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.

. No of evaluation of alternative to location at Fac

No analysis of not good by infected water

Unclear pin point where for public review in DEIS

Beyond environmental from increased use of incinerator not assessed

not comfy w/ proximity of 4 Orthopox contraints in Valley

Little consideration for threats (terrorists, plane, etc.) to labs

public concerns were not addressed in EIS
submitted

better sci. analyses 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.