the 100-meter radius from the lab in which the actual dispersed concentration could present a temporary hazard.

The MPR analysis (based on the exposure time and respiration rate) for the Integrated Research Facility BSL-4 laboratory uses a cautious approach of "maximum possible risk." Specifically, numerous simplifying assumptions are used that we know for certain are more unfavorable than any credible assumptions. For example, we assume that spores, once released, populate a simple cone or spherical pattern; in fact, they would certainly disperse in a far more complex pattern that would inevitably reduce them to nonpathogenic concentrations more rapidly than the MPR analysis will allow. This approach makes the calculations easy to understand, avoids controversies over the details of turbulent dispersion, and gives extra confidence since the actual risks are certain to be less than the risks presented in the analysis. Scenarios for the

BSL-4 facility subjected to MRP analysis are specified below:

1. A researcher is working within a Class 2 BSC that is ducted and located within a BSL-4 laboratory. He is handling a 15 cubic centimeter (cc) conical tube containing a powder-like preparation of purified anthrax containing 10 billion spores. The cap fits loosely. The researcher accidentally drops the tube on the bare, stainless steel surface of the properly operating BSC. The cap comes off of the tube upon impact and a visible cloud of spores is released within the cabinet.

The cabinet is exhausted through a dedicated heating, ventilating, and air conditioning (HVAC) system for the BSL-4 laboratory that contains two properly seated and gasketed high-efficiency particulate air (HEPA) filters, in series, in the exhaust system. The air change rate within the room is 12 air changes per hour (ACH). The typical laboratory dimensions have been provided. The laboratory has a 10-foot ceiling. The exhaust stack height is five meters. The total exhaust air volume from the BSL-4 laboratory is 17,018 liters per second. The exhaust velocity is 20 meters per second.

What is the potential for release of anthrax spores to the external outdoor environment?

The calculated potential release to the environment described in this scenario would be 0.000011 spores. Since release of a partial spore is not feasible, this number is practically rounded to zero.

What is the probability of public health harm?

The safety features designed into the laboratory would prevent even one spore being breathed by an individual in the nearest residence as a consequence of an accidental laboratory spill.

2. A researcher is working within a Class 2 Biological Safety, Type A that is not ducted and located within a BSL- 4 laboratory. He is handling a 15 cc conical tube containing a powder-like preparation of purified anthrax containing 10 billion spores. The cap fits loosely. The researcher accidentally drops the tube on the bare, stainless steel surface of the properly operating BSC. The cap comes off of the tube upon impact and a visible cloud of spores is released within the cabinet.

The cabinet recirculates HEPA-filtered air to the laboratory room; the air is then exhausted through a dedicated HVAC system for the BSL-4 laboratory that contains two properly seated and gasketed high efficiency particulate air (HEPA) filters. The air change rate within the room is 12 air changes per hour (ACH). The typical laboratory dimensions have been provided. The laboratory has a 10 ft. ceiling. The exhaust stack height is 5 meters. The total exhaust air volume from the BSL-4 laboratory is 17,018 liters per second. The exhaust velocity is 20 meters per second (m/s).

What is the potential for release of anthrax spores to the external outdoor environment?

The calculated potential release described in this scenario would be 0.000011 spores. Since release of a partial spore is not feasible, this number is practically rounded to zero.

What is the probability of public health harm?

The safety features designed into the laboratory will prevent even one spore being breathed by an individual in the nearest residence as a consequence of an accidental laboratory spill.

3. A researcher is working within a Class 2 BSC that is ducted and located within a BSL-4 laboratory. He is handling a 15-cc conical tube containing a powder-like preparation of purified anthrax containing 10 billion spores. The cap fits loosely. The researcher accidentally drops the tube on the bare, stainless steel surface of the properly operating BSC. The cap comes off of the tube upon impact and a visible cloud of spores is released within the cabinet.

The cabinet is exhausted through a dedicated HVAC system for the BSL-4 laboratory; however, both HEPA filters were accidentally left out of the filter housings. The air change rate within the room is 12 air changes per hour (ACH). The typical laboratory dimensions have been provided. The laboratory has a 10-foot ceiling. The exhaust stack height is five meters. The total exhaust air

volume is 17,018 liters per second. The exhaust velocity is 20 meters per second.

What is the potential for release of anthrax spores to the external, outdoor environment?

The calculated potential release to the environment described in this scenario would be 1 spore per 8,727 cubic meters of air.

What is the probability of public health harm?

Due to the pressure monitoring devices and alarms included in the building design and the installation, maintenance, testing, and certification program for all HEPA filter installations, the exhaust system would shut down when the HEPA filters did not operate. Therefore, there should not be any biological material (spores) released into the environment. Even if these systems failed and the entire number of aerosolized spores was exhausted from the laboratory, the concentration under the maximum possible risk model would still be only one spore per 8,727 cubic meters of air. As a point of reference, the average breathing rate for a human is 12 liters per minute (1000 liters = one cubic meter), meaning that a human breathes approximately 6,307 cubic meters of air in an entire year.

The risk of public harm is so minute that it may be considered zero.

4. A researcher is working within a Class 2 BSC that is ducted and located within a Biosafety Level 4 laboratory. He is handling a 15-cc conical tube containing a powder-like preparation of purified anthrax containing 10 billion spores. The cap fits loosely. The researcher accidentally drops the tube on the floor of the BSL-4 laboratory. The cap comes off of the tube upon impact and a visible cloud of spores is released within the laboratory room.

The cabinet is exhausted through a dedicated HVAC system for the laboratory; however, both HEPA filters were accidentally left out of the filter housings. The air change rate within the room is 12 air changes per hour (ACH). The typical laboratory dimensions have been provided. The laboratory has a 10-foot ceiling. The exhaust stack height is five meters. The total exhaust air volume is 17,018 liters per second. The exhaust velocity is 20 meters per second.

What is the potential for release of anthrax spores to the external, outdoor environment?

Taking the maximum possible risk approach, assuming that there is no loss of aerosolized spores through sedimentation or impaction on the duct work, approximately 400,000 respirable spores could potentially be released from the BSL-4 laboratory into the dispersal zone resulting in a concentration of one spore per three cubic meters of air.

What is the probability of public health harm?

Using an average breathing rate for a human of 12 liters per minute (1,000 liters equals one cubic meter), an individual would have to breathe one spore per three cubic meters of air concentration for over four hours before even one spore would be inhaled. Clearly, the conservative pathogenic concentration used in this assessment of 500 spores over eight hours would never be achieved. Furthermore, due to the pressure monitoring devices and alarms included in the building design and the installation, maintenance, testing, and certification program for all HEPA filter installations, the likelihood of this modeled release occurring is further reduced. The risk of public harm is so minute that it may be considered zero.

5. A researcher is working within a Class 2 BSC that is ducted and located within a BSL-4 laboratory. He is handling a 15-cc conical tube containing a powder-like preparation of purified anthrax containing 10 billion spores. The cap fits loosely. The researcher accidentally drops the tube on the floor of the BSL-4 laboratory. The cap comes off of the tube upon impact and a visible cloud of spores is released within the laboratory room. At this exact moment, the building is struck by a major electrical outage and the HVAC system fails.

What is the potential for release of anthrax spores to the external, outdoor environment?

None. The Biosafety Level 4 laboratory HVAC system is designed with numerous safety controls in place. In the event that either the exhaust or supply systems shut down, electronic interlocks on these systems assure that the laboratory is not pressurized. In the event of a total electrical outage, when neither exhaust nor supply air is

provided to the laboratory, the pressure differential will drop to zero and the room becomes static with regard to airflow. Additionally, positive pressure bubble dampers, installed for decontamination purposes on BSL-4 laboratories, close and isolate the air in the laboratory. The anthrax spores would not be released into the environment because there would be no pressure in the laboratory to push the air through the series of two HEPA filters. The HEPA filters would continue to provide a physical barrier against release of spores even in the shut-down mode.

What is the probability of public health harm?

None. No spores would be released to the environment.

6. A researcher handling anthrax cultures is hurrying to finish work on a Friday afternoon. Freshly inoculated *B. anthracis* cultures on 5% sheep blood agar plates are placed in the incubator. She places a stock of anthrax spores (10 billion spores in 10 mL of phosphate buffered saline in a 50-cc polypropylene tube) in the secure laboratory refrigerator. In her haste, she does not notice that a heated water bath has been left on and has no water left in it. The water bath does not have an automatic "over temp" switch-off. Sometime late Saturday evening, the water bath overheats and a small fire ignites. Some small cardboard boxes are stored on a shelf above the water bath. The room is sprinklered and alarmed. The Hamilton Fire Department responds to the alarm within four minutes.

What is the potential for release of anthrax spores to the external, outdoor environment?

None. The spores are secured in a locked refrigerator consistent with Department of Health and Human Services Select Agent storage guidance for compliance with the USA PATRIOT Act. The laboratory sprinkler system will discharge as soon as the cardboard combustibles begin to burn, dousing the fire. In the event that the sprinkler fails to completely douse the fire, the Hamilton Fire Department also responds within approximately four minutes. Additionally, one-hour fire rated walls prevent expansion of the fire beyond this laboratory module.

What is the probability of public health harm?

None.

Transportation

Potential impacts from traffic associated with the Proposed Action were evaluated in a residential portion of Hamilton, Montana, where most traffic entering and leaving the RML campus would occur. This area is defined by U.S. Highway 93 North on the east, Ravalli Street on the north, 8th Street on the west, and the southern property line of the RML campus on the south. The amount of existing resident and RML traffic through this area was compared to the estimated additional traffic that would be associated with the Integrated Research Facility.

Based on a July 1995 aerial photograph of the area (NRIS 2002) and property line coordinates available from the Montana Department of Administration (1999), approximately 204 residences are located within the residential area described above. Presently, 250 RML employees (see Section 3.3.2) travel through the area. The number of permanent federal employees would ultimately increase to 350 (see Section 4.2.1). Most of the traffic to and from RML and within the adjacent residential area occurs during the morning and evening commute periods. Peak hour travel during the evening commute is 0.79 trips per household and 0.45 trips per employee (Morrison Maierle 2002).

RML traffic is presently 41 percent of the area's peak hour traffic and would ultimately become 48 percent of the area's traffic with completion of the Integrated Research Facility (see **Table 4-1**). The difference between current and predicted RML employees traffic is 45 trips. When divided by the current number of trips (274), this is a 16 percent increase due to operation of the Integrated Research Facility.

Discussions with Hamilton's city administrator reveal that delivery services to RML would not noticeably change after expansion of the facility. USPS, UPS, FedEx, freight services etc., would continue to use current routes to enter and leave the campus. Administrative support traffic (i.e., errands, deliveries) would be similar to the present condition. Local residents would experience little additional traffic during the day.

The primary approach to RML is from Ravalli Street and South 4th Street (a local collector). South 7th Street is also shown as a local collector in the 2002 Hamilton Transportation Plan, but it would require upgrades (See Section 3.1.1) to function effectively as a local collector.

Table 4-1. Peak Hour Traffic (Current and Expected)

	2002	2006
Residential		
Residences	204	204
Trips	161	171*
RML		
Employees	250	350
Trips	113	158
Total Trips	**274**	**329**

* Reflects a 1.5% increase in traffic per year.

Periods of increased security at RML may cause increased on-street parking adjacent to RML to avoid entry delays.

Transportation of agents would continue to meet requirements outlined in **Appendix C**.

4.2.1.2 No Action

Population and Demographic Trends

Population growth would continue at the current pace under the No Action Alternative (**Table 4-2**). Between 8,000 and 18,000 persons are projected to relocate to Ravalli County by 2010. People are choosing to move to Ravalli County primarily for quality of life issues, not job opportunities.

Table 4-2. Population Projections

Area	2000 Pop.	2010 Pop. (2%/year)	2010 Pop. (4%/year)
Ravalli County*	36,070	7,930 new 44,000 total	17,930 new 54,000 total
City of Hamilton	3,705	695 new 4,400 total	1,795 new 5,500 total

*Based on information in the Ravalli County Economic Needs Assessment (Swanson 2002).

Housing

Under the No Action alternative, annoyances attributed to the proposed Integrated Research Facility construction phase would not occur, and neighbors would not be as concerned about the biological agents used at the Integrated Research Facility.

Housing starts would continue at the same pace as under the Proposed Action, although houses may remain on the market longer with fewer qualified buyers. Housing prices or property values are expected to remain at current levels and to increase or decrease following the real estate market in Hamilton.

Community Safety

Current levels of community services, emergency response training and programs, and infrastructure would not change under the No Action Alternative. Infectious diseases would still be studied in the BSL-2 and BSL-3 laboratories at RML. Reasonably foreseeable actions such as completion of community emergency response protocols are defined in Cumulative Effects, below.

Transportation

The current use of streets by neighborhood residents and RML employees would continue.

4.2.2 Cumulative Effects

Population and Demographic Trends

Population change results from both migration (the number of people moving to an area and away from an area) and natural change (the number of area births and deaths). Natural change alone would lead to a decreasing population in Ravalli County because of a decreasing birth rate and a stable death rate. Assuming that recent population growth trends based on net in-migration to the valley continue during the decade, the Ravalli County Economic Needs Assessment (Swanson 2002) predicts that growth will range from two to four percent per year because "the factor most affecting future growth is what will happen to perceptions of the valley's attractiveness as this fast growth continues and increasingly takes its toll on the very thing enticing more people to move to the valley – the area's scenic qualities and rural character." The population may grow to between

44,000 and 54,000 people by 2010 (**Table 4-2**), leading to lower-end increases of at least 8,000 people, or approximately 800 people per year, and up to 18,000 people, or 1,700 people per year on the higher end. These growth projections do not include additional employment at RML.

Housing

According to the Ravalli County Growth Policy (2002), future trends are difficult to predict, although continued, scattered residential development is expected. Between 3,200 and 6,800 new homes would be needed by 2010 to accommodate projected growth. According to the Ravalli County Economic Development Authority, about 500 homes have been constructed each year since 2000 at prices ranging from $150,000 to $170,000. Commercial and industrial development is expected near existing service centers and along U.S. Hwy 93. Missoula would continue to be the regional economic center.

Community Safety

Under the Proposed Action or No Action alternatives, reasonably foreseeable actions would be completed to improve community safety, including: construction of a new perimeter fence; relocating the main and receiving gates; construction of a new security guard station; installation of a card reader system; installation of security cameras on campus; construction of a new receiving building; and construction of a landscaped crash barrier at 4th and Grove Streets in Hamilton. Additional security guards and NIH police officers would be hired to provide added security and safety. Procedures and protocols would also be established with local emergency response agencies to address responsibilities of each agency in the event of an emergency at RML. Work with infectious agents at the BSL-2 and BSL-3 levels would continue in existing laboratories.

Transportation

Residential traffic is expected to increase at a rate of 1.5 percent per year (Morrison Maierle 2002). Experienced and expected peak hour traffic for 2002 and 2006 is shown in **Table 4-1**. The predicted increase in traffic from residents is four percent (10 trips). When added to the 16 percent increase from the Integrated Research Facility, the result is an overall 20 percent increase.

Reasonably foreseeable actions (described on page 4-1), would result in changes in traffic patterns after construction for employees of RML, as well as changes in the parking situation. Under either alternative, combined with reasonably foreseeable actions, neighborhood parking and traffic would be expected to improve. More off-street parking would be provided for cars at the entrance gate. Additional on-campus parking would be provided for visitors and employees, alleviating parking concerns for residents living near RML. Deliveries to RML would also occur through a gate along the northern boundary of the property near 5th and 6th streets, reducing congestion problems associated with the existing gate at 4th and Grove streets.

4.3 ECONOMIC RESOURCES

4.3.1 Direct and Indirect Effects

4.3.1.1 Proposed Action

Income

According to the Ravalli County Economic Needs Assessment (Swanson 2002), RML is the fourth most important asset of current and potential key economic assets of the county because it "provides area employment for highly educated and well-trained workers and brings large infusions of outside money to the area that finance the laboratory's work." The mere presence of such a laboratory in an expanding field of bioscience research creates an environment for certain types of business development that may be associated with the laboratory's work. The scientific sophistication of this work requires that such businesses have high quality and highly trained workers. This creates the opportunity for expansion of higher paying, higher quality jobs.

The Proposed Action would have direct economic impacts on both the City of Hamilton and Ravalli County throughout construction and operation. Construction workers may temporarily affect the rental market, which is already limited in Hamilton. Sufficient numbers of qualified construction workers may be hard to find in Ravalli County, and the majority of workers may commute from Missoula County for the duration of the Project.

Local retail trade would increase during the construction period. Average construction wages in Ravalli County were $23,653 in 2000. Total annual construction wages are estimated to be $4.7 million. At the current estimated economic multiplier for wages paid from "outside" the community (Nicholson 2002), the maximum expected increase in economic activity would be $18.9 million over the two-year construction period.

When the facility is fully operational, up to 100 new employees would be hired. Because of the specialized nature of the work, the work force would probably be recruited predominately at the national level (65 percent) and from colleges and universities in Montana. The total wages to be paid per year is estimated by RML at $6.6 million. Added to the current $10.4 million annual payroll, RML would contribute $17 million in wages annually. At the current estimated economic multiplier for wages paid from outside the community (Nicholson 2002), RML would contribute $34 million annually to the local economy. Government job growth is particularly valuable to the community because of the relatively high wages that add to the economic base (Nicholson 2002). RML and the proposed Integrated Research Facility meet community economic development goals in the Ravalli County Economic Needs Assessment (Swanson 2002), Ravalli County Growth Policy (2002), and the City of Hamilton Comprehensive Master Plan (1998).

Government and Public Finance

Public revenues would increase with increased income tax on construction and operation payrolls. Public revenues would also increase from the incomes of spouses and older children of RML employees, increased number of vehicles being licensed, and property tax revenues based on new homes and increased property assessments. Property taxes would increase as the needs of the county, cities, and special districts increase with new populations. Revenue or cost increases attributed to the Project would range from one to three percent of the total increased revenue and costs from the projected 8,000 to 18,000 new residents by 2010 (Swanson 2002).

4.3.1.2 No Action

Income

The No Action Alternative would not have direct economic impacts. There would be a minor increase in security staff at RML, but an opportunity to stabilize the local economy with government jobs would be lost, slowing the realization of local economic development goals.

Government and Public Finance

There would be no direct effect from No Action on government and public finance.

4.3.2 Cumulative Effects

4.3.2.1 Proposed Action

The Proposed Action would add new residents to a rapidly growing area, possibly adding stress to community service providers and infrastructure. The potential negative cumulative impacts of Corixa's expansion would include increased demands for housing, schools, and infrastructure. Based on the analyses of socioeconomic impacts for the Proposed Action, there would be adequate housing, school resources, and city infrastructure to accommodate the cumulative impacts of Corixa's and RML's expansions. Positive cumulative impacts from Corixa's expansion would be creation of new high-paying jobs and economic stability for Hamilton and Ravalli County.

4.3.2.2 No Action

Cumulative effects would occur from Corixa's expansion, which would have the same cumulative effects as the Proposed Action.

4.4 NOISE

4.4.1 Direct and Indirect Effects

4.4.1.1 Proposed Action

Construction Noise

During construction of the Integrated Research Facility at RML, short-term noise sources would include operation of heavy mobile equipment (e.g., bulldozers, backhoes, cranes, heavy trucks, pumps, generators, compressors, loaders, and compactors), use of power tools (e.g.,

jackhammers), and use of hand tools (e.g., hammers and drills). Equipment operation would vary considerably during the project and different days. During construction, heavy mobile equipment does not normally run continuously.

Each individual piece of construction equipment can typically generate noise levels up to 90 dBA at a distance of 50 feet from the equipment (USDOT 1995). However, equipment noise can vary considerably depending on age, condition, manufacturer, and use. Since noise is intermittent and the source can vary from day to day, it is difficult to determine the length of time that noise from a particular piece of equipment would persist during normal construction activities. The following construction noise level predictions are based on a conservative assumption that there would be five pieces of large mobile construction equipment operating simultaneously. Calculations indicate that the typical construction noise generated may equal the following approximate noise levels:

- 75 to 90 dBA along the north property line;
- 50 to 80 dBA along the south property line;
- 50 to 80 dBA along the east property line; and
- 65 to 85 dBA along the west property line.

The RML Campus Noise Level Criteria exempts construction noise activities, provided that the construction occurs between 7:00 am and 5:00 pm (Big Sky Acoustics 2003). Construction noise levels would be audible at the receptors located in the neighborhood adjacent to the RML campus. Noise may be considered intermittently adverse during various construction phases. Construction noise normally occurs during the day, and residents are generally less sensitive to noise during the day than at night. Construction noise mitigation measures are described in Chapter 2.

Integrated Research Facility

Noise sources associated with new equipment for the Integrated Research Facility include exhaust fans, air-handling units, cooling towers, and chiller operating simultaneously (for direct effects). Measures to reduce noise in the new operation are included in the design and described in Chapter 2.

Noise levels (**Table 4-3**) from the Integrated Research Facility due to simultaneous operation of the exhaust fans, air-handling units, cooling towers, and air-cooled chiller without the generator (typical daytime operations) would be designed to be less than 55 dBA on the property lines during the daytime. As indicated in **Table 4-3**, noise levels from the RML campus would generally be reduced from current levels. Testing of the emergency generator (which would only occur during the daytime) is expected to raise the noise level slightly, but daytime noise limits would not be exceeded at the property lines. At night, noise levels would not exceed 50 dBA. The Proposed Action would meet RML's new noise guidelines.

Table 4-3.
Estimated Cumulative Noise Levels

Location*	Current	Noise Level (dBA)
1	48	30-35
2	52	30-35
3	52	35-40
4	51	40-45
5	50	45-50
6	44	45-50
7	41	45-50
8	44	50-55
9	43	40-50
10	50	40-45
11	46	35-40
12	47	35-40
13	49	35-40

* See Figure 3-1.

4.4.1.2 No Action

Table 4-3 indicates the anticipated noise levels under the No Action Alternative for locations 1, 2, 3, 4, 9, 10, 11, 12, and 13 (**Figure 3-1**). Locations 5 though 8 would be lower, approximately 35 dBA, as noise in those locations would not be affected by the emergency generator. Noise mitigation devices have been ordered, but not all have been installed. Under the No Action Alternative, in all locations, noise would be similar or slightly reduced from current levels.

4.4.2 Cumulative Effects

Under both the Proposed Action and No Action alternatives, reasonably foreseeable changes in the entrance gate and employee parking area could result in a reduction in noise levels on the east side from traffic, while the north side may experience a slight increase. Additional traffic noise would be confined to periods when employees are arriving and departing. These changes would not exceed RML's draft noise guidelines.

Reasonably foreseeable noise reduction features would result in a slight reduction in noise overall as shown in **Table 4-3**. In some instances, noise would be reduced more than 10 dBA. **Table 4-4** describes how changes in noise levels are perceived. Noise is predicted to be approximately 50 dBA at the south property line and 51 dBA on the west side (2400 feet inside the property line) during daytime hours, meeting RML's draft guideline. Since predicted noise levels from the Proposed Action would be less than the current noise, cumulative effects for the Proposed Action and No Action are the same.

Table 4-4. Perception of Change in Loudness

Change in Sound Level (dBA)	Apparent Change in Loudness to a Person
±1	Imperceptible
±3	Barely audible
±6	Clearly audible
±10	Half as loud or twice as loud as the original noise (significant change)
±20	One quarter as loud or four times as loud as the original (very significant change)

4.5 VISUAL QUALITY

4.5.1 Direct and Indirect Effects

4.5.1.1 Proposed Action

The extent to which the Proposed Action would affect visual quality depends upon the amount of visual contrast created between the proposed facility and the existing condition. The main content of the Proposed Action is construction of the Integrated Research Facility building. In addition to construction of the laboratory facility, other components of the Proposed Action include an addition to the boiler plant and relocation of the chiller and associated fuel tank. These elements would be visible changes to the existing RML campus from Viewpoint 1 (**Figure 4-2**). Ventilation stacks on the Integrated Research Facility would not be visible from Viewpoint 1.

The primary visual impact of the Proposed Action would be addition of a large building introduced into an area of many smaller buildings (**Figure 4-2**). Use of red brick color and texture would blend with existing material throughout the campus. The boiler plant addition would be directly adjacent to the east side of Building 26. The addition would be smaller, but the additional stack would be the same height as the existing stack. The existing and proposed stacks would be about 40 feet apart and 37 feet high. Both stacks would offer linear contrast to surrounding structures.

Proposed landscaping would have an impact on visual quality. This area of the RML campus would be modified from existing vegetation (weeds) to grass and trees placed around the building and its associated paved parking area (reasonably foreseeable action). Open storage areas would be eliminated or relocated away from view. All construction trailers would be removed from RML.

4.5.1.2 No Action

There would be no change from the existing condition described in Chapter 3. Some of the construction trailers would be removed from RML.

4.5.2 Cumulative Effects

Reasonably foreseeable actions would have a visual impact on the RML campus. The addition of a nine- foot fence would interrupt the view of much of the ground level activity within the campus. Street side landscaping, including a sidewalk, would add pleasant views to the campus exterior. Other reasonably foreseeable actions include addition of buildings for visitors, receiving, and storage. Future construction of the receiving and storage building would partially or completely block the view of the Integrated Research Facility from Viewpoint 1.

4.6 HISTORICAL RESOURCES

The analysis of visual impacts on the Historic District requires an assessment based on the Criteria of Effect and Adverse Effect (36CFR 800.9). The Criteria of Effect are listed in Section 800.9(a) and state, in part, that "an undertaking has an effect on a historic property when the undertaking may alter characteristics of the property that may qualify the property for inclusion in the National Register."

The Criteria of Adverse Effect, listed in Section 800.9(b), results in one of three possible outcomes: no effects, no adverse effects, and adverse effects. No adverse effect occurs when there could be an effect, but it would not harm characteristics that qualify the property for the National Register. Adverse effect occurs when the integrity of those characteristics that qualify the property for the National Register could be diminished.

Impacts are measured by the visual character of the historic district, defined by pattern elements and pattern characters. The pattern elements are form, line, color, and texture. The pattern characters are dominance of development, scale of development, diversity of development, and continuity of development pattern (Montana State Historic Preservation Office, 1994). A score of:

0 indicates the element or character is absent;

1 indicates the element or character is present;

2 indicates the element or character has a moderate prominence;

3 indicates the element or character has a high prominence within the view.

4.6.1 Direct and Indirect Effects

4.6.1.1 Proposed Action

The Integrated Research Facility, Building 28, would be a three-story Modern Architecture style structure located north of Building 25, set back from the Historic District. The north elevation would be comprised of a glass curtain wall with projected horizontal and vertical mullions. The other three elevations would share characteristics, including common bond cement blocks on the main story, metal doors, metal clad single-pane fixed windows, and corrugated metal siding on the remaining stories with a pre-finished metal roof. The boiler plant expansion would be an addition to Building 26. The addition would be two stories that would extend across half of the east elevation of Building 26 and a stack extending upward the same distance as the current one (37 feet) on the existing boiler plant. The expansion would have common bond concrete masonry on the main floor with metal siding above. Metal clad fixed windows would be located on the south elevation and the roof would be pre-finished metal.

The RML Historic District is only partially visible from the site of the proposed Integrated Research Facility (**Figure 4-3, Figure 4-4,** and **Figure 4-5**).

Several existing structures, including Buildings 26, 20, 13, and 16, block the view of the historic district from the proposed site. Only portions of Buildings 7 and 6 in the historic district are visible from the site of the Integrated Research Facility. The boiler plant expansion would be located on the east elevation of Building 26. Building 13 blocks the view of the Historic District from the proposed site of the Integrated Research Facility; however, the stack for the new boiler would be visible.

The visual character pattern elements can be characterized by scores of 1 for form, 1 for line, 1 for color, and 1 for texture. A score of 1 reflects that the pattern elements are present in the view shed.

The combined score of pattern elements is 0.25. The pattern characters of dominance, scale, diversity, and continuity have the score of 0.25.

Applying the Criteria of Effect results in a finding of "no adverse effect" on the Historical District. The no adverse effect rating recognizes there could be an effect on the Historic District, but that the effect would not be harmful to the qualities that are inherent in the RML Historic District.

4.6.1.2 No Action

Under this alternative, there would be no change in the visual impact and therefore there would be a finding of no effect.

4.6.2 Cumulative Effects

Reasonably foreseeable actions could have an effect on the historical resources of RML.

Graphics/projects/rml/simulation

Source: CUH2A Smith Carter (2003)

Visual Simulation of Proposed IRF
RML Integrated Research Facility FEIS
Hamilton, Montana
FIGURE 4-2

Figure 4-3. Overview, facing northeast toward proposed location

Figure 4-4. Overview proposed location, facing east toward historic district

Figure 4-5. Overview from physical plant, Building 7, facing west toward proposed construction site.

fence and the road barrier at the corner of 4th and Grove streets would occur within the historic district. The new visitor center and guard station would be visible from the Historic District. At this time, the State Historic Preservation Office (SHPO) has been contacted by RML concerning the reasonably foreseeable actions to allow for review of potential historical resource effects. Since final design of the reasonably foreseeable action has not been completed, continued coordination with SHPO would be completed by RML to ensure issues are addressed, and would result in no adverse effect on the historic district.

4.7 AIR QUALITY

4.7.1 Direct and Indirect Effects

4.7.1.1 Proposed Action

Gaseous and particulate air contaminant emissions are generated during normal laboratory operations at RML. The Proposed Action would increase the overall emissions at RML. Buildings would require steam for heating, autoclaving, and other needs.

Electrical power and natural gas for the Integrated Research Facility and support buildings would be provided by the local utility. Backup (emergency) power for the new laboratory would be provided by a new diesel generator. Incinerator use is estimated to increase from approximately two to three days a week to three to four days a week.

Emissions

Emission points associated with the Proposed Action at RML would not be any closer to population centers or critical air quality receptors since the new laboratory building and boiler would be within the perimeter of RML campus and existing incinerators would be used.

The State of Montana recognizes the use of incineration as a legitimate means of handling infectious or pathological waste. MCA 75-10-1005(4)(a) states, "Treatment and disposal of infectious waste must be accomplished through the following methods: (i) incineration with complete combustion...(ii) steam sterilization...or (iii) sterilization of standard chemical techniques..."

Construction activities associated with the Proposed Action would generate short-term air impacts. These impacts would result from fugitive

dust and gaseous emissions associated with construction equipment. Fugitive dust would be controlled through dust control measures. Gaseous emissions would be controlled through management of construction work hours. Overall, fugitive dust emission resulting from current exposed ground areas would decrease due to site improvements such as vegetation/landscaping and asphalt parking areas.

Air quality impacts resulting from additional natural gas usage at RML are anticipated to be minor (MDEQ 2003). Impacts on air quality would not result from emissions due to increased use of natural gas since sufficient capacity is available from the utility. Additional exploration for natural gas would not be needed to supply the Integrated Research Facility. Additionally, no air quality impacts would result from increased electrical demand since electricity is supplied by Kerr Dam, near Polson, Montana, which has surplus power on the grid.

Table 4-5 contains information on potential emissions from RML, including those associated with the Proposed Action. Values are estimated maximums from the facility and are based on 8,760 operating hours per year (24 hours per day and 365 days per year). For those components that have conditions limited by an operating permit (e.g., operational hours less than 8,760), those limits were used in the potential emission calculation shown in the table.

Air Quality Permit

The air quality permit specifies limits for incinerator charging rate, natural gas usage (for boilers and incinerators), and emergency generator run hours. The permit also specifies reporting requirements to document status of compliance with permit conditions. Additional activities that ensure facility compliance include emission testing and inspections by MDEQ. If the permit conditions are not met (e.g., emission limits exceeded), MDEQ may issue a notice of violation.

The air quality permit technical analysis conducted by MDEQ for permit 2991-04 includes the proposed boiler, emergency power generators, and increased incinerator. Based on review of the application and state and federal rules and regulations, MDEQ has determined that the proposed Project would comply with all applicable ambient standards and meet the provisions of ARM Title 17. MDEQ will continue to monitor activities at RML to ensure compliance with applicable air quality regulations (**Table 4-5**).

Class I Areas

The air modeling analysis conducted for RML predicted air emission would be within Montana and federal air quality standards. These emissions are not expected to visibly affect or modify air quality in Class I areas.

4.7.1.2 No Action

Emissions

Emissions would remain at current levels under the No Action Alternative (See **Table 4-5**).

4.7.2 Cumulative Effects

Under the Proposed Action, the minor increase in emissions would be added to emissions from the other 11 permitted sources in the county. A decrease in particulate matter emissions from reasonably foreseeable actions would occur as undeveloped areas are used for buildings and paved for parking. Since the Proposed Action would comply with ambient air quality standards, cumulative effects would be minimal.

4.8 WATER SUPPLY AND WASTEWATER

4.8.1 Direct and Indirect Effects

4.8.1.1 Proposed Action

Hamilton Water System

The CHDPW system is currently capable of producing a maximum of 2,350 gallons per minute (gpm). The highest production month in 2002 was July when an average of 1,786 gpm was produced (CHDPW 2002). This data indicates that there was about 560 gpm additional production capacity during the period of highest reported demand on the system (July 2002). A certain amount of water is lost through line leakage, recharging the shallow aquifer from which the groundwater is pumped. Assuming that 60 percent of this production capacity is lost to leaks in the Hamilton system, (see Water Supply section in Chapter 3), an

Table 4-5.
RML Emissions

Source	NOx		SOx		CO		PM_{10}		VOCs	
No Action Alternative (Existing) Emissions										
Incinerators (a)	0.8	tons/yr	0.7	tons/yr	0.8	tons/yr	1.6	tons/yr	2.6	tons/yr
	0.2	lbs/hr	0.2	lbs/hr	0.2	lbs/hr	0.4	lbs/hr	0.6	lbs/hr
Steam Generating	10.2	tons/yr	0.1	tons/yr	8.6	tons/yr	0.8	tons/yr	0.6	tons/yr
Boilers (a)	2.3	lbs/hr	0.0	lbs/hr	2.0	lbs/hr	0.2	lbs/hr	0.1	lbs/hr
Emergency Power	14.6	tons/yr	4.4	tons/yr	3.3	tons/yr	0.5	tons/yr	0.5	tons/yr
Generators	58.2	lbs/hr	17.7	lbs/hr	13.3	lbs/hr	2.0	lbs/hr	2.1	lbs/hr
Fuel Tanks	na		na		na		na		0.0	tons/yr
Preferred Alternative Emissions										
Incinerators (b)	1.2	tons/yr	1.1	tons/yr	1.2	tons/yr	2.3	tons/yr	4.0	tons/yr
	0.3	lbs/hr	0.3	lbs/hr	0.3	lbs/hr	0.5	lbs/hr	0.9	lbs/hr
Steam Generating	15.3	tons/yr	0.1	tons/yr	12.9	tons/yr	1.2	tons/yr	0.8	tons/yr
Boilers (b)	3.5	lbs/hr	0.0	lbs/hr	2.9	lbs/hr	0.3	lbs/hr	0.2	lbs/hr
Emergency Power	21.8	tons/yr	6.6	tons/yr	5.0	tons/yr	0.7	tons/yr	0.8	tons/yr
Generators	87.4	lbs/hr	26.6	lbs/hr	19.9	lbs/hr	3.0	lbs/hr	3.1	lbs/hr
Fuel Tanks	na		na		na		na		0.0	tons/yr
Potential to Emit (Maximum Permitted) Emissions										
Incinerators (c,d)	3.3	tons/yr	3.1	tons/yr	3.2	tons/yr	6.5	tons/yr	11.0	tons/yr
	0.8	lbs/hr	0.7	lbs/hr	0.7	lbs/hr	1.5	lbs/hr	2.5	lbs/hr
Steam Generating	42.4	tons/yr	0.3	tons/yr	35.6	tons/yr	3.2	tons/yr	2.3	tons/yr
Boilers (c)	9.7	lbs/hr	0.1	lbs/hr	8.1	lbs/hr	0.7	lbs/hr	0.5	lbs/hr
Emergency Power	60.4	tons/yr	18.4	tons/yr	13.7	tons/yr	2.1	tons/yr	2.1	tons/yr
Generators (e]	241.6	lbs/hr	73.5	lbs/hr	55.0	lbs/hr	8.2	lbs/hr	8.6	lbs/hr
Fuel Tanks	na		na		na		na		0.0	tons/yr

Note: NOx = nitrogen oxides; SOx = sulphur dioxides; CO = carbon monoxide; PM_{10} = particulate matter < 10 microns; VOCs = volatile organic compounds; lbs/hr = pounds per hour; tons/yr = tons per year; na = not applicable

(a) Based on actual facility natural gas usage March 2002 to February 2003: 204 million cubic feet/yr of natural gas
(b) Based on a 50% increase in fuel needs over existing usage
(c) Permit conditional limit of 847 million cubic feet/yr of natural gas
(d) Permit conditional limit of 3504 tons/yr
(e) Permit conditional limit of 500 hours/yr

Source: MDEQ 2003 (Potential to Emit)

additional capacity of about 226 gpm is available for new customers.

The number of employees at RML is expected to increase by approximately 30 percent with the completion of the Integrated Research Facility.

Water consumed at RML is used for drinking water, research experiments, sewage, and industrial process such as boiler water. Work that would be performed at the Integrated Research Facility would be similar to work performed elsewhere on the RML campus. Therefore, experimental, drinking water, and sewage uses may be expected to increase commensurate with the increase in workers. A new boiler is planned as part of the Integrated Research Facility

construction so there would also be an increase in industrial usage. Based on this information, and Hemisphere's (2003) estimated current water usage for RML of 56,000 gallons per day, water consumption at RML would increase by up to 30 percent to about 73,000 gallons per day (an increase of about 17,000 gallons per day or 12 gpm) if the Integrated Research Facility were constructed. This compares with Hemisphere's (2003) estimate of 15,000 gallons per day of effluent from the Integrated Research Facility.

The estimated increase of 17,000 gallons per day represents about a one percent increase in the amount of water distributed by the CHDPW on a daily basis. With respect to available capacity, the Integrated Research Facility would use about 5.3 percent (12 gpm of 226 gpm) of system capacity. Increased demand for water created by operation of the Integrated Research Facility would have a minor impact on the CHDPW municipal water supply system, and the system would be able to handle the increased demand, even with an assumed leakage of 60 percent.

Section 4.2.1.1 estimated that 100 new employees would be added at the facility by 2006 and that households in Ravalli County have an average of 2.45 residents per household. Assuming that thirty percent of the new employees live in Hamilton, and assuming each household has 2.45 people, 30 new households having 75 new residents would result from employment at the Integrated Research Facility. If each person uses an average of 150 gallons per day, there would be an average increased daily usage of 11,250 gallons per day per household. Assuming that all 30 new households are single-family dwellings on half-acre lots and use an average of 1,305 gallons per day to irrigate lawns for 120 days per year, the average amount of water used per household for irrigation would be 12,871 gallons per day. If the estimated increase usage from RML is added to the new resident usage and irrigation, the total increase would be 41,121 gallons per day, or 28.5 gpm during the irrigation season. This would increase the daily quantity of water sold by the CHDPW by about six percent. The existing Hamilton water supply system can adequately supply water for the Integrated Research Facility and water for irrigation and other household purposes for 30 new households. Even if all the new employees chose to live in the service area of the water system, the amount of increased water usage is estimated at 55 gpm, or roughly 24 percent of the available capacity of 226 gpm.

Groundwater

Section 3.8 of Chapter 3 provides an estimate of the amount of water available in the shallow aquifer below Hamilton on a daily basis. An increased use of 17,000 gallons per day by the Integrated Research Facility is estimated to be 0.2 percent of the water available in the portion of the aquifer supplying Hamilton on a daily basis. An increase of 41,121 gallons per day (Integrated Research Facility, households, and irrigation) represents about 0.6 percent of the amount available in the limited portion of the aquifer supplying Hamilton on a daily basis. Therefore, the Proposed Action would depreciate the amount of groundwater available on a daily basis (daily flux in the aquifer) by less than 1.0 percent.

The estimate of aquifer yield clearly shows that groundwater supply is not a limiting factor with respect to construction of the Integrated Research Facility, and the estimate is conservative for several reasons. There is considerably more groundwater flowing beneath the Hamilton area than the calculations shown in Chapter 3, Section 3.8, account for. There are reportedly up to 2,400 feet of unconsolidated sediments underlying the shallow aquifer in Hamilton (USGS 2000). These are ancestral Bitterroot River Deposits that form another aquifer beneath the aquifer currently supplying water to Hamilton. This deeper aquifer contain a larger quantity of groundwater than the shallow aquifer that is currently being utilized. There are also unconsolidated sediments west of the Bitterroot River that are a source of water for many residences west of the river. Hamilton does not currently use these groundwater sources but could in the future, if needed.

Wastewater Treatment

Wastewater discharge at RML would increase the average load by about 17,000 gallons per day (Hemisphere 2003) to about 73,000 gallons per day upon completion of the Integrated Research Facility. The CHDPW wastewater treatment plant is currently operating below design capacity in terms of average and peak flow per day. New

homes built in Hamilton as a result of new employees moving to the area would increase this further. An increase of 15,000 gallons per day of effluent from RML would use some of the additional plant capacity, but would not require an upgrade to provide additional treatment capacity. This compares with Hemisphere's (2003) estimate of 15,000 gallons per day of effluent from the Integrated Research Facility.

Solids removed from the effluent stream are collected as sludge and stored. The CHDPW has reached its solids handling capacity, and the city of Hamilton is planning to construct a temporary solids storage basin to meet current requirements in the interim until a facility expansion plan is prepared (HDR 2003). The CHDPW would need to upgrade solids handling capacity even if the Integrated Research Facility were not built.

The estimated volume of solids in RML's current wastewater stream is small relative to the volume of liquid (Lowry 2003). New operations at the Integrated Research Facility would increase the solids load in wastewater from RML. Based on concentration and solids volume data (Hemisphere Engineering 2003b) for wastewater leaving the Integrated Research Facility, the additional solids produced at the CHDPW as a result of the Proposed Action would be approximately 28 pounds per day, or 10,183 pounds per year. The amount of solids in Integrated Research Facility effluent was estimated using the following calculation from Metcalf and Eddy (1991):

$$M_{Solids} = Q_{Inf.} \times [(BOD_{RMLeff.} - BOD_{CHDPWeff.}) \times NVF + (TSS_{RMLeff.} - TSS_{CHDPWeff})] \times 8.34$$

Where:

M_{Solid} = Mass of removable solids in pounds (lbs)

$Q_{Inf.}$ = Flow rate from RML in million gallons per day (0.015 MG/day)

$BOD_{RMLeff.}$ = Biological Oxygen Demand in RML wastewater (200 mg/L)

$BOD_{CHDPWeff.}$ = BOD limit in CHDPW effluent (10 mg/L)

NVF = nonvolatile fraction of BOD (70%)

$TSS_{RMLeff.}$ = Total Suspended Solids in RML wastewater (100 mg/L)

$TSS_{CHDPWeff.}$ = TSS limit in CHDPW effluent (10 mg/L)

8.34 = conversion factor [(lbs/MG)/(mg/l)]

Approximately 1,000 to 1,200 pounds of solids per day are currently handled at the CHDPW. (Lowry 2003). The 28 pounds of additional solids generated by the Integrated Research Facility represents a 2.3 to 2.8 percent increase in solids load to the CHDPW wastewater facility.

The Proposed Action would not have an impact on the solids handling capacity at the CHDPW because the planned upgrade of the solids handling capacity at the facility would accommodate current and future needs of Hamilton as well as additional solids produced by the Integrated Research Facility.

4.8.1.2 No Action

Hamilton Water System

The No Action Alternative would not have an impact on water supplies in Hamilton or the Bitterroot Valley.

Groundwater

The No Action Alternative would not have an impact on the water source in Hamilton or the Bitterroot Valley based on the estimate of aquifer yield provided in Chapter 3, Section 3.8.

Wastewater

The No Action Alternative would not have an impact on wastewater treatment in Hamilton. The No Action would not have an impact on the solids handling capacity of the plant.

4.8.2 Cumulative Effects

Hamilton Water System

Corixa Corporation operates a private laboratory northeast of Hamilton and is planning to expand the facility beginning in 2003. This expanded facility will receive water from CHDPW. CHDPW anticipates the Corixa facility will require an average of 50,000 gallons per day (35 gpm) of water from the system (Lowry 2003).

The total increased water usage from the Integrated Research Facility, new households (irrigation and non-irrigation), and Corixa's facility is estimated at 539,628 gallons per day, or 374 gallons per minute. This would increase CHDPW current distribution of water by approximately 8.5 percent, and exceed the current availability of

municipal system (226 gpm). However, the potential cumulative effects on the Hamilton Water System are tempered by planned upgrades to the municipal water supply to offset anticipated increases in demand for water. CHDPW plans to bring three new water supply wells on-line to supply an additional 2,500 gpm (Lowry 2003). They also plan to abandon two existing wells that are currently in poor condition that produce a combined 1,300 gpm. The planned upgrades to the system would provide a net gain in production capacity of about 1,200 gpm, more than the cumulative demand on the system of 374 gpm.

Several conservative assumptions were also used in estimating the cumulative demand on the system, including:

- The highest estimated influx of people (18,000 persons) to the area would occur by 2010;
- Ten percent of those relocating to Ravalli County would live in Hamilton. This was based on the current statistics at the Ravalli County Chamber of Commerce;
- Each person uses 150 gallons per day of water;
- New residents live in households with 2.45 residents each;
- Half of the households are multifamily units using minimal irrigation, and the other half are single-family dwelling residences on half-acre lots that use an average of 1,305 gallons per day to irrigate lawns;
- Irrigation season is 120 days per year; and
- Sixty percent of water produced by the system is unaccounted for, leaking out of supply lines.

The increases realized by installing new wells and repairing leaks would provide adequate capacity to supply the increased demand of RML, Corixa, and new homes.

Groundwater

If there is an increased cumulative demand on the Hamilton municipal system of 539,628 gallons per day (see estimate above), approximately 19 percent of the daily amount of groundwater available (flux) in the shallow aquifer beneath Hamilton would be used. (See calculations in Chapter 3, Section 3.8). The underlying aquifer is capable of providing a sufficient amount of groundwater for the projected cumulative demand.

Wastewater

The expanded Corixa facility would be connected to the CHDPW wastewater system (Lowry 2003). CHDPW anticipates that the Corixa facility would discharge approximately 50,000 gallons per day of effluent to the sanitary sewer system. New homes and businesses would be built in the Hamilton area that will be connected to the CHDPW wastewater system. It is possible that within this period, the current wastewater treatment plant would need to be expanded to increase the capacity to treat combined increase in effluent coming from the Proposed Action, Corixa's facility, and new home and business construction. It is also possible that CHDPW wastewater treatment plant would need to be expanded under the No Action alternative due to combined discharges of Corixa's facility and new home and business construction.

Because the solids handling capacity of the wastewater plant would be expanded, reasonably foreseeable activities are not expected to have an impact on the solids handling capacity of the plant.

4.9 UNAVOIDABLE ADVERSE IMPACTS

Unavoidable adverse effects are undesirable effects that cannot be avoided if the Proposed Action or any alternative is implemented.

No unavoidable adverse effects have been identified from implementation of the Proposed Action.

4.10 RELATIONSHIPS BETWEEN SHORT-TERM USE VERSUS LONG-TERM PRODUCTIVITY

Short-term uses associated with the Proposed Action would result in construction and operation of an Integrated Research Facility on the RML campus where other laboratories and office buildings currently exist. Land where the Integrated Research Facility is proposed to be built would be obligated for the duration of the need for the laboratory structure. No action taken in the construction and operation of this facility would preclude returning the land to its current status or to another use in the future.

Continued and future research at RML would have the potential to maintain long-term productivity because of opportunities to develop vaccines, diagnostics, and treatments to control or avoid the effects of infectious disease outbreaks in the world community. Control or avoidance of these effects would result in increasing the productivity and lives of people throughout the world.

4.11 IRREVERSIBLE AND IRRETRIEVABLE COMMITMENTS OF RESOURCES

An irreversible commitment of resources associated with the energy (e.g., electricity, natural gas, fossil fuels) and building materials (e.g., copper wire and piping, brick, steel, concrete, glass, aluminum and other metals) used to build and operate the facility is expected to result from implementation of the Proposed Action. Commitment of these resources could not be reversed, although some materials may be recycled and reused.

An irretrievable commitment of resources would occur from the use of wood in building materials and change in land use for the Integrated Research Facility. Commitment of these resources would be reversible in the long term (beyond 100 years).

CHAPTER 5
RESPONSE TO COMMENTS

DEIS Comment Period

The comment period on the DEIS began on May 23, 2003, with the Notice of Availability that appeared in the Federal Register.

In response to comments on the DEIS, NIH decided to issue a Supplemental Draft EIS (SDIES), which provided more information and more clearly displayed how scoping comments and comments on the DEIS were addressed.

SDEIS Comment Period

The SDEIS was issued on December 29, 2003, with a Notice of Availability that appeared in the Federal Register. A 45-day comment period was allowed. Comments postmarked (or e-mailed or faxed) by February 11, 2004, appear in this chapter. Comments postmarked or received after February 11, 2004, were considered, but no formal response appears. Comments in late responses were similar to the comments below. A public meeting was held on January 22, 2004, where oral comments were taken. Comment from the public meeting can be found in Letter 39 - Public Meeting beginning on page 5-54.

Response to Comments

Each comment letter, e-mail or fax was given a document number and electronically scanned. Minor adjustments may have been made to the scanned file for size, or removing smudges or lines to improve the appearance. Substantive comments were marked with a bracket and given a number, which corresponds with a response found on the right side of the page. No other changes, such as editing or deletions, were made to the documents before they were inserted into this chapter.

Substantive comments were also given sequential numbers, starting over with "1" at each new letter. Comments appear with their letter number followed by the comment.

Agencies must assess and consider comments received on a DEIS. The Council on Environmental Quality NEPA implementing regulations §1503.4(a) lists the following possible responses:

1) Modify alternatives including the proposed action.
2) Develop and evaluate alternatives not previously given serious consideration by the agency.
3) Supplement, improve, or modify its analyses.
4) Make factual corrections.
5) Explain why the comments do not warrant further agency response, citing the sources, authorities, or reasons which support the agency's position and, if appropriate, indicate those circumstances which would trigger agency reappraisal or further response.

Comments were reviewed to determine where flaws in the analysis may have occurred or where mitigation measures may be necessary. When appropriate, changes have been made in the FEIS to address comments. The responses to individual comments reflect where changes have been made or why no change was made. Many comments were addressed in the SDEIS, but were made again. The response to these comments points to the location in the SDEIS where these comments were addressed. The same sections appear in the FEIS.

Many other comments were made which did not merit a response, although they will be considered by NIH in their final decision. These comments generally show support for or opposition to the project, provide personal background information, or contain other information to which a response is not needed.

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Nottingham, Valerie (NIH/OD/ORF)

From: Ira T. Holt [irachar@bitterroot.net]
Sent: Monday, January 19, 2004 2:10 PM
To: ORS RMLEIS (NIH/OD/ORS)
Subject: Supplemental Draft EIS for RML

I have reviewed the Dec 2003 copy of the EIS and believe that the few shortcomings I thought were in the original have been taken care of. The additional data on existing level 4 facilities was the main thing I thought lacking in the original. I have nothing further to add to my original comment that I fully support the proposed action. Thank you-
Ira T. Holt
548 Cielo Vista
Hamilton, MT 59840
406-961-3302

002

Nottingham, Valerie (NIH/OD/ORF)

From: WWFE [wwfe@ism.net]
Sent: Friday, January 16, 2004 9:25 AM
To: ORS RMLEIS (NIH/OD/ORS)
Subject: Rocky Mountain Labs

Hello Valerie Nottingham,

I wish to state my opposition to building a high containment facility at the Rocky Mountain Laboratories in Hamilton, Montana.

2-1 The most dangerous pathogens in the world should be studied in the very locations most likely to be attacked. This lab should be built, for example, in the Pentagon, in Washington DC, not in rural Montana. This is a safety issue. If the pathogen labs are housed in a vitally critical location such as The Pentagon, I would be most assured of the absolute safety of the research.

Please do not permit a BSL-4 lab to be built in Hamilton, Montana.

Sincerely,

Gene Bernofsky
243 Mount Avenue
Missoula, Montana 59801

LETTER 1 - IRA T. HOLT

LETTER 2 - GENE BERNOFSKY

Comment	Response
2-1	Please see Sections 2.2.2 and 4.2.1 where this comment was addressed.

003

Nottingham, Valerie (NIH/OD/ORF)

From: Baltimore, David
Sent: Monday, January 19, 2004 1:20 PM
To: ORS RMLEIS (NIH/OD/ORS)
Subject: to Valerie Nottingham, Re: SDEIS for RML

Dear Ms. Nottingham,

I have read the Supplemental Draft EIS for the proposed BSL-4 facility at the Rocky Mountain Laboratories in Hamilton, MT. I own property and a home in Hamilton and am in the process of making a major investment in the property. I am also a virologist, in fact a Nobel Laureate for my work in virology, and the President of the California Institute of Technology.

I am totally convinced by the SDEIS and by everything I know about high containment facilities that the proposed laboratory will be safe for the residents of Hamilton, even those living closest to the laboratory. The danger in such facilities is quite minimal and then wholly focused on the workers who actually manipulate the virus and virus-infected materials. The idea that an epidemic might occur deriving from activities in the laboratory is not a credible concern to me.

I strongly urge that the BSL-4 facility in Hamilton be built. It will be an important contribution to the national effort to combat terrorism. It will also be of great assistance in dealing with emerging infectious agents like the SARS virus, which are sure to continue to be a problem in America and the world. America needs such facilities. Finally, the existence of the facility in Hamilton will attract skilled personnel to the area and increase the economic, educational and cultural base of Hamilton and Ravelli County.

Thank you for giving me the opportunity to comment on this issue.

Sincerely,

David Baltimore
--
****
David Baltimore
President
California Institute of Technology
Mail Code 204-31
Pasadena, CA 91125

Phone: 626-395-6301
Fax: 626-449-9374

LETTER 3 - DAVID BALTIMORE

LETTER 4 - EARL POLLARD

004 Page 1 of 2

Nottingham, Valerie (NIH/OD/ORF)

From: Earl Pollard [emp@cybernet1.net]
Sent: Saturday, January 03, 2004 11:44 AM
To: ORS RMLEIS (NIH/OD/ORS)
Cc: Bloom, Marshall (NIH/NIAID)
Subject: Fw: Response to RML/ EIS
Follow Up Flag: Follow up
Flag Status: Flagged

Vallerie Nottingham:
My original comments I sent Friday, January 02, 2004, 3:24PM contained a serious omission of the word "not" which I have corrected herein. The second paragraph,7th line should now read ".....he does not speak for even one percent of the citizens of the area...." I appologize for the blunder. Please destroy the initial letter and replace it with these corrected comments.
Earl Pollard
----- Original Message -----
From: Earl Pollard
To: orsrmleis-r@mail.nih.gov
Cc: mblooM@niaid.nih.gov
Sent: Friday, January 02, 2004 3:24 PM
Subject: Response to RML/ EIS

Vallerie Nottingham:
I have received a copy of the EIS and read the entire publication. The previous draft was a good document. The latest report is better. Specifically, the deeper coverage of safety considerations is more comprehensive and should be of great benefit to the vary few detractors who oppose the project. I have written before so I am repeating myself when I write that I reside approximately 100 yards from the North boundary fence line of the RML campus with a direct line of sight to the new level 3 installation. As a member of the Hamilton community with the aforementioned special circumstance I am perfectly at ease with the EIS and look forward to the new facility. My wife and I moved into our new home during the construction of the level 3 lab and watched that project develop to completion.
Now a word about the so-called opposition to the level 4 lab and the entire RML facility. The principle local opposition claims to be the Friends Of The Bitterroot (FOB). Because of my interest in this organization's opposition I attempted to obtain a membership list. Such a list was not available.Apparently the individual who claims to be the spokesman is speaking for himself, which in this case I expect nothing more from this person. Even if he is an authentic spokesman for something called the FOB, he does not speak for even one percent of the citizens of the area including Hamilton. I seriously question that he even speaks for the members of the FOB, whomever they may be. So, when he complains about the lack of attention to the concerns of the citizens of the area I believe he is talking nonsensical claptrap. The second most prominent opponent claimed to represent a shadow organization that stated their goal was a safe lab. Again, a roster of this organization is not available. Actually this spokesperson is on record calling for closing the entire RML.

004a

This "organization" has now metamorphosed into a collection of "professional" protestors who have no connection to Hamilton or the surrounding area. I understand the original spokesperson is at this time one a group of plaintiffs suing the Federal Government for multimillion dollars stemming from the fires of 2000. This would seen to raise a question of conflict of interest.

These words about the opponents to the RML are provided because in my experience your bureaucratic remoteness from the Bitterroot Valley may make it very difficult for you to appreciate the dynamics of the area and possibly cause a distortion of your impressions of the true import of the RML opposition. If I have raised some questions check them out yourself.

Earl Pollard
691 Desta St.
Hamilton

005

Nottingham, Valerie (NIH/OD/ORF)

From: jill davies [rivercare@blackfoot.net]
Sent: Monday, January 12, 2004 12:42 PM
To: Ask RML (NIH/NIAID); ORS RMLEIS (NIH/OD/ORS)
Subject: disease agents at RML

Follow Up Flag: Follow up
Flag Status: Flagged

folks -
I have the Supplemental Draft EIS for the RML proposal to become a
Level 4 lab. App B - Characteristics of Diseases Studied at RML - lists
the disease agents that are at RML, but does not indicate what biosafety
5-1 level they are considered to be. The biosafety level information would
tell the public how each organism is to be handled.
Please send this information to me, either by email or by snail mail:

2397 Chief Victor Camp Rd.
Victor, Mt. 59875

Also, the SDEIS does not indicate exactly when the comment period
closes. Please advise.

thanks - Jill

~~ Jill Davies - - rivercare@blackfoot.net ~~
How we treat the Land is determined by how we view ourselves.
~~~~~The machine model kills living systems.~~~~~
406/ 642-3259

LETTER 5 - JILL DAVIES

Comment	Response
5-1	Diseases in Table B-1 are those currently or previously studied at RML. Those diseases have been studied in BSL-2 or BSL-3 laboratories. Table B-2, Characteristics of Viral Diseases Assigned to Biosafety Level 4, includes those that have to be studied in a BSL-4. The SDEIS states on page 4-5 that "it is not known specifically what agents would be studied at the Integrated Research Facility." This is because the study would depend on national needs at the time as well as emerging diseases not yet identified.
~~~~~

006

DEPARTMENT OF
PUBLIC HEALTH AND HUMAN SERVICES

JUDY MARTZ
GOVERNOR

STATE OF MONTANA

www.dphhs.state.mt.us

GAIL GRAY, Ed.D.
DIRECTOR

PO BOX 4210
HELENA, MONTANA 59604-4210
(406) 444-5622
FAX (406) 444-1970

January 6, 2004

Valerie Nottingham
National Institutes for Health
B13/2W64 9000 Rockville Pile
Bethesda MD 20892

Re: Public Comment on DEIS for Integrated Laboratory Research Facility

Dear Ms. Nottingham:

On behalf of the Montana Department of Public Health and Human Services (DPHHS), I would like to be on record as supporting the proposed expansion of the Rocky Mountain Laboratories (RML) in Hamilton.

This recommendation comes after consulting with Dr. Michael Spence, State Medical Officer; Dr. Todd Damrow, State Epidemiologist; Mr. Terry Krantz, who is overseeing Montana's preparations for public health disaster and bioterrorism planning; and Mr. Paul Lamphier, State Public Health Laboratory Manager.

We are aware of the contents of the DEIS and find the document adequate to support the proposal to proceed.

It is our intention to enhance our relationship with the Rocky Mountain Laboratories and to partner with them in any way possible as we continue our preparedness efforts that have been intensified the past year and a half. We do envision benefits to Montana and the nation overall in terms of scientific advances, bioterrorism preparedness and response capacity. To further that effort, DPHHS employees will be contacting staff at the Rocky Mountain Laboratories to schedule joint meetings between DPHHS preparedness staff and RML staff.

01-09-04P03:15 RCVD

LETTER 6 - GAIL GRAY, MONTANA DEPARTMENT OF PUBLIC HEALTH AND HUMAN SERVICES

Valerie Nottingham
Page 2 of 2
January 6, 2004

Overall, we believe the proposed Integrated Research Facility would directly benefit state and national response and preparedness efforts to prevent future outbreaks involving emerging and re-emerging infectious diseases.

Thank you for this opportunity.

Gail Gray, Ed.D.
Director
Montana Department of Public Health and Human Services

cc Dr. Michael Spence
Dr. Todd Damrow
Terry Krantz
Paul Lamphier

LETTER 7 - GILBERT JELINEK

911 So. 2nd St.
Hamilton
Jan. 6

Dear Dr. Bloom –

Thanks very much for publicly pointing out that Jim Olson is spokesman for a small group of people opposed to the proposed Level 4 construction program. I am sure that you remember that Olson was also one of the vocal critics of 4-lanning Highway 93.

Also, thanks for including me on the list of people receiving the Supplemental E.I.S. I find it very informative and the result of a lot of work.

Here's hoping that it won't be long before the Level 4 program gets underway – so that your medical researchers are handed more tools with which to do your work.

Thanks, again.

Gilbert Jelinek

01-09-04P12:08 RCVD

JAN - 7 2004

RML Integrated Research Facility

Public Meeting – January 22, 2004

Comments on the Supplemental Draft Environmental Impact Statement

IN FAVOR OF LAB EXPANSION

EIS WAS VERY WELL DONE

OVERALL SAFETY RECORD WAS VERY GOOD

Name: DENNIS BARBIAN
Company/Organization: 766 WILLOUGHBY
Address: STEVENSVILLE, MT 59870
City, State, Zip:

Please send comments to: Valerie Nottingham
NIH, B13/2W64
9000 Rockville Pike
Bethesda, MD 20892

Please note that this document will become part of the administrative record for the EIS and will be subject to public review.

Comments must be post marked by February 11, 2004

LETTER 8 - DENNIS BARBIAN

LETTER 9 - L. W. ENQUIST

Nottingham, Valerie (NIH/OD/ORF)

From: Enquist, Lynn [lenquist@molbio.Princeton.EDU]
Sent: Friday, January 23, 2004 9:17 AM
To: ORS RMLEIS (NIH/OD/ORS)
Cc: Enquist, Lynn; Bloom, Marshall (NIH/NIAID)
Subject: BSL4 facility in Hamilton

Follow Up Flag: Follow up
Flag Status: Completed

Dear Ms. Nottingham,

I have read the Supplemental Draft Environmental Impact Statement for the proposed BSL-4 facility at the Rocky Mountain Laboratories in Hamilton, MT.
I am a virologist in the Molecular Biology department at Princeton University. I am the associate chair of the department, the president elect of the American Society for Virology, an author of a popular virology textbook, and the editor in chief of the Journal of Virology. I also am a dedicated fly fisherman who has, many summers over the years, spent many happy hours fly fishing on the Bitterroot River, enjoying the ambience of Hamilton and the Bitterroot valley. I have long time friends in Hamilton and also have a Princeton undergrad from Hamilton in my lab learning basic virology right now.

I worked in two BSL4 facilities in the 1970's , at the NIH campus, (Building 41; where I was then on the research staff) and also at Fort Detrick. In those days, recombinant DNA technology using viruses was done in high containment. Therefore I am familiar with the concept of high containment research and have worked in what were in the mid 1970's, state of the art facilities. It is my judgment that the facility in Hamilton is superior to those old facilities and will be safe for the residents of Hamilton.

I recognize that the world we live in is full of risks and nothing can be guaranteed as risk-free. Indeed, we all must assess relative risks daily and determine when a risk is low or when it is high. In my opinion, the risk of a Hamilton resident encountering an infectious agent from the BSL4 facility is exceedingly low, if not vanishingly small. The scientists who work in the facility will deal directly with infectious agents and the risk to them is also very low as they understand the agents and also are protected by many levels of physical and biological safeguards.

The BSL4 facility in Hamilton is an essential part of our national research effort. The only counter to those who will use science against us is to fight back with research. Knowledge is power, indeed. Research done is this

1

facility will go far to help us understand how to control natural diseases
that plague human-kind like pandemic influenza, SARS, Dengue fever, and West
Nile virus. The Hamilton facility will provide essential resources to carry
out this specialized research. In addition, this facility will attract new
skilled workers and their families to Hamilton who will add to the diversity
and energy of a vibrant community.

I appreciate the opportunity to comment on this issue.

Sincerely,

L. W. Enquist, Ph.D.
Professor of Molecular Biology
and Associate Chair

Nottingham, Valerie (NIH/OD/ORF)

From: kevin dohr [ossitadelsol@yahoo.com]
Sent: Friday, January 23, 2004 10:17 AM
To: ORS RMLEIS (NIH/OD/ORS)
Subject: rocky mountain lab expansion

Follow Up Flag: Follow up
Flag Status: Completed

Dear Ms. Nottingham: This e-mail is being written as a comment on the supplemental environmental impact statement for the proposed expansion at Rocky Mountain Laboratories. Although the supplemental environmental impact statement represents a marked improvement over the original one, my opposition to expansion to a high-containment biological lab remains intact. To my way of thinking it is ill-advised to locate a biosafety level 4 lab in a residential neighborhood in Hamilton, Montana. An alternative site was dismissed
10-1 in the proposal as being too costly but given the risks involved (e.g., on air and water quality and exposing the public to unnecessary danger) and the importance of maintaing a high level of security (which could be more readily achieved by locating the lab away from neighborhoods in a more remote and defensible location) I continue to hold the opinion that an alternative location is the most prudent option. As a resident of the Bitterroot valley I strongly urge you to not proceed with the expansion. I appreciate your time and consideration of my comments. Kevin Dohr, Ph.D.

Kevin Dohr, Ph.D.
1113 Lance Lane
Stevensville, MT 59870

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LETTER 10 - KEVIN DOHR

Comment	Response
10-1	The notion that an Integrated Research Facility (IRF) can be remotely placed and remain scientifically productive is incorrect. Science performed off campus is not dependent upon facilities available on campus. Scientific functions are highly interconnected and rely on core support services in order to make progress and ensure regulatory compliance. Specific support functions such as electron microscopy, hazardous materials handling, select agent tracking, secure shipping and receiving, emergency medical response capability, security screening and handling of visitors needs to occur in very close proximity to the facility and cannot be managed off site. Such functions are already present at the RML campus and would not require duplication at a new remote location. Furthermore, the current federal budget did not consider the need to build additional roads, electrical, natural gas and water utility plants and other requirements typically provided by state, municipal or private enterprises. All of these supportive requirements exist at the RML campus and also the NIH Bethesda Campus thereby eliminating the need for duplication which lowers project cost by considerable orders of magnitude. Please also see Section 2.2.2.2.

Nottingham, Valerie (NIH/OD/ORF)

From: Larry Campbell [lcampbell@bitterroot.net]
Sent: Friday, January 23, 2004 1:44 PM
To: ORS RMLEIS (NIH/OD/ORS)
Cc: Larry Campbell
Subject: comments on RML IRF SDEIS
Follow Up Flag: Follow up
Flag Status: Completed

Larry Campbell
Box 204
Darby, MT 59829

To: Valerie Nottingham
NIH, B13/2W64
9000 Rockville Pike
Bethesda, MD 20892

January 23, 2004

RML SDEIS Comments

I appreciate the opportunity, provided by NEPA, to comment on the SDEIS and I especially appreciate the production of an SDEIS to comment on. The decision to supplement the previous sketchy DEIS is commendable and is a demonstration of how the planning of a project can be improved through public involvement.

The analysis and information in this SDEIS is, however, still lacking. More importantly, the entire framework of analysis has been skewed. One of the critical legs of the NEPA process is that the analysis of an action being contemplated includes a range of alternatives. The reason for this is not simply a technical formality. Any informed decision analyzes various action alternatives and possibly combines parts of various alternatives. The purpose and need set out in this document is artificially constrained and tailor made for, and only for, a BSL lab at the existing RML campus in residential Hamilton. Only one action alternative has ever been analyzed. It is a cut and dried plan. Take it or leave it. The decision we are supposedly awaiting has been a foregone conclusion from the beginning. It is clear NIH did not go through the NEPA hoops to choose No Action. NIH apparently went through the NEPA hoops entirely as a formality of informing the public about what they were going to do. 11-1

But, I believe NEPA is meant to improve decision making by involving the public, not just a mandate to inform the public about a set plan. Even the informational aspect of the process has been short changed by not analyzing a range of alternatives. Neither we the public, nor apparently the decision maker at NIH know what is being traded off, for example, by choosing not to build a new BSL-4 RML lab at a secured location outside of residential Hamilton. At the last meeting Dr. Deborah Wilson, NIH Director of Safety, agreed with my contention that distance from the community would significantly improve community safety. By not analyzing this alternative we don't know how much that extra community safety would cost or how much community safety could be gained. Or, given this decision-that-was-made-from-the- beginning, how much community safety is being sacrificed to save how much money. 11-2 11-3

LETTER 11 - LARRY CAMPBELL

Comment	Response
11-1	Please see Section 1.7.1 where this comment is addressed. The project is not 'artificially constrained' but is truly constrained by the allocated funds.
11-2	Please see Section 1.7.1 where this comment is addressed.
11-3	Please see the Community Risk section in section 4.2.1 where community safety is addressed. The risk analysis revealed that there was no health risk from the release of infectious agents at a distance of 300 feet from the exhaust ducts. The actual distance to the community exceeds 300 feet. Therefore, a more remote location would add no further benefit to public health and safety.

There could be advantages over and above improved security and public safety could be bought by the extra cost by starting from scratch in a smarter location, like less noise and traffic problems. Who knows? No other action options were analyzed.

The rationale given for dismissing all options to relocate RML to a less populated area does not mention the importance of resulting improvements to security and community safety.

11-4 Most of the reasons given for dismissal are not even relevant to some examples of possible alternatives. A BSL 4 lab built downwind, east of town would not require relocation of staff or "necessitate decommissioning and closure of the present RML facility", as stated in this document. The intellectual synergy of integrated lab work could still continue between the existing lab and the more secure BSL-4 lab down wind outside of town.

11-5 I have several more specific concerns about the proposed alternative. I haven't found a discussion about what the result of an explosion might be. This event might have sounded far fetched not long ago. At the last RML informational meeting (12/17/03) Dr. Wilson tried to put the community at ease by saying the heat from an explosion would kill any pathogens. Heat from a significant explosion can be quite local

11-6 and insignificant. People can live through explosions so I'm sure pathogens could too. Explosive events should be considered in the analysis.

11-7 I believe prions can withstand an autoclave. If so, the decontamination plans to autoclave animal cages and bedding appear inadequate for work with TSE diseases.

The shipping of pathogens through the US Post Office may be the weakest link in security. I hope nobody ever goes 'postal' after taking a package home for a dose of whatever biohazard is in that *clearly marked* package.

11-8 MPR is not defined in the acronym section but it stands for Maximum Possible Risk even though the model reduces the possible range in distance of escaped pathogens by assuming zero exhaust velocity. Also, I see reference to 'wind pattern', but I don't see any factor in the model for wind speed (p.4-11) Ignoring wind speed would also lessen the range in distance traveled by escaped pathogens The assumptions of zero exhaust velocity and zero wind produce maximized concentrations of pathogens to look at a in worst case scenario. If a disease can be caused by one spore, bacteria, virus or prion, it would seem that the distance that pathogen could travel in a short period of time could be important information. Community quarantine or evacuation planning could benefit from such information.

11-9 Finally, it is my understanding that a new specialized hospital room is being built in Missoula that is touted as safety mitigation for the proposed project. (Dr. Risi, 12/17/03 RML public meeting) Why not build it in Hamilton? Doesn't the ambulance ride to Missoula (on Highway 93, no less) unnecessarily increase risk of spreading disease to the community all along the route? Why not build a special room at Marcus Daily Hospital and bring the doctor down from Missoula, if needed? That would seem to increase public safety and benefit the community that is being asked to accept the increased risk

Larry Campbell

2/4/2004

Comment	Response
11-4	Please see the Community Risk section in section 4.2.1 where community safety is addressed. There is no benefit to locating the facility downwind from the community because, based on this risk assessment information, even at the location of the closest residence to proposed RML IRF and under the very worst case scenario the risk of public harm is statistically so minute that it may be considered zero. Therefore, a more remote location would add no further benefit to public health and safety.
11-5	The RML IRF was designed to have set backs from the campus perimeter consistent in meeting blast charge weights drawn from the Interagency Security Committee Guidelines for New Construction, Department of Justice Guidelines and the Department of Defense Unified Facilities Criteria. Most of these documents are in the public domain; however, some portions are considered "security sensitive". Additionally, analyses were conducted to assess the effect of satchel charges placed at potentially vulnerable locations of the facility to address issues such as progressive collapse and breach of containment. Any areas shown to be vulnerable during these analyses were reinforced, as appropriate, in the facility design. Details of the analyses are considered security sensitive, as it is prudent to keep such detailed vulnerability information from being available to those who might use the information in a manner that would abrogate the intent for which it was produced. A worst-case scenario modeling a percussive explosion would mimic the release described in Scenario 1 on page 4-11 of SDEIS and FEIS.

[Continued on following page.]

11-6 Please see response to comment 11-5.

11-7 Prions are subjected to chemical treatment, autoclaving, and if appropriate for the waste type, incineration. Please see page 4-9 and FEIS.

11-8 MPR has been added to the list of acronyms and defined in the glossary.

The MPR model does not take into account wind speed. As discussed the SDEIS on page 4-12, the MPR model discounts wind speed and patterns and replaces them with a well defined geometric dispersion model which increases the likelihood that a released particle, or portion thereof, will be identified in a quantitative manner. Addition of wind speed, exhaust velocities, a wind direction, etc. to the model would decrease the worst-case quantification effort because addition of these variables create increased dispersion/dilution of the contaminant.

11-9 Emergency plans will be drafted (see Chapter 4). If it is determined that there is a need for specialized care facilities at Marcus Daly or another regional hospital, RML will enter into agreements with relevant providers and entities.

LETTER 12 - SALLY ROSE

Nottingham, Valerie (NIH/OD/ORF)

From: Sally Rose [Sally.Rose@lee.net]
Sent: Thursday, January 29, 2004 3:00 PM
To: ORS RMLEIS (NIH/OD/ORS)
Subject: biological research laboratory

Attn: Valerie Nottingham

I am VERY opposed to a biological laboratory to study pathogens being built in Hamilton, Montana or anywhere in the United States. Building a laboratory for bioterrorism research is a waste of money badly needed elsewhere and does present a danger to the public. Although Rocky Mountain Labs (or some other lab) may have a good safety record, accidents and unforeseen events do happen.

Sincerely,

Sally Rose
Billings, Mont.

LETTER 13 - BRIAN BACHMAN

Nottingham, Valerie (NIH/OD/ORF)

From: Brian Bachman [bachmanbrian@hotmail.com]
Sent: Friday, January 30, 2004 9:01 PM
To: ORS RMLEIS (NIH/OD/ORS)
Subject: Rocky Mountain Lab Expansion

Dear Ms. Nottingham;

Attached is a letter to Marshall Bloom that outlines two suggestions I have after reading the full supplement to the EIS for the proposed expansion of RML. As a resident of the community, I feel very comfortable with and fully support the expansion. I appreciate the confidence that has been shown to the Rocky Mountain Labs as evidenced by this commitment.

If you have any questions, please feel free to contact me.

Sincerely,

Brian R Bachman
406-363-0123 MT home
206-715-2341 cell

Scope out the new MSN Plus Internet Software – optimizes dial-up to the max!
http://join.msn.com/?pgmarket=en-us&page=byoa/plus&ST=1

No letter was attached.

LETTER 14 - LAURIE LEONARD

Nottingham, Valerie (NIH/OD/ORF)

From: LLittlelouie@aol.com
Sent: Tuesday, February 03, 2004 9:38 PM
To: ORS RMLEIS (NIH/OD/ORS)
Subject: Lab proposal

To Valerie Nottingham,

As a teacher, long time resident of Montana and well informed member of the voting public, I submit this letter in strong opposition to the proposed lab upgrade in Hamilton, Montana. We will not win the war on terrorism or even put up a good fight by exposing our citizens and anyone else to this UN-godlike material.

Laurie Leonard
2734 S 7th St. W
Missoula, MT 59804

Your Complete Family Health Store

Bitterroot DRUG INC
"In the Middle on the Main"

211 Main Street
Hamilton, MT 59840
Phone: (406) 363-2611 • Fax: (406) 363-0131
E-mail: bdrug@mcn.net

February 4, 2004

National Institutes of Health
903 South 4th St.
Hamilton, MT 59840

RE: Expansion Project

To Whom It May Concern:

This is a letter in support of your expansion project. I appreciate that you have held numerous public meetings and gathered comments from concerned citizens prior to making your decision to continue with the project.

I have all the confidence that you will continue to run an efficient and safe facility.

Sincerely,

Wayne A. Hedman

WAYNE A. HEDMAN
RPh/Owner

Cc: Marshall Bloom

LETTER 15 - WAYNE A. HEDMAN

LETTER 16 - PETE BROWN, MONTANA HISTORICAL SOCIETY

MONTANA HISTORICAL SOCIETY
225 North Roberts ❖ P.O. Box 201201 ❖ Helena, MT 59620-1201
❖ (406) 444-2694 ❖ FAX (406) 444-2696 ❖ www.montanahistoricalsociety.org ❖

January 14, 2004

Valerie Nottingham
NIH, B13/2W64
9000 Rockville Pike
Bethesda, MD 20892

Ref: Rocky Mountain Labs Supplemental Draft EIS, December 2003

Dear Ms. Nottingham:

We've reviewed the above referenced document you submitted to us and have no comments on the Integrated Research Facility's (IRF) affect on the RML Historic District. Also, we believe that the increased employee traffic that will come with the completed IRF will not have a significant impact on the Hamilton Historic District.

Sincerely,

Pete Brown

Pete Brown
Historic Architecture Specialist
Montana SHPO
(406) 444-7718

File: NIH-USDHHS/Hamilton/2003122605-3001

01-23-04A09:19 RCVD

STATE HISTORIC PRESERVATION OFFICE ❖ 1410 8th Ave ❖ P.O. Box 201202 ❖ Helena, MT 59620-1202
❖ (406) 444-7715 ❖ FAX (406) 444-6575

LETTER 17 - TY R. CAPELLE

TO: STEPHEN A. FICCA 1/15/2004

DEAR MR. FICCA,
THANK YOU FOR COMPLETING THE SUPPLEMENTAL DRAFT EIS FOR THE ROCKY MOUNTAIN LABORATORIES IN HAMILTON, MT. I AM SURE THAT IT TOOK CONSIDERABLE TIME AND MONEY TO DO THIS. HOWEVER, YOU TOLD US NOTHING NEW. IT ONLY REITERATES ONCE AGAIN THAT MORE IS NOT BETTER.

THE BOTTOM LINE IS THAT YOU INTEND TO BUILD AN UGLY, NOISY AND POTENTIALLY DANGEROUS FACILITY IN THE MISTS OF A BEAUTIFUL, QUIET AND HISTORICAL RESIDENTIAL AREA. THIS IS A MISTAKE.

PLEASE RECONSIDER. IT'S NEVER TOO LATE TO DO THE RIGHT THING.

THANK YOU,
TY R. CAPELLE
714 S. 2ND ST.
HAMILTON, MT. 59840

Rcvd 1/23/04

E. Parnelli Sharp
537 Hudson Lane
Victor, MT 59875
406-961-1705
ParnelliS@aol.com

01-29-04P02:35 RCVD

January 24, 2004

Valerie Nottingham
NIH, B13/2W64
9000 Rockville Pike
Bethesda, MD 20892

Dear Ms. Nottingham,

I am writing this in reference to the open comment period for the SDEIS for the Rocky Mountain Lab Expansion proposal in Hamilton, MT. I am in support of the expansion but have several comments regarding the process.

I am a resident of Victor, MT. This is a small community (less than 600 people) approximately 7 miles north of Hamilton. I am a new to the area, but have had information on this proposed project from long-time residents in Hamilton and Victor. These residents have had somewhat negative opinions about this upgrade to the lab. Once a resident (June 28, 2003), I became very involved through attending the Community Liaison Meetings as an observer. I must admit that the comments from my friends pressed me into finding out more about the lab and the controversy about this expansion. I could not understand why such educated people would be against this opportunity for research to take place in the community. I am not a scientist, nor a researcher. I am a retired educational administrator and consider myself an educated person with an understanding that research is not a pure science; it is a process with experiments and flaws. I have formulated my own opinions and thank you for the opportunity in this comment period to express them.

There is always a problem with change. People don't like it. It is the challenge of the change agent to facilitate the change process. In my opinion as an observer for the past 8 months, the proposed change to move RML from a level 3 lab to a level 4 lab has had its holes, oops, and oversights associated with it. I'm not sure if these can be rectified in the minds of many of the local residents. They have looked to the educated, scientific leaders for structure and direction within the Environmental Impact Study (EIS). They did not find that and are frustrated to the point of not supporting the project. Perhaps better understanding of the purpose of an EIS would have been beneficial. Certainly, ironing out some of what I call the holes, oops, and oversights would have helped. Let me provide specifics for my opinion.

First, let me address what I term - the holes. As stated many times (SDEIS p. 2-1 and throughout), "NIH proposes to construct an Integrated Research Facility to house Biosafety Level (BSL)-2, BSL-3, and BSL-4 laboratories, animal research facilities, administrative support offices, conference rooms, and break areas at the RML Facility in Hamilton, Montana." This statement already sends red flags up to people. Many residents of the community consider this a "done deal". It has already been decided by the government to put this in here at the Hamilton facility. They did not feel that alternatives to Hamilton, MT were
18-1 { considered. It might have been more accepted if the proposed action had been stated, "to provide a highly contained and secure intramural lab at a location in the northwest United States." Then to consider alternatives and zero in on RML because it is the best alternative. But the perception is that this is something forced upon the residents with no alternatives considered.

Secondly, the "oops". In the best attempt of the Associate Director, Dr. Marshall Bloom, to establish a Community Liason Committee (SDEIS, p. 2-11), it is perceived by some residents that the members of the committee are selected individuals "choosen" to support this expansion of the lab. These selected few have

LETTER 18 - PARNELLI SHARP

Comment	Response
18-1	Please see response to comment 10-1.

no structured role or procedure for sharing information presented/discussed at the meetings back to their respective representative group, nor do most of them bring questions forward. No public comment is accepted at the meeting. So, many local residents are wary of what the group represents. Public outreach is essential. A publicized web page and/or newsletter with updated information, specific Community Liaison Meeting agendas and minutes need to be available (The tapes of the sessions are good but, not all residents can get to the library.), and local email contacts listed. Regularly scheduled informal, neighborhood chat sessions would provide neighbors with opportunities to have their opinions voiced and a forum for open communication.

18-2 Third……the oversights. Many have responded that there are several items not addressed in the SDEIS. I can only comment on the one most glaring to me - local, emergency services. There is no emergency plan included in the document and no dedicated, federal dollars to enhance the mostly community, VOLUNTEER emergency personnel. It is stated that certain procedures will be written if and when the project is approved but no assurances are provided for the community. It is essential that assurances such as a timeline as to when the community should expect these components to materialize must be included in the final EIS to be considered by this community. Most of the fire services in Hamilton and surrounding communities are volunteer people. The medical care in Hamilton and other local communities is very small. Medical facilities are limited. There must be dedicated, federal dollars to come with this project to have more personnel hired specifically to expanding these services. Planners of this proposed expansion project and these documents must have overlooked that for 3-4 months out of the year local fire and medical services in Montana are busy with other emergencies (forest fires). Having collaboration with these services during these local emergencies would be disastrous if they were needed to help at RML. More than a memorandum of understanding with local emergency services and hospitals (SDEIS, p. 2-17) is needed. For the record, there is only one local, Hamilton hospital. This critical aspect of dedicated emergency personnel cannot be overlooked in a final EIS. These resources must be expanded.

Dr. Marshall Bloom has conducted himself in the most professional manner considering the governmental circumstances under which he has had to present himself. It is my opinion that the events related to the Environmental Impact Studies for this project have been a classic case of the cart going before the horse. I really want to see a level 4 lab in this community. But, it is essential that it is well thought out, planned in collaboration with the community, and has the needs and concerns of the residents within the mile radius of the lab addressed before any approval is given to this project.

18-3 In closing, I want to return to my observations of many residents of this local area. These residents looked to experienced researchers and scientists to provide the knowledge and structure for this proposed project. They have been shown a poor initial EIS, a project that is perceived as a done-deal, and a SDEIS that still overlooks many of the impacts that such a project will have on this small town and surrounding communities. You must address better community outreach and involvement, and expanded emergency resources to assure a quality, safe, accepted lab expansion in Hamilton, MT.

Thank you for this opportunity to comment on this proposed project.

Sincerely,

Parnelli Sharp

E. Parnelli Sharp

Cc: Dr. Marshall Bloom, RML Associate Director

Comment	Response
18-2	Please see Section 1.7.2 where this comment is addressed.
18-3	Please see Section 1.7.2 where this comment was addressed. Please see description of *Neighborhood Meetings*, which was included in Chapter 2 of the DEIS, SDEIS and is included in the FEIS.

LETTER 19 - GOVERNOR JUDY MARTZ

OFFICE OF THE GOVERNOR

STATE OF MONTANA

JUDY MARTZ
GOVERNOR

STATE CAPITOL
PO BOX 200801
HELENA, MONTANA 59620-0801

January 26, 2004

Valerie Nottingham
National Institutes of Health
B13/2W64 9000 Rockville Pike
Bethesda, MD 20892

02-02-04P03:24 RCVD

RE: Public Comment on DEIS for Integrated Research Facility

Dear Ms. Nottingham:

I am aware that a supplemental draft EIS was issued in late December, 2003 and thus want to, with this letter, renew my support for the Integrated Research Facility (IRF) project at the Rocky Mountain Laboratories (RML) in Hamilton. I believe that this project is based on sound scientific design and rationale, and the project has emerged as a scientific biodefense necessity in our post 9-11 world.

Members of my staff and I have toured the RML campus to discuss the expansion project, see the work being done in these facilities and meet the employees.

My staff and I have also met with representatives from the Department of Public Health and Human Services (DPHHS) regarding the RML project, and we envision an enhanced working relationship between these two entities as a result of the IRF.

These informational meetings, my knowledge of RML's work and safety record, and widespread support from medical professionals in the vicinity have left me certain that proceeding with the IRF is the right thing to do. Montana is fortunate to have a facility of this caliber. RML is clearly doing research on par with the best infectious disease research laboratories in the nation, and the facilities are already world class. My administration hopes to develop a greater working relationship with the experts and resources at RML.

Historically, RML has been a good partner with DPHHS on projects involving microbial pathogens and communicable disease. In fact, DPHHS presently is collaborating with RML on a tick research project regarding a potentially new vector borne illness. We are

TELEPHONE: (406) 444-3111 FAX: (406) 444-4151

Valerie Nottingham
January 26, 2004
Page 2

also aware of an established working relationship between RML and the Ravalli County Health Department on its public health disaster planning efforts.

While the RML biosafety level 4 research facility would not likely lend itself to any new state project partnerships, my administration does see benefits to Montana and the nation overall in terms of scientific advances, bioterrorism preparedness and response capacity.

19-1 Leaders at the state public health laboratory, who are preparing to upgrade to BSL-3 status, realize the primary mission of RML is research and not service testing. Still, the state is interested in exploring a formal working relationship with RML in terms of a backup and consultative capacity in the event of a public health crisis.

Further, state government also hopes to rely on expertise from RML researchers in terms of consultations and advising on projects. We are aware that in addition to interactions with scientists and students from the Montana university system, RML also counts among its regular visitors some of the world's leading scientists, such as:

- Dr. Stanley Falkow of Stanford University, recognized as one of the foremost authorities in the world of infectious diseases, and his wife, Dr., Lucy Tompkins, who is an infectious disease specialist at Stanford Medical School. Dr. Falkow spends much of his summer at RML interacting with staff and students, and has conducted research at RML.
- Noble Prize winner Dr. David Baltimore, president of the California Institute of Technology.
- Stanford University professor Dr. Irving Weissman, originally from Great Falls, who is a world-respected authority on stem cells.
- Dr. Leroy Hood, a Montana native, who runs the Institute for Systems Biology in Seattle.

With this level of science-based support for continued work at RML, and our state's desire for a long-term working relationship with RML, I encourage the IRF project to proceed as planned.

Sincerely,

JUDY MARTZ
Governor

Comment	Response
19-1	Further discussions between the State and RML will occur regardless of the alternative selected.

500 W. Broadway St., P.O. Box 4587
Missoula, Montana 59806-4587
406/329-5630 Fax 406/329-5693
www.saintpatrick.org

ST. PATRICK HOSPITAL AND HEALTH SCIENCES CENTER
Sponsored by the Sisters of Providence

EXECUTIVE OFFICES

January 22, 2004

Ms. Valerie Nottingham
National Institutes of Health
B13/2W64
9000 Rockville Pike
Bethesda, MD 20892

Comment to: Supplemental Draft Environmental Impact Statement
RML Integrated Research Facility

Dear Ms. Nottingham:

I am writing in support of the construction of the integrated research facility that has been proposed for the campus of the Rocky Mountain Laboratories located in Hamilton, Montana.

Rocky Mountain Laboratories proposed facility will be the premiere research facility of its kind in the world when completed. It will be an economic boon to the area and may serve as a magnet for other private research facilities. The potential benefits to the local medical community are enormous, as part of the proposal is the education of local health care providers on the management of potentially exposed individuals and the upgrading of local hospitals to accommodate such persons were an exposure to occur. This type of training and facility upgrades will greatly assist St. Patrick Hospital and Health Sciences Center in our ability to prepare for disasters, infectious diseases, and potential biologic attacks on our community.

The Environmental Impact Statements have more than adequately, in our assessment, evaluated the overall impacts on the community of the construction of the facility. We concur with its conclusions and encourage the final report to continue to consider the proposed construction as the preferred alternative.

Sincerely,

Steven M. Witz, Ph.D.
President and CEO

SMW:seh

02-02-04P03:24 RCVD

LETTER 20 - STEVEN WITZ, ST. PATRICK HOSPITAL

LETTER 21 - DR. GEORGE RISI

consulting
education
clinical practice

Infectious Disease Specialists, PC
George F. Risi MD, FACP
Fellow, Infectious Disease Society of America

Valerie Nottingham
National Institutes of Health
B13/2W64
9000 Rockville Pike
Bethesda, Maryland
20892

02-02-04P03:24 RCVD

Comment to: Supplemental Draft Environmental Impact Statement
RML Integrated Research Facility

January 22, 2004

Dear Ms. Nottingham,

This letter is to reaffirm my support for the construction of the integrated research facility that has been proposed for the campus of the Rocky Mountain Laboratories (RML) located in Hamilton, Montana.

Previously I wrote in support of the initiative after review of the Draft Environmental Impact Statement (DEIS) issued in May of 2003. As the result of input received during the public comment period a supplemental DEIS was composed and released in December 2003. That supplement contains additional information specifically addressing, among other things, the safety record at the major biosafety level 4 (BSL-4) facilities around the world, as well as a maximum possible risk (MPR) analysis assuming catastrophic failure of the multiple safeguards built into the facility. Both of those analyses should go a long way toward assuaging any concerns that individuals have expressed. This is because there were no clinical infections of workers in these labs (3 institutions which over 30 years amassed nearly 500,000 hours of laboratory and field work working with such agents as Ebola, Marburg and other hemorrhagic fever viruses) and there is no measurable risk to the community at large in any of the worst case scenarios investigated in the MPR analysis.

It bears repeating that RML's proposed facility would be the premiere research facility of its kind in the world when completed. It would be an economic boon to the area and could indeed serve as a magnet for other private research facilities. The potential benefits to the local medical community are also enormous, as part of the proposal is the education of local health care providers on the management of potentially exposed individuals and the upgrading of local hospitals to accommodate such persons were an exposure to occur. Such training and facilities upgrades will greatly assist us in our ability to deal with the much more likely possibility of infection in a traveler returning from areas of the world where such emerging infectious diseases are found (SARS in China, Ebola in Africa, Junin in Argentina, to name just a few) as well as with any potential biologic attack on our community.

The supplemental draft EIS is a comprehensive document that more than adequately, in my assessment, evaluates the overall impacts on the community of the

544 w. Broadway, Missoula, MT 59802 risi@saintpatrick.org phone 406-327-1666 fax 406-329-5606

construction of the facility. I concur with its conclusions and encourage the final report to continue to consider the proposed construction as the preferred alternative.

Sincerely,

George F. Risi, MD, FACP, FIDSA
Director, Infection Control
St. Patrick Hospital and Health Sciences Center

LETTER 22 - STATE SENATOR RICK LAIBLE

Montana State Senate

SENATOR RICK LAIBLE
SENATE DISTRICT 30

HELENA ADDRESS:
PO BOX 200500
HELENA, MONTANA 59620-0500
(406) 444-4800

HOME ADDRESS:
529 MOOSE HOLLOW
VICTOR, MONTANA 59875
PHONE: (406) 961-8974
FAX: (406) 961-8975
E-MAIL: ricklaible@aol.com

The Big Sky Country

COMMITTEES:
FINANCE
LOCAL GOVERNMENT
NATURAL RESOURCES

January 22, 2004

Valerie Nottingham
National Institute of Health
B13/2W64, 9000 Rockville Pike
Bethesda, Md. 20892

Re: Rocky Mountain Lab-Hamilton, Mt.

Dear Ms. Nottingham:

Having reviewed the Supplemental Draft Environmental Impact Statement, dated December 2003, for the above project it is quite evident that the safety of the community was of primary concern during the design of the project. The safety record of all Level 4 labs is impeccable and poses virtually and statistically very little threat to the community.

Our current county growth policy, created by a bipartisan community focus group, overwhelmingly supported section 3.6, Economic Development, by boldly highlighting the following beginning statement. "The intent of this countywide goal (economic development) is to promote and encourage a positive environment for existing and new businesses. It proposes a means to evaluate current public needs to improve the business environment in the County. Other collaborative efforts to support businesses are also proposed."

There are some within our community whose primary goal is to stop all growth which is from whom the majority of the opposition is coming. This is not about the safety of the Lab, but the jobs and population growth which the Lab will bring.

I strongly support, and so does the majority of our community, the expansion of the Rocky Mountain Laboratories in Hamilton.

Sincerely,

Rick Laible

02-02-04P03:23 RCVD

LETTER 23 - ANONYMOUS

02-02-04P03:23 RCVD

Commenting on the proposed Lab in Hamilton, MT

January 24, 2004

We reside within a few miles of the proposed lab in Hamilton, MT and **we are against** the proposed building! We want to make it clear that we **do not** want it built! We don't feel that the potential gain is worth the **almost certain catastrophe that will happen someday** if the lab is built – harboring deadly viruses, bacteria, etc.

Arguments can be argued forever, but the bottom line is that this is in our back yard and **we do not want it at all**! Why can't you understand that someday a catastrophic mistake will happen if the lab is built? You're dealing with humans here. People can't be perfect forever. **Sooner or later, a mistake will be let out. Intentional or unintentional – it will happen. Do you really think that there never will be a major mistake?**

We can't even believe that you would consider building such a place. We could care less about the few jobs that would be created. We don't want growth any more. Pretty soon the beautiful place that drew us here will all be developed and then what will we do? **Forget the lab – forget more growth – let things stay the same**.

Sincerely,

A Hamilton, Montana Area Family

02-02-04P03:23 RCVD

1/24/04

Regarding the proposal of building a BSL-4 lab in our neighborhood-

We are residents in the Hamilton, Mt area and we are 100% against building such a lab!

We don't want the lab in our area at all.

It all is made to sound as it is ok and safe, but eventually someone, sometime will error and then it's too late. Then people will say "we never should have built it!"

If it must be built, build it on government lands in the desert somewhere.

Sincerely,

A Hamilton Area Family

LETTER 24 - ANONYMOUS

Citizen comments on RML SDEIS

I have attended numerous information meetings with RML management, and the same questions remain unanswered. One has to wonder if this is a deliberate attempt by the NIH to deceive the citizens of Hamilton. It has been our understanding, all along, that in 2001, President Bush mandated new and expanded research on biological weapons that could be used by terrorists after 9/11. That mandate became the reason for the proposed BSL-4 expansion at RML. Yet, on Jan. 22, 2004, Dr. Bloom stated (to approx. 125 Hamilton citizens), that there would be "NO BIOLOGICAL WEAPONS RESEARCH AT RML". What, then, is the reason for the proposed BSL-4 expansion? What, then, is the reason to put the citizens in harm's way? And I'm sure that the U.S. inability to find biological weapons in Iraq isn't helping the NIH case either. There doesn't seem to be any acceptable reason to bring these deadly pathogens into our community.

25-1

And what about the terrorists? Any suicide bomber with bio weapons and an airplane is certainly concerned that an antidote or vaccine could be discovered at RML, that would counteract his weapon. Logic says that it would be in the terrorists' best interest to destroy the BSL-4 facility, and stop the research. But where does that leave us, the neighbors to RML? Are we nothing more than colateral damage in the eyes of the NIH?

And finally, it would have made the BSL-4 Lab much easier to accept if the NIH had spent a portion of their HUGE budget to improve the City of Hamilton. To my knowledge, the RML never even offered to pay the balance of what they owe on their enormous water bill, much less take the burden off the local taxpayers to improve the water and sewer systems to accommodate the Lab's ever-expanding needs. As a result, the citizens of Hamilton have some of the highest water rates in the State of Montana. We resent being required to subsidize the Federal Government while the officials at RML and NIH get large bonuses. How about providing us with a new fire truck, or an isolation room at the hospital, etc??? You need to pay for the impact you are making here. Our new City Councilors are much more able and competent to negotiate these things than the previous Council, and you should ask for their suggestions. I doubt your BSL-4 will ever be welcome here if you continue to burden the citizens.

25-2

Lorraine Crotty, 1000 S. 2nd Street, Hamilton, MT 59840

LETTER 25 - LORRAINE CROTTY

Comment	Response
25-1	Please see the purpose and need stated on page 1-5 of the FEIS. This information was provided in the DEIS and the SDEIS.
25-2	Please see page 1-11 where this comment is addressed. The NIH is restricted by Federal law from paying for the listed items absent specific authority to do so, and the NIH has no such authority.

LETTER 26 - 28 DOCTORS

Valerie Nottingham
National Institutes of Health
B13/2W64
9000 Rockville Pike
Bethesda, Maryland
20892

02-02-04P03:22 RCVD

Comment to: Supplemental Draft Environmental Impact Statement
RML Integrated Research Facility

January 22, 2004

Dear Ms. Nottingham,

This letter is to reaffirm our support for the construction of the integrated research facility that has been proposed for the campus of the Rocky Mountain Laboratories (RML) located in Hamilton, Montana.

Previously we wrote in support of the initiative after review of the Draft Environmental Impact Statement (DEIS) issued in May of 2003. As the result of input received during the public comment period a supplemental DEIS was composed and released in December 2003. That supplement contains additional information specifically addressing, among other things, the safety record at the major biosafety level 4 (BSL-4) facilities around the world, as well as a maximum possible risk (MPR) analysis assuming catastrophic failure of the multiple safeguards built into the facility. Both of those analyses should go a long way toward assuaging any concerns that individuals have expressed. This is because there were no clinical infections of workers in these labs (3 institutions which over 30 years amassed nearly 500,000 hours of laboratory and field work working with such agents as Ebola, Marburg and other hemorrhagic fever viruses) and there is no measurable risk to the community at large in any of the worst case scenarios investigated in the MPR analysis.

It bears repeating that RML's proposed facility would be the premiere research facility of its kind in the world when completed. It would be an economic boon to the area and could indeed serve as a magnet for other private research facilities. The potential benefits to the local medical community are also enormous, as part of the proposal is the education of local health care providers on the management of potentially exposed individuals and the upgrading of local hospitals to accommodate such persons were an exposure to occur. Such training and facilities upgrades will greatly assist us in our ability to deal with the much more likely possibility of infection in a traveler returning from areas of the world where such emerging infectious diseases are found (SARS in China, Ebola in Africa, Junin in Argentina, to name just a few) as well as with any potential biologic attack on our community.

The supplemental draft EIS is a comprehensive document that more than adequately, in our assessment, evaluates the overall impacts on the community of the construction of the facility. We concur with its conclusions and encourage the final report to continue to consider the proposed construction as the preferred alternative.

Sincerely,

Undersigned

Signature Legend

Tom McMahon, MD
Vascular Surgeon
John T. Lakatua, MD
Nephrology
Howard Chandler, MD
Neurosurgeon
Montana Neurological Associates
Phil Gardner, MD
Otorhinolaryngology
Charles Swannack, MD
Vascular Surgeon
Paul Loehnen, MD
Pulmonary/Critical Care Medicine
Lou Kattine, MD
Vascular Surgery
Michael Curtis, MD
Internal Medicine
Margaret Eddy, MD
Nephrology
Phil Roper, MD
Cardiology
Herb Swick, MD
Director, Institute of Medicine and Humanities
Greg Kazemi, MD
Emergency Medicine
Steven Johnson, MD
Neurology
Stan Seagraves, MD
Internal Medicine
C. Carter Beck, MD
Neurosurgeon
Richard Selman, MD
Pulmonary/Critical Care Medicine

Lar Autio, MD
Family Medicine
Peter Szekely, MD
Internal Medicine
Eric Hughson, MD
Internal Medicine
Douglas Webber, MD
Emergency Medicine
William Bekemeyer, MD
Pulmonary/Critical Care Medicine
Director, ICU, St Patrick Hospital
Jeffrey Haller, MD
Otorhinolaryngology
Chris Mack, MD
Neurosurgery
T. Shull Lemire, MD
Pulmonary/Critical Care Medicine
Director, ICU, Community Hospital
Beth Thompson, MD
Internal Medicine
Tim Donovan, MD
Emergency Medicine
Joe Weydt, MD
Emergency Medicine
Warren Guffin, MD
Director, Emergency Medicine
St Patrick Hospital
Les Whitney, MD
Infectious Diseases
Director, Infection Control
Community Hospital

02-02-04P03:21 RCVD

January 22, 2004

NIH, B13/2W64
9000 Rockville Pike
Bethesda, MD 20892

We oppose building a Bio-4 lab in our community of Hamilton, Montana. We live 4 miles out of town but the threat of an accidental leak of dangerous pathogens to the people of the town and surrounding area is unacceptable. More importantly the threat of terrorists attempting to steal pathogens from this lab is even more dangerous.

Hamilton and Ravalli County do not have the police force nor expertise to combat terrorists. A lab handling such dangerous pathogens should be located in a remote desert area with proper military protection from terrorists threats. The INEL lab in Southern Idaho comes to mind as a more suitable location. Sincerely,

27-1

Ed Bloedel
574 Harvey Lane
Corvallis MT 59828

Gwen Bloedel
574 Harvey Ln
Corvallis, MT.
59828

LETTER 27 - ED AND GWEN BLOEDEL

Comment	Response
27-1	Please see response to comment 10-1.

January 21, 2004

Valerie Nottingham
NIH, B13/2W64
9000 Rockville Pike
Bethesda, MD 20892

Re: Comment on the Supplemental Draft Environmental Impact Statement
Concerning the upgrade of the RML to a Level 4 facility

To Ms. Nottingham:

Enclosed is a letter I sent to the Hamilton City Council, the Mayor and to the local paper, Ravalli Republic in reaction to my deep concern for the placement of such a facility in ANY residential community!

Sincerely,

Cooper Neville
HEIRLOOM OIL PORTRAITURE
220 Fairgrounds Rd.
Hamilton, MT 59840

02-02-04P03:21 RCVD

LETTER 28 - COOPER NEVILLE

January 15, 2004

Hamilton City Council and the Mayor
City of Hamilton
223 South Second St
Hamilton, MT 59840

Firstly: The Mission Statement for the City of Hamilton Montana… "Provide for the Public Health and Safety and promote the Economic Prosperity and Environmental well-being of its citizens" Hamilton City Council

To the Hamilton City Council and the Mayor of Hamilton:

Welcome Tom Peterson, Bob Scott, and Robert Sutherland as the new additions to our city council! May the New Year reflect a refreshed clarity resulting in a healthy dialog in regard to fully comprehending the long-term impact of the former Council's agreeing and supporting the upgrade of the Rocky Mountain Lab to a Level 4 status.

The new Supplemental Draft Environmental Impact Statement addressing this upgrade in our residential community is now available for review. Please read this document and notice the vagueness concerning any 'what if' error scenarios and the impact on the local citizenry…(us!)

28-1 I request that the Council hold the Federal Government via the NIH accountable to clarify for us in detail how we, as a community and as individuals will be compensated and protected in case there is a consequence of human error resulting in illness or death.

28-2 If we, as a community accept this dangerous facility in our neighborhood we want a detailed, legal commitment of being fully educated as to the effect an accident would have on our ground water, air, soil, and of course our individual persons.

Comment	Response
28-1	Please see where this comment is addressed in Section 1.7.3 of the SDEIS. In the event that any property damage, personal injury, or death results from the negligent act or omission of a Federal employee acting in the scope of the employee's official duties, a claim for compensation may be filed in accordance with the Federal Tort Claims Act, 28 U.S.C. 2671-2680.
28-2	Please see where this comment is addressed in Section 1.7.3 of the SDEIS. Please see response to comment 28-1. The Hamilton City Council has no authority to legally bind the NIH to the requested commitments.

28-3 Also, and most importantly, I ask the Council to hold the NIH legally and financially responsible to provide all services needed for a mop-up and to insure again via a Legal Binding Commitment full protection and compensation for all individuals negatively impacted physically, psychologically, or financially because of a lack of containment by a releasing of pathogens.

Let us utilize the deductive process of reasoning by being thorough in our understanding of a full disclosure of ALL VARIABLES concerning this endeavor and all the possible consequences.

Sincerely,

Cooper Neville
Heirloom Oil Portraiture
229 Fairgrounds Rd.
Hamilton, MT 59840

Comment	Response
28-3	Please see where this comment is addressed in Section 1.7.3 of the SDEIS.

January 22, 2004

NIH
B13/2W64
9000 Rockville Pike
Bethesda, Md. 20892

To Whom It May Concern:

I am opposed to the proposed expansion at Rocky Mountain Laboratories that includes a high containment biological lab.

Frankly, I'm very frightened about a level 4 lab operating in our small community of Hamilton. I have suffered with anxiety over this possibility for months.

I doubt the majority of Hamilton citizens would vote in favor of such a facility being built here if given that choice. Alas, we don't have that opportunity. I don't trust the government making these choices for me. I have a hunch most of the residents of Hamilton feel the same way.

29-1 I suggest that before you make a decision on the construction of a level 4 lab here that you contract for a professionally conducted public opinion poll that will give you necessary information to make an informed decision. This could be done fairly quickly by working with the University of Montana, and it shouldn't be too expensive.

Very truly yours,

Joyce N. Mercer

Joyce N. Mercer
711 N. 2nd Street
Hamilton, MT 59840

PH (406) 363-6416

LETTER 29 - JOYCE MERCER

Comment	Response
29-1	Public comment will be considered in the decision.

030

LETTER 30 - DALE HUHTANEN

2441 Old Darby Road
Hamilton, MT 59840-9793
January 30, 2004

Valerie Nottingham,
National Institute of Health
B13/2W64
9000 Rockville Pike
Bethesda, MD 20892

Ref: Comments to Supplemental Draft EIS
for RML-Integrated Research Facility

Dear Ms. Nottingham:

This letter is written as a matter of record regarding my support for the construction of the Integrated Research Facility at RML in Hamilton, MT. I have read both the draft and supplemental draft EIS and continue with my support for the building of such a facility at RML in Hamilton, MT.

As a resident of Ravalli County and as supporter of economic growth and activity in the Bitterroot, I endorse both the construction of the facility and the hiring of the additional 100 plus employees to operate the facility. The estimated construction wages of $5 million and the additional annual salaries of $6.5 million are direct benefits to the City of Hamilton, Ravalli County, and the State of Montana. Also, benefits to each listed agency are increased with additional property taxes, additional payroll taxes, and the economic multiplier regarding the dollars circulated or created by these activities. The construction of this facility and the additional employees will provide an economic stability for the government agencies, to include the City of Hamilton, Ravalli County, and the State of Montana.

I also do not believe that the safety issue or questions raised by others are a risk factor to either the city or county residents. RML has an excellent safety record that negates this issue.

Thank you for allowing me to comment on the supplemental draft EIS.

Yours truly,

Dale E. Huhtanen

031

Laura Jackson
394 Lost Horse Road
Hamilton, MT 59840
January 27, 2004

Valerie Nottingham
National Institute of Health,
B13/2W64
9000 Rockville Pike,
Bethesda, MD 20892

SUBJECT: Rocky Mountain Lab SDEIS comments.

A. LOCATING BSL-4 at RML in HAMILTON

31-1 THE MOST SERIOUS DEFICIENCY IN THE SDEIS REMAINS THE FAILURE TO FULLY CONSIDER ALTERNATIVE LOCATIONS FOR THIS FACILITY SO THAT COMMUNITY MEMBERS CAN REASONABLY EVALUATE THE THREATS TO SAFETY AND OTHER IMPACTS ON THE HAMILTON AREA IN RELATION TO THE SCIENTIFIC BENEFITS THAT MAY BE REALIZED BETTER AT THIS THAN SOME OTHER LOCATION.

More information is given here than in the original DEIS and this provides some helpful clarification. **The repeated reason for not fully exploring other locations is that any other site would not be within the DEIS parameters defined by NIH to evaluate locating the facility at RML (Sections 2.2.2.). This is absurdist logic when the very point in question is the rightness of selecting this location. It unfairly precludes the participation of the citizens most impacted by the selection of the RML site from fairly evaluating the trade offs involved in site selection.**

Some general information on the trade offs between siting at RML and elsewhere is provided in Sections 2.2.2.2 and 2.2.2.3 but major deficiencies remain in the SDEIS:

1. Reluctance of scientists to relocate/difficulty of recruitment of new teams of scientists comparable to those at RML.

   PROBLEMS: No exploration of benefits of other locations where adjacent facilities and scientists might provide even greater benefit than RML. Convenience of the scientists needs to be quantified and fairly weighed against costs to other members of the Hamilton community and neighborhood who should be fairly recompensed if sacrifices are required of them for this project for the larger national good.

2. Construction time frame for a new facility of 10 as compared with 2 years for addition to RML.

LETTER 31 - LAURA JACKSON

Comment	Response
31-1	Please see response to comment 10-1.

0319

31-2 PROBLEMS: No attention is given to possible research benefits that an entirely new facility elsewhere might offer and no actual other location options have been positively explored. Data as to timeframes for upgrades to fulfill the need for BSL-4 at other NIH facilities should be given for comparison. IS THE 2 YEAR TIME FRAME FOR BSL 4 LAB BUILDING ONLY? DOES IT INCLUDE SECURITY UPGRADES (Will BSL-4 be operable without these in place?), VISITOR CENTER AND POWER PLANT?

3. Cost of 1 billion for a new facility compared with 66.5 million Congress has presently allocated.

31-3 PROBLEMS: Because the SDEIS does not examine these alternatives with hard data, it is impossible to properly evaluate construction and community costs. However, if the decision to locate this project in Hamilton is in some measure economic this needs to be clarified. **The decision to save national funding by locating in Hamilton, at the expense of this one community, should be clearly admitted and funds should be committed, in the project budget, for compensation where mitigation is not possible.** It is not right to use the given Congressional appropriation figure as an excuse to sacrifice this one community.

B. NEIGHBORHOOD PROBLEMS NOT MITIGATED

1. **Parking**. No employee parking space is shown outside the security perimeter in the planned design. This means that at high traffic times and at times of heightened security employees will be faced with delays at the guarded entrance and hazardous traffic blocking lines will result. In addition, to avoid these lines and delays employees will choose to park on the neighborhood streets and walk through security (As noted near the end of the section headed "Transportation," SDEIS page 4-15). 31-4 **A large and convenient employee parking area <u>outside</u> the fenced security area is essential to minimize traffic and parking impacts on the neighborhood.**

2. **Noise**

a. Noise duration from incineration is projected to increase one to two days per week.
b. Voluntary Noise Standard levels (55dBA) allow a constant audible industrial hum in the adjacent neighborhood.
c. 31-5 The above standard would be in effect "during the daytime"(Section 4.4.1.1). In summer in western Montana, when neighbors are likely to be trying to enjoy their yards, daytime lasts from before 6 am to after 9 pm.

2

Comment	Response
31-2	Construction of the Proposed Action would be expected to take 2 years. The Proposed Action includes the Integrated Research Facility and boiler plant addition. See page 2-2. Please also see page 4-1 for a list of activities not related to the proposed action that will be accomplished at RML. The schedule for reasonably foreseeable action is currently unknown.
31-3	The decision is economic only in terms of potential economic harm (no harm was identified) and the money available to construct the facility.
31-4	Under another project the NIH is planning for unsecured parking outside of the fence as suggested.
31-5	Daytime hours are defined in the EIS (pgs. 2-8 and 3-9) as 7:00 am to 7:00 pm.

032

RML Integrated Research Facility

Public Meeting – January 22, 2004

Comments on the Supplemental Draft Environmental Impact Statement

1-27-04

I am not against the lab, but I am against a level 4 lab in our City or any City that has NO protection from a terrorist attack. Most of the Citizens of Hamilton Mt. do not want a level 4 lab in our City limits, or any place in the Western part of Montana. The level 4 lab would be too close to schools, residen parks, play grounds and our most precious Bitterrot River. There is absolutly NO protection from terrorist that could fly airplanes from any where to this Western part of Montana. Noise from the lab and traffic using our residential streets would be terrible. We are also concerned about the method these deadly pathogenes would be transported to the lab? Obviously, they would have to use our residential streets. What type of security would be available to protect our neighborhood from terrorist trying to stop a shipment from reaching the lab. The terrorist will do any thing they can to stop us from making a vacine that will stop thier efforts to kill as many people as they can. A level 4 lab needs to be placed on or near a Military Base so it can be protected from any terrorist organization. There are NO Military Bases in Western Montana. NO Military planes or missels to protect us. NO nothing but a chain link fence and a few guards that would not be able to stop a truck loaded with TNT or a plane that is headed straight for the lab. IF you insist on putting a level 4 lab in our City then the lab should be responsible for ALL improvments associated with the lab such as the new water tank and system that the City has burdened us Citizens with. All City residents had our base water base doubled last year to help pay for the new system that the lab will benefit from. The lab should have to pay for all street maintanance going to and from the lab. Put a isolation ward in our Hospital and be responsible for sewer improvements and maintanance. Our cost of living will go out of sight. There are a lot of long time residents senior citizens and retired people living here who will NOT benefit from the lab. The only ones that want the lab here are the ones that will benefit most from it. Construction of the new lab might keep a few contractors in work but after it is built, then what? Where will the jobs be? Many good points were made at the Jan. 22,2004 meeting of why people do NOT want a level 4 lab here please take them into consideration. I am almost 76 years old. I do not want to live the rest of my life in fear.

32-1 32-2 32-3 32-4 32-5 32-6

Name: Eleanor M Prosser

Company/Organization:

Address: 1002 So 2nd St

City, State, Zip: Hamilton Montana 59840

Please send comments to: Valerie Nottingham
NIH, B13/2W64
9000 Rockville Pike
Bethesda, MD 20892

Please note that this document will become part of the administrative record for the EIS and will be subject to public review.

Comments must be post marked by February 11, 2004

LETTER 32 - ELEANOR PROSSER

Comment	Response
32-1	Please see page 1-11 where this comment is addressed.
32-2	Please see Section 1.7.3 where this type of comment is addressed.
32-3	Please see the discussions under Security in Chapter 2 for the Proposed Action and No Action where NIH has established a satellite police force at RML. The police force will provide immediate response to any and all security related incidents and is currently working with local law enforcement and first response units to develop mutual response support agreements, regardless of the alternative selected.
32-4	Please see page 1-11 where this comment is addressed.
32-5	Please see page 1-11 where this comment is addressed.
32-6	Please see page 1-11 where this comment is addressed.

MONTANA
ASSOCIATION OF
COUNTIES

2715 Skyway Drive
Helena, MT 59602-1213
(406) 442-5209
Fax (406) 442-5238
e-mail: maco@maco.cog.mt.u

February 6, 2004

Valerie Nottingham
NIH, B13/2W64
9000 Rockville Pike
Bethesda, MD 20892

Dear Ms. Nottingham:

The Economic Development Committee of the Montana Association of Counties recently learned that the National Institute of Health is considering expansion of the Federal campus on the Rocky Mountain Laboratories of the National Institute of Allergy and Infections Diseases in Hamilton, Montana. We understand the proposed expansion will consist of construction of an Integrated Research Facility that will house research laboratories, offices, conference rooms, animal facilities, and supporting infrastructure as well as a building that will house bio-safety level 4 research laboratories.

We understand the project will provide an infusion of approximately $66 million into Montana's economy during the construction phase and will also add approximately $6 million annually into the local economy during operation.

33-1 The Economic Development Committee offers our support for your project in the interest of national security and safety of all United States citizens. We ask that you implement measures so qualified Montana contractors and trades people can be utilized during the construction phase of the project and, whenever possible, to employee Montanans within the facility when it is operational. Montana's recent economic hardship is of continual concern to us and we recognize this project will increase the long-term commitment to the growth of our state's employment opportunities.

Sincerely,

Anita L. Varone, Chair

02-09-04P02:48 RCVD

MACo

LETTER 33 - ANITA VARONE, MONTANA ASSOCIATION OF COUNTIES

Comment	Response
33-1	Please see Section 1.7.2 where this comment is addressed.

LETTER 34 - DALE HUHTANEN, CITY OF HAMILTON

034

City of Hamilton
223 South Second Street
Hamilton, MT 59840

January 30, 2004

Valerie Nottingham,
National Institute of Health
B13/2W64
9000 Rockville Pike
Bethesda, MD 20892

File: #2004-510
Ref: Comments to Supplemental Draft EIS for RML-Integrated Research Facility

Dear Ms. Nottingham:

This letter is written as a follow-up to my initial letter dated June 24, 2003, regarding my support for the construction for the Integrated Research Facility at RML in Hamilton, MT. I have read both the draft and supplemental draft EIS and continue with my support for the building of such a facility at RML in Hamilton, MT.

As the Grants & Budgets Officer for the City of Hamilton I endorse both the construction of the facility and the hiring of the additional 100 plus employees to operate the facility. The estimated construction wages of $4.7 million and the additional annual salaries of $6.6 million are direct benefits to the City, Ravalli County, and the State of Montana. Also, benefits to each listed agency are increased with additional property taxes, additional payroll taxes, and the economic multiplier regarding the dollars circulated or created by these activities. The construction of this facility and the additional employees will provide an economic stability for the City of Hamilton, Ravalli County, and the State of Montana.

I also do not believe that the safety issue or questions raised by others are a risk factor to the city residents or myself. RML has an excellent safety record that negates this issue.

Thank you for allowing me to comment on the supplemental draft EIS and enter this letter as record.

Yours truly,

Dale E. Huhtanen
Grants & Budgets

Cc: file-City

Phone: 406-363-2101 · Fax: 406-363-0191
website: http://www.cityofhamilton.net

035

2009 Old Ranch Rd.
Hamilton, MT 59840
January 29, 2004

To Whom It May Concern:

We live about 12 miles south of Hamilton and the proposed Level 4 lab at RML.

We have concerns about the potential danger such a facility would pose to our neighbors and friends who live close to the RML facility. RML is located in a developed residential community.

35-1 Burning waste is currently an issue that has not been adequately addressed. What will be the impact of additional toxic waste incineration in such a densely populated neighborhood? Is the particulate matter a potential health hazard? Now? Then?

35-2 If there was "an accident", what measures are in place to adequately deal with isolation and decontamination? Our local hospital and staff are hardly prepared for such an event. This needs to be addressed and a plan must be in effect. Federal money to support such a plan seems appropriate. Our medical facility cannot afford to institute such measures without financial assistance.

We fear that our community could become a target for terrorists if the Level 4 lab was developed here. At the present time, our community is rather benign and I doubt of much interest as a terrorist target. I fear that this will change.

I strongly object to the expansion proposed.

Thank you.

Carol Ann Hansen (Mrs. J.G.)

Carol Ann Hansen (Mrs. J.G.)

James C. Hansen MD
Director Emergency Dept.
Marcus Daly Hospital

LETTER 35 - CAROL ANN HANSEN

Comment	Response
35-1	Please see Section 1.7.3 where this comment is addressed.
35-2	Please see Section 1.7.2 where this comment is addressed.

036

RML Integrated Research Facility

Public Meeting- January 22, 2004

Comments on the Supplemental Draft Environmental Impact Statement

I would like to comment about the proposed expansion of the RML BSL-4. Having attended the meetings and listening to the public comments I have decided that the project should go forward, and the BSL-4 Lab should be constructed. My property is located next to the lab on the Southwest corner. My concern is that of noise. At the present time a patrol vehicle (gas powered golfcart type) passes by my property during the night time hours, usually at 10:30PM, 12:30AM, 2:30AM and 4:30 AM. This can make trying to sleep a problem, especially during the summer, when windows are open. There are ways to reduce this noise problem. Perhaps an electric vehicle, rather than gas powered, would be one solution. Even better than that would be to install in-fer red cameras, which could be monitored from a remote location inside the building. These measures would help with reducing the noise levels for all of those who live along the property lines next to RML. The EIS reviewed noise levels, except that none were done next to my property at location # 6 (SDEIS page 3-9 Figure 3-1) during the hours from 7:00PM to 7:00AM. How can the EIS state that noise levels were within guidelines, when none were taken during those hours? Only 4 out of 13 locations were monitored during nightime hours.(SDEIS page 3-9 Table 3-8) I hope that these concerns will be considered during the review of the Supplemental Draft EIS.

36-1

36-2

Name: Sheryl West
Address: 719 Loma Ln
City, State, Zip: Hamilton, MT 59840-2913

LETTER 36 - SHERYL WEST

Comment	Response
36-1	Adjustments in operation of this vehicle are outside the scope of this EIS.
36-2	Noise generation can be determined based on the operation of various pieces of equipment. When these pieces are not in operation (such as the incinerator and emergency power generator) they are not producing noise. As stated in the DEIS, SDEIS and FEIS, noise reduction equipment has been installed since the monitoring was done (see FEIS pg. 3-9). New information on the effectiveness of the silencer has been included in the FEIS.

January 22,2004

Valerie Nottingham
N.I.H. 313/2W64
9000 Rockville Pike
Bethesda MD.20892

Dear Ms. Nottingham
It has come to my attention that you are taking written comments and proposals on the environmental impact statement for a proposed expansion at Rocky Mountain Laboratories in Hamilton Montana.I am not certain what all these comments and proposals will be but I'm honored to put in my two cents worth.
First I'd like to point out that R.M.L. has been a plus to the community just from the standpoint of it's people who patronize the busineses of Hamilton and the surrounding area, not to mention the important scientific work that trickles down to the human race all over the world. When R.M.L. was first started in Hamilton, one consideration must have been space in relation to the density of the immediate population. At that time the population was just a fraction of what it is today. Hamilton Montana is located in Ravalli County and Ravalli County is the fastest growing county in the state of Montana. Since the National Institutes of Health announced it's intention to build a Biosafety Level 4 Lab in this ever growing populus area , I must frankly state, ''you've got us shaking in our boots.'' I guess when people hear that pathogens like Ebola and the like are to be studied in our ever growing valley,concerns automaticly run high. As just another common taxpayer I would ask that consideration be given to an area of less potential growth. I believe if this were done then security and safety measures could be addressed with far better success. Afterall ,safety and security is whats on everyones mind. I know it is easy for anyone to make a request and expect someone else to carry it out. This is not a burden I will leave unaddressed.
There is another county in western Montana that I believe addresess these issues far better than Ravalli Co, that County is Sanders Co.
The town of Plains lies in the heart of Sanders Co.,affords some of the mildest climate that Montana has to offer and has had very little population
37-1 change in the last several years. Should consideration be given to putting this Level 4 lab elswhere then I would also like to point out some other attributes to consider.
First,there is a 500 acre piece of land that lies in its own seperate valley next to Plains with county road as property boundry on all four sides. This piece of property has about ½ of a mile of mountain stream on its western border and 3 of the 4 sides are paved county road. The property is out of sight of the town, yet is only 3 miles from the hospital. If the future calls for a scientific gated community with on campus housing for its staff, recreational potential on campus and future growth of the facility in general,then I believe this piece of property is worth considering . At any length the potentials here are unique and endless. If there is any posibility that this property would be put under consideration as a potential lab sight,I would gladly fill you in on any other details.

Respectfully

Reini Frank

Reini Frank
803 Indian Prairie Loop
Victor Montana
59875

LETTER 37 - REINI FRANK

Comment	Response
37-1	Please see Section 2.2.2 that talks about other alternatives considered.

038

130 San Vicente Bl.
Santa Monica, Ca. 90402
February 1, 2004

To: Valerie Nottingham
NIH, B13/2W64
9000 Rockville Pike
Bethesda, Maryland 20892
From: C. Savage
Re: Dec. 2003 Supplemental Draft EIS for NIH, Rocky Mountain Laboratories, Hamilton, MT

Following Sept. 11, 2001 I would agree that increased biological research aimed at bioterrorist threats to our country is appropriate and necessary. The Supplemental DEIS, however, does not present a convincing argument that Hamilton, Montana is a suitable location for that research when the issues of protection from terrorist attacks and city infrastructure are considered. Clearly, the expansion of RML is economically advantageous for NIH, which undoubtedly is a driving force behind this proposal.

My initial concerns over the project were: 1) The community's ability to effectively deal with an extreme act of terror (law enforcement, fire and medical services), 2) Safe transportation of pathogens through the Bitterroot Valley in a heightened state of emergency, and 3) the increased load on the Water System in the city of Hamilton.

After reading this new draft I continue to have the same basic concerns:

02-05-04A10:12 RCVD

First, let us consider **Risk Assessment**, which this draft addresses on two levels -- qualitative and quantitative. The qualitative assessment relies on a "literature review " of the last 20 years of BSL-3 and BSL-4 safety records. The quantitative assessment, as stated on page 4-11, "was driven by reasonably foreseeable, credible threat scenarios and addresses spills and work disruption; safety operations and potential failures and; fire."

I am reassured by the many safety precautions that are an integral part of Rocky Mountain Labs and agree that on that level, the facility is soundly constructed. However, when I think of risk these days, it is with the added threat of terrorism attached. Prior to Sept. 11th, the DEIS assessments might have seemed sufficient. Post 9/11/01, however, they are sorely lacking. The terror threat facing us now does not begin to compare to threats during those 20 years covered by the literature review. This document repeatedly dismisses perceived threats as" negligible." In the wake of 9/11 I would maintain that there is no such thing as a negligible threat. The 6 risk scenarios presented on pages 4-11 to 4-14 in no way compare to the devastation we all witnessed in New York. This draft does not present a scenario that depicts a massive terrorist act. On page 4-7 this draft states that "interviews with leaders of the local emergency response agencies indicate that community service providers have few, if any, concerns about their ability to respond quickly and adequately to any emergency that may arise at RML." When you see how metropolitan areas (Seattle, San Francisco, New York, Los Angeles, etc.) in our country respond to each heightened states of emergency (recent ORANGE terror alert status), how can you compare what the community services of the city of Hamilton could present in the way of protection? I think it is extremely naive not to assume that a BSL-4 facility that is proposed as a result of President Bush's call for more bioterrorist research would not itself be an inviting target for terrorists. I do not see that the level of protection that such a facility would warrant could be provided in the Bitterroot Valley with its current resources no matter how well-intentioned the protectors. Actually, I think that the current BSL-3 lab should have more protection than it does.

38-1

My concerns about transporting pathogens through the valley, whether by air or land vehicle

LETTER 38 - C. SAVAGE

Comment	Response
38-1	The literature review is based on past experience. The data has not changed since the review was done, and includes the time since 9/11/2001.

023 8/9

result from the same terror issues. If RML suddenly becomes the receiver of pathogens that a terrorist could use, the town of Hamilton is placed at increased risk.

Finally, with respect to the environment, I actually have many questions about air quality and the incinerator, waste water and the water supply, but I will focus on the latter. On page 4-27 the Draft states "Sixty percent of water produced by the (water) system is unaccounted for, leaking out of supply lines." How can a system with these problems take on new water demands? If the federal government (through NIH) requires Hamilton water, then it should bear part of the cost of shoring up the infrastructure. **38-2**

RECOMMENDATIONS IF THE PLAN PROCEEDS:

1. Federally fund a fire and security force that is prepared to handle any possible terrorist threats directed at Rocky Mountain Lab or the surrounding community. **38-3**

2. Establish and publish in the community an Emergency Response Plan that states specifically what actions would be taken by whom in the event of various attacks of terror (including roles of police, fire, sheriff, highway patrol and medical facilities.) **38-4**

3. Specify what additions would be necessary for Marcus Daly Hospital to handle any emergency related to Rocky Mountain Lab -- including pathogen breaches or terrorist attack. Funding for these upgrades should be federal since the increased risk to the community is due to the President's request and the goals of a federal facility. **38-5**

4. Include in the federal budget all necessary funds to replace or repair inadequate water mains, pipes/sewer lines and roads in the city of Hamilton. **38-6**

The DEIS dismisses a variety of alternatives referring back to the purpose of the Proposed Action *"to provide a highly contained and secure intramural laboratory at RML dedicated to studying the basic biology of agents of emerging and re-emerging diseases, ..." chosen for its "traditional strengths in the area of infectious disease research and the federal funding parameters associated with NIAID's intramural laboratory program..."* With the purpose worded this way you can dismiss almost anything suggested by merely saying the budget doesn't allow it. I would counter with the suggestion that perhaps you reconsider what your budget will and will not allow. **38-7**

I recently heard a terrorist strategist explaining that one of the government's strategies of fighting terrorism is to imagine what actions might cause the most upheaval and then take precautions to thwart such plans. If we start imagining what a terrorist group might do at or around RML, can we envision our community providing the kind of defense that would be needed? When I envision New York City on 9/11, I cannot see Hamilton, Mt. providing those resources. It may be the thinking of NIH that a somewhat rural setting with a lower population than an urban area is desirable for a research facility that might invite terrorist action. I would propose that a breach of security resulting from terrorism could result in pathogens being released not only in the surrounding area, but being transported out of Hamilton to who knows where.

If the NIH budget won't permit expenditures that would make Hamilton better able to present appropriate defensive measures, then perhaps -- we, as a country, can't afford the facility in this location.

Comment	Response
38-2	Please see page 1-11 where this comment is addressed.
38-3	Please see Section 1.7.3 where this comment is addressed.
38-4	Please see Section 1.7.2 where this comment is addressed.
38-5	Please see page 1-11 where this comment is addressed.
38-6	Please see page 1-11 where this comment is addressed.
38-7	Please see response to comment 31-3.

1

SUPPLEMENTAL DRAFT
ENVIRONMENTAL IMPACT STATEMENT

PUBLIC HEARING REGARDING
ROCKY MOUNTAIN LABORATORIES

Taken at City Hall
Hamilton, Montana
Thursday, January 22, 2004 at 7:00 p.m.

Public Comment Section from 8:00 to 9:15 p.m.

PUBLIC HEARING COMMENTS

PRESENTATION BY:

Dr. Marshall Bloom, Associate Director of Rocky Mountain Laboratories

Chris Cerquone, Maxim Technologies

Reported by Debra K. Price, Freelance Reporter
Deposition Express
Grantsdale, Montana 59835

Deposition Express, Grantsdale, Montana
Phone/Fax: 406/375-0455

LETTER 39 - PUBLIC MEETING

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THURSDAY, JANUARY 22, 2004

MR. BLOOM: What we're going to do now is we're going to go into the normal oral comment period. You know as part of the process those comments, oral comments have to be recorded and transcribed, so we have to do a little bit of moving around here. We have a court reporter up here who is going to be transcribing your comments as you talk so when you come to the microphone to state your name, please state it clearly. It took us awhile to figure out who some people were after the last meeting.

Again, I want to point out as you all well know by now, this is not really a question and answer period. This is a time for you to make comments about the draft and supplemental draft, so we have to turn the lights on and move a few things around. I would say if there is anybody who hasn't signed up yet who thinks they might want to make an oral comment, please go up front and write your name. If you decide later on that you want to make a comment when we get through with everybody, you know, you're welcome to make a comment, write your name down and put a check mark. We have to keep a record of everybody who comments. So I'm going to

4

ask you to state your name clearly so she can get it and get it on the tape.

Everybody who comments will get a copy of the final statement and comments will be videotaped and transcribed as part of the record. I'd ask you to come up to the microphone and make sure it's on. State your name before you start your comment and hold it to three minutes a comment. Ken is going to have a sign letting you know when you have 15 minutes -- 15 seconds left. It's perfectly okay to say I endorse what so and so said or something like that.

I would ask you to be respectful of the opinions of folks who might differ from you and we also want you to know that you can written, e-mail, fax, whatever comments will be accepted through midnight on February 1 and the last slide which I'll leave up through the comment period really tells you how you can submit comments, oral comments tonight. You can submit written comments tonight, send comments by fax to that number right there, send an e-mail to Valerie, be written comments to Valerie at this address right here and view the draft EIS right there. I'm sorry that's not possible to read. So we're going to leave this

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slide on so we have to make a few changes in the set up of the room so they're going to bring me the list of the people that signed up. If you would like to get a cookie or glass of punch, go ahead and we'll get back together in just a second.

Let's get started. The first person on the list is Ron Nicholas, the Ravalli County DES Coordinator. It's on, Ron, you have to get right close to it.

MR. NICHOLAS: Does that work? I can leave it up here. My comment is very short, short as this microphone. Before I make my comment, I would like to apologize because I cannot stay and neither can Charmelle Owens from Public Health. We both have prior commitments. We're not leaving because we don't want to listen to what anybody else is saying. In conjunction we formed a comment which reads and this is from our perspective, first of all, we need to comment the Ravalli County Commissioners, State of Montana Disaster Emergency Services and State of Montana Department of Public Health and Human Services have sent letters in support of the Rocky Mountain Lab. The commissioners are comfortable with -- the Ravalli County Commissioners are comfortable with the EIS

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and the scrutinized efforts that have taken place to ensure the health and safety of Ravalli County and its citizens.

RML has taken involved efforts to work with the Ravalli County Public Health Department as well as the Disaster and Emergency Services by participation in the county's local planning and task force committees and has included the county on planning committees within the RML campus that will help ensure public safety. The county is pleased to be a part of a massive research opportunity and opportunities that will enhance the protection of the United States' citizens and feel comfortable with the lab's efforts as it stands. Thank you.

MR. BLOOM: Thanks, Ron. Next speaker is Tim West.

MR. WEST: Thank you, Marshall. My name is Tim West and I live, if you want to look in your book at 3-9, chapter 3, page 3-9, I live in the house directly south of noise location No. 6. I'm concerned about the noise levels that this EIS generates and especially the fact that no nighttime noise levels were monitored. It says out of the 13 locations only 4 of those locations were measured

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Comment	Response
39-1	Please see Section 1.7.3 where comments on noise were addressed.

at nighttime. I suggest that you measure nighttime levels out there, especially at location No. 5 or 6 at 10:30, 12:30, 2:30 and 4:30. And the guy comes by in his little cart that looks like something out of a James Bond movie, it's got more lights on it than an airplane. If you really want to get serious about your experience, put up infrared cameras. Thank you.

MR. BLOOM: Thanks, Tim. Next is John Swanson.

MR. SWANSON: Marshall, my name is John Swanson. I worked for Rocky Mountain Labs as lab chief since 1979 until I retired in 2001. Currently I live a block south of the lab. I have a couple comments. This has been an interesting process going through this EIS. It was begun as an attempt to kind of do a quick and dirty EA and it was clear from the outset that that wasn't going to fly. Those of us that have lived, that live near the lab essentially have put up with the last decade of noise, construction, increased traffic, uglification of the campus, et cetera.

This EIS has really been an opportunity for us to express some of our concerns, for several years, I was very critical about the incinerator

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39-2

1 noise from the lab and after about three years and
2 mainly through this EIS process, the lab finally
3 responded and did something and successfully
4 corrected that problem.
5 Now what I'm worried about is that I think
6 what we're looking at here is the beginning of
7 another ten years of construction. Certainly the
8 BSL-4 is going to take several years. There are a
9 couple other buildings and facilities that are in
10 this plan as attendant structures, yard place,
11 reception hall, the driveway or the parking lot, et
12 cetera.
13 I will also suggest that I'll bet they
14 need a new administration building to house the
15 verging number of administrators in the lab
16 sometime in the near future. My guess is there is
17 so much money available to NIH that they need to
18 put it someplace. They badly need to put it
19 someplace and it's going to be here. Now, I guess
20 my plea is that because NIH has made a good start
21 at interfacing with the neighbors and with the
22 neighborhood and with the community that because
23 we're -- if this thing goes through and probably
24 even if it doesn't go through, we're looking at a
25 prolonged period of more potential problems

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Comment	Response
39-2	Please see Section 1.7.3 where comments on noise were addressed.

emanating from the construction and the enlargement of the laboratory.

I'm not at all concerned about the biological risks that might be perceived to eventuate from such a lab. I'm not worried about that at all. I worked with infectious organisms most of my life so I have a feeling that things are in better shape than they've ever been and they're going to be even better. What I'm worried about is that when the pressure of getting the EIS passed is done, the lab will kind of forget that they're part of the community and they will go their merry way and not pay attention to what we put up with again in probably the next decade building around there. Thank you.

MR. BLOOM: Thanks, John. This is a little bit hard to read. I think it's Kathleen Driscoll, okay.

MS. DRISCOLL: I'd just like to -- one of the items like you saw on the news today was that Mars, the Mars situation kind of turned cattywampus on them and even though you ran all of your tests and possibilities I still have -- a part of me being raised in the Bitterroot here in Hamilton torn that says there's always a possibility that

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everything can fall apart. Helps to have a person like the person previous saying that he feels comfortable with this. But I still have that in the back of my mind along with the people in town

39-3 that were or are our neighbors and I would prefer that you have even more scenarios like that one where it spreads out rather than goes up and see what those possibilities are.

Also, I think that in good faith you should consider instead of contracting with different people in Hamilton to consider actually giving money to the infrastructure because of what's going to happen when this all starts breaking loose. You need to look at the fact that contracts are great, but people need help here. We're a pretty poor community when it comes to the average income rate and though I see a big difference when you work at the lab and have that income base and people that are here trying to keep

39-4 three or four jobs going just to live here. So I would suggest maybe looking at the fact that the infrastructure needs to be pumped up for the worst scenario. Thank you.

MR. BLOOM: Thank you, Ms. Driscoll. Rich Unger.

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Comment	Response
39-3	Please see response to comment 11-8.

Comment	Response
39-4	Please see Section 1.7.3 where comments on community infrastructure were addressed.

MR. UNGER: I know safety seems to be on a lot of people's minds and back when they worked on Rocky Mountain spotted tick fever they had to move around there. I read everything. I'm not concerned with the safety. I thank the lab for what they'd done. I had Rocky Mountain spotted tick fever in 1950 and I have a cousin who developed Lyme disease. And when I went to Vietnam and one of my uncles went to Iwo Jima in World War II, we both received the yellow fever vaccine that was developed here. I think you're doing a good job and I live on Baker Street, so I'm very close to the lab and I think like the safety problem they were concerned where you put a mote around the lab so the ticks wouldn't escape. Now that's past and you've done great work. I'd just like to thank you.

MR. BLOOM: Thank you, Rich. Next name I'm having a little trouble reading, might be Toni Bloom.

MS. BLOOM: You were right. I guess I came early enough that I got in at the beginning. I would just like to say that despite my connections by marriage with science that -- and the lab, I have been really impressed over the last

year with the amount of opportunities for people like me who are not scientists to learn about the research of the lab, the plans for the integrated research facility and the immense amount of redundancy that is being built into the safety issues.

I have been kind of looking at that as someone who has two children who appear to be migrating into scientific research and one of them is particularly interested in public health issues and infectious diseases. It is very comfortable to me to know that labs like this are being built and engineered so that highly infectious agents can be worked on safely by the scientists who choose to do so.

MR. BLOOM: Thank you, ma'am. The next person here is a perhaps, so I'm going to give you the benefit of the doubt. Columbia Pierson.

MS. PIERSON: Hi, everyone. I'm a painter and a writer and I came to the Bitterroot Valley because it seems like a sacred space. And when I found out about this lab being here, I felt rather sick actually and my heart dropped. And then when I found out that the lab may be changed and made to be even more dubious in character, I just -- I

actually wept. What I'd like to see is the whole facility being turned into a school for artists and writers and have the whole thing moved to the middle of Nevada. Thanks.

MR. BLOOM: Thank you, ma'am. Daryl Miller didn't indicate whether he wanted to talk or not, so I'm not -- I'm not sure I know who that is so I guess that's a no. Doug Nation.

MR. NATION: Thank you for this opportunity to speak. I'd like to start off by saying congratulations to RML, NIAID and NIH for the supplemental draft and environmental impact statement. I think this version is much more complete than the initial one. I think it also demonstrates the commitment that RML has to the concerns of the citizens of Ravalli County. I thank you for the effort for doing this and, again, I think you should be commended.

I'd like to speak -- just make a statement or two on the issue at hand, whether or not we should expand or approve the expansion of RML to the BSL-4 lab. I've attended all of the community meetings. I'm a member of the community liaison group, spent a lot of time thinking about this. It seems that the majority of the attackers of this

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1 expansion, the folks that don't think it's just
2 such a good idea seem to concentrate on the
3 potential risk that bringing these agents into the
4 community. But I think any risk assessment, one
5 needs to look not only at the possible risk, and
6 I'm the first one to agree there is certainly a
7 potential risk involved, but one needs to look at
8 not only at the risk but the potential benefit.
9 Dr. Bloom I think mentioned some of the
10 advances in medicine that have come from
11 discoveries made in this lab. I think if we're
12 going to continue the advancement in the
13 pharmaceutical and infectious disease control and
14 treatment, we have to have these facilities. Well,
15 okay, I think most people even agree with that.
16 But the question was is Hamilton the place to do
17 it? The NIAID, the National Institute for Allergy
18 and Infectious Disease, has two campuses; one in
19 Hamilton and one in Bethesda. I think this work
20 needs to be done by the Institute for Allergy and
21 Infectious Disease. The Bethesda campus is full.
22 I think this is the place for it to be. I
23 think we as citizens of this community should be
24 proud of the work that goes on here. And my time
25 seems like it's up, so thank you again for the

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opportunity.

MR. BLOOM: Thanks, Doug. This one has got a question mark by it and I think it's Ken S-T-R-I-G-H. Does that involve anybody? Did I spell your name correctly, sir?

MR. STRIGH: Strigh, yeah. First time I've ever been up in the audience. I'm not a talker, so excuse me. I think everybody in this room realizes that we have to have an infectious disease plant someplace. I think it's a good idea, something that has to happen. I think these diseases are getting more and more complicated, harder to control and they're going to spread like wildfire if we don't have these types of buildings and places. I just don't think it should belong in this valley. I'd hate to see something escape out here and these inversions come along and keep it down here in the valley and we can wipe out maybe half the valley. I know I'm exaggerating a little bit.

39-5

Mr. Bloom mentioned they have one of these places near a child center over there. I just don't think it's necessary to put these places in this type of environment. I can't see why they can't have it maybe out in the middle of the

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Comment	Response
39-5	Please see Section 1.7.3 where comments on outbreaks of agents were addressed. Also, refer to Chapter 4, Community Safety and Risk.

wildlife out here and make a little city for the scientists and so forth. It's just I realize we have to have these places. Again, I'm not much of a talker. I'm surprised I'm going as much as I'm doing. I guess maybe I am a talker.

You know, I'm with it and I'm against it. I just think there should be better places, better ways of doing it. I know safety is important. Senoble, they checked everything out and that wasn't supposed to happen. These spaceships are not supposed to blow up. They are very cautious of these things. But any time mankind gets a hold of something, he can mess up. Like picture me having a fight with my wife and going into the lab and dropping something all over or taking it home maybe. I'm exaggerating again, but I hope you people excuse me and I don't see the card going up, please put it up.

MR. BLOOM: You don't have to talk for a full three minutes. I think the first name of the next individual is Vernon Weiss, spell it please.

MR. WEISS: W-E-I-S-S.

MR. BLOOM: Thanks, Vernon.

MR. WEISS: A number of carpenters, Local 28, and also citizens of Ravalli County, I'm going

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39-6

to just address two issues that we're concerned with if the lab was built. One is that we'd like to see it built by local residents of Montana and particularly Ravalli County. One way to do that is by it being built by a union contractor or at least a union signatory contractor that brings down with it certain restrictions on how many people you can bring in from outside of this area. You can bring in regular management staff and so forth and you can only bring in so many of the rate filed carpenters. I think that will provide a level of safety beyond everything that's being done in that local workers who live right here, we have many members that live right in Hamilton and up and down the Bitterroot, they're going both because they're union members. They're highly trained and skilled and also they have a vested interest in making sure things are done right. If these things that are being done that they feel is unsafe, if workmanship is bad, they're likely to say something about it and get that situation remedied.

The other situation that I'm concerned with is our union scale is about roughly 2 percent and I'll put this in a written letter -- it's roughly 2 percent higher than what the prevailing

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Comment	Response
39-6	Local construction contractors would be invited to bid on the project with the goal to utilize as much local workforce as possible. Prior to bidding, prospective firms will be prequalified to ensure that the quality of work is maintained. The prequalification process will consist of relevant experience, past performance and ability to meet the security background check. The Federal Government requires, at a minimum, that labor rates are no less than the Davis Bacon Wage Rate. Use of union contractors and wages paid would be at the discretion of the firms who submit bids and are selected.

scale is, the federal prevailing wage scale. A 66 million dollar project in Seattle or another large city doesn't affect their wage scale as far as how prevailing wage is figured over the next two or three years. But a 66 million dollar project in Ravalli County, that is two or three dollars below our prevailing scale or below our carpenter scale, would have a drastic affect on wages which is something that's important to everybody. If this is done, if it's built and it's built by union carpenters here and other union trades, built by local people, they'll spend that money in the community. And to spend another 2 percent or 2 and a half percent on the overall project is not a large increase and it's something that money won't be going to wherever the contractor is from. It will be wages spent here in the community, spent over and over again, spent at gas stations and grocery stores and so forth. So that's our concern, thank you.

MR. BLOOM: Thanks, Mr. Weiss. Dennis Daneke.

MR. DANEKE: I'm Dennis Daneke and I work for the Northwest Regional Counsel of Carpenters, our office is in Missoula. We both -- my

counterpart said most of what I have to say. A few other things, Local 28 Carpenters Union in Missoula, the Bitterroot, Flathead, it's all Western Montana. Their motto is we build communities, okay. We don't build houses, we build communities. We're concerned that if this job does not go union or at least union wages and benefits, that it will cost the community 5 point some million dollars in unrealized wealth. These figures, bear with me, are all I could glean from the EIS, so the numbers could be a little bit off.

One other thing I'd like to say is that the EIS says sufficient numbers of qualified construction workers may be hard to find. I disagree. They list 659 in Ravalli County. They do not list the ones who live here and travel out of town because the wages are so low.

MR. BLOOM: Thanks, Dennis. Parnelli Sharp.

MS. SHARP: I'm not very electrical. My name is Parnelli Sharp and first of all I'd really like to send out some thank yous. I'd like to thank individual people who are residents that are here in this room and excuse my back. And I'd like to thank various and sundry groups that are also

represented here in this room. It shows our concern and our willingness to be involved and our wanting to be continued a part of this process. I know that this secondary draft EIS has come out and here we are again and I certainly hope that it doesn't end here.

We are concerned and I do hope that we can come up with some kind of a process, Marshall, where we can help the people that are very, very close neighbors. If and when this does come about, there are concerns about that, very valid concerns about the noise and the construction that will be happening.

We all have concerns about safety issues. And I remember Marshall making a statement one time and I think I might get it right, if I don't, Marshall, help me out; possibility versus probability and that has stuck with me and I've done a lot of thinking about that. I don't want a facility like this in my neighborhood. I'm lucky that I live ten miles away, but I really don't want it here, but I also know the importance of doing that scientific resource -- research, excuse me. And so I guess if it will come, then I will support it. But I also want continued involvement,

21

39-7

Marshall. I want an opportunity to have the community voice involved and possibly involved in making some future decisions rather than having something just kind of come out of the blue. I know a lot of people feel that that has happened. Thank you.

MR. BLOOM: Thank you. Laura Jackson.

MS. JACKSON: My name is Laura Jackson. I've been a resident of the valley for many years. My great grandparents homesteaded here and I have the technical abilities like a cow.

MR. BLOOM: Get close to it.

39-8

MS. JACKSON: Okay. Several things particularly about the EIS, the failure to honestly consider alternatives. I understand the way it's explained and it basically said that because the intent is to expand and put this facility in Hamilton at the Rocky Mountain Lab, therefore other alternatives are irrelevant. This is a logic which is way beyond me and I think it's the major failure of EIS to generally consider for our benefit what the options could be.

In particular, items that are mentioned for justifying the intent to put it here and therefore not considering other places are time

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Comment	Response
39-7	Please see Section 1.7.2 where comments on community participation were addressed.
39-8	Please see Section 1.7.1 where comments on the range of alternatives were addressed.

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that it would be more expeditious to fulfill the commitment to do the research because there are some facilities already here; expense that compared I believe 6 and a half million to a billion dollars, some considerable saving and the convenience and effect on scientists who would not be willing to relocate who are already involved in research here. These are certainly things worth evaluating.

I think if they are considered weighty enough to go ahead with this project then more concern needs to be given to mitigation for the neighborhood. There is a projected 20 percent increase in traffic, an additional day or two of incinerator time per week. The noise levels are supposed to be improved and considered moderate in any case. I own the house that is perhaps most affected by traffic and one of the most affected by noise and sitting out in that yard in the evening is not a pleasant experience in terms of what it was when I purchased that house many years ago expecting to retire and live in it. I've already lost one set of tenants during the past construction. The house was then unrented for quite awhile and I lowered the rent and do have

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39-9

1 tenants in it now. They are of course distressed
2 about construction and it is likely to come up.
3 A particular concern is parking. It is
4 understandable that this is a security problem. I
5 would only say that the planned construction does
6 not provide any non-secure parking which means that
7 the traffic jams will continue as people are being
8 cleared for security. This is a major flaw in a
9 plan. There should be some parking where people
10 can park and walk in. That's all I have time for.
11 Thank you.
12 MR. BLOOM: Thanks. Michael Helling.
13 MR. HELLING: I pass.
14 MR. BLOOM: Donald Sage.
15 MR. SAGE: My name is Donald Sage. I'm
16 grateful that I am able to speak. I just want to
17 say that my mother worked in Rocky Mountain Labs in
18 the '50s and with Rocky Mountain spotted fever
19 research. It was very good work for her. And so
20 Lyme disease -- my daughter this year contracted
21 Lyme disease and I was very grateful for the
22 antibiotics. So part of me is really in favor of
23 the lab, in favor of the science that supports that
24 and another part of me even after reading the EIS
25 recently in my heart I still feel really scared

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Comment	Response
39-9	Please see response to comment 31-4.

about having these level 4 agents in the valley and this beautiful town which has a lot of people that I love in it.

So I just want to say that I appreciate the lot of hard work and careful thought and care that's gone into the planning process, but in my heart I'm still really scared by it. Thank you.

MR. BLOOM: Thank you.

UNIDENTIFIED LADY: Can this microphone be turned up? It's very difficult to hear.

MR. BLOOM: You really have to get right up to it. Larry Campbell. Is that better? Pam, is that better?

MR. CAMPBELL: My name is Larry -- oh, that's working now.

MR. BLOOM: Get some earplugs.

MR. CAMPBELL: My name is Larry Campbell and I'm going to read fast here. I appreciate the opportunity provided by NEPA to comment on the SDEIS and EIS, and I especially appreciate the production of an SDEIS to comment on the decision to supplement the previous sketching. SDEIS is commendable and as a demonstration of how the planning of the project could be improved to public involvement. The analysis and information in this

1 testing is however still lacking, more importantly
2 the entire framework of the analysis has been
3 skewed.
4 One of the critical legs of the NEPA
5 process is that the analysis of the decision being
6 contemplated, including a range of alternatives.
7 The reason for this is not simply a technical
8 formality, an informed decision analyzes various
9 alternatives and possibly combines parts of various
10 alternatives. The purpose and needs set out in
11 this document is tailor made for a BSL-4 lab
12 acting, existing and only existing at RML campus in
13 residential Hamilton. The only actual alternative
14 analyzed is a cut and dried plan, take it or leave
15 it. It has been a foregone conclusion which
16 alternative would be chosen from the beginning.
17 It's clear that NIH isn't going through the NEPA
18 hoops just to choose a no-action alternative. NIH
19 apparently went through the NEPA hoops entirely as
20 a formality of informing the public of what they
21 were planning to do. But I believe NEPA is meant
22 to improve the decision making by involving the
23 public, not just a mandate to inform the public
24 about a set plan.
25 Even the informational aspect of this

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39-10

39-11

1 process has been shortchanged by not analyzing the
2 range of alternatives, neither we the public nor
3 apparently the decision maker at NIH know what is
4 being traded off, for example, by choosing not to
5 build a new BSL-4 lab or an out lab at a secure
6 location outside residential Hamilton.
7 At the last meeting Dr. Debra Wilson, NIH
8 director of safety, agreed with my contention that
9 distance from the community would significantly
10 improve community safety. By not analyzing this
11 alternative, we don't know how much that extra
12 community safety would cost or how much community
13 safety could be gained or given this decision that
14 was made from the beginning how much community
15 safety is being sacrificed to save how much money.
16 There may be advantages over and above the improved
17 security and public safety that could be bought by
18 the extra cost by starting from scratch in a
19 smarter location, like noise, parking, et cetera,
20 maybe coordinated with Corixa, who knows. No other
21 options were analyzed. The rationale given to
22 dismissing all options to relocate to a less
23 populated area -- am I done? That most of the
24 reasons given for dismissal are not even relevant.
25 The BSL-4 lab down in town would not require

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Comment	Response
39-10	Please see Section 1.7.1 where comments on alternatives were addressed.
39-11	Please see response to comment 11-3.

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1 relocation of the staff or necessitate the
2 commissioning or closure of the RML facility as
3 stated in the document. The intellectual synergy
4 could still go on with several more specific
5 concerns.
6 MR. BLOOM: Okay.
7 MR. CAMPBELL: I'm done? I'll send it in
8 in writing. One last thing, I wish you would build
9 a specialized hospital room here in town instead of
10 Missoula. It seems like it increases risk to put
11 somebody that's sick in the ambulance and take them
12 all the way to Missoula.
13 MR. BLOOM: Thanks. George Risi.
14 DR. RISI: Thanks, Marshall, I'm George
15 Risi and I'm a physician specializing in infectious
16 diseases in Missoula. I'm here representing St.
17 Patrick Hospital as well as the Department of
18 Emergency Medicine of St. Patrick's Hospital and
19 Division of Critical Care Medicine at both
20 institutions. The medical community of Missoula is
21 resoundingly in favor of this facility being
22 constructed here. We have reviewed the documents
23 very carefully and are very satisfied with the
24 thoroughness of the supplemental EIS that has been
25 comparatively released. They have absolutely no

39-12

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Comment	Response
39-12	Please see response to comment 11-9.

1 concerns about the safety and I have with me
2 letters from people I mentioned supporting the
3 process going forward.
4 MR. BLOOM: Thank you, Dr. Risi. Next is
5 Jay Evans.
6 MR. EVANS: My name is Jay Evans. I'm a
7 scientist down the road here at Corixa
8 Corporation. I have a Ph.D. in nephrology and I've
9 worked at level 3 laboratories at various places
10 around the country. I must say after working at
11 these different locations and seeing how they
12 interact with the community, I must commend
13 Marshall and RML and the NIAID because they do a
14 lot for this community. They hold community poster
15 sessions telling you about the new lab, answer all
16 the public safety concerns. They have a community
17 liaison group meeting and public seminars. None of
18 the other institutions I've worked at do this or
19 have this level of involvement in the community.
20 I've reviewed the supplemental draft EIS
21 and from being a nephrology, from the safety
22 perspective, I'm a hundred percent satisfied with
23 the safety level and I have no concerns. My family
24 lives in the valley and I have two kids in the
25 local public school system and I feel they're safe

1 even if the level 4 lab is built. Thank you,
2 Marshall and NIH.
3 MR. BLOOM: Thanks, Jay. Seta Loveridge.
4 MS. LOVERIDGE: First I'd like to thank
5 you for the chance to come and talk about the
6 proposed Rocky Mountain Lab expansion. I'd like to
7 start with a story from the first public meeting I
8 attended regarding the proposed expansion. After
9 being rushed through a brief verbal description of
10 the expansion, we were told to check out the artist
11 renditions on the finished project on our way out.
12 From all I could tell Marshall Bloom had been in
13 charge of the meeting, so I went over and attempted
14 to communicate with him. I said I felt many of the
15 locals had come to the meeting to talk about the
16 proposal and felt frustrated with the schedule that
17 did not include time or space for them. Marshall
18 scowled at me and he said and I quote, "Well, then
19 you have a problem. That's your problem."
20 Next I will quote an NIH document, "The
21 RML campus is located in rural Western Montana,
22 well removed from major population centers. The
23 location of the laboratory reduces the possibility
24 that accidental release of biosafety level 4
25 organism will lead to a major public health

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39-13

disaster." Written in this light it sounds like the human population of the Bitterroot Valley is an expendable population.

In addition to my own concerns for the human population, I'm here tonight to speak for all of us, the deer, the bears, the fish, the trees, the mountains, rivers, those who cannot come to this meeting and speak for themselves. The lab is maybe three stones throw from the largest contiguous wilderness in the lower 48.

39-14

As stewards of this international jewel and absolutely priceless chunk of intact earth, I'd like to hear its value is being weighed into the whole of this decision. Why allow this good neighbor to become a huge international target for evildoers and multiply local homeland security issues. Someone needed to come speak for the things wild. Think, I hope you'll agree with me. The wilderness and all who live there are not an expendable population. In the final analysis, we as a species have no right to threaten the welfare of these precious wildlands. Thank you for listening.

MR. BLOOM: Thanks, Seta. Next one is a maybe, Frank Westerman, Westerman, sorry.

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Comment	Response
39-13	The format of the document referred to suggests that it was a document prepared by someone to make a case for the construction of a level-4 biocontainment facility at RML in the approximate style of an NIH space justification document. It was e-mailed to the Director, Division of Intramural Research, NIAID's computer on December 13, 2000. As a matter of routine, it was filed on the computer. It was never put on letter or memo head and was never signed. There is nothing to suggest that anyone in the office further modified the document or used it in any way. It was released as part of a FOIA because it was in a folder on a computer marked Biodefense (the subject of that FOIA). NIAID, NIH does not support the ideas in the document. Please also see response to comment 1-2.
39-14	Please see Section 1.7.3 which addresses comments on the effects of terrorism.

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MR. WESTERMAN: My name is Frank and I'm just another flea on the dog's back. I've got 31 years of experience in the construction field. They called me from out of state to come do tilt up and do cast plate concrete on this Hamilton High School. Where I came from, I did biotech work for Montara in Oyster Point south of San Francisco; HMT which is now a Mack store which is a disk drive manufacturer. I've done cleaning room manufacturing and construction and applied materials in the Silicon Valley. Not to mention I built with three other superintendents, an armory of foremen, 13 buildings on a campus for Sun Micro System which also contained clean room and vacuum facilities.

What I'm here to stress is that there are no corners cut if this comes to be. I know that this has happened because I have worked for some of these contractors here in Montana and I'm not pointing fingers and I'm not saying anything bad, but I believe that I can -- I believe I'm qualified enough to say that they are less qualified, if you will, to be able to perform this magnitude of construction where you have potential disaster to this area. It's very important that you have a

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1 contractor who's competent with skilled labor, with
2 protocol that is bullet proof in order to minimize
3 any type of destruction that can be. Whether you
4 people realize it or not, this is going to happen
5 because it's a money thing, you know, and the thing
6 about it is these people have to have it together.
7 You cannot have amateurs doing this type of thing,
8 whether it's clean rooms, whether it's filtration
9 systems that come out of this roof that I see that
10 -- those orange things, those orange trumpets that
11 I see up there. To me I see it as an -- oh, how
12 would I say, something less than what really could
13 be.
14 But I mean like again I say, it's going to
15 happen, it's a federal money job, Rocky Mountain
16 Lab is here. They're not going to go put it back
17 in the middle of Nevada. Nevada is a -- that's a
18 nuclear dump site down there by Vegas as it is, so
19 that's out of the question. And for what it's
39 20 worth, people, you guys got to keep an eye on the
21 contractors that come in here and do it. Right now
22 you have Standson that is going to GC it or the
23 construction manager or whether they sub it out to
24 a lesser, then that's something this community has
25 to look after.

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Comment	Response
39	Please see response to comment 39-6.

MR. BLOOM: Thanks, Frank. Dan Norman didn't indicate yes or no. Dennis Barbian.

MR. BARBIAN: I'm Dennis Barbian. Actually Doug here expressed a lot of my views so I'm not going to go over that again. He did a very good job. First of all, I want to thank you for all the things you've done in the past in helping fight infectious diseases. I think the supplemental EIS is very well done. I do think that we need this type of facility to counteract infectious diseases. No matter where it is, you're going to have some risk involved. If you are living and walk across the street or driving a car, you have some risk involved. I really appreciate them giving the safety records and the overall safety record in the last 20 years have been very good. So I'm for the lab expansion and I just think that we do need the facility, thank you.

MR. BLOOM: Thank you, sir. Joan Perry.

MS. PERRY: I'm Joan Perry and I'm a little bit confused by the statement that Seta mentioned about the risk being less of a public safety -- public health issue if it's in a small rural town. I've heard a lot of denials about that statement and I don't see anyone taking full

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39-15

ownership for having said that statement. If in fact a rural location is not an advantage for public safety, then it seems to me far more appropriate to locate it in an urban area where support services are already in place. This past week I know that there were a couple of gentlemen from Belgium coming into Corixa. They never could fly in because the inversion. I just can't help but think that mother nature, it's not an appropriate place for a lab and I really think you guys need to take a look at other appropriate places where you start from scratch with a clean slate, no neighbors and just do the whole thing from scratch.

You know my other feelings, Marshall. I still think it's a done deal and I'm a little frustrated to keep coming to these meetings when I know it's going to happen anyway. I'm tired of it and thanks again for the cookies.

MR. BLOOM: Thanks, Joan. Bryon Schwan.

MS. SCHWAN: Good evening. I'm here tonight in lieu of my colleague Alex Bowman, director of science and research, who could not be here who has been working on this issue. We'd like to thank Rocky Mountain Lab and EIS for holding

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Comment	Response
39-15	Please see response to comment 11-3.

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this hearing. We appreciate the opportunity to provide public comment on this significant proposal. In coalition with Friends of the Bitterroot and Coalition for a Safe Lab, Women's Voices for the Earth submitted extensive comments on the original draft EIS. We are pleased that the NIH chose to release the supplemental EIS for our information. We were dismayed that our comments

39-16 were simply ignored in this draft. For example, a comparison of the financial costs of the alternatives which is absolutely standard in EIS was not provided; an analysis of hazardous air pollutants from the increased use of incinerator was not included; an inventory of toxic chemicals proposed to be used on site was not included; a calculation of potential income to the local government from payroll taxes generated by the

39-17 project was not included. There is no analysis of the risks proposed by an accidentally infected lab

39-18 worker. There is no emergency plan included in the SDEIS. The air pollution modeling analysis on the

39-19 nearby class one area was not included and analysis of the solid waste stream expected from the

39-20 (cont. on next proposed lab was not included. No discussion of the conflicts between the proposed project and the

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Comment	Response
39-16	Cost of alternatives is not necessarily required in all EISs. Chapter 1 of the DEIS, SDEIS and FEIS state that the expected cost of the Proposed Action is $66.5 million. Please see Section 1.7.3 where comments on use of the incinerator and use and disposal of hazardous chemicals where addressed. Please see page 4-17 where revenue is predicted.
39-17	The effect of an infected laboratory worker on the community is addressed on page 4-7 under *Agent Communicability and Treatment*.
39-18	Please see Section 1.7.2 where comments on the emergency plan were addressed.
39-19	Additional information on waste disposal was included in Section 2.1.3. Impacts on the Class 1 Airshed are disclosed in section 4.7.1.1 of the SDEIS.

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39-20

1 goals of the Ravalli County growth policy and
2 that's just a few. There is a much longer list.
3 These were all entirely reasonable
4 requests. They were perfectly relevant to the
5 scope of this EIS. However, these comments were
6 not addressed in the supplemental EIS and, in fact,
7 were not even acknowledged. We ask in light of the
8 NEPA procedures that these comments be addressed in
9 the final EIS. Substantial comments from community
10 members should not be ignored. The SDEIS claims
11 the potential risk of release of infectious agents
12 from the level 4 lab is negligible. No matter how
13 small of an epidemic or an incurable fatal disease
14 in our community should not be dismissed as
15 negligible. The potential consequences are too
16 great to be considered negligible. Even if the
17 risk is very small, it cannot be eliminated and it
18 cannot be eliminated. NIH must show how it will be

39-21

19 regulated. This means the NIH must clearly
20 illustrate the plan on how a worse case scenario
21 will be handled.
22 For over a year we have been asking the
23 emergency plan be included in the EIS process for
24 public review. Simply stating that the plan is in
25 progress and emergency responders feel comfortable

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Comment Response

39-20 The project would not conflict with Ravalli County Growth Policy. County officials were interviewed in August 2003 on this issue and determined that the Integrated Research Facility is within the plan.

[Response to 39-21 on following page.]

Comment Response

39-21 In the EIS, reasonable and foreseeable events were extended to worst-case situations ensuring contaminant release. These scenarios were then subjected to quantitative analysis as clearly demonstrated in the risk assessment. The results of these analyses were that no public health harm could be demonstrated. However, procedures and protocols to further mitigate the remaining infinitesimally small risks will be developed (See Section 4.2.2). These will include, but not be limited to,

- Operations and maintenance plans
- Local emergency response and notification plans
- Facility emergency response plans
- Quality assurance protocols and facility certification plans

Such detailed plans cannot be reasonably developed at this time. Details of the emergency response plan will be driven by the agents used in the research protocols to be performed. Agent-specific plans will be developed prior to the commencement of work with a particular agent. The other plans will be developed as the final design becomes available so that the specific features of the facility may be addressed in operations, maintenance, quality assurance, and certification and testing plans. Periodic reevaluation of these plans will be necessary throughout the life of the facility. New plans will be developed as the agents in use change.

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handling the emergency event is not the same thing. The EIS is the one place where the public and the labs review a project and have their say before it is implemented. How often the community assessed the impacts of this lab without it being able to see the plan that ensures the safety in an emergency. From the beginning of the process, it has been clear that the number one concern of the community is safety. The emergency plan is the document that let's the community know you have seriously considered the possibility and have ensured the community has the strong training and equipment and other resources to handle this emergency. The public clearly has a right to review and comment on this information when they're being asked to accept the risks being involved. The emergency plan must be made publicly available as part of the EIS process.

I don't have time to go into all the concerns about the incinerator, but we are concerned that the, you know, increase in the incident rate will be 50 to 100 percent and on top of that the hazardous emissions are not addressed in this EIS. Thank you.

39-22

MR. BLOOM: There was one more individual

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Comment	Response
39-22	Please see Section 1.7.3 where comments on the effects of the incinerator are addressed.

1 who has indicated that he wants to sign up. Is
2 there anybody in the audience who wants to comment
3 and didn't sign up?
4 MR. JENSEN: I signed up and said yes.
5 MR. BLOOM: Oh, I'm sorry, there is. Gary
6 Jensen.
7 MR. JENSEN: My name is Gary Jensen. I
8 live three or four blocks from the lab. I'm not
9 comfortable with having people and all the other
10 bio 4 level agents in my neighborhood. I'm not
11 comfortable with those of you that are comfortable
12 with this. I think that says a lot. I mean, how
13 do you get comfortable with that?
14 I heard Dr. Bloom on the news last night
15 and he said there is "no measurable risk to the
16 community," no measurable risk, and the word we
17 often hear and it's in the latest EIS, negligible.
18 Well, I looked it up. Negligible means so trifling
19 that it may safely be dismissed. Trifling, I wish
20 he'd stop using the word negligible. Just because
21 a risk can't be measured, doesn't mean you
22 shouldn't acknowledge it and acknowledge it and
23 acknowledge it.
24 Of course any time you bring dangerous
25 pathogens into the mix, there are inherent, ever

39

1 present risks, that can hardly be said to be
2 negligible. We're being told we can rest assured
3 because of mitigation measures and protocols and
4 space suits and wrought iron fences and guards at
5 the gate are going to serve to turn immeasurably
6 huge risks into immeasurably trifle ones. I don't
7 buy it. We're being asked to trust science and
8 government.
9 So I find this latest draft troublesome in
10 two ways, first, the business of the negligible
11 risk. It seemed to me that any sincere analysis of
12 the risk being -- we're being asked to swallow
13 would at least mention an awareness of the
14 potential for purposeful release, either by
15 terrorist activity from the outside or by rogue
16 elements on the inside. 9/11 and the anthrax
17 release suggests this is a gross and glaring and
18 probably purposeful down play. I brought this up
19 at the very first meeting I went to and the
20 gentleman from back east was surprised that I even
21 suggested terrorism. I mean, the folks in Bethesda
22 don't even want a fence around their thing he
23 said.
24 I've got to wrap this up. But, anyway,
25 the EIS should not be a PR tool. Those in charge

39-23

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Comment	Response
39-23	Please see response to comment 38-1.

of the lab, I say if you are going to gamble with my future and my children's future the least you can do is be honest about it.

MR. BLOOM: Carol Barbian.

MS. BARBIAN: My name is Carol Barbian. I'm a resident of Ravalli County. I want to go on record as being in favor of the expansion of this lab. I believe that it's a necessary thing that needs to be done. I think there are a lot of bad germs out there that need to be studied and overcome. My son works at the Rocky Mountain Lab. He is very enthusiastic about this expansion and really wants to work in this lab. He would be probably in the first line if something were to happen. Now, I do not want my son to die from some of these bad germs because something happened at the lab, but I also do not want any of my other children to die from some of these germs because something was not done at the lab. Thank you.

MR. BLOOM: This next one I think is the last name is Tilton, this is a maybe; is that right? Oh, okay.

SISTER TILTON: That's right, Sister Rafael Tilton.

MR. BLOOM: Sister, okay.

SISTER TILTON: Hi there. I don't think 66 million dollars is a whole lot of money. If the NIH can put 66 million into this lab, that is I just figured it out, about one-third of the average incomes of the people who get average incomes in this valley, which isn't a whole lot of money, if they've got 66 million just lying around to put into something like this. Now, they can put 66 million then they can put in three times that much, in my opinion, and take care of some of the other impacts that are as someone just said seemingly so negligible.

I was just at the Pine board meeting last night where they were talking about what would happen over on Eastside Highway at Tammany Lane when they put 60 new homes up on the hill and 90 new homes over on Marcus and what kind of lineups you will have in three cars in each of those or at least two because people have to go a long ways to work and we're not all going to be employed here at the lab. So I think that NIH ought to rethink how much they ought to spend.

MR. BLOOM: Thank you, Sister. This next person is another maybe and it's either Kirsten or Kristen Lang.

MS. LANG: My name is Kirsten and I'd like to thank the lab and the NIH for allowing us this opportunity to speak. And, of course, safety is very important to me and my family and I think to this community. And I think that the statement that Seta read is of the utmost importance because what a lot of people in this community that aren't in this room realize is that we are not expendable and they do not realize that not only is the lab doing everything that it can to keep safety levels as high as possible, but my concern is the transportation of these things to the lab. How many hands are these going to go to? How many people are going to be in the process of all these pathogens coming into this community?

The lab can do everything that it possibly can, but it's not going to take care of the postal workers and UPS and the flight attendants and everybody else along the way that's going to be bringing these things here. There is only so much that NIH and the NA whatever acronym -- there is only so much those people can do to protect the people in this community, but they certainly can't protect everybody else along the way. Thank you.

MR. BLOOM: Thank you. Next is I.

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Serenity.

MS. SERENITY: I'm also a resident of this valley and I came here because of the beauty and the wilderness and that it was I thought a safe place. And now here we have an opportunity as people to say no to something that could dramatically affect this area all of our lives. Obviously the government that is involved in this has a game plan and a very strong one that they are throwing thousands and millions of dollars into just like some of these political campaigns we're dealing with. They have a foregone conclusion and they are trying to just make it happen. And yet even though meeting after meeting we express these same concerns that I've heard over and over again that are not addressed here and I find it appalling that your worst case scenarios would say that there's no threat to this. How worse case could you be considering?

39-24 We've talked about what if somebody flew a plane -- we've got planes flying up and down this valley all the time. They could easily without any hesitation ram right into the Rocky Mountain Lab releasing not just one, but hundreds of different pathogens. I mean, all of these different

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Comment	Response
39-24	Please see Section 1.7.3 where comments on increased threat of terrorism were addressed.

scenarios have not been considered in this EIS and I think we are being naive to believe that nothing is going to happen if it is a negligible risk. So I pray deeply that we will defeat this and that we will not have level 4 pathogens in our valley. Thank you.

MR. BLOOM: I've neglected somebody from the previous page who indicated he was a maybe, Ted Kurstettor. Ted, did you want to --

MR. KURSTETTOR: I do.

MR. BLOOM: Okay.

MR. KURSTETTOR: Actually, I don't want to speak about the safety of the lab because surprisingly I'm not terribly concerned about that issue under conditions of the operation. I do -- what I want to speak about is the process that brought us to the point where we are tonight. Most of you are here a year and a half overdue. A year and a half ago the Intermountain Citizens for a Safe Lab convened a meeting in this room and they invited you and they invited other representatives of NIH and they invited a number of even the local politicians, maybe two of whom bothered to show up. You weren't here, so I can't tell you what went on.

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A year later the same thing happened. In that meeting, we had camera crew from the PBS evening news and they got a pretty good shot of the empty chair and sign Marshall Bloom, reserved for Marshall Bloom or other members of the NIH who elected not to come. Instead, the lab convened a group of people called the Citizens of the Liaison group, in my opinion composed of lab proponents and people who were thrilled to be included in the verified atmosphere of the lab and spoken to by the world renowned scientists at the lab only because there may be protests from people in groups to which I am sympathetic and one of which I belong were a couple of dissenting members flailingly invited to come.

By means of these actions and this attitude, you have increased the polarization in this community. You increased the anger among those who are for the lab and those who are not necessarily against it, but have legitimate questions that they wanted answered, not the kinds of questions that you get from going to a dog and pony show. So in closing, I would simply like to say I hope this meeting tonight represents a true change of heart. I hope it represents a

1 willingness on the part of NIH and the lab staff to
2 really get into serious discussions with members of
3 the community who handle legitimate questions and
4 are not necessarily totally against the lab. Thank
5 you very much.
6 MR. BLOOM: Thanks, Ted. Jim Miller.
7 MR. MILLER: Jim Miller. After the
8 anthrax attacks within our country two years ago,
9 it was determined by the administration that there
10 was a need for additional BSL-4 lab space within
11 our country. There are a lot of places where BSL-4
12 labs can be constructed, but the NIH predetermined
13 that the lab would be built at Rocky Mountain
14 Laboratories in Hamilton and nowhere else. The
15 need is additional lab space, BSL-4 lab space in
16 the United States. You might even take that a step
17 further and say regionally we might need BSL-4 lab
18 space in the Western United States or even further
19 you might say space is needed in the Pacific
20 Northwest.
21 In the draft EIS, the NIH has defined
22 their purpose and need as to build the BSL-4 lab at
23 Rocky Mountain Labs and nowhere else. After the
24 anthrax attacks, the president didn't go before the
25 nation and say, gosh, we need more BSL -- we need a

1 BSL 4 at Rocky Mountain Labs. He said we need
2 additional space. Now the NIH has made this
3 incredible leap to building the lab here and
4 nowhere else and I ask myself how or why they made
5 this leap. During the first comment period on the
6 original draft many people commented that there was
7 a need to consider other locations and I've heard
8 that need reiterated here over and over. There was
9 a need to consider other alternatives rather than
10 just one alternative. The supplemental draft EIS
11 dismisses these concerns of our citizens with one
12 sentence, it doesn't meet the purpose and need
13 which is to build the lab here. That's pretty
14 obvious. The intention here is utterly
15 transparent. The defined purpose and need
16 immediately excludes every other possibility for
17 building the lab anywhere else.
18 Believe me, this was not the intent of
19 Congress and the people they represent when they
20 passed the National Environmental Policy Act which
21 governs EIS process. The heart of the
22 Environmental Impact Statement is the development
23 of a full range of alternatives. The law requires
24 that quote, "Agents shall consider a full range of
25 alternatives and shall rigorously explore and

1 objectively evaluate all reasonable alternatives."
2 The reason for this is we can compare different
3 alternatives, we can weigh the different pros and
4 cons of the different alternatives and come to the
5 best solution for our community.
6 MR. BLOOM: All right, Jim.
7 MR. MILLER: The Rocky Mountain Lab may be
8 the best place for a BSL-4 lab, but we're never
9 going to know that because the NIH has shortcut the
10 process to a predetermined conclusion.
11 MR. BLOOM: Thanks. Now Doug.
12 MR. SOEHREN: Hear, hear. Jim says it
13 like it is and I count myself, Jim Miller and many
14 others who spoke tonight --
15 MR. BLOOM: Can you go to the microphone?
16 MR. SOEHREN: Anybody can't hear me?
17 MR. BLOOM: Doug Soehren.
18 MR. SOEHREN: I had spoken many times as
19 has Jim Miller and several others and I was
20 involved in the preparation of the considerable
21 comments that were turned in on behalf of the
22 Coalition of Concerned Citizens groups here in the
23 valley. We put a lot of time and energy into
24 analyzing the documents and analyzing the situation
25 here in the valley. Many of us have been long-time

1 residents here in the valley. We are deeply
2 concerned. We love this place and it is
3 unfortunate. I thought it was really great that
4 you've decided to revise the draft and you did come
5 out with the additional supplement. I think that
6 was smart and I was hopeful that you would address
7 all of our concerns. There isn't nearly enough
8 time for us to list all of the concerns that we
9 turned in that have not been addressed. They need
10 to be and they better be in the EIS or I think that
11 you really are on shaky ground. I think that
12 you're trying to dismiss us and we're not going
13 away. Thank you.
14 MR. BLOOM: Thanks, Doug. There is one
15 more person who signed up, Archeson Harden. Is
16 there anyone else who wants to speak after Mr.
17 Harden who didn't sign up? Okay.
18 MR. HARDEN: I'm sorry to sound like a
19 broken record here. It seems like every time they
20 give me a chance I come out and ask the same
21 questions and I never get answers, so here I am
22 again. I'm not going to thank you folks for
23 letting me be here to speak, because any time you
24 didn't have to, you have refused to listen to
25 anything I have to say. You've only let me speak

50

when you were legally obliged to. So I'm not going to be polite because I think they've been too nice.

My concern and that nobody else seems to have tackled too specifically is the issue of our local infrastructure again. Your analysis of whether or not we need any more improvements to our infrastructure goes to ask the local EMS if they feel comfortable. Well, I guess I feel comfortable. You go to the hospital, well, is there anything we can do for you? We're going to have people down in the valley. Nothing you're going to do for Marcus Daly Hospital is going to make a damn difference. They're going to be overwhelmed pretty immediately, so why waste the money? I don't know, but that's not a very scientific analysis of the needs of the community if you are going to build this thing anyway.

39-25 It seems to me that, one -- I'm going to ramble a little bit here -- the one case you didn't examine in your hazards case, was that of someone getting infected and going out into the community and infecting other people. How would that progress through the community? How many people might get one of these diseases if it did get out?

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Comment	Response
39-25	Please see response to comment 39-16.

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39-26

I mean, you addressed the most illogical ones of all clouds, how far would a cloud of anthrax if we shook it up on the roof travel. That's not what I'm afraid of. I'm afraid of someone getting it or bringing it out on purpose. After all, it appears that the anthrax case was an inside job of somebody who was involved in the business.

We heard from probably -- who isn't here. Now, we heard from an EMT from Atlanta, Georgia, said he moved here because after working the CDC on emergency drills it scared the hell out of him and he wanted to get out of Atlanta. Then you go and ask the local guys who don't have a clue what they're facing, this guy has been doing the drills and talking to the doctors and said, my God, this is scary. And we talk to local guys who probably don't have a clue and say, hey, what do you think? I feel comfortable, sure, no problem. I don't want to sound stupid, but, you know, we have people that know a lot more about it and we don't seem to ask them any questions. Oh, no, let's ask the guys in Hamilton, Marcus Daly, how they think. It's just, you know -- I'm sorry, it's not scientific and it hasn't addressed my issues which I've asked over and over again in writing and verbally.

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Comment	Response
39-26	Please see Section 1.7.3 where comments on the risk of terrorism were addressed.

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39-27

Also if you are going to build it here, seems to me we're not addressing other affects on infrastructure. I mean, are we going to have to build more roads? Does it apply to all the traffic, the people coming in and out of the lab all the time, you know, affect on the water supply, on schools. I know you tell us there are plenty of water, you told us that last summer and two weeks later I notice in the newspaper the mayor was telling us to cut back on water.

MR. BLOOM: Can you wrap it up?

MR. HARDEN: Once again, I have to say the thing is really ugly. As a student of art history and architecture, it's really an eyesore and can we do something about that if you're going to slap it down the middle of town.

MR. BLOOM: Thank you, sir. We have at least one more person signed up, Bob Sutherland.

MR. SUTHERLAND: Thank you. My name is Robert Sutherland. I live in Hamilton. I wanted to address the issue of the impacts of the lab expansion on infrastructure in the City of Hamilton. The EIS does not do much more than state what the impacts will be. I am concerned about, I mean, the impacts outside the fence. That's what I

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Comment	Response
39-27	Please see Section 1.7.3 where comments on the effects of the Proposed Action on traffic, community infrastructure, and water supply were addressed.

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39-28

39-29

1 am concerned about, the noise, the pollution, the
2 traffic and the use of the city water and sewage
3 treatment plan. Some of the statistics that I have
4 read in the supplemental EIS regarding water usage
5 and so on don't square with statistics I have seen
6 elsewhere. I don't know who put those together or
7 why they used the statistics that they did, but it
8 looks like there isn't very much credibility to
9 them.
10 The city has given a pass up to now to the
11 lab expansion. There has been no comment from city
12 government regarding the impacts. It was just a
13 good project as far as the city government has been
14 concerned. This is the same city government,
15 though, that has gotten itself into situations
16 itself where they wanted to construct -- have
17 construction projects and had to give up a lot in
18 negotiation.
19 I can give you an example, the city bought
20 ten acres to put a water tank on next to the
21 existing water tank, didn't realize when they
22 bought it that there were covenants in the deed
23 that wouldn't permit them to build the tank there.
24 Rather than switch that property for a more
25 suitable site, they decided to go ahead with the

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Comment	Response
39-28	Please see Section 1.7.3 where comments on the effects of the Proposed Action on noise, air quality, water, and wastewater were addressed.
39-29	This information has been corrected in the FEIS. See section 4.4.1.1.

cookies left back there. If you think I may have had some problems reading off your name because of the writing, please come up and see me and I'll try to make it legible.

(Public hearing concluded at 9:15 p.m.)

C E R T I F I C A T E

STATE OF MONTANA)
) ss.
COUNTY OF RAVALLI)

I, Debra K. Price, Freelance Court Reporter for the State of Montana, residing in Grantsdale, Montana, do hereby certify:

That I was duly authorized to and did report the public hearing in the above-entitled cause;

That the foregoing pages of this hearing constitute a true and accurate transcription of my stenotype notes of the testimony of said speakers.

I further certify that I am not an attorney nor counsel of any of the parties; nor a relative or employee of any attorney or counsel connected with the action, nor financially interested in the action.

IN WITNESS WHEREOF, I have hereunto set my hand and seal on this the 2nd day of February, 2004.

DEBRA K. PRICE NOTARIAL SEAL STATE OF MONTANA

Debra K. Price
Freelance Court Reporter
Notary Public, State of Montana
Residing in Grantsdale, Montana
My Commission Expires: 12/14/2007

Deposition Express, Grantsdale, Montana
Phone/Fax: 406/375-0455

2/04/04

Valerie Nottingham
National Institute of Health

Brian & Linda Trescott
P.O. Box 1592
Hamilton, MT. 59840

Re: Rocky Mountain Lab in Hamilton, Montana and
proposed new use/study of world's most toxic diseases
and substances, etc.

We are opposed to the proposed new use for the laboratory here in Hamilton, Montana. We are very concerned, in fact frightened to death, at what would happen IF an accident occurred.

Yes, the lab has a good safety record. But to err is human ! There is no such thing as an accident or mistake-proof person , machine or lab security system for that matter. We don't want it and shouldn't have to have it forced upon us.

It also brings new threat to this otherwise quiet hamlet by way of terrorist attacks. We moved here to feel safe. Is there anywhere that will be safe to live a quiet life if things like this are forced on us regardless of whether the citizens of this area want the new changes? I have not spoken to one person who wants the new usage of the lab.

40-1 If these diseases and substances must be studied, why not do it in a safer place which is not next to a large body of water (the river) and surrounded by people, schools, houses, animals, etc. How about putting it out with all the other undesirable sites which already have very strong security measures and safety precautions, such as Hanford nuclear plant in Washington, or in Neveda's area 54 (or whatever it is called).

02-09-04P02:48 RCVD

LETTER 40 - LINDA AND BRIAN TRESCOTT

Comment	Response
40-1	Please see Section 1.7.1 where comments on alternative locations were addressed.

40-2 What is the plan if an accident should occur? It's not IMPOSSIBLE that an accident would occur, is it?

My husband and my health insurance rates went up by $750 last year. At this rate we won't have insurance probably in the near future. A large percentage of people in this area have no insurance at all. What happens if we should need to get treatment because of an accident and are refused? What treatments are there for the world's most deadly & incurable diseases, anyway??????????????? A gun to the head, most likely, is the only cure.

40-3 If it's so safe, why not put this type of lab in your offices there at the National Health Institute?

WE DO NOT WANT THE NEW PROGRAM and never will. We would like an answer to the questions we have posed as soon as possible, as we consider this a matter of possible life and death.

Linda Trescott Brian Trescott

Linda Trescott Brian Trescott

Comment	Response
40-2	Please see Section 1.7.2 were comments on the emergency plan where addressed.
40-3	Please see Section 1.7.1 where comments on alternatives were addressed.

LETTER 41 - DOUGLAS NATION, TROUT UNLIMITED

Nottingham, Valerie (NIH/OD/ORF)

From: Nation, Douglas [dnation@corixa.com]
Sent: Friday, February 06, 2004 4:52 PM
To: ORS RMLEIS (NIH/OD/ORS)
Cc: Bloom, Marshall (NIH/NIAID)
Subject: Comment on RML Supplemental Draft EIS

RML Letter - Final version 02-...

Dear Ms. Nottingham:

Attached is the Board of Directors approved statement from the Bitter Root
Chapter of Trout Unlimited on the Supplemental Draft EIS issued for Rocky
Mountain Lab in Hamilton, MT. We appreciate the opportunity to comment and
to have our comment entered into the record.

<<RML Letter - Final version 02-04.doc>>

Sincerely,

Doug Nation
President, Bitter Root Trout Unlimited
Office phone: (406) 375-2189
Home Phone: (406) 363-2137
e-mail: dnation@corixa.com

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MONTANA TROUT UNLIMITED

January 11, 2004

Valerie Nottingham
National Institutes of Health
B13/2W64
9000 Rockville Pike
Bethesda, MD 20892

Dear Ms. Nottingham:

The Bitter Root Chapter of Trout Unlimited (BRTU), with a membership of approximately 250, is a local chapter of a national organization whose mission is "conserving, protecting, and restoring America's cold water fisheries". The BRTU board members and officers are citizens of Ravalli County, Montana and are a matter of public record. All of our general meetings are advertised and are open to members of the public. BRTU has been active in environmental, recreational, and conservation issues in the Bitterroot valley for over 25 years and has been involved, as either observers or participants, with a number of NEPA processes initiated by Federal agencies in association with their activities in Ravalli County.

BRTU has been an active participant in the Rocky Mountain Lab (RML) Integrated Research Facility (IRF) project. We currently have a seat on the Community Liaison Group (CLG) and have members that have attended most, if not all, of the Town Hall and Open House meetings hosted by RML to provide information and community education on the proposed IRF expansion. One, or more, of our members have also attended all of the IRF meetings related to the EIS and NEPA.

BRTU welcomes the opportunity to comment on the Supplemental Draft Environmental Impact Statement (SDEIS) recently published for the proposed IRF. We feel the current SDEIS report is significantly more complete than the initial draft EIS published earlier in 2003. We also feel that the current SDEIS does comply with the applicable NEPA requirements. The efforts of NIH/NIAID/RML to educate the community on the proposed IRF expansion and address the concerns of the project critics have been commendable. As an environmental organization, we agree with the findings published in the SDEIS that this project will have little or no significant environmental impact on fisheries and water quality in the Bitterroot Valley. **41-1**

Sincerely,

Board of Directors
Bitter Root Chapter of Trout Unlimited
Doug Nation, President

Comment	Response
41-1	Comment noted.

Nottingham, Valerie (NIH/OD/ORF)

From: John Swanson [swanjl@earthlink.net]
Sent: Tuesday, February 10, 2004 12:20 PM
To: ORS RMLEIS (NIH/OD/ORS)
Cc: Bloom, Marshall (NIH/NIAID)
Subject: RML BSL-4 SDEIS+

Dear Ms. Nottingham

This is in response to the Supplemental Draft Environmental Impact Statement
(SDEIS) recently issued for proposed BSL-4 facility at RML.

Sections 2.2.2.1 and 2.2.2.4 suggest that 'A BSL-4 laboratory for NIH use
has been constructed at the Bethesda site' (p.2-17) and 'Bethesda, Maryland
already has a BSL-4 laboratory.' I am confused by these statements. A
relavant question is whether or not the BSL-4 laboratory on the Bethesda
campus is operated as such, or not. **42-1**

If 'NIH is in the process of completing an EIS on a BSL-4 facility at Fort
Detrick planned for NIAID.' as stated on p.2-19, is another really necessary
at RML? Many things have changed since the inception of this NEPA process,
and I wonder if the need for yet another BSL-4 facility is as great as it
was in 2001! **42-2**

Section 4.2.1.1 includes a section on 'Housing' which contains several
problems, in my estimate. The SDEIS suggests that property values in the
area surrounding RML will not be compromised by BSL-4 construction, and they
cite three local realtors (Dowling, Polumski, Rose). That opinion appears
to be an 'off-the-cuff guesstimate' by these three individuals. I doubt
seriously that there was any effort to examine the data concerning property
values in the area over several previous years and whether those values have
changed since commencement of BSL-4 talk; did the evaluation take into
account the recent joint inquiry by six property owners living south of RML
to the U.S. Government (NIH?) regarding its interest in purchasing their
properties and the government's apparently negative response? **42-3**

Such superficial or fanciful treatment for such concerns of RML's neighbors,
of which I'm one, does not inspire confidence in either DEIS or SDEIS.
There seems to have been plenty of whitewash applied here, and that's a
bother in knowing whether matters (biosafety, etc.) that are potentially
much more serious are similarly glossed-over in the process of inclusion.

----and not included in the DEIS or SDEIS is recognition that the RML site
may have additional historical significance. It recently has been rumored
locally that the currrent RML site is where Lewis & Clark, after first

LETTER 42 - JOHN SWANSON

Comment	Response
42-1	NIH has maintained a small BSL-4 laboratory in Bethesda since the 1970s. The laboratory was renovated and reopened as a BSL-4 suit laboratory in 1998. The facility was never intended to be used for long term research. The facility is currently being used as an enhanced BSL-3 laboratory and will be used as a BSL-4 as the need arises.
42-2	Past experience indicates that emerging and re-emerging diseases will continue to pose a threat to the US. The scientific program proposed at RML is different from that of Fort Detrick. RML would include pathogenesis, immune response, vaccine, diagnostics and therapeutics and would focus on vector-borne pathogens, while Fort Detrick will be studying the disease process using physiological monitoring and clinical laboratory testing.
42-3	Please see page 4-2 where comments on neighborhood concerns about property values were addressed.

getting lost and then making their way through what is now western Montana,
had an history-determining golf match two centuries ago with local Native
Americans who had earlier learned the similar, precursor (?) game of
'shinty' from Scottish trappers. The outcome of this golf match was to
decide whether or not Lewis & Clark's party would be permitted to cross the
Bitterroot Range to find the Pacific Ocean. Luckily (?) L & C won,
apparently due to a birdie being made on the last hole by Sakagawia who was
playing for the white explorers' team. Obviously, a happening like this
would endow the RML site with deep historical significance that might be
compromised by future building programs. Perhaps NIH could quickly
construct a RML-L&C Visitors' park-site to attract Lewis & Clark
Bicentennial tourists and use the monetary proceeds to install the BSL-4
facility proposed for RML on the moon, as part of President Bush's recent
proposal to populate that planet, instead of in Hamilton. Wouldn't that be
terrific?

Respectfully,

John Swanson
1015 South Fourth Street
Hamilton, MT 59840
swanjl@earthlink.net
406 363 6269

The Big Sky Country

MONTANA HOUSE OF REPRESENTATIVES

REPRESENTATIVE BOB LAKE
HOUSE DISTRICT 60

HELENA ADDRESS:
PO BOX 200400
HELENA, MONTANA 59620-0400
PHONE: (406) 444-4800

HOME ADDRESS:
241 DALY AVE, PO BOX 2096
HAMILTON, MONTANA 59840
PHONE: (406) 363-4091

COMMITTEES:
TAXATION
EDUCATION
LEGISLATIVE ADMINISTRATION

January 31, 2004

Ms. Valerie Nottingham
NIH B13/2W64
9000 Rockville Pike
Bethesda, MD 20892

Dear Ms. Nottingham;

I was pleased that RML decided after the first public hearing, to respond to the Hamilton community and develop a revised EIS study to deal with those issues that were of major concern. I attended the public hearing on the supplemental draft in order to get a feeling of the crowd reaction to the new draft.

I must first complement Dr. Marshall Bloom and the other RML individuals who presented a very professional introduction and explanation of the proposed construction and management of the level 4 lab. The testimony given at the hearing very closely followed the general public comments that I have received as I visit with people around my district, which includes RML. The public has been and will be supportive of the Lab and the work that is accomplished in the facility. The overwhelming majority of Hamilton residents greatly appreciate the relationship that we enjoy with RML and the staff that is employed there.

As you are aware, there is a contingent that is very vocal against the expansion. You must understand that their objection is not about the potential dangers; (although that is what they claim) it is the extremely narrow agenda of limiting the population growth of the area that drives their efforts. They cannot be ignored, because their tactic is to create unwarranted concern in the neighbors and the community in general. It will work on a few people but I feel should not influence your final decision.

43-1 I sincerely support the expansion plan but, would ask for a consideration. You will notice from the transcript of the hearing, the main concern centers around the light and constant noise level produced on the campus during the night time hours. I am aware that you have in place a noise level regulation, and security dictates the need for illumination. If it were possible to include baffles around the roof air conditioners/compressors to deflect the noise upward it may help with that problem. As for the light situation if it were possible to construct a fence that would shield the nearby neighbors or position the beam as not to have direct line to the homes it may defuse that concern as well.

Again, I support your expansion plan and want to congratulate all of those people who have obviously dedicated a great deal of time and effort in developing and presenting the EIS.

Sincerely;

Bob Lake

cc: Dr. Marshall Bloom

02-09-04P02:48 RCVD

LETTER 43 - BOB LAKE, STATE REPRESENTATIVE

Comment	Response
43-1	Noise mitigations are included in the discussion of the proposed action. These mitigations would reduce the noise to acceptable levels. Please see page 2-8 of the SDEIS.

Nottingham, Valerie (NIH/OD/ORF)

From: tsitlali@juno.com
Sent: Wednesday, February 11, 2004 10:43 AM
To: ORS RMLEIS (NIH/OD/ORS)
Subject: Concerns

Re: Proposed expansion of Rocky Mt. Lab:

I am a resident of Hamilton. I live about 7 blocks east of the lab. I am deeply disturbed by this proposal, and have read both the Draft and the "Supplement" EIS. I have attended meetings. I have submitted letters to NIH about this issue. I do not feel heard. I am not alone.

The current Supplement did not address issues that were important to me, and vital to this community:

44-1
- Financial cost of other locations was not discussed. In fact, there was no discussion of other locations. I would like to see Glasgow Air Force Base investigated as a possible site. It has a 3-mile air strip for delivering sensitive materials. Air Security is available from Malestrom Air Force Base in Great Falls, MT. It has temporary housing for employees (or permanent housing). It is already fenced and gated for security. There is a community nearby that is gasping for more residents.

44-2
- No analysis of air pollutants was included in the EIS. Since I live in the airstream east of the lab, this issue is extremely important. This is one of the key factors in deciding if we can continue to live here should the lab be enlarged.

44-3
- No emergency plans were included, should an employee be infected or should a shipment of sensitive material be disturbed, stolen, etc. There is no way to isolate an infected employee at the local, small and ill-equipped hospital. We have one highway...***one way out for 35,000 people***. We have one (inadequate) airport. How tragic it would be if an incident occurred and people began asking honest questions, like "What were they thinking??" This is a critical issue which hundreds of citizens have questioned to date, without any response from the Institute.

44-4
- As any pilot will inform the committee, Hamilton is a sitting duck for air terrorism. We do not have the air security of other locations in the State; not even advanced radar systems at the airport. Approach by northern or southern routes along the mountains would be extremely easy.
- The sense I received from recent meetings was that since the Chamber of Commerce, Hamilton City Council, Hamilton Downtown Business Association have agreed to the expansion that the Institute considers this a "done deal." It is not. The citizens of Hamilton and the rest of the valley have a right to vote on the presence of Weapons of Mass Destruction in this valley. My belief is a vote would strongly indicate the opposition to this plan.

I am not a fanatic. I'm a social worker. I work with people to improve their quality of life, and with the community to improve the lives of families and children. I deeply approve of having WMD research. ***But I cannot understand placing that research outside of a military installation. This community does not want to be a military target.***

Cordially,
Star Jameson, 253 Roosevelt Lane, Hamilton, MT 59840 (406) 363-4026

LETTER 44 - STAR JAMESON

Comment	Response
44-1	Please see Section 1.7.1 where comments on alternatives were discussed.
44-2	Please see Section 1.7.3 where comments on air quality were addressed.
44-3	Please see Section 1.7.2 where comments on the emergency plan were addressed.
44-4	Please see Section 1.7.3 where comments on the risk of terrorism were addressed.

Nottingham, Valerie (NIH/OD/ORF)

From: Jay Greene [jaygreene37@yahoo.com]
Sent: Tuesday, February 10, 2004 1:18 PM
To: ORS RMLEIS (NIH/OD/ORS)
Subject: Tempting fate

45-1 Kindly add our names to those others in the south valley who are opposed to expanding the venue of the chemists at Rocky Mountain Laboratories to include the importation of arcane (and very dangerous) microbes and viruses...
We moved to the Bitterroot Valley to get as far as possible from ***the missiles*** up along the Highline.
It seems counterintuitive (and certainly counterproductive) that the U. S. is now thinking of bringing another equally worrisome type of ***WMD*** to the valley...

Sincerely

Nadine J. and
J D Greene
131 Silverbow Drive
Victor, MT 59875-9676

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Nottingham, Valerie (NIH/OD/ORF)

From: Steve Slocomb [video@montana.com]
Sent: Tuesday, February 10, 2004 2:43 PM
To: ORS RMLEIS (NIH/OD/ORS)
Subject: Hamilton LAB

46-1 Please include more information on alternative BH4 lab locations, and on measures to be taken if there were to be an escape of a pathogen.

Steve Slocomb
376 Zimmerman Lane
Hamilton, MT
59840

Steve Slocomb
Looking Glass Films
videography/editing
Montana, USA
email: video@montana.com
web: bitterroot.tv

LETTER 45 - NADINE J. AND J. D. GREENE

Comment	Response
45-1	Please see Section 1.1 where this comment is addressed. No Weapons of Mass Destruction research will take place at any NIH facility including RML, as this is forbidden by a national security directive and international law. Please also see section 4.2.1.1, Community Safety and Risk, Risk Assessment section.

LETTER 46 - STEVE SLOCOMB

Comment	Response
46-1	Please see Section 1.7.1 where comments on alternatives were addressed.

Nottingham, Valerie (NIH/OD/ORF)

From: Carolsblum@aol.com
Sent: Tuesday, February 10, 2004 3:57 PM
To: ORS RMLEIS (NIH/OD/ORS)
Subject: public comments on RML SDEIS

Ms. Nottingham:
Please accept the following as my official comments for the Rocky Mountain Lab BSL-4 Expansion SDEIS:

47-1 My main concern is that SDEIS still does not fully develop and analyze more than one alternative, to build the expansion at the RML campus. This is directly contrary to EIS rules which state that a full range of alternatives must be developed and compared to one another in terms of their impacts, risks, benefits, and ability to meet the purpose and need. Furthermore, the SDEIS continues to state that the purpose and need of the project is to build the expansion of the Rocky Mountain Labs to the BSL-4 level. This is blatantly worded in this way to circumvent the possibility of developing and comparing other alternative locations for the BSL-4 lab to be built. I believe that the NIH is only looking at the RML, and not other possible locations, and that this constitutes illegal predetermination in an EIS.

47-2

I am also extremely concerned about the fact that the citizens of the Bitterroot Valley have been illegally denied information that will allow them to fully and meaningfully participate in the National Environmental Policy Act process, because of an illegal denial of a FOIA fee waiver requested by Friends of the Bitterroot, and the subsequent illegal failure to respond within the mandated time frame to the appeal of that denial. This group represents large numbers of citizens in the Bitterroot valley and made this 2nd FOIA request to follow up on information received in the first FOIA. This group widely disseminates the information that they obtain, and this is the only way that the public has access to any information that NIH isn't voluntarily handing out in their completely selective "education" of the public on the issues. I therefore request an extension of the deadline for comments until such time that Friends of the Bitterroot receives the documents that they are entitled to by law.

47-3

Lastly, the SDEIS either doesn't address at all, or inadequately addresses the following issues:

47-4 There is no emergency plan included in the SDEIS, for a whole variety of possible emergencies. There is no mention of what will be done to financially support the community's emergency services, which will need to provide extra training and equipment.

47-5 Incidents of biological agents or toxins released, stolen, or are prohibited from being made public, stated in Homeland Security Act, so that not only can we receive no information about the actual safety record of current BSL-4 labs, but if there is a problem at this lab, if it is built, there is no guarantee that the public will be informed about it. The increased use of the incinerator to burn medical/infectious waste is not adequately addressed. There is not an adequate air pollution analysis. An inventory of toxic chemicals proposed to be used onsite is not made available. There is no analysis of the risks posed by an accidentally infected lab worker. There is not an adequate analysis of the potential income to the local government from payroll taxes. There is not an adequate analysis of the solid waste stream expected from the proposed lab. There is not an adequate analysis of potential conflicts between the proposed projects and the goals of the Ravalli County Growth policy. There is not an adequate analysis of the increased noise and light pollution at night. There is no discussion of the potential for a purposeful release of a hazardous agent or toxin, or what a response plan would include. There is not an adequate analysis of the impacts of the increased traffic in a residential neighborhood. There is no discussion of the risks or safety measures regarding RML and our community becoming a potential target by terrorists.

47-6

47-7 Once again, I am requesting that a new DEIS be released, addressing these issues that have not been addressed, and that NIH already received many requests to address following the first DEIS. And, as stated above, I request an extension of the deadline for comments for this SDEIS until such time that Friends of the Bitterroot receives the documents that they are entitled to by law so that the public can participate in a meaningful manner, as prescribed by NEPA.

Sincerely,

LETTER 47 - CAROL S. BLUM

Comment	Response
47-1	Please see Section 1.7.1 where comments on alternatives were addressed.
47-2	Please see Section 1.7.1 of the SDEIS.
47-3	The NIH has provided in the SDEIS all information relevant to the Proposed Action, including the Proposed Action's environmental impacts. While the Friends of the Bitterroot (FOB) submitted a request for records under the Freedom of Information Act (FOIA), the FOB has refused to pay the standard fees assessed for the records produced pursuant to the DHHS regulations implementing the FOIA, 45 C.F.R. Subpart D. DHHS has carefully considered FOB's request for a waiver to these fees and has determined that no basis exists to grant the waiver under 45 C.F.R. Subpart D or any other law or other authority. The public comment period for the SDEIS was sufficient under the Council on Environmental Quality regulations implementing NEPA and will not be extended.
47-4	Please see Section 1.7.2 where comments on the emergency plan were addressed.

Remainder of responses on following page.

47-5 The Act referred to is the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("Bioterrorism Act"). Section 201 of the Bioterrorism Act ensures that, for security purposes, Federal agencies cannot be made to release certain specific information about select agents -- predominantly related to comprehensive listings of agents and their locations -- under the Freedom of Information Act. However, nothing in the Bioterrorism Act prohibits a facility from voluntarily releasing information to the public about any accident, release, theft, or infection involving select agents. Further, the Bioterrorism Act requires that a facility that handles select agents must notify the Secretary of the Department of Health and Human Services about any release so that the Centers for Disease Control and Prevention (CDC), acting on the Secretary's behalf, can take appropriate action to notify the public and local authorities. CDC's notification is in addition to any actions the facility may take. The facility is not prevented from directly notifying the public about any accident, release, theft, or infection.

47-6 Please see Section 1.7.3 where comments on these concerns were addressed.

47-7 Comments on the DEIS and SDEIS have been addressed in the SDEIS and the FEIS. No additional DEIS will be produced.

Nottingham, Valerie (NIH/OD/ORF)

From: Carolsblum@aol.com
Sent: Wednesday, February 11, 2004 11:26 PM
To: ORS RMLEIS (NIH/OD/ORS)
Subject: RML SDEIS

Carol S. Blum
Hamilton, MT

Valerie Nottingham
NIH
Bethesda, MD 20892

February 11, 2004

Dear Ms. Nottingham:

48-1 Please include the following comment as a supplement to my previous comments on the RML SDEIS. As demonstrated by the recent equipment failure that resulted in the deaths of lab animals at RML, it is clear that humans error and machines fail. It is the norm, not the exception. NIH has stated repeatedly that the risk of a BSL-4 agent release is too small to quantify. It is imperative that the NIH begins to assess this risk based on the circumstances of the accident that just occured at the RML. The risk is certainly not "negligible" as stated in the SDEIS.

Sincerely,

Carol S. Blum

LETTER 48 - CAROL S. BLUM

Comment	Response
48-1	The Integrated Research Facility is designed to eliminate the potential of a human accident causing release of an agent and infection of anyone in the community.

Nottingham, Valerie (NIH/OD/ORF)

From: Hannah L Whitney [hlw@montana.com]
Sent: Wednesday, February 11, 2004 1:35 AM
To: ORS RMLEIS (NIH/OD/ORS)
Subject: RML-expansion-Hamilton,MT

Hannah Whitney
PO Box333
Victor,Mt 59872/10/04

To whom it may concern:

Tell your doctors' lab builders, that we like where we live, obviously they like it here too. If they want to study toxic substances they can do it in an isolated safe place and vacation here. Know too much to be snowed.
Hannah Whitney

LETTER 49 - HANNAH WHITNEY

Nottingham, Valerie (NIH/OD/ORF)

From: John Lehrman [keewaydin@micro-mania.net]
Sent: Tuesday, February 10, 2004 11:57 PM
To: ORS RMLEIS (NIH/OD/ORS)
Subject: Comments on SEIS-rml from J.Lehrman

Dear V. Nottingham,

I am writing in regards to the Rocky Mountain Laboratory(RML) located in Hamilton, Montana. I feel a Level 4 lab in this neighborhood location is inappropriate and irresponsible.

Hamilton's emergency services are finacially struggling and small. Besides being unable to fund the appropriate emergency services, the hospital is physically small and unequipped to handle a biological pathogens outbreak.

Although the RML has an excellent record with few accidents, we must acknowledge the fact that these pathogens will be transported in and out of Hamilton and the possibility of an accident does exist.

Besides these concerns I will briefly list a few other areas of concern.

It is my understanding that through the Public Health Preparedness and Bioterrorism Response Act that information about Released, Stolen, or Lost Agents or Toxins is prohibited from being made public. This is alarming, dangerous, and irresponsible.

The increased use of the incinerator to burn waste and air pollution problems is an issue.

50-1 I would like to see an Alternatives section in the EIS, this is absolutely standard in EIS's.

Noise pollution in the neighborhood and the surrounding areas is a concern.

The increased traffic in the residential area of RML is undesirable.

And lastly, the fact that the Freedom of Information Act requests to NIH for information about the decision process in expanding RML have been repeatedly ignored. One brief memo sent out of the Office of Intermural Research of NIH states this "The RML campus is located in Rural western Montana, well removed from major population centers. The location of the laboratory reduces the possibility that an accidental release of biosafety level-4 organism would lead to a major public health disaster." This statement leaves one uneasy.

Let me state again that the proposed expansion of RML to a Level-4 is inappropriate and irresponsible.

Sincerly,
John S. Lehrman
Hamilton Mt. 59840

LETTER 50 - JOHN LEHRMAN

Comment	Response
50-1	The DEIS, SDEIS and FEIS contain an Alternatives Section at Section 2.2.

Nottingham, Valerie (NIH/OD/ORF)

From: joan [joaniepony@montana.com]
Sent: Tuesday, February 10, 2004 8:57 PM
To: ORS RMLEIS (NIH/OD/ORS)
Subject: rml - comment

In regards to the Bio -Level 4 exspansion on The Rocky Mountain Lab campus,I believe a number of concerns were not adequatey adressed:

51-1 no proper inguiry into real ALTERNATIVES for Bio 4 lab- It seems to me a military base or an urban envoirment where emergency services are available would be more appropriate.

51-2 no examination of the possibility of Earthquake and its damage or how to handle a MAJOR(9-11) type terrorist attack- we need specific PLANS not just reassurances.

51-3 no detailed discussion of the impacts on the local systems ie schools ,roads ,water ,septic etc.

51-4 One of my biggest concerns is the transportation of materials, basically one road in and out of here. The threat of a terrorist hit on Fed Ex or whomever needs to be closely examined.Then spelled out in DETAIL.

If the lab is built I believe that Hamilton and Ravalli County should be compensated for added risks that we would be forced to accept. There would be a need for a new hospital wing, a new middle school , and new airport for emergencies. All of these would be necessary to guarentee safety of our community.

My family and I believe that THE only reason the lab would be built here is the fact that this is an expendable rural community with little health risk due to its low population. It is a bad idea but I am sure its a done deal regardless . This process has been tainted from the start. We may be westerners but we are not stupid. Respectfully submitted,

Joan and David Perry
564 Cielo Vista
Hamilton,Montana 59840

Nottingham, Valerie (NIH/OD/ORF)

From: Steve & Jacque [jre@cybernet1.com]
Sent: Tuesday, February 10, 2004 4:30 PM
To: ORS RMLEIS (NIH/OD/ORS)
Subject: RML

Dear Val
I am 100% in favor of the planned expansion at RML.

Stephen S Ellis M.D.
162 Jayhawk ln
Hamilton, Mt 59840
jre@cybernet1.com

LETTER 51 - JOAN AND DAVID PERRY

Comment	Response
51-1	Please see Section 1.7.1 where comments on alternatives were addressed.
51-2	Please see Section 1.7.3 where comments on earthquakes or terrorism were addressed.
51-3	Please see Section 1.7.3 where comments on these resources were addressed.
51-4	In the event of an accident or "terrorist hit" the Department of Transportation and Federal Bureau of Investigations would respond.

LETTER 52 - STEPHEN S. ELLIS

LETTER 53 - KENT BARBIAN

Nottingham, Valerie (NIH/OD/ORF)

From: Barbian, Kent (NIH/NIAID)
Sent: Tuesday, February 10, 2004 5:37 PM
To: ORS RMLEIS (NIH/OD/ORS)
Cc: Barbian, Kent (NIH/NIAID)
Subject: SDEIS Comment

Ms. Valerie Nottingham,

I have been given substantial time to read and review the SDEIS regarding the lab expansion at Rocky Mountain Laboratories in Hamilton, Montana and wish to comment on it.

First, I would like to state my position: I am FOR the RML Integrated Research Facility! I strongly support RML's mission statement, that is "to play a leading role in the nation's effort to develop diagnostics, vaccines, and therapeutics to combat emerging and re-emerging infectious diseases". Facilities are greatly needed in order to meet this mission and what better place to put these facilities than at Rocky Mountain Laboratories.

Through the SDEIS, the NIH/NIAID has adequately address ALL issues with regards to public safety and environmental impacts/concerns that this expansion may pose to the community as well as the potential benefits to the overall public health in this country. Several public meetings have been held not only to inform and educate the public regarding this expansion, but also to allow for public comment. Overall, the SDEIS has done a phenomenal job in addressing legitimate concerns posed by the community regarding the future lab expansion and has done an outstanding job of providing details on all the issues that needed to be addressed before proceeding.

My hope is that NIH/NIAID proceed as rapidly as possible to begin construction of this much-needed facility.

Kent D. Barbian

Kent D. Barbian, Biologist
Laboratory of Human Bacterial Pathogenesis
Rocky Mountain Laboratories, NIAID/NIH
903 South 4th Street
Hamilton, Montana 59840
(406) 363-9488
kbarbian@niaid.nih.gov

Nottingham, Valerie (NIH/OD/ORF)

From: Rick Fuhrman [rickfuhrman@attglobal.net]
Sent: Tuesday, February 10, 2004 2:59 PM
To: ORS RMLEIS (NIH/OD/ORS)
Subject: Support for RML BSL-4 Facility

Ms. Vallerie Notthingham

I have been, and continue to be, 100% behind the rapid construction and use of a BSL-4 facility.
The Supplemental Environmental Impact Statement , December 2003 only reinforces my support.

RML and NIH have, in my opinion, gone well beyond the extra mile in answering questions and concerns that have been raised. Knowledgeable senior officials and world class experts have repeatedly been available and have addressed questions (repeatedly) with unlimited (to much) patience. Most importantly they have answered questions and concerns with factual information, including detailed descriptions of methodologies that have been employed. Beyond all of that the safety track record of existing BSL-4 labs speaks volumes to this Hamilton resident.

You have done an excellent job of presenting the need for the facilities based on the research objectives evolving from the Presidents directive. I have no doubt that we will live in safer world, including Hamilton, with this facility in place. .

While I remain frustrated with the delays I understand the need for deliberate process. I think deliberate process has been exercised completely and then some, particularly with the recent supplement and presentations. I urge you to move quickly - start building and most importantly ***USING*** the new facility to address your research goals.

Thank you,

Rick Fuhrman
Hamilton, MT

LETTER 54 - RICK FUHRMAN

LETTER 55 - VICKY BOHLIG

GreenPath Properties
Vicky Bohlig, Broker/Owner
217 West Main St. Hamilton, MT 59840

Valerie Nottingham
National Institutes of Health
9000 Rockville Pike
Bldg. 13 Room 2W64
Bethesda, MD 20892
Orsrmleis-r@mail.nih.gov

Feb.10, 2004
(Please note I do not represent Lambros Real Estate.)

I am writing in response to the call for public comment concerning the Supplemental EIS for the Expansion of the Rocky Mountain Lab in Hamilton, MT into a BSL-4 campus. I cannot, in good conscience, approve of this expansion at this site in a rural Montana small-town residential neighborhood and the Supplemental EIS has not convinced me otherwise. Neither do I approve of a similar expansion in a higher density populated neighborhood, such as the one proposed in Boston, for example. It is my belief that a BSL-4 research lab, although necessary for future research and help to humanity, is only appropriately located in an isolated military base, protected and far removed from the general population.

55-1 That being said, I am realistic enough to know that sort of opinion is being discounted as unpractical, too expensive and unpatriotic in the Homeland Security/Patriot Act sacrificial sense. But its omission, this lack of a "build-elsewhere" alternative, is a flaw in the RML SEIS, and perhaps negligent in the NEPA process.

I am not convinced in spite of all the recent public meetings organized by professional federal public relations officers, that the Federal biological research community has Hamilton's best interests in mind. Rather, there is an opportunity to cash in on big monies and is not just research driven but finance driven….. the true motive. The research community is reacting opportunistically and it is Hamilton City and Ravalli County, MT that will feel the effects, good and bad. The bad impacts are what are not being

Comment	Response
55-1	Please see Section 1.7.1 where comments on alternatives were addressed.

addressed in the SEIS in spite of constant and persistent public concern and formalized questions. My experience of the process over almost 2 years has, unfortunately, caused a distrust of RML, which was not there for me in the past. The formalized public meetings, the phony structured Community Liaison Group meetings, the press releases and community outreach events rather than reassuring me have failed to instill trust.

For example, the people are being asked to dismiss any thought of risk. NIH promises risk is negligible. However, there is a refusal to explain this memo "The RML campus is located in rural western Montana, well removed from major population centers. The location of the laboratory reduces the possibility that an accidental release of a biosafety level-4 organism would lead to a major public health disaster." This statement made by someone in NIH of authority makes it clear to me that the sparse surrounding population was a factor to choose and they did consider some risk. True, statistically, there are fewer folks. It does not mean "none" and this risk needs to be addressed. Individual Hamilton lives are as real as individual lives in New York City. **55-2**

I have maintained from my first letter to the editor in 2002 that if the Bitterrooters are being asked to sacrifice, they need to be told their chances and their plan of survival in case of failure. We have been told emergency plans are forth coming but that is not good enough. These plans need to be disclosed in the EIS so we can then see the issues clearly and decide our level of participation. To offer us less, is condescending, paternalistic and in violation of the Montana Constitution, which guarantees freedom of information and public involvement and participation in policy which effects our health and environment. **55-3**

My distrust of RML's intentions started with the EA process over two years ago. These following issues continue to make me wonder how I can trust other assurances from NIH.

The first was how the RML became a BSL-3. I discovered that due to what I consider a NEPA loophole, a remodel project actually allowed RML to go to the BSL-3 level without thorough information and none of its ramifications getting any real public review. Many, many local people of civic importance and leadership were unaware of this major change and feel they were duped.

Comment	Response
55-2	The risk is none, as the risk analysis revealed that there was no real risk from release of infectious agents at a distance of 300 feet from the exhaust ducts. The actual distance to the community exceeds 300 feet.
55-3	Please see Section 1.7.2 where comments on the emergency plan were addressed.

A second issue that made me distrust the Lab's forthrightness was the way the annexation of the property and the hook-ups into the municipal water and sewer system was handled. The Lab surely should have seen that there were weak and confused City Departments of Water and Sewer. Later, as water and sewer billing and rates of usage became suspect, who bothered at the RML to offer information to set it straight? As the City's largest water user, surely the Lab was aware of an under-billing situation. Later this was confirmed and there was a rush to repay the City. But this payment was only partial and every effort was made to hush the scandal and repair the PR damage with not-so-coincidental good neighbor RML press releases.

A third issue was how the RML, behind closed doors with developers "unofficially" used a "straw broker" to buy residential lots adjacent to the RML. Upon this sale, there were recorded covenant changes on these lots that did not get public review that would have been favorable to RML and detrimental to the subdivision homeowners. When this was discovered, everyone involved pleaded innocence and ignorance. I doubt it was a simple mistake.

Other issues eroding my trust was discovering past patterns of improper waste disposal procedures on the RML campus site and in a local landfills, questionable incineration/air pollution problems, excessive noise problems and minimal aesthetic protection during the remodeling projects. This shows to me a RML lack of sensitivity or perhaps even a disregard for the neighborhood's concerns.

The pattern suggested by past RML behavior is "asking for forgiveness from the community after the fact". There is no room for this type of behavior concerning BSL-4 issues. Therefore, I do not trust the assurances BSL-4 will be fine in Hamilton.

I see no efforts in the SEIS to offer alternative sites. I do not see any plans or offers to support or finance emergency services to help the City of Hamilton build infrastructure capacity, police, fire or medical. The City was extremely quick to endorse this BSL-4 project totally for economic development potential but there were no balanced questions about costs. I saw the comments the City of Hamilton Department Heads made and it was pathetic. Where was the City Council to ask the questions I have raised? Where is RML/NIH to offer answers?
Sincerely, Vicky Bohlig 310 Geneva Ave., Hamilton, MT 59840

RML Integrated Research Facility

02-06-04P01:40 RCVD

Public Meeting – January 22, 2004

Comments on the Supplemental Draft Environmental Impact Statement

The stated purpose of the BSL-4 lab is to study and counteract bio-terrorism by groups such as brought down the World Trade towers 9/11/01 after years of planning and training.

The EIS Statement does not address terrorists except for procedure of seeing a suspicious package – completely useless and out of date. If lab research is about to interfer with a planned bio-terrorism attack planned in the USA, it is plausible a couple of "suicide trucks" would come racing south on 5th st, the first blowing the gate, and the second driving thru next to the "containment room", blowing out walls and opening BSL-4 and allowing pathogens and infected lab animals to escape into the surrounding residential areas.

The security cameras mounted on the undestroyed sections of the iron fence protecting the perimeter of the lab campus would record it all!

We cannot depend on Pat Stewart, Marshall Bloom, or our City Administration. Neither the RML or City Auditors, Acct's Payable dept, Public Works, Finance Office ~~[illegible]~~ water or sewer charges at RML are they really dependable?

Name: Richard White

Company/Organization:

Address: 1000 S. Second St.

City, State, Zip: Hamilton, MT 59840

Please send comments to: Valerie Nottingham
NIH, B13/2W64
9000 Rockville Pike
Bethesda, MD 20892

Please note that this document will become part of the administrative record for the EIS and will be subject to public review.

Comments must be post marked by February 11, 2004

LETTER 56 - RICHARD WHITE

Valerie Nottingham
NIH, B13/2W64
9000 Rockville Pike
Bethesda MD 20890
Fax: 301-480-8056

Re: Rocky Mtn Lab Proposal for Bio Level 4

February 11, 2004

Dear Valerie,

I am writing to express my deep concern with the proposal set forth in the Supplemental Draft EIS. It still seems that no real alternatives are being considered and that the government is trying to push this on the citizens of Ravalli County.

In reading the draft EIS the main reason I believe this should not be approved is that we clearly do not have the infrastructure to handle this proposed expansion. Noise, traffic, poor local medical services, extensive water usage and questionable disposal, air inversions, etc. are all legitimate concerns that should prevent this from going any further. These same concerns have been brought up in every meeting I have attended and this draft clearly shows there are no adequate solutions. Regardless if this was the safest lab built, it still would create a burden on the infrastructure that cannot be met even if millions of dollars were available to address them, which they are not.

57-1 I also noticed that the "worst case scenarios" were not worst case by any means. No consideration was given to a plane being flown into the lab, or a disgruntled employee stealing a virus and mailing it, or a "terrorist kidnapping the vehicle in which the viruses were being transported. If anyone of these happened the impact would be catastrophic and not "negligible" as the writers of this would have us believe. The impact on the people of the Bitterroot and our neighboring wilderness area should be significant enough to stop this proposed project dead in its tracks. Isn't it amazing that the only people who seem to favor this are those that would benefit financially.

Please, I beg of you and all those that are making this decision - DO NOT APPROVE THIS! We have given you ample reason over and over again that Hamilton is not the place for a Bio Level 4 Lab. FIND SOME PLACE ELSE!!

I appeal to your higher consciousness.

Sincerely,

I Am Serenity
773 Kindness Way
Hamilton MT 59840

LETTER 57 - I AM SERENITY

Comment	Response
57-1	Please see response to comment 39-21.

Nottingham, Valerie (NIH/OD/ORF)

From: Peter Reynolds [peter@onenessproject.com]
Sent: Wednesday, February 11, 2004 3:17 PM
To: ORS RMLEIS (NIH/OD/ORS)
Subject: "Biosafety" lab 4 in Hamilton Montana

Dear Ms. Nottingham,

58-1 As a citizen of Ravalli County I am writing to express my deep concern that the citizens of this valley have been denied the information they need in order to participate effectively in the NEPA process governing whether the "Biosafety Lab 4" is to located in Hamilton, Montana. We have made a Freedom of Information Act request to retrieve documents which are fundamental to the public in assessing the safety of this installation.

58-2 An NIH memo states "The RML campus is located in rural western Montana, well removed from major population centers. The location of the laboratory reduces the possibility that an accidental release of a biosafety level-4 organism would lead to a major public health disaster." This statement must be explained. It certainly leads one to believe that the residents of Ravalli County are expendable in the search for the most virulent weapons known to man. What other alternatives exist for the location of the lab?

58-3 I also feel that the Supplemental Draft EIS report falls short in many areas. There is no emergency plan specified in that report. If there is a release of toxins or agents the public will not be informed because of measures in the Homeland Security Act. The EIS does not address how an accidentally infected lab work would be dealt with. These are among the many items not adressed.

I strongly feel that the United States Government should not be engaged in doing this kind of research AT ALL. In the end, we need to build a safer world in other ways.

Thank you for the opportunity to comment on this proposed facility.

Sincerely,

Peter Reynolds
465 Weber Heights Road
Corvallis, MT 59828
(406) 961-1484

LETTER 58 - PETER REYNOLDS

Comment	Response
58-1	To the extent that the comment refers to a request for records submitted to the NIH by the Friends of the Bitterroot, please see the response to comment 47-3. To the extent the comment refers to a different request made under the FOI Act, the NIH has provided in the SDEIS all information relevant to the Proposed Action, including the Proposed Action's environmental impacts.
58-2	Please see response to comment 39-12.
58-3	Please see Section 1.7.2 where comments on the emergency plan were addressed. Please see Section 1.7.3 where comments on the use and disposal of hazardous chemicals were addressed. Please see response to comments 39-16, 47-5, and 47-6.

Nottingham, Valerie (NIH/OD/ORF)

From: Millerfob@aol.com
Sent: Wednesday, February 11, 2004 4:05 PM
To: ORS RMLEIS (NIH/OD/ORS)
Subject: RML SDEIS Comments

James B. Miller
541 Mill Creek Trail
Hamilton, MT 59840

Valerie Nottingham
NIH
Bethesda, MD 20892

February 11, 2004

Please accept my comments here on the RML SDEIS as supplemental to the oral comments I presented as a private citizen at the RML public meeting last month.
Regretfully, the NIH has withheld important information from the public pertaining to the proposed RML Biolevel-4 expansion. This information was requested by the Friends of the Bitterroot six months ago under the Freedom of Information Act. I believe that this information is crucial to my meaningfull participation in the NEPA process. I hereby request that the deadline for comments on the RML SDEIS be extended until such time that the our community has access to this information.

59-1

Sincerely,

James B. Miller

LETTER 59 - JAMES B. MILLER

Comment	Response
59-1	Please see response to comment 47-3.

Nottingham, Valerie (NIH/OD/ORF)

From: Millerfob@aol.com
Sent: Wednesday, February 11, 2004 11:16 PM
To: ORS RMLEIS (NIH/OD/ORS)
Subject: RML SDEIS Comments

James B. Miller
541 Mill Creek Trail
Hamilton, MT 59840

Valerie Nottingham
NIH
Bethesda, MD 20892

February 11, 2004

Dear Ms. Nottingham:

Please include the following comment as supplemental to my previous comments on the RML SDEIS. As demonstrated by the recent equipment malfunction that resulted in the deaths of lab animals at RML, it is clear that humans error and machines fail. It is the norm, not the exception. NIH has stated repeatedly that the risk of a BSL-4 agent release is too small to quantify. It is imperative that the NIH begins to assess this risk based on the certainty that humans error and machines fail. The risk is certainly not "negligible" as stated in the SDEIS. **59-2**

Sincerely,

James B. Miller

Comment	Response
59-2	Please see Section 4.2.1.1 of the SDEIS, Community Safety and Risk, where Risk Assessments are addressed.

FRIENDS of the BITTERROOT
P.O. Box 442
Hamilton, MT 59840

January 25, 2004

Valerie Nottingham
NIH, B13/2W64
9000 Rockville Pike
Bethesda, MD 20892

Dear Ms. Nottingham:

The NIH is currently in violation of Freedom of Information Regulation § 5.35(b)(2) for not responding to Friends of the Bitterroot's FOIA appeal, received by the FOIA appeals office November 10th, 2003, by the required deadline. The NIH has also violated 5 U.S.C. 552(a)(6)(A)(iii) and 45 C.F.R. 5.45(a)(1)(2) for not granting our fee waiver request, as required by law. We have notified the NIH that if they do not overturn the fee waiver denial and begin providing the requested information to us, by January 30th, 2004, that we will take this matter up in Federal Court. The NIH has been in possession of our FOIA request for 6 months and has failed to act. As a result, pursuant to 40 C.F.R. 1506.6 (Public Involvement) and 1507.1 (Compliance) Friends of the Bitterroot has been illegally denied important documents and information that are crucial to our meaningful participation in the NEPA process for the proposed BSL-4 expansion at Rocky Mountain Laboratories. For this reason, we require that the deadline for comments on the SDEIS be extended until 45 days after we receive the documents in our FOIA request, to which we are legally entitled. We request a written response by February 6, 2004. **59-3**

Sincerely,

James B. Miller, President

Comment	Response
59-3	Please see the response to comment 47-3.

Nottingham, Valerie (NIH/OD/ORF)

From: Winston Weeks [w.weeks@comcast.net]
Sent: Wednesday, February 11, 2004 4:19 PM
To: ORS RMLEIS (NIH/OD/ORS)
Subject: Letter of Support for FOIA Request

Dear Ms. Nottingham,

As an organization active in protecting the safety of all Americans and believing in the right of citizens to participate in citizen oversight, we fully support the Friends of the Bitterroot's FOIA appeal and the legal statement below.

"We, and the Bitterroot valley citizens whom we represent and inform, have been illegally denied important documents and information that are crucial to meaningful participation in the NEPA process for the proposed

BSL-4 expansion at Rocky Mountain Laboratories (pursuant to 40 C.F.R. 1506.6 and 1507.1). The NIH is currently in violation of Freedom of Information Regulation 5.35(b)(2) for not responding to Friends of the Bitterroot's FOIA appeal, received by the FOIA appeals office November 10th, 2003, by the required deadline. The NIH has also violated 5 U.S.C. 552(a)(6)(A)(iii) and 45 C.F.R. 5.45(a)(1)(2) for not granting a fee waiver request, as required by law. The NIH has been in possession of this FOIA request for 6 months and has failed to act. We view these actions as deliberate stonewalling of our groups and the large number of

citizens that we represent, while NIH hurriedly moves forward with the scoping process on the proposal. For this reason, we require that the
60-1 deadline for comments on the SDEIS be extended until 45 days after we receive the documents in our FOIA request, to which we are legally entitled."

Sincerely,

Winston C. Weeks
Citizens Education Project
Salt Lake City, Utah
801-502-9233

LETTER 60 - WINSTON WEEKS

Comment	Response
60-1	Please see the response to comment 47-3.

Nottingham, Valerie (NIH/OD/ORF)

From: Darel L. Seibert, D.C. [drdarel@yahoo.com]
Sent: Wednesday, February 11, 2004 4:29 PM
To: ORS RMLEIS (NIH/OD/ORS)
Subject: Public comment on expansion at RML

Ms Valerie Nottingham,

Upon review of the supplemental Draft EIS of proposed expansion at RML, I have comments including the following;

The risk to community is listed as "negligible". Possibly this is underrated and should be investigated honestly. Negligible is possibly not an accurate rating if you were to live here. Risks involved with "accidental" exposure are low, but when you consider exponents like workers that do not reveal exposure until after symptoms develop, or to artificially elevate safety records, etc. risks are maybe not as negligible as you would like to think.

61-1 Where in the EIS is the emergency plan contingency addressed? I was unable to find any reference to updated EMS plans, and protocols.

61-2 Increased usage of incinerator at site will add additional pollutants to the air shed, where is analysis of this projected health risk? Concurrently, increased solid waste release will need to be addressed.

Alternatives to site are dismissed as being outside "budget constraints". There are remote military reservations that could be more appropriate for extreme biohazards like these agents, and they have already the infrastructure in place to support the "scientist community". Dismissing the alternatives so easily adds to the feeling that the choice to build upgrade at Hamilton is affected excessively by the "desires" of the scientist community and that they and their families like the idea of living in this beautiful community.

61-3 Where is there analysis of how the increased community loading of the upgrade having been projected to the Ravalli County growth policy standards?

61-4 Traffic will increase in local residential district surrounding the laboratory. This impact needs to be addressed in the EIS. Where is that impact statement, and what proposed upgrades are proposed.

Thank you for interviewing my comments.

Sincerely, Darel L. Seibert, D.C.

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LETTER 61 - DAREL SEIBERT

Comment	Response
61-1	Please see Section 1.7.2 where comments on the emergency response plan were addressed.
61-2	Please see Section 1.7.3 where comments on the increased use of the incinerator were addressed.
61-3	Please see response to comment 39-19.
61-4	Please see Section 1.7.3 where comments on the effects of the Proposed Action on traffic were addressed.

Nottingham, Valerie (NIH/OD/ORF)

From: Darel L. Seibert, D.C. [drdarel@yahoo.com]
Sent: Wednesday, February 11, 2004 9:37 PM
To: ORS RMLEIS (NIH/OD/ORS)
Subject: RML accident 2/7,8/2004

Valerie Nottingham,

Regarding safety measures at RML, the proposed upgrade to BSL-4 EIS indicates that we the Hamilton Montana community and neighborhood citizens have NOTHING to worry about regarding accidents at your installation.

You are abundantly aware at this point that there are instances when your protocols and the installation in general are subject to error. You understand that issues of lack of notification when breaches occur is entirely possible and has occurred in this accident at RML on 2/7,8/2004.

Your attempt to convince the residents of the Hamilton Montana area that these types of accidents do not occur has been breached. You understand that we are concerned and understand that the loss of the laboratory animals is example of how accidents can and will happen.

Our questions pertaining to the safety measures, emergency plans, and general what ifs are grounded in our beliefs that accidents can and do happen.

The simple fact that the accident of 2/7,8/2004 occured is not the only factor here. The fact that the security personel were not notified, and therefore the accident propagated is alarming. This is blantant oversight and irresponsibility on the behalf of RML.

Sincerely, Darel L Seibert, D.C.

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Comments on the Supplemental Draft Environmental Impact Statement (SDEIS) for the Integrated Research Facility, RML

February 2004

Comments submitted with the primary purpose of facilitating the democratic process in helping Mr. Stephen A. Ficca, the Decision Maker, and Dr. Fauci, the Director of NIAID, and the public make a decision based on an open disclosure of a science based analysis of the benefit, costs and risks of the RML BSL-4 lab expansion.

Friends of the Bitterroot

Women's Voices for the Earth

Friends of the Bitterroot
Women's Voices for the Earth
Coalition for a Safe Lab

LETTER 62 - FRIENDS OF THE BITTERROOT, WOMEN'S VOICES FOR THE EARTH, COALITION FOR A SAFE LAB

February 11, 2004

To: Valerie Nottingham
NIH, B13/2W64
9000 Rockville Pike
Bethesda, Maryland 20892

From: Coalition for a Safe Lab
P.O. Box 1803
Hamilton MT 59840

Women's Voices for the Earth
P.O. Box 8743
Missoula, MT 59807

Friends of the Bitterroot
PO Box 442
Hamilton, MT 59840

Subject: Comments and concerns regarding the Supplemental Draft Environmental Impact Statement for the National Institutes of Health, Rocky Mountain Laboratories proposed Integrated Research Facility in Hamilton, Montana

Date: February 11, 2004

Dear Ms. Nottingham,

We appreciate the opportunity to comment on the Supplemental Draft Environmental Impact Statement (SDEIS) for the National Institutes of Health (NIH) Rocky Mountain Laboratories (RML) proposed Biosafety Level-4 (BSL-4) Integrated Research Facility in Hamilton, Montana. Our members in the Bitterroot Valley and surrounding areas have demonstrated considerable interest and concern about this project which poses significant impacts to nearby communities. Our interest is to ensure that the EIS process generates meaningful discussions, disclosures and analyses between NIH, RML and the public about these impacts.

We understand that the SDEIS was released in an effort to include new and significant information and analyses not previously included in the original DEIS. We appreciate this effort, but we are disappointed that the majority of our comments on the DEIS were not addressed in this new document. Althoug somewhat improved, there continues to be a lack of meaningful discussions, disclosures and/or analysis in the SDEIS and believe that it falls short of the thoughtful, thorough analysis and study that characterizes the scientific investigations carried out by NIH. We believe the SDEIS can be significantly improved to provide the information that is needed to assess the risks and establish effective mitigation.

The duties of federal agencies under National Environmental Policy Act (NEPA) are

defined in great detail under the Council on Environmental Quality (CEQ) Regulations found at 40 C.F.R. 1500 et. Seq. The regulations are not discretionary, and apply to all agencies:

> "40 C.F.R. 1500.3 – MANDATE:
> Parts 1500 through 1508 of this title provide regulations applicable to and binding on all Federal agencies for implementing the procedural provisions of the NEPA."

The Supreme Court has instructed that the CEQ regulations are entitled to "substantial deference". (Andrus v. Sierra Club, 442 U.S. 347, 358 (1978); Accord, Robertson v. Methow Valley, 490 U.S. 332 (1989))

Additionally, a number of Circuits have held that the CEQ regulations are controlling. (See, e.g., National Indian Youth Council v. Watt, 644 F.2d 220 (10th Cir. 1981); Sierra Club v. Sigler, 695 F.2d 957 (5th Cir. 1983))

The DEIS acknowledges several times that the NEPA/CEQ regulations are controlling, (DEIS 1-1, 1-2, and 1-6). Furthermore, the DEIS states that: "This document follows the Council of Environmental Quality regulations for implementing procedural provisions of NEPA (40 CFR Parts 1500-1508)." (DEIS 1-1)

We respectfully disagree. We believe that the SDEIS contains fatal procedural flaws and does not fully and completely comply with the CEQ regulations.

The analysis presented in the SDEIS continues to be inadequate given the scope and cost of this project. The NIH has provided several opportunities for the community to ask questions and provide input in the scoping process. As a result, the NIH received hundreds of substantive comments and detailed questions on the project from a caring and interested community. The very brief resulting document does not do justice or show respect for the efforts community members have taken to comment on the project.

The SDEIS does not reflect the competency or abilities of its authors, Maxim Technologies. For example, the Voluntary Cleanup Plan, which Maxim Technologies recently authored for RML, is both longer and more thorough than the SDEIS, despite the fact that it describes a considerably smaller and less expensive project. The community has shown their sincere interest in this project and we deserve more thorough answers to our questions.

62-1 For this reason, a third draft environmental impact statement is warranted to allow for public review of the answers to the questions the public has asked.

The General Administration Manual for the Department of Health and Human Services includes a section on environmental protection outlining procedures for Environmental Impact Statements conducted by the department. Section 30-30-40 states:

"Whenever a draft environmental impact statement is significantly revised because of

Comment	Response
62-1	Please see response to comment 47-7.

comments received or because the nature or scope of the proposed action changes significantly, OPDIVs/STAFFDIVs shall prepare a new draft environmental impact statement for circulation." (Revised General Administration Manual, HHS Part 30, Environmental Protection. Published in the Federal Register: February 25, 2000 (Volume 65, Number 38) Pages 10229-10284.)

Given the continuing significant flaws in the SDEIS and outlined in our comments, your manual requires NIH and RML to significantly improve the SDEIS and republish it for public comment.

62-2 In addition, we, and the Bitterroot valley citizens whom we represent and inform, have been illegally denied important documents and information that are crucial to meaningful participation in the NEPA process for the proposed BSL-4 expansion at Rocky Mountain Laboratories (pursuant to 40 C.F.R. 1506.6 and 1507.1). The NIH is currently in violation of Freedom of Information Regulation 5.35(b)(2) for not responding to Friends of the Bitterroot's FOIA appeal, received by the FOIA appeals office November 10th, 2003, by the required deadline. The NIH has also violated 5 U.S.C. 552(a)(6)(A)(iii) and 45 C.F.R. 5.45(a)(1)(2) for not granting a fee waiver request, as required by law. The NIH has been in possession of this FOIA request for 6 months and has failed to act. We view these actions as deliberate stonewalling of our groups and the large number of citizens that we represent, while NIH hurriedly moves forward with the NEPA process on the proposal. For this reason, we require that the deadline for comments on the SDEIS be extended until 45 days after we receive the documents in our FOIA request, to which we are legally entitled.

If you have any questions you may contact any of the signatories below.

Sincerely,

Alexandra Gorman
Director of Science and Research
Women's Voices for the Earth

James Miller
President, Friends of the Bitterroot

Mary Wulff
Coalition for a Safe Lab

Cc: Dr. Fauci Director NIAID, Stephen A. Ficca, Governor Judy Martz, Senator Conrad Burns, Senator Max Baucus, Representative Dennis Rehberg, Mayor Joe Petrusaitis

Comment	Response
62-2	Please see response to comments 47-3 and 58-1.

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Comments:

62-3 1. The majority of the comments we submitted on the DEIS in July, were not addressed in the SDEIS.

In the document we submitted last July, we included at least 109 distinct substantive comments on the DEIS. Each comment was specifically numbered in the "Detailed Table of Contents" at the beginning of the document. Additional substantive comments were also included in the appendix to our document entitled "RML Draft EIS, Presented to the Town meeting June 25, 2003." We are resubmitting our original comments as we continue to believe that they are relevant to the proposed project and ask that they be addressed in the next draft of the EIS. (Our original comments have been appended to the end of this document.)

The NIH must follow the NEPA guidelines found in 40 CFR 1503.4 with respect to responding to public comments. 40 CFR 1503 states:

"*Sec. 1503.4 Response to comments.*

(a) An agency preparing a final environmental impact statement shall assess and consider comments both individually and collectively, and shall respond by one or more of the means listed below, stating its response in the final statement. Possible responses are to:
(1) Modify alternatives including the proposed action.
(2) Develop and evaluate alternatives not previously given serious consideration by the agency.
(3) Supplement, improve, or modify its analyses.
(4) Make factual corrections.
(5) Explain why the comments do not warrant further agency response, citing the sources, authorities, or reasons which support the agency's position and, if appropriate, indicate those circumstances which would trigger agency reappraisal or further response.
(b) All substantive comments received on the draft statement (or summaries thereof where the response has been exceptionally voluminous), should be attached to the final statement whether or not the comment is thought to merit individual discussion by the agency in the text of the statement."

None of the individual substantive comments constituted more than a page or two, and thus could not be considered "exceptionally voluminous". We fully expect, in accordance with 40 CFR 1503.4, that each one of our comments will be individually responded to in the final EIS.

It appears, however, (given the content of the current SDEIS), that NIH may have considered the many of our comments to "not warrant any further agency response". We look forward to seeing an official response to these comments which includes an explanation why each comment did not warrant further response "citing the sources,

Comment	Response
62-3	Please see the responses for comment 62-4 through 62-14.

authorities, or reasons which support the agency's position and, if appropriate, indicate those circumstances which would trigger agency reappraisal or further response."

2.) Comments that must be addressed through 40 CFR 1503.4 section (a) (2) "*Develop and evaluate alternatives not previously given serious consideration by the agency.*"

The NIH has received numerous requests from the public (throughout the EIS process) for a full analysis of alternative locations for the proposed IRF. According to the SDEIS, a full ten percent of comments received focused on a need for additional alternatives (SDEIS, p 1-9). We noticed that while some additional wording was added to the "rationale for dismissing" the proposed alternatives in the SDEIS, we were disappointed to see that there were still no alternatives in the document other than the proposed alternative and the no action alternative. While Congress allocated $66.5 million to NIAID in Public Law 107-117, Congress did not specify the location of the expansion in the law. We continue to believe this lack of analysis of alternative locations to be inadequate, especially for a project of this size and scope, and given the extensive public interest in alternative locations. According to 40 CFR 1502.14 the Alternatives section is "the heart of the environmental impact statement". We believe it deserves much greater attention.

Specifically, we would like to comment on the "rationales for dismissing" two of the proposed alternatives.

Section 2.2.2.1 of the SDEIS (pp. 2-17 and 2-18) proposes a rationale for dismissing the alternative to build the IRF in Bethesda, MD. It states, "*Based on the NIH Bethesda Master Plan, there are currently no available spaces on either campus capable of accommodating the Proposed Action. All unoccupied sites have been developed or are otherwise allocated.*" This appears to be saying that the Master Plan blocks the NIH from developing any new projects not already included in the Master Plan. However, a brief review of the EIS for the NIH Bethesda Master Plan reveals a very different opinion. That EIS clearly states:

62-4

" *The proposed action is a Master Plan that would guide and coordinate physical development of the NIH Bethesda campus in terms of buildings, utilities, roads and streetscape, landscapes, and amenities over the next 20 years in response to projected NIH administrative, research and infrastructure support needs (Draft NIH Master Plan, Main Campus, NIH, 1995). The Master Plan does not commit NIH to any of the projects proposed. Implementation of any project in the Master Plan is dependent on congressional funding… While the Master Plan makes relatively specific estimates for growth in campus population and facilities over the next 20 years, actual growth on campus will depend on future congressional and presidential policy decisions, as well as Federal budgetary constraints. Changes in national health policy could occur over the next decade, and NIH's mission could be significantly affected as a result. The Master Plan is a guiding map on how growth would take place on the Bethesda campus, were it to occur. The growth anticipated in the Master Plan may not occur to the extent indicated." (From 1.5 SUMMARY OF PROPOSED ACTION) (Emphasis added)*

"The Master Plan is a general planning document to guide physical development at NIH Bethesda. It is intended that it be flexible to meet changing NIH needs. NIH may deviate from the plan in siting some specific buildings or facilities. The Master Plan does not commit NIH to implementing specific projects

Comment	Response
62-4	The master plan does not block NIH from developing new projects in Bethesda. While development is flexible within designated land use areas, the land has to be vacant and available for construction. The SDEIS notes that there is no readily available land on the Bethesda campus. Relocating existing facilities, revising the master plan, demolition, etc., would require hundreds of millions of dollars and take up to 10 years, making this alternative unrealistic.

indicated or illustrated in the plan." (From Section 1.8 APPROVALS/ACTIONS REQUIRED BY OTHER GOVERNMENT AGENCIES) (Emphasis added)

(Source: Final Environmental Impact Statement, Vol. 1 of 2 for The 1995 Master Plan Available at: http://ocl.od.nih.gov/95EIS03.htm)

It is quite clear, that in the last two years that changes both in "national health policy" and the "NIH mission" have occurred with respect to its new charge to fight bioterrorism. In addition, congressional funding has already been allocated to the proposed IRF, whereas, it has not yet been allocated to several of the proposed projects in the Master Plan. Stating that "all unoccupied sites have been developed or are otherwise allocated" is simply inaccurate, given that the Master Plan is designed to be flexible, and not all parts of the plan have been funded. It is illogical that NIH would refuse to even consider prioritizing the placement of a congressionally funded building that directly meets the needs of a new Presidential directive on its Bethesda campus over an unfunded building that does not meet those needs. Therefore, we conclude that this SDEIS does not, in fact, present a rationale for dismissing this alternative. A fully developed alternative to build the IRF in Bethesda must be included in the next draft of the EIS. **62-5**

Section 2.2.2.3 of the SDEIS proposes the rationale for dismissing the alternative of constructing the IRF at an alternate location (p.2-19). It states, "*Locating the BSL-4 laboratory at a separate location from the existing RML campus would eliminate the connected research on projects that use BSL-2 and BSL-3 facilities, making research inefficient and impractical.*" The proposed IRF includes new BSL-2 and BSL-3 laboratory space, meaning that connected research at different biosafety levels could still occur in the IRF even if it was at a separate location. In addition, it is very clear that NIH researchers are extremely efficient and adept at working with one another even when they are not located in the same building. The NIH-Bethesda campus houses thousands of scientists who work closely and regularly with their colleagues who are located in off-campus buildings in Rockville, MD several miles away. Regular shuttle bus services between the campuses as well as use of technology such as email, telephone and even videoconferencing make this arrangement perfectly workable and not at all to the detriment of the science performed by NIH. It is doubtful that the researchers at RML would be any less able to establish a good working relationship with researchers at a satellite facility located outside of the Hamilton town center, but within a few minutes drive. There is no reason why an off-campus building of Rocky Mountain Laboratories could not be constructed to house the IRF facility without "making research inefficient and impractical". The only other rationale proposed for dismissing this alternative was a conflict with "federal funding parameters". It is unclear how that conclusion can be drawn without either detailing what the cost of a satellite facility would be or what the federal funding parameters in fact are. According to 40 CFR 1502.23: **62-6**

"Sec. 1502.23 Cost-benefit analysis.
If a cost-benefit analysis relevant to the choice among environmentally different alternatives is being considered for the proposed action, it shall be incorporated by reference or appended to the statement as an aid in evaluating the environmental consequences."

Comment	Response
62-5	This alternative still does not meet the purpose and need, as stated in the DEIS and SDEIS. Additionally, there is no environmental advantage over the alternatives that were considered in detail. Please see page 2-17 of the SDIES.
62-6	Please see response to comment 10-1.

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62-7 Simply stating that the alternative fails to meet federal funding parameters is not a cost-benefit analysis. If the alternative is being dismissed as too expensive, a cost-benefit analysis must be done and included in the next draft EIS to verify this statement. Again, we conclude that no rationale for dismissing this alternative has been presented in this SDEIS. A fully developed alternative for building the IRF at an alternate location must be included in the next draft of the EIS.

3) Clarification needed on the study of biological weapons

62-8 According to the SDEIS, "*RML does not work on and will not work on or develop biological weapons as this is forbidden by a national security directive and international law. President Nixon, in 1969, agreed to a National Security Decision Memorandum (35), which renounced the use of lethal methods of bacteriological/biological agents. The U.S. signed...*" [SDEIS 1-1). Neither the National Security Decision Memorandum (35) nor the Convention cited prohibit the study of biological weapons for peaceful purposes - and in fact explicitly state study of biological weapons for peaceful purposes is allowed. We can only conclude that NIH continues to refuse to respond to continued questions as to whether or not any biological weapons will be present at RML. 40 CFR 1506.6 (f) states:

"*Make environmental impact statements, the comments received, and any underlying documents available to the public pursuant to the provisions of the Freedom of Information Act (5 U.S.C. 552), without regard to the exclusion for interagency memoranda where such memoranda transmit comments of Federal agencies on the environmental impact of the proposed action. Materials to be made available to the public shall be provided to the public without charge to the extent practicable, or at a fee which is not more than the actual costs of reproducing copies required to be sent to other Federal agencies, including the Council.*"

In order to comply with the CEQ, NIH must answer the following questions as a minimum:

62-9 1. Is there any law or regulation that prohibits the presence of an agent that was designed as a biological weapon to be present at RML? YES___ NO___.

62-10 2. Is there any law or regulation that prohibits the creation of an agent that is designed as a biological weapon to be present at RML for study for peaceful purposes? YES___ NO___.

62-11 3. Will agents be present that NIH will consider as classified information that they will refuse to disclose for any reason, including national security reasons? YES___ NO___.

62-12 4. Have there been agents present whose presence NIH has or would now consider as classified information or have or would refuse to disclose for any reason, including national security reasons? YES___ NO___.

Comment	Response
62-7	Additional information on the estimated cost of constructing an Integrated Research Facility at some new intramural location has been included in Chapter 2.
62-8	Page 4-5 states "NIH and its associated laboratories including RML, do not, and would not, work with weapons-grade material." This statement is also included in the DEIS on page 4-2.
62-9	No. Please see page 1-1 of the FEIS were this has been addressed.
62-10	No. Please see response to comment 62-9.

Remainder of responses on following page.

62-11 The general policy of the government is not to restrict information about fundamental research. (See National Security Decision Directive 189, September 21, 1985). However, it is possible that some information about research conducted at the RML could be classified. Information can be classified only under Executive Order 13292 (March 28, 2003), which sets very specific requirements for classification. To be designated as "classified," information that is owned, produced by or for, or controlled by the Government must fall into one of eight categories defined in the Executive Order, and disclosure of the information would have to be reasonably expected to result in identifiable or describable damage to the national security (i.e., national defense or foreign relations of the U.S.), including defense against transnational terrorism. Of note, scientific information falls in a classification category only when it is related to national security.

62-12 Yes. Agents that are on the NIH inventory that are currently classified have been present at RML in the past.

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62-13 5. Explain why the "worst case" scenario model for a release from RML was declared classified because, according to the author (verbal communication), they did not want to educate terrorists while at the same time NIH claims that biological weapons will not be "worked on" by RML.

62-14 4) Numerous citations from Chapters 3 and 4 were not included in the "Literature Cited" section on pages L-1-5.

Citations to credible documents are crucial to providing accurate information in a Draft EIS. Without a complete bibliography, it is impossible for the public to verify the accuracy of the claims made in the document. Where possible, for citations that are listed as "Name, year. Personal communication" which refer to letters, emails or other written correspondence, copies of the those documents must be included in the appendix for public review. The missing citations include:

P. 3-4
Bartos, 2003
Wilson, 2003 (This citation appears to be incorrect, the text has nothing to do with the safety of BL-4 agents.)

P.4-2:
Rollins, 2003
Bowers, 2003
Halladay, 2003
Dowling, 2003
Polumsky, 2003
Rose, 2003

P. 4-7:
Risi, 2003
Wilson, 2003a
Auch, 2003
Hoffman, 2003
Neff, 2003
Bartos, 2003 (Presumably, this should have been cited.)

P.4-8:
Harding & Byers, 1999
Johnson, 2003

P.4-10:
NSF (National Sanitation Foundation) 2002
First, 1996

Comment	Response
62-13	Please see response to comment 39-21.
62-14	These references have been included or corrected. We apologize for the oversight.

WHO, 2002
U.S. DOT, 2001
Rotz, 2002
Brachman, 1966
Risk Assessment Scenarios - No author or citation were provided for this risk assessment.

P. 4-26:
USGS, 2000
HDR, 2003

There may be others which we missed. The entire document should be carefully reviewed to ensure the bibliography in the Literature Cited section is complete and accurate.

62-15

5) Comments that must be addressed through 40 CFR 1502.14 (f) "Include appropriate mitigation measures not already included in the proposed action or alternatives."

In section 6.2.3 of our comments on the DEIS we listed a series of reasonably foreseeable scenarios. They included:

6.2.3a Staff infections that are isolated to lab environment.
6.2.3b Staff infections that result in a community wide epidemic.
6.2.3c Release of infections through escaped animals.
6.2.3d Release of infectious prions through the incinerator including an assessment of recombination after cooling in the smokestack.
6.2.3e Release of infectious agents through water via sewage, wetlands, or surface water.
6.2.3f Release of infectious agents through ground due to spills or purposeful dumping.
6.2.3g Release of infectious agents when being transported.
6.2.3h Release of infectious agents through water via sewage, wetlands, or surface water.
6.2.3i Release of infectious agents because of an out of control fire.
6.2.3j Release of infectious agents through intentional acts by a staff member.
6.2.3k Release of infectious agents due to a terrorist attack with a bomb or aircraft.
6.2.3l Release of infectious agents due to the safety committee and staff failing to understand the behavior and danger of a new pathogen under study.
6.2.3n Release of infectious agents due to a failure of the safety systems.
6.2.3o The causal release environment: accidental spill, fire, terrorist explosion.
6.2.3p Release through steam exhaust.

We asked NIH to disclose the risks of these scenarios. These risks were not adequately assessed. And some of the above scenarios were never considered, addressed or even mentioned in the SDEIS. We again ask that the risks from these scenarios be analyzed in the next DEIS. In addition, we ask that mitigation measures be included in the next DEIS for those risks which cannot be eliminated.

Comment	Response
62-15	Measures are to be included "to mitigate adverse environmental impacts" (CEQ 1502.16(h)). Since there were no adverse impacts identified from the items listed, no mitigation is necessary. Please see Section 1.7.3 where comments on the potential increased threat of outbreak are addressed.

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62-16 6) Detailed risk analysis and mitigation measures (such as the emergency plan) must be included in the next DEIS for the risks of laboratory-acquired infections.

Appendix D of the SDEIS "Review of the Biocontainment Laboratory Safety Record" provides clear evidence that accidents do occur in BSL-4 labs that can lead to laboratory-acquired infections, and that laboratory-acquired infections have occurred at Rocky Mountain labs BL-2 facilities. The conclusion of this report, however, states "*The zero numerator of infections in these three laboratories and the huge denominator of exposure hours make it impossible to provide a number for "risk of infection" to either laboratory workers or outside communities*." It appears to be saying that because an laboratory-acquired infection has never occurred at nay of the three BL-4 labs investigated, the risk of such an infection cannot be quantified. Interestingly enough, in Chapter 4, a quantitative risk assessment of accidental release of anthrax (a scenario which has presumably never happened at a BL-4 lab either) was able to calculate a risk as precise as ".000011 spores released to the environment." Seeing as the original DEIS claimed the risk of release to the community "cannot be quantified", and the SDEIS followed up by actually quantifying it, it seems likely that the risk of a laboratory-acquired infection can in fact (and should) be quantified in the next DEIS.

In addition, extremely pertinent information on laboratory-acquired infections is missing from Appendix D. This report shows that multiple accidents including needle sticks, animal bites, tears in gloves and suits and containment failures occurred in the three BL-4 labs researched. While it is fortunate that none of those accidents led to clinical infections, it is clear that any of those accidents could have led to an clinical infection. It is well-documented that needle-stick accidents (for example) are a pathway for transmitting disease. Clearly, the fact that no clinical infections occurred in the three labs had nothing to do with safety aspects of a BL-4, or characteristics of BL-4 diseases, but rather is directly related to the quality and timing of the care the exposed worker received. As soon as such a significant laboratory accident happens, the risk of a clinical infection can only be lessened by the quality and timing of medical treatment of the exposed worker. How, where, how soon were the exposed workers at the three labs given treatment for their exposure? What experience, knowledge, equipment was available to the healthcare providers who treated the exposed workers? This pertinent information was not included in the report, but should have been.

The very best (and likely, only) mitigation measure for the risk of laboratory-acquired infections is a well structured, well funded emergency plan. The current lack of an emergency plan is a serious omission. It is the document that provides the details of how exactly the risk of an laboratory-acquired infection would be handled. It is the only document that allows the public to know that our current medical and emergency resources are adequate to mitigate this risk. Clearly we cannot accurately assess the risk, which is dependent on the adequacy of our community's ability to respond, until we know how well we will be able to mitigate it. The NIH cannot legally wait until after the NEPA process is finished to ascertain the magnitude of the risk of an incurable, fatal infection in an RML employee. The emergency plan must be included in the next DEIS.

Comment	Response
62-16	Please see response to comment 62-15.

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62-17 7) Mitigation measures involving Marcus Daly Hospital and St. Patrick Hospital must be included.

Section 4.2.1.1 of the SDEIS briefly discusses "emergency response". It states, "Mr John Bartos of Marcus Daly Hospital…did question whether capital improvements would be needed should a life-threatening injury be transported to Marcus Daly Hospital for stabilization…"(P. 4-7). On Page 3-4, it states that Marcus Daly Hospital could not handle more than 10 emergency patients. Thes two statements create significant public concern about the adequacy of Marcus Daly Hospital to handle a life-threatening emergency at the lab. No other BL-4 lab in the country is in a location that faces this problem. All BL-4 labs are within very close proximity to large medical facilities capable of handling significant numbers of highly infectious emergency patients. The problem in Hamilton is not unsolvable. Mitigation alternatives which provide additional resources for Marcus Daly Hospital to be better prepared to handle an emergency at the lab must be included in the next DEIS.
Similarly, little detail is provided on the abilities of St. Patrick Hospital to respond to an emergency. Page 4-7 states "*St. Patrick Hospital meets all required standards for handling infectious disease cases.*" This statement neglects to mention how many highly infectious emergency patients St. Patrick Hospital would be able to handle. This is pertinent information in determining the hospital's ability to handle a major accident at the lab. Mitigation alternatives which provide additional resources for St. Patrick Hospital to be better prepared to handle an emergency at the lab must be included in the next DEIS.

62-18 8) Inaccuracy regarding claim that it takes 48 hours for an exposed person to become contagious.

Section 4.2.1.1. includes a section on "Agent Communicability and Treatment" which states: "*Infectious disease specialists now know that it takes at least 48 hours for an exposed person to become contagious, regardless of microbe type.*"(P. 4-7) Firstly, there is no citation included to back up this incredible claim. Secondly, the claim directly contradicts information provided by NIH in Appendix B of the SDEIS "Characteristics of Diseases Studied at RML". In Table B-2 in this appendix, it clearly shows that both plague and Congo-Crimean hemorraghic fever can have incubation periods of just one day before the first signs of disease appear. This means that these particular diseases have been known to be infectious in as short a time period as 24 hours. In addition, diseases such as Nipah virus encephalitis and the South American arenaviral hemorrhagic fevers have "unknown" incubation periods. No certainty can be expressed in terms of how long it takes an exposed person to become infectious for these BL-4 diseases.
The second claim that is made in this section is "*This [the 48 hours] provides adequate time to transport and initiate treatment to benefit the individual and isolate a potentially exposed person from the greater population.*" This claim assumes that the exposure is identified immediately by the exposed worker. In the case of a ripped or torn suit, the exposure may not be identified until the next day when the suit is worn again. Clearly

Comment	Response
62-17	Please see response to comment 62-15.
62-18	This statement should have been attributed to Dr. George Risi, which has been included in the FEIS. Communicability and "first signs of disease" are not the same thing, and it does not mean that infection can be passed within 24 hours.

these two claims are incorrect and misleading and should be changed or removed in the next DEIS.

9) Inaccuracy regarding claim about temperature required for certification of RML's incinerators.

Section 4.2.1.1 of the SDEIS includes a section on "Inactivation of materials infected with agents of transmissible spongiform encephalopathies (prion diseases) which states: "*The incinerator at RML is a Consumat 325 Incinerator. Both state and federal authorities license it as a hospital medical infectious waste incinerator. To be certified as such, the two-stage incineration process must allow for a minimum of 4 hours of burn time at approximately 1800°F (983°C)*" (p4-9). Once again, there is no citation given for this claim. Close inspection of RML's Air Quality Permit 2991-04 reveals that there is no temperature requirement for the incinerator. Federal regulations on medical waste incinerators, found in 40 CFR 60 Subpart Ce, also omit any requirements for minimum burn time or temperature. Montana's state regulations for medical waste incinerators are identical to the federal regulations. In addition, a presentation by Dr. Caughey made at a December 2002 RML CLG meeting indicated that the RML incinerator is fired for a minimum of four hours at 1400°F (760°C) and then at 1800°F for just a few seconds. There is no indication from MT DEQ that RML has asked to change their incinerator firing temperature or include a minimum temperature requirement in their permit (Source: Eric Merchant, MT DEQ, personal communication). The SDEIS should have been more carefully factchecked before being released to the public. This misleading inaccuracy must be fixed in the next DEIS.

62-19

10) Inaccuracy regarding claim about incineration as "method of choice" for inactivating pathogens.

62-20

Section 4.2.1.1 of the SDEIS also states: "*High temperature incineration continues to be the method of choice for medical and veterinary wastes as it has been demonstrated to be effective at inactivating all types of pathogens*" (P. 4-9). Again, there is no citation given for this inaccurate claim. In reality, incineration is no longer considered the method of choice for medical and veterinary wastes in the U.S. due to the recently promulgated strict federal regulations which were put in place to help reduce the excessive air pollution problems caused by incinerators. Since these regulations were promulgated a few years ago, hundreds of medical facilities around the country have chosen to shut down their waste incinerators and have substituted safer, cleaner, equally effective non-incineration technologies such as autoclaves. Even the NIH in Bethesda does not consider high temperature incineration the "method of choice" as their incinerator was shut down several years ago. In Montana, the also trend has been quite clear. In the last few years the medical waste incinerators at Fort Harrison V.A.M.C. in Helena, St. Joseph's Hospital in Polson, Mahlstrom Air Force Base in Great Falls, and Corixa Corp in Corvallis have all been replaced with non-incineration alternatives. RML operates the only remaining

Comment	Response
62-19	The RML Incinerator is subject to compliance with 40 CFR 60, Subparts Ce and Ec. Monitoring requirements for a Medium Intermittent Hospital Medical Waste Incinerator include that facilities establish the appropriate maximum and/or minimum operating parameters for each control system per 40 CFR 60, Subpart Ec, 60.56c and 60.57c. The current operational requirement for secondary chamber temperature is in excess of 1800°F and load input is mechanically locked out until the upper chamber reaches that temperature. Minimum or maximum incinerator operating parameters are established from air emission operational testing data. These parameters are submitted to the State for review and approval. 40 CFR 60, Subpart Ec, 60.51c relating to definitions states under *shutdown* that for intermittent HMIWI, shutdown shall commence no less than 4 hours after the last charge to the incinerator. One minute monitoring of all operating parameters is required by both State and Federal regulations and documentation verifies that the load input does not occur until the temperature of the secondary chamber reaches 1800°F and that that temperature is maintained until 4 hours after the last load input.
62-20	The DEIS, SDEIS, and FEIS contain a citation to support this statement. Additional information and a reference have been added to the FEIS (see pages 4-9 and 4-23).

medical waste incinerator in the state. This misleading and incorrect claim must be removed in the next DEIS.

11) Confusing language in describing risk.
PAGE S-4 of the SDEIS states "*Theoretically, human error or multiple, simultaneous mechanical failures could lead to accidental release of biological materials from a biosafety laboratory. The overall safety record of biomedical and microbiological laboratories also indicates that there is not a risk of accidental release.*" Then later on this page it states that "*The overall safety record of biomedical and microbiological laboratories indicates that there is not a significant risk of accidental release*".
These statements are confusing and potentially seem to contradict one another. The first claims that an accidental release could happen yet there is no risk of it happening. The second merely claims that there is no significant risk of an accidental release happening. This section should be reworded for clarity in the next DEIS.

12) Additional questions not answered and analyses not included in the SDEIS.

62-21 PAGE 1-13 of the SDEIS states that "No construction on the IRF has occurred." However, the contractor hired by NIH has purchased several lots of land adjacent to the lab. Why isn't this addressed anywhere else in the SDEIS?

62-22 PAGE 2-6. SDEIS states that the alkaline hydrolysis process tissue digester would inactivate prions. Is this digester in the budget for the proposed IRF? Or is the digester also planned for RML in the case of the no action alternative. It is not included in the list of upgrades in Section 2.1 on Page 2-1, even though it would clearly act as equipment useful to existing labs working on prion diseases on the RML campus. Please clarify.

62-23 PAGE 2-7 states "HEPA filters would be changed every five years". Is this adequate? How often would they be inspected/checked to assure they are functioning correctly?

62-24 PAGE 2-12 states "*Generation of low-level radioactive waste is anticipated to increase about 30 percent with construction of the Integrated Research Facility... Use of sulfur 35 is likely to increase*," Sulfur 35 emits a weak beta particle and its half-life is 87.4 days. Analysis of the health risks (for Hamilton citizens and those that consume water and live in or near Hamilton area) of low-level radiation into the Hamilton City Sewer system should be included. Health effects of low-level radiation on fish and wildlife should be included.

62-25 PAGE 2-16. Please include an analysis of safety for transport and disposal of all long half-life radioactive waste, in and out of Hamilton, along the route transported, as well as at the disposal site.

62-26 PAGE 3-19. "*Sludge is then composted during warm-weather months. The compost is made available for land application but is not allowed for use on vegetable gardens*". Include an analysis of health risks to animals that may graze on the land where sewage sludge is applied. Health problems in animals that graze on the land could devastate the

Cont on next page

Comment	Response
62-21	Purchase of land by a contractor is not construction.
62-22	Please see Section 2.1.3 for a description of the proposed action.
62-23	Please see Section 2.1.3 of the SDEIS. As stated, the filters would be certified once a year, which includes testing.
62-24	RML has a very effective decay-in-storage program for sulfur-35. The sulfur-35 containing liquids are stored for decay in a locked double containment storage area.
62-25	RML has shipped only naturally occurring radioactive materials on one occasion. The designated destination for any radioactive waste shipped from Montana is the U.S. Ecology Facility in Richland, WA. Brokers and transporters must meet all requirements of DOT and NRC.

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62-26 cattle, farm, and ranching industry in Montana and thus have an adverse effect on the economy. Include a study or analysis of the possibility of transmissible spongiform encephalopathies being transmitted to grazing animals in this manner.

62-27 PAGE 4-1. With regard to animal deliveries. How are the animals caged, transported and then handled before and after arrival for delivery at Rocky Mountain Labs? Who accepts delivery of such animals? How are the animals handled and transported to holding facilities after arriving at RML? Who is responsible for handling animals delivered to RML?

62-28 PAGE 4-6. Manipulation by man can make diseases more virulent. Will RML be "manipulating" diseases to make the more virulent? please include details explaining this process and under what circumstances it may occur at RML.

62-29 PAGE 4-11 through 4-14.
Risk to the community must be seriously considered and mitigation alternatives must be analyzed. The SDEIS claims that the potential risk of a release of infectious agents from the proposed lab is "negligible". Any risk, no matter how small, of an epidemic of an incurable fatal disease in our community should not be dismissed as "negligible". The potential consequences are much too great to be considered "negligible". Even if the risk is very small - if it cannot be eliminated the NIH must show how it will be mitigated. This means the EIS must clearly illustrate the plan for how a "worst case scenario" will be handled.

62-30 PAGE 4-11 through 4-14. Scenarios should be included where a pathogen DOES get out of the lab, for any reason, whether by accident or covert design, and then show how the situation would be mitigated.

62-31 PAGE D-2. The review of work done included only intramural laboratories. The review of accidents, exposures and deaths should include all laboratories in the United States.

62-32 PAGE D-4 and D-11. The last sentence of this report says "This report is included in the Final Environmental Impact Statement of the Integrated Research Facility." This must be inaccurate as (hopefully) the Final EIS has not yet been written. It appears that this report was written and released prior to the release of the Supplemental Draft Environmental Impact Statement and may show predetermination of the proposed project at RML.

13) Comment on the List of Preparers.
The SDEIS makes a point of including RML personnel in order to attempt to convince the public that the preparers of the SDEIS are qualified. However, of those names added, only the authors of the "worst case study" and Appendix D appear to have been "primarily responsible for preparing". The other additions are reviewers and do NOT appear to be the original authors of any portion of the document.

62-33 14) The Worst Case Scenario (P. 4-11) is inadequate for assessing risk.

Comment	Response
62-26	Additional information on disposal of prion contaminated material has been included in section 2.2.1.1 of the FEIS. These disposal methods preclude any risk of contamination of sewage sludge from RML prion research. All other liquid waste is fully decontaminated prior to release into the wastewater stream.
62-27	Animals are purchased from USDA inspected and certified vendors. Transport cages meet USDA specifications. Once delivered to the climate controlled receiving area, Veterinary Branch Technicians transport the cages/animals to the animal facilities. Health checks are performed and animals are transferred to clean cages. The Chief of the Rocky Mountain Veterinary Branch is responsible for the handling procedures of animals delivered to RML.
62-28	No experiments designed to enhance the virulence of any biologic agent are envisioned. Frequently natural disease agents are made less virulent by handling in tissue culture.
62-29	There is no indication or history to indicate that the Integrated Research Facility has the potential to cause an epidemic of any size. It is, therefore, a negligible risk, effectively no risk, that does not need to be mitigated and is appropriately analyzed and disclosed in the SDEIS.

Remainder of responses on following page.

62-30 The Integrated Research Facility would be designed to never allow a pathogen to escape the laboratory, and history proves the design to be effective in achieving this goal. Please also see response to comment 62-98 where HEPA filters are discussed.

62-31 Since the Proposed Action is an intramural facility, it is appropriate to review the operation of intramural facilities for a history of their safety. Please also see response to comment 63-22. Incidents in other US and international labs do not bear on the results of NIH laboratories as NIH has no control over operating procedures of other laboratories. The NIH would be responsible for the safety in the Integrated Research Facility and maintain its high standards. These standards have resulted in the outstanding safety record cited in Appendix E.

62-32 The report was placed in the document before the decision was made to issue a supplemental draft. The wording should have been changed to say as much. It is also included in the FEIS.

The report was prepared as an important part of the NIH's full analysis of the environmental impacts of the proposed action. Without the report, the NIH would not be able to make an informed decision on the action. The NIH will not decide which action to take until after the Final EIS is published and the NIH issues its Record of Decision.

62-33 Please see response to comment 39-21.

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The Worst Case Scenario (P. 4-11) is inadequate for assessing risk because:
1) The model and its assumptions are classified - giving the public no way to review or challenge assumptions made. Other, unclassified approaches would be equally or more valid.

2) The scenario does not deal with the issue that has been repeatedly raised in public comments: An infected staff member spreading an infection the community.

62-34

15) Most of our comments regarding risk were ignored in the SDEIS.

These include questions about the effectiveness of HEPA filters; assessing risk based on the probable increase of experiments by a factor of ten (The Appendix D analysis includes the assumption that the probability of a release is a statistically independent function of the number of experiments performed).

16) Lack of discussion of how safety rules will be enforced.

The SDEIS ignores the issue raised by NIH's own disclosure of repeated unsafe practices and staff ignoring safety rules. While the SDEIS discusses the safety rules, it contains no statement regarding how those rules would be enforced. Given RML's record, the risk analysis must assume that safety and fire safety rules continue to be violated at current rates.

17) Documentation to back up claims should be included in appendices of the SDEIS.

It is standard practice in an EIS to include full copies of reports, analyses and other communications which were produced in order to provide information for the EIS. This is true especially when the information is not otherwise publicly available. The following documents must be included as appendices in the next draft of the DEIS.

- Air Dispersion Modeling for the RML incinerator (Doucet and Mainka, 1999)
- BSL-4 Facility Noise Analysis Report (Big Sky Acoustics 2002)
- Geotechnical investigation for proposed IRF (GMT Consultants, 2002)
- Full report of Quantitative Risk Assessment Scenarios addressed in Chapter 4
- Complete data from Dr. Johnson's report in Appendix D. (It is unclear why a table of the Safety Record for RML is included but not a similar table for the three BL-4 labs researched. The summary of safety record information from these facilities is not sufficient.)
- Hemisphere's report on current water usage at RML

18) Typo on Page 4-11
On page 4-11, it should read "The Public Health Preparedness and Bioterrorism Response Act of 2002" not 2001. (It was signed by President Bush June 12, 2002.)

19) Analysis of estimated water usage on p. 4-25 must be corrected and clarified.

Comment	Response
62-34	Please see Section 1.7.1 where comments on additional information were addressed. Also see Section 1.7.3 where comments on risk were addressed.

The analysis of water usage on p 4-25 is highly confusing and seemingly inaccurate. It should be made clear if this analysis was prepared by a water consultant - or by Maxim Technologies. If the analysis was prepared by Maxim, citations should be included for the varied assumptions made in the analysis. Specifically, it states:

"*Assuming that thirty percent of the new employees live in Hamilton…*" What is the basis for this assumption? Is that the known ratio of current RML employees? If so, this information should have a citation to back it up. Otherwise, to be conservative, the assumption should be that all 100 new employees live in Hamilton.

"*If each person uses an average of 150 gallons per day, there would be an average increased daily usage of 11,250 gallons per day per household.*" Actually, with 2.45 person per household, the increased daily use should be 367.5 gallons per day per household (150 x 2.45). For all 30 houses combined, the average daily use would be 11,025 gallons per day. Also, a citation should be provided for the estimate of 150 gallons per day per person.

"*Assuming that all thirty new households are single family dwellings on half acre lots and use 1,305 gallons per day to irrigate lawns for 120 days per year, the average amount of water used per household for irrigation would be 12,871 gallons per day.*" The first part of this sentence seems to be be saying that each household uses 1,305 gallons per day to irrigate, which contradicts with the conclusion of the sentence which says that each household uses 12,871 gallons per day for irrigation. If the 1,305 gallons per day per household number is correct, a citation should be provided for this estimate. It should be made clear that during the 120 irrigation days the water usage would be 39,150 gallons per day for all 30 households (1,305 x 30).

"*If the estimated increase usage from RML is added to the new resident usage and irrigation, the total increase would be 41,121 gallons per day or 28.5 gpm.*" It appears that this would not be true during the 120 irrigation days. Estimated new usage at RML (17,000 gallons per day) plus estimated daily household use for 30 houses (11,025 gallons per day) plus estimated daily irrigation use for 30 houses (39,150 gallons per day) equals and increase of 67, 175 gallons per day. This should be clarified.

"*… the available capacity of 226 gpm.*" A citation for this statistic should be provided. Presumably, given the enormous amount of water used for irrigation during the summer months, the "available capacity" of water in Hamilton is greater during the winter than during the summer. Does the 226 gpm figure refer to summer capacity or winter capacity? If it is an average of the whole year, the available capacity for summer should be calculated. And the estimated increase in use during the summer should be compared to this summer capacity number to ensure adequate supply during the time of greatest demand.

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Appendix A: Unified Comments submitted on the DEIS, July 2003

Executive Summary

Unified public comments of Coalition for a Safe Lab, Friends of the Bitterroot and Women's Voices for the Earth on the National Institutes of Health proposed BSL-4 Integrated Research Facility in Hamilton, Montana

The members of Coalition for a Safe Lab, Friends of the Bitterroot and Women's Voices for the Earth have demonstrated considerable interest and concern about the proposed BSL-4 facility's impacts on our communities. Our interest is to ensure that the public process generates meaningful discussions, disclosures and analyses between National Institutes of Health, Rocky Mountain Laboratories and the public so informed decisions can be made.

Our groups wish to thank the community and members of the public who have given thoughtful time and consideration to the proposed BSL-4 expansion. A commensurate commitment by National Institutes of Health needs to be reflected in the discussion and through disclosure of critical information that the public has asked for to assess the risks and establish effective mitigation actions for a BSL-4 facility.

The Supplemental Draft Environmental Impact Statement submitted by National Institutes of Health is entirely inadequate in its' analysis of safety, health, social, economic and environmental issues and must be corrected with substantive information republished for public comment.

The impact statement exhibits substantial bias toward expansion of a BSL-4 facility in Hamilton, Montana. Furthermore, the public record shows a stance of predetermination and irrevocable commitment of resources for locating a BSL-4 facility at Rocky Mountain Laboratories prior to requesting input from the public on the decision.

The scope of the impact statement was arbitrarily limited to avoid consideration of valid and publicly supported alternatives. The location of alternative sites should not be dismissed based on a lack of budgetary, financial, or logistical analysis in the impact statement. An expanded BSL-4 capability is part of a federal effort to prepare contingencies for responding to the use of infectious diseases as agents of bioterrorism. By adopting a purpose that precludes reasonable consideration of alternatives, the impact statement exhibits an indefensible bias that cannot be rectified in this document.

National Institutes of Health has failed to propose adequate measures mitigating safety, health, social, economic and environmental impacts from the BSL-4. The lack of appropriate mitigation measures makes the proposed action unacceptable.

National Institutes of Health failed to take a hard look disclosing the risk of an infectious disease or biological agent escaping, or accidentally or intentionally being released into our environment. Such an analysis is a requisite requirement for the public to fairly judge the

cost, benefits and risks of locating a BSL-4 facility in Hamilton, Montana.

The impact statement fails to disclose and mitigate fire protection, emergency planning, preparedness, response and communication measures to protect lab workers and the community in the event of a release of an infectious disease, biological agent or hazardous materials. There is also a lack of discussion concerning coordination with Local and State Emergency Planning Agencies and Task Forces for responding to emergencies, and preparing contingencies for protecting the safety and health of affected communities.

The impact statement fails to effectively incorporate pollution prevention strategies to mitigate noise, lighting, air and water pollution, energy consumption, solid, hazardous and radioactive materials use and treatment, and generation and treatment of pathogenic wastes. The impact statement also fails to satisfy public concern over financial impacts to local government infrastructure, available medical services, the safety of employees and nearby communities and our environment.

The impact and risk of lab-acquired infectious diseases for workers at Rocky Mountain Laboratories is not discussed yet it is known that at least three such incidents have occurred at the facility in Hamilton, Montana as a result of poor adherence to standard biosafety practices and faulty safety equipment.

The impact statement fails to adequately disclose:

* Impacts on nearby neighborhoods including noise, transportation, traffic safety, and property values for households and businesses located within the vicinity of the Rocky Mountain Laboratories facility.

* Impacts on the environment including air, water, wetlands, endangered species, and the use, treatment and disposal of solid, hazardous, radioactive and pathogenic wastes.

* Real and potential conflicts between the proposed action and objectives of land use plans including Ravalli County's Growth Policy which protects identified community values.

In summary, a number of socio-economic, health, safety and environmental costs the public raised were not satisfied in the impact statement. The absence of meaningful measures to mitigate these impacts underscores the inadequacy of the purported benefits of locating a BSL-4 facility in rural Montana.

The members of Coalition for a Safe Lab, Friends of the Bitterroot, Women's Voices for the Earth have provided detailed comments requesting disclosure of critical information that the public needs to make an informed decision about locating a BSL-4 facility at Rocky Mountain Laboratories in Hamilton, Montana. The National Institutes of Health has an obligation to provide that information to the public.

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1. Our members will be affected by this project.

Our groups have over 1,000 members who live, work, recreate, run businesses, pay local taxes, and own property in the immediate area around the proposed project.

The proposed BSL-4 facility's:

- Potential economic benefits,
- Potential improvements in treatment from RML research,
- Potential economic reverses,
- Net impact on taxes,
- Potential environmental damage, and
- Risk of serious illness or death affects our members directly.

2. The document is not a valid Draft EIS and should be corrected and republished for Public Comment.

CEQ 1502.9 requires a Draft EIS to be redone and republished for comment if it fails to meet the requirements of NEPA:

> "The draft statement must fulfill and satisfy to the fullest extent possible the requirements established for final statements in section 102(2)(C) of the Act. If a draft statement is so inadequate as to preclude meaningful analysis, the agency shall prepare and circulate a revised draft of the appropriate portion. The agency shall make every effort to disclose and discuss at appropriate points in the draft statement all major points of view on the environmental impacts of the alternatives including the proposed action."

2.1 The DEIS exhibits substantial bias toward the Proposed Action.

The General Administration Manual, HHS Part 30, Environmental Protection includes detailed procedures for compliance with NEPA for agencies within the Department of Health and Human Services (HHS). These procedures clearly state the types of alternatives that must be considered, as well as rules regarding which alternatives cannot be automatically excluded. It also states that:

"*Draft environmental impact statements shall not exhibit biases in favor of the proposed action.*" (30-30-30 B.1.)

2.1.1 Bias is evidenced by establishing a purpose that by definition allows for no alternatives other than the No Action alternative.

2.1.2 Several of the analysis of impacts in the DEIS only disclose the positive aspects of the agencies preferred alternative and fails to disclose the negative impacts – a further evidence of bias.

For example, the discussion of the impact of the proposed action regarding income in paragraph 4.3.1.1 under the discussion of Economic Resources only list the wages and economic activity multipliers due to construction and additional employment in the laboratory. The negative economic impacts that would result from an event that infected people in the community are not mentioned in spite of the fact that there is a "Potential added risk to the community from the Proposed Action…" (DEIS 4-2).

62-35

Cont. on next page

In fact, the DEIS should analyze and disclose the impact on real estate values, rental income, and the local economy if an infection is released to a community from a biological laboratory anywhere in the country and internationally. Such an event is likely to be newsworthy and increase the perception that living near a BSL-4 laboratory is

62-35 dangerous with the result of decreased property values and business activity around all such laboratories. As the probability of a single event rises with the increased number of laboratories and experiments within those laboratories, the possibility of accidents increases. A historical precedence for such a connection is the nuclear industry and the Three Mile Island release of nuclear material.

As the discussion continues in section 4.3.1.1 we see the discussion going from a discussion specific dollar amounts in the millions contributed to the economy to the net impact on public finance as a factor that "cannot be predicted". Clearly, the authors of the document have the tax structure for the United States, Montana, and Hamilton available. Clearly, they had estimates of the number of new households available (DEIS 4-2). When the dollars that will be paid in wages will favor the NIH's proposed alternative, we see specific numbers backed up by a complete study in the list of references. Yet, when the outcome is likely to be negative the NIH suddenly finds that is "cannot be predicted."

The discussion of Community Safety in 4.2.1.1 is highly biased claiming that the added risk "cannot be effectively quantified". NIH Uses this as an excuse to make unsubstantiated claims to dismiss, without analysis the community safety issues raised in scoping. The claim: "In more than 30 years of working with BSL-4 agents in the U.S., there has never been a confirmed release to a community from a laboratory (Wilson 2003)" (DEIS 4-2) is made to appear to be substantiated with a reference in the apparent hope the reader will not check the bibliography. When we look up the reference, we find this claim is a verbal communication from a staff member from the very agency attempting to promote the proposed alternative. In fact, the press reports that there is DNA analysis evidence that the anthrax powder that appeared in our nation's capital came from a BSL-4 U.S. government lab.

62-36 The section goes on to state that: "It is not specifically known what agents would be studied at the Integrated Research Facility." NIAID certainly knows the agents that would be candidates for study. Some of BSL-4 assigned agents are listed in Appendix B, but the risks and consequences to the community are not discussed in anywhere near the detail needed for the reader to assess any risk.

The attempt to dismiss scoping comments related to the use of "weapons-grade material" is unsubstantiated, with no reference to a regulation or agency commitment to preclude the study of weapons grade material – an apparent contradiction to the stated purpose of studying agents that might be used for bioterrorism.

> "As a result, President Bush tasked the National Institute of Allergy and Infectious Diseases (NIH) to increase its research into the development of safe and effective countermeasures to protect the public against the threat of biological agents that might be used for bioterrorism." (DEIS S-1).

At the same time this section dismisses any risks with unsubstantiated and misleading claims, it provides more specific details on safety measures that cast a positive light on the proposed alternative.

Comment	Response
62-35	Please see Section 1.7.3 where comments on the social and economic impacts were addressed, and Section 4.2.1.1, Community Safety and Risk, where Risk Assessments are addressed.
62-36	Please see section 1.7.3 where comments requesting a full description of agents were addressed.

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2.1.3 The DEIS fails to study and disclose in detail the No Action alternative to provide the public with a baseline by which to compare, contrast and consider the merits of No Action and the Proposed Action.

For example, Environmental Consequences:

62-37 **Emissions**
"Emission would remain at current levels under the No Action alternative."(DEIS 4-14) Though current levels of pollutants may remain near current levels, there are environmental consequences under the No Action alternative.

62-38 **Water Supply**
"The No Action alternative would not have an impact on water supplies in Hamilton or the Bitterroot Valley. " (DEIS 4-15) Clearly, current water use by RML does have an impact on the environment.

62-39 **Wastewater**
"The No Action alternative would not have on impact on wastewater treatment in Hamilton. The No Action would not have an impact on the solids handling capacity of the plant." (DEIS 4-15) Clearly, wastewater discharge by RML does have an impact on the environment.

The DEIS fails to provide the minimum standard for analysis and disclosure of impacts for the proposed and no action alternatives and must do so.

2.2 The DEIS fails to meet the standard for depth and thoroughness of analysis of impacts.

The following areas are examples of areas in which the DEIS fails to provide meaningful analysis or disclosure:

62-40 **Social Resources**

Housing: No discussion of impact on open space, farmland, wildlife, noxious weeds. *The indirect and cumulative impacts of housing employees on these and other resources must be analyzed and disclosed.*

Community Safety: No analysis of risk or disclosure of consequences to the community.

Education: No analysis of the impact on education except for unsubstantiated claims that education capacity is adequate.

In the following comments, numerous other examples of failure to provide the analysis required by a DEIS are cited.

Comment	Response
62-37	Please see Section 1.7.3 where comments on air quality were addressed.
62-38	Please see Section 1.7.3 where comments on the impacts on the City of Hamilton water supply were addressed.
62-39	Please see section 1.7.3 where comments on the Proposed Action's effects on the City of Hamilton water and wastewater systems were addressed.
62-40	Effects on open space (including farmland) have been added to Chapter 4 of the FEIS. Please see Section 1.7.3 where comments on the effects on wildlife, noxious weeds and community safety were addressed. The school superintendent is the official considered as the credible source on the status and capacity of schools in the district.

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2.3 No one who prepared the DEIS appears to have the experience in safety or microbiology to assure the public that the DEIS has the scientific integrity required by NEPA.

62-41 The list below shows the entire list of qualifications for the preparers of the DEIS. We see no documented experience in microbiology, health, or safety. In fact, the preparer assigned to Human Health is educated in zoology and fish and wildlife management. The preparer assigned to community safety is educated in environmental studies and biology. (DEIS-List of Preparers)

- BA/Urban Affairs
- BS/Petroleum Engineering
- BS/Geography
- MS/Hydrogeology, BS/Biology
- MA/Interdisciplinary Studies (History/Anthropology), BA/Geology
- MS/Hydrogeology, BS/Geology
- MS/Environmental Studies, BS/Biology
- BS/Earth Sciences (Geology and Soil)
- MS/Geology (Hydrogeology), BS/Earth Science (Geology)
- BS/Forest Resource Management
- PhD/Environmental & Forest Biology, MS/Zoology, BS/Fish & Wildlife Mgmt.
- Graphic Artist

For these reasons the DEIS fails to meet both the National Environmental Policy Act and Health and Human Services requirements for a Draft Environmental Impact Statement. In order to comply, a compliant DEIS must be prepared and republished for public comment.

Comment	Response
62-41	Please see section 1.7.5 where comments on the preparers of the DEIS were addressed.

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3. Project was predetermined and irrevocably committed resources.

3.1 The decision to build a BSL-4 laboratory at RML was made prior to requesting scoping comments from the public.

This is evidenced in articles written by the Director of NIH (FAUCI, 2002). On June 10, 2002, Dr. Fauci, the Director of NIH announced to Congress the decision to put a BSL-4 lab at Rocky Mountain Laboratory in Hamilton, Montana.

Excerpt from Homeland Security: The Federal and Regional Response Field Hearing before the Subcommittee on Environment, Technology, and Standards Committee on Science, House of Representatives, One Hundred Seventh Congress Second Session; June 10, 2002:

Mr. BARTLETT. "Thank you very much. I wonder if you could spend just a moment letting the audience know how unique a Level 4 containment facility is and how few of them there are in the world?"

Dr. FAUCI. "Yes. A Level 4 facility is the highest level facility for a microbe. There are very few of them in this country. There is one if Fort Dietrich, there is one at the CDC in Atlanta, there is one operational in Texas and one planned in Texas. We are planning two additional ones right now, and those are the two I mentioned. The one that we are going to be partnering with the Department of Defense up at Fort Dietrich to make that a much more enhanced biodefense arena, and one that we are going to be putting in Rocky Mountain Laboratory, which is an NIH facility in Hamilton, Montana."

This is clearly a violation of CEQ 1502.2 (g): "Environmental impact statements shall serve as the means of assessing the environmental impact of proposed agency actions, rather than justifying decisions already made."

Public handouts provided by NIH at scoping meetings in Hamilton, MT stated that the proposed project "will be" constructed.

This attempt at providing a foregone conclusion clearly had the effect of making many of the public believe that the decision had been made – inhibiting the public input process required by NEPA. The attempt to intimidate the local public and make them feel that there was no alternative to having the proposed project implemented is poor public process and a violation of the spirit and letter of NEPA.

3.2 Construction began for proposed alternative, and irrevocably committed resources.

62-42 • Construction of a "construction office" onsite. (Comments by Will Daellenbach, Project director for the overall RML facilities upgrade, at the 6/4/03 Citizen's Liaison Group (CLG) meeting. The minutes of that meeting state: "Will also wanted the group to know that the majority of the construction performed up to date has been done by local contractors/subcontractors.") This irrevocably commits government funds for construction that will not be needed if the no action alternative is selected. This illegal

Comment	Response
62-42	Please see Section 1.7.5 where comments that construction had already begun were addressed.

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62-43 • Hiring of Higgins Development Partners to manage the project to the extent that any government funds are obligated for construction.

62-44 • Hiring of Skanska as a general contractor for the project. (CLG meeting minutes 6/4/03) This appears to irrevocably commit government funds for startup costs and/or for termination costs if the project does not go forward. The contractor has no role in preparing the information to support any analysis or information provided in the DEIS (See DEIS List of Preparers). If the contract allows obligation of government funds prior to the Record of Decision, it should be terminated immediately.

3.3 Purchase of land by BSL-4 expansion project managers Higgins Development Partners adjacent to RML for resale to RML.

[Hamilton City Council member] "Williamson expressed some concerns regarding property purchased by Higgins Development. Dr. Bloom explained that they had a problem on the south border, with residences close to the perimeter. There was an opportunity to acquire six lots to the north (on 6th Street). The developer overseeing the lab construction purchased the land with the idea that the lab would eventually acquire the property. The goal was to eliminate an unsafe area. They originally had hoped to enclose the lots within the campus area to use for parking, laying down pipes, etc. That was the original intent. However, Higgins Development did not fully research the property, and there may be zoning issues. The need is no longer critical at this time, and the lab still hopes to acquire the property." (Hamilton City Council Minutes 4/15/2003)

62-45 We hereby request under the Freedom of Information Act and under the disclosure requirements of NEPA that ALL correspondence, emails, and phone records related to purchase of these lots by Higgins. We specifically ask which government employees or contractors hired to help prepare the DEIS initiated, suggested or had prior knowledge of the above-mentioned purchase.

3.4 Apparent Violation of Antitrust, Federal Procurement, and Conflict of Interest Laws.

62-46 In addition to the predetermination issues with the purchase, the purchase also appears to violate Federal Procurement Laws and the Antitrust act. NIH's developer had inside information unavailable to the public or other businesses. NIH's developer had knowledge that these lands had a potential use for the laboratory expansion. In fact, it appears that it was plans they developed that created the need. NIH's developer used this inside knowledge to attempt to make a profit at the expense of the taxpayer. NIH's developer used this inside knowledge to acquire an unfair and illegal advantage over other businesses and individuals doing business with the government.

We request that the purchase of the above-mentioned lots by NIH's contractor be fully investigated, the results be disclosed to the public, and any violations of law or regulation be rectified.

Comment	Response
62-43	Please see section 1.7.5 where comments that construction had already begun were addressed.
62-44	Please see section 1.7.5 where comments on expenditures were addressed.
62-45	Please see response to comment 58-1. The requirements for submitting a request for DHHS records under the Freedom of Information Act are set forth in 45 CFR Part 5.
62-46	When the property was available for purchase, anyone could have bought it. It is not a conflict of interest, unfair, or illegal for a party interested in purchasing property to have an idea how the property may be used by themselves. No government funds have been used in the purchase of lots in Hamilton for the purpose of the Integrated Research Facility and the purchase was not made at the request or direction of the NIH or any NIH official. Higgins Development Partners purchased this land when it became available in the event that RML wanted to use it in the future.

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4. Scope is too limited.

62-47 NIH has arbitrarily limited the scope of the DEIS. This is an obvious and transparent attempt to limit the scope to a location and budget that was predetermined to avoid considering a reasonable range of alternatives, and disclosing the rational for the choice of location or budget tradeoffs.

The scope of the EIS should be to develop a regional center of excellence within the Northwestern portion of the United States for the study of emerging Category A, B, and C biological pathogens and respond to biological terrorism.

The DEIS itself shows that the BSL-4 need is part of a national initiative to respond to terrorism and the nationwide threat of emerging diseases.

The NIH and RML have published numerous pronouncements that the expansion to RML to include an expanded integrated laboratory (including a BSL-4 lab) is part of a national initiative. A sample of these statements by NIH officials is contained in Appendix A.

4.1 The DEIS itself shows that the scope of this decision includes locations throughout the western United States.

NIH has a nationwide infrastructure in which to carry out its expanded research program.

> "NIH is organized into several divisions, with RML part of NIH's Division of Intramural Research. NIH is one of 27 Institutes or Centers of NIH." (DEIS 4-1)
>
> "NIH has developed a research agenda for "Category A" agents (USDHHS 2002b)." (DEIS 1-4)
>
> "This research agenda acknowledges that certain research on potentially deadly disease agents must be conducted in appropriate containment facilities."

The need is a national need that is not specific to RML.

> "As a result, President Bush tasked the National Institute of Allergy and Infectious Diseases (NIAID) to increase its research into the development of safe and effective countermeasures to protect the public against the threat of biological agents that might be used for bioterrorism. These goals are commensurate with past and current research by NIAID." (DEIS S-1)

The DEIS recognizes that the proposed alternative is designed to meet this national need.

> "As part of the expanded research program, NIH's Proposed Action to construct an Integrated Research Facility… at the RML." (DEIS S-1)

Comment	Response
62-47	As explained in the EIS, the scope of the project is established by the purpose and need, which itself is established by agency authority. The purpose and need for the project is at the agency's discretion.

4.2 The NIH and RML have issued several reports and public pronouncements that show that the scope of the decision includes locations throughout the western United States.

See samples from the public record in Appendix A.

4.3 The budgetary constraint is arbitrarily imposed in the defined scope of the DEIS.

62-48 This is an obvious and transparent attempt to avoid considering rational for the choice of location or budget tradeoffs. The overall NIH budget for BSL construction is over $500 million. (PALMORE 2002)

4.4 The DEIS fails to comply with the NEPA/CEQ's regulations regarding the scoping process, (40 CFR 1501.7; 1508.25).

62-49 The DEIS apparently refused to consider public input suggesting reasonable alternatives, and unduly limited the Proposed Project's "Scope" to build it at the RML in Hamilton, Montana (DEIS S-2, 2-1, 1-6, 2-9, A-10). This appears to be in significant conflict with the regulations.

1501.7 SCOPING.

"There shall be an early and open process for determining the scope of issues to be addressed and for identifying the significant issues related to a proposed action. This process shall be termed scoping.

As soon as practicable after its decision to prepare an environmental impact statement and before the scoping process the lead agency shall publish a notice of intent (1508.22) in the FEDERAL REGISTER except as provided in 1507.3(e). (a) As part of the scoping process the lead agency shall: .... (2) Determine the scope (1508.25) and the significant issues to be analyzed in depth in the environmental impact statement. (3) Identify and eliminate from detailed study the issues which are not significant or which have been covered by prior environmental review (1506.3), narrowing the discussion of these issues in the statement to a brief presentation of why they will not have a significant effect on the human environment or providing a reference to their coverage elsewhere. .... (c) An agency shall revise the determinations made under paragraphs (a) and (b) of this section if substantial changes are made later in the proposed action, or if significant new circumstances or information arise which bear on the proposal or its impacts."

1508.25 SCOPE.

"Scope consists of the range of actions, alternatives, and impacts to be considered in an environmental impact statement. The scope of an individual statement may depend on its relationship to other statements (1502.20 and 1508.28). To

Comment	Response
62-48	Please see response to comments 62-7 and 62-47.
62-49	Please see response to comment 62-47, and Sections 1.7 and 1.7.1 where comments on the alternatives were addressed.

determine the scope of environmental impact statements, agencies shall consider 3 types of actions, 3 types of alternatives, and 3 types of impacts. They include: (a) Actions (other than unconnected single actions) which may be: (1) Connected actions, which means they are closely related and therefore should be discussed in the same impact statement. Actions are connected if they: (i) Automatically trigger other actions which may require environmental impact statements. (ii) Cannot or will not proceed unless other actions are taken previously or simultaneously. (iii) Are interdependent parts of a larger action and depend on the larger action for their justification. (2) Cumulative actions, which when viewed with other proposed actions have cumulatively significant impacts and should therefore be discussed in the same impact statement. (3) Similar actions, which when viewed with other reasonably foreseeable or proposed agency actions, have similarities that provide a basis for evaluating their environmental consequences together, such as common timing or geography. An agency may wish to analyze these actions in the same impact statement. It should do so when the best way to assess adequately the combined impacts of similar actions or reasonable alternatives to such actions is to treat them in a single impact statement. ... (b) Alternatives, which include: (1) No action alternative. (2) Other reasonable courses of actions. (3) Mitigation measures (not in the proposed action).

(c) Impacts, which may be: (1) Direct; (2) Indirect; (3) cumulative."

It appears that NIH's mind was made up from the beginning - that there was only one "Action Alternative" this DEIS would analyze. The issue was appropriately and timely raised by the public, there is an already built BSL-4 available, another is being planned or built (Texas), and there appears there may other BSL-4 proposals in other States.

The DEIS arbitrarily and capriciously restricted the "scope" of it's analysis and range of alternatives.

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62-50

5. Range of alternatives is inadequate and the No Action Alternative is not studied in detail.

5.1 The NIH's DEIS fails to comply with the NEPA/CEQ Regulations regarding a range of alternatives.

The DEIS failed to develop and/or consider a reasonable range of alternatives.

5.1.1 The NEPA/CEQ alternative section is described as "the heart of the environmental impact statement," 40 CFR 1502.14.

Hence, "[t]he existence of a viable but unexamined alternative renders an environmental impact statement inadequate." (Citizens for a Better Henderson v. Hodel, 786 F.2d 1051, 1057 (9th Cir. 1985))

NEPA provides that all agencies of the Federal Government shall, to the fullest extent possible, "study, develop, and describe appropriate alternatives to recommended courses of action in any proposal which involves unresolved conflicts concerning alternative uses of available resources." (42 U.S.C. 4332(2)(E)); (Idaho Conservation League v. Mumma, 956 F.2d 1508, 1519 (9th Cir. 1992))

5.1.2 The DEIS only analyzes one action alternative.

NIH's DEIS states the following: "Project Alternatives - The only alternative to the Proposed Action discussed in detail in this EIS is the No Action Alternative. Under the No Action Alternative, the Proposed Action would not be implemented." (DEIS S-2) Proposed Action and Alternatives - "Detailed discussions of the following topics are presented in this chapter: The Proposed Action; and, Alternatives to the Proposed Action including the No Action Alternative and Alternatives considered but eliminated from detailed study." (DEIS 2-1)

Decision to be Made: "Based on the environmental analysis and consideration of public comments on the Proposed Action, NIH will decide: • Whether to construct an Integrated Research Facility including a Biosafety Level 4 laboratory at RML;" and "The scope of the Project is confined to issues and potential consequences relevant to the decision. The decision is subject to and would implement direction from higher levels." (DEIS 1-6)

"NIH ... has identified the Proposed Action as the preferred alternative." (DEIS 2-10)

Alternatives Considered But Eliminated From Detailed Study (DEIS 2-9) states: "This section describes alternatives that were eliminated from further review in the EIS." They were eliminated because they were: "considered technically infeasible, provided no environmental advantage" … "or would not meet the purpose and need of the Proposed Action."

Comment	Response
62-50	Please see Section 1.7 where comments on the range of alternatives were addressed. To be viable, an alternative needs to (among other things) meet the purpose and need of the project. There were no issues (unresolved conflicts) identified with the Proposed Action that were not addressed by the No Action Alternative.

5.1.3 Pubic scoping comments specifically asked that the NIH consider the following reasonable alternatives to the Proposed Action.

5.1.3a Relocate Rocky Mountain Laboratories to a Less Populated Area (DEIS 2-9)
Rational for Dismissing: "This alternative does not meet the purpose and need 'to provide a highly contained and secure intramural laboratory for continuation of research into emerging infectious disease within the budgetary constraints of NIH at the Rocky Mountain Laboratories facility in Hamilton, Montana'. Congress has authorized expenditure of $66.5 million for construction of an Integrated Research Facility. Construction ... at an alternate site would require additional funding to provide infrastructure and research laboratory support currently in-place at RML." (DEIS 2-10)

5.1.3b Construct Integrated Research Facility (BSL-4) at Alternate Location (DEIS 2-10)
Rational for Dismissing: [Lack of scientific integration; eliminates connected research; would be inefficient and impracticable.] "Additionally, this alternative fails to meet the need for this project, 'to efficiently and effectively provide a realistic, orderly, and comprehensive effort to safeguard the health of the American people through detection, investigation, control, and prevention of disease'." "This alternative also fails to meet the budgetary constraints in the purpose of the Project and the effectiveness and efficiency part of the need for the Project." "Issues addressed through this alternative are also addressed through the No Action Alternative". (DEIS 2-10)

62-51 **5.1.3c NIH's DEIS arbitrarily and capriciously refused to consider reasonable alternatives to the agency's Proposed and Preferred alternative that were suggested by the public during scoping.**

Examples of suggestions made during scoping were to locate the BSL-4 in military installations or locations remote from populations.

5.1.3d The DEIS failed to fully disclose, and failed to take a hard look at the fact that there is an already completed, but not used, BSL-4 lab in Bethesda, Maryland.
A recent newspaper article stated the following regarding the unused Bethesda BSL-4 lab: "A Biosafety Level 4 lab was built several years ago on the Bethesda, MD campus of NIH but it has never been used for this purpose. Maryland has a ten-member congressional delegation, more than three times the numerical strength of Montana's contingent. Hundreds of other members of Congress live in Bethesda, an affluent suburb of Washington, D.C." (BIO-FEAR IN THE BITTERROOT VALLEY; Medford Mail Tribune; by Les AuCoin; Environmental News Service 7/14/03)

And, from Dr Fauci's testimony on June 10, 2002, it appears that there are three currently operating BSL-4 facilities in the United States: Atlanta, Georgia; Fort Dietrich, Maryland; and 'one operational in Texas'. Dr Fauci also indicated there were apparently at least two more BSL-4 facilities "planned" to be built at that time; one in Texas and one at the RML in Hamilton, Montana. (Homeland Security: The Federal and Regional

Comment	Response
62-51	Please see Section 1.7 where comments on alternatives were addressed.

Response Field Hearing before the Subcommittee on Environment, Technology, and Standards Committee on Science, House of Representatives, One Hundred Seventh Congress Second Session; June 10, 2000)

5.1.3e The NEPA/CEQ regulations (40 CFR 1500, et seq.) go into substantive detail describing Federal Agency requirements and obligations regarding "alternatives".

1500.2 - POLICY:

"Federal agencies shall to the fullest extent possible: (b) Implement procedures to make the NEPA process more useful to decisionmakers and the public; ... and to emphasize real environmental issues and alternatives. Environmental impact statements shall be concise, clear, and to the point, and shall be supported by evidence that agencies have made the necessary environmental analyses. (d) Encourage and facilitate public involvement in decisions which affect the quality of the human environment. (e) Use the NEPA process to identify and assess the reasonable alternatives to propose actions that will avoid or minimize adverse effects of these actions upon the quality of the human environment. (f) Use all practicable means, consistent with the requirements of the Act and other essential considerations of national policy, to restore and enhance the quality of the human environment and avoid or minimize any possible adverse effects of their actions upon the quality of the human environment."

1502.1 PURPOSE:

"The primary purpose of an environmental impact statement is to serve as an action-forcing device to insure that the policies and goals defined in the Act are infused into the ongoing programs and actions of the Federal Government. It shall provide full and fair discussion of significant environmental impacts and shall inform decisionmakers and the public of the reasonable alternatives which would avoid or minimize adverse impacts or enhance the quality of the human environment. Agencies shall focus on significant environmental issues and alternatives and shall reduce paperwork and the accumulation of extraneous background data. Statements shall be concise, clear, and to the point, and shall be supported by evidence that the agency has made the necessary environmental analyses. An environmental impact statement is more than a disclosure document. It shall be used by Federal officials in conjunction with other relevant material to plan actions and make decisions."

1502.14 ALTERNATIVES INCLUDING THE PROPOSED ACTION:

"This section is the heart of the environmental impact statement. Based on the information and analysis presented in the sections on the Affected Environment (1502.15) and the Environmental Consequences (1502.16), it should present the environmental impacts of the proposal and the alternatives in comparative form, thus sharply defining the issues and providing a clear basis for choice among options by the decisionmaker and the public. In this section agencies shall: (a) rigorously explore and objectively evaluate all reasonable alternatives, and for alternatives which were eliminated from detailed study, briefly discuss the reasons for their having been eliminated. (b) Devote substantial treatment to each

alternative considered in detail including the proposed action so that reviewers may evaluate their comparative merits. (c) Include reasonable alternatives not within the jurisdiction of the lead agency. (f) Include appropriate mitigation measures not already included in the proposed action or alternatives."

1502.24 METHODOLOGY AND SCIENTIFIC ACCURACY:
"Agencies shall insure the professional integrity, including scientific integrity, of the discussions and analyses in environmental impact statements."

1506.1 LIMITATIONS ON ACTIONS DURING NEPA PROCESS:
"(a) Until an agency issues a record of decision as provided in 1505.2 ... no action concerning the proposal shall be taken which would: (1) Have an adverse environmental impact; or (2) Limit the choice of reasonable alternatives."

62-52 There apparently is an unused existing BSL-4 facility in Maryland, another in Texas is "planned", and it appears that others are being "planned or proposed" around the nation. The DEIS failed to comply with NEPA's requirements by refusing to develop a reasonable range of alternatives.

62-53 The DEIS apparently failed to develop or consider a reasonable range of alternatives, failed to comply with the scoping regulations, and failed to provide an accurate Cost-Benefit Analysis. In doing so, it appears the DEIS is not in compliance with 40 CFR 1500.2, 1502.1, 1502.14, 1502.16, 1502.24, 1506.1, 1502.23, 1501.7, and 1508.25, et seq.

5.2 The NIH dismisses and ignores nearly all citizen suggested mitigation measures.

62-54 **5.2.1 The DEIS does not develop mitigation alternatives suggested in scoping.**
Below is the DEIS mitigation discussion from Section 1.7.1 (DEIS 1-8 and 1-9). The bracketed items notes NIH's response/disposition of the suggested measures by citizens:

"1.7.1.1 Mitigation Measures
Potential mitigation measures raised by those individuals providing comments during scoping include:

• Adoption of pollution prevention strategies to avoid or reduce the amount of pollution generated at the facility. Efforts are described in the *Disposal of Non-Contaminated Material.* **[This recommendation is not, in fact, discussed in the referenced section.]**

• *Waste* that has not come in contact with a biohazardous, radioactive or chemical material is considered non-contaminated and would be disposed of as general waste. This would make up the majority of waste from the facility. **[This confirms what already happens.]**

• Improving parking for workers and visitors during and after construction of the

Comment	Response
62-52	Please see Section 1.7.1 where this comment was addressed.
62-53	A cost/benefit analysis is not required in the CEQ regulations for implementing NEPA.
62-54	Please see Section 1.7.2 where comments on mitigation measures were addressed. Please also see response to comment 62-15.

Integrated Research Facility. This is part of the *Reasonably Foreseeable Actions* as described on page 4-1. **[This was apparently adopted.]**

62-55 • Implementation of a car-pooling program for workers commuting to the RML campus. This measure will not be included in the Proposed Action as parking and traffic are addressed under social issues. **[Refused without comment.]**

62-56 • Adopting a policy of studying only those agents associated with emerging diseases at the Integrated Research Facility, and not agents associated with bioterrorism or biodefense. This is addressed through the *Purpose and Need* section on Chapter 1. **[The referenced chapter states that no weapons grade material will be studied – without any citation to a regulation or other agency commitment. However, this does not answer the recommendation. The recommendation is not discussed. It should also be noted that under recently passed laws, that there are plans to use weapons grade material, but the agency would be prohibited by recently passed antiterrorism laws from disclosing that fact to the public.]**

62-57 • Creation of a citizen oversight committee to monitor activities at the Integrated Research Facility. This measure will not be included in the Proposed Action because monitoring is done by RML for a number of state and federal agencies and the results are made public. The Community Liaison Group, composed of community members, serves to monitor activities at RML. The RML Institutional Biosafety Committee and the Chapter 1 Purpose and Need RML Animal Care and Use Committee also have community representatives. **[This recommendation is ignored. The Community Liaison Group does not monitor the activities of RML and only serves as a forum for formal interactions with the agency related to the proposed alternative.]**

• Improving aesthetics of the campus. This measure is included in the Proposed Action, as well as *Reasonably Foreseeable Actions* as described on page 4-1. Aesthetics were considered in the design of the building, as well as effects analysis. **[This recommendation was apparently adopted.]**

62-58 • Implementation of regular effluent monitoring of air emissions and wastewater discharges are included in *Air Treatment* and *Waste Decontamination* in Chapter 2. **[This recommendation is ignored without comment in the referenced section.]**

62-59 • Use of local contractors for design and construction of the Integrated Research Facility to the greatest extent possible. NIH has hired a national design and engineering firm that specializes in designing and building BSL-4 laboratories. **[This is refused.]**

62-60 • A commitment for direct improvements to the hospital, streets, and emergency response agencies by NIH. This is included in the *Reasonably Foreseeable*

Cont. on next page

Comment	Response
62-55	Please see Section 1.7.2 where comments suggesting carpooling were addressed.
62-56	Please see Section 1.7.2 where comments regarding a policy of studying only those agents associated with emerging diseases were addressed.
62-57	Please see Section 1.7.2 where comments on creation of a citizen oversight committee were addressed.
62-58	Please see Section 1.7.2 where comments on implementation of regular effluent monitoring of air emissions and wastewater discharges were addressed.
62-59	Please see Section 1.7.2 where comments on using local contractors were addressed.

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62-60 *Actions* as described on page 4-1. **[This is ignored.]**

• Noise and light reduction through more landscaping and buffering. This measure is included in the Proposed Action, as well as *Reasonably Foreseeable Actions* as described on page 4-1, and was considered in the design of the building as well as effects analysis. **[This is adopted.]**

• Establishment of a process where neighbors could bring concerns to RML during and after construction of the Integrated Research Facility. This measure was included in the Proposed Action. Meetings with neighborhood representatives would be held regularly before, during, and after construction. In addition, the Community Liaison Group, including local residents, addresses any issue brought to it. **[This is adopted.]**

62-61 • Purchase of homes at fair market value for anyone that requested it within a few blocks of the Integrated Research Facility because of a perceived fear of lost value once the Integrated Research Facility is completed. This measure is not included in the Proposed Action because there is no indication that the Proposed Action will have a negative effect on property values (see Chapter 4). **[The possibility of negative impacts on property values is not mentioned in the referenced section. See comments below in which NIH's contractor bought homes in anticipation of selling them to the government in anticipation of the implementation of the proposed project.]**

62-62 This treatment of citizen's comments again shows bias toward the proposed alternative. The writers of the DEIS attempt to make it look to the reader as if all of the recommended mitigation measures by citizens are discussed. In fact, the mitigation measures that the agency did not choose to adopt are ignored without comment.

5.2.2 The DEIS also ignores mitigation alternatives.

The NIH recognizes a duty to include mitigation in the proposed action.

> "In accordance with section 40 CFR 1502.16 (Regulations implementing the Procedural Provisions of NEPA), the following are the required disclosures, and where they can be found:
>
> • Means to mitigate adverse environmental impacts (Chapter 4)." (DEIS 1-2)

A number of scoping comments recommended specific mitigation measures.

> "Six percent identified potential mitigation measures," (DEIS1-8).

A look at Section 4 shows that no mitigation measures are proposed or analyzed. The only discussion of mitigation measures is a general reference to mitigation in the Ravalli County Growth Plan.

Comment	Response
62-60	Please see Section 1.7.2 where comments on a commitment for direct improvements were addressed.
62-61	Please see Section 1.7.2 pf the SDEIS where comments on the purchase of homes at fair market value were addressed.
62-62	The responses to comment 62-54 through 62-61, and many others, indicate that comments were not ignored. Section 1.7.2 starts out with how comments were initially included. None of the comments listed above are included in the "Additional mitigation measures" section, but were included in the original DEIS.

CEQ 1502.14 (f) states that a DEIS alternatives should: "Include appropriate mitigation measures not already included in the proposed action or alternatives."

62-63 Yet no alternatives are developed for mitigation.

Additional alternatives must be considered.

62-64

5.3 Alternate Locations Must Be Considered.

NIH is required to consider a reasonable range of alternatives. The alternatives must include considering other locations as well as mitigation measures suggested by citizens and the DEIS analysis itself.

5.3.1 Relocate Rocky Mountain Laboratories to a Less Populated Area (DEIS 2-9)

Rationale for Dismissing

"This alternative does not meet the purpose and need 'to provide a highly contained and secure intramural laboratory for continuation of research into emerging infectious disease within the budgetary constraints of NIH at the Rocky Mountain Laboratories facility in Hamilton, Montana." "Congress has authorized expenditure of $66.5 million for construction of an Integrated Research Facility." (DEIS 2-10)

5.3.2 Construct Integrated Research Facility (BSL-4) at Alternate Location (DEIS 2-10)

Rationale for Dismissing

[Lack of scientific integration; eliminates connected research; and would be inefficient.] "Additionally, this alternative fails to meet the need for this project, 'to efficiently and effectively provide a realistic, orderly, and comprehensive effort to safeguard the health of the American people through detection, investigation, control, and prevention of disease'." "This alternative also fails to meet the budgetary constraints in the purpose of the Project and the effectiveness and efficiency part of the need for the Project." "Issues addressed through this alternative are also addressed through the No Action Alternative". (DEIS 2-10)

"NIH ... has identified the Proposed Action as the preferred alternative." (DEIS 2-10)

5.3.3 Location Alternatives Should Not Be Dismissed

The General Administration Manual also states:

> 30-30-30 C.: "Alternatives. Environmental impact statements must explore and evaluate reasonable alternatives to the proposed action in terms of their environmental consequences, benefits and costs, and contribution to the underlying purpose or goal. Discussion of alternatives must be sufficiently in-depth to permit a meaningful comparison of alternative courses of action.
>
> 2. Action Alternatives. One or more alternative courses of action directed at achieving the underlying purpose or goal. The environmental impact statement cannot automatically exclude actions:

Comment	Response
62-63	Please see Section 1.7 where comments on alternatives were addressed. Please also see response to comment 62-15.
62-64	Please see Section 1.7.1 where comments on alternatives were addressed.

Outside the expertise or jurisdiction of Departmental organizations, e.g., examining the possible use of other real properties other than that proposed for transfer by HHS; or

Which only partially achieve an underlying goal or objective, e.g., funding a health care facility at a lower capacity for patient care. However, action alternatives considered must be reasonably available, practicable, and be related to the underlying purpose or goal. An environmental impact statement must include all reasonable alternatives.

In Section 2.2.2.2 (DEIS 2-10) the suggested alternative of "Construct Integrated Research Facility (BSL-4) at Alternate Location" was dismissed for insufficient reasons.

62-65 The first reason stated is that "locating the BSL-4 separate from the rest of RML would eliminate the connected research on projects that use BSL-2 and BSL-3 facilities." The proposed project includes the building of both BSL-2 and BSL-3 facilities, so it is difficult to see how the project if built elsewhere would separate that research. Secondly, two of the potential locations recommended in the scoping process were the NIH campus in Bethesda and the CDC campus in Atlanta. Both campuses already have BSL-2, BSL-3 and even BSL-4 laboratories that the research in the new lab can be connected to, and could benefit from.

62-66 The second reason this alternative was dismissed was because it fails to meet the need "to efficiently and effectively provide a realistic, orderly and comprehensive effort to safeguard the health of the American people through detection, investigation, control and prevention of disease." There is no reason why a lab in Bethesda or Atlanta would not be able to meet this need.

62-67 The last reason for dismissing an alternative location is that it fails to meet "budgetary constraints." It is unacceptable to simply state that it fails to meet "budgetary constraints" without clearly establishing the budget for the project. The only budgetary information in the DEIS is a single statement:

"Congress has authorized expenditure of $66.5 million for construction of an Integrated Research Facility." (DEIS 2-10)

62-68 Cont. on next page

5.3.4 A full financial analysis for the preferred alternative as was requested specifically in scoping comments is needed to understand the "budgetary constraints" of this authorized expenditure.

A detailed description of the costs of the preferred alternative proposed in an EIS is absolute standard of disclosure. Similarly, a full financial analysis of other alternatives including construction of the lab at an alternative location and the no-action alternative are also needed for comparison. It is unacceptable to simply state:

"Construction of the facility at an alternate site would require additional funding to provide infrastructure and research laboratory support currently in-place at RML." (DEIS 2-10)

Comment	Response
62-65	Please see Section 1.7.1 where comments on alternatives were addressed.
62-66	Please see Section 1.7.1 where comments on alternatives were addressed.
62-67	Please see Section 1.7.1 where comments requesting more information on the budget and finances were addressed.

62-68 A full financial analysis of the required "additional funding" is needed to justify this claim in the DEIS.

62-69 **5.4 Mitigation Alternatives Must Be Considered.**

The HHS General Administration Manual states:

> "30-50-60 E. Responsibilities. Except for proposals for legislation, OPDIVs/STAFFDIVs shall prepare EISs in two stages: Draft and final. The responsible official will ensure that:
>
> 1. Appropriate mitigation measures are included in the proposed action or alternatives;"

In addition, CEQ 1502.14 requires mitigation alternatives.

5.4.1 Local government financial impact mitigation.

Section 4.2.2 briefly discusses impacts to community safety, but does not analyze the direct and indirect economic effects of these impacts. The section states:

> "Procedures and protocols would also be established with local emergency response agencies to address responsibilities of each agency in the event of an emergency at RML." (DEIS 4-7)

62-70 These procedures and protocols will require local emergency response agencies to acquire both new equipment and extensive training. *The costs for this equipment and training are economic effects of the preferred alternative and must be calculated and presented in the Economic Resources Direct and Indirect Effects - Government and Public Finance section (Section 4.3.1.1 DEIS 4-8).*

Mitigation alternatives that would offset these financial impacts to local emergency response agencies should be discussed as well. Mitigation alternatives would include alternatives that offer funding to local emergency response agencies and hospitals to cover the costs of training, drills and equipment.

5.4.2 Safety mitigation.

62-71 Public comments submitted thus far reveal that community safety is one of the greatest concerns of neighbors and nearby residents with respect to the preferred alternative. *A detailed explanation of the mitigation strategies that would be implemented to offset the significant consequences of a release of an agent to the community or environment must be included in this DEIS.*

Section 4.2.1.1 of the DEIS states:

Comment	Response
62-68	More information on the established budget has been included in the "Background" in Chapter 1.
62-69	Please see Section 1.7.2 where comments on mitigation measures were addressed. Please also see response to comment 62-15.
62-70	Please see Section 1.7.3 where comments on community infrastructure were addressed. No mitigation is necessary.
62-71	Please see Section 1.7.3 where comments on the increased threat from the Integrated Research Facility were addressed.

"Numerous means would be employed to control access to agents and the facility and reduce the potential for release of an agent to the environment or community. These include:
• Specialized laboratory construction;
• Employee screening and training;
• Site security;
• Air and wastewater treatment;
• Backup systems; and
• Emergency response." (DEIS 4-5)

Each of these means needs to be described in detail as a mitigative action in the DEIS. In particular, the mitigative action of emergency response (i.e. the emergency plan and protocols) must be included in full in the DEIS.

62-72 **5.4.3 Pollution Prevention strategies.**
Pollution prevention has been identified as an important mitigation strategy by the Department of Health and Human Services. There should be a significant emphasis on pollution prevention in this DEIS.

The HHS General Administration Manual states the following with regard to pollution prevention:

"30-10-30 Strategy

HHS has adopted and will adhere to a Code of Environmental Management Principles (CEMP) to help achieve the goals of the HHS environmental protection program. As part of the effort to implement these principles throughout HHS, all OPDIVS/STAFFDIVS will integrate the following principles into their environmental protection programs:
1. Management Commitment--Written top management commitment to improved environmental performance by establishing policies which emphasize pollution prevention and the need to ensure compliance with environmental requirements.
2. Compliance Assurance and Pollution Prevention--Proactive programs that aggressively identify and address potential compliance problem areas and utilize pollution prevention approaches to correct deficiencies and improve environmental performance.

30-50-05 Definitions and Acronyms

'Pollution Prevention' includes, but is not limited to, reducing or eliminating hazardous or other polluting inputs, which can contribute to both point and non-point source pollution; modifying manufacturing, maintenance, or other industrial practices; modifying designs; recycling (especially in-process, closed loop recycling); preventing the disposal and transfer of pollution from one media to another; and increasing energy efficiency and conservation. Pollution prevention

Comment	Response
62-72	Please see Section 1.7.2 where comments on pollution prevention strategies were addressed.

> can be implemented at any stage--input, use or generation, and treatment--and may involve any technique--process modification, waste stream segregation, inventory control, good housekeeping or best management practices, employee training, recycling, and substitution. Any reasonable mechanism which successfully avoids, prevents, or reduces pollutant discharges or emissions other than by the traditional method of treating pollution at the discharge end of a pipe or stack should, for purposes of this chapter, be considered pollution prevention.
>
> 30-50-65 Contents of an EIS
>
> C. Pollution Prevention. Pollution prevention should be an important component of mitigation of the adverse impacts of a Federal action. To the extent practicable, pollution prevention considerations should be included in the proposed action and in the reasonable alternatives to the proposal, and should be addressed in the environmental consequences section of the EIS (40 CFR 1502.14(f), 1502.16(h), and 1508.20)."

Unfortunately, the words "pollution prevention" only occur once in the entire document (DEIS1-8) in Section 1.7.1.1. This section refers to a discussion of pollution prevention strategies purported to be discussed in the section titled "Disposal of Non-Contaminated Material" (DEIS 2-8). That entire section reads as follows:

"Disposal of Non-Contaminated Material
Waste that has not come in contact with a biohazardous, radioactive or chemical material is considered non-contaminated and would be disposed of as general waste. This would make up the majority of waste from the facility." (DEIS 2-8)

62-73 *Specific pollution prevention strategies must be developed and discussed in this DEIS.*

5.4.4 Failure to disclose planned noise reduction measures.
Section 4.4.1 of the DEIS states:

> "The Proposed Action would meet RML's new draft noise guidelines. Existing noise sources would continue as described under No Action." (DEIS 4-8)

Section 4.4.2 of the DEIS states:

> "Reasonably foreseeable noise reduction features would result in a slight reduction in noise overall as shown in Table 4-2." (DEIS 4-9)

62-74 The actual noise reduction features however are not described in the DEIS. *These features are mitigative strategies that should be addressed clearly in this section.*

40 CFR 1502.1 states:

Comment	Response
62-73	Please see Section 1.7.2 where comments on pollution prevention were addressed. As noted, DHHS's regulations on the inclusion of pollution prevention applies to "potential compliance problems." No compliance problems would occur under the Proposed Action.
62-74	Please see Section 1.7.2 where comments on noise reduction were addressed.

> "[Environmental Impact] Statements shall be concise, clear, and to the point, and shall be supported by evidence that the agency has made the necessary environmental analyses."

62-75 Simply stating that noise guidelines will be met and that noise reduction features will reduce noise does not comprise "evidence that has the agency has made the necessary environmental analyses." *If Big Sky Acoustics has completed an analysis for RML it should be described and included as an appendix to the DEIS for public review.*

62-76 According to Table 4-2 (DEIS 4-9) it appears that the emergency generator and the incinerator are the two pieces of equipment on site that contribute the loudest noise. The preferred alternative includes the addition of another emergency generator that must be tested regularly and a significant increase in use of the incinerator. **It must be clarified as to how the preferred action will lead to a decrease in noise levels from the current situation.**

62-77 Secondly, Section 4.4.1.2 (DEIS 4-8) claims that the No Action alternative would lead to no change in noise levels from RML. It is our understanding, from the presentation at a CLG meeting, that RML's draft noise guidelines are being implemented independently of the BSL-4 project. Yet this section implies that without implementing the preferred alternative, RML would not take action to meet the draft noise guidelines. *Please clarify if the noise reduction program - inspired by complaints from the community - is dependent on building the BSL-4. If it is not dependent on the preferred alternative, Section 4.4.1.2 should be changed to reflect the noise improvements that will be conducted regardless to meet the draft noise guidelines.*

5.4.5 Lack of air pollution prevention strategies.

Section 4.7.1 of the DEIS states:

> "Incinerator use is estimated to increase from approximately two to three days a week to three to four days a week." (DEIS 4-13)

62-78 Very clearly the preferred alternative will increase rather than prevent air pollution. Unfortunately, in Section 4.7 **Air Quality Direct and Indirect Impacts** no analysis is given of the exact increase in emissions. Simply stating that the total permit emission allowance will not change is not an analysis of the direct impact. There are emission factors for the incinerator for both criteria and hazardous pollutants, which RML uses to create an emission inventory sent to Montana DEQ each year. *A current emission inventory for all of these pollutants should be in the DEIS along with a comparative expected emission inventory reflecting the increased use of the incinerator.*

An air pollution prevention mitigation alternative for this increased pollution should be included in the DEIS. The most obvious and practicable pollution prevention alternative is to utilize an alternative method of disposal instead of the incinerator. An alternative disposal method is both readily available and inexpensive (i.e. the landfill in nearby

Comment	Response
62-75	The noise analysis was summarized in the DEIS, SDEIS and FEIS and is included in the administrative record, as indicated.
62-76	Please see Section 1.7.3 where comments on the effects of the Proposed Action and noise (and clarification of the analysis) were addressed.
62-77	Please see Section 1.7.3 where comments on the effects of the Proposed Action and noise (and clarification of the analysis) were addressed.
62-78	Please see Section 1.7.3 where comments on the increased use of the incinerator were addressed.

62-79 Missoula.) It is clear from the DEIS that all waste that is generated by a BSL-4 is fully decontaminated before leaving the building - thus there is no 'need" for incineration of this waste from a medical waste decontamination standpoint. *A full analysis of this reasonable air pollution prevention mitigation alternative must be included in the DEIS.*

62-80 The addition of a new emergency power generator will also increase air emissions. Scoping comments specifically requested NIH to consider the use of SCONOX technology to control emissions from the new emergency generator. *This pollution prevention alternative should be discussed in the DEIS.*

5.4.6 Lack of energy conservation strategies.

Energy conservation and increased energy efficiency is not adequately discussed in the DEIS. 40 CFR 1502.16 requires that an EIS disclose:

> "Energy requirements and conservation potential of alternatives and mitigation measures."

The comments on energy consumption in section 2.1.2 simply states that:

> "Several power-saving devices would be incorporated into the proposed facility, including, but not limited to, energy saving equipment and lighting, enhanced insulation, and provisions for a heat recovery system." (DEIS 2-7)

62-81 In addition there is not even a section on energy consumption in the Environmental Consequences chapter. This does not satisfy the NEPA requirements. *A full energy consumption analysis of the preferred alternative must be included in the document. How much energy will be needed to operate the lab? In addition, energy saving conservation alternatives must be presented in the document for comparison.*

5.4.7 Lack of light pollution prevention strategies.

The planned outdoor lighting for the preferred alternative is not addressed in the DEIS, despite specific scoping comments that were submitted regarding a concern about light pollution from the proposed project. There is concern and disappointment in the community regarding the flood lighting currently used on the new BSL-3 building at RML. *Please discuss the planned outdoor lighting for the preferred alternative and the light pollution prevention strategies that will be employed.* 62-82

5.4.8 Lack of hazardous materials use reduction strategies.

The only reference to hazardous substances in the DEIS is a brief paragraph in Section 2.1.2 which states:

> "Use, storage, and disposal of hazardous waste are accomplished in accordance with applicable state and federal regulations. RML is currently stressing waste minimization practices that would also be applied to the Integrated Research Facility. Waste minimization practices include ordering necessary laboratory chemicals in smaller quantities." (DEIS 2-8)

Comment	Response
62-79	Please see response to comment 62-20.
62-80	Please see Section 4.7 where comments on air quality were addressed.
62-81	Please see section 1.7.1 where comments on energy consumption were addressed.
62-82	Please see Section 1.7.3 where comments on impacts associated with lighting were addressed.

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62-83 Despite a specific scoping request for detailed information on current and expected chemical use and waste disposal, the DEIS does not include any accounting for the types of hazardous chemicals to be used, how they will be disposed of, or how much increased use there will be with the new lab. *A current chemical use and chemical waste inventory must be included in the DEIS.* (Note: Appendix F: "Chemical Use and Chemical Waste Inventories" of RML's Voluntary Cleanup Plan released by Maxim Technologies in June 2003 would be a good place to start finding this information). *There should also be a section under Environmental Consequences regarding hazardous substances - estimating the increased use and disposal of hazardous substances that will be associated with the preferred alternative. The "waste minimization practices" mentioned in the DEIS should be listed and the extent of the pollution prevention quantified.*

5.4.9 Lack of water conservation strategies.

62-84 The preferred alternative will significantly impact water usage at the facility. *Measures to reduce water consumption and wastewater must be included as pollution prevention alternatives in the DEIS.*

Comment	Response
62-83	Please see Section 1.7.3 where comments on increased use and disposal of hazardous chemicals were addressed.
62-84	Please see Section 1.7.2 where comments on the pollution prevention strategies were addressed.

6. Failure to Disclose Impacts.

6.1. The DEIS apparently failed to provide an accurate Cost-Benefit Analysis (40 CFR 1502.23).

40 CFR 1502.23 COST-BENEFIT ANALYSIS: If a cost-benefit analysis relevant to the choice among environmentally different alternatives is being considered for the proposed action, it shall be incorporated by reference or appended to the statement as an aid in evaluating the environmental consequences. ...

While perhaps not a "normal" cost/benefit analysis, NIH's DEIS did use the following financial statement to claim that a reasonable alternative suggested by the public could not be feasible: **Construct Integrated Research Facility (BSL-4) at Alternate Location**.

NIH's Rational for Dismissing [in part]: "This alternative also fails to meet the budgetary constraints in the purpose of the Project and the effectiveness and efficiency part of the need for the Project." "Issues addressed through this alternative are also addressed through the No Action Alternative". (DEIS 2-10)

62-85 The above DEIS statement does not appear to be accurate or correct. NIH fails to disclose that there is an already built BSL-4 facility in Bethesda, Maryland. It appears plain that it certainly would be "cost effective" to use it, rather then spend over $66 million dollars on a new BSL-4 lab in Hamilton, Montana. The "no action" alternative does not really apply well either because of the unused Bethesda facility. There's already one existing - there has been a previous "Federal Action" that could completely meet the "Purpose and Need" except apparently that it's not in Hamilton, Montana. It appears that this does not comply with 1502.23 nor does it evidence a hard look and full disclosure.

6.2 Potentially significant adverse impacts were not adequately analyzed, discussed or disclosed as required by the NEPA/CEQ.

6.2.1 "Hard Look" is required by NEPA.

62-86 The DEIS failed to provide any meaningful analysis or disclosure regarding potentials and/or adverse impacts of an escape or release of an agent from the proposed RML BSL-4 facility.

"NEPA ensures that important effects will not be overlooked or understated only to be discovered after resources have been committed or the die otherwise cast." (Robertson v. Methow Valley Citizens for Council, 490 U.S. 332, 342; 109 S. Ct. 1835, 1845 (1989))

Compliance with NEPA occurs only when an agency takes a "hard look" at the environmental consequences of its actions. (Sierra Club v. Kleppe, 427 U.S. 390, 410, n21)

Comment	Response
62-85	Please see Section 1.7.4 where comments on the budget were addressed. Please also see response to comment 62-7.
62-86	Please see Section 1.7.3 where comments on the potential risk were addressed.

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The first criterion that must be addressed is whether or not the agency took a "hard look" at the problem. (Marsh v. Oregon Natural Resources Council, 490 U.S. 360, 378 (1989); see also, Maryland National Capitol Park and Planning Commission v. United States Postal Service, 487 F.2d 1029, 1040 (D.C. Cir. 1973); Central Audubon Society of Arkansas v. Dailey, 977 F.2d 428, 434 (8th Cir. 1992))

The National Environmental Policy Act (NEPA), 42 U.S.C. 4321, et seq., and implementing regulations promulgated by the Council on Environmental Quality, 40 C.F.R. 1500 et seq., require the preparation of an Environmental Impact Statement for major federal actions that may significantly affect the environment.

62-87 NIH has stipulated that proposing to build a BSL-4 facility at RML is such an action by their preparation of the EIS. Therefore, that EIS must address all significant adverse environmental consequences, direct or indirect, that may be caused by the agency's activities. 42 U.S.C. 4332 (2) (C) (ii); 40 C.F.R. 1502.16; 40 C.F.R. 1508.8.

6.2.2 The DEIS admits that there is a risk to the community, but fails to disclose the consequences.

The NIH's DEIS disclosed the following information:

> "The potential for a release of an agent from RML and the increased likelihood of terrorism as a result of the Proposed Action is reduced by the physical and procedural safety measures inherent to RML and Proposed Action." (DEIS S-3)
>
> **Summary Comparison of Alternatives**
> Proposed Action - Community Safety: "Remote increased risk to the community."
> No Action - Community Safety: "No increased risk to the community." (DEIS 2-11)
>
> **Environmental Consequences - Community Safety**
> "Potential added risk to the community from the Proposed Action cannot be effectively quantified." (DEIS 4-2)

The DEIS describes the agents that will be studied in the proposed BSL-4 facility as:

> "Dangerous/exotic agents which pose high risk of life-threatening disease, aerosol-transmitted lab infections; or related agents with unknown risk of transmission." (DEIS 1-5)

The NIH says that the potential for release or terrorism is "reduced" (DEIS S-3) but they do not say it is eliminated entirely or that there is no potential whatsoever. The DEIS acknowledges that there is a "remote increased risk" from the Action Alternative, and there is "no increased risk" from the No Action Alternative (DEIS 2-11). The DEIS claims that the "potential added risk" ... "cannot be effectively quantified"(DEIS 4-2).

Comment	Response
62-87	The DEIS, SDEIS, and FEIS do address effects of the Proposed Action and No Action Alternatives. Although the CEQ regulations do state that an EIS must be completed when there would be significant effects, the decision to prepare an EIS does not necessarily mean that significant effects would occur or that all effects would be significant.

62-88 **6.2.3 The DEIS must disclose the consequences of reasonably foreseeable risks.**
This is needed even if the probability is assessed to be low. The importance of such an analysis cannot be overstated. Such an analysis is essential for identifying mitigation measures, safety protocols, community health and service needs, health risk to people, risk to wildlife, risk to property values, and risk to businesses. As a minimum, the DEIS should disclose the consequences of the following events:

62-89 Cont. on next page

6.2.3a Staff infections that are isolated to lab environment.
This should include both those that are isolated to the laboratory and those in which the staff member infects other people. This is certainly a realistic scenario since RML has had recent staff exposure, have been infected and/or carriers in the past, and have infected their spouses.

6.2.3b Staff infections that result in a community wide epidemic.

6.2.3c Release of infections through escaped animals.

6.2.3d Release of infectious prions through the incinerator including an assessment of recombination after cooling in the smokestack.

6.2.3e Release of infectious agents through water via sewage, wetlands, or surface water.

6.2.3f Release of infectious agents through ground due to spills or purposeful dumping.

6.2.3g Release of infectious agents when being transported.

6.2.3h Release of infectious agents through water via sewage, wetlands, or surface water.

6.2.3i Release of infectious agents because of an out of control fire.
This is particularly important since RML continually fails fire inspections. (See Appendix B and comments under 6.3).

6.2.3j Release of infectious agents through intentional acts by a staff member.

6.2.3k Release of infectious agents due to a terrorist attack with a bomb or aircraft.

6.2.3l Release of infectious agents due to the safety committee and staff failing to understand the behavior and danger of a new pathogen under study.

Comment	Response
62-88	Please see Section 1.7.3 where comments on risk were addressed.

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62-89

6.2.3m Release of infectious agents due because a HEPA filter fails to stop the agent. See Appendix C for a government report on the failure to test HEPA filters to verify their specified performance. Also analyze HEPA filter failure modes, and operation when incorrectly maintained or used.

6.2.3n Release of infectious agents due to a failure of the safety systems. This should include a Failures and Effects Analysis for each component and the system as a whole.

6.2.3o The causal release environment: accidental spill, fire, terrorist explosion.

6.2.3p Release through steam exhaust.

62-90

6.2.4 Refusal to disclose the risks or consequences to human health is a violation of Federal Regulations.

Essentially, the NIH is saying that they cannot "effectively" determine or express the quantity of the risks or impacts from escape or release of agents. Nor is there any indication they tried. This does not appear to be in compliance with the following CEQ regulations, and especially, the requirement of 1502.22(b)(4).

6.2.4.a NIH is required to assess consequences.

40 CFR 1502.16 ENVIRONMENTAL CONSEQUENCES:

"This section forms the scientific and analytic basis for the comparisons under 1502.14. It shall consolidate the discussions of those elements required by sections 102(2)(C)(i), (ii), (iv), and (v) of NEPA which are within the scope of the statement and as much of section 102(2)(C)(iii) as is necessary to support the comparisons. The discussion will include the environmental impacts of the alternatives including the proposed action, any adverse environmental effects which cannot be avoided should the proposal be implemented, the relationship between short-term uses of man's environment and the maintenance and enhancement of long-term productivity, and any irreversible or irretrievable commitments of resources which would be involved in the proposal should it be implemented. This section should not duplicate discussions in 1502.14. It shall include discussions of: (a) Direct effects and their significance (1508.8). (b) Indirect effects and their significance (1508.8). (c) Possible conflicts between the proposed action and the objectives of Federal, regional, State, and local (and in the case of a reservation, Indian tribe) land use plans, policies and controls for the area concerned. (see 1506.2(d).) (d) The environmental effects of alternatives including the proposed action. The comparisons under 1502.14 will be based on this discussion. (e) Energy requirements and conservation potential of various alternatives and mitigation measures. (f) Natural or depletable resource requirements and conservation potential of various alternatives and mitigation measures. (g) Urban quality, historic and cultural resources, and the design of the built environment, including the reuse and conservation potential of various alternatives and mitigation measures. (h) Means to mitigate adverse environmental impacts (if not fully covered under 1502.14(f))."

Comment	Response
62-89	Please see Section 1.7.3 where comments on risk were addressed.
62-90	Please see Section 1.7.3 where comments on risk were addressed.

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62-91

6.2.4b DEIS fails to comply with regulations in discussing risk.

40 CFR 1502.22 INCOMPLETE OR UNAVAILABLE INFORMATION:

"When an agency is evaluating reasonably foreseeable significant adverse effects on the human environment in an environmental impact statement and there is incomplete or unavailable information, the agency shall always make clear that such information is lacking. ... (a) ... (b) If the information relevant to reasonably foreseeable significant adverse impacts cannot be obtained because the overall costs of obtaining it are exorbitant or the means to obtain it are not known, the agency shall include within the environmental impact statement: (1) A statement that such information is incomplete or unavailable; (2) a statement of the relevance of the incomplete or unavailable information to evaluating reasonably foreseeable significant adverse impacts on the human environment; (3) a summary of existing credible scientific evidence which is relevant to evaluating the reasonably foreseeable significant adverse impacts on the human environment, and (4) the agency's evaluation of such impacts based on theoretical approaches or research methods generally accepted in the scientific community. For the purposes of this section, "reasonably foreseeable" includes impacts which have catastrophic consequences, even if their probability of occurrence is low, provided that the analysis of the impacts is supported by credible scientific, is not based on pure conjecture, and is within the rule of reason."

40 CFR 1508.27 SIGNIFICANTLY:

"Significantly" as used in NEPA requires considerations of both context and intensity: (a) Context. This means that the significance of an action must be analyzed in several contexts such as society as a whole (human, national), the affected region, the affected interests, and the locality. Significance varies with the setting of the proposed action. For instance, in the case of a site-specific action, significance would usually depend upon the effects in the local rather than in the world as a whole. Both short and long-term effects are relevant. (b) intensity. This refers to the severity of impact. Responsible officials must bear in mind that more than one agency may make decisions about partial aspects of a major action. The following should be considered in evaluating intensity: (1) Impacts that may be both beneficial and adverse. A significant effect may exist even if the Federal agency believes that on balance the effect will be beneficial. (2) The degree to which the proposed action affects public health or safety. (3) Unique characteristics of the geographic area such as proximity to historic or cultural resources, park lands, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas. (4) The degree to which the effects on the quality of the human environment are likely to be highly controversial. (5) The degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks. (6) The degree to which the action may establish a precedent for future actions with significant effects or represents a decision in principle about a future action. (7) Whether the action is related to other actions with individually insignificant but cumulatively significant impacts significance exists if it is reasonable to anticipate a cumulatively significant

Comment	Response
62-91	Please see Section 1.7.3 where comments on risk were addressed.

> impact on the environment. Significance cannot be avoided by terming an action temporary or by breaking it down into small component parts. (8) The degree to which the action may adversely affect districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places or may cause loss or destruction of significant scientific, cultural, or historic resources. (9) The degree to which the action may affect an endangered species or its habitat that has been determined to be critical under the Endangered Species Act of 1973. (10) Whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment.

The DEIS disclosed that the: "Potential added risk to the community from the Proposed Action cannot be effectively quantified." (DEIS 4-2)

It appears that the DEIS's dismissive treatment of the safety concerns and risks analysis fails to comply with 40 CFR 1502.16, 1502.22, 1502.24, 1508.8 and 1508.27, et seq.

6.2.4c Risk assessment is a common practice of the Federal Government.
In other situations the Federal Government has undertaken a risk assessment even though the probabilities were not firmly defined.

Risk assessments are required in DOD Acquisitions (DOD 2000). For an example of how these methods are applied to RML risks, see Appendix C.

The fact that it is difficult to assess risk in this case does not mean that it is impossible to quantify in an EIS. For example, in the Bison Management Plan for the State of Montana and Yellowstone National Park brucellosis transmission was identified as a potential significant impact within the scope of the EIS. That EIS clearly states (National Park Service FEIS Volume I, page 29) that there has never been a documented transmission of brucellosis between buffalo and cattle: "No documented cases exist of wild, free ranging male bison transmitting brucellosis to domestic cattle." Nevertheless, a detailed analysis of the potential for Yellowstone buffalo to transmit brucellosis to cattle was calculated and included in the EIS (Volume I Environmental Consequences - Impacts on Socioeconomics pages 514-557). *Similarly a full risk analysis of the potential for a release of a BSL-4 agent to the community can and must be included in this DEIS.*

6.2.4d Risk assessment is a stated need in NIH and Biological Safety Principles.
The CDC and NIH document the need (NIH/CDC, 1999) and textbooks on the subject also document the need for risk assessments. (FLEMING, 2000).

6.2.5 Claim that there has never been a "confirmed" release is entirely unsubstantiated.

NIH's DEIS tries to allay the public's concerns about risk, safety, and adverse impacts by unequivocally stating that: "In more than thirty years of working with BSL-4 agents in the U.S., there has never been a confirmed release to the community from a laboratory (Wilson, 2003)." (DEIS 4-2)

The DEIS only later discloses elsewhere, that the Wilson quote was only in the form of a "personal communication"(DEIS L-5).

62-92 The citation to back up the claim is a personal communication with Dr. Deborah Wilson. No explanation of Dr. Wilson's background or occupation other than "OSHB, DS, NIH." These acronyms need to be clarified. In addition, the fact that the oldest BSL-4 in the U.S. at CDC in Atlanta was built in 1978 (just 25 years ago, not 30) the credibility of the "personal communication" is weakened. A more credible source should be cited for this claim, or it should be removed from the document.

6.2.6 There has been a reported terrorist attack using agents traced to a US government BSL-4 Lab.

The press has reported DNA analysis evidence of the anthrax powder that appeared in our nation's capital came from a U.S. government-run BSL-4 lab.

62-93 **6.2.7 The DEIS ignores the fact that the risk of a release of infectious material to the surrounding community will rise significantly with the addition of new laboratories and the increase in frequency of experiments.**
According to our information regarding Dr Fauci's hearing testimony, it appears that there are only three currently operating BSL-4 facilities in the United States; CDC in Atlanta, Georgia; Fort Dietrich, Maryland; and 'one operational in Texas'. (Dr. Fauci; June 10, 2002; Homeland Security)

The 12/15/2000 memo released under the FOIA by NIAID's Mr. Paul Marshall (FOIA Coordinator) appears to place the BSL-4 labs in different locations: "Biosafety level-4 laboratory space in the United States is currently limited to three facilities located in Bethesda and Fredrick, Maryland, and Atlanta, Georgia. One additional facility is planned for construction in Galveston, Texas".

If it is accurate that there are three currently "operating" BSL-4 labs in the United States, then that very small number of operating BSL-4 labs is what the NIH is holding up to demonstrate the BSL-4 lab's 'perfect' safety record.

Additionally, according to a Missoulian newspaper article, the DEIS may have made an error when they stated that BSL-4 labs have operated for 30 years with a perfect safety record: "Karl Johnson, the virologist who built the first BL-4 in 1978 in Atlanta ... said Hamilton and the Bitterroot Valley have nothing to worry about. BL-4 labs are safe, necessary and will allow even better research to go on in Montana." Johnson is on a committee reviewing the design plans for Rocky Mountain Labs' proposed BL-4. (Missoulian State Bureau, 'In the 'Hot Zone'; by Jennifer McKee; September 15, 2002)

62-94 Subtracting 1978, (assuming it even actually "started" in 1978), from 2003 indicates it's really only about 25 years, not 30 years, that the one particular CDC Atlanta lab has been in operation. The DEIS failed to disclose when either of the other two operating BSL-4 labs were built and actually went into operation.

Cont. on next page

Comment	Response
62-92	This information was included in the List of Preparers in the SDEIS. It appears again in the FEIS. Please also see Appendix D, Review of Biocontainment Laboratory Safety Record.
62-93	Please see Section 1.7.3 where comments on risk were addressed.

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62-94 The bottom line is that it is likely that no BSL-4 facility in the U.S. has operated safely for 30 years as was stated in the DEIS.

It appears that only one lab has operated for about 25 years (or less, counting construction time); and, no data has been given for how long the other two existing labs have been in actual operation. Three BSL-4 labs operating 25 years, or likely less, is a very small sample or data base for the NIH's DEIS to use to assume, and/or assure the public of, absolute safety. This does not appear to rise to NEPA's requirement for a "hard look" and "full disclosure".

Some proponents for the new BSL-4 facility in Hamilton have dismissed public concerns regarding the potential risks of constructing the lab.

A newspaper article by the Medford Mail Tribune discussed some of the risk and safety concerns: RML has a long record of discovery and safety. It developed a vaccine for Rocky Mountain spotted fever and discovered the bacterial makeup of tick-borne Lyme disease. However, Dr. Linda Perry, a former employee at RML says that, unlike previous RML research, the work proposed for the new lab will involve mysterious pathogens, such as the flesh-eating Ebola virus about which little is known. "Science has little understanding of how these disease agents are spread," Perry said. "This alone heightens the risk of an employee not realizing he or she is infected and walking out of the lab into the community." Once loosed among unsuspecting residents, Perry says the lab's mystery disease agents could turn Hamilton into a "biological ghost town." (Bio-fear in the Bitterroot Valley; Medford Mail Tribune; by Les AuCoin; Environmental News Service 7/14/03)

In that same article, the newspaper further reported that: ... others say they are willing to be convinced the lab will be safe but the nagging question remains: "Why Hamilton?" Along with many residents of Ravalli County, they suspect, as in the case of the government's storage of radioactive wastes at Hanford, WA and Yucca Mountain, that NIH picked their town because it is geographically remote and politically weak. A Biosafety Level 4 lab was built several years ago on the Bethesda, MD campus of NIH but it has never been used for this purpose. Maryland has a ten-member congressional delegation, more than three times the numerical strength of Montana's contingent. Hundreds of other members of Congress live in Bethesda, an affluent suburb of Washington, D.C. However, opponents used the Freedom of Information Act to access NIH documents concerning Hamilton. One memo cited the town's "rural location" and "sparse population" to suggest that a release of deadly pathogens would not cause "catastrophic damage." "That's an unsigned memo written on a paper with no letterhead," [an RML representative] protested. "You can't associate it with NIH's official attitude." Still, someone at NIH thought those thoughts. .... (Bio-fear in the Bitterroot Valley; Medford Mail Tribune; by Les AuCoin; Environmental News Service 7/14/03)

It appears possible that the Bethesda, Maryland citizens were concerned enough about the BSL-4 facility at NIH that they prevented its use - after it was physically constructed.

Comment	Response
62-94	The DEIS never says that BSL-4 labs have operated for 30 years with a perfect safety record. The DEIS (and FEIS) says that in 30 years of working with BSL-4 agents in the U.S., there has never been a confirmed release to the community from a laboratory. The citation and statement are correct.

Additionally, the 12/15/2000 memo released under FOIA by Mr. Paul Marshall, (FOIA Coordinator, NIAID) raised the disturbing possibility that Hamilton, Montana was a desirable place to build a new BSL-4 lab because "... the RML campus is located in western Montana, well removed from major populations centers. The location of the laboratory reduces the possibility that an accidental release of a biosafety level-4 organism would lead to a major public health disaster."

Nuclear power plants were once considered fairly safe - until the well-publicized incidents at Three Mile Island, Chernobyl and Hanford. And, it appears that no new nuclear plants have been built in the U.S. since.

62-95 **6.2.8 With a Ten Fold increase in BSL-4 experiments the probability of a single community release over 25 years can raise over nine times that of the previous 25 years.**

Clearly, the risk of a single release event increases with the number of laboratories and experiments. The DEIS admits that there is a finite risk. The RML and other BSL labs often experience accidents and annually have several staff infections as a group. The risk of at least one release can be high even if the risk associated with current levels is low. For example:

If the risk of an infectious agent a release to the community over a single experiment is *R*. And given that *N* experiments per year are performed. And the probability of release for each experiment is statistically independent then the risk of a single event in a year, then the likelihood of at least one release event in a year *Rs* is:

$Rs = 1 - (1 - R)^N$

If R = 0.0001% and N = 10,000, then Rs = 1% change of at least a single event in one year.

If we assume that the current situation of a few BSL-4 labs operating results in 10,000 experiments (N) per year and that each experiment has a low probability of a single event (R). Then, over 25 years at the above-assumed rates, the odds are 5 to 1 that no event would have occurred.

If the number of experiments are increased 10-fold as seems to be contemplated by the NIAID, then Rs = 9.5% chance of a single event in one year. This would give a high probability of an event in the next 25 years of 92% of at least one release.

Of course this situation could be rectified by increasing safety procedures and reducing the current risk (R) to R`. If R` is one tenth of the current risk, then the probability of an event in the next 25 years would become 22%. This certainly would indicate that extreme safety measures beyond those currently in place would be prudent.

62-96 *The DEIS must perform an analysis of the safety risk and examine the impacts of increased experiments in the risk.*

Comment	Response
62-95	There is no evidence to support this statement.
62-96	Please see Section 1.7.3 where comments on risk were addressed.

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62-97 **6.2.9 Specific information requested to aid in understanding the analysis.**
Ref. DEIS 2-1 and 2-8. *Who is going to train them and supervise? How much experience do they have?*

62-98 Ref. DEIS 2-2. *Disclose the safety record of HEPA filters and the ability to test their effectiveness to the specifications claimed in the DEIS.*

62-99 *What is the present existing level of treatment at the water treatment plant? Describe and explain in detail.*

62-100 Ref. DEIS 2-8. Laboratory security, "safety policies and procedures would be reviewed whenever an incident occurs or a new threat is identified." *Who would be reviewing the safety and policy procedures? Would the policies and procedures be reviewed more often, absent an incident or event? If there were an incident, would this information be released and/or made available to the public in a timely manner?*

62-101 Ref. DEIS 2-9 and 4-1. *When will the emergency plan be available for review by the public? It should be released as part of the DEIS.*

62-102 Ref. DEIS 2-10. "Relocation would take approximately 10 years and an estimated $1 billion." *How was this estimate made?*

62-103 Ref. DEIS 2-10. *Regarding $66.5 million for construction which has been allocated by Congress, please provide budget line item and, if it is included in a larger line item, to what uses the other allocations will be put.*

62-104 Ref. DEIS 3-4. *What level of training do the security guards currently working at RML have? What level of training and experience would federal security guards have?*

62-105 *Is there a fire protection plan for RML? If so, the DEIS should reference it.*

62-106 Ref. DEIS 3-5. Health Care. *What plan is in place if an employee of RML is exposed to a pathogen? A deadly pathogen? How would the person be transported to the hospital? How would the transportation vehicle be decontaminated after exposed person was transported? How long would a decontamination procedure take and how long would it tie up resources, or be out of commission, due to transport and decontamination?*

62-107 Ref. DEIS 3-5. Transportation. "Nearly 69 percent of recorded collisions occurred on U.S. 93." Note that, according to MDT Annual Safety Report, US Highway 93 has an accident rate significantly better than the other roads in Ravalli County, on average. Thus, the reference here is flawed.

This may not be reassuring since pathogens will most likely be transported via ground shipments and along Highway 93, increasing the likelihood of the transport vehicle getting into a collision and possibly releasing deadly pathogens into the environment or exposing the driver of the transport vehicles and others who may be at the scene of the

Comment	Response
62-97	Please see Section 1.7.1 where comments on the required training for laboratory workers and their supervision where addressed.
62-98	Information on the safety of HEPA filters may be found online at http://www.engr.psu.edu/ae/wjk/fom.html. It discusses single HEPA filters and their efficiencies related to microbial aerosols. The Integrated Research Facility would use double HEPA filtration.
62-99	Please see Section 4.8.1.1 where the Hamilton water system is discussed.
62-100	Please see Section 1.7.1 where comments on safety procedures were addressed.
62-101	Please see Section1.7.2 were comments on the emergency plan were addressed.
62-102	Please see Section 2.2.2.2.
62-103	Please see Section 1.7.4 where issues or concerns outside the scope of the EIS were addressed.

Remainder of responses on following page.

Comment	Response
62-104	All contract security guards must successfully complete training in Basic Security Training Curriculum (training in topics such as firearms safety/handling, vehicle inspection techniques, security patrol methods, search and seizure, enforcing the law, communication, ethics and professionalism), orientation training and supervisory training. Guards and supervisors complete a quarterly refresher training based on basic and orientation training topics. Police officers within the Division of Police must graduate from the Federal Law Enforcement Training Center's Mixed Basic Police Officer Training Program, or a Police Academy that meets the criteria. They must also complete 40 hours of annual in-service training, semi-annual firearms training, security training, specialized training, and supervisor/ management training.
62-105	Please see Section 2.1.1 where fire protection is addressed.
62-106	Please see Section 1.7.1 where requests for additional information on the alternatives were addressed.
62-107	Please see Section 1.7.2 where comments on the emergency plan were addressed.

accident.

6.2.10. Community Safety discussion is misleading.

Section 4.2.1.1 states:

> "…the nature of transmission of many diseases that would be studied at RML provides a natural mechanism controlling their spread in a community." (DEIS 4-5)

The claim being made is that some BSL-4 diseases are those that require an intermediate host or direct contact with infected bodily fluids, which reduces the risk of spread within a community. However, it must be made clear in this section that U.S. government's priority for research in new BSL-4 labs is to study diseases which could be used as an agent of bioterrorism - diseases for which person-to-person aerosol transmission is possible. Section 125 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 states:

> "Section 319F(h) of the Public Health Service Act, is amended to read as follows:
>
> 319 F (h) (2) Priority. --The Secretary shall give priority under this section to the funding of research and other studies related to priority countermeasures…
>
> (4) Priority countermeasures. --For purposes of this section, the term `priority countermeasure' means a drug, biological product, device, vaccine, vaccine adjuvant, antiviral, or diagnostic test that the Secretary determines to be--
>
> (A) a priority to treat, identify, or prevent infection by a biological agent or toxin listed pursuant to section 351A(a)(1), or harm from any other agent that may cause a public health emergency;

62-108 Tick borne diseases, or other diseases which are difficult to transmit person to person are not usually considered diseases which "may cause a public health emergency" and thus are not a priority for funding. *The claim that "many" of these diseases would be studied at RML is therefore misleading and should be removed from the DEIS.*

6.2.11 Impact and risk of lab-acquired infections or diseases for RML workers is not disclosed.

Standard and Special Safety Practices for Biosafety Laboratories (DEIS-Appendix C) as it applies to existing BSL-3 facilities has not prevented lab-acquired infections or occupational diseases for RML employees and scientists.

Poor adherence to lab safety procedures or practices at Rocky Mountain Labs led to an incident in April 2001 involving the exposure of virulent Y. Pestis, the cause of plague, in lab environment and to workers who entered the lab. After the incident, Ted Hackstadt, Chair of Rocky Mountain Lab's Biosafety Committee recommended: "that all work with

Comment	Response
62-108	This assumption that **only** diseases that can be used for bioterrorism would be studied at the Integrated Research Facility because of funding priorities is incorrect. Please see Chapter 1.

virulent Y. Pestis be suspended until it can be carried out in the new facility under strict BL3 containment."

(Ted Hackstadt, PHD Chair RML Biosafety Committee to [name deleted], memorandum on Possible Y. Pestis exposure, April 17, 2001)

As of 1999, there was no national reporting system in place for lab-acquired infections of diseases or illnesses. Two separate lab-acquired diseases and claims for compensation have been made at Rocky Mountain Labs for exposure to Chlamydia and Tuberculosis. An additional employee claim for compensation was filed for lab exposure to Y. Pestis.

(Biosafety in Microbiological and Biomedical Laboratories Manual, U.S. Dept of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention and National Institutes of Health, 4th Edition, May 1999 (Guest Editor: David Hackstadt PHD RML)

Nigel Strozier, Claims Examiner Dept. of Labor, Employment Standards Administration, Officer of Worker's Compensation, Occupational Disease Claim, February 9, 1999.

Employment Standards Administration, Office of Workers Compensation, Occupational Disease Claim, December 7, 2000.

Notice of Occupational Disease and Claim for Compensation, Dept. of Labor, Employment Standards Administration, Office of Workers Compensation, May 3, 2001)

62-109 *Provide a risk analysis of current and projected health impacts of RML workers acquiring infectious disease(s) or being exposed to aerosolized biological agent(s).*

Lab Inspection and NIH Lab Safety Surveys (2000-2002) found numerous examples of poor adherence at Rocky Mountain Labs to standard biosafety practices and inadequate or improperly maintained safety equipment:

- Blocking or obstructing safety features of Biosafety Cabinets and Chemical Fume Hoods
- Disabling audible alarms on Biosafety Cabinets and Chemical Fume Hoods
- Storing chemicals in Biosafety Cabinets
- Storing incompatible chemicals together
- Improperly identifying or not labeling chemicals
- Failing to secure gas cylinders
- Blocking sprinklers
- Blocking pathways
- Failing to provide safety showers, eye and hand wash stations in labs
- Improper placement of safety/biohazard signs on lab doors
- Overfilling sharps containers
- Providing out-of-date fire extinguishers
- Overloading outlets
- Wedging BSL-2 lab doors open

Comment	Response
62-109	Please see Section 1.7.3 where comments on increased risk were addressed.

(LAB INSPECTION SUMMARY 2000; NIH Lab Safety Surveys, 8/25/00; 9/15/00; 7/19/01; 7/23/01; 7/26/01; 7/27/01; 8/1/01; 8/07/01; 7/25/02; 7/30/02; 7/31/02; 8/1/02; and 8/6/02)

In March 1994 a lab worker removed his flow hood while handling Mycobacterium tuberculosis a "pathogenic material highly resistant to anti-tuberculosis drugs." Co-workers informed him that biosafety cabinet exhaust "fan was malfunctioning." The lab worker was unaware of the malfunctioning safety feature as "the audible alarm was disabled since the hoods require so long to balance."

(Clifton E. Barry III Unit Head Mycobacterial Research Unit, LICP, to RML Biosafety Committee, memorandum on Potential Exposure [of name deleted] to Mycobacterium, April 21, 1994.)

In 1996 Rocky Mountain Labs was notified that hospital-grade facemasks for lab workers conducting pathogenic tuberculosis research did not "efficiently filter out aerosolized bacteria."

(Clifton E. Barry III Tuberculosis Research Unit, LICP, RML, DIR, NIH to Biosafety Committee, memorandum on Notification of skin test conversion of [name deleted] and procedural changes in the P-3 facility, August 30, 1996)

6.2.12 Biosafety procedures are inadequate because they are not mandatory.

The safety publications issued by NIH are for guidance only and therefore lack the essential requirement to insure that safety requirements will be complied with. In fact, the failure to impose safety requirements increases the risk of accidents.

62-110 *The DEIS should assess the impact on safety in an environment where the staff does not have specific requirements for compliance that is enforced by an independent chain of command.*

The DEIS should clearly spell out which requirements are enforced and which are optional.

6.3 Failure to disclose and mitigate Fire Protection, Emergency Planning, Preparedness, Response and Communication Measures.

62-111 The proposed action and no action alternatives fail to adequately disclose and mitigate fire protection, community safety, emergency containment of an infectious agent or hazardous chemical accident at RML. These failures include system inadequacies, planning and preparedness measures, training and provision of equipment to protect the community, emergency responders and lab employees. Emergency response is identified (DEIS 4-5) as a means to "reduce the potential for release of an agent to the environment or community." Yet this aspect of prevention and containment is sorely lacking in

Cont. on next page

Comment	Response
62-110	Please see Section 1.7.3 where comments on increased risk were addressed. Please also see Section 1.7.1 where requests for addition information on the alternatives were addressed.

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62-111 analysis of baseline conditions and disclosure of critical information for the public to make informed comments.

RML's Emergency Plan (DEIS 2-9) states that: "Local police, fire, and other emergency responders would be informed of the types of biological materials used in the laboratory and consulted in developing an emergency response plan."

It is unacceptable from a community standpoint to simply "consult" emergency responders in planning contingencies for emergencies at RML's expanded BSL-4 facility.

62-112 *Police, fire fighters, hazardous materials response, medical services personnel are an integral part of community safety and need to be involved in each phase of communicating, planning, preparing, responding, containing and mitigating emergencies that do and will arise at RML. Include the information in a new DEIS.*

RML has failed to adequately describe the full range of existing emergency preparedness and community safety issues as evidenced by statements such as this (DEIS 4-7):

62-113 "Procedures and protocols would also be established with local emergency response agencies to address responsibilities of each agency in the event of an emergency at RML." In other words, these procedures and protocols are not currently in place.

A July 2002 Fire Protection Survey Report of RML identified Priority fire prevention, protection and response issues at which resources should be directed to correct these valid concerns. Designation of a Priority fire safety issue presents: "major life safety hazards or conditions which could severely impact on the ability to accomplish vital missions and are those which attention and resources should be directed." Priority fire safety issues identified at Rocky Mountain Labs in July 2002 fire inspector report include:

- Absence of an on-site preventative maintenance program for fire protection systems - fire suppression and fire alarms for all buildings on campus.

- Absence of a formalized fire protection agreement with local fire department for response and abatement of emergencies covering: 1) Emergency forces notification, 2) Incident command structure, 3) Preplanning of target hazards, 4) Joint training efforts, and 5) Replacement of lost and damaged equipment.

- Developing a basic level training program for Fire Brigade commensurate with hazards at Rocky Mountain Labs and expected levels of performance, and provision of personal protective equipment.

- Examining procedures for retransmitting fire alarms to emergency responders. On-site security do not to automatically call Hamilton Fire Department during a fire alarm, instead "off-duty maintenance personnel are paged to investigate the condition."

(Fire Protection Survey Report, July 30, 2002)

Comment	Response
62-111	Please see Section 1.7.2 where comments on the emergency plan were addressed.
62-112	Please see Section 1.7.3 where impacts on the community infrastructure were addressed.
62-113	Please see Section 1.7.3 where impacts on the community infrastructure were addressed.

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62-114 **6.3.1 Under the No Action alternative, describe how RML has effectively corrected and addressed each of the Priority fire safety issues identified in the 2002 fire inspection.**

The 2002 Fire Protection Survey Report also notes: "Formal communications procedures are critical in dealing with the response to fire and hazardous materials incidents involving chemicals and biological agents."

(Fire Protection Survey Report, July 30, 2002)

62-115 **6.3.2 Under the Proposed and No Action alternatives, describe how RML has effectively incorporated local emergency responders in its formal communications systems for fire prevention, emergency planning, preparedness and response efforts.**

In the minutes of RML's Safety Committee there is a discussion on an Evacuation Plan for RML: "Kaye [Bergman] mentioned that with no general alarm yet in place for all buildings, we currently do not have a method for personnel in all parts of the grounds to hear a signal for evacuation." The minutes also noted: "Breach in air handling [of a Biosafety Cabinet] in Building 6 on April 23, 2002."

(RML Safety Committee Meeting Minutes July 18, 2002)

62-116 **6.3.3 Under the Proposed and No Action alternatives, describe RML's current evacuation plan and provision for alarms systems alerting all RML employees to evacuate the facility.**

Under the No Action alternative, describe how RML meets or exceeds requirements of all applicable codes, standards and guidelines of the National Fire Protection Association, National Institutes of Health and National Electrical Code.

Under the Proposed and No Action alternatives discussion (DEIS 3-4 and 3-5) of affected environment fails to disclose levels and availability of local Hazardous Materials training, equipment and response personnel for existing or needed contingencies at RML

62-117 **6.3.4 Describe the procedures for verifying the efficacy and safety of protective gear and lab equipment at RML.**

As late as December 2000, Rocky Mountain Labs had no procedure in place to ensure that pathogens received by the facility were inactive as required. Additionally, lab safety hoods were not operating properly, and deficiencies in air handling were still being identified.

(RMMB Meeting Minutes, Claude Garon, Lori Lubke, Dave Dorward, Fred Hayes, Elizabeth Fischer, and Penny Gaddy-Rhodes present, Discussion Processing Samples in RMMB, December 4, 2000)

Comment	Response
62-114	The recommendations have been addressed through training, access for first responders, and preventive maintenance contracts have been initiated and in some instances completed. Radios, alarms, and personal protective equipment have been made available. A memorandum of understanding with the local fire department is being executed.
62-115	RML staff meets periodically with representatives from the FBI, U.S. Attorney's Office and other local law enforcement to share information and strengthen communication among these groups. RML is a member of the Montana Anti-Terrorism Task Force, and the Ravalli County Local Emergency Planning Committee, and the Ravalli County Terrorism Preparedness Task Force and will participate in the Ravalli County Pre-Mitigation Plan authorized under the Disaster Mitigation Act of 2000.
62-116	RML's evacuation plan focuses on four response procedures. They include: total evacuation, shelter in place, lockdown, and room clear. The nature of the emergency determines the response. Evacuation drills are conducted semi-annually. Alarm systems consist of an audible alarm and a strobe light. The evacuation team has 50 full time employees.
62-117	Depending on the system, inspections occur with each use, daily, monthly, quarterly, and annually.

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62-118 **6.3.5 Describe the procedures for verifying that pathogens transported to RML are inactive, and how these procedures will be implemented for BSL-4 pathogens.**

62-119 **6.3.6 Describe the procedures for verifying operational capability of safety features on biosafety cabinets.**

62-120 **6.3.7 Describe in detail what, if any, consequences are instituted at RML for lab employees who fail to follow safe practices and procedures for studying and handling biological agents.**

6.4. Impact on the Environment is not disclosed.

6.4.1 Air Quality.

The environmental impact of the project on air quality must be discussed in greater detail. The only data given is Table 4-4 (DEIS 4-14) showing potential maximum emissions. This is inadequate to assess the actual impacts of the proposed project and does not take into account the pollution prevention mandate of the Department of Health and Human Services. *A full comparative analysis is required to show existing air quality conditions, the impact on air quality from the preferred alternative, the impact on air quality from pollution prevention alternatives (such as elimination of the incinerator as a disposal method, and the use of SCONOX technology.) Please include the following information:*

62-121

No Action Alternative:
Current emissions (at current average use levels)
Current maximum potential to emit
Impact on ambient air quality (i.e. the results of analysis done by Doucet and Mainka, 1999)

Preferred Alternative:
Expected emissions (at expected use levels)
Expected maximum potential to emit
Impact on ambient air quality (including during atmospheric inversions)

Pollution Prevention Alternatives:
Expected emissions (at expected use levels)
Expected maximum potential to emit
Impact on ambient air quality (including during atmospheric inversions)

6.4.2 Lack of analysis of impact to nearby Selway Bitterroot Wilderness.

The nearest Class 1 Area is the Selway Bitterroot Wilderness just six miles west of RML. Section 4.7.1.1 of the DEIS states:

> "The air modeling analysis conducted for RML predicted air emission would be within Montana and federal air quality standards. These emissions are not expected to visibly affect or modify air quality in Class I areas." (DEIS 4-14)

Comment	Response
62-118	Pathogens are not required to be inactive to be transported.
62-119	Please see Section 1.7.1 were requests for additional information on the alternatives were addressed.
62-120	Administrative penalties are applied as prescribed by Personnel regulations.
62-121	Please see Section 1.7.3 where comment on the impacts on air quality were addressed.

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62-122 No source is referenced for this analysis. Simply stating that the impacts on air quality are not expected to affect the Class 1 area does not constitute "evidence that the agency has made the necessary environmental analyses." (40 CFR 1502.1) *The analysis should be clearly explained, referenced and included as an appendix in the DEIS.*

6.4.3 Lack of analysis of air quality during inversions.

62-123 The analysis referred to (DEIS 3-16) regarding modeling of meteorological data with respect to atmospheric inversions should also be clearly explained, referenced and included in the DEIS. *All analyses on the impact of air quality by the different alternatives should consider the impact on air quality during atmospheric inversions.*

6.4.4 Unclear claims on particulate matter emissions.

Section 4.7.2. Cumulative Effects, states:

> "Under the Proposed Action the minor increase in emissions would be added to emissions from the other 11 permitted sources in the county. A decrease in particulate matter emissions from reasonably foreseeable actions would occur as undeveloped areas are used for buildings and paved for parking." (DEIS 4-14*)*

62-124 As stated above, no data is included to allow one to compare current emissions with expected emissions. Thus, the phrase "minor increase in emissions" is vague and subjective. The phrase needs to be clarified with data. Secondly, the confusing claim that particulate matter emissions would decrease is also unjustified with data. No data is presented (nor any analyses referenced) regarding current or expected fugitive dust emissions, which might decrease with development and paving. The DEIS appears to imply that this uncalculated decrease in particulate matter emission are expected to offset the "minor increase" in particulate matter emissions that are predicted by the increase in use of the incinerator, the added emergency generator and new boiler. *This claim is highly doubtful and must either be justified with data, or reworded for accuracy.*

6.4.5 Surface Water – Failure to disclose impacts.

Failure to disclose impact on MPDES permit.

62-125 Rocky Mountain Laboratories currently holds an MPDES permit for discharge into the Bitterroot River. This permit is never mentioned in the DEIS. *If there are any impacts to this permit or this discharge on surface water, it should be clearly states in the DEIS. If there are no impacts, this should also be clearly stated.*

62-126 **6.4.6 Ground Water quantity and quality – Failure to adequately analyze impact.**

The analysis of ground water does not assess the cumulative impacts of the large use by RML and the impact of the unique waste generated by RML that may end up in the ground water.

6.4.7 Impacts of solids in wastewater not adequately addressed/analyzed.

Section 4.8.1.1 states:

Comment	Response
62-122	Please see Section 1.7.3 where impacts on air quality were addressed.
62-123	Please see Section 1.7.3 where impacts on air quality were addressed.
62-124	Please see Section 1.7.3 where impacts on air quality were addressed.
62-125	Until 2002, RML held a Montana Pollution Discharge Elimination System Permit (MPDES No. MT0028487) that allowed discharge of cooling water and stormwater to an area west of the C&C ditch. The discharge outflow for this permit was located approximately 100 feet northwest and down gradient of the facility. Due to changes in facility operations, cooling water is no longer discharged and the permit was allowed to expire on November 30, 2002. An industrial stormwater permit is not required under RML's Standard Industrial Classification (SIC) Code (SIC Code 8071).
62-126	Please see Section 1.7.3 where impacts on water and wastewater were addressed.

"The load of solids in RML's current wastewater stream is small relative to the volume of liquid (Lowry 2003). New operations at the Integrated Research Facility would increase the solids load in wastewater from RML, but the increase is not quantifiable." (DEIS 4-15)

While this section has more detailed information on the amount of water they expect to consume with the new lab, the DEIS claims that the increase in solids loads in RML's wastewater is "not quantifiable". The claim that the load of solids is "small relative to the volume of liquid" is referenced to a personal communication with the Director of Public Works. This is a general statement of common knowledge, not an analysis of solids loads in wastewater. The load of solids in the wastewater is an important issue - as the solids treatment at CHDPW is already at near capacity. *The increase in solids need to be quantified, in order to determine if RML alone would cause the CHDPW to need to upgrade their solids handling system.* The document (DEIS 3-18) indicates several ways in which the solids load would increase: increased use of the incinerator means more blow down water from the incinerator scrubber, and more dust suppression from removal of incinerator ash.

62-127

In addition, the document (DEIS 2-6) discusses the addition of the biowaste cookers, which will discharge into a 12,000-liter holding tank -which will be added slowly (in order to dilute the solids) to the rest of the wastewater stream. The identification the size of the holding tank needed indicated that an estimate of the amount of solids expected to be generated has been made. The calculation to predict the amount of solids in the wastewater is not impossible or "not quantifiable." *Calculations can and must be done to assess the impact of solids from the preferred alternative on the solids load to CHDPW.*

62-128

6.4.8 Lack of accounting for discrepancy between water usage/wastewater disposal.

Section 3.8 states that the current average monthly water consumption is 1.7 million gallons which calculates to roughly 55,000 gallons per day (DEIS 3-18). This section later states that RML's current wastewater effluent rate is 15,000 gallons per day. Section 4.8 however states that wastewater discharge would increase by 15,000 gallons per day to a total of 60,000 gallons per day (DEIS 4-15). *The discrepancy between the two wastewater estimates should be reconciled. In either case, the water consumed but not discharged as wastewater (which is either 10,000 gallons per day or 40,000 gallons per day depending on which estimate is correct) should be accounted for in the DEIS.*

62-129

6.4.9 Wetlands - Impacts not fully analyzed.

Impact of fugitive dust from construction on wetlands.

Section 3.9.4.1 (DEIS 3-21) states that: "The closest wetland is approximately 430 feet west" of the site for the BSL-4 lab. This wetland will likely be impacted by fugitive dust and increased sediment loading from wastewater runoff during construction. *An analysis of this impact and mitigation measures to prevent impacts must be included in the DEIS.*

62-130

Comment	Response
62-127	Please refer to Section 1.7.3 where comments on wastewater were addressed. According to CHDPW's wastewater engineer, the CHDPW facility is already at its solids handling capacity and the City of Hamilton is planning to construct a temporary solids storage basin to meet current requirements in the interim until a CHDPW facility expansion plan is prepared. The CHDPW would need to upgrade solids handling capacity even if the Integrated Research Facility were not built.
62-128	Please see Section 1.7.3 where impacts on the community infrastructure were addressed.
62-129	Please see Section 1.7.3 where impacts on the community infrastructure were addressed.
62-130	Please see Section 1.7.3 where impacts on the community infrastructure were addressed.

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6.4.10 Endangered Species.

RML claims (DEIS 3-23) that: "The proposed laboratory expansion would not disturb areas beyond the existing campus area; therefore, no effect on threatened or endangered species or their critical habitat would result from the Proposed Action."

62-131 Though the "nearest known bald eagle nest" (DEIS 3-23) is identified at the Teller Wildlife Refuge, the DEIS does not disclose how wintering and migrating bald eagles utilize the habitat adjacent to RML along the Bitterroot River for perching, foraging and loafing. Bald eagles are particularly sensitive to noise, and noise disturbances that cannot be observed from the bald eagles position.

62-132 Table 3-7 Measured Noise Around RML shows that dBA appears to peak on the southwest corner of campus and the west fence line (DEIS 3-9). Construction noise over the next two years combined with operation of the facility could become a human disturbance factor for threatened bald eagles. *Under the proposed action, provide a biological discussion of all direct, indirect and cumulative noise factors that could disturb bald eagles and their habitat adjacent to the RML facility along the Bitterroot River.*

> "Sounds that are sporadic and observable may affect bald eagle nesting and perching behavior more than constant, predictable sounds produced by activities that can not be observed (MTFWP, Dennis Flath and Kurt Alt, and private consultant, Al Harmata per. Comm. 11/02/98, USFS Stangl pers. Comm.)." (Biological Assessment for the Horse Butte Bison Capture Facility - Site A2 Annual Operation from November 1 through April 30 Threatened and Endangered Wildlife, Janine Stangl, Sandy Kratville and Marion Cherry, November 30, 1998 page 14)

62-133 *Disclose the USFWS March 11 2003 communication on threatened and endangered species and their habitat.*

Yellow-billed Cuckoo

In Section 3.9.8.1, the paragraph on the Yellow-billed Cuckoo, states: "Yellow-billed Cuckoo are not known to occur in the Project Area". No reference is cited for this claim.

62-134 *Given the Yellow-billed Cuckoo is a transient species and select well-concealed nest sites, and has been determined by the USFWS to potentially occur on the site, additional research is needed to determine whether or not the Yellow-billed Cuckoo inhabits the site and may be impacted.*

6.4.11 Wildlife.

62-135 *The DEIS should include a discussion of wildlife, including deer, rodents, fish, and bird that enter and leave the compound. An analysis of their risk of contacting toxins, physical hazards, lab animals and infections should be disclosed.*

Comment	Response
62-131	Please see Section 1.7.3 where comments on the effects of Threatened and Endangered Species were addressed. Bald eagles are sensitive to loud, rapid-fire noises such as those used (with limited success) to get them to move away from military installations and airports.
62-132	Please see Section 1.7.3 where comments on the noise analysis were addressed. Please also see response to comment 36-2.
62-133	As stated in the EIS, the US Fish and Wildlife Service provided a list of endangered and threatened species. The list included all of Ravalli County.
62-134	A reference has been included. Yellow-billed cuckoo habitat does not occur in the immediate location of the proposed construction.
62-135	Laboratory animals are kept in biosafety containment and therefore wildlife are not at risk for contact with toxins, laboratory animals, and infections. It is not anticipated that wildlife will come in contact with any physical hazards due to construction or operation of the Integrated Research Facility or RML.

6.4.12 Solid waste disposal.

The only reference in the DEIS to the non-infectious solid waste stream generated by RML is in Section 2.1.2:

> "**Disposal of Non-Contaminated Material**
> Waste that has not come in contact with a biohazardous, radioactive or chemical material is considered non-contaminated and would be disposed of as general waste. This would make up the majority of waste from the facility." (DEIS 2-8)

62-136 The impact of solid waste should be given at least the same amount of analysis and attention as impact of wastewater analyzed in this DEIS. Stating that non-infectious waste would be disposed of "as general waste" is entirely vague. *This DEIS must include a full analysis of both the current and expected solid waste stream from RML. This analysis should include a general breakdown of types of waste, and data on the quantity of waste generated and method of disposal. The breakdown of waste that is land filled versus incinerated must be presented. The financial and environmental impacts of pollution prevention alternatives including the elimination of incineration as a disposal method must be discussed in this analysis.*

6.4.13 Radioactive Material Use and Waste Disposal

No reference is made in the DEIS to RML's past, current or projected use and disposal of radioactive material, yet this issue has significant impacts and effects on safety, health and the environment. *A full comparative analysis of the use and disposal of radioactive material should be included for all alternatives in the DEIS.*

62-137 Cont. on next page

Specifically, this analysis should at minimum:

Discuss and provide information on the status of RML's Nuclear Regulatory license #25-01203-01.

Provide current and projected data on the amounts and kinds of radionuclides shipped to RML, and generated by the facility's cesium irradiator.

Provide current and projected data on the amounts, treatment and media disposition of solid and liquid radioactive wastes at RML.

Using the last 5 years of radioactive material use and waste disposal at RML as a baseline, provide scientific information on the health risks of radiation exposure to RML employees, an individual residing in Hamilton, a fetus or embryo.

Provide a meaningful discussion and information on safe procedures for handling radioactive material in a lab environment, securing and storing radioactive material at RML and treating radioactive waste materials.

Comment	Response
62-136	Please see Section 1.7.3 where comments on the impacts on the community infrastructure were addressed.

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62-137 *Provide scientific information on the cumulative impacts of RML incinerating and discharging radioactive waste into Hamilton city sewer. Include a discussion on the final disposition of incinerator ash.*

Discuss and provide information of past radioactive disposal practices at RML that required environmental remediation and cleanup.

Comment	Response
62-137	Please see Section 1.7.1 of the SDIES where requests for more information on the alternatives were addressed. Information on RML handling of radioactive materials has been included under the description of the No Action Alternative and expected use under the Proposed Action in Chapter 2. RML's use of radioactive materials is regulated by the Nuclear Regulatory Commission to ensure that it has no effect on human health. Waste disposal methods are included in the description of the No Action alternative in Chapter 2. Past actions requiring remediation are outside the scope of the current EIS analysis.

7. Failure to Disclose Impacts on Local Governments.

The direct and indirect effects on government and public finance are briefly discussed in section 4.3.1.1 (DEIS 4-8). This section states:

> "Public finance revenues would increase with increased income tax on payrolls from construction and operation of the Integrated Research Facility, as well as the incomes of spouses and older children of RML employees, increased number of vehicles being licensed, and property tax revenues based on additional new homes and increased property assessments. Property taxes would increase as the needs of the county, cities, and special districts increase with new populations. How much increased revenue or cost could be attributed to the Proposed Action cannot be predicted." (DEIS 4-8)

7.1 Revenues from income tax, vehicle licenses and property taxes can and should be estimated for this DEIS.

These are not impossible calculations - especially given that the DEIS has identified both the number of expected new residents to Missoula and the wages they will be paid. The financial analysis is a significant factor in determining the impact the project will have on the economy.

In Section 4.3.1.2 the DEIS states:

> "The No Action alternative would not have direct economic impacts. An opportunity to stabilize the local economy with government jobs would be lost, slowing the realization of economic development goals." (DEIS 4-8)

The Ravalli County Economic Needs Assessment states that total personal income for Ravalli County is $626 million, and that approximately 50% or $313 million of total personal income represent earnings. (Swanson, 2002, p. 9) *Please justify how the additional $4.7 million in wages generated by the preferred alternative (a 1.5% increase in local earnings) would serve to "stabilize the local economy" or reword this claim for accuracy.* (**Swanson,** 2002 Ravalli County Economic Needs Assessment, The Bitterroot Valley Economy, prepared for the Ravalli County Economic Development Authority by Dr. Larry D. Swanson, November 2002.) **62-138**

The DEIS makes the following claim:

> "Government job growth is particularly valuable to the community because of the relatively high wages that add to the economic base (Nicholson 2002)." (DEIS 4-7)

Our reading of the Nicholson report finds no such claim or conclusion. *Please indicate the correct source for this statement.* **62-139**

Comment	Response
62-138	Please see Section 1.7.3 where comments on the social and economic impacts were addressed. The word "stabilize" has been replaced with the word "enhance" in the FEIS.
62-139	Please see Section 1.7.3 where comments on the social and economic impacts were addressed. The source for this statement has been corrected in the FEIS.

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7.2 Section 4.2.2 briefly discusses impacts to community safety, but does not analyze the direct and indirect economic effects of these impacts.

The section states:

> "Procedures and protocols would also be established with local emergency response agencies to address responsibilities of each agency in the event of an emergency at RML." (DEIS 4-7)

62-140 These procedures and protocols will require local emergency response agencies to acquire both new equipment and extensive training. *The costs for this equipment and training are economic effects of the preferred alternative and must be calculated and presented in the "Direct and Indirect Effects - Government and Public Finance" (Section 4.3.1.1 DEIS 4-8).*

Comment	Response
62-140	Please see Section 1.7.3 where comments on the impacts on community infrastructure were addressed.

8. Failure to Fully Disclose Impact on Neighbors.

62-141 The environmental impacts to nearby neighbors of RML are of considerable concern and deserve much greater attention than they received in this DEIS. *The DEIS should have a clear comparative analysis of current conditions and expected conditions both during and after construction of a BSL-4 facility.*

8.1 Noise impacts.

62-142 The section on noise in Chapter 4 needs to be expanded and clarified. Table 4-2 (DEIS 4-9) is not clearly written. Does the "measured dBA" column refer to a maximum or average measured dBA (as more than one measurement was taken in each location)? *This column should have a range that can be compared with the "predicted range" column. Also a third column for expected range of noise during construction is also needed.* Comments were made at a CLG meeting that noise from RML is louder when experienced on the second floor of their homes - such as on an upstairs balcony. *An analysis of sound levels at varying elevations must be in this section, and included in Table 4.2.*

8.2 Transportation and Traffic impacts.

62-143 Section 4.2.1.1 (DEIS 4-5) states that traffic would increase around the RML campus both during and after construction. No estimate is given of the expected increase (in numbers of trips) of traffic during construction, but it does state that after construction the increase would be about 200 trips per day. There is however no context given for this number. *An estimate of current traffic (in trips per day) must be included in this section in order to be able to assess what 200 additional trips per day would mean. An estimate of the number of trips during construction should also be included. The DEIS states that a shuttle system to an offsite parking lot may be implemented. This is an excellent example of a pollution prevention mitigation alternative which should be analyzed in the DEIS in comparison to an alternative in which all construction workers make individual trips to the site each day. These different options should be analyzed and included in the DEIS.*

8.3 Traffic Safety.

62-144 There is no discussion of the impacts of the proposed project on traffic safety. Section 3.2.6. (DEIS 3-5) states that current accident rates in Hamilton have been "average" but does not provide any numerical data on numbers of accidents. *This information should be included with an estimate of any increase in accidents due to increased traffic expected with the project. In addition an analysis should be conducted of construction traffic patterns and the expected impact on safety for children. Will large trucks or other machinery regularly drive past schools, parks or other locations where children cross often? How can this impact be mitigated to improve safety in these locations?*

Comment	Response
62-141	Please see Section 1.7.3 where comments on the effects of the proposed action were addressed.
62-142	Please see Section 1.7.3 where comments on the effects of the proposed action on noise were addressed.
62-143	Please see Section 1.7.3 where comments on the effects of the proposed action on traffic were addressed.
62-144	There is no reason to expect the accident rate to increase due to the proposed action. There is no need to mitigate to improve safety because there are no impacts on traffic safety from the proposed action.

9. Failure to Fully Disclose Economic Impacts.

9.1 Lack of analysis of impact to housing values.

The only statement about the impact of the preferred action on the property values of neighbors is in Section 1.7.1.1 which states:

> "…there is no indication that the Proposed Action will have a negative effect on property values." (DEIS 1-9)

There is however, also no evidence that any analysis was done of the potential impact of a BSL-4 lab on nearby property values. There are other BSL-4's in the country and Canada, with nearby housing. *A study should be done to evaluate the impacts of property values in the areas surrounding those labs in order to support the claim that property values will not be affected.* Many studies have shown that other types of controversial development such as landfills, power plants, nuclear reactors, Superfund sites have had negative impacts on property values from the stigma of both real and perceived risk. (The Impact of Hazardous Material on Property Value available at http://www.mundyassoc.com/articles/impact.htm and An Interregional Hedonic Analysis of Noxious Facility Impacts on Local Wages and Property Values, David E. Clark, Marquette University, and Leslie A. Nieves, Argonne National Laboratory, Journal of Environmental Economics and Management, Volume 27, pages 235-253 1994.) **62-145**

This analysis should include the effect on property values if a newsworthy release event occurs in other locations in addition to the effect on values due to a local event. This analysis should include a range of events that would increase the perceived risk and fear level in the public and, in turn, that fear level on property values. **62-146**

Impacts to property values area a significant issue and must be carefully evaluated as a potential socioeconomic risk of the preferred alternative.

9.2 Failure to adequately assess whether the economic benefits from construction and operation would be local or not.

The DEIS should clearly show how the policies and procedures used during construction and operation would be allocated geographically. The DEIS should analyze both wages (and the location of workers) as well as the cash flow of overhead and profit (and where they enter the economy) in order adequately show the people of Ravalli County and the Decision Maker the economic benefits of the project. **62-147**

Comment	Response
62-145	Please see Section 4.2.1.1 where comments on the effects of the Proposed Action on housing were addressed. Please also see response to comment 62-146.
62-146	Please see Section 4.2.1.1 where comments on the effects of the Proposed action on property values were addressed.
62-147	Please see Section 1.7.3 where comments on social and economic impacts were addressed. The DEIS (pg. 4-7) says that "The Proposed Action would have direct economic impacts on both the City of Hamilton and Ravalli county…" This information is also included in the FEIS.

10. Failure to Disclose Potential Conflicts between the Proposed Action and Objectives of Federal, state and local land use plans, policies and controls.

Section 40 CFR 1502.16 states that an EIS must disclose:

> "(c) Possible conflicts between the proposed action and the objectives of Federal, regional, State, and local (and in the case of a reservation, Indian tribe) land use plans, policies and controls for the area concerned."

The DEIS addresses this requirement by stating:

> "The RML and the proposed Integrated Research Facility meet community goals listed in the 2002 Ravalli County Economic Needs Assessment, Ravalli County Growth Policy, and the City of Hamilton Comprehensive Master Plan." (DEIS S-3)

62-148 *There are however several conflicts that were not disclosed but which need to be discussed in detail in the DEIS.*

10.1 Conflicts with goals in the Ravalli County Growth Policy.

Ravalli County Growth Policy, Countywide Policy 1.6: "Promote control of noxious weeds."

62-149 DEIS (S-3) states that the site is currently vegetated by weeds. Disruption of soil during construction could promote weed growth onsite and on adjacent property. *Please discuss how construction and landscaping of the project will be managed to prevent spread of weeds on the campus.*

Ravalli County Growth Policy, Countywide Policy 2.3:

> "Encourage the protection of water quantity and quality; including the mitigation of adverse cumulative impacts of private, commercial and public development."

62-150 Section 4.8 (DEIS 4-14) states that the preferred alternative is expected to require an additional 14 gallons per minute (7.3 million gallons per year). This will have a considerable effect on water quantity in Ravalli County. *Please discuss how water consumption will be mitigated in accordance with the growth policy. For instance, what specific water conservation efforts will be implemented by Rocky Mountain Laboratories to help offset this effect?*

Countywide Policy 3.3:

> "Promote alternatives to burning to assure air quality."

Comment	Response
62-148	The words "economic development" have been inserted between community and goals in the FEIS.
62-149	Please see response to comment 39-19.
62-150	Please see Section 1.7.3 where comments on City of Hamilton water supply were addressed. The analysis showed that the Proposed Action would not have a "considerable effect on the water quantity in Ravalli County." No mitigation is necessary.

Section 4.7.1 of the DEIS states:

"Incinerator use is estimated to increase from approximately two to three days a week to three to four days a week." (DEIS 4-13)

62-151 *As opposed to promoting alternatives to burning, the preferred alternative will increase burning by as much as 50 percent. Please justify why this is not a direct conflict with Countywide Policy 3.3.* It is clear that alternatives to the incinerator are readily available i.e. a very inexpensive landfill in nearby Missoula. It is also clear from the DEIS that all waste that is generated by a BSL-4 is fully decontaminated before leaving the building - Thus there is no need for incineration of this waste from a medical waste decontamination standpoint.

"Countywide Policy 3.6: Encourage the use of efficient heating systems."

62-152 Section 2.1 states (DEIS 2-1) that the proposed action includes a new addition to boiler Building 26 to house a new natural gas-fired boiler. *Please discuss the options considered for this new boiler, and clarify why this new boiler is considered "efficient".*

"Countywide Policy 4.1: Encourage development that will minimize or avoid additional costs to existing taxpayers.
and
Countywide Policy 4.5: Developers will be responsible for providing the infrastructure necessary within the development such as community water, sewage treatment and roads. A system of 'nexus and proportionality' will govern external infrastructure costs attributable to the developer."

62-153 *Please explain in detail how the preferred alternative will be a development that will minimize or avoid additional costs to existing taxpayers. External infrastructure costs also include improved Hazmat and emergency services. Please calculate the costs of any additional training and equipment for Hazmat and emergency services that will be needed in accordance with the emergency plan for the preferred alternative. Please discuss what proportion of these costs will be attributable to RML.*

"Countywide Policy 7.5: Encourage minimizing light pollution in new development in order to protect visibility of the night sky and enhance public safety."

The planned outdoor lighting for the preferred alternative is not addressed in the DEIS, despite specific scoping comments that were submitted regarding a concern about light pollution from the proposed project. In terms of setting a precedent, the flood lighting currently used on the new BSL-3 building at RML does not meet countywide policy 7.5.

62-154 *Please discuss the planned outdoor lighting for the preferred alternative and how it will meet countywide policy 7.5.*

Comment	Response
62-151	Please see response to comment 62-20. Additional information has been included in the FEIS in Section 4.7.1.
62-152	Please see response to comment 39-19.
62-153	Please see response to comment 39-19.
62-154	Please see response to comment 39-19.

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62-155

10.2 Lack of Discussion concerning coordination with local Emergency Planning Agencies LEPC, EPTF, Homeland Security Taskforce, Red Cross etc.

The DEIS should also address any conflicts with federal, state or local plans other than 2002 Ravalli County Economic Needs Assessment, Ravalli County Growth Policy, and the City of Hamilton Comprehensive Master Plan.

At a minimum, the DEIS should also address any potential conflicts with the Weapons of Mass Destruction/Terrorism Strategic Plan for Montana, and both the Ravalli and Missoula County Disaster and Emergency Plans. In addition, the DEIS should include a discussion of any coordination RML has done with local Emergency Planning Agencies LEPC (Ravalli and Missoula Counties), Emergency Planning Task Force (Ravalli and Missoula Counties), the Montana Homeland Security Taskforce, State Emergency Response Commission (SERC), MT Disaster and Emergency Services and the Red Cross.

Comment	Response
62-155	Montana DES stated that the project does not conflict with the Weapons of Mass Destruction/Terrorism Strategic Plan for Montana, since it is a planning document that assesses the vulnerability of bioterrorism in Montana by county for the purpose of allocating resources for bioterrorism prevention. RML participates in the Ravalli County disaster and emergency planning. Conflicts with other jurisdictions were not identified in the EIS because none could be found.

11. Failure to Address Scoping Comments.

The DEIS failed to address scoping comments adequately. The failures regarding Range of Alternatives and the Scope of the project are discussed in Sections 4 and 5 above.

11.1 Failure to List Scoping Issues and Concerns determined to be Outside the Scope of the EIS.

Section 1.7 discusses the four categories public comments were assigned to, namely:

"Issues identified in the comments were assigned to the following four categories:

- Issue or concern that could develop an alternative;
- Issue or concern that could result in a mitigation measure;
- Issue or concern that could be addressed by effects analysis; or
- Issue or concern outside the scope of the EIS." (DEIS 1-8)

The first three categories are addressed in sections 1.7.1, 1.7.1.1 and 1.7.2. However, the final category - " Issue or concern outside the scope of the EIS" is not discussed at all. It is common practice in a DEIS to list the comments that were categorized as outside the scope with an explanation for each. *Given that so many public comments appear to have been dismissed, and that this has caused dissension in the community, it is extremely important that the DEIS include a section detailing and justifying why public comments have been categorized as outside the scope.*

62-156

11.2 Failure to Address Effects Analysis Comments Listed in 1.7.2

Section 1.7.2 lists the effects analysis comments purported to be addressed in the DEIS. Unlike Section 1.7.1, no references are included in this section as to where one can find further discussion of these issues. One reason for this is that many of the issues listed are not in fact addressed later in the EIS. For example:

11.2.1 "Impacts on community infrastructure such as schools, roads and emergency response agencies."

With respect to schools, the DEIS states that:

> "Duane Lyons, Hamilton School Superintendent, reports that the middle school and high school have sufficient capacity to handle up to 100 new students. The elementary schools are at capacity; another facility is available if necessary." (DEIS 3-4)

62-157

The social and financial impacts of opening a new elementary school could be significant to the community and needs to be discussed in detail in the DEIS.

Comment	Response
62-156	Please see Section 1.7.4 where comments that were considered outside the scope of the EIS were addressed. The comments determined to be outside the scope of the analysis were generally statements for or against the project or random tidbits of information that could not be formulated into an "issue." All comments are available in the administrative record. See the following few responses for how these issues were addressed.
62-157	Please see Section 1.7.3 where comments on the impacts on community infrastructure are addressed. The DEIS and SDEIS state that "School capacity is adequate for growth, especially since school-aged levels are decreasing." There is no evidence that the Integrated Research Facility would cause the need for a new school.

With respect to roads the DEIS states that:

> "New signals may be warranted at two locations on U.S. 93; one at Pine Street and another at Ravalli Street (seven blocks and three blocks north of RML, respectively." (DEIS 3-5)

62-158 *It is unclear if these signals are warranted due to existing conditions or to impacts from the proposed lab. If it is the latter, a financial analysis of the new signals must be included in the DEIS.*

62-159 With respect to emergency response agencies (DEIS 2-9) mentions that the Emergency Plan will be updated and emergency personnel will be notified of the types of biological materials being used in the lab. *The financial impact of these actions needs to be discussed in detail. Specifically, the answers to these questions need to be addressed in the DEIS:*

What equipment will emergency responders need to protect themselves in responding to an emergency?

What training will be required?

How will this be paid for and what will it cost to the taxpayers? Hospital staff needs to be mentioned in this section as well - What additional equipment, training or personnel will hospital staff need and what will that cost?

11.2.2 "Increased use and disposal of hazardous chemicals by the Integrated Research Facility."

There is one brief paragraph (DEIS 2-8) that states that hazardous chemicals will be handled according to federal regulations and then confusingly states that hazardous waste generation will continue to decline rather than increase. The historical trend may show a decline, but the preferred alternative will likely result in an increase from current levels. Despite a specific scoping request for detailed information on current and expected chemical use and waste disposal, the DEIS does not include any accounting for the types of hazardous chemicals to be used, how they will be disposed of, or how much increased use there will be with the new lab. As mentioned above, the Voluntary Cleanup Plan for RML released by Maxim Technologies in June 2003 includes an appendix titled: "Appendix F: Chemical Use and Chemical Waste Inventories." This information has been compiled by the very same consultants who wrote the DEIS. *It must be included in the next DEIS. In addition, a detailed accounting of the expected increase in chemical usage associated with the proposed BSL-4 lab must be included.* **62-160**

Comment	Response
62-158	The signals may be warranted due to the current traffic situation.
62-159	Please see Section 1.7.3 where comments on community infrastructure are addressed.
62-160	Appendix. F of the Voluntary Cleanup Plan was compiled by RML personnel from manifests of the shipment of hazardous wastes for the years 1986 - 2001. No volumes were given for those years. RML is classified as a "small quantity generator" of hazardous waste by the Montana Dept. of Environmental Quality. Volumes of hazardous chemical waste are not expected to increase if the Integrated Research Facility is built. Even though employee population is expected to increase 15% - 20%, the recent emphasis on minimizing hazardous waste and ordering only those quantities actually needed is expected to offset that increase. Implementation of the NIH environmental management system should reinforce current efforts.

11.2.3 "Potential increased threat of outbreak of agents through transport, internal sabotage, inadvertent releases, and outside terrorism."

Section 4.2.1 briefly addresses these key concerns with the statement:

> "Potential added risk to the community from the Proposed Action cannot be effectively quantified." (DEIS 4-2)

62-161 This is an inadequate response. *A full risk assessment of the potential increased threat from these four issues (i.e. outbreak of agents through transport, internal sabotage, inadvertent releases, and outside terrorism) must be clearly laid out in the DEIS. The mitigation plans for each of these potential threats must also be clearly laid out in the DEIS.*

11.2.4 "An emergency plan to be implemented should a laboratory worker be exposed to an agent or in the unlikely release of an agent to the neighborhood."

62-162 The emergency plan is a key mitigation tool to offset the significant impacts of the preferred alternative. Simply stating that an emergency plan will be prepared before use of the facility is not in the spirit of NEPA. Detailed information about the emergency plan is equally important in assessing the potential impact of the facility as the specifications for containment design that are spelled out in Chapter 2. It is unacceptable to have one but not the other. *The DEIS must include the full emergency plan.*

11.2.5 "Impacts on animals used for experiments."

62-163 The only references to animals in the DEIS are found in the appendices. An analysis of impacts to animals used for experiments is never discussed. *This analysis must be included in the DEIS.*

Additionally, the care, treatment and facilities used to contain animals at RML needs to be included in the DEIS. Include a discussion of the humane treatment of lab animals.

The risk of an animal infected escaping into the facility and the environment must be part of the DEIS discussion.

11.2.6 "Impacts on air quality associated with the increased use of the incinerator."

62-164 The air quality section (DEIS 4-13) does not discuss the before and after levels of emissions. It has one table listing "maximum permitted potential to emit" which represent the very high levels of emissions allowable in the permit. There is no accounting for the actual levels currently experienced now (no action alternative) versus the levels that would be experienced if the lab goes in (preferred alternative). *There needs to be an comparative analysis of the actual increase in air quality emissions associated with the expected increased use of the incinerator.*

Comment	Response
62-161	Please see Section 1.7.3 where comments on the increased threat were addressed.
62-162	Please see Section 1.7.2 where comments on the emergency plan were addressed.
62-163	Please see Section 1.7.1 where questions about animals used for experiments were addressed.
62-164	Please see Section 1.7.3 where comments on the effects of the increased use of the incinerator were addressed.

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11.2.7 "Discontinuing the incineration of plastics."

62-165 A word search of the DEIS finds that this phrase in Section 1.7.2 is the only place where the word "plastics" is used in the entire document. *Incinerating plastics - which is of considerable concern to the community - is never discussed in the DEIS and needs to be from a public health, workplace safety and environmental perspective.*

Comment	Response
62-165	In response to this comment, the effects of the incineration of plastics is addressed on page 3-16 of the SDEIS. The by-product concentration is 1/100th of the permitted limit and well below federal standards to protect human health.

Comments on the Supplemental Draft Environmental Impact Statement, Integrated Research Facility,RML, February 2004 Friends of the Bitterroot – Women's Voices for the Earth – Coalition for a Safe Lab

12. Failure to disclose adequate information about current available infrastructure.

62-166 Specific scoping comments were submitted asking the NIH to address the capabilities of the medical and emergency services in the area in detail. However, Section 3.2.5 (DEIS 3-4) only briefly discusses current infrastructure relating to community safety. This section needs to be expanded significantly. *A subsection on Hazmat capability needs to be added to this section. The health care section needs to be expanded to better describe the current capabilities (and lack thereof) of Marcus Daly hospital to handle infectious disease patients. This should include the number of physicians on staff currently board certified in infectious disease, the specialized equipment (isolation rooms etc.) available etc. In addition, a section on the same capabilities of St. Patrick hospital in Missoula must also be included in this section.* Simply stating that "a full range of specialty medical services are available in Missoula" is inadequate to address this important issue.

Comment	Response
62-166	Please see Section 1.7.1 where requests for additional information on the alternatives were addressed.

13. The NIH failed to prepare a Programmatic Environmental Impact Statement (PEIS) on increasing funding and thereby greatly expanding BSL-4 facilities.

The NEPA/CEQ regulations require that broad federal actions, such as proposing to double or triple the number of existing BSL-4 facilities in the U.S. be evaluated.

1502.3 - STATUTORY REQUIREMENTS FOR STATEMENTS.

"As required by sec. 102(2)(C) of NEPA environmental impact statements (1508.11) are to be included in every recommendation or report. On proposals (1508.23) For legislation and (1508.17). Other major Federal actions (1508.18). Significantly (1508.27). Affecting (1508.3, 1508.8). The quality of the human environment (1508.14)"

1502.4 - MAJOR FEDERAL ACTIONS REQUIRING THE PREPARATION OF ENVIRONMENTAL IMPACT STATEMENTS.

"(a) Agencies shall make sure the proposal which is the subject of an environmental impact statement is properly defined. Agencies shall use the criteria for scope (1508.25) to determine which proposal(s) shall be the subject of a particular statement. Proposals or parts of proposals which are related to each other closely enough to be, in effect, a single course of action shall be evaluated in a single impact statement. (b) Environmental impact statements may be prepared and are sometimes required, for broad Federal actions such as the adoption of new agency programs or regulations (1508.18). Agencies shall prepare statements on broad actions so that they are relevant to policy and are timed to coincide with meaningful points in agency planning and decisionmaking. (c) When preparing statements on broad actions (including proposals by more than one agency), agencies may find it useful to evaluate the proposal(s) in one of the following ways: (2) Generically, including actions which have relevant similarities, such as common timing, impacts, alternatives, methods of implementation, media, or subject matter. (3) By stage of technological development including federal or federally assisted research, development or demonstration programs for new technologies which, if applied, could significantly affect the quality of the human environment. Statements shall be prepared on such programs and shall be available before the program has reached a stage of investment or commitment to implementation likely to determine subsequent development or restrict later alternatives. (d) Agencies shall as appropriate employ scoping (1501.7), tiering (1502.20), and other methods listed in 1500.4 and 1500.5 to relate broad and narrow actions and to avoid duplication and delay."

1502.5 TIMING.

"An agency shall commence preparation of an environmental impact statement as close as possible to the time the agency is developing or is presented with a proposal (1508.23) so that preparation can be completed in time for the final statement to be included in any recommendation or report on the proposal. The statement shall be prepared early enough so that it can serve practically as an important contribution to the decisionmaking process and will not be used to rationalize or justify decisions already made (1500.2(c), 1501.2, and 1502.2). For instance: (a) For projects directly undertaken by Federal agencies the environmental impact statement shall be prepared at the feasibility analysis (go - no go) stage and may be supplemented at a later stage if necessary. (b) .... (c) .... (d) ...."

Greatly expanding the number of BSL-4 facilities in this country raises the possibilities for, and risk of unintentional releases. It is very unclear (perhaps intentionally) exactly how many new BSL-4 facilities are being planned, proposed or built. It appears that at a minimum, the number of those labs will double and will be placed across the U.S.

Rather then applying the NEPA process early, and taking a hard look at the potential for catastrophic adverse impacts stemming from the decision to fund and build many more BSL-4 facilities, NIH apparently instead chose first to build and fund the facilities and then do impact analyses on the individual labs.

The DEIS described the agents that will be studied in the proposed BSL-4 facility in Hamilton as: "Dangerous/exotic agents which pose high risk of life-threatening disease, aerosol-transmitted lab infections; or related agents with unknown risk of transmission." (DEIS 1-5) The above statement would likely apply to each of the BSL-4 labs under consideration or construction across the nation.

The DEIS also brushed off, or otherwise dismissed out-of-hand any potentials for release of life-threatening diseases or organisms or the risks thereof. Since NIH has taken that arbitrary and capricious position (little or no risk, and no analysis) in a DEIS, it is highly likely that they will take that unreasonable "position" regarding funding and construction of BSL-4 facilities elsewhere in the country.

62-167 The anthrax released in the 2001 attacks apparently came from a United States facility. It would appear necessary to consider in an overall context, the increased potential for similar occurrences, and other potential for unintended releases, because of NIH's early programmatic decisions and increased funding to greatly expand those numbers of facilities.

It appears that by their failure to apply NEPA early in the planning process, NIH has failed to comply with 40 CFR 1502.3, 1502.4, and 1502.5, et seq.

Comment	Response
62-167	Please see Section 1.7.4 where comments regarding a programmatic EIS were addressed.

14. RML will be prohibited by law from telling the public what BSL-4 agents are under study, and informing the public about any release of BSL-4 agents into the community.

Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, federal officials are specifically prohibited from disclosing information regarding what biological agents and toxins are being used in a BSL-4 lab or transported to the lab.

Federal law also prohibits the disclosure of any notification of a release, theft, or loss of a listed biological agent or toxin. Any person violating the law prohibiting public disclosure of the use of these biological agents and pathogens may be subject to a civil penalty up to $500,000. If there is a release of biological agents and toxins from the biocontainment area, federal law gives the Secretary of Health and Human Services the sole discretion to determine if the release poses a threat to our community's public health or safety. Only upon such a determination by the Secretary, may the relevant state and local public health authorities and the public be notified. In the event of a public health emergency resulting from release from the BSL-4 lab, public health authorities and the public will not be notified until the Secretary is satisfied that such an emergency exists. If the Secretary determines the release or theft does not pose a threat, federal law ensures that the public will never know about the release or theft.

62-168

The DEIS should analyze and disclose the additional risk of delays in emergency response, inability of both the public and local responders to have the information needed to respond to a release or epidemic caused by a release of an infectious disease or agent.

The DEIS should disclose and analyze the social impacts to nearby residents of knowing that they could be at risk of exposure to an infectious disease or agent and not be told under the law.

The DEIS should disclose and analyze the affect that this law will have in creating a hesitance for new residents to live near a lab and for mobile populations to move away.

We lose local control to protect our community, our families and our children.

Comment	Response
62-168	Please see response to comment 47-6.

Appendix A – Announcements and Reports Showing that Officials from NIH Stating the Plans to Build a BSL-4 Laboratory at RML as a Forgone Fact.

1) Q&A From NIH Website Regarding RML Expansion.

January 29, 2002: "For that research to be carried out safely for both the scientists and the community, a new 'biocontainment' facility will be constructed on the RML campus."

April 16, 2003: "For that research to be carried out safely for both the scientists and the community, NIH plans to construct an additional research facility on the RML campus."

January 29, 2002: "When will it be completed? Preliminary planning for the facility will begin immediately. The design should be finished within one year and construction may take up to two years. A stringent certification process will be required prior to its use with agents at the BSL-4 level."

April 16, 2003: "When will construction of the building be completed? Preliminary planning for the facility has been completed; the project is now in design development. An Environmental Impact Statement (EIS) is being prepared to address possible environmental impacts of the project. No construction can begin until the EIS process is completed. The design should be finished within one year; construction may take up to two years. BSL-4 laboratories also must undergo a stringent certification process before they can be used."

2) Ravalli Republic, "Lab to play expanded role fighting bioterrorism," February 11, 2002.

"Officials at the National Institute of Allergy and Infectious Diseases recently announced that a new research lab will be built at the Hamilton campus to help develop new diagnostics, vaccines and treatments for diseases caused by the intentional release of pathogens into human populations. In order to protect the safety of scientists and the community, [Deputy Director of the Division of Intramural Research Karyl] Barron said, a biocontainment facility will be constructed with the highest possible safety standards - known as biosafety level 4."

3) NIH Record, "New Facilities To Bolster Anti-Bioterror Effort," April 2, 2002.

"But we need some new facilities to make our program really fly," Kindt added. He said a new BSL 3/4 facility at RML has been funded, and described a new campus building dedicated to counter-bioterrorism and emerging disease research - Bldg. B,

which will include BSL-3 labs. "Bldg. B will feature 175,000 gross square feet of space, including six floors and a ground-floor vivarium. We're in the conceptual design phase now. Groundbreaking for the new lab building is expected in mid to late 2003, with completion anticipated in 2005."

4) Missoulian, "Montana lab poised to lead in bioterrorism defense," April 8, 2002.

"The new lab was planned before Sept. 11 and the string of anthrax attacks that followed, administrator Pat Stewart said. Rocky Mountain already was studying organisms that could be used in biological attacks, and Stewart said existing expertise at the Rocky Mountain complex is the main reason for building the new lab there."

5) Ravalli Republic, "Leading the charge - High-level addition will propel Rocky Mountain Labs to forefront of battle on terror," April 10, 2002.

"[Dr. Thomas] Kindt told the group gathered in the Hamilton Middle School auditorium at noon that one of the finest labs of its kind will open at Rocky Mountain Laboratories this month allowing research to begin that has been backed up for years. And in another couple of years an even more secure, high-tech lab will open at the Hamilton campus."

"In order to carry out our agenda, we need a biosafety level 4 lab at Rocky Mountain Labs," he said. "We will prepare ourselves with a number of facilities."

6) Homeland Security: The Federal and Regional Response Field Hearing before the Subcommittee on Environment, Technology, and Standards Committee on Science, House of Representatives, One Hundred Seventh Congress Second Session, June 10, 2002.

http://commdocs.house.gov/committees/science/hsy80094.000/hsy80094_0.HTM

Mr. BARTLETT. "Thank you very much. I wonder if you could spend just a moment letting the audience know how unique a Level 4 containment facility is and how few of them there are in the world?"

Dr. FAUCI. "Yes. A Level 4 facility is the highest level facility for a microbe. There are very of the in this country. There is one if Fort Dietrich, there is one at the CDC in Atlanta, there is one operational in Texas and one planned in Texas. We are planning two additional ones right now, and those are the two I mentioned. The one that we are going to be partnering with the Department of Defense up at Fort Dietrich to make that a much more enhanced biodefense arena, and one that we are going to be putting in Rocky Mountain Laboratory, which is an NIH facility in Hamilton, Montana."

7) National Advisory Allergy and Infectious Diseases Council, Meeting Minutes, September 23, 2002.

"III. ANNUAL UPDATE OF DIVISION OF INTRAMURAL RESEARCH ACTIVITIES - Thomas J. Kindt, Ph.D., Director, DIR, NIH

Dr. Kindt described facilities and staff increases in the Division of Intramural Research (DIR). The DIR staff now consists of 1,200 people, including 92 tenured scientists and 27 on tenure track. Two new facilities, Building B on campus and Twinbrook 3 in Rockville, will be constructed soon, and there will be expansions at the Rocky Mountain laboratory."

8) NIH Record, Biodefense Effort Firms Up in Post-Attack Year, October 1, 2002.

"Fauci touched briefly on a raft of research highlights: NIH, the CDC and the Department of Defense are working on a better anthrax vaccine, one that will employ a recombinant protective antigen; following "very impressive" animal trials, a phase I trial in humans of a new Ebola virus vaccine is expected in coming months, largely a tribute to the "spectacular job" done by Dr. Gary Nabel at NIH's Vaccine Research Center (a combination vaccine is also planned to combat not just Ebola but also Lassa and Marburg viruses, which also cause viral hemorrhagic fever); four new Biosafety Level 3 or higher laboratories are in the works (a BSL-3/4 lab and animal facility at Rocky Mountain Laboratories, a BSL-3/4 clinical facility at Ft. Detrick, a BSL-3 lab and vivarium in NIH's new Bldg. B and a BSL-3 lab at the Twinbrook facility in Rockville)."

9) Missoulian, "Hot Zone," September 15, 2002.

"The lab submitted requests to build a BL-4 several years ago, but nothing happened until the terrorist attacks, said Pat Stewart, the lab's chief administrator."

"Karl Johnson, the virologist who built the first BL-4 in 1978 in Atlanta and gained fame as the researcher who identified Ebola, said Hamilton and the Bitterroot Valley have nothing to worry about. BL-4 labs are safe, necessary and will allow even better research to go on in Montana. Johnson is on a committee reviewing the design plans for Rocky Mountain Labs' proposed BL-4."

Appendix B – Sample of Instances Of Serious Infections Caused by Accidental Exposure In BSL-2 to 4 Laboratories in the United States.

" BACTERIAL AGENTS - Part 1

Bacillus anthracis Bordetella pertussis Brucella Campylobacter

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"AGENT: Bacillus anthracis

Forty (40) ***cases of laboratory-associated anthrax***, [Emphasis Added] occurring primarily at facilities conducting anthrax research, have been reported (66, 151). No laboratory-associated cases of anthrax have been reported in the United States since the late 1950's when human anthrax vaccine was introduced.

Naturally and experimentally infected animals pose a potential risk to laboratory and animal care personnel.

LABORATORY HAZARDS: The agent may be present in blood, skin lesion exudates, cerebrospinal fluid, pleural fluid, sputum, and rarely, in urine and feces. Direct and indirect contact of the intact and broken skin with cultures and contaminated laboratory surfaces, accidental parenteral inoculation, and rarely, exposure to infectious aerosols are the primary hazards to laboratory personnel.

RECOMMENDED PRECAUTIONS: Biosafety Level 2 practices, containment equipment and facilities are recommended for activities using clinical materials and diagnostic quantities of infectious cultures. Animal Biosafety Level 2 practices, containment equipment and facilities are recommended for studies utilizing experimentally infected laboratory rodents. A licensed vaccine is available through the Centers for Disease Control and Prevention; however, immunization of laboratory personnel is not recommended unless frequent work with clinical specimens or diagnostic cultures is anticipated (e.g., animal disease diagnostic laboratory). Biosafety Level 3 practices, containment equipment and facilities are recommended for work involving production volumes or concentrations of cultures, and for activities which have a high potential for aerosol production. In these facilities immunization is recommended for all persons working with the agent, all persons working in the same laboratory room where the cultures are handled, and persons working with infected animals.

"AGENT: Bordetella pertussis

Bordetella pertussis, a human respiratory pathogen of worldwide distribution, is the causative agent of whooping cough. The disease is typically a childhood illness; however, the agent has been associated, with increased frequency, in adult illness (106, 112, 130). Several outbreaks in health-care workers have been reported in the literature (106, 112). Adolescents and adults with atypical or undiagnosed disease can serve as reservoirs of infection and transmit the organism to infants and children (135). ***Eight cases of infection with B. pertussis in adults have been documented at a large research institution. The individuals involved did not work directly with the organism, but had access to common laboratory spaces where the organism was manipulated. One case of secondary transmission to a family member was documented (122). A similar incident occurred at a large midwestern university resulting in two documented cases of laboratory-acquired infection and one documented case of secondary transmission (146). Other laboratory-acquired infections with B. pertussis have been reported, as well as adult-to-adult transmission in the workplace (19, 35). Laboratory-acquired infections resulting from the manipulation of clinical specimens or isolates have not been reported. The attack rate of this airborne infection is influenced by intimacy and frequency of exposure of susceptible individuals.*** [Emphasis Added]

LABORATORY HAZARDS: The agent may be present in respiratory secretions, but is not found in blood or tissues. Since the natural mode of transmission is by the respiratory route, the greatest potential hazard is aerosol generation during the manipulation of cultures or concentrated suspensions of the organism.

RECOMMENDED PRECAUTIONS: Biosafety Level 2 practices, containment equipment, and facilities are recommended for all activities involving the use or manipulation of known or potentially infectious clinical materials or cultures. Animal Biosafety Level 2 should be used for the housing of infected animals. Primary containment devices and equipment (e.g., biological safety cabinets, centrifuge safety cups, or specially designed safety centrifuges) should be used for activities likely to generate potentially infectious aerosols. Biosafety Level 3 practices, procedures, and facilities are appropriate when engaged in large scale production operations. The current pertussis vaccine may not provide complete and permanent immunity; however, a booster dose of pertussis vaccine is not recommended for use in persons who have passed their seventh birthday (50).

"AGENT: Brucella (B. abortus, B. canis, B. melitensis, B. suis)

B. abortus, B. canis, B. melitensis, and B. suis have all caused illness in laboratory personnel (129, 151, 176). Brucellosis is the most commonly reported laboratory-associated bacterial infection (127, 143, 151). Hypersensitivity to Brucella antigens is also a hazard to laboratory personnel. Occasional cases have been attributed to exposure to experimentally and naturally infected animals or their tissues.

LABORATORY HAZARDS: The agent may be present in blood, cerebrospinal fluid, semen, and occasionally urine. ***Most laboratory-associated cases have occurred in research facilities and have involved exposure to Brucella organisms being grown in large quantities. Cases have also occurred in a clinical laboratory setting: direct skin contact with cultures or with infectious clinical specimens from animals (e.g., blood, uterine discharges) are commonly implicated in these cases. Aerosols generated during laboratory procedures have caused large outbreaks (95). Mouth pipetting, accidental parenteral inoculations, and sprays into eyes, nose and mouth have also resulted in infection.*** [Emphasis Added]

RECOMMENDED PRECAUTIONS: Biosafety Level 2 practices are recommended for activities with clinical specimens of human or animal origin containing or potentially containing pathogenic Brucella spp. Biosafety Level 3 and Animal Biosafety Level 3 practices, containment equipment and facilities are recommended, respectively, for all manipulations of cultures of the pathogenic Brucella spp. listed in this summary, and for experimental animal studies. Vaccines are not available for use in humans.

"AGENT: Campylobacter (C. jejuni/C. coli, C. fetus subsp. fetus)

C. jejuni/C. coli gastroenteritis is rarely a cause of laboratory associated illness. ***Three laboratory-acquired cases have been documented (138, 149, 155).*** [Emphasis Added] Numerous domestic and wild animals, including poultry, pets, farm animals, laboratory animals, and wild birds are known reservoirs and are a potential source of infection for laboratory and animal care personnel. Experimentally infected animals are also a potential source of infection (155).

"LABORATORY HAZARDS: Pathogenic campylobacters may occur in fecal specimens in large numbers. C. fetus subsp. fetus may also be present in blood, exudates from abscesses, tissues, and sputa. Ingestion or parenteral inoculation of C. jejuni constitute the primary laboratory hazards. ***The oral ingestion of 500 organisms caused infection in one individual (163).*** [Emphasis Added] The importance of aerosol exposure is not known.

RECOMMENDED PRECAUTIONS: Biosafety level 2 practices, containment equipment and facilities are recommended for activities with cultures or potentially infectious clinical materials. Animal Biosafety Level 2 practices, containment equipment and facilities are recommended for activities with naturally or experimentally infected animals. Vaccines are not available for use in humans.

Comments on the Supplemental Draft Environmental Impact Statement, Integrated Research Facility,RML, February 2004 Friends of the Bitterroot – Women's Voices for the Earth – Coalition for a Safe Lab

Appendix C – Presentation by Friends of the Bitterroot and Coalition for a Safe Lab at Town Meeting and RML Citizen's Liaison Group

Nottingham, Valerie (NIH/OD/ORF)

From: animals@bitterroot.net
Sent: Wednesday, February 11, 2004 4:45 PM
To: ORS RMLEIS (NIH/OD/ORS)
Subject: Supplemental Draft Environmental Impact Statement comments for proposed upgrade at Rocky Mountain Labs

Importance: High

Subject: Supplemental Draft Environmental Impact Statement comments for proposed upgrade at Rocky Mountain Labs

To:
Valerie Nottingham
orsrmleis-r@mail.nih.gov
National Institutes of Health
9000 Rockville Pike
Bldg. 13, Room 2W64
Bethesda, MD 20892-5746

From:
Mary& Greg Tilford
PO BOX 1645
Hamilton MT 59840

63-1 We, and the Bitterroot valley citizens whom we represent and inform, have been illegally denied important documents and information that are crucial to meaningful participation in the NEPA process for the proposed BSL-4 expansion at Rocky Mountain Laboratories (pursuant to 40 C.F.R. 1506.6 and 1507.1). The NIH is currently in violation of Freedom of Information Regulation 5.35(b)(2) for not responding to Friends of the Bitterroot's FOIA appeal, received by the FOIA appeals office November 10th, 2003, by the required deadline. The NIH has also violated 5 U.S.C. 552(a)(6)(A)(iii) and 45 C.F.R. 5.45(a)(1)(2) for not granting a fee waiver request, as required by law. The NIH has been in possession of this FOIA request for 6 months and has failed to act. We view these actions as deliberate stonewalling of our groups and the large number of citizens that we represent, while NIH hurriedly moves forward with the scoping process on the proposal. For this reason, we require that the deadline for comments on the SDEIS be extended until 45 days after we receive the documents in our FOIA request, to which we are legally entitled.

LETTER 63 - MARY AND GREG TILFORD

Comment	Response
63-1	Please see response to comment 47-3.

Subject: Supplemental Draft Environmental Impact Statement comments for proposed upgrade at Rocky Mountain Labs

To:
Valerie Nottingham
National Institutes of Health
9000 Rockville Pike
Bldg. 13, Room 2W64
Bethesda, MD 20892-5746

From:
Mary& Greg Tilford
PO BOX 1645
Hamilton MT 59840

63-2 The citizens of the Bitterroot Valley have been illegally denied information that will allow them/us to fully and meaningfully participate in the National Environmental Policy Act process, and so I **request an extension of the deadline for comments until such time that we receive the documents that we are entitled to by law.**

The **NIH is illegally withholding that information and other important documents relating to the proposal.**
In our Freedom Of Information Act request we asked for all documents and correspondence relating to the NIH memo that states **"The RML campus is located in rural western Montana, well removed from major population centers. The location of the laboratory reduces the possibility that an accidental release of a biosafety level-4 organism would lead to a major public health disaster."**

63-3 The SDEIS says that "four additional alternatives were considered, but eliminated from detailed study." It appears that the 'alternatives' were not seriously considered and eliminated without serious or detailed study. Alternatives need to be seriously studied and considered.

Comment	Response
63-2	Please see response to comment 47-3.
63-3	Alternatives for construction of the Integrated Research Facility elsewhere were considered in the DEIS and SDEIS, but were not studied in detail for the reasons stated in Chapter 2 of those documents.

Subject: Draft Environmental Impact Statement comments for proposed upgrade at Rocky Mountain Labs (cont'd)

63-4 PAGE S-2: SDEIS states that RML does not and will not conduct research to develop 'offensive' biological weapons. See the definition of weaponized below. RML also says they will be testing aerosolized anthrax on non-human primates. Would these types of tests need aerosolized anthrax? And would aerosolized anthrax be considered a weapon? Explain/describe how aerosolized anthrax would not be considered "weaponized".
http://www.newsmax.com/archives/articles/2001/10/21/140757.shtml
"Weaponized" simply means that a biological agent is processed so that it can be easily delivered to harm or kill humans.

http://www.pbs.org/wgbh/nova/bioterror/ask_011121.html
Ask the Expert Responses from Dr. Jonathan Tucker
Posted November 21, 2001
Q: What exactly does it mean to "weaponize" a biological agent. How do weaponized and nonweaponized anthrax differ?
A: "Weaponization" refers to a variety of activities aimed at rendering a biological pathogen more virulent, enhancing its stability and shelf-life, and processing it so that it can be more readily delivered as a fine-particle aerosol capable of infecting the targeted population through the air. Non-weaponized anthrax would be in the vegetative (non-spore) form, which would die off rapidly after dispersal. Weaponized anthrax would be in the spore form and probably dried and milled to a fine powder, with chemicals added to reduce clumping and to enhance aerosolization…"

63-5 PAGE S-4. SDEIS says 'theoretically, human error or multiple, simultaneous mechanical failures could lead to accidental release of biological materials from a biosafety laboratory. the overall safety record of biomedical and microbiological laboratories also indicates that there is **not** a risk of accidental release." Then in the next column, under the no action alternative, it says that there is "not a **significant** risk of accidental release".
Is there, or is there not a risk? Is the risk 'negligible'? Is the risk "negligible" or is it "not significant"?

63-6 The risk scenarios do not address the possibility if something **does** get out of the lab. the scenarios all have the same positive outcome. SDEIS needs to outline some scenarios with pathogens that are transmissable from human to human, or animal to human, and then mitigate the risks.

Comment	Response
63-4	In accordance with the 1975 Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction (ratified by the U.S.), NIH will not produce weaponized (per definition of Dr. Jonathan Tucker) anthrax or any other agent.
63-5	For the risk assessment, "negligible" and "not significant" can be interpreted to mean the same thing.
63-6	Please see response to comment 11-8.

Subject: Draft Environmental Impact Statement comments for proposed upgrade at Rocky Mountain Labs (cont'd)

PAGE 1-1. anthrax attacks: anthrax was from a lab in the United States. Shown to be the Ames strain from the lab in Iowa. If someone can walk out of a lab with a pathogen then the community would be at risk.

63-7 PAGE 1-13. "No construction on the IRF has occurred." however, the contractor has purchased several lots of land north of Rocky Mountain Labs. why? Was this addressed anywhere else in the SDEIS?

63-8 PAGE 2-6. SDEIS says that the alkaline hydrolysis would inactivate prions. is this system in the budget for the proposed upgrade? or would it be added later? or added at all?

63-9 PAGE 2-7. "HEPA filters would be changed every five years". is this adequate? how often would they be inspected/checked to assure they are functioning correctly?

63-10 PAGE 2-12. "Generation of low-level radioactive waste is anticipated to increase about 30 percent with construction of the Integrated Research Facility…Use of sulfur 35 is likely to increase…" Sulfur 35 emits a weak beta particle and its half-life is 87.4 days. Analysis of the health risks (for Hamilton citizens and those that consume water and live in or near Hamilton area) of low-level radiation into the Hamilton City Sewer system should be included. Health effects of low-level radiation on fish and wildlife should be included.

63-11 PAGE 2-16. Analysis of safety for transport and disposal of all long half-life radioactive waste, in and out of Hamilton, along the route transported, as well as at the disposal site.

63-12 PAGE 2-17. Emergency plan. "A memorandum of understanding is planned with local emergency services and hospitals, outlining RML's expectations in regard to the transportation, acceptance, admittance, and short, and long-term care of patients under various injury scenarios, including patients believed to be exposed to agents." The emergency plan is not included in the SDEIS and should be made available to the public for review before the Final EIS is released.

Comment	Response
63-7	Please see response to comment 62-46.
63-8	The digester is part of the Proposed Action and is therefore covered in the cost of the Proposed Action.
63-9	Please see response to comments 62-23 and 62-98.
63-10	Please see response to comment 62-58.
63-11	Please see response to comment 62-25.
63-12	Please see response to comment 63-12.

Subject: Draft Environmental Impact Statement comments for proposed upgrade at Rocky Mountain Labs (cont'd)

63-13 PAGE 2-17 Range of alternative locations were dismissed and not seriously studied or considered. A full analysis and serious consideration of the range of alternatives should be included.

63-14 PAGE 2-18. How did the persons preparing the SDEIS approximate the figures of building the proposed facility at a different location? A full and documented analysis should be included of the cost of the facility being built in a different location.

63-15 PAGE 3-4. "Marcus Daly [hospital] could not handle more than 10 emergency patients at a time (Bartos 2003." This citation does not appear in the 'literature cited' section of the SDEIS on page L-1. Included in the Final EIS should be the citation and memo, personal communication or study that was done by Mr. Bartos.

63-16 PAGE 3-19. "Sludge is then composted during warm-weather months. The compost is made available for land application but is not allowed for use on vegetable gardens". Include analysis of health risks to animals that may graze on the land where sewage sludge is applied. Health problems in animals that graze on the land could devastate the cattle, farm, ranching industry in Montana and thus have an adverse effect on the economy. Include a study or analysis of the possibility of transmissible spongiform encephalopathies being transmitted to grazing animals in this manner.

63-17 PAGE 4-1. With regard to animal deliveries. How are the animals caged, transported and then handled before and after arrival for delivery at Rocky Mountain Labs? Who accepts delivery of such animals? How are the animals handled and transported to holding facilities after arriving at RML?

63-18 PAGE 4-6. Manipulation by man can make diseases more virulent. Will RML be "manipulating" diseases to make the more virulent? Please include details explaining this process and under what circumstances it may occur at RML.

Comment	Response
63-13	Please see Section 1.7.1 where comments on the range of alternatives were addressed.
63-14	This information has been included in the FEIS. See Section 2.2.2.
63-15	Please see response to comment 62-14.
63-16	Please see response to comment 62-26.
63-17	Please see response to comment 62-27.
63-18	Please see response to comment 62-28.

63-19 PAGE 4-7. Citations, "Auch 2003, Hoffman 2003 and Neff 2003", do not appear in the Literature Cited section on page L-1. Include the letters, memos, emails, personal communication in the Final DEIS.
Subject: Draft Environmental Impact Statement comments for proposed upgrade at Rocky Mountain Labs (cont'd)

PAGE 4-11 through 4-14.
Risk to the community must be seriously considered and mitigation alternatives must be analyzed. The SDEIS claims that the potential risk of a release of infectious agents from the proposed lab is "negligible". *Any risk*, no matter how small, of an epidemic of an incurable fatal disease in our community should not be dismissed as "negligible". The potential consequences are much too great to be considered "negligible". Even if the risk is very small - if it cannot be eliminated the NIH must show how it will be mitigated. This means the EIS must clearly illustrate the plan for how a "worst case scenario" will be handled.

63-20

PAGE 4-11 through 4-14. Scenarios should be included where a pathogen DOES get out of the lab, for any reason, whether by accident or covert design, and then show how the situations would be mitigated. These would be considered "worst-case scenarios", possibly including scenarios where the outcome is not so positive.

63-21

PAGE D-2. The review of work done included only intramural laboratories. The review of accidents, exposures and deaths should include all laboratories in the United States. This should include the incidence in Taiwan where a "senior researcher" was working with SARS in a BL4, was exposed, and subsequently infected, and then traveled out of his lab and possibly exposed other people outside of the lab, who later on came into the United States. If it happened there, it can happen here as well. This type of scenario should be included in the risk assessment and then the possible outcome mitigated.

63-22

PAGE D-4 and D-11. The last sentence says "This report is included in the Final Environmental Impact Statement of the Integrated Research Facility." It appears that this report was written and released prior to the release of the Supplemental Draft Environmental Impact Statement and shows predetermination of the proposed project at RML. It was decided long ago that this project would be built in Hamilton.

63-23

Comment	Response
63-19	Please see response to comment 62-14.
63-20	Please see response to comment 11-8.
63-21	Please see response to comment 11-8.
63-22	Incidents in other US and international labs do not bear on the results of NIH laboratories as NIH has no control over operating procedures of other laboratories. The NIH would be responsible for the safety in the Integrated Research Facility and would maintain its high standards. These standards have resulted in the outstanding safety record cited in Appendix E.
63-23	Please see response to comment 62-32.

Subject: Draft Environmental Impact Statement comments for proposed upgrade at Rocky Mountain Labs (cont'd)

63-24 Recommended alternatives for the mitigation of increased air pollution from the incinerator have not been analyzed.

The SEIS indicates that the use of the incinerator will increase by 50-100% if the BL-4 lab is built. This means that the toxic air emissions from the incinerator will increase by 50-100%. The NIH is mandated by its own policies to consider reasonable pollution prevention alternatives in the proposed action of an EIS. We recommended several pollution prevention alternatives to help avoid this increase in emissions from the incinerator, including substituting non-incineration alternatives. These suggestions were ignored.

Section 4-2 of the SEIS makes the claim that

"*High temperature incineration continues to be the method of choice for medical and veterinary wastes as it has been demonstrated to be effective at inactivating all types of pathogens.*"

This claim is simply no longer true in the United States. Hundreds (if not thousands) of medical waste incinerators all over the country have shut down in the last few years alone due to the availability of cleaner, cost-effective, non-incineration technologies for handling medical waste. As a matter of fact no medical facility in the entire state of Montana other than Rocky Mountain Labs relies on incineration to dispose of its medical waste.

The SEIS makes very clear that any BL-4 lab waste will be completely decontaminated before it is removed from the BL-4 lab - therefore (despite the implications made in the SEIS) the incinerator is not needed for the purpose of inactivating pathogens from this lab. It is simply being used as a cheap way to dispose of waste -at the expense of the air quality and health of the people of Hamilton. The NIH is proposing a 50-100% increase in toxic air emissions to the community to save a little money at Rocky Mountain Laboratories. Clearly there is an opportunity here to prevent this air pollution, as mandated by NIH policies - a non-incineration alternative must be analyzed in this EIS. 63-25

Comment	Response
63-24	The RML air quality permit mandates require that the incinerator operate within narrow constraints of operational parameters. Annual Air Emissions Testing results indicate that with the efficient scrubbing system of the Consumat 325, incinerator effluents are far below EPA requirements.
63-25	Non-incinerator alternatives do not provide the redundancy of pathogen inactivation that is provided by incineration.

Subject: Draft Environmental Impact Statement comments for proposed upgrade at Rocky Mountain Labs (cont'd)

SDEIS Chapter 3, Affected environment, population trend, Housing, education, Law Enforcement, Fire protection, income.

Population increase in Ravalli County is predicted:
(Helena-AP February, 2004) -- A new population study says Ravalli County will be Montana's magnet for growth during the first quarter of this century. That's more than twice the statewide rate, and would give the county just over 60-thousand residents. Among the ten fastest-growing counties, eight are in the western half of the state.
The projections come from N-P-A Data Services in Washington, D-C.
Jim Sylvester, an economist at the Montana Bureau of Business and Economic Research, said Friday that big losses or gains affect school enrollment, taxes, real estate values and political power.
Rising populations mean higher property prices and that results in higher taxes that some longtime residents cannot afford, he said. Some schools will find they don't have enough room for all the students; others will not have enough pupils to stay open, he added.
Ravalli County is no stranger to boomtown growth. It led the state in 1990s with more than a 40 percent increase in population.
Commissioner Alan Thompson said it's difficult for services to keep up with the rising demand from more and more people.
"It impacts the infrastructure, our ability to provide services, the school system and causes us to play catch-up constantly because your tax base is not there," he said.
While differing views on the county's growth abound, he said the increasing population is changing the rural nature of the area. "I'm not real crazy about a lot of people moving into the valley," Thompson said.
Patrick O'Herren, Ravalli County planning director, has seen the area's growth up close and believes the trend will continue.
"We see more subdivisions coming in on a weekly basis than I would have imagined a year ago," he said. "Developers cannot find enough available lots to meet the demand they have for new houses. There's a desire to protect what is valuable in Ravalli County, while still accommodating people who want to come here and enjoy it," he said.

Subject: Draft Environmental Impact Statement comments for proposed upgrade at Rocky Mountain Labs (cont'd)

It is clear that there will be added burdens on the taxpayers, added burden to the infrastructure of Hamilton and surrounding areas, added burden/impacts on the environment if the proposed Level 4 lab is built.
Hamilton is an inappropriate location for such a facility.

We would also like to request a **new** Supplemental Draft Environmental Impact Statement be provided, since the questions, concerns, and comments in the first Supplemental are inadequately addressed.

Sincerely,
Mary& Greg Tilford
PO BOX 1645
Hamilton MT 59840

Nottingham, Valerie (NIH/OD/ORF)

From: animals@bitterroot.net
Sent: Wednesday, February 11, 2004 8:56 PM
To: ORS RMLEIS (NIH/OD/ORS)
Subject: Supplemental Comments on SDEIS for RML

Importance: High

Ms. Nottingham,
It has come to my attention on the eve of the comment period deadline,
that quite a few animals died at Rocky Mountain Labs this last weekend,
as a result of a failed computer system.
This is just another reason that the proposed Level 4 lab should not be
built at Rocky Mountain Labs.
I would appreciate this whole scenario being included in the NEXT
Supplemental Draft EIS.

63-26 Thankyou

Mary Tilford
PO BOX 1645
Hamilton MT 59840

Comment	Response
63-26	Please see response to comment 39-21.

Nottingham, Valerie (NIH/OD/ORF)

From: carolyn mast [mastcl@yahoo.com]
Sent: Wednesday, February 11, 2004 5:56 PM
To: ORS RMLEIS (NIH/OD/ORS)
Subject: comments on the RML 2nd draft EIS

Valerie Nottingham
9000 Rockville Pike
Bethesda, MD 20982

Dear Valerie,

My main concern about the first draft EIS is that a great majority of the comments submitted have never been addressed by the NIH. As a citizen of the Bitterroot Valley, I feel that I have been illegally denied information that will allow me to fully and meaningfully participate in the NEPA process. The information I am talking about is the NIH's response to the comments from the Bitterroot Valley community. Because a great majority of the comments have not been addressed, I do not feel confident or secure that the RML is doing what they legally need to be doing which is to present all the applicable information regarding the level 4 extension. There is a large lack of information regarding environmental and community safety. Since these comments have not been addressed, I feel very uneasy and I request an extension of the deadline for comments until we citizens get the responses to the first set of comments which is entitled to us by law. **64-1**

A number of comments submitted on the first draft requested a medical facility with a doctor who specializes in infectious diseases be located on the RML campus. If this medical facility with its isolation room were located on the RML campus, it would help put the community at ease. Another thing that would put the community at ease would be to have a dedicated helicopter at RML for the sole purpose of transporting an infected worker directly to Bethesda, MD for treatment. Transporting an infected person to Missoula is a ridiculous idea. The ambulance workers are not experts in dealing with these diseases, not to mention any other person who comes into contact with the ambulance. There may be one doctor in Missoula who could be of assistance if an infected person ended up in Missoula, but the vast majority of all the other hospital staff are not trained in treatment of these types of infectious diseases. Basically, too many other people could get infected along the way. This, is one of the largest concerns of the citizens of the Bitterroot Valley. If the NIH made these concessions, the community would feel safer. The community would also feel better about RML, thinking that they care about the concerns of the community in which they live. Not addressing this huge concern is a slap in the community's face. I feel that this issue is the single most important issue of the Bitterroot community, and if the NIH made these concessions, the community would feel better about RML and about building the level 4 lab. **64-2**

By the NIH not addressing this concern or any of the

LETTER 64 - CAROLYN MAST

Comment	Response
64-1	Please see response to comment 47-3.
64-2	Please see response to comment 11-9.

other concerns of the community, it is hard for me at this point to spend much time making other comments on the second draft EIS. If I look back at all the time put into the first sets of comments on the first draft EIS, I cannot help but think that my comments might not get addressed. The Bitterroot community would love to feel good about RML and the level 4 extension. But, since the NIH has not addressed the community's concerns with responses to comments, or with some concessions, the community is not feeling too good about RML.

Sincerely,

Carolyn Mast

Do you Yahoo!?
Yahoo! Finance: Get your refund fast by filing online.
http://taxes.yahoo.com/filing.html

Nottingham, Valerie (NIH/OD/ORF)

From: Bob Scott [discovry@MONTANA.COM]
Sent: Wednesday, February 11, 2004 7:17 PM
To: ORS RMLEIS (NIH/OD/ORS)
Subject: RML Biosafety Lab 4 DEIS comment

Valerie Nottingham
National Institutes of Health
9000 Rockville Pike
Bldg. 13, Room 2W64
Bethesda, MD 20892

Please include the following comments in the permanent record for this proposal.

I am a long time resident of Hamilton, and have resided at the same address on the north side of Hamilton for the last 18 years. I grew up in Hamilton within one block of the Rocky Mountain Laboratory. Although I have never worried about the activities at RML (my mother worked at RML for many years in the 1950's and 1960's), I have recently become quite concerned about the proposed new activities and the scale of the activities proposed in the recently released DEIS. I seems to me that the current proposal could have severe negative impacts for our community.

The fact that this proposal seems to have grown out of the newly created "War on Terror," suggests that the RML may be taking on a wholly new character and one that could seriously and detrimentally affect our lives and the local environment in a way that the old lab never could.

As the Biosafety Lab 4 planned for Hamilton on 4th Street will be responsible for researching "dangerous/exotic agents which pose high risk of life-threatening diseases," including such agents as Ebola, Encephalitis, Marburg Fever, and Mad Cow disease, it seems prudent to investigate what possible dangers this could present to our town and the surrounding area. The Supplemental Draft Environmental Impact Statement raises my level of concern above previously released documents, and has compelled me to comment.

65-1 In particular (and this is by no means a complete list), the Supplementary DEIS has no emergency plan included, no real provision for emergency services support, makes increased use of the incinerator to burn medical/infectious waste, has insufficient air pollution analysis, and no analysis of the risks posed by an accidentally infected lab worker. And there are no real alternatives to the building the Biosafety Lab 4 in Hamilton which are presented the document.

Last year I was elected to the City Council of the City of Hamilton. As a Councilor, I am responsible, in a relatively direct way, for protecting the interests of the citizens of Hamilton and the welfare of our city. The Supplementary DEIS suggests that my job is going to be much more difficult if the Biosafety Lab 4 is built as currently described. There is nothing in the DEIS that indicates any resources will be provided to the City of Hamilton to deal with the impact of the Biosafety Lab 4. There are no resources, financial or otherwise, suggested that would help us mitigate the impacts to our infrastructure including our sewer system, water system, wastewater treatment plant, streets, law enforcement capability, and many other City systems during the normal operations of the fully completed lab complex. And, equally if not more importantly, there are no resources provided to help the City of Hamilton deal with the possible emergencies (such as dangerous disease outbreaks or terrorism incidents) that could result from the existence of the Biosafety Lab 4.

LETTER 65 - BOB SCOTT

Comment	Response
65-1	Please see Section 1.7.2 where comments on the emergency plan were addressed. Please see Section 1.7.3 where comments on the use of the incinerator were addressed. Please see Section 1.7.1 where comments on the alternatives were addressed.

65-2 I ask, as a resident and a public official, that the Final DEIS address the resources the City of Hamilton will need to cope with the impacts of the Biosafety Lab 4 project. Otherwise, the project could face severe opposition from parts of the community that will be left to provide those resources unaided by the Federal government.

Bob Scott
102 Geneva
Hamilton MT 59840
406-363-0234

Comment	Response
65-2	Please Section 1.7.3 where comments on the effects on community infrastructure were addressed.

Nottingham, Valerie (NIH/OD/ORF)

From: Ted Kerstetter [tedker@spamarrest.com]
Sent: Wednesday, February 11, 2004 7:18 PM
To: ORS RMLEIS (NIH/OD/ORS)
Subject: RML expansion to BSL-4 level

Dear Ms. Nottingham;

Below,I quote from a *Friends of the Bitterroot* statement, with which I fully concur. There are hundreds of Bitterroot Valley (MT) residents who are outraged at NIH ignoring a legal FOIA request. Please believe that we will not be dissuaded or intimidated by NIH intransigence and are perfectly prepared to move to the level of federal courts if we must.

66-1 "Bitterroot valley citizens have been illegally denied important information and documents relating to the proposed RML Biolevel-4 expansion. This information was requeste by *Friends of the Bitterroot* six months ago in a FOIA (Freedom of Information Act) request, and we as citizens need that information in order for us to fully and meaningfully participate in the NEPA process. We therefore request that the deadline for comments be extended until we have access to this information that we as citizens of the United States are legally entitled."

--

Ted Kerstetter
Hamilton, MT

LETTER 66 - TED KERSTETTER

Comment	Response
66-1	Please see response to comment 47-3.

Nottingham, Valerie (NIH/OD/ORF)

From: cynthia [cynthia@blackfoot.net]
Sent: Wednesday, February 11, 2004 9:25 PM
To: ORS RMLEIS (NIH/OD/ORS)
Subject: Response to EIS on BSL-4 lab at RML

February 11, 2004

To Valerie Nottingham:

I am writing this in regards to the Rocky Mountain Labs proposed construction and operation of the BSL-4 laboratories.

Firstly I would like to address the documents asked for through the FOIA stating that the "The RML campus is located in rural western Montana, well removed from major population centers. The location of the laboratory reduces the possibility that an accidental release of a biosafety level-4 organism would lead to a major public health disaster." We have not received all information pertaining to this, and the citizens of the Bitter Root valley are entitled to all information to make informed and thorough comments because this affects every aspect of our lives. I request that an extension of the deadline be extended until such time that we receive the documents that we are entitled to by law. **67-1**

Furthermore, my main concerns are the containment of and disposal of the hazardous material at the lab; the amount of particulates generated during the incineration of said contaminants; and the amount of water the lab will use, including for the showering of the employees working in the BSL-4 labs. This water may end up in the ground water around the facility. **67-2**

Another concern is the fact that the lab doesn't have to inform the public if any of the pathogens at the lab are lost or stolen stated in the Homeland Security Act. That is just wrong! **67-3**

I think that this administration is trying to play on people's fears to justify building and operating a BSL-4 lab.

The Bitter Root valley is too beautiful of a place to contaminate with the hazardous materials that the lab will be manufacturing. Why not build such a lab on George W. Bush's ranch in Texas?

James D. Cerasoli
3803 Reed Butte Rd.
Stevensville, MT 59870

LETTER 67 - JAMES CERASOLI

Comment	Response
67-1	Please see response to comment 47-3.
67-2	Please see Section 1.7.3 where comments on increased use of the incinerator are addressed.
67-3	Please see response to comment 62-136.

Nottingham, Valerie (NIH/OD/ORF)

From: cynthia [cynthia@blackfoot.net]
Sent: Wednesday, February 11, 2004 10:06 PM
To: ORS RMLEIS (NIH/OD/ORS)
Subject: response to Draft EIS on BSL-4 lab @ RML

February 11, 2004

To Valerie Nottingham:

I am writing this letter in regards to the Supplemental Draft of the EIS concerning the RML facility in Hamilton, MT, and the proposed construction of a BSL-4 lab at this complex. I highly disagree with such a facility at this location and will outline my reasons below.

68-1 The first point to address is that we as citizens of the Bitter Root valley have not received all the information that we asked for under the Freedom of Information Act, and until such time we cannot fully make informed decisions until we have all pertinent information concerning this facility. I request that we have an extension on the deadline because of the information that we have not yet been given.

Concerning the information not yet fully released on the NIH memo that states " The RML campus is located in rural western Montana, well removed from major population centers. The location of the laboratory reduces the possibility that an accidental release of a biosafety level-4 organism would lead to a major public health disaster." I would like to say that Hamilton, MT is a substantial community, and that the Bitter Root valley is one of the fastest growing areas of the state, with growth projected to go up 60% by 2025. It is not prudent to build such a facility in this setting. I also believe that many times in looking at where to house a BSL-4 lab, the natural environment is often overlooked. MT is still a fairly intact ecosystem as far as quality of water, air, and the land which includes all of the wildlife. A BSL-4 lab should not be constructed in a place such as this, where the pristine quality and health of the environment is of utmost importance.

68-2 There are many points to cover that were not addressed, or not addressed sufficiently in the Supplemental Draft Environmental Impact Statement: There is no emergency plan included in the EIS. How would emergency services be supported with federal help? How much money and training would be provided? The idea that released, stolen, or lost agents or toxins are prohibited from being made public, stated in the Homeland Security Act is an outrage and reason enough to not build such a facility. The increase of use of the incinerator to burn medical/infectious waste is not fully addressed, and the Bitter Root valley is not a place to have an incinerator period, and certainly not to increase output. The increase in water usage per day I feel is too much, especially with the rapid growth that is occurring in this area. One must remember that Montana is a semi-arid climate, and is suffering through many years of drought, as is most of the western United States. We will have to make good decisions about how our water is being used, and a BSL-4 lab should not be a priority for our precious water. Alternatives to building in Hamilton which are standard in EIS's were not provided. The transportation of pathogens is another issue that must be addressed. Winter driving in MT can be very treacherous, and this is another reason that the valley is an improper place for such a facility.

68-3 There are so many reasons that a BSL-4 lab should not be built in Hamilton, MT, and I close as I started that there must be an extension to the deadline until we receive all information pertaining to the documents and correspondence requested.

LETTER 68 - CYNTHIA SANTOS

Comment	Response
68-1	Please see response to comment 58-1.
68-2	Please see Section 1.7.2 where comments on the emergency plan are addressed.
68-3	Please see Section 1.7.3 where comments on the impacts on the water supply are addressed. Please see Section 1.7.1 where comments on alternative locations are addressed. In the SDEIS, please see Appendix C – Transportation of Agents.

The concerns and dangers of a BSL-4 lab exponentially outweigh the positive aspects of locating it in Hamilton, MT. I trust that you consider all that I have said in far away MD, and understand the reasons to go with the No Action alternative.

Cynthia Santos
4581 Rathbun Lane
Stevensville, MT 59870

Nottingham, Valerie (NIH/OD/ORF)

From: Brian Jameson [brianvayu@juno.com]
Sent: Wednesday, February 11, 2004 10:17 PM
To: ORS RMLEIS (NIH/OD/ORS)
Subject: comment for revised draft eis

69-1 I appreciate that NIH has tried to address many concerns of the citizens of the Bitterroot Valley. However, I am not in support of this project. I don't think that the draft eis has analyzed the water supply realistically, I don't think that alternative sites have been given due consideration, I don't think that the increased incineration of toxic materials has been given wise consideration, I don't think that the lack of security here has been given wise consideration.

Truthfully, I don't think it is a good idea to put a BSL-4 lab here in the Bitterroot Valley. The idea seems to be primarily due to the call by President Bush for more bioterrorist research.

The lab as it is has been functioning well and proudly recognized throughout the community. I would like to see the lab continue as it is, a BSL-3 lab.

sincerely, Brian Jameson

LETTER 69 - BRIAN JAMESON

Comment	Response
69-1	Please see Section 1.7.1 where comments on alternative locations are addressed. Please see Section 1.7.3 where comments on the impacts on the water supply and effects of increased use of the incinerator are addressed.

Nottingham, Valerie (NIH/OD/ORF)

From: s cole [bttrtsharon@yahoo.com]
Sent: Wednesday, February 11, 2004 10:54 PM
To: ORS RMLEIS (NIH/OD/ORS)
Subject: RML Integrated Research Facility

Valerie Nottingham

I have worked at RML for 49 years, working with bordetella pertussis, both group A and B streptcoccus, AIDS, gonococccus and Q-fever, retiring 01-01-03. I feel that I have a very good sense of the work done in RML and the people that work there. I attended one of the meetings held about the proposed BL-4. I am for the project and would have no qualms about living next to the perimeter fence on the downwind side. I believe that this project would be a good thing for Hamilton and the schools. I know how the researchers here have worked with the schools to further the students understanding about scientific research.

This is a personal note regarding my impressions of the situation here. There are certain people who are adamantly against the project and no amount of information will change their minds.

Robert L Cole

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LETTER 70 - ROBERT COLE

Nottingham, Valerie (NIH/OD/ORF)

From: Suzanna McDougal [sumac@northlink.com]
Sent: Wednesday, February 11, 2004 11:51 PM
To: ORS RMLEIS (NIH/OD/ORS)
Subject: FW: RML comment deadline: Feb 11

Attention Valerie Nottingham:
CONCERNING:
Rocky Mountain Labs
Biosafety level 4
Comment deadline: February 11, 2004

A Biosafety Lab 4 planned for Hamilton on 4th Street and will be responsible for researching "dangerous/exotic agents which pose high risk of life-threatening diseases." (DEIS, 1-5). Included in the list are: Ebola, Encephalitis, Marburg Fever, and Mad Cow disease.

71-1 The citizens of the Bitterroot Valley have been illegally denied information that will allow us to fully participatein the National Environmental Policy Act process. I am requesting an extension of the deadline for comments until I receive the documents that I am entitled to by law.

71-2 The NIH is illegally withholding information and other important documents relating to the proposal.
In our Freedom Of Information Act request we asked for all documents and correspondence relating to the NIH memo that states "The RML campus is located in rural western Montana, well removed from major population centers. The location of the laboratory reduces the possibility that an accidental release of a biosafety level-4 organism would lead to a major public health disaster." This has not been forth coming. This must be sent as entitled by law.

71-3 These points have not been addressed and I request that you do so now and provide an extension of the deadline for comments.
1. No emergency plan was included in the Supplemental Draft Environmental
Impact Statement. We must have this in the SDEIS.
2. Emergency services have not been detailed, incase of an accident.
3. Released, stolen, or lost agents or toxins are prohibited from being made public, stated in Homeland Security Act. We need to know if this were to ever happen in our community. Our right to know is affected here.
4. Increased use of the incinerator to burn medical/infectious waste is dangerous to our health and our children's.
5. Air pollution analysis must be available for the citizens of the Hamilton, MT area.
6. Inventory of toxic chemicals proposed to be used onsite must be detailed and that information given to the public.
7. There is not an analysis of the risks posed by an accidentally infected lab worker. This must be included.
8. What is the potential income to the local government from payroll taxes?
9. What is the solid waste stream expected from the proposed lab?
10. There are conflicts between the proposed projects and the goals of the Ravalli County Growth policy.
11. What will the noise level be and what lights will glare into the houses near the lab at night?
12. You did not address the traffic in the neighborhood adjoining the lab. What will the increase be and how will it affect the homes that are next to the lab?
13. What is the potential target by terrorist?

Suzanna McDougal

LETTER 71 - SUZANNA MCDOUGAL

Comment	Response
71-1	Please see response to comment 47-3.
71-2	Please see response to comment 58-1.
71-3	Please see Section 1.7.2 where the emergency plan comment is addressed.
	Please see Section 1.7.2 where the emergency response comment is addressed.
	Please see response to comment 62-136.
	Please see Section 1.7.3 where the increased use of the incinerator and air pollution comments are addressed.
	Please see Section 1.7.3 where the use of toxic chemicals comment is addressed.
	Please see response to comment 39-16 for effects of an exposed laboratory worker.
	Please see response to comment 39-15 on tax revenue.
	Please see response to comment 39-19 for consistency with the Ravalli County Growth Policy.
	Please see Section 1.7.3 where comments on noise, light, traffic, and the increased threat of terrorism are addressed.

PO Box 1335
Hamilton, MT 59840

Emailing my comments to:
Valerie Nottingham
Orsrmleis-r@mail.nih.gov

Valerie Nottingham
National Institutes of Health
9000 Rockville Pike
Bldg. 13, Room 2W64
Bethesda, MD 20892

Nottingham, Valerie (NIH/OD/ORF)

From: DorindaTroutman@aol.com
Sent: Thursday, February 12, 2004 12:05 AM
To: ORS RMLEIS (NIH/OD/ORS)
Subject: Comment on RML Environmental Impact Statement

Ms. Nottingham:

I did not find the new environmental impact statement enlightening, nor an improvement over the original. My concerns having to do with human error, location in the middle of a small town, and in the middle of a beautiful mountain valley have not been met.

Last week's problem with a malfunctioning heating system and warning system at the Lab is just one small reminder of how things can go wrong.

I quote from the NIH press release, (that has not been released to the press) follows:
"A temperature sensor that regulates the flow of hot air into an animal research holding facility malfunctioned between 4 p.m. Saturday, Feb. 7, and 8 a.m. Sunday, Feb. 8, at the Rocky Mountain Laboratories (RML) in Hamilton, MT. When animal technicians arrived to feed and water the animals Sunday morning they discovered the malfunction. RML maintenance personnel, the chief veterinarian and the chairman of the RML Animal Care and Use Committee (ACUC) were immediately notified.

The malfunction created a constant flow of hot air into a 10,000 square-foot animal facility. For a period of time temperatures in some animal holding rooms reached 100 degrees Fahrenheit, or about 25 degrees above normal. An alarm properly activated in the facility and in a maintenance area. At the time, however, the alarm was not programmed to notify RML security employees, who are on duty 24 hours per day.

The malfunction resulted in the deaths of some squirrel monkeys and hamsters due to complications of hyperthermia. The holding facility sustained no breach in containment, and all animals remained in their cages. At no time was there any risk to staff in the facility or to persons in the surrounding area."

Although this "accident" did not harm humans, it is exactly the type of simple mishap that concerns me when working with such deadly pathogens.

72-1 Please answer my questions of how this kind of error, or any other, may never be repeated in any manner again at RML.

Sincerely,
Dorinda Troutman
PO Box 174
Hamilton MT 59840
406-363-1806

LETTER 72 - DORINDA TROUTMAN

Comment	Response
72-1	It is impossible to guarantee that a malfunction, mishap, or error will never occur. Safety mechanisms and backup systems greatly reduce the likelihood of an incident.

Nottingham, Valerie (NIH/OD/ORF)

From: cindy nicholls [nickmt23@earthlink.net]
Sent: Thursday, February 12, 2004 12:13 AM
To: ORS RMLEIS (NIH/OD/ORS)
Subject: EIS comments

Dear Ms Nottingham,

73-1 I am writing to continue to voice my concern for the proposed Bio Level 4 lab planned for Hamilton. I feel that many, many peoples concerns and questions were not addressed. I especially wish to know how the public would be protected from an accidentally infected lab worker-one who does not know he has been infected and goes out o the grocery or the high school basketball game and exposes everyone else.

73-2 Also, Hamilton does not have the medical services to treat an accidental exposure of any magnitude above one person being affected. Have you seen our hospital?
Where is the emergency evacuation plan for the county????
Alternative sites were not provided in your eis.

73-3 I am also very disturbed to learn of the computer malfunction resulting in the "cooking to death" of 13 squirrel monkeys and numerous hamsters and rats over this past weekend. Your alarms went off but not to the people who could have saved the animals. A similar malfunction could prevent us from knowing of an accidental release of deadly pathogens. Nothing is fail safe. This lab needs to be on a military base where people choose to be working in such an environment, Not in a residential neighborhood in a valley with one 2 lane road leading north or south for an escape.

Sincerely,
Cindy Nicholls

LETTER 73 - CINDY NICHOLLS

Comment	Response
73-1	It is virtually impossible for a laboratory worker to become infected without knowing it. Please also see response to comment 71-3.
73-2	Please see Section 1.7.2 where this comment was addressed.
73-3	Please see Section 1.7.1 where this comment was addressed.

Nottingham, Valerie (NIH/OD/ORF)

From: Vogt [calamity@montana.com]
Sent: Thursday, February 12, 2004 12:31 AM
To: ORS RMLEIS (NIH/OD/ORS)
Subject: Rocky Mountain Lab

Dear Valerie Nottingham:

Apparently accidents DO happen. This time we were all lucky.

I am intensely bothered by the idea that my neighbors and I appear to be the expendible portion of the population. We have been denied access to important information as related to the expansion of the Rocky Mountain Lab to a Biolevel-4. Considering the gravity of this decision I wouldn't think that it would be unreasonable to extend the deadline in order to allow this information to reach the Americans who have a legal right to it. **74-1**

Please see to it that justice remains an American tradition.

Sincerely,

Marla-Jane Vogt
Hamilton, Montana

HEATING MALFUNCTION CAUSES RESEARCH SETBACK

A temperature sensor that regulates the flow of hot air into an animal research holding facility malfunctioned between 4 p.m. Saturday, Feb. 7, and 8 a.m. Sunday, Feb. 8, at the Rocky Mountain Laboratories (RML) in Hamilton, MT. When animal technicians arrived to feed and water the animals Sunday morning they discovered the malfunction. RML maintenance personnel, the chief veterinarian and the chairman of the RML Animal Care and Use Committee (ACUC) were immediately notified.

The malfunction created a constant flow of hot air into a 10,000 square-foot animal facility. For a period of time temperatures in some animal holding rooms reached 100 degrees Fahrenheit, or about 25 degrees above normal. An alarm properly activated in the facility and in a maintenance area. At the time, however, the alarm was not programmed to notify RML security employees, who are on duty 24 hours per day.

LETTER 74 - MARLA-JANE VOGT

Comment	Response
74-1	Please see response to comment 47-3.

The malfunction resulted in the deaths of some squirrel monkeys and hamsters due to complications of hyperthermia. The holding facility sustained no breach in containment, and all animals remained in their cages. At no time was there any risk to staff in the facility or to persons in the surrounding area.

The affected animals were involved in research on transmissible spongiform encephalopathies (TSE), also known as prion diseases. These are fatal brain diseases associated with the accumulation of misshapen protein molecules. These diseases include chronic wasting disease in deer and elk, bovine spongiform encephalopathy (mad cow disease), scrapie in sheep and Creutzfeldt-Jacob disease in humans. All macaques involved in the research survived, as did many of the squirrel monkeys and hamsters, which will allow those experiments to continue.

The sensor malfunction was repaired by 9 a.m. on Sunday, and the system was tested and is functioning. The temperature sensor has been reprogrammed to notify security employees and other key RML officials whenever the temperature fluctuates up or down 5 degrees from the normal temperature (normal range from 72 to 78 degrees Fahrenheit) for more than 10 minutes.

The squirrel monkey research, begun in April 2003, is designed to determine whether non-human primates become infected when exposed to infected tissue from deer or elk with chronic wasting disease. Such research could help determine whether, and how, other types of TSEs become infectious in different species.

Drs. Richard Race and Bruce Chesebro and the team of TSE researchers estimate the incident will set back portions of their research project about 12 to 18 months. Dr. Chesebro called the loss of the animals a tragedy. The team will continue its experiment with the surviving animals, however, and with new animals to replace those that died.

An RML veterinary pathologist has examined the dead animals to learn more about their deaths and to recover any research information that may be useful to the TSE experiment, such as whether brain tissues showed signs of CWD infection.

An emergency meeting of the Animal Care and Use Committee was held to review and document the incident. The committee will send documentation to the director of the Office of Animal Care and Use, National Institutes of Health.

###

Media inquiries can be directed to RML Public Affairs at 406-375-9690.

RML is part of the National Institute of Allergy and Infectious

Diseases, a component of the National Institutes of Health (NIH). NIH 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.

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

Prepared by:
Office of Communications and Public Liaison
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Bethesda, MD 20892

U.S. Department of Health and Human Services

Nottingham, Valerie (NIH/OD/ORF)

From: Doug Soehren [dsjl@micro-mania.net]
Sent: Thursday, February 12, 2004 1:01 AM
To: ORS RMLEIS (NIH/OD/ORS)
Cc: Doug Soehren
Subject: Comments to RML SDEIS

Valerie Notingham

National Institutes of Health NEPA coordinator,

Please enter the following comments in the EIS records for the proposed Rocky Mountain Laboratories proposed BSL 4 expansion project.

75-1 The range of alternatives studied is still inadequate. You need to consider building in other locations.

75-2 We and many other citizens of the Bitterroot Valley have been illegally denied information that will allow us to fully and meaningfully participate

in the National Environmental Policy Act process.

We are members of one or more groups who submitted an FOIA request for information relevant to the NEPA process which these comments are a part. An apparently willful failure to comply with this request since last summer has illegally denied us access to information that should be analyzed by the public before any decision to implement this project is made.

75-3 We request an extension of the deadline for comments until such time that we receive the documents we are entitled to by law and have had time to analyze them.

Another issue of great concern to us has recently come to light and should be resolved before this proposal is considered further:

75-4 A reading of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, particularly Title II, Sec. 351A, leaves us with the impression that the NIH and the RML are prohibited from advising our local health authorities in the event of loss, theft or spill of infectious agents within the RML facility. This is not acceptable and must be addressed immediately.

75-5 A comprehensive emergency plan is still noticeably absent from the SDEIS.

LETTER 75 - DOUG SOEHREN

Comment	Response
75-1	Please see Section 1.7.1 where this comment is addressed.
75-2	Please see response to comment 58-1.
75-3	Please see response to comment 47-3.
75-4	Please see response to comment 62-136.
75-5	Please see Section 1.7.2 where this comment is addressed.

Your assessment of risk is overoptimistic. You have failed to learn the lessons of history and seem to be ignoring our warnings that the proliferation of deadly organisms you seek to study has as much potential to harm humanity as it does to aid it. You fail to acknowledge the risk of proliferated organisms finding their way into the hands of terrorists by way of disgruntled employees or sold by scientists to the highest bidder. We hate to think of these risks but they are very real as history has shown.

You ignore your responsibility to the public and your mandate under NEPA to fully disclose these risks in the SDEIS.

75-6 Your assertion that "RML does not and will not conduct research to develop offensive biological weapons" is meaningless. We are familiar with the workings of US Government bureaucracies. We know how reality differs from the image and the rhetoric. We have been alive too long with our eyes and ears open to believe the assurances of one of your many contractors who processes documents for money.

We know this project is about money. It's not about health or safety or security. We have seen and heard from the short sighted and the greedy who are lining up for the jobs and the contracts and the handouts. We are not among them. We don't want your money and we don't want you to put our lives and health at needless risk.

Sincerely,

Doug Soehren

Joetta Lawrence

Comment	Response
75-6	Please see response to comment 63-4.

Nottingham, Valerie (NIH/OD/ORF)

From: Kierstin Lange [klange1@qwest.net]
Sent: Thursday, February 12, 2004 1:44 AM
To: ORS RMLEIS (NIH/OD/ORS)
Subject: ROCKY MOUNTAIN LAB

Dear Ms. Nottingham and the staff at NIH and NIAID,
I am writing regarding the proposed expansion of the Rocky Mountain Lab in Hamilton. Here are a few of my concerns:

76-1
1. **No EMERGENCY PLAN included in the SEIS**
2. **No analysis of the adequacy EMERGENCY SUPPORT SERVICES in comparison to urban settings.**

76-2
3. **RELEASED, STOLEN, LOST AGENTS or TOXINS are PROHIBITED from being made PUBLIC, as stated in as stated in the Bioterrorism Preparedness Act**

76-3
4. **FREEDOM of INFORMATION ACT requests have been ignored**

76-4
5. **No analysis of the risks posed by an accidentally INFECTED LAB WORKER.**

76-5
6. **Increased use of the INCINERATOR to burn waste**
7. **Increased NOISE and TRAFFIC in residential neighborhoods**
8. **ALTERNATIVES - which are absolutely standard in EIS's - were not provided.**
9. **PURPOSEFUL RELEASE or POTENTIAL TARGET by terrorists**

We, and the Bitterroot valley citizens whom we represent and inform, have been illegally denied important documents and information that are crucial to meaningful participation in the NEPA process for the proposed BSL-4 expansion at Rocky Mountain Laboratories (pursuant to 40 C.F.R. 1506.6 and 1507.1). The NIH is currently in violation of Freedom of Information Regulation 5.35(b)(2) for not responding to Friends of the Bitterroot's FOIA appeal, received by the FOIA appeals office November 10th, 2003, by the required deadline. The NIH has also violated 5 U.S.C. 552(a)(6)(A)(iii) and 45 C.F.R. 5.45(a)(1)(2) for not granting a fee waiver request, as required by law. The NIH has been in possession of this FOIA request for 6 months and has failed to act. We view these actions as deliberate stonewalling of our groups and the large number of citizens that we represent, while NIH hurriedly moves forward with the scoping process on the proposal. For this reason, we require that the deadline for comments on the SDEIS be extended until 45 days after we receive the documents in our FOIA request, to which we are legally entitled.

These are not small, insignificant issues.

76-6
Our community may be *well removed from major population centers* and may *reduce the possibility that an accidental release of biosafety level-4 organism would lead to a major public health disaster,* however, we want all the information on the table. There has been some blatant disregard for requests for information and risk

LETTER 76 - KIERSTIN LANGE

Comment	Response
76-1	The emergency plan comment is addressed on page1-10 of the SDEIS. An analysis of emergency support services was included in Chapter 4 of the SDEIS.
76-2	Please see response to comment 62-136.
76-3	Please see response to comment 58-1.
76-4	Please see response to comment 71-3.
76-5	Please see Sections 1.7.1 and 1.7.3 where comments were addressed.
76-6	Please see response to comment 47-3.

anaylsis that are of greatest importance to us.

Incidents such as these are examples of negligence and potential danger, especially when it is not reported to the community until the day of the comment deadline!

" The malfunction created a constant flow of hot air into a 10,000 square-foot animal facility. For a period of time temperatures in some animal holding rooms reached 100 degrees Fahrenheit, or about 25 degrees above normal. An alarm properly activated in the facility and in a maintenance area. At the time, however, the alarm was not programmed to notify RML security employees, who are on duty 24 hours per day."

Please consider the potential impact on our beautiful valley and community.

Thank you.
Sincerely,
Kierstin Lange

Nottingham, Valerie (NIH/OD/ORF)

From: Judy Hoy [bwrehab@mtwi.net]
Sent: Thursday, February 12, 2004 1:57 AM
To: ORS RMLEIS (NIH/OD/ORS)
Subject: Rocky Mountain Lab Expansion to Biolevel-4.

Dear Ms. Nottingham,

77-1 I would like to request that the deadline for comments on the RML Biolevel-4 expansion be extended until the citizens of Ravalli County and surrounding area are provided with the information which they requested under the FOIA. While I completely support the RML's work, a Biolevel-4 laboratory can be much more hazardous to the health of the people and animals in a large area surrounding the laboratory. Therefore it is essential that the citizens of Ravalli County are able to make an informed decision based on all available information as to whether we want a Biolevel-4 lab in our community.

It is my understanding that RML recently had an unfortunate accident with the heating which caused the deaths of important study animals. I used to be on the ACUC committee and it was my understanding several years ago, when a similar incident caused study animal deaths, that an alarm system such as the new alarm system just put in place was put in place several years ago. Some of the deaths were to primates in the recent accident, which is very concerning to me.

Please provide the citizens with the information they requested, and note that I fully believe that a Biolevel-4 laboratory in Hamilton, Montana is unwise and a waste of taxpayers money. The RML always needed more Biolevel-3 space to study the diseases and other problems which are much more of a threat.

I have also voiced my concern for the health of the families of scientists moving to the Bitterroot Valley because of the extremely high rate of developmental malformations in wildlife and domestic animals here.

Sincerely,
Judy Hoy

LETTER 77 - JUDY HOY

Comment	Response
77-1	Please see response to comment 47-3.

LETTER 78 - CONNIE JOHNSON

Dear Ms Nottingham ~

I'm happy to see a supplemental draft EIS for the RML expansion was prepared, since the first was so flawed & limited. Though the Supplement stinks too.

It's obviously biased towards the expansion. The alternatives still aren't realistically considered. It's obvious the decision was made years ago and this small rural community was chosen because the amount of citizens knowledgeable enough to speak out against it are few. So big government can march in & do whatever they want.

I'm opposed! And I'm embarrassed by "my" government once again.

Sincerely
Connie Johnson
415 S 8th St
Hamilton, MT
59840

ATTORNEY GENERAL
STATE OF MONTANA

Mike McGrath
Attorney General

Department of Justice
215 North Sanders
PO Box 201401
Helena, MT 59620-1401

February 11, 2004

Ms. Valerie Nottingham
NIH B-13/2 W 64
9000 Rockville Pike
Bethesda, MD 20892

VIA FAX (301) 480-8056

Re: Rocky Mountain Laboratories

Dear Ms. Nottingham:

Please accept this letter in support of the proposed expansion of Rocky Mountain Laboratories in Hamilton.

As Montana's attorney general, I take seriously the challenges of homeland security and public safety. The upgrade to Biosafety Level 4 in Hamilton would allow the most talented of scientists to scrutinize the most dangerous of diseases.

As a native Montanan, I know the history of the Rocky Mountain Labs and the facility's importance to the Bitterroot Valley. The labs have a long history of doing important work while meeting demanding standards for safety and quality.

I have visited the lab and reviewed the supplemental Environmental Impact Statement and other relevant materials. I am confident that the plans to expand the Hamilton facility and upgrade it to Biosafety Level 4 are thorough and that the possible threat to the community is neglible.

Very truly yours,

MIKE McGRATH
Attorney General

mm/lds

LETTER 79 - MIKE MCGRATH, ATTORNEY GENERAL OF MONTANA

LETTER 80 - ROBERT SUTHERLAND

614 South Second Street
Hamilton, Montana 59840
(406) 375-9126
February 11, 2004

Valerie Nottingham
NIH, B13/2W64
9000 Rockville Pike
Bethesda, MD 20892

Regarding the DEIS for the Rocky Mountain Laboratories expansion project.

Dear Ms. Nottingham:

Last Fall I was elected to the Hamilton City Council, along with a slate of candidates that campaigned for reform of the way Hamilton city government has been managed. All three of us on the slate were elected by a two to one majority. The three new members of the council, along with one incumbent are cooperating in a four to two majority.

As of today, the city administrator has resigned, and the next two highest-salaried city employees have indicated that they plan to leave as well. All this has happened while the council members have had their hands full, trying to take care of the backlog of business that the previous council have left undone. This council have not yet had time to begin investigating the rationale for the decisions that were made by the mayor and the former administrator regarding the RML expansion project, but it is clear that these officials could not have been acting in the interests of the citizens and businesses of Hamilton.

The city government is now considering proposals by real estate developers that would make use of city water and sewer services and street maintenance, and that would have impacts on the costs of traffic and pedestrian safety, fire protection and police protection. The costs of those services to the residents and businesses of this city and those impacts are being considered against the benefits of the proposed developments. The same considerations will be given to the very significant impacts that the Lab expansion will have, particularly during the construction phase, on the immediate neighborhood of the Lab and on city resources used by the Lab. Those impacts are far more important than the way they are depicted in the DEIS or the Supplemental Draft, and I believe that that is due to the very bland reponses made to the NIH interrogatories by city officials who apparently were not representing the City of Hamilton's interests.

Sincerely,

Robert Sutherland

RML Integrated Research Facility

Public Meeting – January 22, 2004

Comments on the Supplemental Draft Environmental Impact Statement

I understand that all kinds of scenarios have been examined showing that the level 4 lab will be safe. However, humans will be employed there and humans are sometimes ignorant. I personally know of one RML employee who brought home animal bedding + feces for that person's garden mulch before other employees discovered this error. I also know of another person who is the proud owner of a heavy-duty stainless steel animal cage from RML. Both people were well-meaning citizens that made hazardous mistakes. Humans would be working with extremely hazardous chemicals at the proposed bio-level 4, and humans have (and will) make mistakes – not to mention the toxic chemicals legally dumped on the lab property ~~at~~ in the recent past!

81-1

* There's a lack of alternatives to the Hamilton RML expansion
* Hazardous emissions of increased use of incinerator was not addressed.
* I'm not comfortable with biolevel 4 pathogens in this valley
* The public concerns submitted were not addressed in the EIS.

Name: Sally Blevins
Company/Organization:
Address: PO Box 2796
City, State, Zip: Hamilton, MT 59840

Please send comments to: Valerie Nottingham
NIH, B13/2W64
9000 Rockville Pike
Bethesda, MD 20892

Please note that this document will become part of the administrative record for the EIS and will be subject to public review.

Comments must be post marked by February 11, 2004

Please NO MAILING USE

LETTER 81 - SALLY BLEVINS

Comment	Response
81-1	Please refer to Sections 1.7.1 and 1.7.3 in the SDEIS where these comments were addressed.

. [illegible] of consideration of alternatives to location at [illegible]

No analysis of risk posed by infected water

[illegible] for public review in Supp DEIS

hazard emissions from increased use of incinerator not addressed

not comfy w/ broad 4 Dorthogyne contaminants in Valley

Little consideration for threats (terrorists, planes, etc.) to lab

public concerns submitted were not addressed in EIS

better sci. analysis of Emer. services in Valley

February 10, 2004

Valerie Nottingham
NIH, B13/2W64
9000 Rockville Pike
Bethesda, MD 20892

Dear Ms. Nottingham,

This letter is in response to the supplemental draft environmental impact statement (SDEIS) on the proposed Rocky Mountain Laboratories (RML) Integrated Research Facility containing a Biosafety Level 4 (BSL-4) laboratory. Comments are as follows:

82-1 1. The SDEIS fails to justify the need for construction of a BSL-4 lab at RML. The statement on page 2-17 that "Construction of the proposed Integrated Research Facility at RML at the Bethesda, Maryland campus would not meet the purpose "to provide a ... intramural laboratory at RML" " does not answer this question, but simply dismisses it. As indicated in my previous letter on this issue, the reasons given for construction at RML which include the existence of BSL-2 and BSL-3 labs, expertise in infectious diseases, core of unparalleled scientific knowledge, and existing infrastructure, are far surpassed by the existing labs, expertise, core of knowledge, and infrastructure at the main NIH campus in Bethesda, MD. The Bethesda campus employs over 15,000 staff and scientists versus 224 at RML. The main campus offers a broader level of scientific expertise, greater core of knowledge, and far superior infrastructure than is available at RML. In addition, the main campus enjoys excellent support services from the Bethesda community, including the nation's best fire, law enforcement, and biohazard expertise. RML is served by a volunteer fire department, a small local police force, and few trained biohazard personnel. Finally, NIH's main campus already houses a BSL-4 lab that is not being used for BSL-4 level research. The availability of a broad base of scientific expertise, superior infrastructure and support services, and an existing BSL-4 facility make the main NIH campus in Bethesda the most appropriate site for an additional NIH BSL-4 laboratory.

82-2 2. The SDEIS fails to consider project alternatives to building a BSL-4 lab at RML. Rather it again dismisses this possibility because it "does not meet the purpose and need to provide a .... laboratory at RML" (pg 2-18). This statement alone indicates that NIH has no intention of considering other sites. NIH has already decided that RML is the only option for this lab and local concerns are obviously irrelevant to the individuals making this decision. For all the reasons raised previously by myself and other concerned citizens, including the existence of a deadly disease only nine blocks from Main St. in a town with limited fire, police, and biohazard personnel, surrounded by residential houses and a middle school in a neighborhood of families with small children and elderly singles, the potential risks are unacceptable to many residents. Increased traffic, increased potential for exposure to lab pathogens, and potential difficulties in selling homes so close to a deadly disease lab single out these residents as being heavily impacted by the proposed facility. Alternative building sites in this immediate area were dismissed due to the additional time and effort it may cost NIH, although the statement that relocation would take 10 years and $1 billion dollars is so greatly exaggerated as to be ridiculous. The supplemental DEIS does not answer any of the concerns raised by the citizens of Hamilton. The revised document is a joke unworthy of a government agency.

LETTER 82 - LINDA PERRY

Comment	Response
82-1	Please see Section 1.7.1 where this comment is addressed.
82-2	Please see Section 1.7.1 where this type of comment is addressed.

82-3 3. The SDEIS fails to consider adequately the potential impacts of a BSL-4 lab on the health, safety and welfare of community residents. The DEIS conceded that "it is not specifically known what agents would be studied at the integrated research facility". Nonetheless, the next paragraph indicated that "the nature of transmission of many diseases that would be studied at RML provides a natural mechanism controlling their spread in the community". Since new viruses and virus-induced diseases have appeared with increasing frequency in recent decades and since this trend promises to continue, there is no way of predicting the nature of the agents to be studied or the modes of transmission that will dictate their potential for spread through the community. To ensure the continued health and safety of valley residents, full disclosure and compensation should be offered as follows:

82-4 a. Full disclosure of all BSL-4 biological agents that enter RML's BSL-4 lab. This should be accomplished through reporting in the Ravalli Republic newspaper within 72 hours of arrival on the RML campus. Each report should include the symptoms of accidental exposure to the relevant agent and steps to follow in the event of a suspected exposure. This will provide emotional assurance to community members regarding the risks or lack thereof of agents under investigation as well as a protocol for early detection, containment, and treatment of any accidental exposures.

82-5 b. Full disclosure of all laboratory accidents involving hazardous agents, including chemical, biological, and/or radioactive materials. Accidents should be reported to the Ravalli Republic newspaper within 24 hours of filing at RML and published in the next edition in a space designated for RML reports. Follow-up reports of actions taken in response to each accident should also be reported and published in the same manner as described above. This will provide assurance to community members that the research being performed at RML provides a minimal risk to their health and welfare, which is a major concern to many area residents and the very foundation of RML's local support.

82-6 c. A specific community information officer versed in the current status of RML's BSL-4 research should be appointed from RML as a contact person for community members with questions or concerns. A similarly versed community information officer should also be appointed from the main NIH/NIAID campus in Bethesda, MD for community members with additional questions/concerns. Each position should carry primary as well as alternate information officers to ensure the availability of at least informed individual during regular business hours (8 am to 4:30 pm EST, weekdays). The same or alternate individuals should be designated as emergency contact community information officers to cover after hours and weekend emergencies. Phone numbers and addresses of these information officers should be made public, and updated as needed. This will provide an information pathway for local residents with questions or concerns of local and/or national relevance.

82-7 d. NIH should provide full medical coverage for any community member that acquires a lab-related infection. This includes all expenses incurred during diagnosis and/or treatment (acute and/or chronic) of any infection and/or disease with an agent being maintained in a BSL-3 or BSL-4 biocontainment lab on the RML campus. A death benefit should be awarded to the survivors of any individual who succumbs to a lab-related infection or disease. This will ensure that community members who are negatively impacted by the research being performed at RML have access to the best medical care available regardless of their health insurance status. This is particularly important in

Comment	Response
82-3	Please see Section 1.7.3 where comments on health and safety were addressed.
82-4	Please see response to comment 62-11.
82-5	Please see response to comment 47-5 and 58-3.
82-6	RML recently hired a Public Information Officer.
82-7	Please see Section 1.7.2 where information about filing claims for personal injuries were addressed.

Ravalli County where at least 20% of the population lacks medical insurance coverage of any kind. It also provides for long-term financial support of victims' families.

82-8 e. RML/NIAID/NIH should provide free training for Missoula and Ravalli County emergency personnel, including police, fire, medical, and biohazard specialists, in the recognition and management of an accidental release of a BSL-4 agent into the community. In addition, RML/NIAID/NIH should contribute to the salaries plus benefits for any additional staff that must be employed by these emergency agencies to provide adequate community protection from an outbreak of infectious agents from RML.

82-9 f. RML/NIAID/NIH should publish an emergency evacuation plan for Ravalli County residents in the event of an accidental release of infectious agents from the BSL-4 laboratories.

82-10 g. NIAID/NIH should provide tax assistance to Ravalli County to cover the increased costs associated with RML expansion at any location. Road, school, water, and other expenses directly or indirectly attributable to the proposed expansion should be paid by the government agency responsible for the expenses, not by the residential taxpayer who receives no benefit from this facility.

None of these issues were addressed in the SDEIS. None of them. We are still awaiting a response to our concerns. The residents of this valley do not consider themselves as being expendable, but it appears that NIH does. I am ashamed to have worked for such an organization with such little regard for the public it serves.

Sincerely yours,

Linda L. Perry, Ph.D., D.V.M.

Linda L. Perry PhD, DVM
631 Bowman Rd.
Hamilton, MT 59840

Comment **Response**

82-8 While NIH does not have legal authority to support training and hiring of community emergency personnel directly, funds for training and enhancement of emergency personnel staff, if needed, may be available through State and Federal programs for public health emergency preparedness supported by the Federal Emergency Management Agency (FEMA) of the Department of Homeland Security (DHS), and sister agencies of the NIH at the Department of Health and Human Services (HHS), including the Health Resources and Services Administration, and the Centers for Disease Control and Prevention. Information about those programs is available through the DHS and HHS websites. Further, DHS and HHS have emergency response personnel who can be called into action to support State and local efforts as needed. Local emergency responders could obtain public information from the NIH.

82-9 Please see Section 1.7.2 where comments on an emergency plan were addressed.

82-10 Please see Section 1.7.3 where comments on the impacts on community infrastructure, including schools, roads, and emergency response were addressed.

February 10 '04

To Whom It May Concern:

I am a resident of Corvallis, Montana an adjacent town to Hamilton, Montana the future home of a "Level-4" lab. My wife and myself would like to go on record as opposing this lab in a beautiful, Western Montana area. I do realize that this type of Research is necessary, but would be better served in a more selective area with a modern facility, with modern up to date security, and with minimum impact on its environment. I believe the cost

83-1

LETTER 83 - KENNETH AND BARBARA STRIGH

Comment	Response
83-1	Please see Section 1.7.1 where this comment is addressed.

Page 2

Difference between a new facility and a retrofit building is small compared to other Government expenditure, such as "War", killing people instead of saving people.

I believe the present Rocky Mountain Lab will be well suited to be left as is and with no impact on the citizens.

This new lab could be in a very selective area, low density population and provide additional jobs.

Again this new "Level 4" lab would create new employment, in a new modern facility,

Page 3

with up to date security, better expansion opportunities and less environmental issues, creating a better situation for all concerned.

I am an-aged retiree with Macular Degeneration, hence I do not have the ability to study all "documentation." Please excuse my writing and my informal letter

Concerned Citizens.
Kenneth + Barbara Stigh
488 Covey Run Rd
Corvallis, MT, 59828
406 961 4877

LETTER 84 - ENVIRONMENTAL PROTECTION AGENCY

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 8, MONTANA OFFICE
FEDERAL BUILDING, 10 West15th Street, Suite 3200
HELENA, MONTANA 59626

Ref: 8MO

February 3, 2004

Ms. Valerie Nottingham, Chief
Pollution Control Section, EPB, ORS,
National Institutes of Health, B13/2W64
9000 Rockville Pike
Bethesda, Maryland 20892

Re: Supplemental Draft EIS for Rocky Mountain Laboratories Integrated Research Facility

Dear Ms Nottingham:

The Environmental Protection Agency (EPA) Region VIII Montana Office has reviewed the December 2003 Supplemental Draft Environmental Impact Statement (SDEIS) for the Rocky Mountain Laboratories (RML) Integrated Research Facility. The EPA reviews EISs in accordance with its responsibilities under the National Environmental Policy Act (NEPA) and Section 309 of the Clean Air Act. Section 309 of the Clean Air Act directs EPA to review and comment in writing on the environmental impacts of any major Federal agency action. The EPA provided comments on the earlier May 2003 Draft EIS for this project on July 15, 2003, and is updating agency DEIS comments based on our review of this SDEIS.

We are pleased that the SDEIS includes additional analysis and disclosure regarding community risk assessment for the proposal, including potential risks of release of biological agents to the community (including a literature review of laboratory acquired infections; a review of all infectious disease research protocols; review of all accidents, injuries and illnesses at NAAID laboratories; review of RML medical waste incinerator operations, infectious waste handling procedures, animal containment, and procedures for biological material shipment). Additionally a Maximum Possible Risk (MPR) model developed by NIH was used to assess risk of infectious agent release to the surrounding Hamilton community using anthrax spores.

We are also pleased that regular community liaison group meetings are held at the RML campus to provide a forum for discussion of public issues and concerns about RML, and that the community group will be used for oversight and monitoring of activities at the Integrated Research Facility. It is important for the NIH to implement a comprehensive risk notification and communication program for the Hamilton community. A comprehensive risk notification and communication for the Hamilton community should help provide assurances to the public that risk of escape or release of disease causing agents will be reduced to as close to zero as possible to help allay public concerns.

The EPA's more detailed questions, concerns, and/or comments regarding the analysis, documentation, or potential environmental impacts of the Rocky Mountain Laboratories Integrated Research Facility SDEIS are included in the enclosure with this letter. The EPA's comments include a rating of both the environmental impact of the proposed action and the adequacy of the NEPA document (see explanation of EPA DEIS rating criteria enclosed). Based on the procedures EPA uses to evaluate the adequacy of the information and the potential environmental impacts of the proposed action and alternatives in an EIS, the Rocky Mountain Laboratories Integrated Research Facility DEIS has been rated as Category EC-2 (Environmental Concerns-Insufficient information).

EPA has concerns regarding responses to potential infections of facility staff; adequacy of backflow prevention devices on the water supply; adequacy of the liquid waste decontamination system; and risk of release of formaldehyde to the environment during gas decontamination procedures. EPA recommends development of a comprehensive risk notification and communication program for the local community. EPA recommends that additional information and discussion be included in the final EIS.

EPA appreciates the effort that went into the preparation of this SDEIS, and we thank you for the opportunity for review and comment. If you have any questions please contact Mr. Steve Potts of my staff in Helena at (406) 457-5022 or in Missoula at (406) 329-3313.

Sincerely,

John F. Wardell
Director
Montana Office

Enclosure

cc: Larry Svoboda/Julia Johnson, EPA, 8EPR-N, Denver
Aubrey Miller, EPA, 8EPR-PS, Denver
Terry Grotbo, Maxim Technologies, Helena

U.S. Environmental Protection Agency Rating System for Draft Environmental Impact Statements Definitions and Follow-Up Action*

Environmental Impact of the Action

LO - - Lack of Objections: The Environmental Protection Agency (EPA) review has not identified any potential environmental impacts requiring substantive changes to the proposal. The review may have disclosed opportunities for application of mitigation measures that could be accomplished with no more than minor changes to the proposal.

EC - - Environmental Concerns: The EPA review has identified environmental impacts that should be avoided in order to fully protect the environment. Corrective measures may require changes to the preferred alternative or application of mitigation measures that can reduce these impacts.

EO - - Environmental Objections: The EPA review has identified significant environmental impacts that should be avoided in order to provide adequate protection for the environment. Corrective measures may require substantial changes to the preferred alternative or consideration of some other project alternative (including the no-action alternative or a new alternative). EPA intends to work with the lead agency to reduce these impacts.

EU - - Environmentally Unsatisfactory: The EPA review has identified adverse environmental impacts that are of sufficient magnitude that they are unsatisfactory from the standpoint of public health or welfare or environmental quality. EPA intends to work with the lead agency to reduce these impacts. If the potential unsatisfactory impacts are not corrected at the final EIS stage, this proposal will be recommended for referral to the Council on Environmental Quality (CEQ).

Adequacy of the Impact Statement

Category 1 - - Adequate: EPA believes the draft EIS adequately sets forth the environmental impact(s) of the preferred alternative and those of the alternatives reasonably available to the project or action. No further analysis of data collection is necessary, but the reviewer may suggest the addition of clarifying language or information.

Category 2 - - Insufficient Information: The draft EIS does not contain sufficient information for EPA to fully assess environmental impacts that should be avoided in order to fully protect the environment, or the EPA reviewer has identified new reasonably available alternatives that are within the spectrum of alternatives analyzed in the draft EIS, which could reduce the environmental impacts of the action. The identified additional information, data, analyses or discussion should be included in the final EIS.

Category 3 - - Inadequate: EPA does not believe that the draft EIS adequately assesses potentially significant environmental impacts of the action, or the EPA reviewer has identified new, reasonably available alternatives that are outside of the spectrum of alternatives analyzed in the draft EIS, which should be analyzed in order to reduce the potentially significant environmental impacts. EPA believes that the identified additional information, data, analyses, or discussions are of such a magnitude that they should have full public review at a draft stage. EPA does not believe that the draft EIS is adequate for the purposes of the National Environmental Policy Act and or Section 309 review, and thus should be formally revised and made available for public comment in a supplemental or revised draft EIS. On the basis of the potential significant impacts involved, this proposal could be a candidate for referral to the CEQ.

* From EPA Manual 1640 Policy and Procedures for the Review of Federal Actions Impacting the Environment, February, 1987.

EPA Comments on the Rocky Mountain Laboratory Supplemental Draft EIS

Brief Project Overview:

The National Institutes of Health (NIH) prepared this December 2003 Supplemental Draft EIS to further evaluate proposed construction and operation of an Integrated Research Facility at the Rocky Mountain Laboratories (RML) in Hamilton, Montana. An earlier Draft EIS had been prepared and released for comment in May 2003.

The proposed Integrated Research Facility would include high containment, secure Bio-Safety Level - 4 (BSL-4) laboratories, as well as BSL-2 and BSL-3 laboratories, animal research facilites, offices, conference rooms, and break areas. BSL-4 labs are necessary for research into the most dangerous and exotic agents which pose a high risk of life-threatening disease, aerosol transmitted lab infections or related agents with unknown risk of transmission. BSL-4 is required for research of certain agents and experiments, such as testing of vaccines for dangerous emerging infectious microbial agents and developing therapies. Existing facilities to conduct BSL-4 research are presently limited to Atlanta, Georgia; Frederick and Bethesda, Maryland; and San Antonio and Galveston, Texas.

The RML currently has BSL-2 and BSL-3 labs, and needs to improve and expand its research facilities, including development of BSL-4 lab capabilities to conduct basic biological research on new diseases (e.g., HIV/AIDS, hantavirus pulmonary syndrome, West Nile fever, severe acute respiratory syndrome (SARS), plague, ebola virus, etc.,) and drug resistant pathogens (tubercolosis, malaria, Staphylococci aureus). In addition to basic biological research on disease causing mechanisms, RML research involves study of host immune response, new and improved vaccines and treatments, and techniques for rapidly and accurately identifying diseases and disease agents. The improved facilities are needed to improve the nation's ability to study and combat emerging infectious disease including causes, diagnosis, prevention and cure of human diseases and to protect public health in keeping with NIH's mission. NIH and its labs such as RML do not and would not work with weapons grade material, or any research associated with smallpox.

Two alternatives were considered in detail in the DEIS: the proposed action (and preferred alternative) to build and operate the Integrated Research Facility, and No Action, continuation of current RML operations. Four additional alternatives were also considered and dismissed. These include building the facility at Bethesda, Maryland; relocation of RML to a less populated area; construction of a BSL-4 research facility at another location; and construction of a research facility by another agency or at another NIH location.

The proposed action would be approximately 105,000 square feet of new buildings constructed within the 33 acre RML campus. Facilities would include a new BSL-4 laboratory located within the central core of the building surrounded by a buffer corridor between the lab

1

and the exterior; a new chilled water plant and emergency power backup system; a new additior to Boiler Building 26 to house a new natural gas fired boiler; and construction of a below grade systems and utility distribution tunnels to service the Integrated Research Facility. The BSL-4 lab at RML would be a suit laboratory (page C-11). Research will include pathogenesis, immur response, vaccine, diagnostics and therapeutics work and will focus on vector borne pathgens. RML does not and will not conduct research to develop offensive biological weapons.

Comments:

1. We are pleased that the SDEIS includes additional analysis and disclosure regarding community risk assessment for the proposal, including potential risks of release of biological agents to the community (pages S-4, 4-7 to 4-14). This risk assessment information includes: a literature review of laboratory acquired infections; a review of al infectious disease research protocols; review of all accidents, injuries and illnesses at NAAID laboratories; review of RML medical waste incinerator operations, infectious waste handling procedures, animal containment, and procedures for biological material shipment. Additionally a Maximum Possible Risk (MPR) model developed by NIH was used to assess risk of infectious agent release to the surrounding Hamilton community using anthrax spores.

   We are very pleased that quantitative and qualitative risk analysis revealed that the potential risk of release of infectious agents to the community surrounding RML is negligible, and that the SDEIS reports that there is no probability of public health harm. The literature review and NIAID retrospective study of all NIAID laboratories indicates that there is no evidence that any microorganism was released from these laboratories; nor were there any infections in adjacent civilian communities (page 4-8). The safety anc health risk assessment information provided by NIH indicates that in more than 30 years of working with BSL-4 agents in the U.S there has never been a confirmed release of an infectious agent to a community from a laboratory (page 4-5).

2. We are pleased that regular community liaison group meetings are held at the RML campus to provide a forum for discussion of public issues and concerns about RML, and that the community group will be used for oversight and monitoring of activities at the Integrated Research Facility (page1-8). It is important for the NIH to implement a comprehensive risk notification and communication program for the Hamilton community.

   This should occur in combination with the ongoing efforts to develop detailed plans in accordance with applicable regulatory guidances, standards, and safety practices for infectious agents and BSL-4 labs to ensure: 1) the security of the facility and materials transported in and out; 2) adequate safeguards against potential air, water, and solid waste/sewage release of infectious agents; and 3) adequate knowledge and training of facility workers. A comprehensive risk notification and communication for the Hamilton

84-1

2

Comment	Response
84-1	Please see Section 1.7.1 where this comment is addressed. The items mentioned will be considered when the emergency plan is revised.

community should help provide assurances to the public that risk of escape or release of disease causing agents will be reduced to as close to zero as possible to help allay public concerns.

Strong community involvement, risk management, and incident investigation programs similar to those developed for communities which are home to chemical demilitarization facilities (e.g., Tooele Army Depot) may provide useful lessons and insights which can serves as a model and help allay public concerns. Risk notification and communication is key to improving public understanding and trust, and effectively addressing public health and safety concerns. You may contact Dr. Aubrey Miller, Regional Medical Officer and Toxicologist with EPA Region 8, if you have questions about this risk notification and communication program (303-312-7023).

3. Thank you for including the Appendix E, Standard and Special Safety Practices for Biosafety Laboratories, that describes safety equipment, facility design and construction, biosafety levels, transport and transfer of biological agents, and special practices. This information provides improved understanding of proposed measures to reduce risks of release of disease causing organisms from the facility. We are pleased that proposed integrated research facility, including BSL-4 laboratory, would have special engineering and design features to prevent microorganisms from escaping into the environment, and that laboratory staff would have thorough training in handling hazardous, infectious agents; understanding primary and secondary containment functions of standard and special practices; containment equipment; laboratory characteristics; and be supervised by trained and experienced scientists (page 2-1).

4. Thank you also for including additional information regarding alternatives considered but eliminated from detailed study (pages 2-17 to 2-19). It is important for the alternatives analysis to include consideration of all reasonable alternatives, including discussion of alternatives considered but eliminated from detailed study (i.e., building the facility at Bethesda, Maryland; relocation of RML to a less populated area; construction of a BSL-4 research facility at another location; and construction of a research facility by another agency or at another NIH location). The SDEIS indicates that there are no available spaces on the existing Bethesda or Rockville, Maryland laboratory campuses capable of accommodating the proposed integrated research facility, and it is not practicable for a variety of reasons to relocate RML or to build the proposed integrated research facility at a more isolated alternate location.

5. We are pleased that the Emergency Plan would be updated to include the new Integrated Research Facility (page 2-12). It is important that emergency responses and contingencies be developed to address all potential threats and risks at the facility, from power failures to severe weather to uncontrollable natural events to criminal or terrorist activities to risk of infected insect, bird, rodent or small mammal or unknowing human contamination/transmission vectors for escape or release of disease causing agents.

3

Ideally we believe the details of such an Emergency Plan should be provided, although we agree that any information that would compromise security should not be released.

6. It is stated (page 4-7) that it takes at least 48 hours for a person exposed to infectious agents to become contagious regardless of the microbe type, and this provides adequate time to transport and initiate treatment and to isolate a potentially exposed person form the greater population. Is there potential for RML workers to become infected without their knowing it, so that they unknowingly return to their homes in the community after such a 48 hour period elapses and pose a contagious threat? **84-2**

7. It is stated that water supply to the Integrated Research Facility to the existing water main would be made with a backflow prevention device (page 2-2). Will this backflow prevention device (e.g., backflow prevention valve) adequately assure that potential backflow contamination of the Hamilton water supply by microbial agents from RML will not occur? Would potential for backflow contamination be eliminated by providing a separate water tank and water distribution system for RML to isolate it from the Hamilton water distribution system? **84-3**

8. There is some concern that harmful infectious agents or hazardous materials may have potential to escape the research facility through the wastewater stream. The description of the proposed waste decontamination system and alkaline hydrolysis process digester that would decontaminate liquid wastes is appreciated (page 2-6). We did not see information on the liquid waste decontamination system and alkaline hydrolysis process digester in Appendix E of the SDEIS. It would be helpful if the monitoring proposed to validate that adequate destruction of microbial agents has taken place in the digestion process were described in more detail. **84-4**

It is important that alkaline sludges and waste streams be adequately neutralized before disposal or discharge. Where will sludges and waste streams from the alkaline hydrolysis process be disposed of? **84-5**

We understand that odorous waste and emissions can be an issue with the alkaline hydrolysis digestion type of digestion process. Are there any measures being proposed to control potential odors emitted by this process? Also, are any environmental, safety or hazardous waste concerns anticipated with transport or use of hazardous alkaline reagents (e.g., sodium hydroxide) at the facility? **84-6**

We suggest that redundant monitoring of high temperatures and pH levels be included in the system designs to assure that bio-waste cookers and digesters adequately operate at sufficiently high temperatures and/or high pH levels to fully destroy microbial agents, and convert proteins, nucleic acids and lipids to harmless compounds. It was stated in Appendix C of the DEIS that the process used for decontamination of liquid wastes must be validated physically and biologically (page C-12), but we did not see further **84-7**

Comment	Response
84-2	There is virtually no chance that an accident that could cause an infection would go unnoticed. This type of accident would require a puncture or tear in a suit. Please see Appendix E for the BSL-4 procedures that would be followed.
84-3	A separate water tank is not needed as the backflow device has proven to be very effective and the accepted method of construction. This device will assure one way direction of flow to the new building and prevents any water from traveling back into the Hamilton City water system. The potential for backflow contamination is eliminated.
84-4	Please see Section 2.1.3 regarding waste decontamination. More specific protocols will be developed with the cooperation of the manufacturers of system components.
84-5	The organic component and pH of the effluent waste from a tissue digester are not at levels appropriate for direct discharge to the sanitary sewer. Discharge from the tissue digester will be collected in a holding tank. The contents of the holding tank will be incrementally added to the blending tank of wastewater discharge for the entire building. The dilution of the waste will in turn reduce its BOD, COD, and TSS levels to acceptable levels for discharge into the sewer.
84-6	Odorous emissions for the alkaline hydrolysis process are minimal. This equipment will be located in a well ventilated room which houses only this process. All chemical used in the process will be stored on site in minimum quantities necessary for use. Storage and use of all chemicals will follow the policies of the NIH Chemical Hygiene Plan.

Remainder on following page.

84-7 All controls for the BSL-4 liquid waste system are redundant including temperature and pH monitoring of the waste load. The system testing of the liquid waste decontamination system will include efficacy monitoring using biological indicators. Physical monitoring will include verification of physical parameters recorded by the electronic monitoring systems.

information on this process in Appendix E of the SDEIS.

84-8 9. Thank you for including information on gas decontamination procedures using paraformaldehyde in Appendix E (age E-49, E-62 to E-70). Will gas decontamination procedures adequately provide for control potentially hazardous fugitive gas emissions (e.g., escape or release of formaldehyde)? Information on health concerns associated with formaldehyde use can be found at http://www.epa.gov/iaq/pubs/formald2.html .

10. We are pleased that the RML will comply with applicable air quality permitting requirements of the Montana Dept. of Environmental Quality to maintain compliance with National Ambient Air Quality Standards (NAAQS) and Prevention of Significant Deterioration increments (pages 3-17, 4-23).

11. We are pleased that no construction would occur in or near riparian areas or wetlands, and that no liquids or wastes would be discharged to wetlands during construction and operation of the Integrated Research Facility (page 3-22).

12. Thank you for including information about property values in the vicinity of other BSL-4 laboratories (page 4-2). This information should be of interest to local Hamilton residents who live near RML.

13. We are also pleased that noise reduction features are proposed that would reduce noise from the proposed action to less than current noise levels (page 4-19).

5

Comment	Response
84-8	The BSL-4 containment facility is routinely tested to be gas tight. No fugitive gas emissions are expected. In the event of fugitive gas emission, the neutralization process would immediately begin.

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LIST OF AGENCIES AND ORGANIZATIONS TO WHOM THE EIS WERE SENT

Agencies and Organizations

Alberton Public Library

Anthrax Vaccine Network, Inc., Kathryn D. Hubbell, Pres.

Attorney General, State of Montana, Mike McGrath,

Bitterroot Disposal

Bitterroot Drug, Wayne A. Hedman, Owner

Bitterroot Public Library, Nansu Haynes

Bitterroot RCND

Bitterroot Valley EMS, Joe Kerr, Kendall Neff and Terri Shively

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Chamber of Commerce, Bob Thomas, President

City of Hamilton City Administrator, Mark Shrives

City of Hamilton Finance Officer, Dale Huhtanen

City of Hamilton Grants & Budgets, Dale E. Huhtanen

City of Hamilton Mayor

City of Hamilton Public Works, Lorin Lowry

City of Hamilton Sewer Dept

City of Hamilton Water Dept.

Coalition for a Safe Lab, Mary Wulff

CSKT, D. Fred Matt

Darby Public Library

Disaster & Emergency Services, James Greene, Administrator

Fergus County Commissioners

Flathead County Commissioners

Friends of the Bitterroot, Jim Miller

Gallatin County Commissioners

Governor of the State of Montana, Judy Martz

Granite County Commissioners

GreenPath Properties, Vicky Bohlig,

Hamilton City Council, Dayle Anderson, Mike LaSalle, Mel Monson, Carol Schwann, Jerry Steele, Claudia Williamson

Hamilton City Police, Alan Auch

Hamilton Fire Department, Buzz Greenup, Jesse Wilson

Hamilton Land Use & Planning

Hamilton Public Schools Mr. Duane Lyons, Superintendent

Heirloom Oil Portraiture, Cooper Neville

Hill County Commissioners

House District 59, Mr. Ron Stoker

House District 60, Mr. Bob Lake

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Institute of Medicine and Humanities, Herbert M. Swick, MD

KLLyncoln, Inc., Karen Linsley Lyncoln

Lake County Commissioners

Lambros Real Estate, Vicky Bohlig, Broker

Lewis & Clark County Commissioners

Madison County Commissioners

Marcus Daly Hospital, John Bartos

McCone County Commissioners

MDEQ, Jan Sensibaugh

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MDEQ; Planning/Prevention & Asst, Art Compton, Administrator

MDEQ; Tom Ellerhoff, Admin Officer

Missoula County Commissioners

Missoula Public Library

Missoulian, Michael Moore

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NIAID, Will Daellenbach
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Northwestern Energy, Pat Asay
O'Connor Center for the Rocky Mountain West
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Powder River County Commissioners
Prudential Ranch & Land, Shirley Dowling, CLG Member
Pyramid Construction, Michael Helling
Ravalli County Commissioner, Jack Atthowe, Greg Chilcott, Betty Lund and Alan Thompson
Ravalli County Detention Center, Patrick Hirt
Ravalli County Economic Development Authority, Betty Davis, Emil Erhart and Monte K. Drake
Ravalli County Museum, Helen Ann Bibler
Ravalli County Sheriff's Office
Ravalli County Superintendent of Schools
Rocky Mountain Laboratories, NIAID/NIH, Kent D. Barbian, Biologist
Rocky Mountain Labs, Kristine Schmitt
Rocky Mountain Rider Magazine, Veronica Grainger
Roosevelt County Commissioners
Rosebud County Commissioners
Sanders County Commissioners
St. Patrick Hospital & Health Sciences Center
Sweet Grass County Commissioners
Treasure County Commissioners
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GLOSSARY AND ACRONYMS

AIDS	Acquired Immune Deficiency Syndrome
BSC	Biological Safety Cabinet
BSL	Biological Safety Level
CDC	Centers for Disease Control
CEQ	Council on Environmental Quality
CFR	Code of Federal Regulations
CHDPW	City of Hamilton Department of Public Works
CLG	Community Liaison Group
dBA	Decibels, "A" Weighted Scale
ESA	Endangered Species Act
FEMA	Federal Emergency Management Agency
HEPA	High Efficiency Particulate Air
HIV	Human Immunodeficiency Virus
IATA	International Air Transportation Association
KV	Kilovolt
KW	Kilowatt
MDEQ	Montana Department of Environmental Quality
MFWP	Montana Department of Fish, Wildlife and Parks
MGD	Million Gallons per Day
MMCFY	Million Cubic Feet per Year
MPR	Maximum Potential Risk
MTNHP	Montana Natural Heritage Program
NEPA	National Environmental Protection Act
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
°C	Centigrade
°F	Fahrenheit
OD	Office of the Director
ORS	Office of Research Services
OSHA	Occupational Safety and Health Administration
PSD	Prevention of Significant Deterioration
RML	Rocky Mountain Laboratories

SARS	Severe Acute Respiratory Syndrome
SHPO	State Historic Preservation Office
SVOC	Semi-Volatile Organic Compound
TMDL	Total Maximum Daily Load
USDHHS	United States Department of Health and Human Services
USEPA	United States Environmental Protection Agency
USFWS	United States Fish and Wildlife Services
VOC	Volatile Organic Compound

Action Area – As defined by the US Fish and Wildlife Service, all areas to be affected directly or indirectly by the Federal action and not merely the immediate area involved in the action. This term is used in this EIS only for Threatened and Endangered Species.

Aerosol – a suspension of fine solid or liquid particles in gas (smoke, fog, and mist).

Affected Environment – the conditions of the area to be affected or created by the alternatives under consideration.

Alkaline Hydrolysis Process Tissue Digester - a process where strong chemical solutions and high temperatures are used to dissolve and sterilize animal tissue.

Allergic – having an abnormal reaction to environmental substances.

Alluvium - clay, silt, sand, gravel, or similar material deposited by running water.

Amino Acid - the chief components of proteins synthesized by living cells or are essential components of the diet.

Antigenic – Ability to be recognized by antibodies.

Aquifer - water-bearing layers of permeable rock, sand, or gravel.

Autoclave - an apparatus using superheated steam under high pressure for sterilization.

Bacteriology – the study of bacteria.

Biodefense – measures taken or planned to provide safety and security against biohazards.

Biohazard – containing material that may cause illness or disease.

Biological Safety Cabinet (Class II, type A or type B) – Equipment designed as a primary means of containment developed to provide personnel, product and environmental protection while working with infectious microorganisms.

Biological weapon – any material that can be deliberately distributed to cause illness or death by disease.

Bioterrorism – the use of microorganisms that cause human disease, or of toxins derived from them, to harm people or to elicit widespread fear or intimidation of society for political or ideological goals.

Carbonate - a salt or ester of acid containing carbon.

Chemical Shower – a sealed shower stall in which biological decontamination of a positive pressure personnel suit is performed, using a chemical decontaminant.

Communicable Period – The time during which and infections agent may be transferred directly from an infected person to another uninfected person.

Community Stakeholders – people in the community who are able to influence public opinion or who may be impacted by the proposed activities.

Connected Actions - are closely related and 1) automatically trigger other actions, 2) could not or would not proceed unless other actions are taken previously or simultaneously, and 3) are interdependent parts of a larger action and depend on the larger action for their justification.

Containment - describing safe methods for handling, managing, and maintaining infectious materials in the laboratory environment. The purpose of containment is to reduce or eliminate exposure of laboratory workers, other persons, and the outside environment to potentially hazardous agents.

Council on Environmental Quality – Established by Congress under the Executive Office of the President to oversee the National Environmental Policy Act (NEPA) to ensure that federal agencies meet their obligations under NEPA.

Cumulative Effects – impacts which result from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions. Cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time.

Decontamination – the process of removing harmful substances (biological, chemical or nuclear).

Direct Effect – effects which are caused by the action and occur at the same time and place.

Drug-Resistant – microbes that are able to survive medication normally used to fight them.

Emerging infectious disease –A previously unknown infectious disease, or an infectious disease new to a particular location.

Endemic – A disease that occurs continuously in a particular population.

Environmental Justice - Avoiding disproportionately high and adverse human health or environmental impacts on minority and low-income populations.

Epidemiology - branch of medical science that deals with the incidence, distribution, and control of disease in a population.

Etiologic Agent – the cause or origin of an infectious disease.

Exotic agent – Pathogens or microbes not naturally occurring in a given location.

Fair Market Value - a price at which both buyers and sellers are willing to do business.

Fauna – animal life.

Host - a living insect, animal or plant providing subsistence to a parasite

Immune Response – a natural response within the human body that occurs when a foreign molecule is detected and rendered harmless.

Immunization – a process by which medical therapy creates natural resistance within the human body .

Immunologic – pertaining to the immune system.

Immunology – study of the immune system and its responses to foreign molecules.

Incubation Period – The time interval between infection and the appearance of the first sign or symptom of the disease.

Indigenous Agent – naturally occurring in a given location.

Indirect Effects –impacts caused by an action that are not directly attributable, but instead, evolve over time. Infectious – A microbe or pathogen able to cause disease.

Infectious Agent – Pathogens or microbes able to cause disease.

Infectious Disease – and illness caused by microorganisms that can be spread from one person to another.

Ingestion –entry into body through swallowing. Intramural Laboratory – laboratories located on federal land assigned to the National Institute of Health and staffed by federal scientists.

Irreversible Commitment of Resources – those that cannot be reversed, except perhaps in the extreme long term. Examples included species extinction, permanent removal of minerals.

Irretrievable Commitment of Resources – those that are lost for a period.

Labor income - income from work or earnings.

Life-Threatening Disease – illness that may cause one to die.

Lipids - the principal structural components of living cells,. Low-income population - refers to a community in which 25% or more of the population is characterized as living in poverty, as determined by statistical poverty thresholds used by the U.S.

Microbe – microorganism.

Microorganism – a microscopic organism. Those of medical concern interest include bacteria, viruses, fungi, and protozoa.

Minority Population - refers to an area where minority individuals comprise 25% or more of the population. Minorities are people who classified themselves as African Americans, Asian or Pacific Islanders, American Indians, Hispanics of any race or origin, or other non-White races.

Mitigation – measures taken or planned to reduce or avoid impacts.

Monitoring – repeated measurement taken to ascertain effects, document compliance or effectiveness of protection measures.

Mucous Membrane – thin layer of skin that secretes mucous.

Negative Pressure – a term used when describing controlled, interior air flow that identifies a space that has lower air pressure from adjacent spaces.

Nucleic Acids - any of various acids (as DNA or RNA) that are composed of nucleotide chains.

Pathogen – a microscopic organism that causes infection and/or disease.

Pathogenesis – the mechanism by which an infectious agent leads to disease or clinical illness.

Peptides -A short chain of amino acids, usually a segment of a larger protein.

Per Capita Income - all personal income divided by total population.

Percutaneous Injury – cut or puncture of the skin.

Personal Income - all income received by individuals from all sources.

Positive Pressure –a term used when describing controlled, interior air flow from a higher air pressure space to an adjacent lower air pressure space. .

Positive Pressure Personnel Suit – A containment suit worn for protection in a Biological Safety Level 4 environment that maintains positive pressure throughout air line supplied breathing air.

Poverty - having an income below what is necessary for basic necessities – adequate housing, food, transportation, energy, health care, etc.

Preferred Alternative – the alternative that the agency is currently considering selecting.

Primary Containment -protection measures from exposure to infectious agents for personnel within the immediate laboratory environment. .

Prions - a protein particle that lacks nucleic acid and is believed to be the cause of various infectious diseases of the nervous system (as bovine spongiform encephalopathy and Creutzfeldt-Jakob disease).

Proposed Action – the activities initially described to meet the purpose and need.

Proximity Reader System – a security device that reads a card held near it to verify is access is authorized.

Reasonably Foreseeable Action – activities that are planned, which will occur in the near future, yet are not part of the Proposed Action.

Reemerging Infectious Diseases – illnesses that have been previously identified and largely controlled that have recently become more active in the human population.

Reservoir of Infection – Any animal, plant, plant, soil, or substance (or combination) in which the infectious agent normally lives and multiplies; and serves as a source of infection.

Riparian Areas – areas near water (streams, rivers, lakes, wetlands).

Salmonid – from the family *Salmonidae* (such as salmon and trout).

Sanitary Sewer – system to remove and sanitize waste and wastewater before discharge.

Scope – the range of topics considered within the environmental impact statement.

Secondary Barriers - separation between primary containment areas and non-containment areas within a laboratory facility.

Secondary Containment - provides protection of the environment external to the laboratory from exposure to infectious materials, and is provided by a combination of facility design and operational practices.

Seismic - of, subject to, or caused by an earthquake or relating to an earth vibration.

Serologic Surveillance Program – regular blood testing for exposure to agents.

Sharps – objects capable of causing punctures or cuts, which may be contaminated.

Spirochetal Relapsing Fevers – a variable, acute, epidemic disease marked by recurring high fever, usually lasting 3 to 7 days caused by slender, spirally-undulating bacteria, transmitted by the bites of lice and ticks.

Tissue Culture – the process of growing live cells outside the body for study purposes.

Transmission – mechanism by which an infectious agent is spread from source a person.

Unavoidable Adverse Effects – adverse effect that can not be avoided if the proposed action is implemented.

Wetlands - areas that are inundated or saturated by surface or ground water at a frequency and duration sufficient to support, and that under normal circumstances do support, a prevalence of vegetation or aquatic life that requires saturated or seasonally saturated soil conditions for growth and reproduction. Wetlands generally include swamps, marshes, bogs, and similar areas.

APPENDIX A
Strategic Plan for Biodefense Research

This document is available online at
http://www.niaid.nih.gov/biodefense/research/strategic.pdf

NIAID
BIODEFENSE
Preparing Through Research

NIAID Strategic Plan for Biodefense Research

February 2002

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

National Institute of Allergy and Infectious Diseases

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NIAID Strategic Plan for Biodefense Research

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Introduction

Recent deliberate exposure of the civilian population of the United States to *Bacillus anthracis* spores by means of the United States Postal Service revealed a gap in the nation's overall preparedness against bioterrorism. These attacks uncovered an unmet need for tests to rapidly diagnose, vaccines and immunotherapies to prevent, and drugs and biologics to cure disease caused by agents of bioterrorism. An important component of the overall effort to fulfill these needs is biomedical research, and in this regard, we need a substantial and accelerated research and development agenda to accomplish short- and long-term goals aimed at protection of the United States and the world population against present and future attacks by these agents.

Definition of Bioterrorism

For the purposes of this plan and the research agenda that follows from it, bioterrorism is defined as the use of microorganisms that cause human disease, or of toxins derived from them, to harm people or to elicit widespread fear or intimidation of society for political or ideological goals. From a scientific and medical perspective, this form of terrorism is best seen as a variant of the general problem of emerging infectious diseases, the only difference being that increased virulence or spread into a susceptible population is a deliberate act of man rather than a consequence of natural evolution. The NIAID strategic plan focuses on this concept of bioterrorism. Closely related, but separate from it, are acts of terrorism resulting from the use of chemical toxins, nuclear energy, or organisms or toxins primarily affecting other animals or plants. Research on the public health consequences of these forms or terrorism are the purview of other U.S. Government agencies.

NIAID's Strategic Plan

NIAID is the primary Institute at the National Institutes of Health (NIH) for emerging infectious disease research, including that on agents of bioterrorism. The mission of NIAID is to carry out the research needed to understand the pathogenesis of these microbes and the host response to them, and to translate this knowledge into useful interventions and diagnostic tools for an effective response. Accordingly, NIAID is committed to an agenda of basic and translational research for bioterrorism defense, working with partners in academia, industry, and other private and public-sector agencies. NIAID has developed this Strategic Plan to guide the implementation of the necessary research and development program. It is important to emphasize that the Strategic Plan focuses on both basic research and the application of that basic research to predetermined goals, including the development of products such as diagnostics, therapeutics, and vaccines. In the traditional manner, NIAID will provide support for the pursuit of fundamental research questions concerning microbes and the specific and nonspecific host defense mechanisms against these microbes. In addition, the Institute will work with partners in the private and public sectors to ensure that the fruits of basic research are rapidly translated into products that can be used in the worldwide Biodefense and emerging infection effort. Finally, NIAID also will collaborate with other agencies and organizations on research related to other forms of terrorism where scientific overlap and mutual opportunity exist for scientific or public health gain.

Microbes and Their Products as Agents of Bioterrorism

A number of agents (select agents) are recognized as having bioterrorism potential (Lane et. al. *Nature Medicine*. 7, 1271-1273, 2001). Research focused on these select agents will be strongly emphasized in our initial activities. We recognize that these select agents have characteristics in common with other pathogens, especially those recognized as causing naturally occurring emerging or reemerging diseases. Biologic agents that have potential to become civilian bioterrorist agents, and will be emphasized in the plan, have many of the following characteristics:

- High morbidity and mortality
- Potential for person-to-person transmission, directly or by vector
- Low infective dose and high infectivity by aerosol, with a commensurate ability to cause large outbreaks
- Ability to contaminate food and water supplies
- Lack of a specific diagnostic test and/or effective treatment
- Lack of a safe and effective vaccine
- Potential to cause anxiety in the public and in health care workers
- Potential to be weaponized

The Strategic Plan should not be limited to preexisting lists of agents (CDC Category A, B, and C—www.bt.cdc.gov/Agent/Agentlist.asp#categoryadiseases) but should remain flexible and based on characteristics that make an agent a feasible threat against civilian populations. Agents that fit some or all of these criteria will be given high priority for research and development at NIAID (see NIAID http://www.niaid.nih.gov/dmid/bioterrorism/bandc_priority.htm).

This group includes pathogens or toxins that can contaminate food and water supplies and certain zoonotic agents that can spread infection to humans from domestic animals. A number of the emerging and reemerging pathogens, such as West Nile virus, influenza viruses, and drug-resistant *Streptococcus* and *Staphylococcus* also are recognized as having many characteristics that make them potential agents of bioterrorism. In addition, chimeric organisms engineered by relatively simple genetic manipulations may pose a significant threat. Goals include development of procedures to detect such agents and development of safe vaccines, biologics, and drugs to prevent or cure illness associated with them. For many reasons, particularly a lack of adequate facilities, study of these organisms has received little attention in the recent past. Therefore, the agenda must allow for acquisition of basic information on the pathogens and the host responses to them to allow development of effective Biodefense strategies.

Role of Host Defense in Combating Agents of Bioterrorism

In addition to research and development targeted to pathogens and their toxic products, we must study both the innate and adaptive host defense mechanisms to protect against infection and disease. We can exploit recent advances in understanding the innate immune system and host response to new generation vaccines to improve vaccines and to provide the means for enhancing immunity in threatened groups. This work may include development of specific immunotherapeutics and global advances in techniques of vaccinology, such as development of improved adjuvants to hasten onset of immunity and to increase the potency and lengthen the time of protective responses. Attention to duration of specific responses both at the B- and T-lymphocyte level is indicated to determine the immune status of persons under threat from agents of bioterrorism.

We must take special note of the populations within our communities that have compromised immunity or increased risk because of occupational exposure. In addition, the very young and the elderly, pregnant women, and those with immune function suppressed by disease or by drug regimens constitute groups with special vulnerability to the threat of infection. The research agenda must consider their needs.

Biocontainment Facilities Needed to Accomplish Research Goals

Achievement of the goals in this agenda requires the construction and certification of appropriate biocontainment facilities. Facilities and procedures for the handling of these potentially lethal agents in a manner aimed at eliminating the threat to laboratory and clinical personnel or to adjacent communities are an integral element of the program. These needs include facilities in which preclinical testing of vaccines and drugs can be accomplished using appropriate animal models, as well as clinical areas for isolation and study of patients exposed to bioterrorism agents.

Summary

The NIAID research and development plan comprises a broad and comprehensive agenda with the ultimate goal of providing a strong research base that translates

into effective products to combat agents of bioterrorism. The scientific needs and areas of NIAID research emphasis have been divided into six sections:

Biology of the Microbe	Therapeutics
Host Response	Diagnostics
Vaccines	Research Resources

As detailed below, the research agenda includes specific milestones directed at immediate goals as well as crucial enhancement of information and capability to deal with any present or future threats from biologic agents directed toward the civilian population.

Biology of the Microbe

Research into the basic biology and disease-causing mechanisms of pathogens that may be used as bioterrorist agents is critical to any efforts to develop interventions against bioterrorism. Such research includes identifying and understanding the microbial components that define a pathogen's life cycle, transmission, virulence, and invasiveness. Two recently developed, powerful, and increasingly important tools that can be used to dissect these factors are genomic sequencing and proteomics. These tools, which already have been applied to other complex organisms such as *H. plyori* and *M. tuberculosis*, have uncovered potential new targets for vaccines, therapeutics, and diagnostics.

Goals

- Expand the focus of genomic and proteomic data collection and analysis of microbes that can be used as bioterrorist agents by
  - Sequencing the genomes of select organisms and strains
  - Developing central bioinformatic resources or tools for rapid use of genomic information
  - Emphasizing research in genomic, proteomic, and structural analyses
- Expand basic research opportunities on microbial physiology, ecology, molecular pathogenesis, and animal model development for Category A, B, C, and D organisms

Host Response

To develop potent, safe, and effective vaccines, accurate diagnostics, and immunotherapeutics against microbes that can be used as bioterrorist agents, it is critical to improve our understanding of the complex parameters of innate and adaptive immunity. Because most potential bioterrorist agents would infect via the respiratory or oral routes, the plan includes specific studies on mucosal immunity at these sites. Crosscutting, multidisciplinary research will facilitate translation of the considerable body of basic knowledge that exists into vaccines, passive therapies, and diagnostic methods focused on bioterrorist agents. In the same way, new discoveries of immunologic principles or applications will help ensure a robust pipeline of improved or novel products.

Goals

- Expand the understanding of and ability to modify the innate and adaptive immune response to Category A, B, C, and D organisms by
  - Defining specialized innate and adaptive immune mechanisms used by the respiratory and/or oral-gastrointestinal systems
  - Mapping the protective epitopes for each agent, their respective toxins, and pathogenic factors using computational methods, genomics, proteomics, structural biology, and immunochemistry
  - Applying computational methods to model and predict immune responses
  - Refocusing basic immunology projects to include responses against potential bioterrorist agents
  - Expanding studies on host/pathogen interactions
- Facilitate clinical research on human immunology that will assist in identifying targets within innate and adaptive immune pathways by
  - Defining interactions between innate and adaptive immune systems
  - Discovering new recognition and signaling molecular pathways involved in innate immunity
  - Assessing relevant immune polymorphisms within the population

- Develop a comprehensive catalog of the variations in human immunologic responses

Vaccines

Vaccines are one of the most successful public health measures. The key features of vaccines to be developed for civilian use against bioterrorism agents will include the rapidity by which an immune response can be elicited, whether the vaccine can modulate the clinical course of an exposed person, the safety of the vaccine in all segments of the population, and the ease of administration or use. Because of the high public health concerns associated with these pathogens, smallpox and anthrax vaccine development will remain the highest priority.

Goals

Develop and test vaccine candidates for civilian bioterrorism threats with an immediate emphasis on the licensure of new generation smallpox and anthrax vaccines by

- Expanding the infrastructure for clinical testing and evaluation to rapidly test the new generation anthrax and smallpox vaccines under development
- Establishing a centralized immunology laboratory to develop and validate tests required for licensure of smallpox and anthrax vaccines
- Supporting the continued development of newer generation smallpox and anthrax vaccines with emphasis on increased safety and timely response
- Understanding and preventing complications of smallpox vaccine such as eczema vaccinatum and vaccinia gangrenosa
- Developing animal model capability and providing the required standardization and validation, including challenge of nonhuman primates, that will be necessary for licensure of smallpox and anthrax vaccines
- Identifying, prioritizing, and supporting the development of vaccines for other high-priority agents of potential bioterrorism
- Developing animal model capability and providing the required standardization and validation for development of vaccines against other select organisms

- Developing cell-culture-based approaches for viral vaccine development
- Developing improved vaccine approaches by focusing basic research interests to expand knowledge on
    - Potential targets for vaccine design
    - Vaccine delivery systems
    - B- and T-cell protective responses
    - Adjuvant development based on innate immunity
    - Potential regulation of the innate immune system as a primary defense
    - Differences in the innate and adaptive immune systems of human neonates, infants, pregnant women, immunocompromised populations, and the elderly (including genetic polymorphisms) that may influence responses to vaccines, both general and specific
- Ensuring manufacturing capacity for all delivery vehicles, vectors, and types of vaccines
- Expanding preclinical toxicology capability needed for vaccine development

Therapeutics

The development of new anti-infectives and immunotherapies, including antitoxins, and the screening of existing therapeutic agents to determine whether they have activity against select agents of bioterrorism remain a top priority. Although it has been shown that many of the bacterial agents in categories A, B, C, and D are sensitive to a number of antibiotics, licensure of these products for use in humans will require additional information. In addition, the underlying concern about the ease of development of antimicrobial resistance will factor into our need to increase this category of options. There are currently no antivirals or antisera licensed for use against smallpox and no antitoxin or other antisera licensed for use against anthrax. One antiviral, cidofovir, which is under IND for use as a backup to vaccinia immune globulin (VIG) in the setting of vaccinia immunizations and as a potential therapy in smallpox outbreaks, requires hospitalization during administration. VIG, which is required for the evaluation of smallpox vaccine candidates, is in extremely limited supply. The need to develop

and license a cadre of validated antimicrobials, alternatives to existing immunotherapies, and antitoxins, with a focus on smallpox and anthrax, will receive the highest priority.

Goals

Increase the number of licensed antimicrobials, immunotherapeutics, and antitoxins available for responding to select agents of bioterrorism through accelerated screening of new and existing agents by

- Expanding capacity for *in vitro* and *in vivo* evaluation of antimicrobials, immunotherapeutics, and antitoxins
- Developing a replacement to existing VIG
- Establishing additional agent-specific high-throughput screens
- Developing the animal model capability, including BSL-4 challenge on nonhuman primates and providing the required validation of animal models that will be necessary for licensure of new therapeutics for anthrax and smallpox
- Identifying, prioritizing, and supporting the development of other therapeutic interventions for specific agents
- Synthesizing, if needed, active lead compounds in sufficient quantities for preclinical pharmacokinetics, animal model efficacy, mechanisms of action, and toxicology studies
- Developing the animal model capability and the validation and standardization needed to assess efficacy
- Establishing required safety and pharmacokinetics data needed for licensure of new compounds
- Focusing basic research interests to expand knowledge on
    - Potential targets for therapeutic intervention
    - Discovery, characterization, optimization, and development of monoclonal and polyclonal antibodies

- Discovery and development of soluble receptors and mediators of the innate immune system as effective immunotherapeutic agents
- Differences in immune systems of human neonates, infants, pregnant women, immunocompromised subpopulations, and the elderly (including genetic polymorphisms), which may impact immunotherapeutics

Diagnostics

One of the hallmarks of a successful bioterrorist agent is clinical misdiagnosis or delayed diagnosis. The ability to rapidly identify the introduction of a bioterrorist agent into the civilian population will require highly sensitive, specific, inexpensive, and easy-to-use diagnostic tools located at primary care institutions. Ideally, these tests could also evaluate the possible spectrum of antimicrobial resistance and be connected to a central database. Centralized confirmatory testing also should be expanded to include routine evaluations of positive samples for weaponization, genetic profiling, and bioengineered properties. The theoretical ability to design and develop such assays exists. For example, we have microchip-based platforms, which could contain thousands of microbial signature profiles that are either nucleic acid or protein based. Identification of the microbial signatures is ongoing. If bioterrorism-based diagnostics could be combined with other more common and routine diagnostic needs, the value of these diagnostics to primary care institutions would ensure interest and use.

Goals

Expand interest and direction in the development of highly sensitive, specific, inexpensive, and easy-to-use tools for clinical diagnosis of potential agents of bioterrorism by

- Emphasizing this research interest
- Focusing genomic and proteomic analysis on identification of microbial signatures
- Providing standards for validation and comparison of potential products

Research Resources

The lack of routine clinical importance, and thus the absence of scientific and clinical expertise associated with the microbes, is another hallmark of a successful bioterrorist agent. The ability to develop the tools and interventions needed in a public health emergency will require the attention of the scientific community to these areas. The development of centralized sources of generalized as well as specific expertise in bioterrorism areas, such as *in vivo* and animal model development, production of standardized and validated reagents and tests, expertise in the development and humanization of antibodies, bioinformatics, diagnostic validation, and vaccine production (GLP/GMP pilot lots), will be required to speed the development of new generation products.

Goals

Expand the development of general and specific research resources to assist in the rapid development of new tools and interventions for use in bioterrorism by

- Developing 6 to12 regional Centers of Excellence for Bioterrorism and Emerging Diseases Research
- In addition to general capabilities, each center would develop a specialized expertise of importance to product development. Suggested areas of applied research emphasis include diagnostic development and validation, small- and large-animal model development, assay development and validation, immunotherapeutics, and host/pathogen interactions
- Encouraging and developing relationships between academia and industry
- Developing a centralized research reagent repository for standardized reagents that could be centrally controlled and accessed by appropriate investigators
- Developing BSL-3/4 capability at Centers of Excellence for Bioterrorism and Emerging Diseases Research
- Providing sufficient nonhuman primates to complete the testing and analysis of the therapeutic and vaccine products that are developed
- Expanding research training opportunities
- Expanding NIH clinical and basic research capabilities

Implications of Biodefense Research for Other Diseases

The positive spinoffs for other diseases that will result from the large investment in research on Biodefense will be substantial. First, many of the organisms in question and a host of other emerging infectious diseases and drug-resistant microbes are significant public health threats in endemic areas, especially in the developing world. Basic and translational research aimed at them will have direct and obvious benefit to the people threatened by them in nature. Second, research on microbial biology and pathogenesis of these organisms will enhance understanding of other more common and naturally occurring infectious diseases, both in the United States and around the world. Third, advancements in the arena of diagnostics, therapeutics, and vaccines will improve our ability to diagnose, treat, and prevent major killer-diseases, such as malaria, tuberculosis, HIV/AIDS, and a spectrum of emerging and reemerging diseases. Fourth, basic research will greatly enhance our understanding of the molecular and cellular mechanisms of the innate immune system and its relationship to the adaptive immune system, and lead to improvements in the treatment and prevention of immune-mediated diseases, such as systemic lupus erythematosus, rheumatoid arthritis, and other autoimmune diseases. Finally, improved understanding of the mechanisms of regulation of the human immune system will have positive spinoffs for diseases such as cancer, immune-mediated neurologic diseases, and allergic and hypersensitivity diseases, as well as for the prevention of rejection of organ transplantation.

APPENDIX B
Characteristics of Diseases Studied at RML

Table B-1
Characteristics of Primary Diseases That Are Being Or Have Been Studied at the RML

Disease	Infectious Agent	Occurrence	Reservoir[1]	Transmission[2]	Incubation Period[3]	Communicable Period[4]
Bacterial diseases						
Lyme Disease	*Borrelia burgdorferi*	Along the Atlantic coast, concentrated between Massachusetts and Maryland; upper Midwest; and local areas of California and Oregon. Cases reported from 47 states, Canada. Also occurs in Europe and Asia.	Primarily wild rodents.	Primarily ticks of the genus *Ixodes*.	3-32 days, mean of 7-10 days.	No evidence of person-to-person transmission.
Endemic Relapsing Fever	*Borrelia hermsii*	Endemic in the United States	Rodents and soft-bodied ticks	Ticks *Onitodoros hermsii*	5-15 days.	No person-to-person transmission
Plague	*Yersinia pestis,*	Wild rodent plague occurs in the western U.S.; large areas of South America; north central, eastern, and southern Africa; central and southeast Asia, and south-eastern Europe near the Caspian Sea; and localized areas in the Russian Federation and Kazakhstan. Recent outbreaks of have occurred in in Africa and Asia, and local outbreaks South America.	Wild rodents, rabbits and hares, wild carnivores and domestic cats.	People generally become infected by being bitten by an infected rodent flea or handling an infected animal; rarely by airborne droplets from human patients or household cats with plague pharyngitis or pneumonia.	1-7 days.	Fleas may remain infective for months. Pneumonic plague may be highly communicable under some conditions. Bubonic (swollen lymph nodes) form is rarely transmitted directly.
Tuberculosis (TB)	*Mycobacterium tuberculosis* complex. Includes *M. tuberculosis* and *M. africanum* from humans, *M. bovis* from cattle	Worldwide.	Humans, rarely primates. Possibly diseased cattle, swine, badgers, and other mammals	Coughing or sneezing by people with tuberculosis of the lungs or throat. Rarely transmitted through direct contact with broken skin or mucous membrane. Bovine tuberculosis may be acquired from tuberculosis cattle or unpasturized milk products.	2-10 weeks. Latent (inactive, asymptomatic) infection may persist for a lifetime.	As long as viable tubercle bacilli are being discharged while coughing.

Table B-1
Characteristics of Primary Diseases That Are Being Or Have Been Studied at the RML

Disease	Infectious Agent	Occurrence	Reservoir[1]	Transmission[2]	Incubation Period[3]	Communicable Period[4]
Salmonellosis	*Salmonella enterica serovar Typhimurium*	Worldwide	Wide range of domestic and wild animals, including poultry, swine, cattle, rodents, and pets; also infected humans.	Eating contaminated food (raw or undercooked). Fecal-oral transmission from person to person.	6-72 hours	Extremely variable, throughout the course of infection; usually several days to weeks.
Antibiotic-resistant Staphylococcus infection	*Staphylococcus aureus*	Worldwide	Humans, rarely animals	Person-to-person.	Variable and indefinite. Often 4-10 days.	Variable: as long as purulent lesions continue to drain or the carrier state persists.
Streptococcal epidemics and vaccine development	*Streptococcus pyogenes*	Worldwide	Humans	Person-to-person, often through exposure to large respiratory droplets from an infected patient or carrier, or direct contact.	Short; usually 1-3 days.	10-21 days in untreated and uncomplicated cases. Weeks to months in untreated conditions with purulent discharges.
Psittacosis (Parrot fever)	*Chlamydia psittaci*	Worldwide	Primarily parakeets, parrots and love birds; less often in poultry, pigeons, canaries and sea birds.	Inhaling the agent from desiccated droppings, secretions, and dust from feathers of infected birds.	1-4 weeks.	No person-to-person transmission. Infected birds may shed the agent intermittently, and sometimes continuously for weeks to months.
Chlamydial Pneumonia	*Chlamyid pneumoniae,* strain TWAR	Worldwide	Humans; no avian associations, not dogs or cats.	Unknown, possibly direct contact with secretions, spread via particles to which bacteria adhere, and airborne spread.	Unknown, possibly at least 20 days	Unknown, but believed to be 8 months or more.

Table B-1
Characteristics of Primary Diseases That Are Being Or Have Been Studied at the RML

Disease	Infectious Agent	Occurrence	Reservoir[1]	Transmission[2]	Incubation Period[3]	Communicable Period[4]
Conjunctivitis ("pinkeye")	*Chlamydia trachomatis*	Worldwide	Humans	Direct contact with infectious eye or nasal discharges, or contact with contaminated towels or clothing.	5-12 days	As long as active lesions are present.
Sexually transmitted Chlamydia	*Chlamydia trachomatis*	Worldwide	Humans	Person-to-person transmission through sexual intercourse.	7-14 days.	Unknown
Rickettsial diseases						
Q Fever	*Coxiella burnetii*	Reported from all continents. Endemic in areas where reservoir animals are present. Veterinarians, ranchers, farmers, meatpackers, lab workers are at high risk.	Sheep, cattle, goats, cats, dogs, some wild mammals, birds, ticks are natural reservoirs	Commonly transmitted by airborne coxiellae in dust particles contaminated with birth fluids or excreta from infected animals.	usually 2-3 weeks.	Direct person-to-person transmission is unlikely. Possibly through contaminated clothing.
Rocky Mountain Spotted Fever	*Rickettsia rickettsii*	Throughout the U.S, and in Canada, Central and South America.	Ticks, small and medium-sized mammals.	Ticks	3-14 days	No person-to-person transmission.

Table B-1
Characteristics of Primary Diseases That Are Being Or Have Been Studied at the RML

Disease	Infectious Agent	Occurrence	Reservoir[1]	Transmission[2]	Incubation Period[3]	Communicable Period[4]
Viral Diseases						
Acquired Immuno-deficiency Syndrome (AIDS)	Human immunodeficiency virus (HIV), a retrovirus. Two serologic types: HIV-1 and HIV-2.	Worldwide	Humans	Person-to-person transmission through sexual contact, sharing HIV contaminated needles and syringes, transfusion of infected blood or its components, transplant of infected tissues or organs. Transmission through bodily secretions has not been reported.	Generally 1-3 months. Time from infection to diagnosis can be <1 year to 15 years or more.	Unknown; presumed to be throughout life.
Non-HIV retroviral infections e.g., (Adult T-cell leukemia, T-cell lymphosarcoma, peripheral T-cell lymphoma)	Retroviruses; e.g. human T-cell lymphotrophic virus (HTLV-I, HTLV-II)	Japan, Caribbean, Pacicfic coast of South America, equatorial Africa, southern USA.	Humans	Infection early in life primarily through breast milk. Also through transfer of blood or blood products, IV drug use, or sexual activity.	Exposure through breast milk leads to tumor development in the adult with a peak at age 50.	Throughout infection.
Aleutian mink disease parvovirus	Parvoviruses	Worldwide	Wild and domestic mink and mustelids	Contact with infected animals through biting, urine and respiratory secretions,	Variable; 20-90 days.	Throughout infection
Rabies	Rabies virus; a rhabdovirus of the genus *Lyssavirus*	Worldwide	Wild and domestic canids, skunks, raccoons, mongooses, and certain bats are primary reservoirs.	Saliva of a rabid animal is introduced by a bite or scratch, rarely through a break in the skin or intact mucous membrane.		While theoretically possible, person-to-person transmission has never been documented.

Table B-1
Characteristics of Primary Diseases That Are Being Or Have Been Studied at the RML

Disease	Infectious Agent	Occurrence	Reservoir[1]	Transmission[2]	Incubation Period[3]	Communicable Period[4]
Agents of transmissible spongiform encephalopathies (prion diseases). A group of degenerative diseases of the brain associated with an abnormal from of prion protein						
Transmissible Spongiform Encephalopathy (TSE)	Believed to be a self-replicating prion protein.	Reported from countries all over the world. Examples of TSEs include: scrapie, in goats and sheep; bovine spongiform encephalopathy (BSE), in cattle; chronic wasting disease (CWD) of deer and elk; Creutzfeldt-Jakob disease (CJD), variant CJD, Gerstmann-Sträussler-Scheinker syndrome, kuru and fatal familial insomnia in humans.	For human-related TSEs, human cases are the only known reservoir. While there is no documentation of human infection acquired from animals, this has been suggested.	Unknown; but there have been cases of CJD acquired from tissue transplants and grafts to eye and nervous system, injections of growth and other hormones. Variant CJD may be acquired through consumption beef with BSE	15 months to 30 years or more.	Tissues of the central nervous system are infectious throughout illness. Lymph tissues and other organs may be infectious before signs of illness appear.
Scrapie[7], TSE of sheep and goats. Not know to infect humans.	Believed to be a self-replicating prion protein.	Worldwide	Sheep and goats	Through exposure to fluid and tissue of infected sheep or goats.	2-5 years.	Immediately post-partum.

[1] Reservoir of infection – Any animal, plant, plant, soil, or substance (or combination) in which the infectious agent normally lives and multiplies; and serves as a source of infection.

[2] Transmission – Mechanism by which an infectious agent is spread from source or reservoir to another person.

[3] Incubation Period – The time interval between infection and the appearance of the first sign or symptom of the disease.

[4] Communicable Period – The time during which and infections agent may be transferred directly from an infected person to another uninfected person.

Source: APHA. 2000. The control of communicable diseases manual (17th edition), J. Chin, editor. American Public Health Association, 800 I Street, NW, Washington, DC 20001-3710.

Table B-2

Characteristics of Viral Diseases Assigned to Biosafety Level 4.[1]

Disease	Infectious Agent	Occurrence	Reservoir[2]	Transmission[3]	Incubation Period[4]	Communicable Period[5]
Tick-borne encephalitdes a. Central European tick-borne encephalitis (CEE Subtype) b. Russian Spring-Summer Encephalitis (FE Subtype	A complex within the flaviviruses; minor antigenic differences exist. Viruses causing these diseases are closely related.	CEE Subtype Predominates in Europe, while FE Subtype has been found predominantly in the far eastern region of the former Soviet Union.	Ticks or ticks and mammals in combination. Rodents and other small mammals and birds serve as sources of tick infections with CEE and FEE Subtypes.	Bite of an infected tick or by consumption of milk from certain infected animals.	7-14 days.	No direct person-to-person transmission.
Congo-Crimean hemorrhagic fever	Congo-Crimean hemmorhagic fever virus (Bunyaviridae, *Nairovirus*)	Observed in the steppe regions of western Crimea, Kersch Peninsula, Kazakhstan, Uzbekistan, Rostov and Astrakhan regions of Russia, Albania and Bosnia-Herzogovina, Bulgaria, Iraq, Arabian Peninsula, Pakistan, western China, tropical Africa and South Africa.	Hares, birds and *Hyalomma* ticks. Domestic animals may serve as hosts. Hosts are unknown in tropical Africa.	Bite of an infected adult tick. Direct person-to-person transmission through contact with blood and secretions from infected patients. Infection also associated with butchering infected animals.	1-12 days, usually 1-3 days.	During period of infection. Highly infectious in hospital setting; infections are common following exposure to blood and secretions.
Ebola hemorrhagic fever	Ebola virus; a filovirus, related to but antigenically distinct from Marburg virus.	Confirmed cases reported from Africa in the Democratic Republic of the Congo, Republic of the Congo, Gabon, Sudan, Ivory Coast, and Uganda.	Unknown despite extensive studies. Believed to be animal-borne	Person-to-person transmission through direct contact with infected blood secretions, organs or semen. Risk is highest during late stages of illness. Under natural conditions, airborne transmission among humans has not been documented.	2-21 days	As long as blood and secretions contain virus.

Table B-2

Characteristics of Viral Diseases Assigned to Biosafety Level 4.[1]

Disease	Infectious Agent	Occurrence	Reservoir[2]	Transmission[3]	Incubation Period[4]	Communicable Period[5]
Nipah virus encephalitis[7].	Nipah virus; a paramyxovirus	Malaysia	Maybe fruit bats. Infected pigs may serve as a source of human exposure.	Believed to be by transmitted via aerosols, but transmission efficiency from pigs to humans is low. No documented person-to-person transmission.	Unknown	Unknown
South American arenaviral hemorrhagic fevers: a. Argentinian b. Bolivian c. Venezuelan d. Brazilian	Tacaribe complex of arenavirus: a. Junín virus. b. Machupo virus. c. Guanarito virus. d. Sabiá virus.	a. Argentinian pampas. b. Rural northeastern Bolivian c. Venezuelan d. Brazilian	Wild rodents; but unknown for Sabiá virus.	Transmission to humans occurs primarily by inhalation of small particle aerosols derived directly from rodent excreta containing virus, saliva, to body fluids. Virus deposited in the environment may also be infective when ingested or by contact with cuts or abrasions. While uncommon, person-to-person transmission of Machupo virus has been documented in health care and family settings.		
Kyasanur Forest disease	*Flavivirus belonging to the tickborne encephalitis-louping Ill complex.*	Kyasanur Forest of the Shimonga and Kanara districts of Karnataka, India.	Probably rodents, shrews, monkeys, and ticks.	By bite of infective (especially nymphal) ticks; most likely *Haemaphysalis spinigera*.	3-8 days.	Not directly transmitted from person to person. Infected ticks remains so for life.
Omsk hemorrhagic fever	*Flavivirus belonging to the tickborne encephalitis-louping Ill complex.*	Forest steppe regions of western Siberia; within the Omsk, Novosibirsk, Kurgan and Tjumen regions.	Rodents, including muskrat, and ticks.	By bite of infective (especially nymphal) ticks; most likely *Dermacentor reticulates and D. marginatus*. Direct transmission from muskrat to human occurs, with disease in families of muskrat trappers.	3-8 days.	Not directly transmitted from person to person. Infected ticks remains so for life.

Table B-2

Characteristics of Viral Diseases Assigned to Biosafety Level 4.[1]

Disease	Infectious Agent	Occurrence	Reservoir[2]	Transmission[3]	Incubation Period[4]	Communicable Period[5]
Lassa fever	Lassa virus; an arenavirus, serologically related to lymphotocytic choriomeningitis, Machupo, Junín, Guanarito and Sabiá viruses.	Sierra Leone, Liberia, Guinea and regions of Nigeria.	Wild rodents; in west Africa, the *Mastomys* species complex.	Primarily through aerosol or direct contact with excreta of infected rodents deposited on surfaces such as floors and beds or in food and water. Direct contact with blood through inoculation with contaminated needles and pharyngeal secretions or urine of infected patient. Infections can also spread by sexual contact.	6-21 days.	During acute febrile phase when virus is present in the throat. Virus may be excreted in urine of patients for 3-9 weeks from onset of illness.
Marburg fever	Marburg virus; a filovirus, related to but antigenically distinct from Ebola virus.	Zimbabwe, Kenya, Democratic Republic of the Congo. Six cases in Germany and Yugoslavia in 1967 followed exposure to African green monkeys from Uganda.	Unknown despite extensive studies. Believed to be animal-borne	Person-to-person transmission through direct contact with infected blood, secretions, organs or semen. Risk is highest during late stages of illness. Under natural conditions, airborne transmission among humans has not been documented	3-9 days	As long as blood and secretions contain virus

APPENDIX C
Transportation of Agents

TRANSPORTATION OF BIOLOGICAL AGENTS

Biological agents and infectious substances are closely related terms found in transfer and transportation regulations. Biological agents including infectious substances may exist as purified and concentrated cultures but may also be present in a variety of materials such as body fluids, tissues, and soil samples (USDHHS 1999). Federal and state agencies' recognition of these materials as hazardous, results in strict enforcement of regulations applicable to transportation and transfer.

Federal agencies with regulatory authority include the U.S. Department of Transportation (DOT), U.S. Postal Service (USPS), U.S. Department of Health and Human Services (USDHHS), and the International Civil Aviation Organization (ICAO). The National Institutes of Health (NIH) policy manual refers the user to policies specific to transportation and transfer of biological agents that have been developed, and reference requirements of the aforementioned agencies (USDHHS 1998).

Transportation

Transportation refers to packaging and shipping biological agents and materials by land, air, or sea, generally or by a commercial carrier. Regulations concerning transportation of biological agents are aimed at ensuring that the public and workers in the transportation chain are protected from exposure to any agent in the package. Protection during transportation is achieved through:

- Requirements for rigorous packaging that will withstand handling and contain all liquid material within the package without external leakage, and specific requirements of shipping carriers;
- Appropriate labeling with biohazard symbol and other labels to alert workers in the transportation chain to hazardous contents of the package;
- Documentation of hazardous contents of package should such information be necessary in an emergency situation; and,
- Training staff in the transportation chain to respond to emergency situations.

Packaging and Shipping

The safe transportation of hazardous materials is a matter of concern to the public, Congress and Federal, state and local officials. To ensure public safety and minimize risks posed by hazardous materials in transportation, Congress requires the Secretary of Transportation to prescribe regulations for safe transportation of hazardous materials.

The Research and Special Programs Administration is the agency within the Department of Transportation responsible for developing and issuing hazardous materials regulations (HMR: 49CFR Parts 171-180). The HMR govern the classification, hazard communication, and packaging of hazardous materials for transportation.

Also regulating the packaging and shipping of dangerous goods is the International Civil Aviation Organization. The International Air Transport Association (IATA) annually publishes the *IATA Dangerous Goods Regulations.* This manual is based on the International Civil Aviation Organization Technical Instructions. It incorporates additional operational requirements, which provide a harmonized system for operators to accept and transport dangerous goods safely and efficiently. In recent years, the DOT regulations and the ICAO regulations have been revised to reflect, generally, the same requirements.

Infectious substances are one class (Division 6.2) of hazardous materials regulated under these rules. An infectious substance may not be offered for transportation or transported interstate of foreign commerce by rail, water, air or highway unless published requirements are met.

Packaging is the essential component in the safe transport of dangerous goods. The IATA and DOT Regulations provide specific packing instructions for all dangerous goods. The packing instructions require the use of UN performance-tested specification packaging. Infectious substances require tertiary containment where the primary and secondary inner containers are watertight. An inner container must be capable of withstanding internal pressure of 95 kpa at -40 degrees F to 131 degrees F. Outer packaging must be capable of passing a 9 m drop test, penetration testing and a vibration standard. Dangerous goods must be properly identified, classified, packed, marked, labeled, documented and in the condition for transport in accordance with these regulations.

Training is also an essential element in maintaining safe transportation of dangerous goods. It is required that all individuals involved in the preparation or transport of dangerous goods be properly trained to carry out their responsibilities. Depending on the job-function, this may entail only familiarization training or may also include more detailed training in the intricacies of the regulations. It is important to remember that dangerous goods are very unlikely to cause a problem when they are prepared and handled in compliance with DOT and IATA regulations.

The proper declaration of the dangerous goods by the shipper ensures that all in the transportation chain know what dangerous goods they are transporting, how to properly load and handle them and what to do if an incident or accident occurs during transport.

In addition to the IATA and DOT regulations for transport, several agencies of the US Government require permits or declarations for transport or transfer of infectious or hazardous materials:

US Department of Health and Human Services, Public Health Service

US Department of Agriculture, Animal Plant Health Inspection Service, National Center for Import and Export

US Department of Interior, US Fish and Wildlife Service

US Department of Commerce, Export Administration Regulations

Labeling

In accordance with U.S. DOT, Research and Special Programs Administration requirements, as specified under 49 CFR Part 172.323 and 172.432, substances classified as a Biohazard (primarily medical wastes) or as an Infectious Substance (bloodborne pathogens) are specifically labeled. These labels, illustrated in Figure C-1, must be present on two opposing sides or ends of the package, measure a minimum of 6 inches on each side, and must be visible from the direction it faces.

In addition, NIH specifically requires that the correct UN number [i.e. UN2814 (human) or UN2900(animal)] must be recorded on the front of the outside packaging followed by the proper shipping code. All packages must also be marked on the outside with the name and telephone number of a person responsible for the shipment.

Documentation

Several agencies require NIH to obtain specific permits prior to shipment of hazardous biological substances depending on the nature of those substances. Permitting authorities include the following:

- Director, Centers for Disease Control, Public Health Service, USDHHS - pursuant to Section 215 of the Public Health Service Act, as amended (42 U.S.C. 215) and Sections 71.54 and 72.3 of Title 42 of the Code of Federal Regulations (CFR).
- U.S. Department of Agriculture (USDA) regulations (Section 122.2 of Title 9, CFR, and Title 7 CFR Part 330).
- U.S. Fish and Wildlife Service (USFWS), U.S. Department Interior (50 CFR Parts 13 and 14).
- Department of Commerce – the Export Control Act of 1949 (as amended).

- CDC/NIH publication, Biosafety in Microbiological and Biomedical Laboratories provides guidance for classification and containment standards for Biosafety Level (BL) agents 1-4.

Training

Selected research laboratory employees do receive training that is specific to the transportation of bloodborne/airborne pathogens. All research laboratory employees receive overall training and numerous safeguards have been implemented as policy or by law that apply to the handling practices required in the transportation of these materials. Notable regulations administered by the Occupational Health and Safety Administration (OSHA) under 29 CFR Part 1910.1030 include the following:

- Exposure Control Plan, 29 CFR 1910.1030(c)(1): Each employer having an employee(s) with potential for occupational exposure to bloodborne pathogens is required to establish a written Exposure Control Plan designed to eliminate or minimize employee exposure potential. Elements of the Exposure Control Plan include: evaluation of exposure incidents; accessibility to employees; annual review and updates; incorporation of improvements in technology; and, input solicited from non-managerial employees.
- Exposure Determination, 29 CFR 1910.1030(c)(2): Exposure determinations shall be prepared for employees with potential for occupational exposure including lists of job classifications, and specific tasks and procedures that pose potential risk.
- Engineering and Work Practice Controls, 29 CFR 1910.1030(d)(2): Work practice controls shall be used to eliminate or minimize employee exposure. Employees are required to provide facilities and training of employees regarding the following work practices: washing; contaminated sharps disposal; puncture resistant and leakproof containers; prohibited practices in designated areas (e.g., eating, smoking, applying cosmetics); food and drink storage; handling practices to prevent splashing or spattering; container labeling; and, equipment and shipping container decontamination.
- Personal Protective Equipment, 29 CFR 1910.1030(d)(3): Employers shall provide appropriate personal protective equipment to employees when there is potential for occupational exposure. Employers responsibilities in providing such equipment include the following: ensuring employee use of the appropriate equipment; ensuring accessibility to the equipment; cleaning, laundering, and disposal of equipment; repair and replacement as needed to maintain its effectiveness; and, providing designated equipment removal and storage areas.

Transfer of Biological Agents

Transfer refers to the process of exchanging materials between facilities (USDHHS 1999). Regulations concerning transfer of select agents are intended to ensure the change in possession of select materials is within the best interests of the public and the nation. Security in transfer is achieved by the following:

- Justification of need for the select agent in the transfer process, and subsequent approval of the transfer process by a federal authority;
- Documentation of personnel and facilities involved in the transfer; and,
- Notice of delivery.

Justification and Approval

In accordance with 42 CFR Part 73, NIH and CDC require completion of CDC Form EA-101 for transfer of any select agent. Completion of the form is intended to provide adequate justification for the transfer, and acquire all necessary approvals. Specific information required by CDC Form EA-101 includes:

- Name of requestor and requesting facility;
- Name of transferor an transferring facility;

- Names of responsible facility officials for both transferor and requestor;
- Facility registrations numbers;
- Name of the agent(s) being shipped;
- Proposed use of the agent(s); and,
- Quantities (number of containers and amount per container) of agent(s) being shipped.

Personnel and Facility Documentation

CDC Form EA-101, as discussed above, requires of NIH employees requesting and transferring select agents, the officials responsible for approving those requests, and the facilities receiving and transferring the material.

Notice of Delivery

In accordance with *42 CFR Part 72/RIN 0905-AE70, CDC* requires notice of delivery of materials known to contain etiologic agents. Requesting facility responsible official must acknowledge receipt of the agent telephonically or otherwise electronically within 36 hours of receipt and provide a paper copy or facsimile transcript of receipt to the transferor within three business days of receipt of the agent.

Upon telephonic acknowledgment of receipt of the agent, the transferor shall provide a completed paper copy or facsimile of CDC Form EA-101 within 24 hours to registering entity in accordance with 72.6(c)(2) for filing in a centralized repository.

References

USDHHS 1998. U.S. Department of Health and Human Services, NIH Policy Manual, 3035 – Working Safely With Hazardous Biological Materials, Issuing Office: ORS/DS 496-2960. Release Date: 05/06/98.

IATA Dangerous Goods Regulations (DRG)

US Department of Transportation (49 CFR Parts 171-180)

US Department of Health and Human Services, Public Health Service (42 CFR Part 71: Foreign Quarantine, Part 71.54 Etiologic Agents, Hosts and Vectors); (42 CFR 72: Interstate Shipment of Etiologic Agents)

US Department of Agriculture, Animal Plant Health Inspection Service, National Center for Import and Export (7CFR 340); (9 CFR Parts 92, 94, 95, 96, 122 and 130)

US Department of Interior, U.S. Fish and Wildlife Service (50 CFR Part 14: IMPORTATION, EXPORTATION, AND TRANSPORTATION OF WILDLIFE)

US Department of Commerce, Export Administration Regulations (15 CFR chapter VII, subchapter C); (15 CFR Parts 730 to 799)

US Postal Service (39 CFR Part 111: Mailability of Etiologic Agents)

US Department of Labor, Occupational Safety and Health Administration (29 CFR Part 1910.1030)

APPENDIX D
Review of Biocontainment Laboratory Safety Record

Biosafety at National Institute of Allergy and Infectious Diseases:

1982-2003

Karl M. Johnson, M.D.

October 15, 2003

Biosafety at National Institute of Allergy and Infectious Diseases

1982-2003

The National Institutes of Health and the Centers for Disease Control (NIH/CDC) first promulgated National Guidelines for safe work with a broad range of infectious organisms in 1980. Four levels of physical containment and work practices were designated for agents with different virulence for humans and relative risk of infection from aerosols induced by laboratory manipulation. Biosafety Level 3 (BSL-3) is reserved for organisms that cause serious disease and which are known to be infectious via the respiratory route. Examples include *Mycobacterium tuberculosis* and West Nile virus. For such agents all procedures must be carried out in biosafety cabinets (BSC) fitted with high efficiency filters (HEPA). Centrifuges require sealed rotors so that aerosols that ensue if a tube breaks during spinning runs will be contained until the rotor is opened under the BSC. Air in such laboratories is maintained at negative pressure relative to hallways and cannot be blended with air to other laboratories and offices in order to prevent potential infection to others in the building. More and more such laboratories also have HEPA filters on laboratory room exhaust.

In addition to agents known to be aerosol transmitted, microbiological science continues to confront newly discovered viruses and bacteria for which aerosol infectiousness is uncertain. The NIAID has adopted a policy for such organisms that stipulates BSL-3 equipment and practices in BSL-2 laboratories with negative pressure. Work with the Human Immunodeficiency Virus (HIV) in the early 1980s led to adoption of that strategy for HIV and its close animal virus relatives, a policy that continues. Similar standards were initiated for work with hepatitis viruses at request of senior investigators, largely because new agents that cause hepatitis continue to emerge and little is known in early years regarding their infectiousness as aerosols.

This review is 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, MD, and at the institute's Rocky Mountain Laboratories in Hamilton, Montana.

Senior scientists were interviewed to ascertain agents 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 the past 21 years all such accidents were to be reported quickly to the NIH Occupational Medical Service (OMS) for epidemiologic and medical evaluation as well as immediate prophylactic treatment if indicated. Invasive wounds in course of laboratory work and clinical care of persons with chronic HIV infection are of continuing concern. The OMS is now able to provide antiviral therapy within two hours of an accident on a 7day/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 for 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 six month

intervals; all others 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 Rocky Mountain Laboratories were reviewed with biosafety and scientific staff at that facility.

The detailed report is organized by Laboratory within the NIAID Division of Intramural Research. Agents, research agendas, containment 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 agent 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 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 2000 person hours per year in exposure to microbial organisms, impressive numbers emerge as shown in the following Table.

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	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	0	2	15
Total	1	4	24

* One HIV invasive accident treated with anti-retroviral drugs. No infection ensued.

One clinical infection without sequelae and four silent infections in more than three 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.

Biosafety in NIAID laboratories demands, and receives, constant vigilance. I recommend, however, better documentation of communication between the OSHB and NIH Division of Engineering Services. I was unable to find very many records of specific facility problems and their outcomes. It might be well to have a brief computerized form for registry of each event that requires action, together with follow-up reports that find their way to OSHB.

Another concern is design and function of air handling systems for BSL-3 laboratories. In both Building 10 and the new Building 50, BSC IIB cabinets directly ventilated externally are an essential part of the overall exhaust system that always must be greater than the input air. If room negative pressure diminishes, the BSCs also shut down, a poor condition if aerosols are being generated in course of the work. Much better would be to have IIA BSCs as workstations. These would continue to capture aerosols regardless of overall room negativity. Hoods would not have to run continuously and room failure would not also release aerosols into the laboratory. The Uninterrupted Power Supply installed in Building 50 was a prudent decision. I hope that these questions will be/have been considered in the current renovation of Twinbrook III as BSL-3 laboratory. Finally, it was a pleasure to receive frank, careful responses from all the scientists I approached. They willingly turned from their particular microbial environments to candidly discuss the history of their work from a safety perspective.

This report is included in the Final Environmental Impact Statement of the Integrated Research Facility.

Biosafety at BSL-4

More than 20 Years Experience at Three Major Facilities

Karl M. Johnson, M.D.

October 15, 2003

Biosafety at BSL-4:
More than 20 Years Experience at Three Major Facilities

WHAT IS BSL-4, AND HOW DID WE GET THERE?

Special containment for work with infectious microbes in the United States originated during World War II in response to intelligence that the German army had a program for development of biological, in additional to chemical weapons that had been used during the first World conflict. Temporary facilities were established in a suburb of Frederick, Maryland, later to become the permanent Fort Detrick. During the 1950s and 1960s several agents, most notably the bacteria that cause plague and anthrax and the rickettsial organism that causes so-called Q fever, were produced in large quantities and in forms with properties that make highly infectious tiny particles in the air. The term used was, and is, 'weaponized.'

Infections among those working with these and other microbes were a recurrent problem. Under the inspired leadership of the late Dr. Arnold G. Wedum, recognized today throughout the world as the "Father of Biosafety," Fort Detrick borrowed technology from the nuclear industry to prevent such infections, especially those induced by small aerosols that arose during the course of routine laboratory manipulations. Stainless steel cabinets (termed Class III) were constructed and assembled in continuous airtight lines. Each had at least one pair of sealed glove ports to allow manipulation of hazardous materials in a sealed-off environment. Incubators, microscopes, and doors leading directly to autoclaves and to animal cabinets were integral to the cabinet line. The cabinets had a constant supply of filtered air and filtered exhaust fans to remove any particles generated during the work sessions. Air pressure in cabinet lines was negative to the laboratory room and the exhaust was filtered. The room itself also was negative to the rest of the building, and exhaust air was filtered before release to the environment. Thus workers, others in the building, and the outside community, were all protected against aerosol infection from agents otherwise intended for battle.

During these same two decades, new organisms with serious human pathogenicity were discovered in nature on several continents. Most of these, all of which were viruses, caused a syndrome (with variations) known as acute viral hemorrhagic fever (VHF). There was no specific treatment or vaccine available for any of them, except for the classical virus that causes yellow fever. That disease is now recognized as the prototype of VHF. Even more disturbing was the fact that aerosols were infectious for laboratory staff for most of these agents. Virology at Fort Detrick quickly entered the Class III cabinet habitat.

The recognition of Marburg virus in 1967 propelled the Centers for Disease Control (CDC) into this arena. That agency was asked to help with field studies designed to uncover the African reservoir for the virus, and it was decided that diagnostic reagents were needed. Visions of travelers returning from parts of the globe endemic for HF agents became a chronic concern. A small Class III cabinet laboratory was established in 1970 at the CDC. It had about 70 linear feet of cabinet line and a staff of two persons who tested samples from wild animals for infection and made diagnostic reagents for Marburg and other viruses of concern.

One year previously (1969), President Richard Nixon unilaterally terminated the national program of offensive biowarfare at Fort Detrick. Most of the buildings were given over to the National Cancer Institute. But the Army now expanded its defensive program. A new facility was constructed that became the principal laboratory of the U. S. Army Medical Research Institute for Infectious Diseases (USAMRIID). It opened in early 1971 with a mission to develop technology for detection and identification of potential biowarfare agents, to understand pathogenesis of the new VHF agents, to search for specific antiviral therapies, and to develop vaccines.

Another VHF agent, Lassa virus, appeared in Nigeria in 1969. When Marburg virus attacked two young Australians traveling in southern Africa in 1975, CDC Director David Sencer decided that it was time to

reinforce the nascent Special Pathogens Branch. A surplus large trailer was obtained from NIH and outfitted as a new laboratory for work with VHF agents. It had a Class III cabinet line. Space previously used as offices was redesigned as the first completely suited laboratory and animal room. Workers wore special positive pressured suits that could be hooked up to hoses from the ceiling that provided clean breathing air. Suits came in several sizes and each worker was now able to have gloves that truly fit their hands. All work was to be done in movable Class II laminar flow biosafety cabinets (BSC) that pulled air across the work surface then filtered it, with about half recirculated in the box and the rest released into the laboratory. Similar filtered enclosures were employed to house infected animals. Laboratory exhaust air was twice filtered before release to the environment, all solid wastes were autoclaved in double-door machines installed through a laboratory wall, and all liquid wastes were pressure cooked at high temperature before cool down and released to sanitary sewers. Workers leaving the laboratory stood in a chemical shower to decontaminate the "space" suits before doffing scrub suits and showering before leaving the facility. Various alarms and redundant systems were installed to ensure that power, continuous negative pressure, and breathing air were always available in emergency. Needles and scalpels were used as infrequently as possible and plastic ware replaced glass for almost all procedures.

The new CDC laboratory was opened at the end of 1978. Laboratories utilizing positive pressure suits also were ready at USAMRIID within months. These configurations allowed convenient installation and maintenance of new instruments and other equipment that was being developed for molecular work on viruses. The principles of biocontainment were: (1) capture each small particulate aerosol immediately where it is generated, (2) ensure that workers have functional hands, life support, minimum exposure to invasive accidents, and ready access to the tools required for research, and (3) make sure that systems for prevention of escape of aerosolized viruses to the environment are redundant. The BSC cabinets were the primary containment, the exhaust-filtered laboratories were the secondary, and even these were redundant.

By 1976, some leading molecular microbiologists became worried that new technology could potentially create novel organisms that might conceivably become Andromeda strains. The Director of the National Institutes of Health (NIH) ordered new guidelines for standards of microbiological safety for diverse agents with known properties of human pathogenicity and modes of transmission, as well as for newly discovered agents. The first edition of the NIH/CDC guidelines was published in 1980. Most work could be done in ordinary laboratories at BioSafety Level 2 (BSL-2). Others that cause more serious illness in humans, and/or for which no treatment is available, were assigned to BSL-3. All work was to be done in Class II biosafety cabinets. Room air was to be under negative pressure relative to hallways with no recirculation to other space in the building.

BSL-4 was reserved for VHF agents, certain tick-borne encephalitis viruses, and a simian herpesvirus for which human infection is almost universally fatal. At the time, this meant USAMRIID and CDC Special Pathogens, but authorities in South Africa were progressively concerned about VHF on their continent. Ebola virus, an even more virulent relative of Marburg, had been discovered in 1976. Rift Valley fever virus had caused its first-ever epidemic that included hemorrhagic fever. Crimean-Congo virus was a new concern. To meet these challenges, a BSL-4 laboratory, modeled on the Detrick and Atlanta prototypes, was constructed outside Johannesburg and commissioned in 1980. It had both suit and cabinet-line laboratories.

These three laboratories were virtually *the* sites of BSL-4 viral work during the past 22-30 years. With experience over time, most investigators chose to work primarily in the positive-pressure suit environment. Indeed, at the end of the1980s, CDC moved into new large laboratories that were almost devoid of Class III cabinet lines. Moreover, the Johannesburg laboratory, now part of the National Institute for Communicable Diseases (NICD), recently removed its Class III cabinets in order to expand positive-pressure suit space. Only the British BSL-4 laboratories continue to depend on Class III cabinet line configurations. All recently constructed Level 4 facilities in other countries, as well as those proposed for ours, are positive-pressure suit labs. Accordingly, this review will not include biosafety at the Porton Down facility. We are concerned principally with the track record of, and a risk analysis for, BSL-4 positive-pressure suit laboratories.

That record is exemplary. Most individuals who begin work in BSL-4 suites are already experienced microbiologists. Specific training for use of the positive-pressure suits and for safe execution of all procedures is standard practice at all of the laboratories. In context of current international concern regarding potential use of some of these viruses as weapons of terror, access to the facilities and to individual laboratories is carefully controlled. At two of the facilities in the United States individual security clearance is required to qualify for work at the BSL-4 level. The viruses under study do not escape, neither by accident nor by covert design. Reviews of individual facilities are summarized below.

USAMRIID — 1972-2003

Persons Interviewed:

Drs. Peter Jahrling, Chief Civilian Scientist; Gerald Eddy, retired Chief, Virology Division.

Research Program:

Pathogenesis of viral infections in animal models, including clinical and anatomical pathology. Quantitative susceptibility of animals to aerosol infection by VHF pathogens. Development of diagnostic assays and air sampling detectors. Molecular anatomy and genetics of agents. Drug screening program in search of anti-viral compounds. Development of live attenuated, inactivated, and recombinant vaccines.

Agents Studied:

Machupo, Junin, Guanarito, Sabia, and Lassa arenaviruses; Marburg and Ebola; Rift Valley fever and Crimean-Congo hemorrhagic fever viruses; Tick-Borne encephalitis virus. *Yersinia pestis* and *Bacillus anthracis.*

Animals Used:

Mice, hamsters, guinea pigs, non-human primates, wild rodents, lambs,

Site:

Two buildings, Fort Detrick, Maryland. Total BSL-4 space: about 6500 sf. One third is animal space and suit/cabinet ratio of lab space is about 2:1.

Time Devoted in BSL-4 Space:

Approximately 343,980 hours. (6.5 persons/8 hour day x 1680 hours/year x 31.5 years).

Laboratory Accidents and Outcomes:

During early years when work was completely in cabinets, invasive accidents resulted in treatment with human plasma containing specific antibodies to virus in question, as well as confinement in an isolation suite in one building that was also set up as an intensive care facility in event that a worker became ill after accidental exposure to an agent. Two invasive accidents were of most concern:

November 1979. Accidental finger puncture with needle on a syringe loaded with Lassa virus. Ribavirin and immune plasma were given. (This was an experimental therapy for monkeys under development at the Institute.) No illness or serological evidence for infection occurred.

December 1982. During autopsy, a bone fragment of a monkey infected with Junin virus punctured a finger. Immune plasma was used and no clinical or subclinical infection ensued.

CDC SPECIAL PATHOGENS

Persons Interviewed: Senior Scientists and Author

Research Program:

Development of diagnostic methods and reagents for diagnosis of all BSL-4 agents. Pathogenesis of viral infections in animal models, including natural wild reservoirs. Molecular anatomy and genetics of VHF agents. Limited vaccine development work. Response to VHF epidemics in natural settings. Diagnosis, clinical pathology and virology, discovery of new agents.

Agents Studied:

Five arenaviruses, Marburg, Ebola, Crimean-Congo HF virus, Rift Valley fever virus, Nipah and Hendra viruses, Russian spring summer encephalitis and Tick-Borne encephalitis viruses, Omsk and Kyasanur Forest disease viruses, Hantavirus (animal work only).

Animals Employed:

Mice, hamsters, guinea pigs, non-human primates, rats, five wild rodent species for rodent-borne agents.

Sites:

Building A: 1970-78. About 70 linear feet of Cabinet line.

Building B: 1979-1989. About 900 sf with 30 ft cabinet line, 300 sf positive-pressure suit lab and 200 sf of positive-pressure suit animal space.

Building C: 1990-2003. About 5000 sf of which approximately 30% is animal space. Laboratory is entirely positive-pressure suit operated.

Time Devoted in BSL-4 Space:

120,560 hours.

Laboratory Accidents and Outcomes:

Animal bite; Hantavirus infected rodent, no infection.

Animal bite; animals being inoculated with Hantavirus. Pre-inoculation bite from rat.

Needle stick to worker prior to setting up an inoculum with mouse-adapted Ebola virus. No infection.

Autoclave door interlock failed and a load not autoclaved was opened, but not handled. No infections resulted.

Multiple events over the years of outer gloves or suits developing tears or holes detected during work. Such incidents are evaluated and followed up. No treatments were ever used and no infections resulted.

Facility/System Failures: None of note that caused interruption of work.

National Institute for Communicable Diseases

Johannesburg, South Africa, 1980-2003

Person Interviewed:

Dr. Robert Swanepoel, BSL-4 Laboratory Director

Research Program:

Diagnostic reagents and support for all HF outbreaks in Africa and neighboring regions when requested,; pathogenesis of infections in animals, especially candidate wild reservoir species; clinical virology; molecular biology of selected hemorrhagic fever viruses; field investigations of natural history of disease outbreaks; and seroepidemiology of infections in humans and animals.

Agents Studied:

Marburg and Ebola viruses, Rift Valley fever virus, Crimean-Congo HF virus, ten hantaviruses.

Animals Employed:

Mice, guinea pigs, rabbits, bats, tortoises, pigeons, snakes, roaches, spiders, frogs, millipedes, snails, 20 species of wild rodents, hares, hedgehogs, guinea fowl, chickens, etc. Much animal work was devoted to a search for wild reservoirs of Marburg and Ebola viruses.

Site:

Rietfontein, 4500 sf. Space divided into 721 sf positive-pressure suit lab and 222 sf similar animal holding room, plus cabinet lab of 999 sf (now defunct). Remaining 1443 sf devoted to change rooms, showers, and service corridors.

Time Devoted in BSL-4 Space:

Approximately 40,000 hours in nearly 23 years.

Laboratory Accidents and Outcomes:

Bat bite through double gloves. No infection.

Multiple other accidents. Those exposed are monitored closely for 21 days, during which time they are not permitted to leave town—as are all employees after their last day of work inside BSL-4 space. No infections recorded.

Facility/System Failures:

Only one that caused shutdown of operations. About 5 liters of highly concentrated Marburg virus was suddenly aerosolized when worker opened chamber to add a bit more fluid without closing the nitrogen pressure tank and bleeding off pressure. Laboratory was mopped for several hours with glutaraldehyde, and finally decontaminated with formaldehyde gas. No infection occurred in two "exposed" workers. There was no breach in BSL-4 containment, and no infections occurred in neighboring open-air monkey colonies on the campus. This was a maximum challenge to BSL-4 containment, and I am aware of no other event remotely comparable in terms of concentration and volume of a highly lethal virus.

Summary

No clinical infections occurred at three institutions during work with BSL-4 agents, mostly hemorrhagic fever viruses during the past 31 years. Almost half a million hours of laboratory (and field) exposure have been recorded, the majority of which was time spent in positive pressure suits. Nor have there been major defects or incidents in operation of the physical facilities. No escape of any agent with clinical consequences for neighboring communities occurred.

Invasive injuries were infrequent, eloquent testimony to the awareness of the dangers and the daily care observed by workers who volunteer for such duty. One laboratory inadvertently carried out a maximum aerosol challenge to BSL-4 containment with a highly pathogenic hemorrhagic fever virus. Virus did not escape the laboratory, nor was a worker infected.

The zero numerator of infections in these three laboratories and the huge denominator of exposure hours make it impossible to provide a number for 'risk of infection' to either laboratory workers or outside communities. Nevertheless, that number must be small. When the value of diagnosis, treatment, and control of deadly outbreaks of hemorrhagic fever over the past three decades is added to this equation, risk/benefit clearly comes out in favor of continued operation of BSL-4 laboratories.

Indeed, considering new challenges posed to the world community by these agents, it is fair to conclude that more such facilities are needed. Better therapeutic agents are desperately needed. High priority also must go to the development of vaccines that can protect laboratory and hospital personnel in countries where natural epidemics occur, as well as first responders to intentional aerosol attack on any community.

This report is included in the Final Environmental Impact Statement of the Integrated Research Facility.

ROCKY MOUNTAIN LABORATORY (RML) Safety Record

Persons Interviewed: Ted Hackstadt, John Portis, Bruce Cheesbro, Tom Schwan, Mike Parnell, Cliff Barry, Joe Hinnebusch, Jim Musser, Mort Peacock

BSL-3 Agents: *Coxiella burnetti, Rickettsia rickettsii, Chlamydia trachomatis*						
Period	**Research Program**	**Animals Utilized**	**Location**	**Avg Persons/ Day**	**Exposures/Infections/Remedies to Infectious Agents**	**BiosafetyFacility Systems, Problems & Remedies**
1982-1988	Pathogenesis, cell biology, immunology, genetics of distinct strains of agents. Recombinant antigen development, vaccine development.	Guinea pigs, mice, one experiment with *C. burnetti* in dogs.	Bldg 16 East room, bench 800 sf. Bldg 16, East, animal 300 sf.	Bench 5.3 Animal 2.0	None	Heating in Bldg 16 poor. Labs extremely cold in winter. Pumps sometimes failed so lack of water threatened animal health. Exhaust ventilation in Bldg 16 failed several times during 1980s. Staff was not immunizaed against *C. burnetti* so repeated ventilation problems caused sealing of animal room from the laboratory area in 1988. Animal studies dropped for several years.

BSL-3 Agents: *Coxiella burnetti, Rickettsia rickettsii, Chlamydia trachomatis*						
Period	**Research Program**	**Animals Utilized**	**Location**	**Avg Persons/ Day**	**Exposures/Infections/Remedies to Infectious Agents**	**Biosafety Facility Systems, Problems & Remedies**
1990-2002	Work continued on pathogenesis, genetics, and biology of organisms in cells.	None	Bldg 16 East room, bench 800 sf.	Bench 10.0	1998: Research fellow hospitalized for pneumonia in left lung. *C trachomatis* isolated and specific sero-conversion was documented. Uneventful recovery with antibiotic therapy. Researcher did sonication of cultured organism in Class II Biosafety Cabinet (BSC) two days prior to onset of illness. Three large scale purifications of organisms done during 3 week period before illness. The specific source of infection remained indeterminant. All procedures were reviewed with staff. Particle masks were adopted for all aerosol-generating procedures and for 30 minutes after completion of these. Centifuge rotors were to be opened only in BSC and both the instrument and rotors were to be examined for leaks after each run. Alcohol-soaked sponges were required to surround the sonication tube and all worker faces were to stay outside the glass front of the BSC. No further infections since that time.	No new problems.
2002-2003	Resumption of full program including use of animals for ricksettsial agents. Virulent strains will be utilized.	Guinea pigs and mice.	Bldg. 25 bench 560 sf; Animals (see Biosafety column.)	Bench 6.0 Animal (see Biosafety column.)	None	Beginning in 2002, BSL-3 animal work for all agents at RML was transferred to the new building 25. Space devoted to animals is 1000 sf. Animal species so far housed are mice, guinea pigs, and non-human primates. Persons per day for operation are 2.0.

BLS-3 Agent: *Mycobacterium tuberculosis*						
Period	**Research Program**	**Animals Utilized**	**Location**	**Avg Persons/ Day**	**Exposures/Infections/Remedies to Infectious Agents**	**Biosafety Facility Systems, Problems & Remedies**
1993-2001	Genetics and immunology. No drug-resistant strains utilized. Mutants were generated. Lipid and protein content as weel as replication dynamics of these mutants were markers utilized to determine relative virulence. Electron microscopy of human tissues.	Mice. Limited experiments with wild strains.	Bldg HD-2 Bench 540 sf; Animal 580 sf. Bldg 5 Electron microscopy ~400 sf.	Bench 7.0 Animal 2.0	1996: Laboratory technician converted PPD skin test for the agent. There was no history of an obvious invasive accident or any apparent breakdown in laboratory procedures to prevent aerosols. Worker treated for 6 months with isoniazid. No pulmonary or other evidence of disease occurred. Major modifications instituted in equipment and procedures to prevent aerosol infection: (1) New high-speed sealed centrifuge rotor. (2) Large plastic bottles as visable secondary containment for roller bottles. (3) Upgraded NIOSH-approved face masks. (4) Additional UV fixture for dirty dress-out chamber. (5) Autoclave treatment for ice buckets leaving lab. Relocation of ice machine inside the laboratory. (6) Chest xrays each six months; all personnel, even those PPD positive when initially employed in lab.	Exhaust fan broke in HD-2 and BSC also failed. A winter pipe break in same building flooded the laboratory. Research program moved to Twinbrook II, Rockville, MD, in 1998. Electron microscopy with outside collaborators continues.

BLS-3 Agent: *Mycobacterium tuberculosis*						
Period	**Research Program**	**Animals Utilized**	**Location**	**Avg Persons/ Day**	**Exposures/Infections/Remedies to Infectious Agents**	**Biosafety Facility Systems, Problems & Remedies**
1993-2001	*M tuberculosis* exposures continued.				2000: PPD skintest conversion. Employee treated with isoniazid. No clinical or radiological evidence for disease ensued. Employee worked in the Electronic Microscopy Branch (EMB) in Bldg 5. Work involved prep of samples submitted by outside collaborators in EM. Centrifigation done outside BSC. Although all samples supposedly were inactived before receipt at RML, suspicion is that residual live bacteria were source of infection. Several modifications to equipment and procedures instituted; (1) A modern sealed centrifuge was installed. (2) Bldg 5 air handling was upgraded and alarms for BSC function were provided. (3) Documented inactivation protocols and safety tests must now accompany materials received from outside sources. (5) All samples to be processed as though they still contain viable organisms.	
2002-2003	Global genetic analysis using microarray technology for different strains of bacteria. No drug resistant strains in use.	None	Bldg. 25 Bench 560sf	Bench 1.5	None	None

BSL-3 Agent *Yersinia pestis*						
Period	**Research Program**	**Animals Utilized**	**Location**	**Avg Persons/ Day**	**Exposures/Infections/Remedies to Infectious Agents**	**Biosafety Facility Systems, Problems & Remedies**
2002-2003	Interactive cell and animal biology of bacterial strains and mutants in mice and fleas.	Mice, fleas	Bldg 25 Bench 560 sf Animal (see above)	Bench 6.0 Animals (see above)	None	None
BSL-3 Agent Transmissible Spongiform Encephalopathy (TSE)						
2022-2003	Prion genetics and studies on transmissibility of strains from different animal species.	Mice, non-human primates	Bldg 25 Bench 560 sf Animal (see above)	Bench 6.0 Animal (see above)	None	Work with TSE agent causing scrapie antedates formulation of national guidelines and was done less than BSL-2 containment. Recent program initiated after certification of new BSL-3 labs in Bldg. 2. 5
BSL-2/3 Practices Agent *Yersinia pestis*						
Date	**Research Program**	**Animals Utilized**	**Location**	**Avg Persons/ Day**	**Accidental Exposures to Infectious Agents**	**Biosafety Facility Systems, Problems & Remedies**
1986-2000	Rapid detection of agent, PCR technology used when available. Establishment of flea colonies. DNA probe developed, fraction I antigen cloned. Most work with avirulent	Mice, fleas.	Bldg 12, Bench 100 sf; Animal 100 sf. Bldg 13, Insectary 125 sf.	Bench 2.0 Animal 1.2	None	None

	bacterial strains. Few experiments with virulent bacteria for immunization studies.					
2000-2002	Continued	Mice, fleas	Bldg 5, Rm 5203 Bench, 600 sf. Bldg 12, animal, 100 sf. Bldg 13, Insectary, 125sf	Bench 4.0 Animal 0.2	2001: An open container of *Y. pestis* fell off a shaker during the night. Several workers entered the lab next morning and the accident was immediately discovered. Surfaces were decontaminated and lab was closed until a new BSL-3 was available. No infections occurred.	None
BSL 2/3 Practices Agent: Lentiviruses						
Date	**Research Program**	**Animals Utilized**	**Location**	**Avg Persons/ Day**	**Accidental Exposures to Infectious Agents**	**Biosafety Facility Systems, Problems & Remedies**
1987-1997	Cell culture work for drug screening. Molecular biology of HIV.	None	Bldg 5 Bench 300 sf.	Bench 1.5	1987: Worker punctured finger on broken cover slip in HIV lab. No medical treatment. No infection occurred.	None
1998-2001	No change	None	Bldg 10 Bench 300 sf.	Bench 1.5	None	None
2002-2003	Current program includes cell culture assay. Insertion of co-receptors into HeLa cells gives stainable virus plaques in 3 days. Work includes cloning, tests for differential cell susceptibility, and creation of pseudotype HIV/SIV viruses with	Mice	Bldg 3 Bench 600 sf. Bldg 13 Animal 150 sf.	Bench 1.5 Animal 0.5	None No needles used in work; no significant concentration of virus is done. Personnel tested for HIV antibodies annually.	None

	a few experiments in mice. Transgenic rats will be used in future.					
BSL 2/3 Practices Agent: *Chlamydia trachomatis*						
Date	**Research Program**	**Animals Utilized**	**Location**	**Avg Persons/ Day**	**Accidental Exposures to Infectious Agents**	**Biosafety Facility Systems, Problems & Remedies**
2002-2003	Basic pathogenesis. Antigens as vaccine candidates.	Mice, non-human primates	Bldg 1 Rms 1201 and 1202 Bldg 2 Rms 2204, 2206, 2208. Bench 2102 sf. Bldg 13 Animal ~300 sf (shared)	Bench 13 Animal 0.5	None	None

APPENDIX E
Standard Operating Procedures for a BSL-4 Facility

The following documents are the standard operating procedures used in Biosafety Level 4 laboratories at the NIH facility in Bethesda, Maryland. Standard procedures for the Integrated Research Facility would be written if the decision is made to select the proposed action. Those standard operating procedures would be similar to these, covering the same subjects with the same amount of detail. In most cases, the procedures would be the same, unless different equipment would be used.

Part 1 is the Standard Operating Procedures.

Part 2 is Decontamination Equipment and Procedures.

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ACRONYMS

AAALAC	**American Association for Accreditation of Laboratory Animal Care**
AALAS	**American Association for Laboratory Animal Science**
ACUC	**Animal Care and Use Committee**
ARAC	**Animal Research Advisory Committee**
BMBL	**Biosafety in Microbiological and Biomedical Laboratories**
BSC	**Biological Safety Cabinet**
BSL	**Biosafety Level**
CDC	**Centers for Disease Control and Prevention**
DES	**Division of Engineering Services**
DOT	**Department of Transportation**
DS	**Division of Safety**
HEPA	**High Efficiency Particulate Air**
IBC	**Institutional Biosafety Committee, NIH**
ICD	**Institute/ Center/ Division**
ILAR	**Institute of Laboratory Animal Resources**
IPM	**Integrated Pest Management**
MCL	**Maximum Containment Laboratory**
MPW	**Medical Pathological Waste**
NIH	**National Institutes of Health**
NRC	**Nuclear Regulatory Commission**
OD OIR	**Office of the Director, Office of Intramural Research**
OMS	**Occupational Medical Service**
OSHA	**Occupational Safety and Health Administration**
OSHB	**Occupational Safety and Health Branch**
PI	**Principal Investigator**
PHS	**Public Health Service**
PRC	**Policy Review Committee, NIH**
RSB	**Radiation Safety Branch**
USDA	**United States Department of Agriculture**
USFWS	**United States Fish and Wildlife Service**
VHP	**Vapor Phase Hydrogen Peroxide**

Part I – Standard Operting Procedures

1.0 INTRODUCTION

1.1 PURPOSE

Operational and safety procedures for the Biosafety Level Four (BL-4) Laboratory (also referred to as the Maximum Containment Laboratory [MCL]), Building 41A, National Institutes of Health (NIH), are contained within this manual. Three laboratory/animal suites are housed within the unit. In some circumstances, processing BL-3 agents may require BL-4 containment. Most of these BL-4 pathogens are highly virulent for humans and infectious by the aerosol route. They often are capable of direct transmission from person to person; and produce diseases for which there is no specific treatment or prevention available.

1.2 POLICY STATEMENT

Operational and safety procedures described in this manual shall apply to all program and support personnel associated with the facility. Modifications to these procedures or to the facility shall not be made without written approval of the NIH Institutional Biosafety Committee (IBC), Policy Review Committee (PRC) and the Chief, Occupational Safety and Health Branch (OSHB).

NO PERSON SHALL WORK IN THE MCL WITHOUT HAVING READ THIS MANUAL AND ATTENDED REQUIRED TRAINING SESSIONS CONDUCTED BOTH BY THE PRINCIPAL INVESTIGATOR AND THE MCL FACILITY MANAGER AND/OR THE MCL OCCUPATIONAL SAFETY AND HEALTH SPECIALIST, OF BUILDING 41A.

NO PERSON SHALL WORK ALONE IN THE MCL AT ANY TIME.

THE RESPONSIBILITY FOR MAINTAINING A CLEAN LABORATORY ENVIRONMENT REMAINS WITH ALL INDIVIDUALS WHO WORK IN THE MCL. THE RESPONSIBILITY FOR HOUSEKEEPING IN THE MCL IS PART OF DAILY OPERATING PROCEDURES.

Use of the MCL shall be limited to programs specifically approved by the NIH IBC, PRC and the Chief, OSHB.

1.3 RESPONSIBILITIES AND AUTHORITY

1.3.1 Chief, Occupational Safety and Health Branch

The MCL shall be the direct responsibility of the Chief, OSHB, NIH, who shall ensure that the procedures in this manual are followed at all times. The Chief may delegate authority for conducting specific programs in the MCL to other appropriate personnel as necessary.

1.3.2 Principal Investigator (PI)

The PI shall have direct responsibility for conducting the research in a manner that minimizes risks in the MCL. He/she has responsibility for the following:

Approval: Obtaining the necessary approval from the NIH IBC and PRC for the research program prior to the commencement of work in the MCL. The PI shall develop the animal protocol, and coordinate that protocol with the ICD veterinarian and the MCL Occupational Safety and Health Specialist.

Biohazards: Ensuring that program and support personnel (prior to working in the MCL) (i) are aware of biohazards and precautions to be taken in conducting the research program; (ii) are advised of the nature and

assessment of the real and potential biohazards and (iii) are informed of the indicators of accidental infections.

Medical Surveillance: Recommending appropriate (i) immunizations, (ii) serologic monitoring, (iii) other medical monitoring and (iv) post exposure prophylaxis.

Medical Clearance: Obtaining medical clearance for all employees from OMS - within the three months - prior to training in the MCL. All immunizations/testing shall be updated at that time for each employee.

Training: Instructing and training the program staff in the practices and techniques required for the safe conduct of the research program and the operation of the MCL.

Supervision: Supervising the program staff to ensure that their performance complies with the required standards of safety in the MCL.

Emergencies: Preparing, in collaboration with the Facility Manager, procedures for dealing with accidental spills and overt exposures among program personnel. Reporting to the Chief, OSHB, the Medical Director, OMS and the Facility Manager, problems pertaining to the (i) exposure of personnel, (ii) compromise of biological or physical barriers or (iii) major equipment failure which could compromise safe operations in the MCL (Section 2.2.5). Contacting any employee with an unexplained work absence. The employee shall be contacted by 10:00 a.m. on the day of the unexplained absence. The PI shall seek the advice of the Chief, OSHB and the Medical Director, Occupational Medical Service (OMS).

Monitoring of Operations: Correcting procedures that may result in hazardous incidents or problems. Notifying the IBC, PRC and OSHB of (i) such modifications in program, (ii) new safety procedures and (iii) any unexpected experimental results, e.g. unexpected results in laboratory experiments.

1.3.3 Facility Manager

The Facility Manager of the MCL is directly responsible to the Chief, OSHB, or his/her designee, and shall supervise the day-to-day operations of the MCL. The Facility Manager has the responsibility for the following.

1. Emergencies: Notifying the Chief, OSHB, immediately, of any incident or problem that compromises the safety of the staff or the integrity of the MCL.
2. Training: Training in collaboration with the PI and with the assistance of the MCL Occupational Safety and Health Specialist in the required training program for new staff or visiting scientists designated by the Chief, OSHB.
3. Decontamination: Supervising (i) decontamination procedures for all equipment or other material which leaves the MCL, and (ii) the annual gaseous decontamination of the MCL with the assistance of the MCL Occupational Safety and Health Specialist.

1.3.4 MCL Occupational Safety and Health Specialist

The Occupational Safety and Health Specialist is responsible for the following:

1. Assist the PI with research projects in the MCL.
2. Ensuring that physical containment systems, support equipment, waste disposal, and operation of the MCL are in accordance with the design of the MCL.
3. Ensuring that MCL maintenance procedures are conducted in a manner that precludes hazard to personnel and preserves the integrity of the MCL.
4. Acting as liaison with the staff for engineering and safety support systems. In the event that the MCL Occupational Safety and Health Specialist is unable to attend to these duties, the designated personnel of the OSHB staff will take on these duties on a rotating basis.
5. Assisting with the required training program for new staff, visiting scientists, and animal care personnel designated by the Chief, OSHB.

6. Decontamination procedures for equipment or other material before it leaves the MCL, and the annual decontamination of the MCL.
7. Perform daily Critical Systems checklist for the MCL.

1.3.5 Other Personnel Working in the MCL

1. All persons working in the MCL shall comply with the policies and practices established by the NIH IBC, PRC, the Chief, OSHB and the PI.
2. All personnel working in the MCL shall follow all safety practices and procedures required by good laboratory practice, the CDC and NIH publication entitled *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) and OSHA.
3. They shall report to the Facility Manager and/or Occupational Safety and Health Specialist any event that may (i) constitute potential exposure, (ii) result in creation of a potential hazard, (iii) impair safe operations in the MCL.
4. An employee who becomes ill with any febrile illness shall immediately notify his/her supervisor.

1.3.6 Policy Review Committee

The PRC shall be appointed by the Deputy Director for Intramural Research (OD DIR), NIH. The PRC shall consist of a member of the NIH IBC; the Chief, OSHB; a member of the ICD Animal Care and Use Committee (ACUC); ICD Scientific Director of the appropriate Institute; and accredited members may be requested to participate on an ad hoc basis. Non-NIH personnel may be requested to participate depending on the particular research under consideration. The functions of the committee are to (i) the PRC shall assess the program relevance, policy aspects and priority of the proposed studies; (ii) advise on the use of vaccinations as additional protection for MCL staff (with consultation with OMS); (iii) evaluate potential methods of treatment or post-exposure prophylaxis that could be applied to MCL personnel and (iv) advise in the evaluation and management of potential MCL exposures.

1.3.7 Application Procedures

Intramural applications will be reviewed in the following order: (i) Laboratory/Branch Chief, (ii) Scientific Director of the Institute, (iii) the NIH IBC, (iv) the ACUC, if required and then (v) the PRC.

Extramural applications will generally be reviewed in the following order: (i) the relevant ICD program officer, (ii) the NIH IBC, (iii) the ACUC, if required, (iv) the PRC, and then (v) results of these reviews will be returned to the sponsoring ICD for implementation. Each extramural application will have an intramural collaborator identified by the Scientific Director of the appropriate ICD.

All applications will be required to include a detailed protocol, which will be reviewed on the basis of scientific merit and biosafety standards.

The PI is responsible for completing the following forms:

1. A "Request to Use the Maximum Containment Laboratory Checklist" (Appendix A) and an "Authorization for Entry into the MCL" (Appendix B) must be signed and approved by the NIH IBC, PRC, OSHB and OMS before work is initiated.
2. All users of radioactive materials must first attend and successfully complete the "Radiation Safety in the Laboratory" course and register with the Radiation Safety Branch (RSB).
3. A Registration Of Materials (Potentially) Pathogenic to Humans document (Appendix R) and an Animal Study Proposal, shall be submitted to the NIH IBC, the ACUC and PRC, if applicable.

2.0 OPERATIONS AND SAFETY PROCEDURES

2.1 EMPLOYEE TRAINING AND ORIENTATION

Training, unique to the MCL, is provided by the PI and OSHB. Training requirements are listed on the Training Checklist for Authorization to Work in the MCL (Appendix D). The form must be signed by the Facility Manager or the Occupational Safety and Health Specialist upon completion of the checklist activities, and placed in the Facility Core Center file. A copy shall also be kept by OSHB. The training will include:

1. Formal safety briefing by OSHB, including training and orientation in MCL techniques and procedures
2. Reading the MCL Safety and Operations Manual
3. Briefing on the Entry and Exit Procedures (Section 2.2.4 and Section 2.2.3)
4. Attending the NIH courses on Laboratory Safety and HIV and other Bloodborne Pathogens.

2.2 EMPLOYEE SAFETY

2.2.1 Personal Protection Equipment

The primary source of protection for personnel working in the MCL is the *CHEMTURION* encapsulating positive pressure suit (Appendix E).

Positive air pressure is maintained by umbilical-fed air which is supplied to the suit through the air inlet manifold assembly fitted with a HEPA filter. This filter is located on the right front torso and prevents intake of potentially contaminated air from the laboratory. Air hoses are located throughout the MCL.

2.2.2 MCL Access

Access is limited to staff members and individuals who have a work-related need to be in the MCL. Access requires the approval of the IBC, PRC and Chief, OSHB. Building 41A entry involves the use of a proximity card. Proximity cards shall be issued by the Facility Manager. A proximity card is a controlled item to be used only by the person to whom it is issued and must never be loaned. A floor plan of Building 41A showing the proximity card readers is in Section 5.1.

A biohazard warning sign, incorporating the universal biohazard symbol, will be placed on the interior MCL entry door of Building 41A.

2.2.3 Entry Procedures

Each day, prior to entry of personnel into the MCL, the MCL Occupational Safety and Health Specialist shall perform a Critical Systems check (Appendix G) to ensure that the MCL is safe for operation. This inspection will specifically include proper functioning of the air handling system, processed waste system and breathing air system, as well as notation of any obvious problems with the other systems. This checklist shall be filed in the Facility Core Center. Laboratory personnel shall not enter the MCL until the checklist has been completed and signed. If the MCL Occupational Safety and Health Specialist cannot perform the Critical Systems check, the MCL Occupational Safety and Health Specialist shall notify the Chief, OSHB, or the Facility Manager. When such notification is given, an OSHB staff member, appointed by the Chief, OSHB, must make the Critical Systems check of Building 41A. All personnel shall sign-in daily on the Personnel Log Sheet (Appendix H) located in the Facility Core Center.

Personnel who plan to enter the MCL before 8:00 AM or exit after 6:00 PM on weekdays, or anytime on weekends or holidays, must notify the MCL Occupational Safety and Health Specialist (6-2346) and NIH security (6-5685). The MCL Occupational Safety and Health Specialist shall be notified 24 hours prior to that day.

On the weekends, it is the responsibility of the MCL scientific personnel who enter the MCL to coordinate with OSHB to have the Critical Systems check completed prior to entering the MCL.

Personnel must enter the MCL through the change rooms and decontamination shower. The sequence shall be reversed to exit. The procedure of donning a positive pressure suit requires the presence of a second individual to ensure complete sealing of the outer plastic closure. The procedures for entry are outlined in detail in Appendix F.

Any overt spills that contaminate the positive pressure suit should be decontaminated immediately through the use of disinfectants, which are located in multiple sites throughout the laboratory. Do not wait until the exit decontamination shower to tend to any possible contamination of the positive pressure suit.

2.2.4 Exit Procedures

Proceed to the boot area and remove the protective footwear and leave on the racks provided. Enter the decontamination shower/airlock and attach suit to an air line. Ensure both doors (with inflatable gaskets) are securely closed. For detailed operation of decontamination shower, see Section 3.3.8 and Appendix I.

2.2.5 Suit Malfunction

Suits are checked for air leaks prior to entry to the MCL as described in Appendix F. If a leak or rip is discovered while in the laboratory, DO NOT DISCONNECT the suit from air supply. Immediately disinfect the area around the hole and dry; then cover with tape (vinyl tape is stationed at several locations throughout each laboratory). EXIT THE LABORATORY AS SOON AS PRACTICAL. REPORT ANY BREACH OF SUIT INTEGRITY TO THE MCL OCCUPATIONAL SAFETY AND HEALTH SPECIALIST. Check major seams in the suit if the disposable jump suit contains wet spots after exiting decontamination shower. Contact the MCL Occupational Safety and Health Specialist if this occurs.

2.2.6 Spill Cleanup

Spills in the MCL involving infectious agents, radioisotopes, and chemicals must be dealt with promptly and in a manner to eliminate the hazard. All spills will be reported to the MCL Facility Manager and/or the MCL Occupational Safety and Health Specialist. Areas in which spills of potentially infectious materials occur will be thoroughly treated with a disinfectant solution to inactivate the biological agent. Small spills on counter tops or in biological safety cabinets will be wiped up and any absorbent materials used in the cleanup will be bagged and autoclaved. Larger spills on the floor will be disinfected and flushed with water into the floor drain. Decontaminate the area with an appropriate disinfectant. Minimize the volume of water used for the water rinse. All liquid waste in the MCL is automatically processed by heat treatment and then pH balanced prior to disposal.

Notify the MCL Staff (who will notify the Radiation Safety Branch) immediately of spills of radioactive material under the following circumstances:

1. a large activity (millicurie quantities) spilled,
2. a large volume (>1 liter) spilled,
3. a large area (>10 square feet) is contaminated,
4. personnel contamination or injury occurred.

Radioactive materials spill cleanup

1. Place absorbent material over the spill to keep it from spreading.
2. Notify others in the area, and limit access to the spill area.
3. Monitor yourself and others for contamination and decontaminate if you find any.

4. Label the boundaries of the spill area with "Caution Radioactive Material" tape.
5. Gather cleaning supplies such as moistened paper towels and scouring powder or any commercially-available detergent.
6. Minimize the volume of water used to decontaminate.
7. Begin cleaning at the edges of the spill and work towards the center (lowest to highest level of contamination).
8. Dispose of all cleanup materials in double plastic bags and label as radioactive waste, include the type of isotope, activity, date and your initials.
9. Re-survey yourself for contamination, including the bottom of boots, to ensure that no spreading of contamination has occurred.
10. After decontamination is complete, a thorough smear survey of the area should be completed to ensure that removable contamination is <2,200 dpm/100cm^2 in a restricted area and <220 dpm/100cm^2 in an unrestricted area.

If the spill also contains infectious material, label the bag with the infectious agent and treat the area with the appropriate dilution of disinfectant. The bagged radioactive material will be stored in a central radiation storage area and removed when appropriate.

2.2.7 Illness Notification

Any employee who becomes ill with any febrile illness shall immediately notify his/her supervisor. If the supervisor cannot be reached, the employee shall immediately notify OSHB and/or the Facility Manager of Building 41A. Phone and pager numbers are listed on the Illness Surveillance Notice (Appendix J) provided to each MCL employee.

2.3 RADIOACTIVE MATERIAL

2.3.1 Radioactive Isotope Authorization in the MCL

Authorized use of radioactivity in the MCL shall conform to the policies, practices, and guidelines set forth by the NIH Radiation Safety Branch (RSB) and The National Institutes of Health Radiation Safety Guide, in compliance with Rules and Regulations established by the United States Nuclear Regulatory Commission and outlined in "Standards for Protection Against Radiation" Title X, Code of Federal Regulations, Part 19, 20.

RSB shall be notified at least one month prior to use of radioactive materials in the MCL. A protocol shall be submitted to RSB for all work involving radioactive material. The removal of radioactive waste and all laboratory surveys shall be conducted as recommended by RSB.

2.3.2 Records

KEEP A RECORD OF ALL RADIOACTIVE MATERIALS USED EACH DAY (Appendix K).

Attach to all radioactive waste containers, a Radioactive Waste Pick-up Receipt (NIH 88-35) labeled with the type of isotope, the approximate amount of radioactivity present in mCi, the date and the initials of the laboratorian.

A daily survey is required whenever radioactive materials in unsealed form are manipulated. A survey using an instrument such as a Geiger-Mueller counter is acceptable as long as it is sensitive enough to detect the nuclide used. The use of the nuclide I-125 requires a survey instrument equipped with a low energy sodium iodide crystal. For low energy beta emitters such as H-3, C-14, S-35 or P-33, contamination surveys shall be conducted using swipes (or smear wipes), which are counted using a liquid scintillation counter.

Any area found to be contaminated must be decontaminated immediately. If an item of equipment is contaminated, but has been dedicated for continued use with radioactive materials where re-contamination is likely, it shall be labeled as contaminated and dedicated for use with radioactive material.

An area where radioactive materials are used or stored shall be appropriately posted with a visible "Caution Radioactive Materials" sign. The sign must indicate the Authorized User responsible for the room, along with telephone numbers for business and after hours contact. Once each month, a complete contamination survey of each posted area must be completed using swipes. At least ten probable places of contamination must be surveyed and the swipes counted by appropriate techniques. Any radioactive contaminated areas found during the monthly survey must be decontaminated. This survey, including a diagram of the lab showing locations of major equipment and swipe areas, is required to be documented on form NIH 88-12, "Monthly Laboratory Contamination Survey." After completion, the original copy of the survey must be submitted to RSB. Additionally, one copy must be filed in your Radiation Safety Records book for the lab. These surveys shall be retained for three years in your records book for inspection by RSB personnel or NRC inspectors.

2.3.3 Waste Storage Removal

Radioactive waste material will be stored in containers behind Plexiglas shields until removed from the MCL. Waste materials will be tagged with Radioactive tape and labeled with the type of isotope, the approximate amount of radioactivity present (in total mCi), the infectious agent, the date and the initials of the person who generated the waste. Solid waste will be stored in autoclave bags in a designated radiation storage area and will be removed from the MCL by autoclaving. Due to the potential for contamination by autoclaving of radioactive liquids, this type of waste will be decontaminated by the addition of a suitable decontamination solution to inactivate any potentially infectious agents and removed when the laboratory is decontaminated for annual maintenance. All radioactive waste with a half-life of <100 days must be separated from waste with a half-life of >100 days.

In the event of a radioactive spill that precludes adequate cleanup, the event will be reported to the Facility Manager and/or the MCL Occupational Safety and Health Specialist who will notify the RSB Health Physicist.

2.4 EXPERIMENTAL ANIMALS

2.4.1 General

Animal research shall follow the guidelines established by the NIH Animal Research Advisory Committee (ARAC), the American Association for Laboratory Animal Science (AALAS), and the American Association for Accreditation of Laboratory Animal Care (AAALAC), the publication entitled *Guide for the Care and Use of Laboratory Animals, and the PHS.*

1. The housing, care, and handling of animals must conform to the current guidelines specified in the Institute of Laboratory Animal Resources (ILAR) publication entitled Guide for the Care and Use of Laboratory Animals.
2. All protocols involving the use of animals shall be approved by the appropriate NIH ICD Animal Care and Use Committee and the Chief, OSHB.
3. The use of sharp instruments in the MCL should be kept to a minimum. The use of glass is prohibited unless specifically approved by the Facility Manager and/or Occupational Safety and Health Specialist. Needle-locking (Luer-Lok) hypodermic syringes shall be used when syringes are necessary.
4. Doors to the laboratory/animal rooms must be kept closed at all times.

5. Only trained personnel are permitted to handle the experimental animals. The handling of infected animals, alive or euthanized, and secretions/excretions from such animals should be done carefully to minimize contamination of the laboratory area and damage to the positive pressure suit.
6. Squeeze-back cages will be used to physically control and house all nonhuman primates. Nonhuman primates must be anesthetized during procedures that require close contact or handling by personnel in the MCL.
7. All animals must be euthanized and then autoclaved (121.5 ˚C X 65 min) prior to removal from the MCL. Autoclaved bags shall be placed in MPW boxes and disposed of in accordance with NIH policy and procedures. See section 2.4.5.
8. All animal tissues for histopathology must be decontaminated prior to removal from the MCL. For this purpose, tissues will be placed in an ample volume of an appropriate fixative in a screw cap bottle for a minimum of 72 hours, transferred to a new bottle containing fresh fixative, and then removed from the MCL via the dunk tank in the equipment room to the Facility Core Center. The appropriate fixative shall be determined prior to initiation of a research project.
9. All blood and serum specimens removed from the MCL for serologic testing must be in screw cap vials. The exterior of the vials shall be (i) decontaminated, (ii) double-bagged using heat-sealed plastic bags, and (iii) removed from the MCL through the dunk tank. Virus in the samples should be inactivated by gamma-irradiation from a 60Co source (5 X 106 rads) before the plastic bags are opened. Animal sera should be exposed to 2 X 106 rads.

2.4.2 Inoculation of Animals with Infectious Material

1. Inoculation of experimental animals will be done only in a BSC. All animals must be anesthetized for inoculation with an infectious agent to avoid accidental injury, to the human handler(s).
2. Syringes and hypodermic needles shall be discarded into a sharps container immediately after use. Needles shall not be recapped after use. When the sharps containers are three fourths full, they shall be placed in autoclave pans and autoclaved for removal from the MCL.

2.4.3 Collection of Biological Samples from Live Animals

1. The collection of biological materials (including blood samples and bodily excretions or secretions) from live animals should be done in the BSC in the animal/laboratory room. If the animal is too large to be restrained in the BSC, the protocol requesting this exemption, shall be submitted to the PRC prior to the initiation of the research project.
2. Venipuncture sites shall be swabbed with an appropriate disinfectant.
3. Syringes and needles shall be discarded into a sharps container immediately after use. Needles shall not be recapped after use.

2.4.4 Housing Infected Animals

1. Only cages and water bottles approved by OSHB will be used for animals in the animal/laboratory suites.
2. Cages housing infected animals must be labeled to indicate the name of the infectious agent(s) in use, and the name and phone number of the person responsible for the care of the animals.
3. Animals in cages with contact bedding should be transferred to clean cages at least once each week unless otherwise directed. Care should be exercised to minimize aerosols from soiled cage bedding and other refuse. All used cages and refuse from the animal rooms must be autoclaved (121.5 ˚C X 90 min) before removal from the MCL.

2.4.5 Handling Animals

1. Care shall be exercised handling animals and their housing units to minimize the aerosolization of infectious materials.
2. Whenever feasible, disposable surgical or medical gloves shall be worn over the outer gloves on the positive pressure suit when handling infected or potentially contaminated animals.
3. While performing surgical procedures on infected animals, a disposable gown shall be worn over the positive pressure suit and disposable gloves over the suit gloves. The BSC surface should be washed down with an appropriate disinfectant upon completion of the procedure(s). Used instruments shall be placed in a discard pan or tray containing an appropriate decontaminating solution for the prescribed period of time, cleaned and sterilized.
4. Forceps or gloved hands shall be used to remove dead animals from cages. Forceps shall be stored in an appropriate disinfectant solution and gloves shall be washed with disinfectant after handling dead animals.
5. Dead animals shall be placed in closed leak-proof, double bags before transport to an autoclave, refrigerator, or freezer. Each container shall be identified with the date, investigator's name, and the infectious agent.
6. All animals must be euthanized and then autoclaved (121.5 ˚F X 90 min) prior to removal from the laboratory. Euthanized animals shall be stored in a refrigerator or freezer if the autoclave is not available for immediate use. Euthanized animals shall be autoclaved in an open bag containing water. Autoclaved bags shall be placed in MPW boxes, labeled and properly disposed of in accordance with NIH policy and procedures.
7. An animal that escapes during handling shall be considered potentially contaminated with the infectious agent(s) in use the MCL. Consequently, such animals shall be euthanized unless the responsible investigator directs otherwise.

2.4.6 Necropsy

1. All necropsies of animals will be done in the BSC, or on a downdraft necropsy table within the MCL.
2. Disposable gloves and disposable gowns must be worn over the positive pressure suit when performing necropsies on infected or potentially contaminated animals.
3. Care should be exercised when performing a necropsy to prevent damage to the protective suit by sharp bone fragments or instruments.
4. Upon completion of a necropsy, all animal tissues not saved for histopathology shall be placed in appropriately labeled, leak-proof bags, and autoclaved. Autoclaved bags should be removed from the autoclave, double bagged and placed in MPW boxes. All boxes should be sealed and labeled by the laboratorian. Consult the MCL Occupational Safety and Health Specialist for information on proper disposal of the MPW boxes. All instruments should be placed in the appropriate decontaminent for the prescribed period, scrubbed, and autoclaved. The BSC or downdraft table surface shall be cleaned with the appropriate decontaminanting solution.
5. The disposable gown and gloves worn when performing a necropsy shall be placed into an autoclave bag, autoclaved, and disposed of in a MPW box in accordance with NIH policy and procedures.

2.5 REGISTRATION, STORAGE, AND TRANSPORT OF INFECTIOUS AGENTS

2.5.1 Registration of Infectious Agents

All BSL-2, 3, and 4 agents as defined in "Biosafety in Microbiological and Biomedical Laboratories" (HHS Publication No. [CDC] 93-8395) will be registered and approved for use in accordance with NIH guidelines.

A Registration of Materials (Potentially) Infectious for Humans (HPRD) Appendix R, must be approved by the NIH IBC and OSHB before studies with the agent(s) are initiated.

The Chief, OSHB, must approve all infectious agents or materials brought to the NIH. Certain agents require that PHS and United States Department of Agriculture (USDA) permits for the transport of the agent be obtained prior to shipment of the material from point of origin to the NIH. If the agent has not been previously handled at the NIH, OSHB shall be notified of the nature of the agent and its intended use.

2.5.2 Storage of Infectious Agents

1. Infectious or toxic materials shall be stored only in refrigerators, incubators, or freezers which are marked with the universal biohazard symbol.
2. Transportation of all infectious or toxic materials within the MCL shall be placed within a secondary, unbreakable container.
3. All infectious or toxic materials stored in refrigerators or freezers must be properly labeled and stored in containers capable of withstanding the thermal shock of freezing and thawing. GLASS IS NOT ALLOWED IN THE MCL WITHOUT EXPRESS APPROVAL OF THE FACILITY MANAGER. Each container should be labeled with the identity of the infectious agent, the date of the preparation, the name of the responsible laboratorian and a reference number which links the material to the more inclusive information contained in the inventory databases.
4. When work is completed and prior to exiting the MCL, all infectious cultures or toxins will be removed from work benches and cabinets and stored in a designated refrigerator, incubator or freezer. Material to be discarded will be placed in a sealable container, placed in a discard pan containing a decontaminant, placed on a cart and transported to the autoclave.
5. Labware containing infectious liquids must be stored and transported in a leak proof container which has sufficient capacity to contain the liquid (in the event of breakage of the labware).

2.5.3 Removal and Transport of Infectious Materials

Infectious Agents

1. Containers of infectious or toxic substances for transport from the MCL will be placed in a larger, unbreakable container having solid sides, bottom, and a leak proof cover. The surface of the carrier shall be decontaminated by passage through the dunk tank.
2. Infectious, toxic, radioactive or recombinant DNA materials shall be shipped off-campus in accordance with NIH/CDC Safety Guidelines and Department of Transportation (DOT) shipping regulations. The Chief, OSHB, or his/her designee will approve all requests for shipments of infectious materials. When the transfer permit is approved, the shipment will be handled by the NIH Shipping Office. If the infectious agent is exotic in origin, the recipient of the material must have a PHS (and possibly USDA, and/or United States Fish and Wildlife Service [USFWS]) permit to ship infectious agents. Permit labels shall be attached to the package (UN Class 6.2) with the appropriate "BIOHAZARD INFECTIOUS MATERIAL" labels.
3. The Chief, OSHB, will approve all shipments of BL-4 agents.
4. The shipment of any material containing radioactivity shall be handled by RSB: (i) An appointment must be made with the Materials Control Unit (6-3277), (ii) 24 hour advance notice is required by RSB.

Tissues for Histopathology

5. Prior to removal from the laboratory, tissues should be processed as follows:
6. The tissue should be sectioned into small pieces that are easily fixed. Generally, sections should be less than 1 cm. cubes.

7. The material should be placed in at least 10 X volume of an appropriate fixative. For most purposes, 2% glutaraldehyde can be used for fixation of tissues intended for electron microscopy.
8. The fixed material should be changed to fresh fixative in a new screw cap container 3 days after initial fixation. The container of fixed material may be surface decontaminated and removed from the MCL area by submersion in the dunk tank in the equipment room. The fixed material shall be placed in a leak proof, unbreakable container for transport from Building 41A.

2.6 WASTE MANAGEMENT IN THE MCL

All infectious or toxic materials, contaminated reusable labware and contaminated waste will be autoclaved prior to washing or disposal by the laboratorian. Contaminated materials will be placed directly into an autoclave or held in a covered container for subsequent autoclaving. Water should be added to all containers to be autoclaved. After autoclaving, package all disposable items in MPW boxes in accordance with NIH policy and procedures.

Radioactive waste: Contact the Health Physicist, RSB (6-5774), to arrange pick up of materials (see Radiation Safety Manual). Arrangement for autoclaving and pick up is the responsibility of the individual who has generated the specific radioactive waste.

Items will be segregated before autoclaving as follows:

1. Syringes, needles, and other sharp objects: place in authorized sharp containers with no re-capped needles.
2. Disposable soft materials: paper and plastic, plastic wrapping from pipettes and plastic pipettes shall be placed in autoclave bags. Autoclave bags shall be placed in a leak proof pan.
3. Other disposable materials: vessels, tubes, pipettes, and metal shall be placed in an autoclavable container/or pan.
4. Reusable labware: place in autoclavable containers. Autoclave out of the MCL, transport to the appropriate Institute for washing.
5. Animal cages: animal cages are to be placed in the autoclave with as little disturbance to bedding as possible.

2.7 MAINTENANCE SUPPORT ACTIVITIES

2.7.1 Shutdown of the MCL

The MCL is decontaminated annually or at the end of each research project (whichever occurs first), and will be used to service all scientific and communication equipment of the MCL. All investigators will be responsible for completing the AMCL Checkout Procedure (Appendix L) at the end of the research project. This shutdown is coordinated with DES, and will be used to inspect all aspects of the integrity and safety features of Building 41A. The protocol and list of responsibilities for the gas decontamination of Building 41A is in Appendix M. Refer to Section 2.8 for staff responsibilities.

2.7.2 Decontamination Airlock Area

In the event that equipment must be removed from the MCL prior to the annual Facility decontamination, the item is cleaned of all chemical and biological material, and moved to the Decontamination Airlock area (see section 3.3.2) to be decontaminated prior to removal from the Facility. See Appendix N for VHP procedures.

2.8 MAINTENANCE DUTIES OF STAFF

2.8.1 Facility Manager

The Facility Manager shall coordinate maintenance duties with DES and the MCL Occupational Safety and Health Specialist. In the absence of the MCL Occupational Safety and Health Specialist, other OSHB staff members will be responsible for these duties. Assignment of these alternates will be made by the Chief, Safety Operations Section, OSHB.

The Occupational Safety and Health Specialist shall be responsible for the following:

1. Autoclave Quality Assurance.
2. Ensure that the decontaminant in the Decontamination Shower tank and dunk tank are maintained at the appropriate level.
3. The coordination of the removal of the decontaminated waste and material from the autoclave and dunk tank.
4. Maintain an adequate supply of laboratory disposable jump suits, clean towels, soap, and shampoo in the dressing room.
5. Place used laundry in bags for pick-up by Housekeeping.
6. Ensure that suit rooms are supplied with caps, inner gloves, heavy-duty gloves to be taped to the suits, tape, scissors, and 70% alcohol.
7. Perform the critical systems check daily.
8. Maintain entry and exit records on the computer database, monitor the closed circuit TV system and issue the proximity card keys.

2.8.2 All MCL Laboratorians

Before entering the MCL:

Ensure that the Critical Systems checklist (Appendix G) has been completed. This checklist shall be on file in the Facility Core Center. A notice will be posted in the outer change room upon completion of the Critical Systems checklist. This inspection is completed daily by the Facility Manager or the MCL Occupational Safety and Health Specialist.

Inside the MCL:

1. The first person who enters the MCL each day must complete the Interior Checklist (Appendix O) to assess any malfunctions of the systems.
2. Keep the MCL change room and suit room clean and orderly.
3. Place all trash in autoclave bags, add water, and autoclave. On the clean side of the autoclave, at the end of the autoclave cycle place all autoclave bags in MPW boxes. All MPW boxes shall be disposed of in accordance with NIH policy and procedures.
4. After each use of the BSC, pour one to two inches of the appropriate decontaminating solution into the bottom of each discard pan used in the BSC and autoclave discard pan.
5. Clean BSC work surface after each use with appropriate decontaminating solution. Place clean discard pans in the BSC.
6. Autoclave all waste animal food, animal waste pans and cages before removal from the MCL. (See 3 above)

DISPOSAL Of EUTHANIZED ANIMALS AND ANIMAL TISSUES IS THE RESPONSIBILITY OF THE INVESTIGATOR. Place animals/tissues in autoclave bags, add water, and autoclave.

After exiting the MCL:

REMOVE THE BAGS WITH THE EUTHANIZED ANIMALS AND ANIMAL TISSUES FROM THE AUTOCLAVE, DOUBLE BAG AND PLACE IN MPW BOXES. PLEASE CONSULT THE MCL OCCUPATIONAL SAFETY AND HEALTH SPECIALIST TO COORDINATE APPROPRIATE PICKUP OF MPW BOXES IN ACCORDANCE WITH NIH POLICY AND PROCEDURES.

3.0 BUILDING SYSTEMS

3.1 BUILDING OVERVIEW

Building 41A houses the MCL which is designed as a BL-4 laboratory. The building contains a Facility Core Center, mechanical areas on both east and west sides of the building with air handling equipment housed in the area above the MCL. Entrance into the building is through proximity card accessed doors.

The MCL consists of three laboratory/animal suites, one equipment room, autoclave staging area, decontamination airlock, VHP control room and a small storage closet. Building 41A has many special features.

1. Filtration of supply air is through high-efficiency particulate air (HEPA) filters. Exhaust air is filtered through two HEPA filters in series before being discharged.
2. Laboratorians wear impermeable, positive pressure, supplied breathing air suits while working in the MCL. The air supply is regulated for breathing and suit cooling.
3. All liquid effluent is decontaminated. This Liquid Effluent Treatment System involves steam sterilization, cooling and neutralization to assure proper pH and temperature of effluent is achieved before release to the sanitary sewer.
4. The entry corridor and mechanical areas are "clean", however, for security purposes, access is proximity card controlled.
5. Two double door autoclaves with interlock mechanisms which are accessible from the "clean" corridor as well as the MCL. Solid waste is removed from the MCL only after autoclaving.
6. Access to the laboratory suites through a clean change room. This area contains lockers for storage of personal clothing, supplies of disposable jump suits and gloves to be worn under positive pressure suits, HEPA filters for air lines, clean towels, soap and shampoo for the personal shower and laundry bags for disposal of soiled linen. A toilet and personal shower are located in the inner change area.
7. A suit room contains the positive pressure suits, heavy duty gloves and supplies for attaching gloves to suits.
8. The decontamination shower has interlocking doors. The boot area is located just beyond the decontamination shower in the MCL main corridor.
9. Each laboratory/animal suite contains a BSC.
10. A supply closet with limited storage capabilities for operating supplies.
11. A manually operated emergency shower and emergency breakout panel located at the south end of the main corridor of the MCL.
12. A Decontamination Airlock is located at the north end of the MCL main corridor for VHP decontamination.

3.2 SECURITY

3.2.1 Monitoring of Facility

The MCL security is provided by 24 hour camera surveillance and the NIH police who patrol the NIH campus.

3.2.2 Authorization of Personnel for Entry

Access to Building 41A and the MCL is restricted to those personnel who must enter for program or support needs. Such employees will (i) be briefed on the potential hazards of the BL-4 agents handled in the laboratory, (ii) be familiar with the standard and emergency procedures described in the Safety and Operations Manual, Building 41A, and (iii) participate in the required MCL training. New staff members shall work in the MCL only after receiving authorization from the Chief, OSHB, or the Facility Manager. A minimum two-week training period shall be preceded by an orientation to the MCL presented by OSHB.

Persons who are not an employee of the NIH but who are Apeer scientists/collaborators, may qualify for entry or work in the MCL but only with approval of the NIH IBC, PRC, and Chief, OSHB. Non-employee visitors will be briefed on the potential hazards of the laboratory by the Facility Manager and/or the Occupational Safety and Health Specialist. These visitors will be familiar with the procedures described in the Safety and Operations Manual, Building 41A and attend the required MCL training.

Authorized service personnel may enter the Facility Core Center corridor or the mechanical areas for routine monitoring and service during duty and non-duty hours. Persons other than MCL staff, will not enter the MCL when the facility is operational and viable materials are present unless approved by the Chief, OSHB, or the Facility Manager and/or the Occupational Safety and Health Specialist.

3.2.3 Facility Utilization

Use of the facility shall be limited to programs approved by the NIH IBC, PRC and the Chief, OSHB. No changes and/or additions to approved programs and projects can be made without written approval of the foregoing.

3.3 SYSTEMS

3.3.1 Alarms

Visual strobes of 70,000 candle power are located throughout the MCL to indicate a fire emergency or failure of the HVAC and breathing air systems. Telephones and fax machines are available for normal and emergency use. Alarm indicators are located in the Facility Core Center and indicate the following: (i) decontamination tank level; (ii) air balance inconsistency; (iii) unauthorized entry and (iv) improper use of interlocked doors. Mechanical system alarms are automatically relayed to the Building 41A engineer, (East Mechanical Office in Building 41A), and South Maintenance Engineering in Building 37.

3.3.2 Decontamination Airlock

The Decontamination Airlock serves as an airlock between the main corridor of the MCL and the exterior of Building 41A. This space may be used to surface decontaminate large pieces of equipment using the VHP unit before removal from the MCL (Appendix N). If necessary, formaldehyde can be used as a decontamination agent. The doors of this space are interlocked and are only opened with a manual key lock from within the MCL.

3.3.3 Autoclaves

Two double-door autoclaves, one large and one small, are in the MCL. Each is interlocked so that it cannot be opened to the clean corridor of Building 41A until a sterilization cycle has been completed. Standard operating procedures are found in Appendix P. All solid waste, discard pans, animal cages, animal waste, bedding and feeding apparatus are sterilized by autoclaving before removal from the MCL. The automatic timing system on the autoclaves places the autoclaves in a stand-by mode. Between the hours of 6:00 am - 7:00 pm, Monday - Friday, the autoclaves are in an operational mode. Autoclaves are maintained by a maintenance contractor. Notify the MCL Occupational Safety and Health Specialist immediately if a problem occurs.

3.3.4 Biological Safety Cabinets

The MCL contains three Class II, Type A laminar flow BSC, one in each laboratory/animal suite. The cabinets are certified annually as part of the facility maintenance.

3.3.5 Breathing Air (Suit Air)

Breathing air is supplied from specially designed compressors through constant temperature air dryers. Mechanical refrigeration is used to remove moisture from compressed air while providing a constant outlet air temperature. The dryers are designed to deliver the air at constant temperatures. The facility is equipped with redundant air compressors to minimize disruption of service.

In the event of the failure of both compressors, emergency bottled breathing air is supplied through a duplex manifold which is designed for service in locations where a constant and adequate supply of air is needed. The manifold is designed to changeover from one bottle to another automatically. It is recommended that in the event of failure of the breathing air compressors, MCL personnel shall store project work and exit the MCL. Strobes will indicate such an emergency (see section 3.3.1) throughout the MCL. The mechanical system alarm panel will indicate an alarm state in (i) the Facility Core Center, (ii) East Maintenance Office, Building 41A and (iii) South Maintenance Unit Office, Building 37.

3.3.6 Laboratory Gases

The laboratory compressed gas manifold is designed to provide an uninterrupted supply of gas to the MCL piping system. The manifold provides for automatic changeover from the depleted bottle to a secondary bottle with no fluctuation in delivery pressure. Pressure gauges on the manifold indicate the system status and alert staff about the need to replace any depleted cylinders.

3.3.7 Communications

Communications between the MCL and the Facility Core Center or staff may be accomplished in four ways:

1. intercom
2. telephone
3. fax
4. 2-way headphone systems worn inside of the personal protective suit.

The intercom system operates between the Facility Core Center, dressing room and the MCL. Telephone and fax can be accessed to anyone outside the MCL. See Appendix C for a list of telephone numbers. They are primarily used for communication between personnel inside the MCL and the OSHB staff. The fax is used to send data and other written communication out of the MCL. Books and papers cannot be removed from the MCL.

3.3.8 Decontamination Shower

The facility has a decontamination shower, which also serves as an air lock between the MCL and the "clean" area. All personnel enter and exit the MCL through the decontamination shower/air lock (Appendix I).

The decontamination shower is equipped with interlocking doors having inflatable gaskets. Inflation of the gasket is controlled with the door handle; depressing the handle deflates the gasket. It is essential that personnel ensure complete closure of the door after passage, to allow the door gasket to fully deploy and maintain containment.

When exiting the MCL, enter the decontamination shower next to the boot area. Initiate automatic cycle by pressing the green push-button labeled “START” located on the upper left side of the MCL shower door. When the automatic cycle is completed, press the door handle down, allow the gasket to deflate and exit the shower.

Gravity feed operation of the shower in the event of a power failure or accident is performed by using the manual pull handle suspended from the ceiling of the shower. Pull the manual handle to release decontaminating solution; to stop the manual shower, release handle.

3.3.9 Emergency Showers

An emergency shower, which operates identically to the manual shower in the decontamination shower, is located at the south end of the main corridor of the MCL. The pull chain is located in front of the break out panel. This shower and break out panel are to be used only in life threatening situations.

3.3.10 Ventilation

The airflow within the MCL is of critical importance to the containment function of the laboratory. Outside air enters through HEPA filters and airflow is of a directional nature, proceeding from areas of higher pressure (clean side) into areas of lower pressure (MCL). All air is double HEPA filtered before being exhausted to the outside.

3.3.11 Liquid Effluent Treatment System

All liquid waste is discharged through a closed system into decontamination tanks located in the sub-basement of Building 41. Each tank is steam processed and subsequently, partially cooled. The contents are then transferred to other tanks for pH neutralization and further cooling. This processed waste effluent is then allowed to enter the sanitary sewer system. (See section 5.6) The operation of the Liquid Effluent Treatment System is the responsibility of the Division of Safety.

3.4 LABORATORY EQUIPMENT OPERATION

3.4.1 Carbon Dioxide Incubators

CO_2 incubators shall be moved into the MCL when the program requires them.

The investigators shall maintain this equipment.

3.4.2 Centrifuges

An ultracentrifuge and/or a centrifuge required for a current project shall be located in the equipment room. Maintenance will be performed as needed by MCL staff or by an authorized service representative during the annual shutdown of the MCL. Tabletop centrifuges are located in the laboratory/animal suites.

3.4.3 Water Baths

Water baths shall be located in the laboratory/animal suite as needed. Maintenance is performed during the annual shutdown and as needed. All water baths are checked according to standard laboratory practices. Water baths shall (i) not have mercury thermometers; (ii) have automatic shutoffs for low water level and (iii) over temperature controls.

3.4.4 Microscopes

Any microscopes required for the research program shall be located in the laboratory/animal suite of the MCL. Microscopes shall be serviced annually during shutdown. Maintenance is performed as needed.

3.4.5 -20°C and -80°C Mechanical Freezers

Freezers shall be located in the MCL equipment room or as required by the research program. Repairs and maintenance are performed as needed and during annual shutdown.

3.4.6 Refrigerators

Laboratory refrigerators and a refrigerator for storage of animal food shall be located in the equipment room of the MCL.

3.4.7 Scintillation Counter

If radioactive material is used in the MCL, the radioactive material shall be contained in scintillation vials and removed from the MCL through the dunk tank. Access to a liquid scintillation counter will be required by RSB.

3.5 ANIMAL SUITE

3.5.1 Housing

Animals are housed in appropriate cages recommended by the "Guide for the Care and Use of Laboratory Animals" (U.S. Department of Health and Human Services published 1996) unless other arrangements have been approved by the ARAC.

3.5.2 Sanitation

Cages are changed according to species. All cages, pans and bedding are autoclaved out of the suite. The Institute using the MCL for a research project shall be responsible for changing and washing the cages. The animal suite is cleaned by the laboratory staff responsible for the animals.

3.5.3 Food

Food for all animals is obtained by the animal care staff, and moved into the MCL via the large autoclave. The food shall be stored in closed containers. All uneaten or spoiled food is autoclaved out of the laboratory before being discarded.

3.5.4 Records

Animal records are maintained within the MCL until experiments are completed. Records are attached to the cage; with the exception of non-human primate records which are kept in a notebook. The records may be transferred only by facsimile at any time.

3.5.5 Pest Control

An integrated pest management program (IPM) is in place for Building 41A (Appendix Q). A synopsis of the integrated pest management plan follows.

1. IPM is an approach to controlling pests that minimizes reliance on the use of pesticides and emphasizes management of the environment (i.e., personnel procedures and facility conditions) to prevent pests from becoming a problem.
2. The rigorous sanitation and maintenance requirements associated with operating this facility should preclude the establishment of pest "infestations" within the containment area. The most likely source of pest problems will be the incidental ingress of pests through doorways, and the introduction of pests with animal feed and goods/supplies brought from home or laboratories.
3. Pest management surveys inside the containment area will occur upon request of the Facility Manager, in order to diagnose and resolve specific pest issues. The exterior of the building, the mechanical rooms, the locker room and the Facility Core Center will be monitored and observations recorded in a logbook kept in the Facility Core Center. One Pest Management Unit staff member, and a back up, will be assigned to perform this task.

4. The primary pest control tactics used in Building 41A will be non-chemical, i.e., traps, exclusion, removal/disposal. If the use of a pesticide is necessary, only baits and solid formulations of pesticides will be used. This will eliminate the potential for drift and volatilization of petroleum distillates and solvents associated with the use of some liquid and aerosol formulations of pesticides.
5. An IPM logbook will be compiled and maintained by pest management personnel. This logbook will contain MSDSs and labels for all pest management products that may be used in and around Building 41A. In addition, the logbook will contain protocols and procedures for performing routine and emergency pest management services and reporting pest activity, IPM reports and recommendations, and pest data.

3.6 ANNUAL INSPECTION AND PREVENTIVE MAINTENANCE

An annual inspection of the MCL is carried out by OSHB and coordinated with the Division of Engineering Services to inspect all aspects of the integrity and safety features of Building 41A. Maintenance of the scientific and communications equipment is done during the annual shut down.

4.0 EMERGENCY PREPAREDNESS PLAN

4.1 INTRODUCTION

This plan establishes the procedures to follow in the event of a fire, medical emergency or bomb threat at the NIH Maximum Containment Laboratory (MCL), Building 41A. The priority consideration in the event of an emergency is the protection of the health and safety of personnel working in the MCL.

Safety procedures described in this plan shall apply to all MCL activities and all program and support personnel. Modifications to these procedures or to the facility shall not be made without written approval of the NIH Institutional Biosafety Committee (IBC), Policy Review Committee (PRC) and the Chief, Occupational Safety and Health Branch (OSHB).

4.2 DEFINITIONS

1. Biosafety Level (BL). A combination of laboratory facilities, safety equipment and microbiological procedures used in handling etiologic agents, encompassing four levels of potential hazard with BL-1 providing the least risk and BL-4 the highest. This combination is appropriate to the potential hazard of the etiologic agent in question and is designed to protect the worker, environment and the community.
2. *CHEMTURION* Suit. A totally encapsulating, positive pressure biological/chemical protective suit constructed of 20mil chlorinated polyethylene. Breathing air is supplied to the suit by an umbilical hose.
3. Decontamination. The physical or chemical process by which an object, area, or person contaminated with a harmful or potentially harmful etiologic agent, is made safe for handling or use.
4. Emergency. An event in the MCL which may involve: 1) exposure or injury of personnel, 2) compromise of biological and/or physical barriers or 3) major equipment failure which could compromise safe operations in the facility. Refers to all situations (fire, medical, etc.) in which a rapid response is necessary to limit injuries to MCL personnel and/or maintain the operational integrity of the facility.
5. Fire and Emergency Response Section. The NIH Fire Department is the primary responder to all fire, rescue, technological and medical emergencies on the Bethesda campus.
6. Incident Commander (IC). The senior emergency response professional (fire or police department representative) on the scene, who is in charge of the incident scene and responsible for all decisions pertaining to the management of the emergency situation.

4.3 RESPONSE TO FIRES

In the event of a fire in the mechanical spaces or office area, efforts to extinguish the fire by MCL personnel should be attempted only after the fire department has been notified, and if the fire is limited in size and egress from the area will not be compromised. Do not attempt to fight a fire in an animal/laboratory room while wearing a *CHEMTURION* suit.

Open flames are not to be used in the MCL, unless it involves repairs to the laboratory and a hazardous work permit has been obtained and the proper safeguards are in place. There are fire extinguishers and an automatic, quick response sprinkler system located throughout the Facility Core Center, animal/laboratory rooms and mechanical spaces of Building 41A. The MCL has a primary exit, the personal decontamination shower room and a secondary exit, the emergency breakout panel at the south end of the marshaling corridor. There is a manual fire alarm pull station located near the primary and the secondary exit and near the entrance door to the Facility Core Center. All program and support personnel should familiarize themselves with the location of all exits, fire extinguishers and manual fire alarm pull stations. Section 5.2 is a Floor plan of Building 41A showing the locations of these fire safety devices.

If you are in the office or change room area and see smoke or flames:

1. Notify everyone in the MCL of the fire by pulling the nearest fire alarm manual pull station and phoning 911 - tell the NIH Fire Department your location, name and the nature of the emergency.
2. Don gloves and go to the decontamination shower area and assist individuals in removing their *CHEMTURION* suit. In a life-threatening emergency, immediate personal safety overrides maintenance of containment. Evacuation takes priority and a decontamination shower is not required.
3. Exit and move away from the building. The facility manager or his/her designee will report to the Fire Department IC and provide details of the emergency including whether or not all MCL staff have safely evacuated the building, the nature of the emergency and the biological agents in use.
4. In the event that additional decontamination steps may need to be taken, all MCL staff must remain in the same area. Potentially contaminated MCL personnel shall not make physical contact with other individuals.

If you are in an animal/laboratory room and can safely do so:

1. Turn off all electrical appliances.
2. Secure all infectious materials in a refrigerator, freezer, or incubator.
3. Close all animal cages and leave the cages in place in the room.
4. Close the laboratory door as you leave the room.
5. Proceed to the primary exit and leave the facility through the decontamination shower. In a life threatening emergency, a decontamination shower is not required.

If the primary exit is blocked, proceed to the emergency breakout panel at the south end of the marshaling corridor and leave the MCL.

1. Remove the *CHEMTURION* suit once you are safely outside the MCL. Minimize any contact with the outside of the suit or gloves and place the suit inside-out on the ground.
2. Move away from the building to the designated marshaling area and report to the Facility Manager or his/her designee. Potentially contaminated personnel will avoid any contact with other individuals. Additional decontamination steps may need to be taken.

If you are in either the east or west mechanical room and see smoke or flames:

1. Activate the alarm by pulling the nearest fire alarm manual pull station and dial 911 - tell the NIH Fire Department your location, name and the nature of the emergency.

2. Use a fire extinguisher only when the fire is limited in size and egress from the room will not be compromised.
3. Immediately exit the facility and report to the designated marshaling area.

4.4 RESPONSE TO MEDICAL EMERGENCIES

This section outlines responsibilities and procedures for response to the various types of medical emergencies which may occur within the Maximum Containment Laboratory.

4.4.1 Potential Exposure To Biological Agents

Any potential exposure shall be reported to the Occupational Medical Service (OMS) and to the Facility Manager (or the MCL Occupational Safety and Health Specialist) and the Chief, OSHB immediately. An evaluation will be made as to the actual risk and the course of action to be taken.

If a significant risk is judged to have occurred, then the OMS, will be responsible, in consultation with appropriate medical specialists and the OSHB, in decisions regarding the management of the exposure situation. Management may range from no action, other than correction of the conditions that led to the situation, in the case of negligible risk; to close monitoring of the person for fever and/or other symptoms; to isolation and possibly treatment with prophylactic drugs or other modalities.

4.4.2 Potential Skin Or Aerosol Exposure To Biological Agents

Any breach in the integrity of the *CHEMTURION* suit will be managed as described in section 2.2.5 (Suit Malfunction) of the *Maximum Containment Laboratory Safety and* Operations Manual. After the laboratorian exits the MCL, the exposure will be reported to the OMS for medical monitoring and counseling. Also, the Facility Manager (or the Occupational Safety and Health Specialist) and the Chief, OSHB will be notified. If the exposure is judged to be of very low risk, the employee will be instructed to be alert for any possible signs of illness. If the exposure is thought to be of potential significance, management will be discussed between the OMS, appropriate medical specialists and the Chief, OSHB. The IBC and PRC will be informed if the risk level is judged to be high.

4.4.3 Potential Percutaneous Exposure To Biological Agents

1. The wound site will be treated with a disinfectant, available at each sink in the MCL, for a minimum contact time of ten minutes.
2. The person will exit the MCL immediately, following established decontamination shower procedures.
3. Additional application of disinfectant and thorough washing of the affected area for ten minutes with soap and water will be conducted in the change room lavatory.

These events will be reported to the MCL Facility Manager (or the Occupational Safety and Health Specialist), the Chief, OSHB and the OMS as soon as feasible. Routine first-aid and an accident report for the cut or needle injury will occur through the OMS according to NIH policy. The post exposure management of the infectious hazard will be discussed between the OMS, appropriate medical specialists and the Chief, OSHB; if the risk level is judged to be high, the IBC and PRC will be notified. A NIH Notice of Traumatic Injury Form must be completed.

4.4.4 Health Emergencies Within the MCL

Effective treatment of known life-threatening situations must take precedence over the threat of the MCL microbial environment. Because the major risk to emergency medical personnel is through aerosols, their entry into the MCL suites should generally not be permitted. If there has not been major contamination of the affected worker, decontamination of the suit exterior in an emergency can be less thorough than in

ordinary circumstances, particularly given the Blood borne pathogen protection that is exercised by professional Emergency Medical Technicians (EMTs). The telephone should be used to notify persons outside the MCL to mobilize assistance. All of the following procedures must be done promptly to ensure rapid, safe patient transport to definitive medical care.

1. Call for help: Dial 911.
2. Give your location and the type of medical emergency.
3. Provide basic first aid if possible.
4. Emergency response staff will enter the containment area and will be responsible for extracting and decontaminating a patient(s) with serious injuries or other life-threatening conditions. Special considerations include:

4.4.5 Handling of Ambulatory Patients

In a situation where the patient can walk with assistance, without compromising their well-being, the patient may take a routine decontamination shower and exit in the normal manner.

1. Protective clothing: It may be necessary to remove the patient's protective *CHEMTURION* suit while still in the MCL. The positive pressure suit surface is sprayed with the disinfectant appropriate for the biological agent(s) in use, prior to removal of the suit. The suit may be doffed after it has been sprayed with the disinfectant. The patient may then be treated for injuries or illness by the emergency response personnel.
2. Decontamination of the patient: An evaluation must be made by the Facility Manager to ensure that the patient was not exposed to a BL-3 or BL-4 agent. If it is determined that an exposure has occurred, the patient will be decontaminated and transported to Suburban Hospital by the responding EMTs. Patients wearing *CHEMTURION* suits will have their suit promptly sprayed with an appropriate decontaminant. When the patient arrives in the suit room, the suit will be removed. Once the protective suit is removed from the patient there is little, if any, likelihood of exposure of response personnel to an infectious agent.
3. Minimize the number of emergency responders and the amount of medical equipment entering the MCL. The patient(s) will be available for transport in either the suit room adjacent to the primary exit or outside the building.
4. Emergency response personnel, who have entered the MCL to assist the patient, will not exit with the patient but must go through appropriate decontamination procedures.
5. Hypoxia is an immediate threat unique to the MCL environment and is caused by inadequate oxygen supply to or distribution within the *CHEMTURION* suit. If this condition is suspected as a cause of loss of consciousness of a co-worker, the suit should be opened and the body adjusted to allow free breathing. This procedure should be done in an area in which it is unlikely that aerosols have been recently generated.

4.5 BOMB THREAT/INCIDENT

The chance of urban terrorism against an NIH facility is remote but a situation which nonetheless must be included in an Emergency Preparedness Plan. This section lists the sequence of steps to take in the event that either a suspicious package is discovered in or near Building 41A or a potential bomb threat concerning the MCL is received by phone. In both cases, remain calm and follow the instructions detailed in this section.

Engage the caller in conversation, be calm and, if possible, take notes to determine:

- exact location of the bomb
- source of the threat
- time of explosion

- background noises on phone
- peculiarities of the caller's voice
- gender and approximate age of the caller

If possible, have someone else listen on an extension or a speaker phone. Immediately upon termination of the call, and before using the phone to call the police, dial *69 and attempt to obtain the telephone number from where the threat originated.

Call the NIH Police 911.

Never touch a suspected bomb device; turn off all types of radios and transceiver equipment near the suspected area.

If building evacuation is necessary, leave in an orderly manner. Activation of the fire alarm system will not be used. The order to evacuate will be given by telephone or messenger.

4.5.1 Evacuation Procedures

1. Evacuate the building when given the order. If you can *safely* do so; secure all infectious materials in a refrigerator, freezer or incubator, close all animal cages and leave the cages in place in the room.
2. Exit through the normal entrance in an orderly fashion. In a life threatening emergency, a decontamination shower is not required. Emergency exits will not be used unless there has been a detonation.
3. Do not turn lights on or off. Leave the area as you found it.
4. Quickly scan your work area prior to leaving the building and report to the NIH Police any suspicious briefcases, bags, or packages, which appear to be out of place.
5. MCL occupants, who have exited the building without following the proper decontamination procedures, should remain isolated from other individuals and emergency responders since additional decontamination steps may need to be taken.
6. Personnel will evacuate the building to a designated marshaling area, at least 300 feet upwind from the facility, or where directed by the emergency response personnel. Personnel will return to the building when authorized by the Police Department IC.

4.6 EMERGENCY CALL LIST

FIRE/AMBULANCE/RESCUE/POLICE 911

ENGINEERING

NON-EMERGENCY CALL LIST

Occupational Safety and Health Branch

Occupational Medical Service

NIH Police

NIH Fire Department

Radiation Safety Branch

Environmental Protection Branch

Community Health and Pest Management

Buildings Maintenance Unit

Grounds Maintenance

LAB PHONE NUMBERS

MAIN Office	Rm 114
Suit Room	Rm 115
Sub-Basement	Rm 117
East Mechanical	
Guard Booth at 41A	

5.0 FLOOR PLANS

Removed for security reasons.

5.1 BUILDING 41A BASIC FLOOR PLAN

5.2 BUILDING 41A EMERGENCY PREPAREDNESS FLOOR PLAN

5.3 BUILDING 41A EMERGENCY GENERATOR POWER

5.4 BUILDING 41A ALARM SYSTEMS

5.5 BUILDING 41A GAS DECONTAMINATION

5.6 BUILDING 41A WASTE PROCESSING SYSTEM MCL

6.0 REFERENCES

1. Life Safety Code (NFPA 101) including Standards Referenced in Chapter 32 which include:
    a. NFPA 13 - Standard for the Installation of Sprinkler Systems.
    b. NFPA 30 - Flammable and Combustible Liquids Code.
    c. NFPA 45 - Standard on Fire Protection for Laboratories Using Chemicals.
    d. NFPA 70 - National Electrical Code.
    e. NFPA 72 - Installation, Maintenance and Use of Protective Signaling Systems.
    f. NFPA 72E - Standards on Automatic Fire Detectors.
    g. NFPA 80 - Standard for Fire Doors and Windows.
    h. NFPA 90A - Standard for the Installation of Air Conditioning and Ventilating Systems.
    I. NFPA 110 - Standard for Emergency and Standby Power Systems.
    j. NFPA 241 - Safeguarding Building Construction and Demolition Operations.
2. BOCA National Building Code including current supplements.
3. BOCA National Mechanical Code including current supplements.
4. Washington Suburban Sanitary Commission Regulations.
5. Model Energy Code.
6. OSHA Safety and Health Standards (29CFR 1910) including current revisions.
7. Maryland Stormwater Guidelines for State and Federal Projects.

8. American Society of Heating, Refrigeration and Air Conditioning Engineers (ASHRAE) edition of:

a. Refrigeration.

b. Equipment Handbook.

c. Fundamentals Handbook.

d. HVAC Systems and Applications Handbook.

9. Industrial Ventilation - A Manual of Recommended Practice by the America Conference of Government Industrial Hygienists.

10. Prudent Practices for Handling Hazardous Chemicals in Laboratories, National Research Council (19).

11. Additional NIH Standards.

a. Biosafety in Microbiological and Biomedical Laboratories, CDC/NIH, HHS Publication No. (CDC) 88-8395.

b. General Design Criteria for NIH Laboratory Use of Chemical Carcinogens.

c. NIH Safety Publications

I. The National Institutes of Health Radiation Safety Guide.

ii. The NIH Guidelines for Laboratory Use of Chemical Carcinogens.

d. Sprinkler System Design Criteria.

e. Waste Disposal at NIH.

f. Penetrations in NIH Buildings (Policy Memorandum #35).

g. Fire Protection (Policy Memorandum #34).

h. Shelving Heights in Laboratories.

I. NIH Guidelines for Controls.

j. Guide for the care and use of laboratory animals (NIH Publication 86-23)

7.0 APPENDICES

APPENDIX E-1 Request to Use NIH Maximum Containment Laboratory Checklist
APPENDIX E-2 Authorization For Entry Into The MCL
APPENDIX E-3 Internal Facility Telephone Numbers
APPENDIX E-4 OSHB MCL Training Checklist
APPENDIX E-5 CHEMTURION Extended Wear Model 35 Biological/Chemical Protective Suit
APPENDIX E-6 *CHEMTURION* Suit Dress Procedure
APPENDIX E-7 MCL Critical Systems Checklist
APPENDIX E-8 MCL PERSONNEL LOG-IN SHEET
APPENDIX E-9 Decontamination Shower Exit Procedures
APPENDIX E-10 Illness Surveillance Notice
APPENDIX E-11 Check-Out Procedures
APPENDIX E-12 Gas Decontamination Of Building 41a
APPENDIX E-13 Decontamination Airlock
APPENDIX E-14 MCL: Interior Checklist
APPENDIX E-15 Decontamination Autoclaves Standard Operating Procedures
APPENDIX E-16 Pest Management Program

Appendix E-1
Request to Use NIH Maximum Containment Laboratory Checklist

1. Scientific Director concurrence .	Yes	No
Abstract-Precis (limited to one page)	Yes	No
Protocol Background	Yes	No
Rationale	Yes	No
Protocol (detailed experimental design)	Yes	No
Discussion of Special Safety Issues	Yes	No
Statement of Potential Public Concerns	Yes	No
Personnel Listing and Background Information	Yes	No
a. Curriculum vitae(for scientific personnel)	Yes	No
9. Statement of demonstrated experience	Yes	No
10. Special language requirements	Yes	No
11. Other	Yes	No
Animal Study Proposal (as appropriate)	Yes	No
Statistical Considerations (with animal use)	Yes	No
Human Pathogen Registration Document (HPRD)	Yes	No
Recombinant DNA Registration Document (RDNA)	Yes	No
Radiation Safety Review (as appropriate)	Yes	No
Acknowledgment of Risks Statement	Yes	No

Appendix E-2
Authorization for Entry Into The MCL

This certifies that I have been informed of the potential hazards posed by the research to be conducted in the Maximum Containment Laboratory (MCL), Building 41A. I am familiar with the standard and emergency procedures described in the Safety and Operations Manual for Building 41A. I have been provided the OSHB required training and an OMS preplacement medical evaluation. I shall report immediately any known or suspected exposure to the agent or symptoms of infection with the agent to OMS and the MCL Occupational Safety and Health Specialist.

Attached are the following documents:

1. OSHB MCL Training Checklist
2. Human Pathogen Registration form, Animal Study Proposal and rDNA Registration form as applicable

_____

Signature Date

_____ is authorized to enter and work in the MCL for the period_____to_____.

_____

Chief, Occupational Safety and Health Branch Date

_____

MCL Facility Manager/Occupational Safety and Health Specialist Date

(Original to OSHB, Copy to Principal Investigator & Employee)

Appendix E-3
Internal Facility Telephone Numbers

Not transmitted for security reasons.

Appendix E-4
OSHB MCL Training Checklist

SECURITY

1. Cardkey access
2. Hours of operation

ENTRANCE PROCEDURES:

1. Sign in, Building 41A Facility Control Center
2. Critical Systems Checklist
3. Disposable jumpsuit
4. Two-way radio head set (communication system)
5. Positive pressure suit

1) Preparation of suit
2) Check suit for defects
3) Donning of suit
4) Repairing suit
5) Operation of air lines

6. Airlocks

1) Explanation of interlock mechanism
2) Entrance to MCL through decontamination shower
3) Manual pull handle for decontamination shower
4) VHP Decontamination procedures

7. Protective boots
8. Internal Systems Checklist

HANDLING OF SUPPLIES/EQUIPMENT

1. Entry of material
2. Removal of material
3. Operation of Autoclaves
4. Transport of material within MCL
5. Storage
6. Packaging of material for shipment

COMMUNICATION OUT OF THE MCL:

1. Intercom
2. Telephone
3. Fax
4. Two-way radios

EMERGENCY PROCEDURES:

1. Location of alarms for:

1) Fire
2) Breathing air/HVAC
3) BSC failure
4) Status Panels (Other mechanical system failures)

2. Biological, chemical, and radioactive spill containment and clean up
3. Potential exposures
4. Health emergency

WASTE DISPOSAL

1. Medical Pathological Waste
2. Radioactive waste
3. Chemical waste
4. Multi-Hazard/ Mixed waste
5. Contaminated animals
6. Liquid waste

EXIT FROM MCL

1. Decontamination Shower

1) Normal operation
2) Emergency operation
3) Personal Shower (optional)

2. Decontamination airlock
3. Emergency Door (using the manual deluge shower)

REPORTING ACCIDENTS AND INCIDENTS TO THE FACILITY MANAGER AND/OR THE OCCUPATIONAL SAFETY AND HEALTH SPECIALIST.

1. Parenteral exposures
2. Needle sticks
3. Animal bites
4. Spills

The items on this checklist have been explained and/or demonstrated to me.

_____

Trainee

Date

_____

Trainer

Date

Appendix E-5
CHEMTURION Extended Wear Model 35
Biological/Chemical Protective Suit

The *CHEMTURION* Model 35 is a totally encapsulating biological/chemical protective suit. ILC Dover, Inc developed and manufactured this suit, and it has proven itself ideal for use in laboratory environments. This conformally fitting *CLOROPEL* suit with its 300E visor offers definite benefits where prolonged use and space limitations often cause worker fatigue. High volume air flow, made possible by multiple exhaust valves, supplies added cooling. These combined features provide comfort during extended wear thus increasing efficiency and productivity.

AIR SUPPLY: Umbilical-fed air is directed into a 1/4 inch NPT brass fitting. Positive air pressure in the suit is maintained by four exhaust valves, two located in the legs, and two located in the upper back. Each valve is protected by an integral splash cover.

VENTILATION: The suit air distribution system is metered to the arms and legs for cooling and to the hood spray bar for CO_2 wash, breathing, cooling, and defogging. The hood vent assembly contains an air noise suppressor to allow normal communication through the suit wall.

ENTRY: Suit entry is from the front.

CLOSURE: Outer extruded closure in conjunction with inner restraint zipper. Outer extruded closure made of *CLOROPEL* utilizes two (2) parallel sealing lips, providing an effective penetration barrier.

HOOD/VISOR: The hood contains press-polished optical grade 40 mil vinyl in the visual area. Internal easement permits head movement for 300 degrees of vision.

CONSTRUCTION: The suit is designed to minimize seams and permit user mobility without excessive suit shifting. The seams are dielectrically heat sealed. The suit incorporates molded wrist cuffs with mating rubber wrist rings for attachment of chemical protective gloves. The suit legs terminate in integral booties worn inside chemical protective boots.

MATERIALS: Suit--20mil light blue *CLOROPEL* (chlorinated polyethylene), Visor-40 mil vinyl.

SIZES: The suit is available in four sizes to fit 5'0" to 6'6". A belt is added to support optional equipment and to allow for a more conformal fit.

WEIGHT: Approximately 4 pounds.

DATA PACK: A data package is provided with each suit which contains pertinent information regarding operation, maintenance, testing, material compatibility, and critical applications criteria.

ACCESSORIES: HEPA Filters and suit air conditioners are available.

Appendix E-6
CHEMTURION Suit Dress Procedure

Before **each** use, the positive pressure suit **must** be inspected for defects. Everyone **must** have an **observer** while following the inspection procedure and donning the suit. The following procedure should be used.

When entering the outer change room, turn on the "Occupied" sign near the entrance door to allow privacy.

After entering the outer change room, remove all jewelry and street clothes, and store them in a locker. Lockers shall be cleaned once a week.

Don a disposable laboratory jump suit. This clothing is authorized for use inside MCL and will never be worn outside these areas. Only persons who have donned a laboratory jump suit may proceed into the suit area.

Select a pair of surgical gloves of the appropriate size in the supply area (between the personal shower and the suit room), and take them into the suit room.

Turn off the Occupied sign when entering the suit room.

Perform positive pressure inspection. Check the positive pressure suit to ensure that (i) there are no rips in the seams, (ii) the gloves on the suit do not have any holes or tears and (iii) there are no other apparent problems with the suit.

1. Lay the positive pressure suit on the table in the suit area.
2. Seal the four exhaust valves with vinyl tape.
3. Attach outer gloves to each arm of the suit, insuring that the gloves are in the proper position.
4. Close the zipper.
5. Close the exterior rubber seal over the zipper.
6. Attach the air line to the suit to pressurize it. Observe the suit closely, as it will inflate rapidly. Be prepared to remove the air line quickly.
7. Inspect the suit for defects, then deflate the suit. Deflation of the suit occurs with the opening of the exterior rubber seal.
8. Remove the vinyl tape from the valves.

Don surgical gloves and draw them up and over the cuffs of the laboratory jump suit. Tape gloves to the jump suit using vinyl tape.

Voice activated, two-way headphones shall be worn inside the suit to dampen sound and allow communication with others working in the MCL. These headphones are stored in the suit room.

Lay the suit down on the floor, straddle the suit at the "waistline", facing the feet.

Put one foot at a time into the feet of the suit.

Put the right arm into the right sleeve, put the hood on, than put left arm into the left sleeve.

Close the zipper.

Close the exterior rubber seal over the zipper. Everyone must have another individual check the outer plastic closure to ensure it is sealed from top to bottom.

Attach the air line to the suit. **Make sure the suit is connected to air lines at all times**, unless changing air stations.

Once the suit has been checked, disconnect the air line and enter the decontamination shower/air lock. The doors of the decontamination shower are **interlocking**. Therefore, one door must be closed and sealed before the opposite door can be operated. Allow the outer door to close and the gasket to reinflate, and then open the inner air lock door and proceed into the boot area.

Don protective footwear stored in the boot area and proceed into the MCL.

Sign the MCL interior checklist (see Appendix 7) and fill in the required items if no one else has done so. Record in the log the agents with which you are working.

Proceed with work in the MCL. Adhere to standard procedures that are used in the BL-4 laboratory, including the use of the BSC for **ALL** bench work with infectious agents (see BMBL for reference). Animal inoculations with infectious agents shall be done only in the BSC to reduce the risk of spreading infectious aerosols or infectious materials around the laboratory/animal rooms.

Appendix E-7
MCL Critical Systems Checklist

Check to indicate status is normal

GROUND FLOOR

A. Exterior Door Secure:

B. Alarm Panel, corridor:

Alarm Lamp Test

Pressurization Rm.114 ____ LET Sys ____ LCD Sys

Pressurization Rm116 ____ AHU #1 ____ AHU #2

Pressurization Rm.115 ____ Breathing Air Sys ____ Spares

Equipment door override ____ Shower door override

Ex Fan #1____ Ex Fan #2

C. Review computer proximity card history: Comments_____

FCC Door Secure: _____ Air Lock Alarm Panel: _____

D. Autoclaves:

Large: Paper:_____ Cartridge:_____ Small: Paper:_____ Cartridge:_____

Weekly autoclave validation test, Date:_____

EAST MECHANICAL ROOM

A. Exterior door secure: _____

B. Supply and Exhaust Readings for the MCL: Enter PL; 4T the last two digits of the room #, then SW for supply or EW for exhaust for each room of the MCL; record readings in cfm.

14SW		15SW		16SW		17SW		10SW	
14EW		15EW		16EW		17EW		10EW	

C. Liquid Decontaminant Tank #9:

Level: _____ Comments_____

Firetrol, Inc. Pump Control Panel Mode:

Line Pressure Gauge (right of mix tank):_____psi. **Normal: 50 psi**

Pump Discharge Pressure:_____ psi. **Normal: 53 psi**

Tank: Auto_____, Manual Valve (under tank #8):_____

Inlet Valve: Tank: Open_____, Closed_____

Manual Drain Valve: Tank: Open_____, Closed_____ In-line Pressure: #1_____ #2_____

D. Travaini Breathing Air Compressors: Power On_____,

Pump monitors: Pump #1_____hrs. Pump #2_____hrs.

Line Pres_____ **Normal: 98-100 psi**

Water gauge: Pump #1:_____ Pump #2:_____ **Normal: 42psi**

Breathing Air Reservoir water drain (to be opened each Monday):_____

Carbon Monoxide Monitor:_____ppm. **Normal: 0.00 ppm**

E. UltraAir Compressor (Walz and Krenzer Doors): Compressed Air Gauge:_____ **Normal: 39-40psi**

Compressed Gases	Left Bank	Right Bank
Emergency Breathing Air	psi	psi
Carbon Dioxide (CO_2)	psi	psi
Argon	psi	psi
Nitrogen (N_2)	psi	psi

UPPER MECHANICAL SPACE

A. Air Drying Units Power ON #1_____ #2_____

Temperature: _____°F

B. Decontamination Deluge Tanks

North Tank #1:_____ gal. Comments_____

South Tank #2:_____ gal. Comments_____

WEST MECHANICAL SPACE

Exterior Door Secure:_____

	VFD (**Normal: 90-98%**)	Magnehelic	Static Pressure
Supply Fan #1	%	inches	inches
Supply Fan #2	%	inches	inches

PROCESSED WASTE: DAILY READINGS

Exterior Door Secure:_____ Manual Pressure Release Handle: Tank #1_____Tank #2_____

Pressure: Gauge: Tank #1_____ Tank #2_____

Normal: 0 PSI, during the cook cycle: 48 - 65 PSI

Temperature: **Normal: approximately 80°F**

Gauge: **In the cook cycle - Tank #1 or #2: 250-264°F**

Tank #1_____ Tank #2_____ Tank #3_____ Tank #4_____

Tank #5_____

Water Level:

Normal: High Water Level (HWL): 63" or less. In the cook cycle, the HWL is 63" - 73"

Low Water Level (LWL) - 3"

Tank #3, #4, and #5: HWL - 45" - 48"; LWL - 3-5"

Gauge: Tank #1_____ Tank #2_____ Tank #3_____ Tank #4_____ Tank #5_____

Temperature Chart: Date of Change:_____ Filed:_____

REMARKS:_____

_____

_____

_____

Signature:_____Date:_____Time:_____

MCL: Critical Systems Checklist - Narrative

The purpose of this checklist is to monitor and maintain a record of the status of Containment and Life Support features of the MCL. The Critical Systems Checklist is normally completed by OSHB personnel before 8:00 AM on regular workdays. On holidays and weekends, the checklist shall be completed by MCL Staff before anyone enters the MCL. Most observations vary little from day to day, so be sure to be alert for anything unusual. If any questions arise, contact Building 41A Maintenance (402-3039), South Building Maintenance (6-6484) or OSHB (6-2346).

FACILITY CORE CENTER CORRIDOR

1. Door secure - A check indicates the single north entry door was checked and found to be secure.
2. The alarm panel in corridor 101 is located inside and to the left of the entry door. A light on this panel indicates an alarm situation. Indicate with a check if there are no apparent alarms. Any alarms shall be reported immediately to Building 41A Maintenance and OSHB. No one shall enter the MCL until the source of the alarm has been resolved.
3. Review computer proximity card history for the previous evening and note if there were any abnormal entries.
4. Autoclaves
5. A check indicates autoclaves were checked. Autoclave is in standby mode prior to 7:00 am. If autoclave is running - indicate in the proper blank. If the steam is on and the autoclave is open, contact the Occupational Safety and Health Specialist to determine status. The supply of autoclave paper should be sufficient for the day.

EAST MECHANICAL AREA

1. Door secure - A check indicates the exterior door and the interior door to the east mechanical area was found to be secure.
2. Use the computer in the east mechanical area office to record the supply and exhaust fan readings for the MCL. For example, enter Shift P, L. Enter 4T14SW to get the supply fan reading for room 114. Enter 4T14EW to get the exhaust fan reading. To print the CFM for the 41A, enter PL4T*W, hit enter, print. To print the pressures for 41A, enter 4T*P, hit enter and print.

LIQUID DECONTAMINATION TANK

Indicate with a check if level of Tank #9 is between the low and high level alarms. Comments, note anything unusual e.g., no volume change, that may indicate a malfunction. Contact South Building Maintenance (6-6484) or Building 41A Maintenance (2-3039), if there are any questions or irregularities noted. Read and record status of control panel and valves. A check indicates condition. Note that manual drain valve is closed except during drain mode.

DECONTAMINATION SHOWER TANK INSTRUCTIONS

ALL PERSONNEL SHALL WEAR A FULL FACESHIELD AND GLOVES WHEN PERFORMING THIS PROCEDURE. THE APPROPRIATE PROTECTIVE EQUIPMENT IS LOCATED NEXT TO THE TANK LOCATED NEXT TO THE TANK.

1. Check level of decontamination solution.
2. Manually add appropriate decontamination solution to the Mix Tank. The measurement of water is automatic.
3. Set the automatic timer to control the operation of the mixer.
4. Ensure lid on the Mix Tank is securely closed.
5. Complete Decontamination Shower Mix Tank record on the Critical Systems Checklist.

An alarm is activated when the volume falls below gallons. If it approaches this level please alert the Occupational Safety and Health Specialist on call. The in-line fluid pressure should have a reading of 10 psi., notify Building 41A Maintenance (2-3039), if it is more than ±5 psi. The line pressure gauge should have a reading of 50 psi. The pump discharge pressure (above the pumps) should have a reading of 53 psi.

6. Travaini Breathing Air compressors

Check and record that the power switches are ON. These power switches are red and black with arrows on them. The arrows should be in an Aup@ position. There is a red strobe located on the top of the Travaini Breathing Air control panel. This strobe should not be on at any time. The strobe will be on only in the event of a malfunction in the breathing air system. **No one shall enter the MCL until this malfunction has been located and resolved.** Record pressures from tank pressure gauge to the right of water tank. Normal is 98 - 100 PSI. Check and record water gauge pressures on each pump. The normal reading is 42 psi; if a pump is running, the reading will be 36 -38 psi. The black bypass valves, located above pumps 1 and 2 should be checked. This valve should not be full open, but just slightly open. Record the number of hours each pump has been run, the monitor is located on compressor control panel. At 1000 hours, pumps must be greased with Lithium grease (one shot only). At 3000 hours, the filters on each pump must be changed. When the water tank pressure reaches 91 psi, one pump will turn on. The pump will run for ten minutes, and then the second pump will run. This alternating schedule is normal for these pumps. The breathing air reservoir is located behind the Travaini Panel. At the base of the reservoir, there is a green release drain. This drain shall be opened each Monday until all the water has drained out of the system. **The carbon monoxide monitor should read 0 - 1 part/million. 10 parts/million is unsafe. No one should enter the MCL if the monitor has a reading of 10 parts/million. The carbon monoxide monitor should be calibrated every 6 months.** Check and record pressures of reserve

emergency cylinders in the A-Bank (left) and B-Bank (right) on the monthly record attached to the tanks. If a reading varies more than 50-100 PSI from the normal reading, contact Building 41A Maintenance. Record pressure (PSI) on daily checklist.

7. Read and record the pressure (PSI) of the UltraAir Compressor air gauge (Walz and Krenzer Doors)
8. Read and record individual pressure for CO_2, argon, and N_2 cylinders. If either tank is <300 PSI, contact Building 41A Maintenance.

Upper Mechanical Space

1. The power should be ON for both air drying units, indicate with a check .
2. Read and record the volume of liquid in each tank. Record on the daily Critical Systems Checklist.

West Mechanical Space

1. Indicate with a check if the exterior door is secure.
2. On the VFD Panel, read and record the supply fan efficiency in %.
3. Read and record the magnehelic and static pressure gauges for both supply fans.

Process Waste System

1. The Process Waste System is a fully automatic waste processing system. Under normal operating conditions, none of the controls shall be changed. The pressure gauges for tanks 1 and 2 are located on top of each tank. The manual pressure release handle is located on the pressure line above each tank. This handle should always be in the **closed** position.
2. The temperature gauges for tanks 1 and 2 are located behind the tanks, at approximately the three-quarter point of the tanks. The temperature gauges for tanks 3, 4, and 5 are located at the rear base of the tanks.
3. The water level gauges for all the tanks are located on the west wall on the Powers Process Control panel. The water level shall be recorded in inches of water.
4. The Honeywell Temperature Charts shall be (i) changed each week, (ii) dated and signed on the reverse of the chart, (iii) and filed in the Facility Core Center.

Remarks

Note here any deviations or comments for the record. Sign, noting date and time.

Appendix E-8
MCL PERSONNEL LOG-IN SHEET

Date/time entry	Signature	Activity	Date/time exit	Signature	Comments

Appendix E-9
Decontamination Shower Exit Procedures

I. Description of Decontamination Shower Airlock

A. Stall

1. Shower jets projecting from the four corners of the shower stall and overhead.
2. Shower basin with an outlet drain, which leads to the Process Waste tanks located in the sub-basement of Bldg. 41.
3. Green start button located on the south wall
4. Manual deluge shower head and handle

B. Shower doors

1. The doors are air gasketted, stainless steel, and interlocking.
2. The gasket is disengaged by pushing down on the door handle.
3. The exterior decontamination shower door may not be opened unless a decontamination cycle is run.
4. In the event of an emergency, there are manual overrides of the interlocking doors located in the interior of the shower and in the suit room adjacent to the door. These manual overrides are activated by gently pulling down on the lever. The release of air from the gasket can be heard as it deflates.

C. Cycle

1. Cycle is activated by pushing the green Astart@ button.
2. Pre-mixed decontamination solution sprays through the shower jets for the first half of the cycle followed by a clear water rinse.
3. Water is tempered to 80° F.

II. Decontamination shower procedures for exiting the MCL

A. Remove boots and leave in boot area, enter the decontamination shower, and close shower door. Door will automatically lock.

B. Connect to airline.

C. Push “start” button to activate the cycle.

D. During the decontamination cycle, lift arms above the head and turn 360 degrees; physically scrub the suit with gloved hands.

E. After the water stops, open the exterior door and exit the shower.

F. Close the exterior door, to allow the next individual to exit the MCL.

G. Remove the positive pressure suit, spray the interior of the suit with the alcohol solution provided in the suit area.

H. Hang the suit on the overhead hooks in the suit area.

I. Turn on the "Occupied" light (located on the east wall of the suit room) for privacy. Enter the inner change room, dispose of the jump suit in the designated waste container.

J. Take a personal shower if desired. Eyeglasses worn in the MCL must be washed during the personal shower.

K. Redress, place the towel in the hamper in the outer change room, and exit the dressing room. Turn off the "Occupied" sign.

L. Sign out on the personnel log and record any condition requiring OSHB attention.

III. Malfunction of Liquid Chemical Decontamination System

A. Report to the MCL Occupational Safety and Health Specialist if shower jets are not functioning.

B. When the decontamination shower cycle does not function properly, the manual decontamination system may be activated. Use the pull handle on the deluge shower.

1. First dowse the suit thoroughly with disinfectant.
2. Scrub suit with gloved hands.
3. Repeat step.
4. Exit the shower and continue with standard procedures.
5. Inform OSHB as quickly as possible.

Appendix E-10
Illness Surveillance Notice

Employee Name: _____

Address: _____

_____

Phone:_____

Symptoms:_____

_____

_____

_____

PI Signature

Chief, OSHB:_____

Phone(H):_____ Phone(W):_____

Pager:_____

Principal Investigator:_____

Phone(H):_____ Phone(W):_____

Pager:_____

Facility Manager: _____

Phone(H):_____ Phone(W):_____

Pager:_____

Occupational Safety and Health Specialist:

_____

Phone(H):_____Phone(W):_____

Pager: _____

Occupational Safety and Health Specialist:

_____

Phone (H):_____Phone(W):_____

Pager:_____

Safety Operations Section, OSHB, Phone: 496-2346

Occupational Medical Service, Phone: 496-4411

NIH Security, Phone: 496-5685

Fire/Ambulance, Emergency: 911 (on campus)

Appendix E-11
Check-Out Procedures

_____

Name (Investigator) Date

1. Remove and properly store all Biological Material from refrigerators and/or freezers.

_____

Signature, Facility Manager or Occupational Safety and Health Specialist Date

2. Empty locker

_____

Signature, Facility Manager or Occupational Safety and Health Specialist Date

3. Removed from Building 41A proximity card user list

_____

Signature, Facility Manager or Occupational Safety and Health Specialist Date

4. If Visiting Scientist at the NIH, return NIH identification.

_____

Signature, Facility Manager Date

Appendix E-12
Gas Decontamination of Building 41a

Gas decontamination of the MCL of Building 41A is necessary at the end of a research project or annually, whichever comes first. After decontamination has been completed; (i) preventive maintenance will be performed on all equipment in the MCL; (ii) HEPA filters shall be tested and changed if necessary; (iii) all building systems maintenance (eg. HVAC, plumbing, electrical, etc.) to the building shall be performed at this time.

Pre-decontamination Procedure

A. Empty refrigerators and mechanical freezers. Turn off (unplug) and defrost freezer, mop up water, and prop doors open. Unplug icemaker, turn off water valve, open door, and allow to drain.

B. Surface decontaminate delicate equipment (e.g., microscopes) and move to the VHP decontamination airlock if it is to be removed from the MCL.

C. Dispose of all animals and animal food in the MCL.

D. Empty laboratory of unused labware and laboratory supplies and place them in the autoclave.

E. Unplug centrifuges, incubators, and other fixed equipment. Leave doors open.

F. Pour appropriate decontaminating solution into all sink traps and floor drains.

G. Open all cabinet doors and drawers.

H. Arrange for maintenance of laboratory equipment on maintenance contracts and all operating systems of the MCL during shutdown period.

I. If radioactive materials were used, the following clearance procedures must be performed before the shutdown period:

1. All radioactive materials must be removed and secured in another properly posted lab or disposed of through the radioactive waste disposal service.
2. All items which are potentially contaminated with radioactive materials, e.g., refrigerators and centrifuges, shall be decontaminated and removed to another posted laboratory or stripped of all "Caution Radioactive Material" labels if radioactive materials are removed.
3. Empty radioactive waste containers must be decontaminated and moved to another posted laboratory or removed by the radioactive waste disposal service.
4. Any area of contamination at levels greater than 220 dpm/100 cm^2 (22 dpm/100 cm^2 for alphas) must be decontaminated until an appropriate survey indicates less than allowable limits.
5. Clearance must be scheduled by contacting the RSB. RSB will review the survey performed by lab personnel, spot-check the MCL laboratory/animal suite, and if no problems are found, remove the "Caution Radioactive Material" sign at the entrance to the MCL and replace it with a RSB clearance certification.
6. As long as an RSB clearance certification is posted at the entrance to the MCL laboratory/animal suite, no radioactive materials can be used or stored in that laboratory/animal suite. When radioactive materials are to be used in the laboratory/animal suite again, lab personnel must notify the RSB to remove the clearance certification and post the laboratory/animal suite with a "Caution Radioactive Material" sign.

Procedure

A. Calculate the total volume of the area for gaseous decontamination.

1. Calculate the amount of paraformaldehyde to be used. Multiply the area volume (cubic feet) by 0.3 to determine the amount of paraformaldehyde/grams. Total volume of laboratory area is 10,650 cubic feet. The required amount of paraformaldehyde is 3195.0 grams.

2. This amount of paraformaldehyde will provide an equivalent formaldehyde concentration of 0.8% by weight or 10,000 parts per million by volume in air.

   NOTE: Do not to use a greater amount of paraformaldehyde than is required. An excess amount can cause the formaldehyde to polymerize on surfaces as a white powder which is combustible in this form.

3. Calculate the amount of ammonium carbonate necessary to neutralize the formaldehyde gas. The ratio is 1:1.1 of paraformaldehyde to ammonium carbonate by weight. The required amount of ammonium carbonate is 3514.5g.

B. Assemble necessary equipment and materials.

1. Obtain the following:
   a. 10 electric frying pans
   b. Water
   c. 24 spore strips
   d. 5-10 extension cords
   e. Pre-measured paraformaldehyde (See attached floor plan).
   f. Pre-measured ammonium carbonate (See attached floor plan).
   g. 5 sheets aluminum foil

D. Decontamination of MCL

1. Clean all surfaces in the MCL with the appropriate decontaminent and place spore strips throughout the facility.
2. The electrical power controls for the dedicated decontamination sockets are in the West Maintenance Area. These controls are (i) marked with the corresponding room numbers, (ii) the toggle switches have three positions, (iii) when the toggle switch is in the center position, these dedicated sockets are without electrical power, and (iv) these switches will be maintained in the off position when not in use for decontamination purposes.
3. Place and connect the pans to the electrical sources following the attached floor plan which indicates the toggle positions with the corresponding sockets.
4. Close the isolation dampers of each room.
5. Open the pass through doors between the laboratory/animal rooms.
6. Fill the floor drains with decontamination solution.
7. Spread the pre-measured paraformaldehyde in the designated electric frying pans and add water. Spread the pre-measured ammonium carbonate in the remaining electric frying pans and cover with aluminum foil.
8. Set the thermostat control of the electric frying pans at 450Ef (maximum operating temperature).
9. Inflate the gaskets on the doors.
10. Turn on electrical power to paraformaldehyde frying pans, and allow to heat until all the paraformaldehyde cooks off.
11. “Bump" the blower in the BSC for 3 to 5 seconds four times during the paraformaldehyde cook-off (at 25%, 50%, 75% and 100%)
12. Turn off electrical power to paraformaldehyde frying pans. **Allow overnight contact time.**

13. Turn on electrical power to ammonium carbonate frying pans, allow to heat until the ammonium carbonate cooks off. **Allow overnight contact time.**
14. Open isolation dampers of each room. Allow the rooms to vent overnight.
15. Collect and incubate spore strips.

Appendix E-13
Decontamination Airlock

I. Vapor Phase Hydrogen Peroxide (VHP) Decontamination Procedure

A. Prior to Decontamination Date:

1. Determine suitability of material/equipment. [Note: The VHP is suitable for clean surface decontamination of objects. It there is any protein or chemical material on the surface of the object, decontamination of that area may be ineffective.]
2. Notify MCL Occupational Safety and Health Specialist of intent to decontaminate material using the VHP (using form, Appendix 13a).
3. Review VHP protocol with the MCL Occupational Safety and Health Specialist.
4. Consult AMSCO VHP Equipment Manual to determine cycle parameters.

B. Day 1

1. Record decontamination information on VHP Log.
2. Move material/equipment to be decontaminated into the VHP room/airlock. Do not block outlets.
3. Place spore strips: near door, on floor, and on material/equipment to be decontaminated.
4. Close inner door and tape with "DO NOT ENTER" yellow tape. **LEAVE ROOM SEALED, WITH DAMPERS CLOSED OVERNIGHT.**
5. Run decontamination cycle.

C. Day 2

1. Open airlock dampers and allow room to ventilate for 3-4 hours.
2. The exterior airlock door shall only be opened by the MCL Occupational Safety and Health Specialist.
3. Open exterior airlock door, recover spore strips.
4. Incubate spore strips per standard protocol. Do not remove materials or permit work to progress in the decontamination chamber until no growth has been verified for at least 24 hours.
5. Upon completion of spore strip testing, remove equipment through exterior airlock door. Close exterior door, the gasket will re-inflate. If any service work is to be performed on the equipment in the decontamination chamber, equipment should be wiped off prior to servicing.
6. Arrange for OSHB personnel to remove "DO NOT ENTER" yellow tape.

Appendix E-14
MCL: Interior Checklist

Check to indicate status is normal:

Restroom supplies: Toilet Paper: _____ Paper Towels: _Soap:_____

Cleaning Products: _____

Directional Airflow: _____

Emergency Door Secure:_____

1. Exhaust filters _____ (date of last change on filters) (Change Annually for lab only work. If using animals, animal care staff will advise)

2. Autoclaves Large Small

3. Waste Containers (empty daily)

4. Lab Supplies:

5. Facsimile:
   Paper
   Toner

Fax this list to the facility core center: 0-1377

Appendix E-15
Decontamination Autoclaves
Standard Operating Procedures

1. Please contact the MCL Occupational Safety and Health Specialist prior to operation of the autoclave to coordinate the removal of the MPW boxes after sterilization of the waste material. Remove and inspect the chamber strainer grate. Clean the strainer before each autoclave run. Check printer for adequate paper; if print is difficult to read, please change cartridge. Multiple Diak tubes should be included with each cycle.
2. Load the autoclave, arrange multiple Diak tubes with waste material, and close the door.
3. The cycles are pre-programmed. Consult programming list posted on autoclaves. Select the desired cycle for the material to be autoclaved. Use the gravity cycle for decontamination loads containing small amounts of liquids. The liquid cycle is for large volumes of liquids and requires a longer time for the pressure to return to normal after sterilization. The vacuum cycle is appropriate for dense material, e.g. feed, and animal litter. NOTE: Waste decontamination cycle is 90 minutes for BL-4. Longer runs may be required for large volumes of waste, particularly animal waste. If in doubt, contact the MCL Occupational Safety and Health Specialist in the Building 41A Facility Core Center, or OSHB (6-2346).
4. When the cycle is complete, open the clean side door and remove the sterilized materials. Remove the printed tape-record of the run and place it with the autoclaved materials. NOTE: This function is normally handled by MCL personnel. It is imperative that the printer tape is placed with the autoclaved materials to show that run parameters have been met. The Diak tubes should be examined to ensure that the autoclave was operating properly.
5. Close the clean side door so the autoclave can be opened from inside the MCL to add a new load. Place autoclaved material in MPW boxes, stamp each box indicating sterilization of the box.
6. At the end of the day, the autoclave will automatically go into standby mode. The autoclave has been pre-set to turn off at 7:00 pm Monday-Friday.

   DO NOT TURN OFF THE MAIN POWER SWITCH TO THE AUTOCLAVES.
7. Once a week, multiple spore strips should be used in the autoclave to monitor the efficacy of the autoclave cycles.

Contact the MCL Occupational Safety and Health Specialist to obtain:

Printer paper or cartridges, waste pick-up information, autoclave pans or bags and biological monitoring material.

Appendix E-16
Pest Management Program

Background

Integrated pest management (IPM) is an interdisciplinary approach to controlling pests. Traditional pest control programs (i.e., extermination) rely primarily on preventive or corrective applications of pesticides. IPM emphasizes managing the environment in order to make it least supportive of pest activity. Detection of pests and pest activity, along with facility conditions and operational practices, are part of the ongoing assessments to identify conditions conducive to pests performed at each service.

Scope of Services

A. Frequency of Service

IPM services will be performed weekly in the mechanical spaces, locker room, building exterior and support areas. At the end of three months, the pest management data will be reviewed and, with concurrence of the Facility Manager, the frequency of service may be decreased to twice per month. This decision will be based on the number of pests trapped or sighted, conditions in and around the facility, our ability to effectively monitor the facility and the requirements of the facility personnel. The frequency of service may vary somewhat depending upon the season and programmatic changes inside the facility.

B. Areas to be Serviced

Monitors (glue traps) will be placed in the following areas:

- The mechanical rooms
- The locker room
- The Facility Core Center
- The sub-basement of Building 41

C. Service Procedures

1. Pest management personnel will meet with the Facility Manager prior to performing any IPM services.
2. IPM services will consist of the following:

a. Review of logbook and pest management records

b. Discussion(s) with Facility Manager and other personnel concerning pest management issues.

c. Monitoring of all accessible areas for evidence of pests or conditions conducive to pest activity. Monitoring is the fundamental activity in any IPM program. Monitoring is a means of collecting quantitative information on pests and qualitative information on facility conditions and personnel practice that may promote pest activity. The IPM service schedule, training programs, service reports and recommendations, and pest control tactics are all based upon analysis and evaluation of monitoring results. Monitoring is usually performed using traps, visual surveys and interviews with facility personnel.

d. Inspection of all pest management monitoring devices in and outside of the facility. All monitoring devices will be checked, marked with the date and initialed by the pest management personnel at each service. Monitors that contain insects, are dirty or no longer effective will be replaced.

e. Completion of a pest management survey report outlining all services performed, and including recommendations for corrective pest management actions regarding personnel practices and facility repair. A pest management survey of the MCL will be performed after each facility decontamination.

f. A written report of all observations and recommendations will be submitted to the facility manager after each survey.

Survey of the Maximum Containment Laboratory

The MCL will not be surveyed on a routine basis. Pest management personnel will be available to monitor the interior of the containment upon the requested of the facility manager. Live or dead insects or evidence of pest activity (i.e., casts insect skins, feces, body parts, etc.) will be used as thresholds to determine if intervention by pest management personnel is necessary. Often, monitors or other trapping devices can be placed by facility personnel as an interim measure to determine if additional pest management action is necessary.

Emergency Service

In the event of a pest related emergency, PMU staff can be contacted by telephone and pager. A list of Pest Management Unit personnel, pager numbers and home telephone numbers will be provided to the Facility Manager. In the event of a pest related emergency, PMU personnel can be contacted to advise on pest management questions or perform IPM services.

Pest Management Equipment

The following pest management equipment will be used as part of the pest monitoring and control activities in Building 41A:

1. Sticky traps for insects and nuisance arthropods
2. Sticky traps for flies
3. Glue boards for rodents
4. Live traps of rodents (Ketch-all, Tin Cat, Hav-a-Hart traps, etc.)
5. Insect light traps - installed both permanently and temporarily to monitor for and control flying insects
6. Hydramethylnon - solid formulation of an insecticide for use against cockroaches, ants, crickets, etc.
7. Avermectin - solid formulation of an insecticide for use against cockroaches, ants, crickets, etc.
8. Caulk - silicone/acrylic caulks will be used in isolated areas to exclude pests
9. Spring Traps - used to control rats and mice
10. Stored Product Pest traps - these are glue traps baited with insect and insect pheromone attractant. They will be used in the animal feed storage area.

The Facility Manager will be apprised of the placement of all pest management monitoring and control devices. Live traps and glue and snap traps for the control of rodents will only be used in areas of known infestation. Once placed, the traps will be checked daily to ensure the humane treatment and prompt removal of any trapped rodents. The application of insecticides will also only be performed in areas of known infestation. The use of liquid or aerosol formulation insecticides will be restricted to unique application where other control tactics are infeasible or not effective. Liquid or aerosol formulation insecticides will only be applied after consultation with the Facility Manager.

Personnel and Facility Related Issues

Given the high level of sanitation and maintenance associated with the operation of this facility, the opportunity for infestation of this building by insect or rodent pests is minimal. However, the potential for incidental ingress, particularly by ants, night flying insects, crickets, etc. and insect pests from home or laboratories. The following procedures should be used to minimize this problem:

1. Empty all lockers at the end of each week.
2. The Facility Manager should have a master key for all locks used on lockers.
3. Eating is not permitted anywhere in Building 41A.
4. Animal feed should be stored in Building 41A only for a limited amount of time, (i.e., two weeks). If it is not consumed within this time frame, it should be disposed of. This is to prevent stored product pests from becoming a problem in the facility. Also, keep the minimum amount of feed required on hand and store all feed and bedding products in cleanable, sealable plastic containers.
5. All security lighting should be directed at the building from the surrounding area, not mounted on the building.
6. Sodium vapor lights should be used outside the building.
7. Do not landscape with ground covers, such as ivy or pachysandra, or dense shrubs/bushes.
8. The waste should be disposed of in a vertical compactor to deter rodent activity. The compactor should be small enough to facilitate frequent emptying, preventing the accumulation of waste.
9. The seals on both roll-up over head doors should be checked frequently to insure proper seal at the ground.
10. The conduit connecting Building 41 with Building 41A should be treated with a bird deterrent device.
11. Electric insect traps should be installed at all entry/exit doors, and throughout the facility, where practical.
12. Better seals are needed around both roll-up overhead doors and especially at the bottom of the doors. There is also a gap at the top of the door that must be sealed.

Part 2 – Decontamination Equipment and Procedures

Decontamination Equipment and Procedures

INTRODUCTION

Containment of potentially infectious agents in laboratories is managed by laboratory design, the use of good laboratory practices, chemical germicides, and equipment such as biological safety cabinets and autoclaves.

All contaminated materials must be decontaminated before disposal or cleaning for reuse. This includes laboratory surfaces, rooms and equipment, which may require decontamination prior to servicing. It is the responsibility of each person who works in the laboratory to ensure that proper decontamination procedures are followed and that containment is not breached.

The method chosen is determined by the nature of the material to be treated, i.e. if it is disposable, is adversely affected by heat, cannot be penetrated by steam, etc.

AUTOCLAVES

Autoclaves are instruments which maintain saturated steam at high temperatures and under pressure. They are used to sterilize laboratory equipment and materials by destroying potentially infectious agents. A typical autoclave cycle of 15 minutes at 121EC and 15 psi is usually sufficient to kill the most heat resistant microbiological agents, i.e. bacterial spores.

The autoclaves that are used at the WNCBED are all Getinge/Castle models, either M/C 3522, M/C 3622 (gravity) or M/C 3633 (vacuum) autoclaves. There are three types of autoclave cycles: unwrapped, wrapped (employs vacuum pulsing to condition a load prior to processing), and liquid (slow exhaust times). Wrapped and unwrapped cycles are run for solid materials. Liquid loads require slow exhaust times to avoid boiling during pressure reduction. A description of load types and cycle settings should be prepared and posted for each autoclave.

STANDARD AUTOCLAVE CYCLES

Unwrapped cycle

The unwrapped cycle employs a gravity assist during the conditioning phase and the exhaust phase (M/C 3633) or in the exhaust phase only (M/C 3522 and M/C 3622) to displace air.

Wrapped cycle

The wrapped cycle employs a pulse during the conditioning phase of the cycle. This effectively cycles the temperature and allows for the removal of any air pockets that may arise. This cycle also employs a gravity-type exhaust.

Liquid cycle

The liquid cycle employs a gravity assist during conditioning. However, during the exhaust phase, the chamber pressure is gradually decreased. This prevents a vacuum and subsequent boiling of any liquids present.

SAFETY PRECAUTIONS

- Wear protective clothing (ie. autoclave gloves and apron) when removing the contents from the autoclave.
- Autoclaves and contents present severe burn hazards. Standing away from the door minimizes the risk of burns due to evacuation of steam or fluids from the autoclave.

- Autoclaves operate under pressure. To prevent a burn and physical shock hazard never attempt to force autoclave doors open before the end of a cycle or when the jacket pressure is greater than zero.

BIOLOGICAL INDICATORS

Biological indicators are used to develop the processing times for typical loads and monitor the efficacy of the decontamination process. Efficacy monitoring must be done at least once per week in BSL-2 areas, depending on the frequency of use of the autoclave, and with **each load** coming out of BSL-3 and BSL-4 areas. Records should also be kept of the time, temperature and pressure of the load by attaching the autoclave print-out to the log book file. Thermocouples, placed at the centre of the load, may also be used to monitor the internal temperature of the load. These may be used in conjunction with a biological indicator.

The basic procedure for **efficacy monitoring using biological indicators** is the following:

1. Place biological indicator (Getinge/Castle Biosign biological indicators (spores/indicator: 10^4 *B. stearothermophilus* and 10^6 *B. subtilis var. niger*, 3M Attest Rapid Readout biological indicator or Raven Prospore biological indicators (liquid loads)) in the center of a typical load (each different type of load should be tested separately).
2. The load is processed according to standard operating procedures, taking into account the lag time necessary for the internal temperature in the center of the load to reach the sterilization temperature (this time will vary depending on the nature of the load being sterilized); even though the spores of *B. stearothermophilus* are killed when exposed to 121EC for 15 minutes, the total cycle time depends on the load.
3. After completion of the cycle, the autoclave is opened and the biological indicator is removed.
4. Biosign indicators are taken to the Biosafety lab and incubated at 55EC, along with a positive control that did not go through the autoclave process; they are examined at 24- and 48 h. for growth; a color change from red to yellow indicates growth and sterilization failure (i.e., parameters of time and/or temperature have not been met in the test indicator).
5. Absence of growth in the test indicators signifies that sterilization of the load was achieved, representing a 4-6 $\log_{10}$ reduction in *B. stearothermophilus* spores.
6. Attest Rapid Readout biological indicators are taken to Biosafety lab and incubated at 60C. (Note: Attest Auto-reader must be calibrated with a STERILIZED, non-incubated Attest Biological Indicator). A positive control of the same lot number that did not go through the autoclave process must be included.
7. Absence of fluorescence in 3 hrs indicates that sterilization was successful.
8. Prospore biological indicators are taken to biosafety lab and incubated at 56C along with a positive control that did not go through the autoclave process; they are examined periodically for growth.
9. Growth is indicated by a color change from purple to yellow. This indicates a failure of the sterilization cycle.
10. Failure to achieve sterilization may be due to improper loading or overloading of the autoclave (i.e., the center of the load failed to achieve sterilization temperature), or insufficient sterilization time; the process should be repeated until the necessary loading configuration and sterilizing time have been determined; this time and load configuration should be used for all subsequent cycles for that type of load.

NOTE: Chemical indicators for steam, time and temperature are useful for day-to-day monitoring but must not be used as an indicator of sterility. Biological indicators are required to indicate sterility; labels and tapes that only indicate the attainment of temperature, not its duration, are not recommended.

MAINTENANCE

Daily

1. Clean sediment screen. Remove the sediment screen from the chamber drain and clean thoroughly. It can be removed and replaced without tools.
2. Clean exterior surfaces. Routinely clean the exterior surfaces with Tec Surf (Castle Part No. 47104) or other mild cleaning agent. Do not use strong or harsh solutions which may damage painted surfaces.
3. Clean accessories. Clean loading carts, racks, shelves, baskets, trays, etc. with a mild detergent and water solution.
4. Clean chamber interior. Clean interior surfaces of sterilizer chamber with a mild detergent and water solution. Rinse with water.
5. Clean material handling carts. Clean material handling carts with a mild detergent and water solution. Rinse with water.

Monthly, 3-Month, Semi-Annual, Annual

Routine maintenance will be the responsibility of the Operations & Maintenance (O & M) group. The EHS group will perform a thermocouple test on all autoclaves annually following scheduled maintenance or following unscheduled repairs.

When Required

1. Replace ink cartridge. When replacing the ink cartridge, care should be taken not to twist or bend the pen arm. A deformed or bent pen arm could record a false reading. Removal: Hold the pen arm with one hand and pull the old pen straight off the end of the arm. Replacement: Place the new pen cartridge on the top of the pen arm (pen downward and outward) and push the cartridge into the remaining clip. Be sure the pen fits into the notch in the end of the arm.
2. Replace door gasket(s) (M/C 3522).
   a) Remove the sterilizer front trim panel, which is secured with 4 screws. Remove the hex nut and rubber door stop bumper from the lower frame cross member.
   b) Allow sterilizer to cool before removing the gasket. Remove the gasket by pulling it out of the head ring gasket groove, with the door at the fully lowered position.
   c) Remove any sharp edges of burrs from the gasket groove that may damage the gasket.
   d) Clean the gasket groove with alcohol to remove any foreign material that may have collected in the groove.
   e) Ensure the replacement door gasket is clean. Place the gasket splice at the top centre of the gasket groove and press it into place. Divide its length evenly and press the gasket into place at the bottom center of the gasket groove. Press the gasket, evenly divided, into the centre of the gasket groove on the sides, and then the four corners. Make sure the gasket is fully recessed to prevent damage by the door and replace the rubber bumper and front trim panel.

PASS-THROUGH CHAMBERS

The laboratory is equipped with a number of pass-through chambers which are designed to enable to laboratory staff to safely transfer materials from the clean side to the dirty side without compromising the containment capabilities of the area. It is imperative that the sequence of events be followed to ensure directional airflow is maintained during the procedure.

TRANSFER OF MATERIALS (CLEAN TO DIRTY)

Operation of the pass-through is a two-person operation, one on the dirty side and one on the clean. The controls for the ventilation adjustments are located on the dirty side and must be configure properly prior to opening of the clean side door.

1. Establish voice communication between the two sides of the pass-through.
2. Prior to opening of the clean side door, close the atmospheric vent (ball valve, #1), which enables equalization of the pressure when the pass through is not in use and the open the ventilation valve (exhaust duct, #2) to provide additional negative air flow.
3. Open the clean side of the pass-through and place the materials into the chamber.
4. Reseal the clean side door and notify the individual on the dirty side that the door is secure.
5. On the dirty side, close the ventilation valve (exhaust duct, #2) and the open the ball valve (atmospheric vent, #1).
6. Open the dirty side door to the pass-through. Remove the materials.
7. Disinfect the chamber and close the dirty side door.

DISINFECTANT DUNK TANKS

The chemical decontamination of material allows for some heat-sensitive equipment or material to be removed from the containment area. Chemicals, reagents or some tools will not withstand the heat and pressure that is used in autoclaves without breaking down. The dunk tank is used to decontaminate the outside surface of the containers that hold the material mentioned above. The use of the dunk tank requires the approval of the Biosafety Officer, and usually requires at least two people. **It may require other approvals to move live agents out of containment.**

From the Dirty Side

1. Fill out the log book indicating the:
    a. Date,
    b. Disinfectant in the tank,
    c. Material to be disinfected,
    d. Type of packaging,
    e. Person responsible for the material,
    f. The person placing the material into the tank, and
    g. The time the material entered the tank.
2. Unclip the locks and lift the door of the tank to open.
3. Place the material into the tank, making sure that it is pushed through to the other side (below the baffle), using the support rod. Air tight containers will float, so make sure that the basket is in place on the other side. Large objects will have to be checked to make sure that they do not displace more liquid than is required to maintain the airlock.
4. Close the door to the tank and replace the clips.
5. Contact the person who will be receiving the material on the clean side of the tank (this can be the Biosafety Officer (BSO), a staff member of the section, or the glass-wash person) and make arrangements for the time that is required. This should be arranged in advance. The minimum contact time is very important and depends on the decontaminant and its concentration. It may vary from 10 minutes to half an hour. This will be posted on both sides of the tank when the tank is filled.

From the Clean Side

No one should take anything out of the Dunk Tank unless they have been contacted by the BSO or the person who placed material into the tank. In order, to take biological (the BSO) or chemical waste (Chemical Safety Officer) out of containment other forms must be filled out in advance.

1. Open the door to the tank.
2. Lift the basket and let it drain. If the container has trapped any decontaminant, make sure it is emptied before removing.
3. Remove the material and allow it to dry off on the stainless steel cart.
4. Fill in the log including the :
   a. Date,
   b. Disinfectant,
   c. Material,
   d. Time and
   e. Your name.
5. Replace the basket.
6. Close the door to the tank.
7. Take the cart to the wash up area where it can be rinsed off.

MAINTENANCE

The level of disinfectant in the dunk tank is critical. The level of disinfectant must never be allowed to reach the barrier in the tank since this will cause a breach in the biocontainment barrier of the suite. Levels on the dunk tanks should be monitored on a daily basis and the level increased when they reach 3 cm below original full level. Some disinfectants can be replenished and some must be replaced. This can be determined by the manufacturer's product information. When you are checking the fill level it is necessary to check the condition of the gaskets on the doors.

Changing the Disinfectant

Changing the disinfectant is the operator's responsibility. The following sequence should be followed.

1. Seal and secure the access door on the clean side of the dunk tank. The door should be taped and labelled "Do Not Open" to avoid inadvertent opening while the tank is empty.
2. A hose should be attached to the drain on the dirty side of the dunk tank. Some tanks are direct gravity and some are pump assisted. The hose should be placed in a drain or a receptacle for disinfectant disposal later.
3. Open the drain valve and empty the tank. If the tank is pump assisted, do not turn on the pump until the drain valve is open.
4. When the contents of the tank are drained, rinse the tank with about 10 liters of water.
5. Turn off the pump and close the drain valve. Check the condition of the epoxy coating on the inside of the tank. If this coating is damaged, notify the Biosafety Officer.
6. Replenish the disinfectant in the tank.

FORMALDEHYDE DECONTAMINATION

The chief use of formaldehyde at Federal Laboratories is for DECONTAMINATING such things as laboratory equipment, light bulbs, computers - in fact, just about any clean item that needs to be taken out of the Biocontainment area but which cannot be decontaminated by steam sterilization or by immersing in the

dunk tank. It is also used for decontamination of room spaces such as animal rooms and air locks.

IT IS ESSENTIAL THAT AT LEAST TWO PERSONNEL, FAMILIAR WITH DECONTAMINATION WITH FORMALDEHYDE, BE AVAILABLE DURING ANY DECONTAMINATION PROCEDURE, AND SHOULD BE SUPERVISED BY A QUALIFIED REPRESENTATIVE OF SAFETY AND ENVIRONMENTAL SERVICES.

DECONTAMINATING BIOLOGICAL SAFETY CABINETS (BSC)

RECOGNIZE THAT IT IS VERY DIFFICULT TO ACHIEVE A 100% SEAL ON BIOLOGICAL SAFETY CABINETS - PARTICULARLY OLDER ONES. THEREFORE, ONLY PERSONNEL INVOLVED IN THE DECONTAMINATION SHOULD BE PERMITTED IN THE AREA WHERE THE DECONTAMINATION IS IN PROGRESS.

Equipment

- CERTEK Model # 1414RH Formaldehyde generator/neutralizer
- Paraformaldehyde, flake or prills are preferred, but powder may be used
- Ammonium carbonate
- Clear plastic tubing, 3/8 I.D. and tubing clamps
- Preformed "Blank-off" plates or clear polyethylene sheeting, 6 mil minimum thickness
- Duct tape
- De-ionized water is preferred. Tap water may be used
- Hygrometer and thermometer
- Respirator for formaldehyde. Must be properly fitted for personnel.
- Rubber gloves
- Formaldehyde detector tubes, such as Drager #QS-5462, and pump

Preparation

1. Determine the size of the space to be decontaminated by measuring the height, width, and depth in feet. Multiply the height by the width by the depth to determine the volume of the enclosure in cubic feet. For purposes of this calculation, items inside the space to be decontaminated are considered not to occupy any space (See Appendix 1 for BSC volumes).
2. Place a thermometer and hygrometer inside the enclosure **and** determine the temperature in degrees Fahrenheit and the relative humidity. Be sure that enough time is allowed for these gauges to stabilize so that an accurate reading may be determined.
3. The temperature should remain between 16 and 32 degrees C. for the best results. Relative humidity must be held between 50 and 90%. If the relative humidity is less than 60%, it must be increased by boiling water into the enclosure from the water canister on the generator. Add approximately 10 cc of water to the calculated amount, for water that will remain in the tubing and canister. Place biological indicators into the enclosure at this time.
4. Seal the enclosure with the blank-off plates and attach blower hoses. Operate the blower to determine if you have unrestricted airflow.
5. Determine the volume of paraformaldehyde required by multiplying the cubic feet of space to be decontaminated by .3 grams.
6. After determining the amount of paraformaldehyde required, the quantity of ammonium carbonate needed to neutralize this paraformaldehyde can be found. Multiply the grams of paraformaldehyde by the factor of 1.1 to determine the quantity of ammonium carbonate required. (Ammonium carbonate is very hygroscopic. The factor above is based upon the use of

fresh material. Should the ammonium carbonate be old, the factor will have to be increased to allow for the moisture that the ammonium carbonate has absorbed. Excessive ammonium carbonate simply causes an ammonia smell at the end of the process).

Setup

1. Place rear of generator as close to the formaldehyde insertion point as possible. Open the rear compartment of the cover, exposing the canisters.
2. Connect tubing from the three canisters (FOR-M, NEUT, and WATER, if required) to access openings in the space. (Of course, it is not necessary to connect tubing to the "WATER' canister if no water is to be added and the Bypass feature is to be used.) Also, connect tubing from the space for return air to the generator. This port is the one with the filter in the glass bottle adjacent to the formaldehyde canister. It is recommended that the tubing from the canisters be as short as possible and that the return-air tubing be the long one. Make sure that the tubing is replaced periodically and that they are not plugged.

   ALWAYS SECURE TUBING TO PREVENT IT FROM DISCONNECTING FROM THE INJECTION POINTS ON THE BLOWER HOUSING.
3. Remove the lid from the canister marked "FORM". Place the amount of paraformaldehyde that was determined to be sufficient in Step #5 above into the canister. Reinstall the lid.
4. Remove the lid from the canister marked "NEUT". Place the quantity of ammonium carbonate that was determined in Step #6 above in this canister. Rubber gloves should also be worn when weighing and handling the ammonium carbonate. Ammonia gas will build up inside the container of ammonium carbonate; therefore, care should be used in handling the ammonium carbonate to avoid breathing this concentrated gas. A chemical fume hood should be used to weigh the chemicals.
5. If water is required as determined in Step #3 above, add the water to the canister marked "WATER". Remember to add an additional 10 cc's to allow for water that will remain in the tubing and canister. Set the "Humidify/Bypass" switch to the Humidity position. If it is not necessary to add water, set the "humidify/Bypass" switch to the Bypass position.

   CAUTION!! DO NOT FORCE LID ONTO THE 'WATER' CANISTER - MAKE SURE THAT IT SLIPS ON EASILY. IT IS DESIGNED TO SLIP OFF EASILY IN THE EVENT OF A BLOCKAGE IN THE LINE.

   If the lid is not properly placed on the canister, the 'Lid Open" light will illuminate.

   Should the 'Lid Open" light be activated during the humidity insert cycle, the process will stop to allow the laboratory staff to determine the cause. The process will have to be re-initiated. DO NOT ATTEMPT TO RESTART IN THE MIDDLE OF THE CYCLE.
6. Set required "CONTACT TIME" on the Timer.
7. Plug the electrical cord of the Formaldehyde Generator into a 115v single-phase 60-cycle power supply.
8. Turn "POWER" switch to the "ON" position. This should cause the "Power On" and "Power Loss" lights to energize. The "Power Loss" light indicates that the generator has experienced a "Power Loss" since completing the previous cycle.
9. Push the button marked "RESET". This programs the generator to begin the next cycle. Please note that the "Sequence Complete" light is now activated, indicating that the previous cycle was successfully completed. If this light is not energized, the sequence timer did not reach its zero position from the previous cycle. See "Sequence Indicator Lights" section of these instructions for

an explanation of the various cycles and indicators, and the procedures to be followed to correct this situation.

DURING THE VARIOUS HEATING CYCLES THAT FOLLOW THE CANISTERS BECOME VERY HOT. DO NOT TOUCH THE CANISTERS UNTIL THEY HAVE HAD SUFFICIENT TIME TO COOL.

10. Push the "Start" button. This activates the "Auto Sequence" light and one or two of the following: (a) If the "Humidify/Bypass" switch is in the humidify position, the heater on the "WATER" canister begins to heat the water to boil it off. - or (b) If the "Humidify/Bypass" switch is in the bypass position, the formaldehyde insert cycle begins. The "Form Insertion" light is energized, the pump begins, and "FORM" canister heater is activated. The Formaldehyde Insert Cycle automatically begins after all the water is boiled off if the "Humidify/Bypass" switch is placed in the "Humidify" position.
11. It takes approximately 15-30 minutes to boil off the water, depending upon how much water must be vaporized.
12. The "Formaldehyde Insert" cycle operates for 50-55 minutes. After this cycle is complete, the blower and formaldehyde heater are deactivated. The "Contact Timer" is then activated and controls the instrument until the selected "Contact Time" is timed out.
13. At the end of the "Contact Time", the "Neutralizer" canister heater, blower and solenoid valves are activated and the neutralization insertion begins. The "Neut Insert" light will be activated. This cycle requires 50-55 minutes.
14. At the completion of the neutralizer insert cycle, the "Neut Contact" light is activated and this portion of the cycle begins. There is a built-in hold time of 50-55 minutes for this chemical reaction to occur. If there was a small amount of formaldehyde and neutralizer used, this cycle may be shortened by advancing the control timer at the rear of the unit. Caution must be used to ensure that enough time is allowed for the formaldehyde to be completely reacted with the ammonium carbonate.
15. At the end of the "Neut Contact" cycle, the instrument goes into the 'Form Insert" cycle for approximately 1 minute. This prepares the instrument for the next cycle.
16. If the cycle was completed successfully as programmed, the "Sequence Complete" light will then be energized. The unit will remain in this configuration until the power switch is moved to "Off".
17. At the end of the cycle, the following items need to be noted, and for laboratory safety, recorded on a permanent record:
    a. Date and Time
    b. Equipment or space decontaminated
    c. Weight of Paraformaldehyde and ammonium carbonate used
    d. The contact time as recorded on the timer
    e. The lot number of the spore strip or other biological indicator if one was used.
18. Prior to opening the space, open the formaldehyde canister and Neutralization canister to ensure that both were depolymerized. Carefully open the space, making sure that complete neutralization occurred.
19. At the end of the cycle, the product of the neutralization, hexamethylene tetramine, a white powder may be visible. This may be cleaned off with a rag dampened with ethanol or left for approximately 8 hours and it will also depolymerize from the surface.

HEPA HOUSINGS

Prior to breaching the security of the HEPA housing, it is required that they be decontaminated to protect the technician from exposure to etiologic agents and to prevent the release of diseases to the environment. This is done prior to HEPA change, HEPA certification and repairs to housings or dampers.

Equipment

- CERTEK Model # 1414RH Formaldehyde Generator/Neutralize
- Decontamination cart with 5 hp blower
- Sections of 3in decon hosing
- Formaldehyde warning tape and signs
- Biological indicators
- Paraformaldehyde, flake or prills are preferred, but powder may be used
- Ammonium carbonate
- Clear plastic tubing, 3/8 I.D. and tubing clamps
- Duct tape
- Deionized water - preferred. Tap may be used
- Hygrometer and thermometer
- Respirator for formaldehyde. Must be properly fitted for personnel
- Rubber gloves
- Formaldehyde detector tubes, such as Drager #QS-5462, and pump

Preparation

During the decontamination, it should NEVER be assumed that the bioseal dampers will contain the formaldehyde gas in the housing. Therefore, notification of laboratory staff and restricted access to the areas affected is required until the decontamination is complete.

1. Determine the size of the space to be decontaminated by measuring the height, width, and depth in feet. Multiply the height by the width by the depth to determine the volume of the enclosure in cubic feet. For purposes of this calculation, items inside the space to be decontaminated are considered not to occupy any space.
2. Determine the temperature in degrees Fahrenheit and the relative humidity at the balancers sampling port, located just prior to the exhaust box.
3. The temperature should remain between 16 and 32 degrees C. for the best results. Relative humidity must be held between 50 and 90%. If the relative humidity is less than 60%, it must be increased by boiling water into the enclosure from the water canister on the generator. Refer to the graph or Psychrometric Chart Method near the end of these instructions to determine the amount of water required. Add approximately 10 cc of water to the calculated amount.
4. Determine the volume of paraformaldehyde required by multiplying the cubic feet of space to be decontaminated by .3 grams.
5. After determining the amount of paraformaldehyde required, the quantity of ammonium carbonate needed to neutralize this paraformaldehyde can be found. Multiply the grams of paraformaldehyde by the factor of 1.1 to determine the quantity of ammonium carbonate required. (Ammonium carbonate is very hygroscopic. The factor above is based upon the use of fresh material. Should the ammonium carbonate be old the factor will have to be increased to allot for the moisture that the ammonium

carbonate has absorbed. Excessive ammonium carbonate simply causes an ammonia smell at the end of the process.)

Setup

1. Place the rear of Generator and decon cart as close to the formaldehyde insertion point as possible. Open the rear compartment of the cover, exposing the canisters.
2. Connect tubing from the three canisters (FOR-M, NEUT, and WATER, if required) to access openings in the fan housing. (Of course, it is not necessary to connect tubing to the "WATER' canister if no water is to be added and the Bypass feature is to be used.) Also, connect tubing from the space for return air to the generator. This port is the one with the filter in the glass bottle adjacent to the formaldehyde canister. It is recommended that the tubing from the canisters be as short as possible and that the return-air tubing be the long one. Make sure that the tubing and ports are replaced periodically and that they are not plugged.
3. Seal the housing by notifying the control tech to shut down the fan for the specific area, then the automatic damper should be overridden at the housing to insure that it cannot be accidentally opened at the EMCS during the decontamination process. Then close the manual damper and attach blower hoses. Supply side of air should follow normal flow and be upstream and the return hose should be down-stream. A biological indicator should be placed in downstream hose connection. Open the butterfly valves and operate the blower to determine if you have unrestricted airflow.

ALWAYS SECURE TUBING TO PREVENT IT FROM DISCONNECTING FROM THE INJECTION POINTS ON THE BLOWER HOUSING.

4. Remove the lid from the canister marked "FORM". Place the amount of paraformaldehyde that was determined to be sufficient in Step #5 above into the canister. Reinstall the lid.
5. Remove the lid from the canister marked "NEUT". Place the quantity of ammonium carbonate that was determined in Step #6 above. in this canister. Rubber gloves should also be worn when weighing and handling the ammonium carbonate. Ammonia gas will build up inside the container of ammonium carbonate; therefore, care should be used in handling the ammonium carbonate to avoid breathing this concentrated gas. A chemical fume hood should be used when weighing the chemicals.
6. If water is required as determined in Step #3 above, add the water to the canister marked "WATER". Remember to add an additional 10 cc's to allow for water that will remain in the tubing and canister. Set the "Humidify/Bypass" switch to the Humidity position. if it is not necessary to add water, set the "humidify/Bypass" switch to the Bypass position.

CAUTION!! DO NOT FORCE LID ONTO THE 'WATER' CANISTER - MAKE SURE THAT IT SLIPS ON EASILY. IT IS DESIGNED TO SLIP OFF EASILY IN THE EVENT OF A BLOCKAGE IN THE LINE.

If the lid is not properly placed on the canister, the “Lid Open" light will illuminate.

Should the 'Lid Open" light be activated during the humidity insert cycle, the process will stop to allow for the determination of what the cause was. The process will have to be reinitiate. DO NOT ATTEMPT TO RESTART IN THE MIDDLE OF THE CYCLE.

7. Set required **“**CONTACT TIME" on the timer.
8. Plug the electrical cord of the Formaldehyde Generator into a 115v single-phase 60-cycle power supply.
9. Turn "POWER" switch to the "ON" position. This should cause the "Power On" and "Power Loss" lights to energize. The "Power Loss" light indicates that the Generator has experienced a "Power Loss" since completing the previous cycle.

10. Push the button marked "RESET". This programs the generator to begin the next cycle. Please note that the "Sequence Complete" light is now activated, indicating that the previous cycle was successfully completed. If this light is not energized, the sequence timer did not reach its' zero position from the previous cycle. See "Sequence Indicator Lights" section of these instructions for an explanation of the various cycles and indicators, and the procedures to be followed to correct this situation.

DURING THE VARIOUS HEATING CYCLES THAT FOLLOW THE CANISTERS BECOME VERY HOT. THEREFORE, MAKE SURE THAT YOU NOT TOUCH THE CANISTERS UNTIL THEY HAVE HAD SUFFICIENT TIME TO COOL **DOWN.**

11. Activate the blower motor. Push the "Start" button. This activates the "Auto Sequence" light and one or two of the following: (a) If the "Humidify/Bypass" switch is in the Humidify position, the heater on the "WATER" canister begins to heat the water to boil it off. – or (b) If the "Humidify/Bypass" switch is in the Bypass position, the Formaldehyde Insert cycle begins. The "Form Insertion" light is energized, the pump begins, and "FORM" canister heater is activated. The Formaldehyde Insert Cycle automatically begins after all the water is boiled off if the "Humidify/Bypass" switch is placed in the "Humidify" position.
12. Boiling off the water takes approximately 15-30 minutes depending upon how much water must be vaporized.
13. The "Formaldehyde Insert" cycle operates for 50-55 minutes. After this cycle is complete, the blower and formaldehyde heater are deactivated. The "Contact Timer" is then activated and controls the instrument until the selected "Contact Time" is timed out.
14. At the end of the "Contact Time", the "Neutralizer" canister heater, blower and solenoid valves are activated and the neutralization insertion begins. The "Neut Insert" light will be activated. This cycle requires 50-55 minutes.
15. At the completion of the neutralizer insert cycle, the "Neut Contact" light is activated and this portion of the cycle begins. There is a built in hold time of 50-55 minutes for this chemical reaction to occur. If there was a small amount of formaldehyde and neutralizer used, this cycle may be shortened by advancing the control timer at the rear of the unit. Caution must be used here to ensure that enough time is allowed for the formaldehyde to be completely reacted with the ammonium carbonate.
16. At the end of the "Neut Contact" cycle, the instrument goes into the 'Form Insert" cycle for approximately 1 minute. This prepares the instrument for the next cycle.
17. If the cycle was completed successfully as programmed, the "Sequence Complete' light will then be energized. The unit will remain in this configuration until the power switch is moved to "Off".
18. At the end of the cycle the following need to be noted, and for laboratory safety, recorded on a permanent record:
    a. Date and Time
    b. Equipment or space decontaminated
    c. Weight of Paraformaldehyde and ammonium carbonate used
    d. The contact time as recorded on the timer
    e. The lot number of the spore strip or other biological indicator if one was used.
19. Prior to opening the space, open the Formaldehyde canister and Neutralization canister to ensure that both were depolymerized. Close the butterfly valve at the return end of housing and remove the biological indicator. **Do Not open the housing until the results of the biological indicator are received.** Carefully open the space, making sure that complete neutralization occurred. **Respiratory protection should be worn at this time.**

20. At the end of the cycle, the product of the neutralization, hexamethylene tetramine, a white powder may be visible. This may be cleaned off with a rag dampened with ethanol or left for approximately 8 hours and it will also depolymerize from the surface.

AIR LOCKS, ANIMAL CUBICLES, AND LABORATORIES

Equipment

The equipment necessary for the formaldehyde decontamination of air locks, animal cubicles and laboratories is all the same, i.e.:

- Electric frying pans capable of 400 °F
- Paraformaldehyde, flakes or prills are preferred, but powder may be used
- Ammonium carbonate
- Extension cords, two types needed: 1) twist-loc male end with standard female end; 2) standard male and female ends
- Deionized water-preferred. Tap may be used
- Hygrometer and thermometer
- Full-face respirator with cartridges suitable for formaldehyde. Must be properly fitted for personnel
- Rubber gloves
- Formaldehyde Detector Tubes, such as Dräger #QS-5462, and pump
- Duct tape
- Polyethylene vapor barrier, 6 mil
- *Biosign* Biological Indicators, and incubator (37°C)
- Formaldehyde Warning Tape and Signs

Preparation

IT IS ESSENTIAL THAT AT LEAST TWO PERSONNEL, FAMILIAR WITH DECONTAMINATION WITH FORMALDEHYDE, BE AVAILABLE DURING ANY DECONTAMINATION PROCEDURE, AND SHOULD BE SUPERVISED BY A QUALIFIED REPRESENTATIVE OF SAFETY AND ENVIRONMENTAL SERVICES.

During these decontaminations it should NEVER be assumed that the bioseal doors or poly protection will contain the formaldehyde gas in the area being decontaminated. A buffer zone surrounding the area should be established with Formaldehyde Tape and access controlled.

NOTE: For room decontaminations with formaldehyde gas, all room and biological safety cabinet bioseal dampers must be completely closed and the room must be completely sealed to render the room air-tight, i.e. if the room has submarine doors they should remain closed through entire procedure and if the area is not equipped with bioseal doors (H-block BSL-3), all perimeter doors must be sealed with poly and duct tape.

Formaldehyde gas has specific limitations. It will not effectively decontaminate porous or organic materials (i.e., paper, cardboard, cloth, Styrofoam, etc.) materials and these should be cleared from the area and decontaminated in some other way. Also, Ammonium Carbonate will not effectively neutralize any formaldehyde gas which penetrates these materials and will cause an exposure problem when handled.

1. Determine the size of the room to be decontaminated by measuring the height, width and depth in feet. Multiply the height by the width by the depth to determine the volume of the room in cubic feet. For the purpose of this calculation, items inside the room are not considered to occupy any space

2. Determine the volume of paraformaldehyde required by multiplying the cubic feet of the space to be decontaminated by 0.3 grams.
3. The quantity of ammonium carbonate needed to neutralize this amount of paraformaldehyde can be calculated by multiplying the grams of paraformaldehyde by the factor of 1.1. (NOTE: Ammonium carbonate is very hygroscopic. The factor above is based on the use of fresh chemical. For older ammonium carbonate, the factor will have to be increased to allow for the moisture that the chemical has absorbed. Excessive ammonium carbonate causes an ammonia smell at the end of the process.)
4. Weigh out predetermined amount of chemicals into *Zip-lock* plastic containers (946ml), or other suitable container on a top-loading laboratory balance located inside a fumehood.
5. Determine the temperature and humidity inside of the room by taking a reading with *Velocicalc Portable Air Velocity Meter,* using the temperature and humidity settings, on the clean side of the exhaust duct (i.e. the clean side of the bioseal damper). The temperature should be 21.1EC (70EF) or higher, and humidity should be 60 to 85%. If the relative humidity is < 60% it must be increased by adding a predetermined amount of water to the pan containing the paraformaldehyde.

Setup

1. Place electric frying pans around room being decontaminated near to outlets using extension cords. Two frying pans are needed at each location, one for the paraformaldehyde and one for the ammonium carbonate.
2. NOTE: In rooms where decon can be done remotely (e.g. HC BSL-4 lab), the outlets (red) are marked decon only (one twist-loc receptacle and one standard receptacle at each point). In this case, the parafarmaldehyde pan is connnected to an extension cord with a twist-loc male plug into the special receptacle. The ammonium carbonate is attached to a regular 3-prong extension cord and into the receptacle next to the one for paraformaldehyde.
3. Duct tape temperature setting dial to maximum on the pan; plug in pan in lab to test before filling with chemical.
4. Fill electric frying pans with appropriate chemical. Add predetermined amount of water to pan containing paraformaldehyde if the relative humidity in the room is < 60%.
5. NOTE: If the electric frying pans are being filled in a BSL-3 area, full-face respiratory protection is needed. A positive-pressure suit will be used in BSL-4.
6. Place a number of biological indicators around the room.
7. or barrier protected containment areas (e.g. HC BSL-4): Leave laboratory. Start decon via remote buttons on outside of lab. Timing sequence is 2 1/2 hours burn off for paraformaldehyde, 4 hours contact time followed by 2 1/2 hours burn off for ammonium carbonate, then 4 hours contact time.
8. For containment areas not protected with bioseal doors and sperate decontamination circuitry: Electric frying pans containing paraformaldehyde and ammonium carbonate should be hooked up to 20 amp separate electrical circuits so that they can be turned on from outside of the containment suite at the required times. The timing sequence is the same as noted above. Before sequence is started, all perimeter doors must be sealed with poly and duct tape to be air tight.
9. After complete sequence is timed out, air system must be re-started. Ventilation system should be run at least 24 hours prior to monitoring for residual gases.
10. Using a full face respirator, collect all biological indicators, then incubate at 37°C for 48 hours (the room is not considered 'clean' until there is a negative result for all biological indicators).
11. Using a full-face respirator, enter room and take an air quality reading with the Dräger Formaldehyde Detector system with activator tube. If there is less than .04 ppm formaldehyde detected, personnel may enter the area without face protection.

12. If there is a residue left on the surfaces in the lab, full-face respirators, gloves and cover-alls are to be worn to clean the lab (use an ammonia-based cleaning compound). This residue occurs if there is repolymerization of the paraformaldehyde on the lab surfaces.