



Innovation for Our Energy Future

April 28, 2006

Edward H. Hammond
Director
The Sunshine Project
P.O. Box 41987
Austin, TX 78704

Dear Mr. Hammond:

Pursuant to your letter request to Arjun Singh dated March 13, 2006, which has been directed to me for reply, enclosed please find the minutes of the last three annual meetings of the National Renewable Energy Laboratory (NREL) Institutional Biosafety Committee (IBC) since May 1, 2003, which NREL elects to voluntarily release to you.

You also requested completion of the following statement:

The National Renewable Energy Laboratory IBC HAS / HAS NO implemented written policies for the identification, review, and oversight of research involving any of the seven categories of experiments of concern identified by the National Academies of Science in its report Biotechnology Research in an Age of Terrorism (the "Fink Committee" report).

In response to your request, I can advise you that the NREL IBC has not prepared such written policies. First, since NREL does not receive funding from the National Institutes of Health (NIH), it therefore is not mandated to adhere to the NIH guidelines. NREL voluntarily uses the NIH guidelines as a set of best practices to guide our activities. Therefore, the written policies are not a mandatory requirement for the NREL IBC. Second, developing such policies would serve no useful purpose as no work performed at NREL is covered by the seven categories of experiments of concern identified by the National Academies of Science in its report *Biotechnology Research in an Age of Terrorism*. NREL's mission on behalf of the U.S. Department of Energy is contractually limited to developing renewable energy and energy efficiency technologies and practices, advancing related science and engineering, and transferring knowledge and innovations to address the nation's energy and environmental goals. NREL does not engage in any activity that involves weapons research or development.

Please feel free to contact me at (303) 384-6849 should you have questions.

Sincerely,

A handwritten signature in blue ink that reads "Nancy Dowe".

Nancy Dowe
Senior Scientist I - Microbiology
NREL Institutional Biosafety Panel Chairperson

Enclosures (as stated above)
cc: Arjun Singh, Biosafety Officer, NREL



DRAFT NREL Institutional Biosafety Panel Minutes

Thursday, October 30, 2003

In attendance: Bill Adney, Bev Rahorst, Arjun Singh, Nancy Dowe, Bob Ellis, June Medford, Keith Villa, Jim McMillan

Not present: Chris Gaul

1. **Approval of October 30, 2002 Minutes and October 30, 2003 Agenda** - The meeting started with introduction of the panel members. No changes to the agenda were suggested. The minutes of the October 2002 meeting were approved as written.

2. **Review of IBP Authorizations** -

- No additional authorizations have been submitted or have been reviewed in 2003.
- Authorization 98-001 should be revisited with PI to determine if the IBP is appropriate for the type of working being done, i.e., corn instead of tobacco plants.
- Authorization 98-004 should have the location of FTLB 224 removed as the readiness verification for this room has not been completed. When the readiness verification for this room has been completed, the PI will have to resubmit the IBP for approval. The IBP is still approved for use in FTLB 223.
- Authorizations 98-002 is written only for BL1 work. If BL1-LS work is planned for AFUF 212 (Mini Pilot Plant) a new IBP must be submitted. At this time AFUF 212 is not used for greater than 10 liter work.
- Bill reviewed the rest of the current authorizations with the panel members. These IBPs are either still in use or the researchers want to keep the authorization active. See attached 2003 NREL Institutional Biosafety Panel (IBP) Authorization Form Log for more information on the current IBPs.
- Bill discussed in general terms future potential work with outside partners that would require protection of intellectual property. Outside panel members may be required to sign a nondisclosure agreement for those projects. Some of the outside partner work may be approved with only in-house panel members depending of the type of work and the low risks involved, but the need for high protection of intellectual property.
- There are now five approved authorizations, with four of them located in the FTLB and one in the AFUF.

Action Item: Contact PI of Authorization 98-001 to determine if the IBP is appropriate for the type of working being done, i.e., corn instead of tobacco plants.

Completion:

Action Item: Contact PI of Authorization 98-004 that the location of FTLB 224 has been removed as the readiness verification for this room has not been completed and the PI will have to resubmit the IBP after the readiness verification is completed.

Completion:

Action Item: Contact PI of Authorizations 98-002 that a new IBP must be submitted if BL1-LS work is planned for AFUF 212 (Mini Pilot Plant) as IBP is written only for BL1 activities.

Completion:

3. **Biosafety Program Changes** – The Biosafety Program is in the final stage of the NREL policy review process. We are waiting for approval from the Requirements Management and Implementation (RMI) administrator and then the program will be posted on the ES&S Website.

Action Item: The Biosafety Program is not available on the web as it is still going through the NREL policy review process.

Completion:

5. **2003 NREL Biosafety Program Annual Review Results** - A complete review of biosafety program was not conducted this year. Instead Bob Ellis conducted an audit of AFUF 212 and Process Development Unit (PDU) to determine what requirements would be needed before BSL-2 work could be conducted in these two areas. A copy of the audit is included as an attachment to the minutes.

6. **Membership Changes** – Nancy Dowe was selected to become the new IBP chairperson with Bill remaining as an IBP member. Jim McMillan will remain as a representative from the AFUF. It was suggested that a new member be selected to represent the FTLB.

Action Item: Determine who will be the FTLB representative to the IBP.

Completion:

7. **Permits** - NREL currently has one soil permit which belongs to Bill and will expire 9/30/04. Bill's other permit for Thermophilic eubacteria expired 6/9/03. We are still having trouble tracking down Fred Keller's permit (possibly Erwinia), but will try searching the USDA permit database. Bill may have a new permit in the future.

Action Item: Find information on Fred Keller's permit.

Completion:

8. **Issues Presented by Panel Members**

Bob suggested that the panel think about having one of the panel members become a Registered Biosafety Professional. This certification is based on education and experience levels of the individual. The American Biological Safety Association (ABSA) administers the certification.

Bob attended the last ABSA meeting and attended an excellent presentation on the recombinant updates. He will send the panel members copies of the slide presentation.

9. **Adjournment**

Attached Files

- 2003 NREL Institutional Biosafety Panel Authorization Log
- Audit and Report of NREL's Mini-Pilot Plant (Laboratory 212A) and the Process Development Unit (PDU) – Robert Ellis
- 2003 IBP Roster
- 2003 Permit List
- ABSA Meeting – Recombinant Updates Slide Presentation – *have asked Bob for the slide presentation*

NREL Institutional Biosafety Panel Minutes

Tuesday, November 23, 2004

In attendance: Bill Adney, Bev Hiller, Nancy Dowe, Bob Ellis, June Medford, Keith Villa, Jim McMillan

Not present: Chris Gaul, Arjun Singh

1. **Approval of October 30, 2003 Minutes and November 23, 2004 Agenda** - The meeting started with introduction of the panel members. No changes to the agenda were suggested. The minutes of the October 2003 meeting were approved as written.

2. **Review of IBP Authorizations** -

- Nancy reviewed each of the authorizations with the panel members. These five authorizations are either in use or the researchers want to keep the authorization active. See attached 2004 NREL Institutional Biosafety Panel (IBP) Authorization Form Log for more information on the current IBPs. No additional authorizations were submitted or reviewed in 2004.
 - Authorization 97-001 – had a new BL-1 organism added to the use list. Procedure remains the same.
 - Authorization 97-002 – had a new BL-1 organism added to the use list. Procedure remains the same.
 - Authorization 98-001 should be revisited with PI to correct #6 to read, “The NIH Guidelines apply to containment and growing of genetically engineered plants. The USDA has jurisdiction for field studies.” Also the PI will be contacted to write the authorization for the process that is presently taking place. The authorization will need to be resubmitted if a grant proposal is funded to show the new process or new plants that would be used. Item #10 biological containment needs to be checked for accuracy.
 - Authorizations 98-002 - was written only for BL-1 work, but changes were made to include BL1-LS work for AFUF 212 (Mini Pilot Plant). Recommended that # 7 be reworded to make meaning clearer.
 - Authorization 98-004 - The authorization remains the same for use in FTLB 223, but the location of FTLB 224 and BS-1 LS use was removed as the readiness verification for this room has not been completed. In the future, when the readiness verification for FTLB 224 has been completed, the PI will have to resubmit the IBP for approval.
- Nancy discussed in general terms future potential work with outside partners that would require protection of intellectual property. Outside panel members may be required to sign a nondisclosure agreement for those specific projects.

Action Item: Contact PI authors to get signatures of approved authorizations and return signed copies to IBP.

Responsible Party: Bev Hiller

Completion: Due 12/31/04

Action Item: Contact PI author of authorization 98-002 to reword item #7 to make meaning clearer.

Responsible Party: Bev Hiller

Completion: Due 12/31/04

Action Item: Contact PI author of authorization 98-001 to correct #6 to read “The NIH Guidelines apply to containment and growing of genetically engineered plants. The USDA has jurisdiction for field studies.” Also the PI will be contacted to write the authorization for the process that is presently taking place. The authorization will need to be resubmitted if a grant

proposal is funded to show the new process or new plants that would be used. Item #10 biological containment needs to be checked for accuracy.

Responsible Party: Bev Hiller

Completion: Due 12/31/04

3. Minutes of IBP Meetings and Sunshine Project - The contents of the Sunshine Project was discussed by the panel members. The comments about the NREL program were not flattering.

Action Item: Future minutes of the IBP meeting will be sent to NIH along with the member changes in January for their information.

Responsible Party: Bev Hiller

Completion: Due February 28, 2005

Action Item: It will be check to see if it is permissible to place the IBP minutes on the website for public access. If it is possible, then that is the plan that the IBP members would like to see happen.

Responsible Party: Bev Hiller

Completion: Due January 31, 2005

4. 2004 NREL Biosafety Program Annual Review Results - A self assessment of biosafety program was conducted this year by Bev Hiller Three areas of improvement were noted: start on-line biosafety training, find information on our expired permits, and start a daily/monthly test of our sterilizers

Action Item: All bio-researchers who work with organisms are required to take on-line biosafety training. Started 11/16/04

Responsible Party: Bev Hiller

Completion: Due December 31, 2004

Action Item: Ask Fred Keller about his expired permit.

Responsible Party: Nancy Dowe

Completion: Due December 31, 2004

Action Item: Start autoclave check program with daily test using spore strips and monthly checks using spore test. Keep documentation of test results for review.

Responsible Party: Nancy Dowe

Completion: Due December 31, 2004

5. Membership Changes – Bill Adney will be the representative from the FTLB and it was suggested that Kent Evans be the representative from the AFUF.

Action Item: Ask Kent Evans to be the AFUF representative to the IBP.

Responsible Party: Nancy Dowe

Completion: Due December 31, 2004

6. Permits– All of NREL's permits have expired.

7. Issues Presented by Panel Members

- IBP report was given to NREL Safety Council on 11/16/04. Discussion consisted of review of IBP's proposed 11/23/04 agenda. It was suggested that at the next NREL Safety Council Meeting that it be recommended that Bev attend the ABSA meeting. Next meeting is scheduled for Tuesday, February 15, 2005 from 8:30 to 10:00 AM.
- Information will be forwarded to panel members about draft call list for a new Biosafety group - RMBA - for Rocky Mountain Biosafety Affiliate of the ABSA. - DONE - Bev Hiller 11/14/04

- Bob Ellis will be teaching a biosafety and security training again this summer at CSU. The program consists of two days of plant, three days of general safety/security, and two days of veterinary medicine. The program is set up that you can attend the days of interest and not have to go to the entire program. It is tentatively scheduled for late July/early August.
- The panel discussed if NEPA requirements applied to the proposed genomics lab. It was agreed by all panel members that NEPA does not apply as the proposed work in the genomics labs is analyzing, sequencing, etc. the organisms themselves not producing organisms.

8. Adjournment – at 3 PM

9. Tour of new Biomass Surface Characterization Labs (BSCL) and proposed Genomics/Metabolomics/Proteomics Labs at the FTLB – given by Todd Vinzant and Bill Adney for the outside committee members.

Attached Files

- 2004 NREL Institutional Biosafety Panel Authorization Log
- 2004 Self-Assessment
- 2004 IBP Roster

NREL Institutional Biosafety Panel Minutes

Thursday, October 20, 2005

In attendance: Bill Adney, Bev Hiller, Nancy Dowe, Bob Ellis, June Medford, Keith Villa, Arjun Singh, Paul King, Ed Szydleik

Not present: Kent Evans

1. **Approval of November 23, 2004 Minutes and October 20, 2005 Agenda** - The meeting started with introduction of the panel members. No changes to the agenda were suggested. The minutes of the October 2004 meeting were approved as written. An additional panel member from 5900 Center (Basic Sciences) was added to the roster. The roster was also updated to show Bob's new address.

2. **Review of IBP Authorizations** -

Nancy reviewed each of the authorizations with the panel members. These five authorizations are either in use or the researchers want to keep the authorization active. See attached 2005 NREL Institutional Biosafety Panel (IBP) Authorization Form Log for more information on the current IBPs. One additional authorization was submitted for reviewed in 2005.

- o Authorization 97-001 – No changes
- o Authorization 97-002 – No changes except for authorized employees
- o Authorization 98-001 – Was retired
- o Authorizations 98-002 – No changes except for authorized employees
- o Authorization 98-004 - No changes except for authorized employees
- o Authorization 05-001 – New IBP from 5900 Center

3. **Public Notification** -

The e-mail from UCHSC about public meeting notification was discussed. Suggestions made by the Panel members were:

Action Item: Names of outside Panel members would not be listed on ES&H Biosafety Website

Responsible Party: Bev Hiller

Completion: DONE, October 20, 2005

Action Item: Contact Public Affairs as to best method of posting public notice of next IBP

Responsible Party: Bev Hiller

Completion: Due January 31, 2006

Action Item: How minutes should be written to meet NIH Guidelines and NREL legal requirements.

- o Could have a Statement of Activity or write "Risk Group 1 verified by outside panel members at small scale in order to meet NIH guidelines."
- o It is acceptable to distribute IBP authorizations internally, but not publicly without approval of IBP Chairperson and Legal review.
- o If IBPs are on website, must be in PDF format not Word so changes can be locked out.

Responsible Party: Nancy Dowe

Completion: Due March 31, 2006

4. **Issues Presented by Panel Members** - See #3 above

5. **Adjournment**– at 2:30 PM

6. **Tour of 5900 Center (Basic Sciences) FTLB labs 173, 174, and 178**– given by Paul King for committee members.

Attached Files

- 2005 Revised NREL Institutional Biosafety Panel Authorization Log
- 2005 Revised IBP Roster